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H1N1 influenza and pandemic flu

A special themed issue of the *Health Technology Assessment* journal series

In this issue

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Health Technology Assessment

Volume 14: No 34, July 2010

The National Institute for Health Research

The National Institute for Health Research (NIHR) has been established as a part of the Government's strategy, 'Best Research for Best Health'. It provides the framework through which the research staff and research infrastructure of the NHS in England is positioned, maintained and managed as a national research facility.

The NIHR provides the NHS with the support it needs to conduct first-class research funded by the Government and its partners alongside high-quality patient care, education and training. Its aim is to support outstanding individuals (both leaders and collaborators), working in world-class facilities (both NHS and university), conducting leading-edge research focused on the needs of patients.

This themed issue of the *Health Technology Assessment* journal series contains a collection of research commissioned by the NIHR as part of the Department of Health's (DH) response to the H1N1 swine flu pandemic. The NIHR through the NIHR Evaluation Trials and Studies Coordinating Centre (NETSCC) commissioned a number of research projects looking into the treatment and management of H1N1 influenza.

NETSCC managed the pandemic flu research over a very short timescale in two ways. Firstly, it responded to urgent national research priority areas identified by the Scientific Advisory Group in Emergencies (SAGE). Secondly, a call for research proposals to inform policy and patient care in the current influenza pandemic was issued in June 2009. All research proposals went through a process of academic peer review by clinicians and methodologists as well as being reviewed by a specially convened NIHR Flu Commissioning Board.

The final reports from these projects have been peer reviewed by a number of independent expert referees before publication in this journal series.

Criteria for inclusion in the HTA journal series

Reports are published in the HTA journal series if (1) they have resulted from work for the HTA programme or, in the case of this national priority, the NIHR, and (2) they are of a sufficiently high scientific quality as assessed by the referees and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The research reports in this themed issue were funded through the Cochrane Collaboration; the Health Services Research programme (HSR); the Health Technology Assessment programme (HTA); the Policy Research Programme (PRP); the Public Health Research programme (PHR); and the Service Delivery and Organisation Programme (SDO).

The Cochrane Collaboration is an international not-for-profit and independent organisation, dedicated to making up-to-date, accurate information about the effects of health care readily available worldwide. It produces and disseminates systematic reviews of health-care interventions and promotes the search for evidence in the form of clinical trials and other studies of interventions. Cochrane reviews and the Cochrane Central Register of Controlled Trials are published and updated in *The Cochrane Library* (www.cochranelibrary.com).

The HSR programme aims to lead to an increase in service quality and patient safety through better ways of planning and providing health services. It funds both primary research and evidence syntheses, depending on the availability of existing research and the most appropriate way of responding to important knowledge gaps.

The HTA programme produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The PRP provides the evidence base for policy development on public health and social care issues. It funds research in three main ways: 5-year programmes of research in 16 research units, a primary-care research centre, a public health research consortium, and a surveillance unit; programmes of interlinked studies on key policy initiatives; and single projects and literature reviews.

The PHR programme evaluates public health interventions, providing new knowledge on the benefits, costs, acceptability and wider impacts of non-NHS interventions intended to improve the health of the public and reduce inequalities in health. The scope of the programme is multi-disciplinary and broad, covering a range of interventions that improve public health.

The SDO programme commissions research evidence that improves practice in relation to the organisation and delivery of health care. It also builds research capability and capacity amongst those who manage, organise and deliver services – improving their understanding of the research literature and how to use research evidence.

The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report. The views expressed in this publication are those of the authors and not necessarily those of the NIHR or the Department of Health.

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Themed issue introduction

Welcome to the first of three special themed issues of the *Health Technology Assessment* journal series, relating to NIHR-funded projects into H1N1 influenza and pandemic flu. The influential journal series is now over 10 years old and has published more than 500 titles, covering a wide range of health technologies in a diverse set of applications. In general, the series publishes each technology assessment as a separate issue within each annual volume.

This themed issue departs from that format by containing a collection of reports on projects which have been commissioned by the NIHR through the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) as part of the H1N1 influenza research portfolio. The research within this themed issue has been carried out, not only by the Health Technology Assessment programme (HTA), but also by other NIHR research programmes: the Health Services Research programme (HSR); the Public Health Research programme (PHR); and the Service Delivery and Organisation programme (SDO). It also contains reports carried out under The Cochrane Collaboration and the Policy Research Programme (PRP).

To ensure rapid and timely publication of this vital research, it has been brought together in this series of themed issues to ensure that all NIHR-funded projects into H1N1 influenza and pandemic flu can publish the full results and outcomes from their research in a respected, peer-reviewed resource. The significant impact of *Health Technology Assessment* was again confirmed by its recently published impact factor (2009) of 6.91, ranking the series in the top 10 per cent of medical and health-related journals. It is also indexed on MEDLINE, CINAHL, EMBASE, UK PubMed Central and the Cochrane Library and the ISI Science Citation Index.

The papers in this themed issue report on the ongoing Department of Health response to the H1N1 swine flu pandemic, and we hope that the reports of the work carried out will be of interest and value to readers.

Further details of each of the projects are available on the NETSCC website (www.netscc.ac.uk) and we welcome comments on the themed issue via the HTA website (www.hta.ac.uk).

Professor Tom Walley
Director of NETS
Editor-In-Chief, *Health Technology Assessment*

Exploring the needs, concerns and behaviours of people with existing respiratory conditions in relation to the H1N1 'swine influenza' pandemic: a multicentre survey and qualitative study

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Abstract

Exploring the needs, concerns and behaviours of people with existing respiratory conditions in relation to the H1N1 'swine influenza' pandemic: a multicentre survey and qualitative study

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Background: People with respiratory conditions are a 'high-risk' group for H1N1 pandemic swine influenza ('swine flu'), hence they and their families may have information needs, worries and concerns regarding the condition. Health-related behaviours, including vaccination, are recommended during the pandemic; understanding uptake of these is important.
Objectives: To explore and compare information needs, worries and concerns, and health-related behaviours regarding swine flu in people with respiratory conditions and their family members.
Methods: Mixed-methods study – cross-sectional survey (253 patients, 101 family members); one-to-one interviews (13 patients, seven family members) and focus groups (*n* = three groups, 30 participants). Data collected October 2009–January 2010 from hospital chest clinics (*n* = 7) and patient support groups (*n* = 10) in North West England.
Results: Most patients (P) and family members (FM) wanted more information (*n* = 158, 62.5% P; *n* = 55, 54.4% FM), but few felt completely uninformed (*n* = 15, 5.9% P; *n* = 3, 3.0% FM). Most had already received information about swine flu (*n* = 187, 73.9% P; *n* = 78, 77.2% FM), mainly via a leaflet delivered to their home (*n* = 125, 49.4% P; *n* = 55, 54.5% FM). Information received was considered helpful (*n* = 154, 60.9% P; *n* = 77, 72.6% FM), but many wanted more condition-specific information (*n* = 141, 55.7% P; *n* = 60, 59.4% FM). More patients were worried (*n* = 147, 58.3%) than not worried (*n* = 99, 39.3%) about swine flu. FM were less often concerned about personal risk (*n* = 47, 46.6% worried) than about risk to patients (*n* = 76, 77.6%). Two-thirds (*n* = 161, 63.6% P; 65, 65.6% FM) incorrectly believed patients had increased risk of developing swine flu, but most (*n* = 204, 81.0% P; 89, 89.9% FM) correctly identified patients' greater risk of developing complications. Commonly adopted preventative measures were more frequent hand-washing (107, 42.8% P; 38, 37.6% FM) and greater use of sanitising hand gel (*n* = 100, 40.5% P; 37, 36.6% FM). In total, 212 patients (83.8%) and 69 family members (68.3%) were very/fairly likely to take up swine flu vaccination. Qualitative data mirrored survey findings.
Conclusions: Participants were generally well-informed about swine flu, but more targeted information would have been welcomed. Participants were not highly anxious about swine flu, but did recognise risks for patients. Behaviour change was modest, but in line with recommendations. Vaccination intent was high.
Study registration: The study has been registered as REC/IRAS (Ref 09/H1015/76) and NIHR CSP (Ref 32483).

Contents

List of abbreviations

A&E	accident and emergency department
ABPA	allergic bronchopulmonary aspergillosis
BLF	British Lung Foundation
BME	black and minority ethnic
COPD	chronic obstructive pulmonary disease
GP	general practitioner
HPA	Health Protection Agency
HTA	Health Technology Assessment
ILD	interstitial lung disease
NIHR	National Institute for Health Research
NPFS	National Pandemic Flu Service
UNICEF	United Nations Children's Fund
WHO	World Health Organization

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices, in which case the abbreviation is defined in the figure legend or in the notes at the end of the table.

Executive summary

Background

The H1N1 swine influenza (swine flu) pandemic resulted in mass information campaigns, largely aimed at the general public. Little is known about whether these met the needs of people with respiratory conditions and their families. People with respiratory conditions were identified as being at risk of potentially life-threatening complications of 'swine flu', hence they and their families may have had worries and concerns regarding the condition. A number of health behaviours, including vaccination, were recommended during the pandemic; given their 'high-risk' status, it is important to identify whether these were adopted by people with respiratory problems and their family members.

Objectives

1. To explore, in samples of people with existing respiratory conditions and their family members:
   i. information needs (priority topics of information, preferred sources of information, perceived usefulness of available information, gaps in knowledge/misconceptions) regarding the current swine flu pandemic
   ii. concerns (perceptions of susceptibility, risk of complications, risk of death) regarding the current swine flu pandemic
   iii. health-related behaviours (adoption of recommended preventative measures, avoidance behaviours, anticipated use of health services) with respect to the current swine flu pandemic.
2. To compare information needs, concerns and health-related behaviours of patients and family members.
3. To explore associations between the above factors and condition-related/demographic variables.

Methods

A mixed-methods study involving a cross-sectional questionnaire survey, focusing on current/recent needs, concerns and behaviours, conducted by post and telephone; one-to-one interviews and focus groups were conducted. Inclusion criteria were: adult (18 years or over) with clinician-diagnosed long-term respiratory condition of any severity or family member of such a patient; able to provide informed consent to participate; and able to complete an English-language questionnaire or participate in an interview or focus group conducted in English. Patient and family member questionnaires were developed specifically for the study, with content guided by review of the literature, expertise in the project team and guidance from a User Reference Group, made up of patients with a respiratory problem and their family members. A topic guide, which drew upon questionnaire content, was developed for the interviews and focus groups.

Data were collected from hospital chest clinics ($n = 7$) and patient support groups ($n = 10$) in North West England. Survey data were entered into SPSS v15.0 and first analysed descriptively; logistic regression was planned but rejected owing to results of bivariable analyses of key outcomes. Interviews and focus groups were audio recorded and transcribed verbatim. 'Framework analysis' was used to identify main themes and permit comparisons within and across transcripts.

Results

Sample

Patient questionnaires were completed between 12 October 2009 and 5 February 2010, and family member questionnaires between 17 October 2009 and 2 February 2010. The three focus groups were conducted on 18 November 2009, 19 November 2009 and 19 December 2009, and interviews were conducted between November 2009 and

January 2010. The study sample consisted of 354 survey participants (253 patients and 101 family members); 20 interviewees (13 patients and seven family members); and 30 focus group participants, across three focus groups, most of whom were patients.

Information needs

Most ($n = 158$, 62.5% patients; $n = 55$, 54.4% family members) wanted more information, but few felt completely uninformed ($n = 15$, 5.9% patients; $n = 3$, 3.0% family members). Most had already received information about swine flu($n = 187$, 73.9% patients; $n = 78$, 77.2% family members), mainly via a leaflet delivered to their home ($n = 125$, 49.4% patients; $n = 55$, 54.5% family members) or through mass media sources (e.g. television $n = 116$, 45.8% patients; $n = 44$, 43.6% family members). The health professional from whom patients and family members most commonly received information was their general practitioner (GP) ($n = 75$, 29.6% patients; $n = 21$, 20.8% family members). Doubts were commonly expressed about the credibility of mass media as an information source. Most thought the information received was helpful ($n = 154$, 60.9% patients; $n = 77$, 72.6% family members), but many also wanted more specific information for people with chest problems ($n = 141$, 55.7% patients; $n = 60$, 59.4% family members), especially regarding how swine flu would affect chest problems. Data from focus groups and interviews mirrored survey findings. The data extracts below typify views regarding information provision:

> We got some information through the post, but I'm not sure where that came from, I do recall it had man sort of sneezing on it … and there is an internet site which I think is specific for swine flu and we checked on that one, and that seemed to be enough for us, we didn't really need any more than that. But I've been to the local GP for repeat prescriptions for my wife and there are notices all over the place which really replicate the information that we've got.

> It might be helpful if one could tie specific complaints into the swine flu scene … I have … bronchiectasis … I'm just wondering if I did get swine flu whether that would make the symptoms worse, whether it would complicate matters. I find I haven't got any information on that.

Concerns

More patients were worried ($n = 147$, 58.3%) than not worried (99, 39.3%) about swine flu, although few were extremely anxious. Family members were less often concerned about personal risk ($n = 47$, 46.6% worried) than about risk to patients ($n = 76$, 77.6%). Two-thirds ($n = 161$, 63.6% patients; $n = 65$, 65.6% family members) incorrectly believed patients had increased risk of developing swine flu, but most ($n = 204$, 81.0% patients; $n = 89$, 89.9% family members) correctly identified patients' greater risk of developing complications. Overall, 133 patients (52.7%), but only 28 family members (27.7%), were worried they might die from swine flu, while 65 (66.3%) family members had such concerns for their relative with chest problems. Eighty-eight patients (34.8%) and 31 family members (30.7%) agreed that 'too much fuss is being made about swine flu', particularly by the mass media. Qualitative data mirrored survey findings and the data extracts below were typical:

> No, I mean obviously it crossed my mind and I thought, you can't just isolate yourself, you can't make the front door a barrier because there's germs out there, you've just got to get on with it, just got to get on with your life.

> I only knew what I knew from the news and the papers, like thousands were going to die and all this … [at] the time you believe what you're hearing because you don't know any different and it's quite frightening.

Behaviours

The preventative measures most commonly adopted were increased frequency of hand-washing ($n = 107$, 42.8% patients; $n = 38$, 37.6% family members) and greater use of sanitising hand gel ($n = 100$, 40.5% patients; $n = 37$, 36.6% family members). Most ($n = 171$, 68.4% patients; $n = 70$, 69.3% family members) thought swine flu vaccination would be helpful. 212 patients (83.8%) and 69 family members (68.3%) were very/fairly likely to take up swine flu vaccination, with 84 family members (83.2%) believing that patients should do so. The most common help-seeking behaviour of patients if swine flu was suspected would have been phoning their GP ($n = 81$, 32.0%), but for family members it was staying at home and self-treating ($n = 31$, 30.7%). Media reports influenced likely behaviour, particularly with respect to uptake of swine flu vaccination and use

of antiviral medication. Again, qualitative data echoed survey findings, as these data extracts illustrate:

> No, it's not altered me at all, no. I've just carried on normally… yes, I've started washing my hands regular, I have done that … But as far as being in crowds, no, that hasn't bothered me.

> Well straight, I'd phone the doctor straight away and probably be advised by them. If for any reason I suppose I couldn't get through to the doctor I'd probably phone the helpline, the NHS [Direct] helpline … and see what advice they gave me.

> I think a lot of it, you know, when you read it in the press … I think reports in the press when they say, only 25% of national health workers, the nurses, what have you, have agreed to have it. That then makes me think they know something I don't or – so to me it's very negative the way it's been put into the press, very negative.

Out of all of the bivariable associations between participant characteristics and key outcomes (perceived knowledge about swine flu, concern about the 'fuss' raised over swine flu and intention to have the swine flu vaccination) investigated for patients, only three were statistically significant at the 5% level. Participants educated to degree level or above were more likely to feel that they knew as much as they needed to know or knew quite a lot (66.7%) than those educated to a lower level (50.0%) and with no formal qualifications (34.4%, $\chi^2_{TREND} = 9.25$, df = 1, $p = 0.002$). Participants living alone were more likely to agree that 'Too much fuss is being made about the risk of swine flu' than those living with a partner (45.9% versus 31.5%, $\chi^2 = 4.16$, df = 1, $p = 0.041$). Fewer black and minority ethnic (BME) groups indicated that they were 'very likely' to have the swine flu vaccination (47.6% versus 71.7%, $\chi^2 = 5.23$, df = 1, $p = 0.022$).

In comparable analyses for family members, four different combinations of characteristic and outcome were statistically significant at 5%. Those considering that they knew as much as they needed to or knew quite a lot about swine flu tended to be younger [mean age 55.4 years, standard deviation (SD) 62.7] than those who did not (mean 62.7 years, SD 12.8, $t = 2.43$, df = 87, $p = 0.017$). Participants educated to degree level or above were again more likely to indicate that knew as much as they needed to/knew quite a lot about swine flu (85.7%) than those educated to a lower level (59.7%) and those with no formal qualifications (31.8%, $\chi^2_{TREND} = 12.65$, df = 1, $p < 0.001$). This was also true for feeling that they knew as much as they needed to (66.7% versus 34.2% versus 13.6%, $\chi^2_{TREND} = 12.74$, df = 1, $p < 0.001$). The respiratory diagnosis of the patient was not significantly associated with the family member's intention to have the swine flu vaccination when the miscellaneous 'other' category of diagnoses was included ($\chi^2 = 5.22$, df = 2, $p = 0.074$). However, when patients with diagnoses of asthma and chronic obstructive pulmonary disease (COPD) only were compared, more family members of asthma patients said that they were very likely to have the vaccination (73.7%) than family members of COPD patients (36.8%, $\chi^2 = 5.22$, df = 1, $p = 0.022$).

Conclusions

Our data suggest that people with chest problems and their family members were generally well informed regarding swine flu, but that some gaps in information-giving and knowledge remained. Better targeting of information towards the specific needs of people with respiratory conditions and their families was suggested. Information to help patients and family members discriminate between seasonal influenza, swine flu and symptoms of their respiratory problem was particularly highlighted; developing such information would be challenging, as symptoms overlap. Patients and family members suggested development of information to aid in understanding the likely impact of swine flu on respiratory problems; this need may extend to many long-term conditions.

Most patients and family members were not highly anxious about swine flu. There was some confusion regarding susceptibility to swine flu, suggesting a need for improved communication of the message regarding this issue. Participants clearly recognised patients as being at greater risk than the general population of swine flu complications. Despite this, survey response rates, particularly amongst family members, suggest that the topic of swine flu may have had limited saliency by the time of data collection.

Behaviour change was modest but in line with recommendations from authoritative sources, and

there appeared to be good levels of penetration of some key messages regarding prevention and help-seeking. Vaccination intent was very high in this sample, which may have been due, in part, to effective communication of risk, but may also have been influenced by sample composition. Some concerns about vaccination, especially with regard to safety and interaction with underlying respiratory problems and associated medications, were apparent. This suggests that there is more to be done to ensure appropriate communication of risk. It is also somewhat paradoxical, given the high levels of vaccination intent.

The influence of the mass media on perceptions of, and responses to, the pandemic was apparent, especially within the qualitative data. In particular, questioning in the mass media of the effectiveness of antiviral medications may have affected views on and willingness to take these. Our data highlight a contradiction with respect to the role of the mass media as a communication medium within a pandemic, in that they were widely used but of questionable credibility. Likewise, the data highlight tensions between the use of mass media as a means of raising awareness versus its potential to reduce interest in a pandemic through perceived oversaturation, 'hyping' or misrepresentation of issues.

Recommendations for future research

- Work to identify effective means of delivering targeted information to high-risk groups during a pandemic would be of particular value.
- Follow-up work to establish whether vaccination intentions were followed through (and, if not, why this was the case) would be of value. It would also be interesting to establish why these patients and family members were so highly motivated and whether this could provide lessons for future vaccination programmes.
- Further research to improve understanding of risk perception (from the effects of swine flu and from vaccination) and its influence on decision-making in high-risk groups is needed and could make a valuable contribution to the efficacy of future vaccination programmes.
- Future work is needed to establish whether issues identified by our participants regarding the role of the mass media would also be raised by people with respiratory conditions more widely or by other high-risk groups.
- Given the extensive reporting of the pandemic by the mass media and, indeed, the use by health-related agencies of the mass media to communicate pandemic-related messages, work is urgently needed to explore further the influence of mass media reports on pandemic-related knowledge and behaviour in high-risk groups, and to better understand how mass media can most effectively be used to communicate risk data, especially to high-risk groups, in a pandemic.
- Issues of saliency suggest lessons for timing of future comparable research within a pandemic.
- Our experiences highlight the need to recognise, and develop strategies to overcome, the challenges of including 'hard-to-reach' groups (including family members, BME groups and young adults) when undertaking short projects in the context of an ongoing pandemic.

Study registration

The study has been registered as REC/IRAS (Ref 09/H1015/76) and NIHR CSP (Ref 32483).

Chapter 1
Introduction

Respiratory conditions are highly prevalent in the UK and are the most common reason for general practice consultations and emergency medical admissions to hospital.[1–2] People with respiratory conditions are at high risk for 'seasonal' influenza, and annual vaccination is recommended. However, uptake in 2008–9 was only 45.3%, which, although close to the national average for 'at-risk' groups (47.1%), is below that seen in some other long-term conditions (e.g. coronary heart disease 54.6%, diabetes 67.5%, diabetes on medication 70.6%, stroke/transient ischaemic attack 57.3%).[3] Although vaccination against seasonal influenza is recommended for main carers of individuals with long-term conditions, uptake amongst these in 2008–9 was low (39% of those eligible).[3] People with respiratory conditions have been identified as being at greater risk for developing complications of 'swine flu' – both by authoritative sources[4–8] and in mass media reports that are likely to be read by patients and their family members.[9,10]

During 2009, from the first emergence of H1N1 swine flu cases in Mexico in April 2009, up to the declaration by the World Health Organization (WHO) of a pandemic in June 2009 and beyond, a plethora of information about swine flu appeared, especially on the internet. However, its quality has been variable, and sometimes questionable, with some websites even offering, for sale, dubious 'prevention guides' or 'miracle cures'.[11–14] Some have argued that wide availability of information has resulted in 'an informed public',[15] and an Ipsos MORI poll conducted in May 2009, ahead of the declaration of a pandemic, suggested that individuals felt generally well informed about swine flu.[16,17] However, the same poll also found that over 50% of the 1000 members of the general population polled did not think that swine flu information they had received applied to them.[16,17] At the start of the pandemic there was little specific information available to patients with chest problems and their families from authoritative sources. Although this did change slightly during 2009, the amount of respiratory condition-specific information on swine flu has remained low, and little is known about whether available information met the needs of patients and their families.

The need to balance raising awareness of the pandemic and associated risks against creating undue anxiety, particularly in at-risk groups, was identified.[18–22] Successful 'public communication of risk and uncertainty' was suggested as having a 'critical role' in this.[20] Likewise, the challenges of overcoming complacency or scepticism, either about government-provided information or about the 'real' threat from swine flu, have been highlighted.[17] The WHO and the United Nations Children's Fund (UNICEF) identified the need for 'assessment of knowledge, awareness and perceptions' in at-risk populations in relation to the pandemic.[23]

Government agencies in the UK and elsewhere have provided the public with recommendations regarding preventative measures (e.g. hand-washing, use of tissues) and other behaviours (e.g. self-management, help-seeking),[5,24] some of which have a strong evidence base.[25] The level of 'penetration' (e.g. reaching target groups, uptake of advice) of these recommendations in at-risk groups, such as those with chest problems, is not currently well known.

Previous behaviour-focused public health initiatives regarding respiratory viruses, which used a range of media and approaches, have met with mixed success.[26–29] A survey conducted shortly before the pandemic was declared[16,17] found that 62% of those studied were not undertaking recommended preventative measures. The same study also found low levels of 'avoidance behaviours' (e.g. limiting contact with others). This study, however, involved the general population; whether behaviours have differed in at-risk populations is unclear.

Pressure on services was being reported even before the declaration of the pandemic in June 2009,[18,30] and the launch of the National Pandemic Flu Service (NPFS) towards the end of July 2009[31] was, in part, in response to this; the importance of individuals using services appropriately is therefore apparent. The need for appropriate self-management and advance planning by those with long-term conditions and their families during the pandemic was highlighted.[7,32,33] Equally, however,

given the higher risk of complications in patients with chest problems who develop swine flu, the importance of patients and family members being able to recognise and appropriately respond to symptoms, and seek help when needed, was identified.[4,23,31–33]

In light of these considerations, a study that explored information needs, concerns and behaviours of patients with chest problems and their family members was proposed.

Chapter 2
Methods

Research objectives

1. To explore in samples of people with existing respiratory conditions and their family members:
   i. information needs (priority topics of information, preferred sources of information, perceived usefulness of available information, gaps in knowledge/misconceptions) regarding the current swine flu pandemic.
   ii. concerns (perceptions regarding susceptibility, risk of complications, risk of death) regarding the current swine flu pandemic.
   iii. health-related behaviours (adoption of recommended preventative measures, avoidance behaviours, anticipated use of health services) with respect to the current swine flu pandemic.
2. To compare information needs, concerns and health-related behaviours of patients and family members.
3. To explore associations between the above factors and condition-related/demographic variables.

Study design

Primary research, adopting a mixed-methods, exploratory design, involving quantitative (postal and telephone surveys) and qualitative (focus groups and one-to-one interviews) elements.

Setting

The study was conducted in North West England. This region has a population of 6.7 million, covering a large geographic area from Cumbria in the north to Merseyside and Cheshire in the south.[34] It has two large cities: Manchester and Liverpool. In 2007, 16.2% of the population were aged 65 years or older, and 89% identified themselves as 'white British'.[35] The region's strategic health authority, NHS North West, has responsibility for 24 primary care trusts, 38 hospital trusts (23 acute trusts, seven specialist trusts and eight mental health trusts; 27 trusts had achieved foundation trust status as at June 2010) and the North West Ambulance Service.[36] The region as a whole has consistently higher unemployment and poorer health outcomes (including life expectancy and respiratory disease rates) than are typical for the UK, although there is marked intraregional variation.[37]

Target population

Adults (18+ years) with a clinician-diagnosed chest problem (long-term, non-cancerous conditions, all severity levels) and close family members (18+ years) of such individuals. Both patient–family member dyads and singletons from either group were recruited.

Our definition of family members included spouses/partners; children (only if aged 18+); parents of adult (18+ years) patients; siblings; and other close relatives, such as aunts, uncles, nephews, nieces and cousins. Family members either self-nominated or were given a questionnaire pack by their family member with chest problems.

Inclusion/exclusion criteria

The same inclusion and exclusion criteria were used for survey, focus group and interview elements.

Patients

Inclusion

- Adult (18 years or over).
- Clinician-diagnosed long-term respiratory condition [(including asthma, chronic obstructive pulmonary disease (COPD), interstitial lung disease (ILD), allergic bronchopulmonary aspergillosis (ABPA), cystic fibrosis, bronchiectasis, chronic cough, tuberculosis] of any severity.
- Able to provide informed consent to participate.
- Able to complete an English-language questionnaire or participate in a focus group conducted in English.

Exclusion

- Under the age of 18 years.
- Acute respiratory illness.
- Cancer diagnosis as main respiratory problem (as the focus was on long-term conditions).
- Unable to give informed consent.
- Unable to complete English-language questionnaire or participate in focus group conducted in English.

Family members

Inclusion

- Adult (18 years or over).
- Family member of patient with clinician-diagnosed long-term, non-cancerous respiratory condition.
- Able to provide informed consent to participate.
- Able to complete an English-language questionnaire or participate in a focus group conducted in English.

Exclusion

- Under the age of 18 years.
- Unable to give informed consent.
- Unable to complete English-language questionnaire or participate in focus group conducted in English.

Each of the study components (survey, focus groups and one-to-one interviews) will now be described in more detail.

Survey

Design

Cross-sectional questionnaire survey,[38] involving postal and telephone elements.

Sites

Survey participants were recruited through distribution of questionnaires at seven hospital chest clinics (four district general hospitals, two university teaching hospitals and one specialist centre/tertiary referral centre), from British Lung Foundation (BLF) 'Breathe Easy' patient/carer support groups ($n = 7$ across the North West region) and via a newspaper advertisement (this approach, rather than recruiting through general practices, was adopted because of the extra demand on primary care services due to the pandemic and previous experience of the challenges of conducting research in primary care). The hospital sites all ran several chest clinics each week, with the specialist centre running the most clinics. The sites all had diverse patient populations, including asthma, COPD and ILD, and, at the specialist centre, other conditions, such as ABPA.

Sample

In each group, a sample of $n = 171$ would allow estimation of 95% confidence intervals for percentages with a margin of error of ± 7.5%. The aim was therefore to recruit a minimum $n = 200$ patients and $n = 200$ family members to allow for exclusion of incomplete data sets.

Methods

Study packs (including patient/family member information sheets, consent forms, questionnaires and pre-paid return envelopes) were distributed by clinic staff (typically receptionists or clinic assistants) to consecutive patients attending chest clinics at the seven study sites between October and December 2009 (commencement of data collection was not simultaneous, for operational reasons, at some sites, hence data collection periods ranged from 6 to 12 weeks). Patients self-completed the questionnaire either in clinic (returning it to a drop-off point or clinic staff) or at home, returning it by post. Patient packs contained a family member pack and instructions for the patient regarding distribution of this; family questionnaires were therefore typically returned by post.

For BLF 'Breathe Easy' groups, packs were distributed to members by the group Chair, either at monthly meetings or by post (with a covering letter from the Chair) between November 2009 and January 2010; all questionnaires were self-completed at home and returned by post.

The newspaper advertisement ran once, in the *Manchester Evening News*, a daily newspaper that has wide circulation across the North West of England. It is free within Greater Manchester and distributed at rail stations, etc. It has a readership of approximately 0.5 million, more than one-half of whom are 15–44 years old. It is commonly used to run health-research-related stories and to place study advertisements. It was the publication recommended by the University of Manchester's media team as the best mapping on to the population of choice and being most likely to yield a good response. The advertisement ran on a Thursday (12 November 2009), which

is a particularly good day, as it is when jobs are advertised, hence readership is at its highest. Our advertisement was prominently placed, on p. 2 of the newspaper, and was followed the next day by a short article in the paper regarding the study. It included a study-related telephone number and, after an eligibility check, those who responded were either mailed a study pack for self-completion and return by post or the survey was undertaken over the telephone, according to the participant's preference. A copy of the advertisement is provided in Appendix 1; its wording was guided by our User Reference Group (members of the Central Manchester British Lung Foundation 'Breathe Easy' Group, who have worked with us for several years, advising on such aspects as priority topics for research; study design, especially acceptability and respondent burden; development of patient information sheets and lay summaries of findings), and was also to some extent dictated by requirements of the Research Ethics Committee that reviewed the study.

Instrument

Data were collected by means of patient and family member-specific questionnaires (see Appendices 2 and 3), developed de novo for the study. De novo development was necessary, as no appropriate tool already existed. Questionnaire development was guided by review of the literature[24–29,39–42] (including relevant theory, such as the Health Belief Model[42,43]), pooling of expertise in the project team, and guidance from a User Reference Group (all people with chest problems and/or their family members); where appropriate, items from the Ipsos MORI poll[16,17] were included/adapted. Topics that were addressed included: level of knowledge about swine flu; key information topics; sources of information; perceived usefulness of available information; concerns about swine flu; performance of recommended preventative measures; other behaviours (avoidance, health promotion, use of current medication); and anticipated use of health services. Questions regarding demographic and condition-related data were also included, with choice of items guided by previous work.[16,17,24–29]

The questionnaires were piloted with the User Reference Group, and independently reviewed by a researcher with related experience and two respiratory health-care professionals, and were then revised in response to feedback from these. Piloting established face validity. Psychometric testing was not undertaken owing to the exploratory nature of this study and the rapid turnaround required.

Data analysis

Data were entered into SPSS v15.0 and analysed descriptively. Patient and family member responses were first compared descriptively. We originally intended to fit logistic regression models to assess the association between characteristics of participants and key outcome variables. The latter were selected to represent the three areas of interest in the study (knowledge/information needs; concerns and behaviours):

- perceived level of knowledge about swine flu (recoded for simplicity in two ways as 'As much as I need or want to know' – yes/no, and 'As much as I need or want to know/Quite a lot but I'd like to know more' – yes/no)
- concerns about swine flu (strongly agree or tend to agree with 'Too much fuss is being made about the risk of swine flu' – yes/no)
- intentions about swine flu vaccination (very likely to have swine flu vaccination – yes/no).

The associations between these and characteristics of the participants were assessed first in bivariable analysis using Pearson's chi-squared test for gender, married/living with a partner, ethnicity and respiratory diagnosis, the chi-squared test for trend for highest level of education, and the unpaired *t*-test for age. For patients, only one association turned out to be statistically significant for each of the three outcomes, and it was considered that there was sufficient association present to warrant a more in-depth multivariable analysis using logistic regression. For family members, two associations were statistically significant for perceived knowledge about swine flu and one for each of the other outcomes. The smaller sample size for family members and the limited degree of association both counted against further analysis using logistic regression.

Focus groups

Design

Dual moderator focus groups.[44,45]

Sites

Focus groups were conducted at community-based meetings of BLF 'Breathe Easy' patient support groups across the North West; the aim was to undertake four to six groups. Selection of groups (from among the $n = 25$ in the region) was guided by the BLF's regional development team (who helped us to identify well-established, well-attended groups and advised regarding the

characteristics of these) and by the willingness of groups to participate (none was required to do so); none of the groups had been involved in the survey. Group Chairs were contacted to discuss possible participation of their group and to identify an appropriate meeting date to attend (or, if preferred, to set up a study-specific meeting). Groups were provided with information about the study and at which of their meetings it would take place, ahead of the focus group, in order to enable the group as a whole and individual members to decide regarding participation.

Sample

Focus groups typically involve 8–12 members per group.[44,45] Group sizes in the present study were determined by usual attendance at the BLF 'Breathe Easy' groups (typically $n = 8$–10 attendees, but up to $n = 30$ possible). The aim was to conduct 4–6 focus groups, with an expected sample size of 32–60 participants; this is typical of focus group studies and is at the higher end of recommended sample sizes for qualitative work.[46,47]

Methods

A 'focused conversation' style of interviewing was adopted.[46,47] Discussion was focused using a topic guide (see Appendix 4). Each focus group was, with participants' permission, audio recorded. A 'dual-moderator' focus group approach (whereby one moderator led discussion and another facilitated conduct of the group and took notes) was adopted.[44,45] Each focus group lasted approximately 1 hour and was conducted on one occasion.

Instrument

A topic guide was developed for the study. It addressed the main topics covered in the questionnaires (information needs, concerns and behaviours), the purpose of the focus groups being to explore these issues in greater depth. The guide was used to focus discussion, rather than being a compulsory list of topics to be addressed. Data collection was iterative, hence the topic guide was amended based on issues raised in/emerging from each focus group.

Data analysis

Each focus group was transcribed verbatim. Field notes for each focus group were typed up and appended to the relevant transcript. Framework analysis[48] was used; this is a well-recognised qualitative analysis technique, which is gaining increasing popularity in health services research. It involves the following stages: (1) familiarisation; (2) identifying a thematic framework; (3) indexing; (4) charting; and (5) mapping and interpretation. Analysis occurred within and across transcripts. At least two team members independently coded each transcript and agreed the final coding used. Standard approaches to maintain rigour in qualitative research were adopted.[46,47,49]

Interviews

Design

One-to-one audio-recorded interviews with a purposively selected subsample of survey and focus group participants.[46,47]

Sites

Interviews were conducted in participants' homes, or another location of the participant's choosing.

Sample

The aim was to recruit a purposive subsample[46,47] of up to $n = 20$ individuals from amongst survey and focus group participants; these could be patient–family member dyads or singletons from each group. Purposive sampling criteria primarily related to responses to questionnaire items regarding knowledge, concerns and behaviours. Age, gender, respiratory condition, patient/family member status were also considered. The goal was to secure a range of perspectives.

Methods

A 'focused conversation' style of interviewing was adopted.[46,47] Discussion was focused using a topic guide and by the individual participant's questionnaire responses or issues they raised in the focus group. Each interview was audio recorded, with the participant's permission.

Instrument

The topic guide was as described in 'focus groups' above (see Appendix 4). Additional, individualised questions regarding responses to the questionnaire or issues raised in the focus group were asked.

Data analysis

Data analysis and steps to ensure rigour was as described in 'focus groups' above.[46–49]

Chapter 3

Results: survey

Characteristics of the sample

Questionnaires were distributed to hospital chest clinics and BLF 'Breathe Easy' groups in the North West, typically at weekly intervals, between October 2009 and January 2010. The first patient questionnaire was completed on 12 October 2009 and the last on 5 February 2010, while the first family member questionnaire was completed on 17 October 2009 and the last on 2 February 2010. The number of questionnaires returned from each site varied considerably, which, in part, reflected the size of the respiratory patient population/number of chest clinics at each site. Two sites had very low returns ($n = 2$ and $n = 7$ patient questionnaires, and $n = 0$ and $n = 3$ family questionnaires, respectively), which reflected ongoing problems with staff commitment to distributing questionnaires. At other sites, the number of patient questionnaires returned ranged from $n = 21$ to $n = 83$ and family questionnaires from $n = 9$ to $n = 33$, the highest recruiter being the specialist centre that had the largest patient population/number of chest clinics.

A total sample of 355 patients and family members was recruited (*Table 1*); after exclusion of one very incomplete family member data set, the final sample was 354. The recruitment rate for patients was modest, but not atypical for surveys of this type,[50,51] while family member recruitment was very low and, despite vigorous efforts to increase it, did not reach the minimum of $n = 200$ which had been sought. The newspaper advertisement, which ran on 12 November 2009, yielded a very poor response, with only 16 enquiries, all from patients, although seven of these completed questionnaires (six postal returns and one completed by telephone). Although patients and family members aged < 18 years were excluded from the surveys, we anticipated that some parents of patients < 18 years might respond to the newspaper advertisement, but this did not occur. Placement of a second advertisement (and also of one focusing specifically on family members) was considered but rejected owing to the very poor initial response, high cost and the fact that it required a team member to be on hand all day for approximately 1 week to take calls, which was not considered a good use of time given the low response to the first advertisement.

Characteristics of the 354 participants who were included in the analysis are detailed in *Table 2*.

Table 3 details relationships that the family member sample ($n = 101$) had with their relative with a respiratory condition; more than one-half were spouses, although other relationships, including daughter/son, were also represented.

TABLE 1 *Patient and family recruitment rates for each route* (n = *355)*

Recruitment route	Distributed patient	Returned patient (*n*, %)	Distributed family[a]	Returned family (*n*, %)
Chest clinics	949	207 (22)	949	85 (9)
BLF 'Breathe Easy' group	207	39 (19)	207	17 (8)
Newspaper advertisement	16	7 (44)	7	0
Total	*1172*	**253 (22)**	*1163*	**102 (9)**[b]

a One family member questionnaire went out with each pack but not all will have been passed on by patients to family members.
b One family member questionnaire was excluded as incomplete, leaving $n = 101$ in the family member sample and a combined total sample (patient and family) of $n = 354$.

TABLE 2 *Characteristics of the sample*[a]

Characteristic	Patients (%)	Family members (%)
Age in years		
Median	66	62
Mean	62.9	58.7
SD	13.4	14.3
Range	20–87	18–84
Gender		
Male	99 (39.6)	36 (37.9)
Female	151 (60.4)	59 (62.1)
Highest level of education		
No formal qualifications	69 (30.1)	22 (25.6)
Subdegree level[b]	119 (50.1)	41 (47.6)
Degree level and above	34 (14.8)	23 (26.8)
Married/living with a partner		
Yes	183 (75.0)	75 (74.3)
No	61 (25.0)	17 (25.7)
Ethnicity		
White British	215 (91.1)	87 (98.9)
Other	21 (8.9)	1 (1.1)
Respiratory diagnosis		
	Self	**Of relative with chest problem**
COPD	74 (31.8)	19 (20.4)
Asthma	54 (23.2)	19 (20.4)
Other[c]	81 (34.7)	40 (43.0)
Don't know	24 (10.3)	15 (16.1)

SD, standard deviation.
a Most items had some missing data, hence numbers do not always equal total sample size; percentages given are of valid responses.
b Includes professional qualifications.
c Includes ILD, ABPA and bronchiectasis.

TABLE 3 *Relationships of family member sample (n = 101) with their relative with a respiratory condition*

Relationship	No. (%) of family members
Wife	30 (29.7)
Husband	26 (25.7)
Daughter	14 (13.9)
Son	4 (4.0)
Parent[a]	8 (7.9)
Other	9 (8.9)
Not specified	10 (9.9)

a Owing to inclusion criteria for patients, all were parents of an adult aged 18 years or over.

'Topline' data regarding information needs/knowledge, concerns and behaviours are provided within the main body of the report; more detailed data are provided in Appendix 5. Note that most items had some missing data; percentages given are of valid responses for each item unless otherwise stated.

Information needs and knowledge

Information needs and topics

Table 4 presents data regarding perceived level of knowledge about swine flu.

TABLE 4 *Perceived level of knowledge about swine flu*

How much do you know about swine flu?	Patients: *n* = 253 (*n*, %)	Family members: *n* = 101 (*n*, %)
None of the things I need or want to know	15 (5.9)	3 (3.0)
A bit but I'd like to know more	111 (43.9)	38 (37.6)
Quite a lot but I'd like to know more	47 (18.6)	17 (16.8)
As much as I need or want to know	62 (24.5)	37 (36.6)
No response	18 (7.1)	6 (5.9)

Most participants did not identify particular topics on which they would have liked additional information. Among those who did, the most common for patients were how swine flu would affect people with chest problems ($n = 27$), how serious swine flu is for people with an underlying chest problem ($n = 16$) and how to recognise swine flu symptoms ($n = 14$), and, for family members, the difference between swine flu and other types of flu ($n = 10$) and how to recognise swine flu symptoms ($n = 8$).

Participants' views on the importance of a range of information topics are presented in Appendix 5, *Tables 18* and *19*. All topics were rated as 'very important' by 50% or more of participants. Patient and family member responses were broadly comparable. The topic most commonly selected as 'very important' by both patients and family members was 'How "swine flu" might affect chest problems' (patients $n = 202$, 81.5%; family members $n = 86$, 86.0%). Other topics relating to the effect of swine flu on people with chest problems and recognition of swine flu symptoms also had high percentages rating them as 'very important'. The topic least often rated as 'very important' by patients was 'Whether the families of people with chest problems are more likely to catch swine flu than others' ($n = 128$, 52.7% compared with family members $n = 56$, 56.6%) and by family members was 'How likely it is that you will catch swine flu' ($n = 50$, 50.0% compared with patients $n = 158$, 64.0%).

Information sources

The majority of both patients ($n = 187$, 73.9%) and family members ($n = 78$, 77.2%) had already received information about swine flu. Detailed data regarding sources of information are presented in Appendix 5, *Table 20* (note: participants could indicate more than one source); patients' and family members' views on the importance of information sources were generally very similar.

The most common source for both patients and family members was 'leaflet delivered to my home' (patients $n = 125$, 49.4%; family members $n = 55$, 54.5%), followed by 'television' (patients $n = 116$, 45.8%; family members $n = 44$, 43.6%). Other common sources were 'poster displayed at GP surgery' (patients $n = 109$, 43.1%; family members $n = 37$, 36.6%) and 'newspaper' (patients $n = 91$, 36.0%; family members $n = 36$, 35.6%).

General practitioners (GPs) were the health professionals most often used as an information source (patients $n = 75$, 29.6%; family members $n = 21$, 20.8%). Lay advice from family members and relatives was used by sizeable percentages of both samples, and, indeed, was more commonly used than the GP by family members (patients $n = 54$, 21.3%; family members $n = 23$, 22.8%) Unsurprisingly, more patients than family members cited 'hospital consultant/specialist doctor' as an information source (patients $n = 48$, 19.0%; family members $n = 10$, 9.9%). Interestingly, very few patients or family members had used a community pharmacist as a source of information (patients $n = 12$, 4.7%; family members $n = 4$, 4.0%).

Modest use as an information source was made of resources such as the NPFS, the 'NHS Choices' website and NHS Direct (see Appendix 5, *Table 20*), although a little more use was made of the government's 'pandemic flu' website – www.direct.gov.uk/pandemicflu (patients $n = 26$, 10.3%; family members $n = 15$, 14.9%). None of those who selected 'other' (neither patients nor family members) specified what source this was.

Detailed data regarding the perceived usefulness of a range of information sources for people with respiratory problems and their families are presented in Appendix 5, *Tables 21* and *22* (figures in italics indicate whether individuals would personally have utilised a particular information source). Views on usefulness of information sources were broadly comparable in patients and family

members, as was reported likelihood of personally using a particular information source. Generally, fewer people (both patients and family members) indicated that they would personally 'definitely' have used an information source than rated it as 'very important' for people with respiratory problems and their families, although the differences were often small.

The two information sources most commonly identified as 'very useful' by both patients and family members were doctors, i.e. GPs (patients $n = 188$, 75.2%; family members $n = 78$, 77.2%) and hospital consultants (patients $n = 190$, 76.9%, $n = 73$, 72.3%). Despite being the most common source of information, only 79 patients (31.2%) and 35 family members (34.7%) identified leaflets as a 'very useful' information source. Similarly for television, only 80 patients (32.5%) thought it 'very useful' [and only $n = 49$ (21.0%) would personally 'definitely' have used it], whereas among family members only $n = 31$ (30.7%) considered television 'very useful' and only $n = 17$ (18.3%) would 'definitely' have used it personally. The NPFS was considered 'very useful' as an information source by 124 patients (51.0%) and 55 family members (55.0%), whereas the government's pandemic flu website was identified as a 'very useful' information source by only 79 patients (33.2%), but by a higher percentage of family members ($n = 45$, 45.5%).

Knowledge

To explore knowledge regarding swine flu, participants were asked a series of 'true/false' questions; these data are presented in Appendix 5, *Tables 23* and *24*. In most instances, the majority of both patients and family members could correctly identify which items were 'true' and 'false'. In line with official government information, most patients and family members identified statements regarding the value of hand-washing and use of antibacterial gels in preventing the spread of swine flu as 'true' (hand-washing – patients $n = 240$, 96.8%, family members $N = 96$, 99.0%; antibacterial gels – patients $n = 177$, 72.2%, family members $n = 68$, 70.1%).

There was some confusion about who was most at risk of developing swine flu. Most patients ($n = 153$, 63.0%) and family members ($n = 67$, 69.1%) incorrectly identified people with respiratory problems as being more likely than others to catch swine flu. However, both groups correctly identified these patients' greater likelihood of developing complications following contraction of swine flu. Most patients ($n = 171$, 70.7%) and family members ($n = 64$, 67.4%) incorrectly identified the very young as being most at risk of developing swine flu. A sizeable percentage of both patients (96, 39.8%) and, even more so, family members ($n = 44$, 45.8%) also incorrectly identified older people as having the greatest likelihood of developing swine flu.

There was also some confusion regarding antiviral medications, with 138 patients (56.3%) and 48 family members (50.5%) incorrectly identifying oseltamivir as a vaccine for swine flu, rather than as an antiviral medication. Similarly, 138 patients (59.0%) and 49 family members (51.6%) thought that family members of a person with swine flu would routinely be given antiviral medication, which was contrary to Health Protection Agency (HPA) guidance[52] and official government information for the public.[53]

Ability to identify swine flu symptoms was also explored (see Appendix 5, *Tables 25* and *26*); this is difficult, as there are few (arguably no) distinct symptoms of swine flu.[54] Official guidance to the public at the NHS Choice website[55] indicated that swine flu should be suspected in the presence of fever or high temperature (> 38°C/100.4°F) accompanied by one or more of the following: unusual tiredness, headache, runny nose, sore throat, shortness of breath or cough, loss of appetite, aching muscles, and diarrhoea or vomiting. The majority of both patients and family members identified most of these symptoms as possibly being due to swine flu. However, only 99 (44.6%) of patients identified 'diarrhoea or stomach upset' as possibly being associated with swine flu (although $n = 62$, 66.0% of family members did so) and only 43 (47.8%) of family members associated 'loss of appetite' with swine flu (although $n = 135$, 60.5% of patients did so). Some symptoms in the list had not been indicated in official literature as being suggestive of swine flu (e.g. rash, sudden inability to move limbs) and most patients and family members identified these as not being suggestive of swine flu (see Appendix 5, *Tables 25* and *26*).

Appropriateness of Information

Table 5 presents data regarding satisfaction with the amount of information received and *Table 6* presents participants' views on whether the information was helpful or not. Few in either group who thought that information was unhelpful gave

TABLE 5 *Satisfaction with the amount of information received about swine flu – patients (n = 253) and family members (n = 101)*

	How satisfied or dissatisfied are you with the amount of information available to you on swine flu from any source? (*n*, %)						
	Very satisfied	**Fairly satisfied**	**Neither satisfied nor dissatisfied**	**Fairly dissatisfied**	**Very dissatisfied**	**Don't know**	**No response**
Patients	50	83	58	28	19	9	6
	(19.8)	(32.8)	(22.9)	(11.1)	(7.5)	(3.6)	(2.4)
Family members	27	42	16	12	4	0	0
	(27.6)	(41.6)	(15.8)	(11.9)	(4.0)	(0)	(0)

TABLE 6 *Perceptions of helpfulness of information about swine flu – patients (n = 253) and family members (n = 101)*

	Do you think that the information currently available about swine flu is helpful or not? (*n*, %)			
	Yes	**No**	**Don't know**	**No response**
Patients	154	44	49	6
	(60.9)	(17.8)	(19.8)	(2.4)
Family members	77	10	14	0
	(76.2)	(9.9)	(13.9)	(0)

reasons why, but, among those who did, typical reasons were that there was insufficient information ($n = 29$) and that it was conflicting ($n = 12$).

As *Table 7* illustrates, slightly over one-half of both patients and family members believed that people with chest problems and their families need different information from others regarding swine flu. Few of either group specified exactly how this should differ, with the most common response across the two groups relating to how swine flu would affect the chest problem ($n = 28$).

Concerns

Tables 8 and *9* detail patients' and family members' concerns regarding swine flu and confidence in their ability to recognise and respond appropriately to the condition; *Table 10* presents data from family members with respect to patients.

Table 11 details patients' and family members' views regarding 'overhyping' of swine flu. The views of the two groups were broadly similar, and slightly more of each group indicated that swine

TABLE 7 *Views on whether information needs of people with chest problems and their families differ from those of others – patients (n = 253) and family members (n = 101)*

	Do people with chest problems (or their families) need different information about swine flu from other people, or not? (*n*, %)			
	Yes	**No**	**Don't know**	**No response**
Patients	141	61	46	5
	(55.7)	(24.1)	(18.2)	(2.0)
Family members	60	29	11	1
	(59.4)	(28.7)	(10.9)	(1.0)

TABLE 8 *Concerns and confidence – patients (n = 253)* (n, %)

Concerns/confidence	Very	Fairly	Not very	Not at all	Don't know
Worried about personally catching swine flu?	59 (23.4)	88 (34.9)	85 (33.7)	14 (5.6)	6 (2.4)
Believe self more likely to catch swine flu because of chest problem?	56 (22.1)	105 (41.5)	61 (24.1)	6 (2.4)	25 (9.9)
Believe self likely to develop complications of swine flu?	95 (37.7)	109 (43.3)	18 (7.1)	1 (0.4)	29 (11.5)
Worried that might die from swine flu?	52 (20.6)	81 (32.1)	62 (24.6)	41 (16.3)	16 (6.3)
Confident could recognise swine flu symptoms?	12 (4.8)	92 (36.8)	104 (41.6)	33 (13.2)	9 (3.6)
Confident would know what to do if thought had swine flu?	38 (15.2)	118 (47.2)	77 (30.8)	13 (5.2)	4 (1.6)
Confident could recognise complications of swine flu?	19 (7.6)	74 (29.6)	120 (48.0)	29 (11.6)	8 (3.2)
Confident that vaccination against swine flu will help?	60 (24.0)	111 (44.4)	50 (20.0)	14 (5.6)	15 (6.0)

Most items had some missing data.
Figures in parentheses = valid percentage.

TABLE 9 *Concerns and confidence – family members for themselves (n = 101)* (n, %)

Concerns/confidence	Very	Fairly	Not very	Not at all	Don't know
Worried about personally catching swine flu?	13 (12.9)	34 (33.7)	45 (44.6)	9 (8.9)	0 (0)
Believe self more likely than others to catch swine flu?	10 (9.9)	24 (23.8)	35 (34.7)	24 (23.8)	8 (7.9)
Believe self more likely than others to develop complications of swine flu?	7 (7.0)	23 (23.0)	40 (40.0)	16 (16.0)	14 (14.0)
Worried that they personally might die from swine flu?	7 (6.9)	21 (20.8)	35 (34.7)	34 (33.7)	4 (4.0)
Confident could recognise swine flu symptoms in self?	7 (6.9)	50 (49.5)	25 (24.8)	15 (14.9)	4 (4.0)
Confident would know what to do if thought they had swine flu?	21 (20.8)	59 (58.4)	12 (11.9)	7 (6.9)	2 (2.0)
Confident could recognise complications of swine flu in self?	10 (9.9)	45 (44.6)	31 (30.7)	11 (10.9)	4 (4.0)
Confident that vaccination against swine flu will help self?	21 (20.8)	49 (48.5)	18 (17.8)	4 (4.0)	9 (8.9)

Some items had some missing data.
Figures in parentheses = valid percentage.

TABLE 10 *Concerns and confidence – family sample regarding their family member with a chest problem (*n = *101)*(n, %)

Concerns/confidence	Very	Fairly	Not very	Not at all	Don't know
Worried about family member with chest problems catching swine flu?	45 (45.9)	31 (31.6)	20 (20.4)	2 (2.0)	0 (0)
Believe family member more likely than others to catch swine flu?	34 (34.3)	31 (31.3)	25 (25.3)	5 (5.1)	4 (4.0)
Family member more likely to develop complications of swine flu?	43 (43.4)	46 (46.5)	5 (5.1)	5 (5.1)	0 (0)
Worried that family member might die from swine flu?	30 (30.6)	35 (35.7)	24 (24.5)	4 (4.1)	5 (5.1)
Confident could recognise swine flu symptoms in family member?	8 (8.1)	48 (48.5)	32 (32.3)	8 (8.1)	3 (3.0)
Confident would know what to do if thought family member had swine flu?	21 (21.2)	50 (50.5)	21 (21.2)	5 (5.1)	2 (2.0)
Confident could recognise swine flu complications in family member?	14 (14.1)	42 (42.4)	32 (32.3)	8 (8.1)	3 (3.0)
Confident that vaccination against swine flu will help family member?	33 (33.5)	48 (48.5)	9 (9.1)	3 (3.0)	6 (6.1)

Some items had some missing data.
Figures in parentheses = valid percentage.

TABLE 11 *Views on whether swine flu has been 'overhyped' or not – patients (*n = *253) and family members (*n = *101)*

	'Too much fuss is being made about the risk of swine flu' (*n*, %)						
	Strongly agree	Tend to agree	Neither agree nor disagree	Tend to disagree	Strongly disagree	Don't know	No response
Patients	15 (5.9)	73 (28.9)	56 (22.1)	51 (20.2)	47 (18.6)	8 (3.2)	3 (1.2)
Family members	6 (5.9)	25 (24.8)	26 (25.7)	24 (23.8)	17 (16.8)	0 (0)	3 (3.0)

flu had not been overhyped than considered it had, with around one-quarter of each group being uncommitted.

Behaviours

Impact on daily living activities

Tables 27 and *28* in Appendix 5 present detailed data regarding reported impact of concerns about swine flu on daily living activities, including both health-promoting activities (e.g. increasing exercise, reducing smoking) and activity limitations (e.g. reducing social activities, limiting travel); family members were also asked if their relative with a chest problem had altered behaviour – these data are presented in the final column. Neither patients nor family members reported high levels of alteration of daily activities, and levels were generally even lower for family members than for patients. The most commonly reported behaviour changes in patients were avoiding crowded places ($n = 55$, 21.7%), trying to get more exercise ($n = 53$, 20.9%) and being more careful about taking regular medications ($n = 52$, 20.6%). In family members, the only behaviour changes that more than 10% of the sample indicated having made were avoiding crowded places ($n = 11$, 10.9%) and trying to get more exercise ($n = 14$, 13.9%).

Sizeable percentages of both patients and family members indicated that because of worries

about swine flu they were more anxious about the patient's chest problem (patients $n = 87$, 34.4%; family members $n = 39$, 38.6%), more aware of it than usual (patients $n = 81$, 32.0%; family members $n = 38$, 37.6%) and, especially among family members, constantly on the alert for changes in the patient's respiratory condition (patients $n = 89$, 35.2%; family members $n = 44$, 43.6%). One-quarter of patients also indicated that they were more self-conscious about their chest problem ($n = 64$, 25.3%); family members much less commonly reported feeling self-conscious about their relative's respiratory condition ($n = 13$, 12.9%).

It is important to note that these are self-reported, rather than observed, behaviour changes, and it is also possible that, although asked to consider behaviour specifically with regard to swine flu, some participants may have responded in more general terms.

Adoption of preventative measures

Self-reported levels of adoption of preventative measures are detailed in *Tables 12* and *13*.

Vaccination intentions

More than three-quarters of patients ($n = 197$, 77.8%) and almost two-thirds of family members ($n = 63$, 62.4%) reported having had flu once or more in the past; of these, 140 patients (55.3%) and 32 family members (31.7%) had done so more than once. Patients had more recent experience of flu, with $n = 107$ (42.3%) having had a flu bout within the past 5 years, the comparable figure for family members being $n = 27$ (26.8%).

Previous levels of regular uptake and current intentions regarding the annual seasonal influenza vaccination are provided in Appendix 5, *Tables 28* and *29*. *Tables 14* and *15* present data on intentions and views regarding swine flu vaccination.

Help-seeking

Only 98 patients (38.7%) and 39 family members (38.6%) reported having chosen someone to act as a 'swine flu friend/buddy'. Of those who had not, 58 patients (22.9%) and 29 family members (28.7%) did not think they needed one, while 74 patients (29.2%) and 26 family members (25.7%) did not know what one was. Fifteen patients (5.9%) and four family members (4.0%) did not know

TABLE 12 *Self-reported adoption of preventative measures – patients (*n = *253)* (n, %)

Preventative measure	More frequently	Less frequently	The same	Have not done it at all	Don't know
Washed hands with soap and water	107	1	141	1	0
	(42.8)	(0.4)	(56.4)	(0.4)	(0)
Carried tissues with you	72	5	144	28	0
	(28.9)	(2.0)	(57.8)	(11.2)	(0)
Avoided crowded spaces or large crowds	53	16	142	32	1
	(21.7)	(6.6)	(58.2)	(13.1)	(0.4)
Avoided public transport at peak times	42	11	109	73	3
	(17.6)	(4.6)	(45.8)	(30.7)	(1.3)
Used sanitising hand gel	100	1	92	54	0
	(40.5)	(0.4)	(32.7)	(21.9)	(0)
Worn a surgical mask	4	1	22	219	1
	(1.6)	(0.4)	(8.9)	(88.7)	(0.4)
Avoided touching your face with your hands	18	22	118	81	7
	(7.3)	(8.9)	(48.0)	(32.9)	(2.8)
Disinfected spaces where you live or work	64	6	127	51	0
	(25.8)	(2.4)	(51.2)	(20.6)	(0)
Avoided kissing or hugging people	35	28	130	55	0
	(14.1)	(11.3)	(52.4)	(22.2)	(0)

Some items had some missing data.
Figures in parentheses = valid percentage.

TABLE 13 *Self-reported adoption of preventative measures – family members (n = 101)* (n, %)

Preventative measure	More frequently	Less frequently	The same	Have not done it at all	Don't know
Washed hands with soap and water	38	3	60	0	0
	(37.6)	(3.0)	(59.4)	(0)	(0)
Carried tissues with you	22	3	67	9	0
	(21.8)	(3.0)	(66.3)	(8.0)	(0)
Avoided crowded spaces or large crowds	16	9	54	20	0
	(16.2)	(9.1)	(54.5)	(20.2)	(0)
Avoided public transport at peak times	15	8	40	32	5
	(15.0)	(8.0)	(40.0)	(32.0)	(5.0)
Used sanitising hand gel	37	2	45	17	0
	(36.6)	(2.0)	(44.6)	(16.8)	(0)
Worn a surgical mask	2	6	16	76	1
	(2.0)	(5.9)	(15.8)	(75.2)	(1.0)
Avoided touching your face with your hands	10	6	48	36	1
	(9.0)	(5.9)	(47.5)	(35.6)	(1.0)
Disinfected spaces where you live or work	21	4	53	23	0
	(20.8)	(4.0)	(52.5)	(22.8)	(0)
Avoided kissing or hugging people	11	9	53	27	1
	(10.9)	(8.9)	(52.5)	(26.7)	(1.0)

Some items had some missing data.
Figures in parentheses = valid percentage.

TABLE 14 *Intentions regarding uptake of swine flu vaccination in patients (n = 253) and family members (n = 101)* (n, %)

	Very likely	Fairly likely	Not very likely	Not at all likely	Don't know	No response
Patients	174	38	16	8	13	4
	(68.8)	(15.0)	(6.3)	(3.2)	(5.1)	(1.6)
Family members	53	16	14	10	7	1
	(52.5)	(15.8)	(13.9)	(9.9)	(6.9)	(1.0)

TABLE 15 *Family members' views regarding whether their relative with a chest problem should have the swine flu vaccine (n = 101)*

'Should your family member have the new swine flu vaccine or not?' (*n*, %)						
Definitely	**Probably**	**Not sure**	**Probably not**	**Definitely not**	**Don't know**	**No response**
64	20	10	1	1	2	3
(63.4)	(19.8)	(9.9)	(1.0)	(1.0)	(2.0)	(3.0)

whether they had an identified 'flu friend' or not. Eight patients (3.2%) and three family members (3.0%) gave no response.

Tables 16 and *17* present data regarding initial help-seeking intentions ('what would you do first?') by patients' family members if swine flu was suspected (*Table 16*) and, in the presence of swine flu, if complications were suspected (*Table 17*); family members were also asked to indicate what they would have advised their relative with a chest problem to do – these data are presented

TABLE 16 *Initial help-seeking intentions if swine flu was suspected – patients (n = 253) and family members (n = 101)*

Help-seeking behaviour	Patients (self) (*n*, %)	Family members (self) (*n*, %)	Family members (for patient) (*n*, %)
Go to A&E	19 (7.5)	4 (4.0)	7 (6.9)
Go to GP's surgery	22 (8.7)	7 (6.9)	7 (6.9)
Call GP/health centre	81 (32.0)	29 (28.7)	61 (60.4)
Call a health helpline	62 (24.5)	30 (29.7)	13 (12.9)
Call 'Swine Flu Information'	70 (27.7)	24 (23.8)	11 (10.9)
Stay at home and self-treat	53 (20.9)	31 (30.7)	2 (2.0)
Visit health-related website	12 (4.7)	7 (6.9)	1 (1.0)
Go to community pharmacist	2 (0.8)	1 (1.0)	1 (1.0)
Contact hospital chest clinic	45 (17.8)	N/A	8 (7.9)
Go to hospital walk-in chest clinic	5 (2.0)	N/A	0 (0)
None of these	5 (2.0)	3 (3.0)	0 (0)
Don't know	12 (4.7)	4 (4.0)	1 (1.0)
Other	4 (1.6)	1 (1.0)	0 (0)

N/A, not applicable.

TABLE 17 *Initial help-seeking intentions if complications of swine flu were suspected – patients (n = 253) and family members (n = 101)*

Help-seeking behaviour	Patients (self) (*n*, %)	Family members (self) (*n*, %)	Family members (for patient) (*n*, %)
Go to A&E	23 (9.1)	13 (12.9)	19 (18.8)
Go to GP's surgery	29 (11.5)	11 (10.9)	8 (7.9)
Call GP/health centre	136 (53.8)	56 (55.4)	57 (56.4)
Call a health helpline	22 (8.7)	10 (9.9)	7 (6.9)
Call 'Swine Flu Information'	25 (9.9)	10 (9.9)	6 (5.9)
Stay at home and self-treat	7 (2.8)	4 (4.0)	1 (1.0)
Visit health-related website	2 (0.8)	4 (4.0)	1 (1.0)
Go to community pharmacist	1 (0.4)	0 (0)	0 (0)
Contact hospital chest clinic	24 (9.5)	N/A	8 (7.9)
Go to hospital walk-in chest clinic	4 (1.6)	N/A	2 (2.0)
None of these	0 (0)	0 (0)	1 (1.0)
Don't know	4 (1.6)	0 (0)	1 (1.0)
Other	4 (1.6)	2 (2.0)	1 (1.0)

N/A, not applicable.

in the final column of each table. Note that these data represent behavioural intentions, not observed behaviour.

Participants were also asked to indicate help-seeking behaviour in relation to a list of symptoms, some of which were 'typical' swine flu symptoms (e.g. sore throat, aching muscles), others representing potential complications of swine flu (e.g. change of sputum colour, drowsiness/confusion) or being a 'red flag' symptom (e.g. haemoptysis) – these data can be found in Appendix 5, *Tables 30* and *31*. Family members were additionally asked about help-seeking for their relative with a chest problem in relation to these (Appendix 5, *Table 22*). Phrasing of respiratory symptoms was chosen to minimise confusion with 'usual' respiratory symptoms. Again,

it should be noted that these were self-reported/hypothetical, rather than observed, behaviours.

The vast majority of patients and family members reported that they would seek help in the presence of such symptoms as tachypnoea/dyspnoea (patients $n = 211$, 90.2%; family members for self $n = 82$, 86.3%; family members for relative with chest problems $n = 89$, 94.7%) and haemoptysis (patients $n = 211$, 90.2%; family members for self $n = 82$, 86.3%; family members for relative with chest problems $n = 89$, 94.7%). Interestingly, the percentage of patients who would have sought help for aching muscles ($n = 121$, 53.1%) and a sore throat ($n = 115$, 50.4%) were similar to the percentage who would have sought help for the more clinically significant symptom of drowsiness/confusion ($n = 135$, 59.7%). This was not the case for family members, either on their own or on behalf of their relative with a chest problem.

For all symptoms, family members reported being more likely to help-seek on behalf of their relative with a chest problem than on their own behalf – although the difference was minimal for haemoptysis.

Antiviral medication

Most patients and family members would have preferred to get oseltamivir on prescription (patients $n = 214$, 84.6%; family members $n = 73$, 72.3%), although around one in 10 patients ($n = 31$, 12.3%) and one-fifth of family members ($n = 21$, 20.8) would have welcomed 'over-the-counter' availability. Very few would have wanted to acquire oseltamivir without having to contact a health professional, for example via the internet or from a health food shop (patients $n = 3$, 1.2%; family members $n = 2$, 2.0%). One patient (0.4%) and one family member (1.0%) selected 'other', but did not specify what this would have been, while two family members (2.0%; no patients) chose 'don't know'. Four patients (1.6%) and three family members (3.0%) gave no response.

Self-reported behaviour with respect to obtaining a supply of oseltamivir, if needed, are presented in Appendix 5, *Table 33*; family members were also asked to indicate what they would have advised their relative with a chest problem to do – these data are presented in the final column. By far the most common action for patients and family members (on their own and their relative's behalf) would have been to telephone their GP (patients $n = 152$, 60.1%; family members on own behalf $n = 58$, 57.4%; family members for relative with a chest problem $n = 64$, 63.4%). Other commonly selected options were calling a health helpline (patients $n = 62$, 24.5%; family members on own behalf $n = 23$, 22.8%; family members for relative with a chest problem $n = 24$, 23.8%) and calling the NPFS (patients $n = 62$, 24.5%; family members on own behalf $n = 29$, 28.7%; family members for relative with a chest problem $n = 31$, 31.7%) and, for patients only, going to the GP's surgery ($n = 60$, 23.7%). Only 12 patients (4.7%) and one family member (1.0% on own behalf; none on relative's behalf) reported not knowing how to obtain a supply of oseltamivir if needed.

Bivariable analyses

Out of all of the bivariable associations between participant characteristics and key outcomes (perceived knowledge about swine flu, concern about the 'fuss' raised over swine flu and intention to have the swine flu vaccination) investigated for patients, only three were statistically significant at the 5% level. Participants educated to degree level or above were more likely to feel that, in terms of their perceived level of knowledge about swine flu, they knew as much as they needed to or knew quite a lot (66.7%) compared with those educated to a lower level (50.0%) and those with no formal qualifications (34.4%, $\chi^2_{\text{TREND}} = 9.25$, df = 1, $p = 0.002$). Participants living alone were more likely to agree that 'Too much fuss is being made about the risk of swine flu' than those living with a partner (45.9% versus 31.5%, $\chi^2 = 4.16$, df = 1, $p = 0.041$). Fewer of those from an ethnic minority background responded that they were very likely to have a swine flu vaccination (47.6% versus 71.7%, $\chi^2 = 5.23$, df = 1, $p = 0.022$).

Out of all the bivariable associations investigated for family members, four different combinations of characteristic and outcome were statistically significant at 5%. Those considering that they knew as much as they needed to or knew quite a lot about swine flu tended to be younger [mean age 55.4 years, standard deviation (SD) 62.7] than those who did not (mean 62.7 years, SD 12.8, $t = 2.43$, df = 87, $p = 0.017$). Participants educated to degree level or above were again more likely to feel that, in terms of their perceived level of knowledge about swine flu, they knew as much as they needed to or knew quite a lot (85.7%) compared with those educated to a lower level (59.7%) and those with no formal qualifications (31.8%, $\chi^2_{\text{TREND}} = 12.65$, df = 1, $p < 0.001$). This

was also true for feeling that they knew as much as they needed to (66.7% versus 34.2% versus 13.6%, $\chi^2_{TREND} = 12.74$, df = 1, $p < 0.001$). The respiratory diagnosis of the patient was not significantly associated with intention of the family member to have a swine flu vaccination when the miscellaneous 'other' category of diagnoses was included ($\chi^2 = 5.22$, df = 2, $p = 0.074$). However, when patients with diagnoses of asthma and COPD only were compared, more family members of asthma patients said that they were very likely to have the vaccination (73.7%) than family members of COPD patients (36.8%, $\chi^2 = 5.22$, df = 1, $p = 0.022$).

Chapter 4

Results: interviews and focus groups

Characteristics of the sample

Three focus groups, coded FG1–3, were conducted with BLF 'Breathe Easy' patient/carer support groups in the North West of England, between November 2009 and January 2010. These included a total of 30 participants, with an approximately equivalent number of males and females and a mix of ages and socioeconomic backgrounds; no focus group participants were from black and minority ethnic (BME) groups. We did not collect data regarding diagnosis from focus group participants, but from our knowledge of BLF 'Breathe Easy' group membership in the North West, we know that most members have COPD or are a family member of someone with this condition.

- FG1 was conducted on 18 November 2009. It lasted 45 minutes (with a further 15 minutes for introductions, etc.) and had seven participants (five patients and two family members).
- FG2 was conducted on 19 November 2009. It lasted 30 minutes (with a further 15 minutes for introductions, etc.) and had 14 participants (10 patients and four family members).
- FG3 was conducted on 19 January 2010. It lasted 40 minutes (with a further 15 minutes for introductions, etc.) and had nine participants (six patients and three family members).

A further three focus groups were planned, but were cancelled by the groups – two for local reasons affecting the group (hence rescheduling was not appropriate) and one owing to the poor weather in January 2010 (next meeting too late to reschedule).

Twenty one-to-one interviews were conducted between November 2009 and January 2010. Interviewees were purposively selected from survey participants, to reflect a range of age, gender, diagnosis and swine flu-related information needs, concerns and behaviours, including vaccination intentions. Nineteen interviews took place in participants' homes and one, at the participant's request, was conducted by telephone. Interviews typically lasted about 20 minutes (range 10–36 minutes); the short duration appeared to reflect the interviews being quite focused, interviewees having had prior opportunity (through completion of questionnaires) to consider their responses. Interviewees' median age was 67 years (range 34–85); 10 were male, 10 were female and 18 were 'white British'. Diagnoses (of patients or family members' relatives with a respiratory condition) were asthma ($n = 4$), COPD, including those who described their diagnosis as 'emphysema' ($n = 7$), ABPA ($n = 2$), ILD, specifically interstitial pulmonary fibrosis and sarcoidosis ($n = 2$), and others, including bronchiectasis and multiple respiratory diagnoses ($n = 4$), while one participant did not know the name of his/her diagnosis. Fourteen interviewees were patients and six were family members.

As they are complementary, and similar themes emerged, data from the one-to-one interviews and focus groups have been combined. Interviewees are identified as 'Int', followed by their identification number and an indication of whether they are a patient (P) or family member (F). Focus group members are identified by FG and the number of their focus group (1–3), followed by an identification number (in parentheses) where it was possible to determine the speaker. The main themes that emerged mirrored those in the survey data (information, concerns and behaviours), with 'hype' emerging as a notable category within information needs.

Information

Adequacy of information

The majority of participants considered the volume of information available in relation to swine flu to be sufficient and had accessed information from a range of sources, both formal and informal (*Box 1*). The government was, on the whole, considered to have done a good job regarding information provision (*Box 1*).

Some participants felt that there was an over-reliance on internet-based information:

BOX 1 Typical views on adequacy of information

I don't think there's any excuse for people not having this information 'cos for people who are not on line there's sort of leaflets and doctors' surgeries have got notices up and things have appeared in the national press. So I think it's well covered … I've tended to concentrate on the website, I find that's excellent, so I don't bother to look anywhere else.

[Int17P]

I don't think they could really have done much better, the advertisements and everything [you know] exactly where you should be going to, and what to and not to do under [different] circumstances … I think it's all out there … It was coming from you from all directions … it was just there.

[Int13P]

> Some people haven't got a computer, there should have been more on the TV that told people what was going to happen and how they could have it, the symptoms … if there'd been more information on the TV it might have stopped people from panicking. [The internet] – was better for me because I could read what the symptoms were …
>
> [FG3(7)]

A small number felt that the information available was insufficient, their views being typified by this participant:

> Only just what I've seen on the TV, and that isn't much information really … just basically that you can catch it off other people, make sure you wash your hands … the government ain't really doing that much if I don't know anything about it! … I watch a lot of TV and if I don't know it, there's going to be an awful lot of people out there don't do as well.
>
> [Int2P]

However, what became evident during interviews was that even those who reported having received little information did seem aware of the key messages included in formal information sources, such as the importance of hand hygiene, protecting others when sneezing, and not placing others at risk of infection if symptomatic.

It was also apparent that there were still outstanding information needs, even among those who felt reasonably well informed. One of the main areas participants would have liked to know more about was how to distinguish between swine flu and other forms of flu or symptoms relating to their respiratory condition (*Box 2*). Other areas in which people felt in particular need of information related to how swine flu was likely to impact on them, given that they had an underlying chest condition, and the suitability of the vaccine for them (*Box 2*).

There were also some misunderstandings and misconceptions revealed, as this data extract from one of the focus groups illustrates:

> R: I'm under the impression that all the swine flu injection is for is to give you one less day of the symptoms if you should get it.
>
> I: Right, so it's specifically information about what benefits there are from the injection itself.
>
> R: Yeah, or COPD.
>
> R: I thought the injection was for prevention rather than cure, the same as the flu injection is …
>
> R: It's what I say about who do you believe you see?
>
> [FG1]

A sizeable number of participants did believe that specific information should have been targeted towards people with an underlying chest condition (or indeed any other long-term health condition), as the general information was not considered to indicate how serious swine flu could be in individuals already predisposed to infections (*Box 3*).

Credibility of information

Some sources of information were viewed as more credible than others, with health-care professionals and formal sources (such as government information) being viewed to be generally of a better quality:

BOX 2 *Typical data extracts regarding additional information needs*

I think the vagueness of the symptoms could be confused with perhaps ordinary flu, or just your condition really. You know, if you've got COPD, then it's not necessarily swine flu at all. And I don't really know how you can say it's swine flu without having any tests [others in group agreeing].

[FG1(6)]

[if I] catch it or get it, would I die from it? … 'cos it's quite, really worrying. I mean there's a lot of people out there who's not bothered really, they're not bothered about getting the injection and all that, but to me I think it is important because it's like, obviously it's on the news, it's mentioned a lot, so obviously it is serious … would I be able to fight it off or like, would I die from it or be really, really poorly?

[Int3P]

BOX 3 *Specific information needs for people with chest problems and their families*

It might be helpful if one could tie specific complaints into the swine flu scene … I have … bronchiectasis … I'm just wondering if I did get swine flu whether that would make the symptoms worse, whether it would complicate matters. I find I haven't got any information on that It might be possible to expand the website. Because looking at it now there doesn't seem to be any section that covers that.

[Int17P]

Certain people, like the people from my group for a start with bronchial problems and things … I think the fact that as soon as you have real breathing complications or you felt you couldn't breathe, this should have been highlighted in some way, because you were concerned about being very poorly, tired, high temperatures, feeling unwell, but I can't remember seeing anything where they indicated that if you had like critical things coming up, what you had to do with them … I do think [info should have come] through doctors and things like that perhaps people with heart disease, diabetes, lung disease, any of these categories, for people with long term conditions.

[Int 20P]

> I do take more notice if it comes by post, if it came from the doctor's or it came from, you know, anything with the NHS, I would take more notice of that than I would of the television.
>
> [Int12F]

> They should have an official government site or leaflet with the proper information rather than [media].
>
> [FG3(9)]

> The internet, that's another thing that might have had damaging side effects … if you don't check whose site you're reading from it can be exceedingly misleading.
>
> [Int20P]

However, some participants indicated that even 'official' sources might lack credibility:

> I mean some people still don't believe the official data 'cos they think the government are just lying basically. One of my own brothers thinks that they're just making it up. And I said well, you know, if they did they're going to kill a lot of people and if nothing else the compensation claims would be horrendous, so, you know, it's, unlikely, but I think it is a problem what people get told.
>
> [Int10F]

Many participants referred to the unreliability of information from media sources, in particular given the media focus on promoting viewing or sales figures, as opposed to disseminating balanced advice:

> It's a bit of bunkum a lot of what they say on there [TV] … the trouble with the television is they only give you a certain aspect of it, what they want to tell you … a lot of the things that come through on the news, news bulletins aren't strictly true are they?
>
> [Int4P]

> Well if the government put it into the newspaper it should have a government stamp on, and that's the only bit they can put in to the newspaper, is what the government's told [them, not] … we'll put that in, that'll make it more exciting … an official stamp, so that I

> can say, well that's from the government … it's not from the *Express*, it's not from the *Mirror* making their own bits on … and I think that would be the best idea.
>
> [FG3(8)]

Many participants believed that there had been a considerable amount of hype in relation to swine flu, most of it emanating from the media. This was felt to have had led to a considerable amount of anxiety, and even panic:

> Yeah, at the beginning we thought everybody would die, especially us like with a bad chest. But … I think it made everybody panic … there was a lot of hysteria … I think it was just too much publicity.
>
> [Int9P]

> … the television's the problem isn't it really. Where years ago we would just hear about something in Mexico, sort of like in the early 50s where only a few people had TVs they would have just been saying, oh there's some kind of epidemic up in Mexico, nobody would have bothered about it. But now the TV brings it in to your front room, maybe, it's sensationalism isn't it really.
>
> [Int18F]

Some participants felt that a certain amount of hype was perhaps necessary in order to prevent people from being too complacent about swine flu:

> I feel they've a lot of hype with a lot of things, not just the swine flu, and particularly the media, they like to blow things up, don't they? They like to scare people really. On the other hand I suppose scaring people is only one way to get them to move.
>
> [Int16P]

Others, however, considered that 'overhyping', including by the government, was leading to cynicism and blunting the impact of messages:

> Well, this is one of the problems with this, the civil service get up, things get overhyped, it seems to me that they, this present government doctor over exaggerates everything. I mean … this pandemic has been going to arrive here for the last how many months now, you know? And you get to the point where you're thinking they're just winding us up.
>
> [Int4P]

> I think at first people watch it and at first it's a shock thing, but after a while it's just an advert …
>
> [Int18F]

This perception was reinforced by the fact that the potential impact of swine flu, presented at the outset of the pandemic, did not appear to have materialised in the months that followed. Some felt, however, that 'downplaying' of swine flu, particularly by the media, was premature:

> But with this new thing I find this far more threatening that the media are getting now because they're inferring that it's not as serious as we thought. Which is absolute rubbish, people have died, some people have been left permanently damaged and I think it's rubbish, and they're giving the impression that it's all gone away which it may not have done, I think they're a little premature.
>
> [Int 20P]

Another perceived negative impact of media hype was the fact that key messages were unable to get through as they were hidden amongst the sheer volume of information that was presented to people, a view typified by this data extract:

> Well basically there's tons of information I would say, but unfortunately the newspapers tend to exaggerate it all I think. And what you find you're struggling to do is to pick through what actually you need be watching for, and what you don't … so there's kind of a manic picture of this, people are frightened and I think there are just too many sources of information, that's the impression I get.
>
> [Int15F]

Inconsistency of information was also identified as an issue by some participants:

> The most useful was the television to be honest … 'cos they more or less spelt it out, the only thing was that it kept changing week by week, different criteria, one minute it was specific groups, then it was another group.
>
> [Int1P]

Although many participants had reservations around how the swine flu pandemic had been presented in the media, they did not consider the pandemic as a whole to have been overhyped by the government, particularly given the potential impact of swine flu. In many ways the government

was viewed as being in a 'no-win' situation, whichever course of action they had taken, as this data extract highlights:

> I don't think the government can basically do anything to get it right basically, because they'd just be wasting more money, you didn't need to have all that printing [of new leaflets] and yet if it goes really wrong and nobody takes any notice and say hey, it was only mild, and then they all get it and lots more die, then they'll say, the government should have warned us. So really, like, they're between the devil and the deep blue sea.
>
> [Int20P]

Anxieties and concerns

Overall, participants did not indicate high levels of anxiety or concern about swine flu, although some did indicate that early in the pandemic they and others had been very concerned:

> Alright, a lot of them panicked, but then you can't help panicking can you? If it's somebody, your child or your husband or whoever's close to you, you're bound to panic.
>
> [Int11F]

> I only knew what I knew from the news and the papers, like thousands were going to die and all this … [at] the time you believe what you're hearing because you don't know any different and it's quite frightening … 'cos people saying it [vaccine] hadn't been tested and all this, that loads of people were going to die. Well sadly loads of people die of seasonal flu and it was no higher or lower in particular than anything.
>
> [Int10F]

The presence of an underlying condition in patients and family members, and awareness of how seriously ill patients could be if they developed an infection, was a common source of anxiety:

> … when swine flu kicked off and we thought, well it's a bit more pertinent to us than perhaps to a normal healthy person and to our two sons, they weren't bothered at all, but we were a little bit more worried I think.
>
> [Int19F]

> [with seasonal flu] we all feel quite safe because we've got a protection and we know ordinary seasonal flu can be serious. But we've got our jab and it's protected us. And suddenly there's a flu out there what there hasn't been a jab for, and we can catch it as quick as anybody else. And nobody quite knows what really effect it's going to have on us and I think this has been some of it, because right at this time we're vulnerable, we've no protection given us. And we all feel as we need that protection to get through this … And I think that's making us worry.
>
> [FG1(7)]

Although a number of participants voiced concerns regarding swine flu, very few appeared to be extremely anxious – indeed several indicated that they were not concerned at all or appeared quite fatalistic:

> Well if we get it we get it don't we? But … we're not putting ourselves into a position knowingly that we'll get it, that we'll catch it off anybody else.
>
> [Int4P]

> Well [if I catch it] then I move from here to the graveyard, the cemetery, what the hell, it doesn't really matter [laughing] I've had my three score years and ten, so I'm not bothered.
>
> [Int 5P]

> No, I mean obviously it crossed my mind and I thought, you can't just isolate yourself, you can't make the front door a barrier because there's germs out there, you've just got to get on with it, just got to get on with your life.
>
> [Int18F]

For others, their underlying condition was of greater concern to them than swine flu:

> [My wife's] got such bad problems anyway, it's the least of her problems. I mean she's got sarcoidosis and she's got aspergillosis, there's a third one as well … So the least of her problems is swine flu, I mean she's having to cope with just living with them.
>
> [Int15F]

> I can't eat properly and while I'm eating I'm gasping for breath … so swine flu is the least of my worries, if you know my meaning … this [chest problem] is the priority. If I can get this right, if I can at least walk a little bit more than I can do now, I'd be happy.
>
> [Int5P]

Many of the concerns expressed by participants revealed gaps in information, or failings in information received by individuals, as can be seen from the preceding data extracts, and the role of quality information-giving in allaying concerns was highlighted:

> So when you get informed facts it does make a big, big difference.
>
> [Int10F]

Types of concern

A concern commonly expressed by both patients and family members was how they would know if they actually had swine flu:

> [Re. leaflet] … it just had swine flu on it, like information, like the symptoms, how to recognise it, which is very much like the normal flu what you get. That makes you panic a bit more, thinking god, if you had normal flu, would you have swine flu, or would it just be the normal flu? … I mean I know they say you get a really high temperature, but sometimes you get a high temperature with a normal cold, so it makes it complicated again, so you're thinking, where do I stand?
>
> [Int3P]

> I think that's the main concern of not knowing more than anything. You think to yourself, if you started with a sore throat and aching, that's normal flu. Sore throat, runny nose, you know, aching bones, I mean that's all the normal symptoms of swine flu, so I suppose then if you've got three of them, they say two of them, but surely to god two of them is not swine flu. I mean we could have had it already and we don't know we've had it. And this is the thing, you're still worrying about it, but you could have had it if you've had flu.
>
> [Int11F]

Another common area of concern related to the swine flu vaccine (*Box 4*), even amongst individuals who normally had the annual seasonal influenza vaccine. Safety was viewed as an issue given that it was a new vaccine. Others were concerned that the vaccination could impact on their underlying condition and/or interact with the medications required for their respiratory problem.

One participant was especially anxious about the vaccine and the interview was dominated by discussion of this topic. This participant's fear of the vaccine was greater than that of swine flu, even though she had direct experience, through her daughter, of how ill swine flu could cause someone to become:

> I was a bit concerned when my daughter had it [swine flu], because she was poorly, she was poorly with it … but she did get the Tamiflu and yet, even though I saw her like she was, I still at that time didn't think, 'Oh well, you should have that [vaccine]'.
>
> [Int7P]

Conversely, fear of swine flu itself had led some participants to decide to have the vaccine, or to encourage family members to do so, as a means of alleviating anxiety:

> I was a bit concerned over that because they were saying it's not been checked out enough … and then anyway I just ended up having it … because I don't want to die having swine flu, I don't want to be poorly.
>
> [Int3P]

BOX 4 *Typical data extracts regarding concerns about the swine flu vaccine*

R: How, how has it been tested, has it really and truly been tested as well as we're led to believe it has shall we say?

R: That's the question, yes.

R: Has it been rushed through or, you know, how, how safe is it?

[FG2]

I've been dithering about whether I should have an inoculation or not, but I suppose I really ought to, but – I mean I'm so ill otherwise that I wondered whether it would do me any good [unsure] whether it would make me ill or not really. But if not I don't object to one, it's just I know I'm not very well so, you know, it's going to – if it's going to affect anybody I think it probably will bump me off.

[Int8P]

> I think once he's had it I can relax a bit … psychologically it will do him better because of the complications he's got.
>
> [Int11F]

Behaviour change

Preventative measures

The general lack of anxiety amongst individuals was reflected in the fact that most reported little, if any, change in their behaviour as a result of swine flu. However, it was apparent in most interviews that behaviours recommended by official sources had been taken up, hand hygiene in particular, as the following data extracts illustrate:

> I thought, you've just got to carry on with your life, you know what I mean, I wasn't one of those that sat down and worried myself to death about it. If you're going to get something you get it … I just took extra care. I always carried one of these hand things around with me, always, I still do now. So apart from that I just steer clear of anybody that's sneezing or something, you know what I mean, things like that. You can't avoid it, you've got to carry on with your life. Well that's my philosophy anyway.
>
> [Int16P]

> No, it's not altered me at all, no. I've just carried on normally … yes, I've started washing my hands regular, I have done that … But as far as being in crowds, no, that hasn't bothered me.
>
> [Int14P]

While participants on the whole had not isolated themselves, some were more conscious when in public places or around people who might have been symptomatic:

> I have uh cut down going out, because, I mean I live on my own as well, I've nobody to look after me, and I've just been trying to keep myself protected without shutting myself off, for just thinking a little bit, should I go there.
>
> [FG1(7)]

> I won't go if there's a lot of people – if anyone's say got a cold, it could be a general cold or anything like that: 'don't come into my house' … and I feel a bit rude by saying it, but I'm just scared … I don't know if it's being paranoid or just being cautious.
>
> [Int3P]

Help-seeking

When asked, most participants indicated that they would telephone their GP, an NHS helpline or their respiratory consultant for advice if they felt that they had symptoms which could indicate swine flu:

> I would have phoned the doctor's and asked their advice, but I know there's advice centres, isn't there? And I would have phoned them. And, 'cos I realise that going to surgeries, going to hospitals, is just taking it there, so I wouldn't, the one thing I wouldn't have done was have gone there.
>
> [Int18F]

> Well, straight, I'd phone the doctor straight away and probably be advised by them. If for any reason I suppose I couldn't get through to the doctor I'd probably phone the helpline, the NHS [Direct] helpline … and see what advice they gave me.
>
> [Int12F]

However, other views differentiated between appropriate help-seeking for a person with a long-term condition and the general public (*Box 5*).

> Amongst others, however, there was some confusion about what was appropriate action for people with a respiratory condition:
> I know that they say you can't [go to doctors], but there's a difference between – and this is where I think the problem is, they weren't told what you did if you got really, really poorly with it … [Son, has asthma and was ill with confirmed swine flu. He said 'I can't go', and I said 'Well I'm sorry but I'm taking you in', [daughter in law] said,' oh you can't take him in because they won't let you in'. I said 'look [name] if I don't do something he'll be dead tomorrow'.
>
> [Int20P]

There was considerable reticence about using hospital services, and some confusion about when or whether this would have been appropriate, typified by this data extract:

BOX 5 *Views on appropriate health-seeking for people with long-term conditions*

Well hers would probably be more complicated [if symptomatic] She's got a consultant she sees at hospital, and she's got very complex breathing problems … But that would be her port of call, to me, the consultant would be the expert who would know … [if complications] well there's a chest specialist clinic at [hospital] and he's a recognised world expert in that area, so he'd be the first port of call [by telephone] … I wouldn't move anywhere till we knew what was going on.

[Int15F]

If it was [my wife], I would have been inclined to call an ambulance and get her to hospital quick, because on the two occasions that she's had pneumonia now she's gone down hill very, very quickly … If it was my eldest son, who's a fit and healthy 20 year old, and he wasn't getting better, then I would ring the GP and say, well this stuff either isn't working or – what shall we do next?

[Int19F]

For people with lung disease I would have said … seek advice from your GP or from the hospital … because I think the risk of dying from breathing related things and the pneumonia and the other things were very high … OK don't go to your doctor and put others at risk, but ring and speak to your GP or the hospital regarding this change in your already existing condition, and that would be right across the board [for long-term conditions].

[Int20P]

> I know you could take them to hospital, but I don't know whether it's always a good thing. Unless, I mean it's different if you've got complications of course, I think you'd have to, you know.
>
> [Int12F]

Those who had sought help had typically had positive experiences:

> I thought I was starting with it once, and I did phone the swine flu line up. And they told me to go back to [NHS] Direct, to phone them up, because they felt I needed to talk to somebody with more experience, because of the existing conditions I had. So as soon as I mentioned that, they passed it on. And then from there they said I had to phone my doctor up because of the underlying condition I had, which I did. And the doctor come out to me and they also give you a prescription for the Tamiflu … But that was done for me straight away … the locum was out within an hour, so it was good.
>
> [FG1(7)]

Vaccination uptake

A variety of factors appeared to influence whether participants were likely to have the swine flu vaccine or not. Perception of risk from swine flu was one such factor:

> She [my wife] doesn't, doesn't seem to want to go … she's always had the 12 months' influenza jab … I think it's a good idea to have it if you're offered it. But she seems to think that maybe it's not as bad an epidemic as it's been built up to be in the media and therefore it's probably no greater risk than normal 12 monthly, you know, the annual winter flu that anybody can get. So I think it's on the basis of, 'I probably won't get it', kind of thing.
>
> [Int19F]

> No. The, the surgery asked me if, if I was interested in getting that swine flu uh … And I said what for? I said I've never had a cold in all these years, I've never – I mean I get my usual flu jab … [for] ten years I've been getting [that].
>
> [Int5P]

Others felt that it was better to rely on the body's natural defences to fight off infections:

> I don't worry about medical issues, I tend to find they take care of themselves as long as you look after yourself I think sometimes you're better off letting your body … do its work.
>
> [Int13P]

Information-giving about the vaccine was felt to be lacking, most indicating that they had simply been informed that they were eligible to have the vaccine, rather than being given more detailed information to help them decide on the appropriateness of the vaccine for them:

> I said, what for? I mean I've had my flu jab like, I said isn't that good [enough]. [They said], you're not forced to do it. So I said if it's optional, no thanks … That was on the phone and that was it. No more.
>
> [Int5P]

Some who had already received the vaccine also indicated that they had received little in the way of information at the time of vaccination, as clinics specifically set up for the vaccination programme were very busy:

> Basically it was just like, go in, get the jab, and then out again. No explanations or anything … because everybody come into the surgery at once to get the swine flu and we were like queuing up and it was just jab and out.
>
> [Int2P]

The influence of health-care professionals on the uptake of the vaccine also became apparent during some of the interviews, although participants were not asked directly about this. Some had been encouraged, either by their hospital specialist or their GP to have the vaccine, given that they had an underlying condition:

> Well I was just called up for it from … the doctor's. They asked us if we wanted to have it … I'd already had recommended that we did [from specialist]. Well I did. I was vulnerable. And I was in one of the first batches to go out … You're in and out. You only see the nurses for that anyway.
>
> [Int4P]

> … in my condition, he [doctor] advises that I should, but he's not saying you've definitely got to, I think it's a random choice, you either do it or you don't. The flu, I mean, and warfarin, I mean and things like that, I've got to do it … but he said I would advise that you did.
>
> [Int7P]

A small number of participants had felt slightly pressurised into having the vaccine, even although they had some reservations about taking it:

> … so I said to her, do we have to come? Well she said, well – in other words yeah … my husband's been going for years, but I wouldn't go … Because we had an auntie what died about a week after she'd had one, and I knew somebody else who'd died about a month after having one, 'cos you get, with the flu injection you get like a bit of flu don't you? … they more or less said we had to have it.
>
> [Int9P]

> … even the receptionist pushed me to have it and I said no, I'll have to wait till the doctor decides … so the receptionists are actually pushing you to come in and have your injection, and that's without medical, you know, from the doctor [with] knowledge of what you're on. So any side effects might be more refer to you because you've got a chest problem. They're just thinking because I've got a chest problem you should have it.
>
> [FG3(R8)]

The influence of health-care professionals was also apparent in other ways, their actions having an impact, either positive or negative, on the perceived safety of the vaccine:

> R: I think a lot of it, you know, when you read it in the press … I think reports in the press when they say, only 25% of national health workers, the nurses, what have you, have agreed to have it. That then makes me think they know something I don't or – so to me it's very negative the way it's been put into the press, very negative.
>
> R: But surely I think the ordinary flu jab was very low in the take up from NHS workers anyway, so there's nothing very different in that is there really? Maybe they're anti-injections.
>
> [FG2]

> R: I don't think they know enough about it, and obviously my GP's in the clinic, they've all had it, and obviously they must have done their research into it else they wouldn't have done, and all the receptionists have had it, and I thought, well he wouldn't – you know, going through the doctors, 'cos there's seven, well he wouldn't have had it, you know, things like that. And I felt a bit easier after talking to him, but I'm still not sure. Can you get it twice?
>
> [Int7P]

Although by the time of data collection the majority of participants had been invited to have the vaccine by their general practice, some felt that there had been inappropriate delay in the

vaccine becoming available for them or their family member:

> [My sister's not had it as] there's not been enough vaccines coming through, they've got 500 and the GP has three and a half thousand at risk patients … but of course they've got to fit clinics in, you know, everybody's overworked with the swine – you know, all the surgeries, and they just can't get the clinics … she wouldn't have done it if I hadn't told her to.
>
> [Int 10F]

> I'm 66, and [my GP] said, 'sorry, you don't qualify for it, it's only up to 65, and we're not giving it to other people at the moment, regardless of the, the risk group they're in,' and if I phone him again in January to see if you may get it. Now to me that is a disgrace, it's also going against what the government has said, that it must be for people over six months who are not at the risk group you should be working off [sic], and [locality] has put a limit on them being 65. And this is scary.
>
> [FG1(R7)]

Oseltamivir use

A number of interviewees made reference to oseltamivir when discussing help-seeking. There appeared, amongst the sample, to be reservations about both the efficacy and safety of this product.

> I mean I've heard there's a lot of side effects with them and you can end up poorly with the Tamiflu tablets and I didn't fancy like taking 'em if I didn't have it, if it wasn't necessary.
>
> [Int3P]

> No we accepted that she needs to take protection, so it's silly not to take [the vaccine] – where the Tamiflu thing is I think a totally different thing. I think the injection's more to help you build up the antibodies and so on, whereas the Tamiflu stuff is more you've got it and take this and hopefully it will sort your problems out.
>
> [Int15F]

> I don't even know if Tamiflu works.
>
> [Int18F]

The media appeared to have influenced some participants' views, whereas others were influenced by concerns about interplay with their existing respiratory condition and treatment:

> [Newspaper suggested] it could make you really ill for a few days. Now whether that was a deterrent just to stop people getting it just for the sake of it I don't know. But nevertheless, when it came to me, I mean I was quite concerned about it, because I've got complex needs as you know.
>
> [Int20P]

> I've sort of heard conflicting information about them, so I'm not sure that I would necessarily dash off to get a dose of Tamiflu. Because I mean the thing is it all comes back to this one point that I've made, that really I'm not quite sure what the effect would be with my own particular problem … there is some doubt [from the press] as to whether it is effective and also whether in fact, whether it had any bad side effects.
>
> [Int17P]

At the other extreme, some interviewees made reference to people having obtained oseltamivir as a precautionary measure; this was typically viewed as inappropriate:

> And I know people were stupid, I remember I heard on the radio about a guy whose wife and his daughter, they thought they had the swine flu, but he didn't seem to have the symptoms yet, but he lied over the telephone knowing what the symptoms were. So … that the minute he got it he would start taking the medication, and I think that's what a lot of people have done. And I think people are just – selfishness is just – something like this, a pandemic, brings out the worse [sic] in people. So my view is, I'm glad I didn't take it earlier, than panic. If I did get symptoms now, yeah, I'd take it.
>
> [Int15F]

There was also some confusion about eligibility for and appropriate use of oseltamivir:

> I must admit I've been a bit puzzled by that because many people were treated with Tamiflu when it all started to explode in the first quarter of this year and then we were told after you took it that if you got hit by the second wave you can't take the Tamiflu again. That's really bad.
>
> [Int15F]

Chapter 5
Discussion

Sample

There was a reasonable representation from most demographic groups, although participation of BME groups was modest. The representation of diagnostic groups is fairly typical of that seen in hospital chest clinics; the slight bias towards 'other' diagnoses in the family member sample reflects the relatively high level of participation of family members of patients with ABPA ($n = 9$), mainly from the tertiary centre. Although the high percentage of participants who did not know the name of their own/family member's diagnosis may seem surprising, our previous work has indicated that this is fairly common.[56] The sample's mean age was over 60 years, although there was a good age range that included representation of young adults. The greater incidence of some respiratory conditions (e.g. COPD and ILD) in older people[1,2] may have contributed to the sample's relatively high mean age, as may recruitment through BLF 'Breathe Easy' groups in the North West region, as these are typically attended by more older than younger people. The swine flu pandemic has mainly affected people younger than our sample's mean age. However, age was a secondary consideration in this study. The chosen population was a high-risk group, because of their chest problems, hence, regardless of the high mean age, the sample's needs, concerns, behaviours and views on the adequacy of the government's response to the pandemic remain of relevance. The impact of the smaller than planned family member group sample size is considered under 'Limitations'.

Information

Patients' and family members' responses regarding information were broadly comparable. Many participants, both patients and family members, would have welcomed further information about swine flu, although few felt completely uninformed. There was, however, an interesting contradiction in the data (apparent in survey and qualitative data, but particularly well highlighted in the latter): many respondents reported feeling uninformed/not having received information yet were aware of key messages (e.g. regarding prevention). This suggests that information may have been 'absorbed' from a general background, which is encouraging from the perspective of penetration of messages. It does, however, highlight a well-recognised issue in provision of health-related information regarding retention and recall of material.[57,58]

More participants were 'very' or 'fairly' satisfied with the amount of information they had received about swine flu than were dissatisfied. Likewise, the majority of patients and family members thought that the information they had received about swine flu was helpful. Factors that could have improved the usefulness of information related to volume (with both lack and excess of information being commented upon); credibility, particularly the need for mechanisms to help lay people better identify trustworthy information; and consistency. The last of these is particularly challenging in the context of a pandemic, where the situation is constantly changing and being reviewed,[18–20] which some participants did recognise.

High importance ratings were given to most information topics and responses from patients and family members were broadly similar, although family members were consistently less likely to rate items as 'not at all important'. This apparent lack of discrimination regarding 'important' and 'unimportant' information presents a challenge for information developers when selecting what to focus on or include. Internet-based material may offer the most flexibility in this regard, as readers can be provided with links to allow them to read more widely. However, as some participants noted, there are issues with respect to 'reach' and accessibility of internet-based information (although this may become less of an issue over time and with the government's focus on improving internet access). Written information is arguably the most limited in this respect – yet participants cited this as their main information medium.

Information relating to the risk of developing swine flu and help-seeking was less commonly identified as being of high importance in both groups; this was particularly so for information relating to family members' risk. Interview data suggest that this may have been due, at least in part, to fatalism,

which has implications for education regarding, and uptake of, preventative measures, as was noted in an earlier swine flu outbreak, some decades ago.[59]

Perhaps unsurprisingly, the item in both groups with the highest percentage rating it as 'very important' was 'how swine flu might affect chest problems'. Overall, however, importance ratings for information specifically related to chest problems did not differ markedly from those of more general information (although this may be due to a 'ceiling effect'). This is interesting, as more than one-half of both patients and family members in the survey felt that people with chest problems and their family members needed targeted information and this was also an important theme in the focus group/interview data. Although some information targeted towards people with long-term conditions, including respiratory problems, did emerge during the course of the pandemic (e.g. on government and health-care charity websites[4,7,60,61]), the volume of such information remained low. Providing such targeted information is challenging. Web resources are clearly feasible although, as participants highlighted, may not be accessible to all (and, in this sample, had only modest levels of uptake). Organisations such as the BLF or Asthma UK could be a resource of targeted information, both via websites and to members – but may not have wide 'reach', may have limited resources and, as our data suggest, may not be widely used. Use of primary care disease registers as a means of targeting information is a possibility but primary care services were already heavily stretched in the pandemic[30] and may not, therefore, be able to resource such an endeavour.

The most common medium through which information was received was a leaflet delivered to the participant's home. Although these leaflets were widely delivered to UK households, about one-half of the sample did not appear to have received such a leaflet – or were not aware of having done so. This was actually a slightly higher percentage than reported receiving the leaflet in a UK-based general population survey conducted in May 2009.[16]

Mass media sources were also widely used – but their credibility was limited, which is problematic. The need to ensure that key messages are delivered through the mass media to patients and their family members in a way that is perceived as credible and 'untainted' is apparent. For participants in this study, health professionals, particularly those in primary care, were identified as a key actual and potential information source. Perhaps unsurprisingly, hospital consultants featured relatively highly for patients, but less so for family members. The perceived importance of health professionals regarding information-giving may reflect participants' perceptions of 'special needs' with respect to information and also that they may come into regular contact with health-care services. Only modest numbers had used official websites or telephone helplines – although interview/focus group data suggested that these were perceived as an appropriate 'first line' of information-seeking. The NPFS had been established for several months by the time data collection commenced[31] and more participants considered it to be useful than not. Low levels of usage may therefore reflect perceived and actual need, rather than being a reflection on usefulness.

Participants were asked a series of 'true/false' questions, which enabled understanding of swine flu 'facts' (in so far as these existed) and 'myths'. These questions also enabled some exploration of risk perception and penetration of key messages being disseminated by official sources.[4,7,24,60,61] Both groups were readily able to identify 'myths' (e.g. regarding eating pork products and 'swine flu parties') and some key messages, for example regarding hand-washing. Some of the recommendations in official information for patients/the public had a strong evidence base.[25] In some instances it is perhaps unsurprising that participants were confused, for example on the issue of prophylaxis for close contacts, official guidance from the HPA was that these should be given only to at-risk close contacts on the basis of 'case-by-case' assessment,[52] but even reports aimed at health professionals were sometimes misreporting this guidance.[62]

There was some confusion regarding antiviral treatment (both what it was and who would be eligible for it); the high level of misperception of oseltamivir as a vaccine for swine flu is particularly notable and suggests a need for improved future information-giving. Similarly, a lack of information about the swine flu vaccine was noted, even at the point of administration, which is a cause for concern. The challenge of ensuring fully informed consent in the context of a pandemic, with attendant pressure on services, is apparent. Participants rightly identified themselves as being in an at-risk group, but some then had their expectations confounded by finding themselves in the 'wrong' at-risk group, which led to confusion

and frustration; these data suggest that future information about eligibility for vaccination in at-risk groups needs to be clearer.

There was appropriate recognition of the greater risk posed by swine flu to people with chest problems, in terms of complications and mortality.[4,60,61] However, most patients and family members also considered people with chest problems to be at increased risk of developing swine flu, which was not consistent with key messages being delivered either to the general public or to this group specifically.[4,7,24,60,61] Indeed, there appeared to be limited awareness overall of who was most likely to develop swine flu, as questions regarding particular age groups were also often answered incorrectly. The data highlight a need to improve future communication of information regarding susceptibility. Doing so would be challenging, especially in a media climate that focuses on 'high-impact' stories and may therefore skew public perceptions of susceptibility.

Most patients and family members appropriately identified symptoms that had and had not been indicated as 'typical' of swine flu (e.g. sudden high fever) in authoritative patient information.[4,7,24,60,61] Some 'complications' (as opposed to 'typical' symptoms) of swine flu (e.g. confusion, change of sputum colour) were identified by sizeable numbers of both patients and family members as swine flu symptoms. Over one-half of the patient sample and one-third of the family members were not aware that diarrhoea/stomach upset could be a swine flu symptom. This group of items had the highest non-response rate, for both patients and family members. Participant fatigue is possible, although later questions were answered well. It is therefore possible that at least some of those who did not respond were unsure and hence unwilling to commit.

The importance of the mass media in shaping views on and responses to swine flu and its treatment was readily apparent, particularly in the qualitative data. This was particularly notable with respect to vaccination and, especially, oseltamivir. By the time of this study – and particularly towards the latter part of data collection (December 2009/January 2010), several highly critical articles, some underpinned by criticism from scientists, had appeared, especially in certain sections of the UK mass media, questioning the value of oseltamivir and alleging 'hyping' of the risk of swine flu by pharmaceutical companies to promote product sales.[63–67] A television programme in December 2009,[68] which related to a Cochrane review in a respected medical journal,[69] questioned the efficacy of oseltamivir; this was widely picked up in other sections of the media. Few participants mentioned specific media stories, and none highlighted the television programme noted above. However, many spoke in general terms about stories in the media and it was clear that these were raising doubts for some about whether or not to take oseltamivir, if prescribed, or to be vaccinated. There is a clear tension between the role of the media in tackling controversial issues and raising questions about government policy – legitimate activities within a democracy – and the need to ensure that important public health messages are not drowned out with associated implications for health-related behaviour.

Mass media appeared to have a conflicting role, being both a widely used and influential information source, but also one that lacked credibility and, at times, caused confusion and created anxiety. Participants were widely sceptical about information received through the media, both in terms of accuracy and intention. However, they also recognised the strength of mass media sources and their potential value as means of mass communication regarding swine flu. This duality is important from a policy perspective, with the need to recognise the strengths and limitations of mass media sources in communicating information regarding a pandemic being apparent. Participants made some interesting suggestions to improve the clarity and credibility of future messages, such as 'kite-marking' official information and limiting media sources to reporting only official information and 'facts'. Some of these would be unfeasible or unenforceable. However, the potential usefulness and acceptability of some approaches (e.g. 'kite-marking'), both to intended recipients and to media outlets, could be explored.

Concerns

In the patient sample, more were worried than not worried about swine flu and its associated risks, although interview/focus group data suggested that individuals were typically not highly anxious and, indeed, were sometimes fatalistic or even complacent. Overall, participants appeared to have taken a very measured stance with respect to swine flu, with their perceptions often being coloured by previous experience of ill health.

Almost two-thirds of the patients incorrectly identified themselves as being more likely than others to develop swine flu, but over three-quarters correctly identified their greater likelihood of developing complications.[4,7,24,60,61] There was a relatively low level of confidence in ability to recognise swine flu symptoms and complications, but more regarding taking action if swine flu was suspected.

There were lower levels of concern about personal risk of swine flu in the family sample. Nonetheless, almost one-half of the sample were 'very' or 'fairly' worried about catching swine flu, and one-third were concerned that they might die from it, while around one-third incorrectly identified themselves as being more at risk of catching swine flu or developing complications of it because of their having a family member with chest problems. By contrast, family members' levels of concerns about the risks posed to their relative with a chest problem by swine flu were high – this was supported by interview/focus group data, where family members more commonly spoke about risks for/needs of patients than themselves.

Data from study participants suggest that some key messages regarding risk had penetrated well, whereas others had not done so. The data regarding concerns and risk perceptions contrast with international general population surveys,[70–72] which indicated that by autumn and winter 2009–10 levels of concern about swine flu had dropped markedly and to quite low levels.

Confidence in the benefit of vaccination was high in both groups, and family members were particularly confident of the benefits for their relative with a chest problem – more so, indeed, than patients themselves. This contrasts sharply with general population surveys, though from outside the UK, which indicated lack of confidence in vaccination.[70–72] The UK-based Ipsos MORI poll did not specifically ask about swine flu vaccination (it was conducted in May 2009, well before vaccination programmes began), but at that point 84% of their 1000 respondents disagreed with the statement that 'there is nothing that can be done to treat people with swine flu'.[16] A recent systematic review of the effectiveness of antiviral medications in influenza (not specifically swine flu) showed that such drugs were effective in reducing symptom duration (by 0.5–1.5 days for general populations and 0.5–0.75 days for at-risk groups), although data reviewed were described as often being 'limited'.[69] Interestingly, participants in our study had greater confidence in vaccination than in antiviral treatment. It is not fully clear why this was the case, although in the qualitative data the influence of the media was readily apparent and concerns about interplay with existing symptoms/medications also came into play.

With respect to concerns, the role of the mass media was again apparent, particularly in the qualitative data, with media reports from the time of the initial outbreak in Mexico (April 2009) up to a few months after the pandemic being declared (June 2009) clearly having generated concern and later media treatment of the pandemic (from the latter part of 2009 and early 2010, which coincided with the data collection period for the present study) potentially contributing to complacency. There was some sense that the threat of swine flu had been overhyped – again a common theme in the media, even from before the declaration of the pandemic and certainly by late 2009/early 2010 (when data collection for our study was taking place), by which time it was apparent that the virus was milder than anticipated.[63,66,67] However, fewer in our study than in general population studies in the UK and USA considered that there had been 'overhyping' of the risk from swine flu.[16,70–73] For our participants, the sense of overhyping was tempered by recognition of the potential seriousness of swine flu – or, indeed, any flu – for people with respiratory conditions.

Participants in our study were generally supportive of the government's health services response to swine flu, recognising the tensions and uncertainties inherent in dealing with a pandemic. In this regard, they were similar to participants in the Ipsos MORI general population survey[16] – although this was conducted in May 2009 (and therefore preceded the declaration of the pandemic), hence the data are not entirely comparable. It is interesting that our participants remained so positive about the government's response as, by the time of data collection (and, in some instances, even before the declaration of the pandemic), some sections of the mass media in the UK and internationally – and even some scientists – were becoming increasingly hostile about the effectiveness of governments/the WHO and the perceived influence of pharmaceutical companies.[63–68] The government, the Council of Europe and the WHO are all conducting reviews of responses to the pandemic, in part to address the proportionality of these responses and the influence of the pharmaceutical industry.[74–76]

Behaviours

Our data, as with any survey, addressed self-reported, rather than observed, behaviour. However, particularly given the nature of the behaviours that it would have been necessary to observe in relation to the swine flu pandemic (use of tissues, hand-washing, changes to daily living activities, etc.), observational methods would have been completely unfeasible.

Overall, both groups reported only modest levels of adoption of preventative measures – this is consistent with general population survey data from before the start of the pandemic[16,17] and similar surveys conducted throughout the pandemic outside the UK.[70–72] However, the changes in behaviour reported by respondents were largely appropriate and reflected key health messages.[4,24]

Hand-washing and use of sanitising hand gel were the two most commonly reported preventative behaviours. Very few of either group reported wearing a surgical mask – perhaps unsurprising as this was not recommended by authoritative sources in the UK.[4,24] Patterns of preventative behaviour were similar in the two groups.

Levels of regular uptake of the annual seasonal influenza vaccination were higher among patients than family members, which is consistent with data regarding uptake patterns.[3] Previous vaccination levels in both groups were higher than is typically reported in people with chest problems and family members of people with long-term conditions.[3] Most patients, but fewer family members, intended having the swine flu vaccination – although the latter group were strongly in favour of their family member with a chest problem receiving the swine flu vaccine. The percentage of study participants intending to have swine flu vaccination (83.8% of patients and 68.3% of family members) was much higher than the percentage from clinical risk groups who actually took up the vaccine in North West England (37.3% at the end of February 2010; no data for family carers available[77]). Our data also contrasted with national figures for clinical risk groups both under 65 years and over 65 years (35.7% and 40.0% respectively, at the end of February 2010; no data for family carers available[78]) and with uptake by frontline NHS staff (40.6% in North West[79] and 39.9% nationally[78] at end of February 2010). Our data, collected between October 2009 and January 2010, relate to intended behaviour; we do not know how many actually did take up the vaccination. Those who respond to surveys are more likely to have an interest in the topic,[50] which may explain the exceptionally high levels of vaccination intent in the sample. It is also possible that recruitment through a network of patient support groups may have impacted on these data, as such patients may be more motivated with respect to health care.

Messages from official information sources regarding appropriate help-seeking[4,24] appeared to have been taken on board. If swine flu symptoms were suspected, the most common initial intended help-seeking action was to telephone a GP; the contrast in patients' and family members' self-related behaviour and family members' advice to patients was notable. Patients' and family members' proposed behaviour was consistent with advice from authoritative sources, which advised those in at-risk groups to make early recourse to professional help.[4,24] Although primary care sources and health help/telephone lines would more commonly have been used, it was still the case that more than one-quarter of patients would have sought help from hospital (either A&E department or chest clinic); the small numbers selecting 'walk-in chest clinic' may reflect the lack of availability of these at all sites. The modest use of websites and very low recourse to community pharmacists are notable. Encouragingly, and perhaps related to the reported levels of knowledge and information about swine flu, few patients or family members would not have known what to do on suspicion of swine flu. These data provide useful insights into likely demand on health-care services from this high-risk group and, as with information-giving, highlight the centrality of primary care services, especially GPs, during the pandemic.

Interview and focus group data revealed considerable reluctance to use emergency services and some confusion about when/whether it was appropriate to do so. This is notable, especially as people with respiratory conditions, particularly COPD, are known to be high users of emergency/hospital services, especially during the winter months.[2] The reasons for this reluctance may therefore merit further investigation, as they may have implications for information-giving in future comparable circumstances.

Patients and family members seemed generally able to discriminate between 'typical' swine flu symptoms[55] and 'red flag' symptoms such as chest pain or haemoptysis. However, some symptoms (e.g. confusion/drowsiness, change in sputum

colour and increased wheeze) elicited lower levels of intended help-seeking, despite being a potential cause for concern, particularly in patients. There were relatively high levels of intended help-seeking for problems such as aching muscles, sore throat and tiredness, which were identified in authoritative patient information as 'typical symptoms', rather than complications of swine flu.[55] Family members generally reported greater likelihood of help-seeking on behalf of their relative with a chest problem than on their own behalf, regardless of the symptom. This highlights the well-recognised contribution of family members and informal carers in the management of respiratory conditions, including surveillance/symptom monitoring.[80,81] It also highlights the practical and emotional burden – again well-recognised[80–82] – on family members.

Interestingly, with respect to behaviour, role modelling by health professionals, both directly experienced and as reported in the media,[83–86] also appeared to play an important role. This was particularly the case with respect to perceived credibility and hence likely uptake of swine flu vaccination. Health professionals also appeared to play an important role in persuading – sometimes to the point of perceived coerciveness – patients and family members to take up vaccination, but this was not always accompanied by information-giving to facilitate informed decision-making. Finding ways in which people with respiratory conditions and their family members can be supported in making informed decisions about vaccination is important for the future, particularly given the typically low levels of influenza vaccination uptake in this patient group.

Limitations

The study took place in one geographic region (North West England) and focused on one disease group (people with respiratory problems) and their family members. Survey data were cross-sectional, hence relate only to the time point at which they were collected and collated, in the UK autumn/winter of 2009–10. This was during the anticipated winter peak of the swine flu pandemic in the UK, but occurred several months after the first announcement of the pandemic and associated peak in both reported UK cases and media interest.

The target sample size for the patient group in the survey was exceeded. The response rate from the patient survey, though modest, was fairly typical of this type of survey;[50,51] low and declining response rates have been identified as a methodological issue in survey research for a number of years.[50,51] Our goal of recruiting $n = 200$ into the family sample was not achieved, hence this element of the study was underpowered for logistic regression. However, bivariable analyses on key variables indicated that this would not have been appropriate anyway (although the potential impact of the sample size itself is recognised here). Family members were selected by patients or self-selected, hence we were not able to ensure even numbers of different family relationships. These are acknowledged as limitations of the study. It is not fully clear why the response rate from family members was so poor – however, these are recognised as a 'hard-to-reach' group in health research, not least because of the challenges of accessing them, typically through third parties.[87,88] Possible explanations for the low response rate are that patients were reluctant to pass on questionnaires; that family members were aware of patients' having completed a questionnaire (and possibly even how they had responded), hence did not feel they had anything extra to add; that the extra length of the family member questionnaire was off-putting; or that the issue was not perceived as salient by family members. Sheehan[50] suggests that salience is a more important factor than questionnaire length. Likewise, it is not clear why the response to the newspaper advertisement was so poor; other studies that have used this approach have had a good response[89] and the advertisement was prominently placed in a high-circulation region-wide newspaper. The timing of the advertisement (November 2009) may have been a factor, as the level of media and public interest in the swine flu pandemic was waning by this time;[70–73] this is consistent, again, with Sheehan's[50] assertion regarding the importance of salience in survey response rates. We had planned to undertake between four and six focus groups. Only three were actually undertaken. However, analysis of the data from the three focus groups completed suggested that any additional groups would have been confirmatory, rather than adding any new data.

The sample had a relatively high mean age and only modest representation from BME groups. Poor participation in surveys by young adults and people from BME groups is recognised as a problem nationally and internationally.[90] Given the short duration of the study, our ability to use strategies known to increase participation from hard-to-reach

groups (e.g. through provision of questionnaires in alternative languages and formats[90]) was limited. Recruitment through BLF 'Breathe Easy' groups in the North West may also have had some impact on sample composition, as these are typically attended by more people with COPD than other conditions and most attendees will have moderate to severe disease. Attendees tend to be older individuals and, although there is typically a reasonable gender mix, carers/family members and people from BME groups tend to be under-represented. It must also be recognised that support group attendees may be more highly motivated/interested in their condition than others. These are acknowledged as limitations of this recruitment approach. They are, however, countered by the ready accessibility of the groups and by their being well established, which greatly enhanced questionnaire distribution, response rate and focus group dynamics/discussion. The respiratory clinics that were selected all had diverse patient populations, which included people with asthma. However, people with mild respiratory conditions, particularly asthma, are less likely to attend hospital chest clinics. We considered it inappropriate to collect data in primary care, given the pressure on services during the pandemic. Furthermore, our previous experience in conducting surveys of information needs and treatment decision-making in people with asthma in both primary and secondary care suggests that the response rate from those with mild disease would have been poor anyway, as they do not engage with these issues,[91,92] a key issue in promoting participation in surveys.[50,91]

The instruments used were developed specifically for the study, although they did draw upon existing literature, and, where possible, used questions/phrasing that mirrored those used in the national Ipsos MORI general population poll, conducted on behalf of the HPA.[16,17] They were developed in close collaboration with a User Reference Group, consisting of people with chest problems and their family members. The instruments were designed and tested for use only with people with respiratory conditions and their family members and were only available in English and written format. They would need further validation and revision before they could be used in future studies or developed into other languages/alternative formats. Survey participants were invited to provide 'any other comments', and some of these provided suggestions for future improvement of the questionnaires, including reducing their length, which could facilitate such revision.

The research approach

This project was part of a national programme of commissioned projects relating to swine flu. These were short studies, commencing in September 2009 and having to be completed by January 2010. The studies received expedited research ethics and governance approval and were adopted into the NIHR portfolio.

Expedited approval was invaluable in ensuring that the project could commence in a timely manner and was vital to its feasibility, given the short timescale. It was challenging, however, for both the researchers (with respect to rapidly preparing materials while still ensuring quality submissions, and for staff in research ethics and governance offices) and the committee members (who had to deal rapidly and at short notice with documents); this raises questions about how many such projects could be dealt with by these organisations at any one time. There were particular challenges for work of the sort reported here, which involved development and testing of instruments prior to commencement of the study and, importantly, ahead of submission for ethics and governance approval.

The short duration of the study highlighted numerous practical and organisational challenges. The slowness of many usual procedures (notably recruitment) was challenging and required innovative solutions – although some of these brought their own challenges, as they entailed working outside of usual procedures. Our experience suggests that if the 'rapid-turnaround' approach adopted for this call were to be more commonplace, organisations conducting research, such as universities, would need to adopt new, and in some instances more efficient, ways of working. Having short-duration projects would also have implications for how contract research staff are employed and work.

The short duration of the project meant that the level of direct involvement from the Principal Investigator was necessarily much higher than would otherwise have been the case, especially during the set-up and early stages of the study. If this approach were to be adopted more widely, it would therefore have implications for the Principal Investigators' time and the number of projects in which they could be involved. Principal Investigators and their employing organisations would need to carefully consider the 'cost–benefit' ratio of responding to such calls for research.

The short timescale also meant that there was very little scope for slippage. It is important for funders and researchers to recognise that any delay (even of only a few days), unforeseen circumstances (e.g. as in the our case, the severe winter weather, which affected BLF 'Breathe Easy' group meetings, clinic attendance rates and patients' health and hence ability to take part in the study) or, indeed, sickness within the project team (especially of the Principal Investigator) will have much more marked implications for a study than would usually be the case. Windows for data collection will also be much more circumscribed than usual, which has implications for project timelines and for what can feasibly be done during a study.

On a positive note, the rapid turnaround approach ensured that a large volume of data were collected in a short period of time – although it did circumscribe the extent to which these data could then be analysed and full use made of them. The approach should ensure that data are communicated much more rapidly, with more timely adoption of findings/recommendations, where appropriate.

Having rapid-turnaround projects has significant implications for user involvement in research. It highlights very clearly the importance of researchers developing strong and sustained relationships with users and user groups if they are to be meaningfully involved in such aspects as development of study protocols, instruments and patient information sheets. Had we not already had well-established links with patients and user groups, it would not have been possible to secure meaningful user involvement in such a short study. Likewise, having well-established clinical contacts and networks is vital to the successful setting up and conduct of rapid-turnaround studies. The approach also has implications for the ability to adopt measures to promote inclusion of hard-to-reach groups.

Conducting research during a pandemic was challenging and had implications for what could and could not be attempted. Pressure on services due to the pandemic was apparent – for example, at some sites outpatient clinics were heavily involved in staff vaccination programmes. Research, therefore, was not necessarily always a priority. It is our strong belief that undertaking survey research in primary care during the pandemic would not have been feasible – although we therefore ensured that distribution of questionnaires was minimally burdensome for frontline staff in clinics, we believe that even a small amount of extra burden would have been unacceptable to, and unfeasible for, primary care staff. The situation in a pandemic changes from week to week, which has implications for data collection methods and, especially, instruments – for example, some approaches, such as focus groups, may become unfeasible during a serious pandemic and questionnaires/interview topic guide content may need to be altered. Our survey data collection methods and questionnaires were not altered during the study (although steps were taken to encourage distribution of questionnaires at some sites). The iterative approach used in interviews and focus groups did enable us to feed issues raised by earlier participants/groups and in the media into data collection as appropriate.

The commissioning of studies was such that they were timed to commence and take place during the anticipated winter peak in swine flu. This did not emerge as anticipated. Although this could not have been foreseen, it did have implications for work of the type reported here, which focused on individuals' views and needs, and did, we believe, contribute to the low response rate, especially for the newspaper advertisement.

Chapter 6
Conclusions

Our data suggest that people with chest problems and their family members were generally well informed with respect to swine flu, but that some gaps in information-giving and knowledge remained and better targeting of information towards the specific needs of people with respiratory conditions and their families would have been welcomed. The need for information to help patients and family members discriminate between seasonal influenza, swine flu and symptoms of their respiratory problem was particularly highlighted; development of such information would be challenging, given the overlap between symptoms. Patients and family members also highlighted the importance of information being developed to aid them in understanding the likely impact of swine flu on their respiratory problem. As participants themselves noted, this need may extend to many long-term conditions.

The majority of patients were not highly anxious about swine flu and this was also true of family members. There was some confusion about who was at risk of developing swine flu, suggesting that messages regarding this issue were not as well communicated as they might have been. However, there was a clear recognition of people with respiratory problems as being at greater risk than the general population of swine flu complications. Despite this, survey response rates, particularly amongst family members, suggest that the topic of swine flu, by the time the study was commissioned and undertaken, may have had limited saliency.

Behaviour change was modest, but in line with recommendations from authoritative sources, and there appeared to be good levels of penetration of some key messages regarding prevention and help-seeking. Vaccination intent was very high in this sample, which may have been owing, in part, to effective communication of risk, but may also have been influenced by sample composition. Some concerns about vaccination, especially with regard to safety and interaction with underlying respiratory problems and associated medications, were apparent. This suggests that there is more to be done to ensure appropriate communication of risk. It is also somewhat paradoxical, given the high levels of vaccination intent.

The influence of the mass media on perceptions of and responses to the pandemic was apparent, especially within the qualitative data. In particular, questioning in the mass media of the effectiveness of antiviral medications may have affected views on and willingness to take these. Our data highlight a contradiction with respect to the role of the mass media as a communication medium within a pandemic, in that they were widely used but of questionable credibility. Likewise, the data highlight tensions between the use of mass media as a means of raising awareness versus its potential, through perceived oversaturation, 'hyping' or misrepresentation of issues, to reduce interest in a pandemic.

Recommendations for future research

Based on our findings, we make the following recommendations for future research:

- Work to identify effective means of delivering targeted information to high-risk groups during a pandemic would be of particular value.
- Follow-up work to establish whether vaccination intentions were followed through (and, if not, why this was the case) would be of value. It would also be interesting to seek to establish why these patients and family members were so highly motivated and whether this could provide lessons for future vaccination programmes.
- Further research to improve understanding of perception of risk (from the effects of swine flu and from vaccination) and its influence on decision-making in high-risk groups is needed, and could make a valuable contribution to the efficacy of future vaccination programmes.
- Future work is needed to establish whether issues identified by our participants regarding the role of the mass media would also be raised by people with respiratory conditions more widely or by other high-risk groups.
- Given the extensive reporting of the pandemic by the mass media and, indeed, the use by health-related agencies of the mass media to communicate pandemic-related messages,

work is urgently needed to explore further the influence of mass media reports on pandemic-related knowledge and behaviour in high-risk groups and to better understand how mass media can most effectively be used to communicate risk data, especially to high-risk groups in a pandemic.

- Issues of saliency suggest lessons for timing of future comparable research within a pandemic.
- Our experiences highlight the need to recognise and develop strategies to overcome the challenges of including hard-to-reach groups (including family members, BME groups and young adults) when undertaking short projects in the context of an ongoing pandemic.

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Contribution of authors

Ann-Louise Caress (Principal Investigator) led on development of proposal, instrument development, management of study, data analysis and writing report and also provided expertise in patient-focused research and user involvement.

Paula Duxbury (lay member) provided family member perspective and contributed to instrument development and interpretation of qualitative data

Ashley Woodcock (expert in respiratory disease) provided guidance on clinical issues and facilitated recruitment of study sites.

Karen Luker (methodological expert) provided input on selection and application of research methods.

Deborah Ward (infection control expert) provided expertise on the swine flu pandemic and public health issues.

Malcolm Campbell (statistical expert) provided guidance on study design, sample size calculation and data analysis methods and contributed to analysis of quantitative data.

Lynn Austin (postdoctoral research fellow) led on conduct of the study and day-to-day management of the research team, also led on analysis and writing up of qualitative data.

All authors contributed to development of the study proposal and to writing of the final report.

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Appendix 1

Newspaper advertisement for participant recruitment

People with chest problems and swine flu

- Are you at least 18 years of age?
- Do you have a chest problem?

OR

- Do you a have a family member with a chest problem?

If 'Yes', we would like to invite you to take part in a research project about swine flu*

We'd like you to tell us about:

- what information people with chest problems and their family members want regarding swine flu and who they want it from
- whether people with chest problems and their family members have any worries and concerns about swine flu, and what these are
- whether people with chest problems and their family members are doing anything different in their daily lives because of swine flu

If you agree to participate, you will be asked to take part in a telephone survey – our researcher will phone you and it will take about 30–45 minutes to complete.

INTERESTED?

Please phone [NUMBER], so we can tell you more about the study and answer your questions.

*The study is being run by a team from the University of Manchester and Wythenshawe Hospital. It is funded by the National Institute for Health Research, on behalf of the Department of Health, as part of its national swine flu research programme.

Appendix 2

Patient questionnaire*

(*Not in original font/type size.)

People with chest problems and swine flu

Identification Number: _____

Date: _____

1. How much do you know about swine flu? (Please circle *one* answer.)
   1. None of the things I need or want to know
   2. A bit, but I'd like to know more
   3. Quite a lot, but I'd still like to know more
   4. As much as I need or want to know

2. What, if anything, is the 'number one' thing you would like to know about swine flu? (If nothing, please state.)

_____

3a. How important do you think it is for people who have a chest problem to receive information about each of the following topics? (Please circle *one* number *for each item*.)

	Not at all important			→	**Very important**
1. What swine flu is and what it does to your body	1	2	3	4	5
2. Whether swine flu is different from ordinary flu	1	2	3	4	5
3. How serious swine flu is and the outlook for people who catch it	1	2	3	4	5
4. Whether there is a vaccine (flu jab) available for swine flu yet and who will get it	1	2	3	4	5
5. The treatments available for swine flu and how effective they are	1	2	3	4	5
6. What the symptoms of swine flu are	1	2	3	4	5
7. How to recognise if you might have swine flu	1	2	3	4	5
8. What to do if you think you have swine flu	1	2	3	4	5
9. How to recognise complications of swine flu and what to do about them	1	2	3	4	5
10. How likely it is that you will catch swine flu	1	2	3	4	5
11. How to prevent the spread of swine flu	1	2	3	4	5
12. How to reduce your risk of catching swine flu	1	2	3	4	5
13. How swine flu might affect chest problems	1	2	3	4	5
14. Whether people with chest problems are more likely to catch swine flu than other people	1	2	3	4	5
15. Whether the families of people with chest problems are more likely to catch swine flu than other people	1	2	3	4	5
16. Whether people with chest problems are more likely to develop complications or die from swine flu	1	2	3	4	5

	Not at all important			→	Very important
17. Whether treatments for swine flu are safe for people with chest problems	1	2	3	4	5
18. Whether treatments for swine flu can interfere with treatments for chest problems	1	2	3	4	5
19. Where to get information, help or support (e.g. if you are worried or want to know more about swine flu)	1	2	3	4	5

3b. Are there any important items missing from the above list? If so, what are they?

_____

4. How useful do you think each of the following is/could be as a source of information about swine flu for people with chest problems? (Please circle *one* number *for each item*.)

	Not at all useful			→	Very useful
1. Friends/relatives	1	2	3	4	5
2. General practitioner (GP)	1	2	3	4	5
3. Hospital consultant	1	2	3	4	5
4. Other hospital doctor	1	2	3	4	5
5. Specialist nurse (hospital or community)	1	2	3	4	5
6. District nurse	1	2	3	4	5
7. Health visitor	1	2	3	4	5
8. Nurses on hospital wards/at hospital clinics	1	2	3	4	5
9. Practice nurse (GP's nurse)	1	2	3	4	5
10. A&E (casualty) department	1	2	3	4	5
11. Walk-in centre or minor injuries unit	1	2	3	4	5
12. Community pharmacist (chemist)	1	2	3	4	5
13. NHS Direct (staffed phone line)	1	2	3	4	5
14. The HPA	1	2	3	4	5
15. Television	1	2	3	4	5
16. Radio	1	2	3	4	5
17. Posters or billboards	1	2	3	4	5
18. Medical book/journal	1	2	3	4	5
19. Magazines	1	2	3	4	5
20. Newspapers	1	2	3	4	5
21. Leaflets	1	2	3	4	5
22. Government website (www.direct.gov.uk/pandemicflu)	1	2	3	4	5
23. NHS Choices website (www.nhs.uk)	1	2	3	4	5
24. Other website	1	2	3	4	5
25. Health-related charities	1	2	3	4	5
26. Patient support/self-help groups	1	2	3	4	5
27. National Pandemic Flu Service (website and phone line)	1	2	3	4	5

5. Now please tell us which of these items *you personally* would use as a source of information about swine flu. (Please indicate by circling *one* number *for each item.*)

	Not at all useful		→		**Very useful**
1. Friends/relatives	1	2	3	4	5
2. General practitioner (GP)	1	2	3	4	5
3. Hospital consultant	1	2	3	4	5
4. Other hospital doctor	1	2	3	4	5
5. Specialist nurse (hospital or community)	1	2	3	4	5
6. District nurse	1	2	3	4	5
7. Health visitor	1	2	3	4	5
8. Nurses on hospital wards/at hospital clinics	1	2	3	4	5
9. Practice nurse (GP's nurse)	1	2	3	4	5
10. A&E (casualty) department	1	2	3	4	5
11. Walk-in centre or minor injuries unit	1	2	3	4	5
12. Community pharmacist (chemist)	1	2	3	4	5
13. NHS Direct (staffed phone line)	1	2	3	4	5
14. The HPA	1	2	3	4	5
15. Television	1	2	3	4	5
16. Radio	1	2	3	4	5
17. Posters or billboards	1	2	3	4	5
18. Medical book/journal	1	2	3	4	5
19. Magazines	1	2	3	4	5
20. Newspapers	1	2	3	4	5
21. Leaflets	1	2	3	4	5
22. Government website (www.direct.gov.uk/pandemicflu)	1	2	3	4	5
23. NHS Choices website (www.nhs.uk)	1	2	3	4	5
24. Other website	1	2	3	4	5
25. Health-related charities	1	2	3	4	5
26. Patient support/self-help groups	1	2	3	4	5
27. National Pandemic Flu Service (website and phone line)	1	2	3	4	5

6a. Have you already had any information about swine flu? (Please circle *one* answer.)

– Yes
– No

6b. If YES, where from? (Please circle *all that apply.*)

1. Leaflet delivered to my home
2. Leaflet picked up somewhere else
3. Poster displayed at work
4. Poster displayed at GP surgery
5. Poster displayed at hospital
6. Internet – NHS Choices (www.nhs.uk)
7. Internet – government website (www.direct.gov.uk/pandemicflu)
8. Internet – health-care organisation or health-care charity website
9. Internet – other website
10. NHS Direct (phone line)
11. The Swine Flu Information Line (phone line, recorded information)
12. Other telephone helpline (e.g. health-care charity)

13. Friends or relatives
14. General practitioner (GP)
15. Practice nurse (GP's nurse)
16. Receptionist at GP's surgery
17. Community pharmacist (chemist)
18. Specialist nurse (hospital or community)
19. District nurse
20. Health visitor
21. Hospital consultant/specialist doctor
22. Other hospital doctor
23. Hospital doctor's secretary or clinic receptionist
24. Nurses on hospital wards or at clinics
25. Other health professional (e.g. physiotherapist, occupational therapist)
26. Minor injuries clinic or walk-in centre
27. A&E (casualty) department
28. National Pandemic Flu Service (website and phone line)
29. The HPA
30. Television
31. Radio
32. Newspaper
33. Magazine
34. Medical book/journal
35. Patient self-help or support group
36. Other (please state)

_____

7a. How satisfied or dissatisfied are you with the amount of information available to you on swine flu, from any source? (Please circle *one* answer.)
1. Very satisfied
2. Fairly satisfied
3. Neither satisfied nor dissatisfied
4. Fairly dissatisfied
5. Very dissatisfied
6. Don't know

7b. If DISSATISFIED, why is that?

_____

8a. Do you think that the currently available information about swine flu is helpful, or not? (Please circle *one* answer.)
1. Yes
2. No
3. Don't know

8b. If NO, why not?

_____

9a. Do people with chest problems need different information about swine flu from other people, or not? (Please circle *one* answer.)
1. Yes
2. No
3. Don't know

9b. If YES, what is/should be different about the information provided?

_____

10. Swine flu is a form of influenza that originated in pigs, but can be caught by, and spread among, people. How worried, if at all, would you say you are now about the possibility of personally catching swine flu? (Please circle *one* answer.)
    1. Very worried
    2. Fairly worried
    3. Not very worried
    4. Not at all worried
    5. Don't know

11. Because of your chest problem, do you think you are more likely than other people to catch swine flu, or not? (Please circle *one* answer.)
    1. Very likely
    2. Fairly likely
    3. Not very likely
    4. Not at all likely
    5. Don't know

12. If you caught swine flu, how likely do you think you would be to develop complications? (Please circle *one* answer.)
    1. Very likely
    2. Fairly likely
    3. Not very likely
    4. Not at all likely
    5. Don't know

13. How worried are you that you might die from swine flu? (Please circle *one* answer.)
    1. Very worried
    2. Fairly worried
    3. Not very worried
    4. Not at all worried
    5. Don't know

14. How confident are you that you could correctly recognise the symptoms of swine flu? (Please circle *one* answer.)
    1. Very confident
    2. Fairly confident
    3. Not very confident
    4. Not at all confident
    5. Don't know

15. How confident are you that you would know what to do if you thought you had swine flu? (Please circle *one* answer.)
    1. Very confident
    2. Fairly confident
    3. Not very confident
    4. Not at all confident
    5. Don't know

16. How confident are you that you could recognise the complications of swine flu and would know what to do about them? (Please circle *one* answer.)
    1. Very confident
    2. Fairly confident
    3. Not very confident
    4. Not at all confident
    5. Don't know

17. How confident are you that being vaccinated (having a jab) against swine flu would help you? (Please circle *one* answer.)
    1. Very confident
    2. Fairly confident
    3. Not very confident
    4. Not at all confident
    5. Don't know

18. Below is a list of behaviours or activities. For each, could you please tell me if, over the last week, you have done it more frequently, less frequently, or the same, as a result of swine flu? (Please circle *one* answer *for each item*.)

1. Washed hands with soap and water	More frequently	Less frequently	The same	Have not done it at all	Don't know
2. Carried tissues with you	More frequently	Less frequently	The same	Have not done it at all	Don't know
3. Avoided crowded spaces or large crowds	More frequently	Less frequently	The same	Have not done it at all	Don't know
4. Avoided public transport at peak times	More frequently	Less frequently	The same	Have not done it at all	Don't know
5. Used antibacterial gel	More frequently	Less frequently	The same	Have not done it at all	Don't know
6. Worn a surgical mask	More frequently	Less frequently	The same	Have not done it at all	Don't know
7. Avoided touching your face with your hands	More frequently	Less frequently	The same	Have not done it at all	Don't know
8. Disinfected spaces where you live or work	More frequently	Less frequently	The same	Have not done it at all	Don't know
9. Avoided kissing or hugging people	More frequently	Less frequently	The same	Have not done it at all	Don't know

19a. Have you ever had flu in the past? (Please circle *one* answer.)
    1. Yes, once
    2. Yes, more than once
    3. No, never
    4. Don't know/can't remember

19b. If YES, how long ago was your most recent bout? (Please circle *one* answer.)
    1. Within the last year
    2. More than a year ago, but within the last five years
    3. More than five years ago
    4. Don't know/can't remember

20. Have you had the regular winter flu jab in the past? (Please circle *one* answer.)
    1. Yes, regularly each year
    2. Yes, occasionally
    3. No, never
    4. Don't know/can't remember

21. Please indicate by circling *one* answer whether you agree or disagree with the following statement: 'As a result of swine flu, I am now more likely to get the regular winter flu jab'.
    1. Strongly agree
    2. Tend to agree
    3. Neither agree nor disagree
    4. Tend to disagree

5. Strongly disagree
6. Don't know

22. The Government recently announced that a swine flu vaccination programme will be rolled out across the UK starting this autumn. How likely, if at all, are you to take up a swine flu vaccination if offered it? (Please circle *one* answer.)
    1. Very likely
    2. Fairly likely
    3. Not very likely
    4. Not at all likely
    5. Don't know

23a. If you felt you had *swine flu symptoms*, which, if any, of the following would you do *first*? (Please circle *one* answer.)
    1. I would go to an A&E (casualty) department
    2. I would go to my family doctor/GP
    3. I would call my family doctor/GP
    4. I would call a health helpline for advice (e.g. NHS Direct)
    5. I would call Swine Flu Information
    6. I would stay at home and self-treat my symptoms
    7. I would visit an NHS, Department of Health or other health website for advice
    8. I would visit/go and see a community pharmacist (chemist)
    9. I would call the hospital chest clinic/my chest consultant's secretary
    10. I would go to the walk-in chest clinic at the hospital
    11. None of these
    12. Don't know
    13. Other (please specify)

_____

23b. And what else might you do? (Please circle *all that apply.*)
    1. I would go to an A&E (casualty) department
    2. I would go to my family doctor/GP
    3. I would call my family doctor/GP
    4. I would call a health helpline for advice (e.g. NHS Direct)
    5. I would call Swine Flu Information
    6. I would stay at home and self-treat my symptoms
    7. I would visit an NHS, Department of Health or other health website for advice
    8. I would visit/go and see a community pharmacist (chemist)
    9. I would call the hospital chest clinic/my chest consultant's secretary
    10. I would go to the walk-in chest clinic at the hospital
    11. None of these
    12. Don't know
    13. Other (please specify)

_____

24a. If you thought you were developing complications of swine flu, which, if any, of the following would you do *first*? (Please circle *one* answer.)
    1. I would go to an A&E (casualty) department
    2. I would go to my family doctor/GP
    3. I would call my family doctor/GP
    4. I would call a health helpline for advice (e.g. NHS Direct)
    5. I would call Swine Flu Information
    6. I would stay at home and self-treat my symptoms
    7. I would visit an NHS, Department of Health or other health website for advice

8. I would visit/go and see a community pharmacist (chemist)
9. I would call the hospital chest clinic/my chest consultant's secretary
10. I would go to the walk-in chest clinic at the hospital
11. None of these
12. Don't know
13. Other (please specify)

24b.And what else might you do? (Please circle *all that apply*.)

1. I would go to an A&E (casualty) department
2. I would go to my family doctor/GP
3. I would call my family doctor/GP
4. I would call a health helpline for advice (e.g. NHS Direct)
5. I would call Swine Flu Information
6. I would stay at home and self-treat my symptoms
7. I would visit an NHS, Department of Health or other health website for advice
8. I would visit/go and see a community pharmacist (chemist)
9. I would call the hospital chest clinic/my chest consultant's secretary
10. I would go to the walk-in chest clinic at the hospital
11. None of these
12. Don't know
13. Other (please specify)

---

25. Have you chosen anyone to act as a 'Swine Flu Friend/Buddy' for you? (Please circle *one* answer.)
    1. Yes
    2. No, because I don't think I need one
    3. No, because I don't know what one is
    4. Don't know

26. As you may have heard, the antiviral medicines such as Tamiflu can sometimes help to reduce the symptoms of swine flu if taken right away. If you fell ill with swine flu, and wanted to obtain Tamiflu, how would you go about obtaining it, or how have you got it already? (Please circle *all* that apply.)
    1. I would go to an A&E (casualty) department
    2. I would go to my family doctor/GP
    3. I would call my GP/health centre
    4. I would call a health helpline for advice (e.g. NHS Direct)
    5. I would call the National Pandemic Flu Service (NPFS)
    6. I would ask a Flu Friend/Flu Buddy
    7. I would ask my local community pharmacist (chemist)
    8. I would look for information on news programmes on television
    9. I would look for information in the newspapers
    10. I would listen for information on news programmes on the radio
    11. I would look online – on news websites
    12. I would look online – on NHS, Department of Health or other health websites
    13. I would look online – on other websites
    14. I would look online – unspecified
    15. I would contact my chest consultant/the hospital chest clinic
    16. I would contact a chest specialist nurse (hospital or community)
    17. I already have a supply of Tamiflu
    18. None of these
    19. Don't know
    20. Other (please specify)

---

27. If you needed antiviral treatment for swine flu, from where would you prefer to get it? (Please circle *one* answer.)
    1. On prescription (from a GP/family doctor, hospital doctor, nurse, etc.)
    2. 'Over the counter' (from a community pharmacist/chemist)
    3. Without having to contact a health professional (e.g. internet, health food shop, etc.)
    4. Other (please state)

---

28. Please indicate, by circling *one* answer, whether you agree or disagree with the following statement: 'Too much fuss is being made about the risk of swine flu.'
    1. Strongly agree
    2. Tend to agree
    3. Neither agree nor disagree
    4. Tend to disagree
    5. Strongly disagree
    6. Don't know

29. Please tell us if you think each of the following statements is *true or false*. (Please circle *one* option for *each item*.)

1. Very young people are the most likely to get swine flu	True/False
2. Wearing a mask will stop me getting swine flu	True/False
3. People with chest problems are more likely than others to catch swine flu	True/False
4. Washing your hands is very important in preventing the spread of swine flu	True/False
5. The ordinary flu vaccine will protect me from swine flu	True/False
6. People with chest problems are more likely than others to develop complications of swine flu	True/False
7. Older people are the most likely to get swine flu	True/False
8. Tamiflu is a vaccine for swine flu	True/False
9. Swine flu may become more of a problem over the winter	True/False
10. People with chest problems are more likely to die from swine flu than others	True/False
11. It is possible to catch swine flu from eating pork	True/False
12. Using an antibacterial hand wash or gel will stop the spread of swine flu	True/False
13. If your doctor says you need antiviral treatment, you should send someone to collect a prescription for you, rather than going yourself	True/False
14. If someone in a household develops swine flu, all their family can get anti-swine flu treatment (e.g. Tamiflu or Relenza)	True/False
15. Swine flu is very contagious	True/False
16. 'Swine flu parties' are a good way of developing immunity to swine flu	True/False
17. Swine flu is different from ordinary flu	True/False

30. Please tell us if you think any of the following might be a symptom of swine flu or not (Please circle *one* option for *each item*.)

1. Sudden fever (high temperature)	True/False
2. Sudden cough (in people who don't usually have a cough)	True/False
3. Worsening of cough (in people who usually have a cough)	True/False
4. Headache	True/False
5. Tiredness	True/False
6. Producing more sputum (phlegm/mucus) than usual	True/False
7. Chills	True/False
8. Aching muscles	True/False
9. Limb or joint pain	True/False
10. Suddenly becoming breathless (in people who aren't usually breathless)	True/False
11. Worsening of breathlessness (in people who are usually breathless)	True/False
12. Dizziness	True/False
13. Diarrhoea or stomach upset	True/False

14.	Sore throat	True/False
15.	Blurred vision	True/False
16.	Runny nose	True/False
17.	Sputum (phlegm/mucus) turning a different colour than usual	True/False
18.	Loss of memory	True/False
19.	Rash	True/False
20.	Loss of appetite	True/False
21.	Sudden inability to move or control limbs	True/False
22.	Wheezing	True/False
23.	Confusion	True/False
24.	Sneezing	True/False
25.	Chest pains	True/False

31. If you had swine flu, would you get help if you developed any of the following symptoms? (Please circle *one* option for *each item*.)

1.	Fast breathing or feeling much more short of breath than usual	Yes/No
2.	Feeling very tired	Yes/No
3.	Chest pains	Yes/No
4.	Fever (high temperature) that didn't go down after 4 or 5 days	Yes/No
5.	Aching muscles	Yes/No
6.	Producing more sputum (phlegm/mucus) than usual	Yes/No
7.	Worsening of cough or cough that wouldn't go away	Yes/No
8.	Drowsiness or confusion	Yes/No
9.	Coughing up blood	Yes/No
10.	Sputum (phlegm/mucus) turning a different colour than usual	Yes/No
11.	Sore throat	Yes/No
12.	Feeling more wheezy than usual	Yes/No

32. We'd like to know whether worries about swine flu are making you do anything different or feel different (Please circle *all that apply*.)

Because of worries about swine flu:

1. I have stopped or cut down on travelling by public transport (buses, trains, etc.)
2. I am taking things like vitamins or food supplements
3. I am avoiding crowded places (e.g. shops, cinemas, sports events, etc.)
4. I am leaving the house less often
5. I am avoiding contact with my friends and family members
6. I feel that people are worried about being around me
7. I have cut down or stopped smoking
8. I have cancelled a holiday/rearranged travel plans
9. I am keeping my windows and doors closed
10. I feel more anxious than usual about my chest problem
11. I am avoiding contact with children
12. I would not take my medication/use my inhaler in a public place, even if I really needed it
13. I am trying to get more exercise
14. I am not leaving the house at all
15. I feel more self-conscious about my chest problem
16. I am avoiding contact with pets/animals
17. I am using my inhaler(s) more often
18. I would not wish to travel far within the United Kingdom
19. I am eating more healthy foods
20. I am much more aware of my chest problem than usual
21. I am not sleeping well
22. I would not wish to travel abroad
23. I have cut down my usual social activities (e.g. going to the pub, eating out, etc.)
24. I am avoiding contact with people who have been abroad

25. I am constantly on the alert for changes in my chest problem
26. I feel that other people are avoiding me
27. I am more careful about taking my regular medications as instructed
28. I am avoiding eating pork/ham/bacon, etc.
29. I have tried to buy/bought Tamiflu

Now please tell us a bit about yourself:

33. How old are you (in years)?

_____

34. What is your gender? (Please circle *one* answer.)
    30. Male
    31. Female

35. What would you consider your ethnic group to be?

_____

36. Are you married or living with a partner? (Please circle *one* answer.)
    32. Yes
    33. No

37a. What is your current occupation?

_____

37b. If retired or not working, what is your most recent previous occupation?

_____

38. Do you have any of the following? (Please circle *all that apply*.)
    1. CSE/O level/GCSE or equivalent
    2. A level or equivalent
    3. GNVQ
    4. Diploma
    5. Professional qualification (e.g. RGN, Cert Ed, City and Guilds)
    6. College/university degree (undergraduate/bachelor's)
    7. Higher degree (Masters, MRes, PhD)
    8. None of the above
    9. Other (please state which)

_____

39. What is the name of your chest problem? (If you are not sure, please write 'don't know'.)

_____

40. What kind of treatment do you currently receive for your chest problem? (Please circle *all that apply*.)
    1. Tablets
    2. Inhalers
    3. Nebulisers
    4. Oxygen
    5. None of these
    6. Other (Please state which.)

_____

41. How severe would you rate your chest problem as being? (Please circle *one* answer.)
    1. Very mild
    2. Mild
    3. Moderate
    4. Severe
    5. Very Severe
    6. Don't know

42. Do you smoke? (Please circle *one* answer.)
    1. Yes, I currently smoke
    2. No, but I used to smoke
    3. No, I have never smoked

43a. Apart from your chest problem, do you have any other health problems? (Please circle *one* answer.)
    1. Yes
    2. No

43b. If YES, what are these problems?

_____

44. How did you find out about our study? (Please circle *one* answer.)
    1. I was handed a questionnaire at chest clinic
    2. I saw a poster at chest clinic
    3. I saw the piece about the study in the newspaper
    4. Someone (e.g. a friend or relative) told me about the study
    5. Other (please state)

_____

45. Any other comments?

_____

If you want to contact us about this research, details are as follows:

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For independent information about this research, please contact:

The University of Manchester's Research Practice and Governance Co-ordinator
Tel: 0000 000 0000 or 0000 000 0000
E-mail: research-governance@manchester.ac.uk

Further information about swine flu can be found at:

National Pandemic Flu Service (NPFS): 0800 1 513 100
NPFS Textphone for people who are deaf/hard of hearing: 0800 1 513 200
The government's Pandemic Flu website: www.direct.gov.uk/pandemicflu
The NHS Choices website: www.nhs.uk

THANK YOU FOR TAKING TIME TO COMPLETE THIS QUESTIONNAIRE

PLEASE RETURN THE QUESTIONNAIRE TO US IN THE ENCLOSED PRE-PAID ENVELOPE OR, IF COMPLETED WHILST AT CLINIC, ASK THE RECEPTIONIST (OR THE MEMBER OF CLINIC STAFF WHO GAVE YOU THE PACK) WHERE TO LEAVE IT – THANK YOU

YOU DO NOT HAVE TO PROVIDE ANY CONTACT INFORMATION. HOWEVER, IF YOU ARE WILLING TO DO SO (e.g. SO WE CAN SEND YOU A SUMMARY OF STUDY FINDINGS), PLEASE COMPLETE THE SEPARATE SHEET ATTACHED AND RETURN IT WITH YOUR COMPLETED QUESTIONNAIRE – THANK YOU

Appendix 3

Family member questionnaire*

(*Not in original font/type size)

People with chest problems and swine flu

Identification Number: _____

Date: _____

1. How much do you know about swine flu? (Please circle *one* answer.)
   1. None of the things I need or want to know
   2. A bit, but I'd like to know more
   3. Quite a lot, but I'd still like to know more
   4. As much as I need or want to know

2. What, if anything, is the 'number one' thing you would like to know about swine flu? (If nothing, please state.)

_____

3a. How important do you think it is for the families of people who have a chest problem to receive information about each of the following topics? (Please circle *one* number *for each item.)*

	Not at all important			→	**Very important**
1. What swine flu is and what it does to your body	1	2	3	4	5
2. Whether swine flu is different from ordinary flu	1	2	3	4	5
3. How serious swine flu is and the outlook for people who catch it	1	2	3	4	5
4. Whether there is a vaccine (flu jab) available for swine flu yet and who will get it	1	2	3	4	5
5. The treatments available for swine flu and how effective they are	1	2	3	4	5
6. What the symptoms of swine flu are	1	2	3	4	5
7. How to recognise if you might have swine flu	1	2	3	4	5
8. What to do if you think you have swine flu	1	2	3	4	5
9. How to recognise complications of swine flu and what to do about them	1	2	3	4	5
10. How likely it is that you will catch swine flu	1	2	3	4	5
11. How to prevent the spread of swine flu	1	2	3	4	5
12. How to reduce your risk of catching swine flu	1	2	3	4	5
13. How swine flu might affect chest problems	1	2	3	4	5
14. Whether people with chest problems are more likely to catch swine flu than other people	1	2	3	4	5
15. Whether the families of people with chest problems are more likely to catch swine flu than other people	1	2	3	4	5

	Not at all important			→	Very important
16. Whether people with chest problems are more likely to develop complications or die from swine flu	1	2	3	4	5
17. Whether treatments for swine flu are safe for people with chest problems	1	2	3	4	5
18. Whether treatments for swine flu can interfere with treatments for chest problems	1	2	3	4	5
19. Where to get information, help or support (e.g. if you are worried or want to know more about swine flu)	1	2	3	4	5

3b. Are there any important items missing from the above list? If so, what are they?

_____

4. How useful do you think each of the following is/could be as a source of information about swine flu for the families of people with chest problems? (Please circle *one* number for each item.)

	Not at all useful			→	Very useful
1. Friends/relatives	1	2	3	4	5
2. General practitioner (GP)/family doctor	1	2	3	4	5
3. Hospital consultant	1	2	3	4	5
4. Other hospital doctor	1	2	3	4	5
5. Specialist nurse (hospital or community)	1	2	3	4	5
6. District nurse	1	2	3	4	5
7. Health visitor	1	2	3	4	5
8. Nurses on hospital wards/at hospital clinics	1	2	3	4	5
9. Practice nurse (GP's nurse)	1	2	3	4	5
10. A&E (casualty) department	1	2	3	4	5
11. Walk-in centre or minor injuries unit	1	2	3	4	5
12. Community pharmacist (chemist)	1	2	3	4	5
13. NHS Direct (phone line)	1	2	3	4	5
14. The HPA	1	2	3	4	5
15. Television	1	2	3	4	5
16. Radio	1	2	3	4	5
17. Posters or billboards	1	2	3	4	5
18. Medical book/journal	1	2	3	4	5
19. Magazines	1	2	3	4	5
20. Newspapers	1	2	3	4	5
21. Leaflets	1	2	3	4	5
22. Government website (www.direct.gov.uk/pandemicflu)	1	2	3	4	5
23. NHS Choices website (www.nhs.uk)	1	2	3	4	5
24. Other website	1	2	3	4	5
25. Health-related charities	1	2	3	4	5
26. Patient support/self-help groups	1	2	3	4	5
27. National Pandemic Flu Service (website and phone line)	1	2	3	4	5

5. Now please tell us which of these items *you personally* would use as a source of information about swine flu (Please indicate by circling *one* number *for each* item.)

	Definitely would use			→	**Definitely would not use**
1. Friends/relatives	1	2	3	4	5
2. General practitioner (GP)/family doctor	1	2	3	4	5
3. Hospital consultant	1	2	3	4	5
4. Other hospital doctor	1	2	3	4	5
5. Specialist nurse (hospital or community)	1	2	3	4	5
6. District nurse	1	2	3	4	5
7. Health visitor	1	2	3	4	5
8. Nurses on hospital wards/at hospital clinics	1	2	3	4	5
9. Practice nurse (GP's nurse)	1	2	3	4	5
10. A&E (casualty) department	1	2	3	4	5
11. Walk-in centre or minor injuries unit	1	2	3	4	5
12. Community pharmacist (chemist)	1	2	3	4	5
13. NHS Direct (phone line)	1	2	3	4	5
14. The HPA	1	2	3	4	5
15. Television	1	2	3	4	5
16. Radio	1	2	3	4	5
17. Posters or billboards	1	2	3	4	5
18. Medical book/journal	1	2	3	4	5
19. Magazines	1	2	3	4	5
20. Newspapers	1	2	3	4	5
21. Leaflets	1	2	3	4	5
22. Government website (www.direct.gov.uk/pandemicflu)	1	2	3	4	5
23. NHS Choices website (www.nhs.uk)	1	2	3	4	5
24. Other website	1	2	3	4	5
25. Health-related charities	1	2	3	4	5
26. Patient support/self-help groups	1	2	3	4	5
27. National Pandemic Flu Service (website and phone line)	1	2	3	4	5

6a. Have you already had any information about swine flu? (Please circle *one* answer.)
1. Yes
2. No

6b. If YES, where from? (Please circle *all that apply*.)
1. Leaflet delivered to my home
2. Leaflet picked up somewhere else
3. Poster displayed at work
4. Poster displayed at GP surgery
5. Poster displayed at hospital
6. Internet – NHS Choices (www.nhs.uk)
7. Internet – Government website (www.direct.gov.uk/pandemicflu)
8. Internet – health-care organisation or health-care charity website
9. Internet – other website
10. NHS Direct (phone line)
11. The Swine Flu Information Line (phone line, recorded information)
12. Other telephone helpline (e.g. health-care charity)
13. Friends or relatives

14. General practitioner (GP)
15. Practice nurse (GP's nurse)
16. Receptionist at GP's surgery
17. Community pharmacist (chemist)
18. Specialist nurse (hospital or community)
19. District nurse
20. Health visitor
21. Hospital consultant/specialist doctor
22. Other hospital doctor
23. Hospital doctor's secretary or clinic receptionist
24. Nurses on hospital wards or at clinics
25. Other health professional (e.g. physiotherapist, occupational therapist)
26. Minor injuries clinic or walk-in centre
27. A&E (casualty) department
28. National Pandemic Flu Service (website and phone line)
29. The HPA
30. Television
31. Radio
32. Newspaper
33. Magazine
34. Medical book/journal
35. Patient self-help or support group
36. Other (please state)

_____

7a. How satisfied or dissatisfied are you with the amount of information available to you on swine flu, from any source? (Please circle *one* answer.)
1. Very satisfied
2. Fairly satisfied
3. Neither satisfied nor dissatisfied
4. Fairly dissatisfied
5. Very dissatisfied
6. Don't know

7b. If DISSATISFIED, why is that?

_____

8a. Do you think that the information currently available about swine flu is helpful, or not? (Please circle *one* answer.)
1. Yes
2. No
3. Don't know

8b. If NO, why not?

_____

9a. Do the families of people with chest problems need different information about swine flu from other people, or not? (Please circle *one* answer.)
1. Yes
2. No
3. Don't know

9b. If YES, what is/should be different about the information provided?

_____

Questions on the next two pages are about *swine flu and you*

10. Swine flu is a form of influenza that originated in pigs, but can be caught by, and spread among, people. How worried, if at all, would you say you are now about the possibility of personally catching swine flu? (Please circle *one* answer.)
    1. Very worried
    2. Fairly worried
    3. Not very worried
    4. Not at all worried
    5. Don't know

11. Because of your family member's chest problem, do you think *you* are more likely than other people to catch swine flu, or not? (Please circle *one* answer.)
    1. Very likely
    2. Fairly likely
    3. Not very likely
    4. Not at all likely
    5. Don't know

12. If *you* caught swine flu, how likely do you think you would be to develop complications? (Please circle *one* answer.)
    1. Very likely
    2. Fairly likely
    3. Not very likely
    4. Not at all likely
    5. Don't know

13. How worried are you that *you* might die from swine flu?(Please circle *one* answer.)
    1. Very worried
    2. Fairly worried
    3. Not very worried
    4. Not at all worried
    5. Don't know

14. How confident are you that you could correctly recognise the symptoms of swine flu *in yourself*? (Please circle *one* answer.)
    1. Very confident
    2. Fairly confident
    3. Not very confident
    4. Not at all confident
    5. Don't know

15. How confident are you that you would know what to do if you thought *you* had swine flu? (Please circle *one* answer.)
    1. Very confident
    2. Fairly confident
    3. Not very confident
    4. Not at all confident
    5. Don't know

16. How confident are you that you could recognise the complications of swine flu *in yourself* and would know what to do about them? (Please circle *one* answer.)
    1. Very confident
    2. Fairly confident
    3. Not very confident
    4. Not at all confident
    5. Don't know

17. How confident are you that being vaccinated (having a jab) against swine flu would help *you*? (Please circle *one* answer.)
    1. Very confident
    2. Fairly confident
    3. Not very confident
    4. Not at all confident
    5. Don't know

Questions on the next two pages are about *swine flu and your family member with chest problems*

18. How worried, if at all, would you say you are now about the possibility of *your family member with chest problems* catching swine flu? (Please circle *one* answer.)
    1. Very worried
    2. Fairly worried
    3. Not very worried
    4. Not at all worried
    5. Don't know

19. Do you think *your family member with chest problems* is more likely than other people to catch swine flu, or not? (Please circle *one* answer.)
    1. Very likely
    2. Fairly likely
    3. Not very likely
    4. Not at all likely
    5. Don't know

20. If *your family member with chest problems* caught swine flu, how likely do you think they would be to develop complications? (Please circle *one* answer.)
    1. Very likely
    2. Fairly likely
    3. Not very likely
    4. Not at all likely
    5. Don't know

21. How worried are you that *your family member with chest problems* might die from swine flu? (Please circle *one* answer.)
    1. Very worried
    2. Fairly worried
    3. Not very worried
    4. Not at all worried
    5. Don't know

22. How confident are you that you could correctly recognise the symptoms of swine flu in *your family member with chest problems*? (Please circle *one* answer.)
    1. Very confident
    2. Fairly confident
    3. Not very confident
    4. Not at all confident
    5. Don't know

23. How confident are you that you would know what to do if you thought *your family member with chest problems* had swine flu? (Please circle *one* answer.)
    1. Very confident
    2. Fairly confident
    3. Not very confident
    4. Not at all confident
    5. Don't know

24. How confident are you that you could recognise the complications of swine flu *in your family member with chest problems* and would know what to do about them? (Please circle *one* answer.)
    1. Very confident
    2. Fairly confident
    3. Not very confident
    4. Not at all confident
    5. Don't know

25. How confident are you that being vaccinated (having a jab) against swine flu would help *your family member with chest problems*? (Please circle *one* answer.)
    1. Very confident
    2. Fairly confident
    3. Not very confident
    4. Not at all confident
    5. Don't know

26. Below is a list of behaviours or activities. For each, could you please indicate if, over the last week, you have done it more frequently, less frequently, or the same, as a result of swine flu? (Please circle *one* answer for *each item*.)

1. Washed hands with soap and water	More frequently	Less frequently	The same	Have not done it at all	Don't know
2. Carried tissues with you	More frequently	Less frequently	The same	Have not done it at all	Don't know
3. Avoided crowded spaces or large crowds	More frequently	Less frequently	The same	Have not done it at all	Don't know
4. Avoided public transport at peak times	More frequently	Less frequently	The same	Have not done it at all	Don't know
5. Used antibacterial gel	More frequently	Less frequently	The same	Have not done it at all	Don't know
6. Worn a surgical mask	More frequently	Less frequently	The same	Have not done it at all	Don't know
7. Avoided touching your face with your hands	More frequently	Less frequently	The same	Have not done it at all	Don't know
8. Disinfected spaces where you live or work	More frequently	Less frequently	The same	Have not done it at all	Don't know
9. Avoided kissing or hugging people	More frequently	Less frequently	The same	Have not done it at all	Don't know

27a. Have you ever had flu in the past? (Please circle *one* answer.)
    1. Yes, once
    2. Yes, more than once
    3. No, never
    4. Don't know/can't remember

27b. If YES, how long ago was your most recent bout? (Please circle *one* answer.)
    1. Within the last year
    2. More than a year ago, but within the last 5 years
    3. More than 5 years ago
    4. Don't know/can't remember

28. Have you had the regular winter flu jab in the past? (Please circle *one* answer.)
    1. Yes, regularly each year
    2. Yes, occasionally
    3. No, never
    4. Don't know/can't remember

29. Please indicate by circling *one* answer whether you agree or disagree with the following statement: 'As a result of swine flu, I am now more likely to get the regular winter flu jab.'
    1. Strongly agree
    2. Tend to agree
    3. Neither agree nor disagree
    4. Tend to disagree
    5. Strongly disagree
    6. Don't know

30a. The Government recently announced that a swine flu vaccination programme will be rolled out across the UK starting this autumn. How likely, if at all, are *you* to take up a swine flu vaccination if offered it? (Please circle *one* answer.)
    1. Very likely
    2. Fairly likely
    3. Not very likely
    4. Not at all likely
    5. Don't know

30b. When the new swine flu vaccine is produced, do you think *your family member with chest problems* should have it or not? (Please circle *one* answer.)
    1. They should definitely have it
    2. They should probably have it
    3. I am not sure whether they should have it or not
    4. They should probably not have it
    5. They definitely should not have it
    6. Don't know

Questions on the next two pages are about *swine flu and you*

31a. If you felt *you* had *swine flu symptoms*, which, if any, of the following would you do *first*? (Please circle one answer.)
    1. I would go to an A&E (casualty) department
    2. I would go to my family doctor/GP
    3. I would call my family doctor/GP
    4. I would call a health helpline for advice (e.g. NHS Direct)
    5. I would call Swine Flu Information
    6. I would stay at home and self-treat my symptoms
    7. I would visit an NHS, Department of Health or other health website for advice
    8. I would visit/go and see a community pharmacist (chemist)
    9. None of these
    10. Don't know
    11. Other (Please specify)

31b. And what else might *you* do? (Please circle *all that apply*.)
    1. I would go to an A&E (casualty) department
    2. I would go to my family doctor/GP
    3. I would call my family doctor/GP
    4. I would call a health helpline for advice (e.g. NHS Direct)
    5. I would call Swine Flu Information
    6. I would stay at home and self-treat my symptoms
    7. I would visit an NHS, Department of Health or other health website for advice
    8. I would visit/go and see a community pharmacist (chemist)

9. None of these
10. Don't know
11. Other (please specify)

32a. If you thought *you* were *developing complications of swine flu*, which, if any, of the following would you do *first*? (Please circle *one* answer.)
1. I would go to an A&E (casualty) department
2. I would go to my family doctor/GP
3. I would call my family doctor/GP
4. I would call a health helpline for advice (e.g. NHS Direct)
5. I would call Swine Flu Information
6. I would stay at home and self-treat my symptoms
7. I would visit an NHS, Department of Health or other health website for advice
8. I would visit/go and see a community pharmacist (chemist)
9. None of these
10. Don't know
11. Other (please specify)

32b. And what else might *you* do? (Please circle *all that apply*.)
1. I would go to an A&E (casualty) department
2. I would go to my family doctor/GP
3. I would call my family doctor/GP
4. I would call a health helpline for advice (e.g. NHS Direct)
5. I would call Swine Flu Information
6. I would stay at home and self-treat my symptoms
7. I would visit an NHS, Department of Health or other health website for advice
8. I would visit/go and see a community pharmacist (chemist)
9. None of these
10. Don't know
11. Other (please specify)

Questions on the next two pages are about *swine flu and your family member with chest problems*

33a. f your family member with chest problems felt they had swine flu symptoms, which, if any, of the following would you advise them to do *first*? (Please circle *one* answer.)
1. Go to an A&E (casualty) department
2. Go to their family doctor/GP
3. Call their family doctor/GP
4. Call a health helpline for advice (e.g. NHS Direct)
5. Call Swine Flu Information
6. Stay at home and self-treat their symptoms
7. Visit an NHS, Department of Health or other health website for advice
8. Visit/go and see a community pharmacist (chemist)
9. Call the hospital chest clinic/their chest consultant's secretary
10. Go to the walk-in chest clinic at the hospital
11. None of these
12. Don't know
13. Other (please specify)

33b. And what else might you advise them to do? (Please circle *all that apply*.)

1. Go to an A&E (casualty) department
2. Go to their family doctor/GP
3. Call their family doctor/GP
4. Call a health helpline for advice (e.g. NHS Direct)
5. Call Swine Flu Information
6. Stay at home and self-treat their symptoms
7. Visit an NHS, Department of Health or other health website for advice
8. Visit/go and see a community pharmacist (chemist)
9. Call the hospital chest clinic/their chest consultant's secretary
10. Go to the walk-in chest clinic at the hospital
11. None of these
12. Don't know
13. Other (please specify)

34a. If *your family member with chest problems* thought they were *developing complications of swine flu*, which, if any, of the following would you do *first*? (Please circle *one* answer.)

1. Go to an A&E (casualty) department
2. Go to their family doctor/GP
3. Call their family doctor/GP
4. Call a health helpline for advice (e.g. NHS Direct)
5. Call Swine Flu Information
6. Stay at home and self-treat their symptoms
7. Visit an NHS, Department of Health or other health website for advice
8. Visit/go and see a community pharmacist (chemist)
9. Call the hospital chest clinic/their chest consultant's secretary
10. Go to the walk-in chest clinic at the hospital
11. None of these
12. Don't know
13. Other (please specify)

34b. And what else might you advise them to do? (Please circle *all that apply*.)

1. Go to an A&E (casualty) department
2. Go to their family doctor/GP
3. Call their family doctor/GP
4. Call a health helpline for advice (e.g. NHS Direct)
5. Call Swine Flu Information
6. Stay at home and self-treat their symptoms
7. Visit an NHS, Department of Health or other health website for advice
8. Visit/go and see a community pharmacist (chemist)
9. Call the hospital chest clinic/their chest consultant's secretary
10. Go to the walk-in chest clinic at the hospital
11. None of these
12. Don't know
13. Other (please specify)

35a. Have you chosen anyone to act as a 'Swine Flu Friend/Buddy' *for you*?

1. Yes
2. No, because I don't think I need one
3. No, because I don't know what one is
4. Don't know

35b. Has your family member with a chest problem chosen anyone to act as a 'Swine Flu Friend/Buddy' *for them*?
1. Yes
2. No, because they don't think they need one
3. No, because they don't know what one is
4. Don't know

36a. As you may have heard, the antiviral medicines such as Tamiflu can sometimes help to reduce the symptoms of swine flu if taken right away. If *you* fell ill with swine flu, and wanted to obtain Tamiflu, how would *you* go about obtaining it, or how have *you* got it already? (Please circle *all* that apply.)
1. I would go to an A&E (casualty) department
2. I would go to my family doctor/GP
3. I would call my GP/health centre
4. I would call a health helpline for advice (e.g. NHS Direct)
5. I would call the National Pandemic Flu Service (NPFS)
6. I would ask a Flu Friend/Flu Buddy
7. I would ask my local community pharmacist (chemist)
8. I would look for information on news programmes on television
9. I would look for information in the newspapers
10. I would listen for information on news programmes on the radio
11. I would look online – on news websites
12. I would look online – on NHS, Department of Health or other health websites
13. I would look online – on other websites
14. I would look online – unspecified
15. I already have a supply of Tamiflu
16. None of these
17. Don't know
18. Other (please specify)

36b. If *your family member with chest problems* fell ill with swine flu, and wanted to obtain Tamiflu, how would you advise them go about obtaining it, or have they got it already? (Please circle *all that apply*.)
1. Go to an A&E (casualty) department
2. Go to their family doctor/GP
3. Call their GP/health centre
4. Call a health helpline for advice (e.g. NHS Direct)
5. Call the National Pandemic Flu Service (NPFS)
6. Ask a Flu Friend/Flu Buddy
7. Ask their local community pharmacist (chemist)
8. Look for information on news programmes on television
9. Look for information in the newspapers
10. Listen for information on news programmes on the radio
11. Look online – on news websites
12. Look online – on NHS, Department of Health or other health websites
13. Look online – on other websites
14. Look online – unspecified
15. Contact their chest consultant/the hospital chest clinic
16. Contact a chest specialist nurse (hospital or community)
17. They already have a supply of Tamiflu
18. None of these
19. Don't know
20. Other (please specify)

37a. If *you* needed antiviral treatment for swine flu, from where would *you* prefer to get it? (Please circle *one* answer.)

1. On prescription (from a GP/family doctor, hospital doctor, nurse, etc.)
2. 'Over the counter' (from a community pharmacist/chemist)
3. Without having to contact a health professional (e.g. internet, health food shop, etc.)
4. Don't know
5. Other (please state)

37b. If *your family member with chest problems* needed antiviral treatment for swine flu, from where do you think *they* would prefer to get it? (Please circle *one* answer.)

1. On prescription (from a GP/family doctor, hospital doctor, nurse, etc.)
2. 'Over the counter' (from a community pharmacist/chemist)
3. Without having to contact a health professional (e.g. internet, health food shop, etc.)
4. Don't know
5. Other (please state)

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38. Please indicate, by circling *one* answer, whether you agree or disagree with the following statement: 'Too much fuss is being made about the risk of swine flu.'

1. Strongly agree
2. Tend to agree
3. Neither agree nor disagree
4. Tend to disagree
5. Strongly disagree
6. Don't know

39. Please tell us if you think each of the following statements is *true or false*. (Please circle *one* option for each item.)

1.	Very young people are the most likely to get swine flu	True/False
2.	Wearing a mask will stop me getting swine flu	True/False
3.	People with chest problems are more likely than others to catch swine flu	True/False
4.	Washing your hands is very important in preventing the spread of swine flu	True/False
5.	The ordinary flu vaccine will protect me from swine flu	True/False
6.	People with chest problems are more likely than others to develop complications of swine flu	True/False
7.	Older people are the most likely to get swine flu	True/False
8.	Tamiflu is a vaccine for swine flu	True/False
9.	Swine flu may become more of a problem over the winter	True/False
10.	People with chest problems are more likely to die from swine flu than others	True/False
11.	It is possible to catch the swine flu from eating pork	True/False
12.	Using an antibacterial hand wash or gel will stop the spread of swine flu	True/False
13.	If your doctor says you need antiviral treatment, you should send someone to collect a prescription for you, rather than going yourself	True/False
14.	If someone in a household develops swine flu, all their family can get anti-swine flu treatment (e.g. Tamiflu or Relenza)	True/False
15.	Swine flu is very contagious	True/False
16.	'Swine flu parties' are a good way of developing immunity to swine flu	True/False
17.	Swine flu is different from ordinary flu	True/False

40. Please tell us if you think any of the following might be a symptom of swine flu or not. (Please circle *one* option for each item.)

1. Sudden fever (high temperature)	True/False
2. Sudden cough (in people who don't usually have a cough)	True/False
3. Worsening of cough (in people who usually have a cough)	True/False
4. Headache	True/False
5. Tiredness	True/False
6. Producing more sputum (phlegm/mucus) than usual	True/False
7. Chills	True/False
8. Aching muscles	True/False
9. Limb or joint pain	True/False
10. Suddenly becoming breathless (in people who aren't usually breathless)	True/False
11. Worsening of breathlessness (in people who are usually breathless)	True/False
12. Dizziness	True/False
13. Diarrhoea or stomach upset	True/False
14. Sore throat	True/False
15. Blurred vision	True/False
16. Runny nose	True/False
17. Sputum (phlegm/mucus) turning a different colour than usual	True/False
18. Loss of memory	True/False
19. Rash	True/False
20. Loss of appetite	True/False
21. Sudden inability to move or control limbs	True/False
22. Wheezing	True/False
23. Confusion	True/False
24. Sneezing	True/False
25. Chest pains	True/False

41a. If *you* had swine flu, would *you* get help if *you* developed any of the following symptoms? (Please circle *one* option for each item.)

1. Fast breathing or feeling much more short of breath than usual	Yes/No
2. Feeling very tired	Yes/No
3. Chest pains	Yes/No
4. Fever (high temperature) that didn't go down after 4 or 5 days	Yes/No
5. Aching muscles	Yes/No
6. Producing more sputum (phlegm/mucus) than usual	Yes/No
7. Worsening of cough or cough that wouldn't go away	Yes/No
8. Drowsiness or confusion	Yes/No
9. Coughing up blood	Yes/No
10. Sputum (phlegm/mucus) turning a different colour than usual	Yes/No
11. Sore throat	Yes/No
12. Feeling more wheezy than usual	Yes/No

41b. If your family member with chest problems had swine flu, would you get help if *they* developed any of the following symptoms? (Please circle *one* option for each item.)

1. Fast breathing or feeling much more short of breath than usual	Yes/No
2. Feeling very tired	Yes/No
3. Chest pains	Yes/No
4. Fever (high temperature) that didn't go down after 4 or 5 days	Yes/No
5. Aching muscles	Yes/No
6. Producing more sputum (phlegm/mucus) than usual	Yes/No
7. Worsening of cough or cough that wouldn't go away	Yes/No
8. Drowsiness or confusion	Yes/No
9. Coughing up blood	Yes/No
10. Sputum (phlegm/mucus) turning a different colour than usual	Yes/No
11. Sore throat	Yes/No
12. Feeling more wheezy than usual	Yes/No

42. We'd like to know whether worries about swine flu are making *you* do anything different or feel different. (Please circle all that *apply to you*.)

Because of worries about swine flu:

1. I have stopped or cut down on travelling by public transport (buses, trains, etc.)
2. I am taking things like vitamins or food supplements
3. I am avoiding crowded places (e.g. shops, cinemas, sports events, etc.)
4. I am leaving the house less often
5. I am avoiding contact with my friends and family members
6. I feel that people are worried about being around me because of my family member's chest problem
7. I have cut down or stopped smoking
8. I have cancelled a holiday/rearranged travel plans
9. I am keeping my windows and doors closed
10. I feel more anxious than usual about my family member's chest problem
11. I am avoiding contact with children
12. I am avoiding contact with my family member with chest problems
13. I am trying to get more exercise
14. I am not leaving the house at all
15. I feel more self-conscious about having a family member with chest problems
16. I am avoiding contact with pets/animals
17. I would not wish to travel far within the United Kingdom
18. I am eating more healthy foods
19. I am much more aware of my family member's chest problem than usual
20. I am not sleeping well
21. I would not wish to travel abroad
22. I have cut down my usual social activities (e.g. going to the pub, eating out, etc.)
23. I am avoiding contact with people who have been abroad
24. I am constantly on the alert for changes in my family member's chest problem
25. I feel that other people are avoiding me because of my family member's chest problem
26. I am avoiding eating pork/ham/bacon, etc.
27. I have tried to buy/bought Tamiflu

43. We'd like to know whether you think worries about swine flu are making *your family member with chest problems* do anything different or feel different. (Please circle *all that you think apply to your family member with chest problems.*)

Because of worries about swine flu, *my family member with chest problems*:

1. Has stopped or cut down on travelling by public transport (buses, trains, etc.)
2. Is taking things like vitamins or food supplements
3. Is avoiding crowded places (e.g. shops, cinemas, sports events, etc.)
4. Is leaving the house less often
5. Is avoiding contact with their friends and family members
6. Feels that people are worried about being around them due to their chest problem
7. Has cut down or stopped smoking
8. Has cancelled a holiday/rearranged travel plans
9. Is keeping their windows and doors closed
10. Is more anxious than usual about their chest problem
11. Is avoiding contact with children
12. Will not take their medication/use their inhaler in public, even if they really need it
13. Is trying to get more exercise
14. Is not leaving the house at all
15. Is feeling more self-conscious about their chest problem
16. Is avoiding contact with pets/animals
17. Is using their inhaler(s) more often

18. Would not wish to travel far within the UK
19. Is eating more healthy foods
20. Is much more aware of their chest problem than usual
21. Is not sleeping well
22. Would not wish to travel abroad
23. Has cut down their usual social activities (e.g. going to the pub, eating out, etc.)
24. Is avoiding contact with people who have been abroad
25. Is constantly on the alert for changes in their chest problem
26. Feels that other people are avoiding them
27. Is more careful about taking their regular medications as instructed
28. Is avoiding eating pork/ham/bacon, etc.
29. Has tried to buy/bought Tamiflu

Now please tell us a bit about yourself:

44. What is your relationship with your family member with chest problems?
    1. Wife
    2. Husband
    3. Son
    4. Daughter
    5. Parent
    6. Other (please state which)

_____

45. How old are you (in years)?

_____

46. What is your gender? (Please circle *one* answer.)
    i. Male
    ii. Female

47. What would you consider your ethnic group to be?

_____

48. Are you married or living with a partner? (Please circle *one* answer.)
    i. Yes
    ii. No

49a. What is your current occupation?

_____

49b. If retired or not working, what is your most recent previous occupation?

_____

50. Do you have any of the following? (Please circle *all that apply*.)
    1. CSE/O level/GCSE or equivalent
    2. A level or equivalent
    3. GNVQ
    4. Diploma
    5. Professional qualification (e.g. RGN, Cert Ed, City and Guilds)
    6. College/university degree (undergraduate/bachelor's)
    7. Higher degree (Masters, MRes, PhD)
    8. None of the above
    9. Other (please state which)

_____

51. What is the name of your family member's chest problem? (If you are not sure, please write 'don't know'.)

_____

52. How severe would you rate your family member's chest problem as being? (Please circle *one* answer.)
    1. Very mild
    2. Mild
    3. Moderate
    4. Severe
    5. Very severe
    6. Don't know

53. Do you smoke? (Please circle *one* answer.)
    1. Yes, I currently smoke
    2. No, but I used to smoke
    3. No, I have never smoked

54. How did you find out about our study? (Please circle *one* answer.)
    1. My family member with a chest problem gave me the questionnaire
    2. I saw a poster at chest clinic
    3. I saw the piece about the study in the newspaper
    4. Someone (e.g. a friend or relative) told me about the study
    5. Other (please state)

_____

55. Any other comments?

_____

If you want to contact us about this research, details are as follows:

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For independent information about this research, please contact:

The University of Manchester's Research Practice and Governance Co-ordinator
Tel: 0000 000 0000 or 0000 000 0000
E-mail: research-governance@manchester.ac.uk

Further information about swine flu can be found at:

National Pandemic Flu Service (NPFS): 0800 1 513 100
NPFS Textphone for people who are deaf/hard of hearing: 0800 1 513 200
The government's Pandemic Flu website: www.direct.gov.uk/pandemicflu
The NHS Choices website: www.nhs.uk

THANK YOU FOR TAKING TIME TO COMPLETE THIS QUESTIONNAIRE

PLEASE RETURN THE QUESTIONNAIRE TO US IN THE ENCLOSED PRE-PAID ENVELOPE OR, IF COMPLETED WHILST AT CLINIC, ASK THE RECEPTIONIST (OR THE MEMBER OF CLINIC STAFF WHO GAVE YOU THE PACK) WHERE TO LEAVE IT – THANK YOU

YOU DO NOT HAVE TO PROVIDE ANY CONTACT INFORMATION. HOWEVER, IF YOU ARE WILLING TO DO SO (e.g. SO WE CAN SEND YOU A SUMMARY OF STUDY FINDINGS), PLEASE COMPLETE THE SEPARATE SHEET ATTACHED AND RETURN IT WITH YOUR COMPLETED QUESTIONNAIRE – THANK YOU

Appendix 4

Interview and focus group topic guide

Introductory question

- Have you heard about swine flu? (Probe: where/who from?)

Information needs

- What, if anything, is the number one thing you'd like to know about swine flu? (Probes: key information topics, priority information.)
- Do people with chest problems/family members need different information from other people? (Probe: specific topics, differences between patients and families.)
- How well informed to do feel about swine flu? (Probes: gaps in knowledge, usefulness of information, volume of information.)
- Which sources of information have you found most/least useful? (Probes: preferred sources, quality, accessibility and credibility of information.)

Concerns

- How worried are you about swine flu? (Probes: susceptibility, severity, consequences.)
- Are you more worried about swine flu because you have/your family member has chest problems? (Probes: susceptibility, severity, consequences.)

Behaviours

- Do you know what the government is recommending that people do to help stop swine flu spreading? (Probes: recommendations, behaviours regarding these.)
- What would you do if you thought you had swine flu? (Probes: awareness of recommendations, likely actions taken, use of health services.)
- What would you do if you thought you were developing complications of swine flu? (Probes: awareness of symptoms, likely actions taken, use of health services.)
- Are you doing anything different from normal because of swine flu? (Probes: avoidance behaviours, health promotion, medication use.)

Appendix 5

Additional survey data

TABLE 18 *Importance of information topics – patients, (n = 253)*

	Very important →				Not at all important
Information topic	**1**	**2**	**3**	**4**	**5**
What swine flu is and what it does to your body	181 (73.0)	45 (18.1)	18 (7.3)	2 (0.8)	2 (0.8)
Whether swine flu is different from ordinary flu	153 (62.2)	63 (25.6)	22 (8.9)	3 (1.2)	5 2.0)
How serious swine flu is and the outlook for people who catch it	185 (74.9)	48 (19.4)	12 (4.9)	0 (0)	2 (0.8)
Whether there is a vaccine available for swine flu yet and who will get it	180 (73.5)	42 (17.1)	20 (8.2)	0 (0)	3 (1.2)
The treatments available for swine flu and how effective they are	186 (76.2)	38 (15.6)	18 (7.4)	0 (0)	2 (0.8)
What the symptoms of swine flu are	186 (75.6)	48 (19.5)	8 (3.3)	2 (0.8)	2 (0.8)
How to recognise if you might have swine flu	188 (76.4)	45 (18.3)	9 (3.7)	1 (0.4)	3 (1.2)
What to do if you think you have swine flu	192 (78.7)	39 (16.0)	10 (4.1)	1 (0.4)	1 (0.4)
Recognising complications and what to do about them	189 (76.8)	48 (19.5)	7 (2.8)	0 (0)	2 (0.8)
How likely it is that you will catch swine flu	158 (64.0)	46 (18.6)	32 (13.0)	7 (2.8)	4 (1.6)
How to prevent the spread of swine flu	176 (71.3)	44 (17.8)	22 (8.9)	2 (0.8)	3 (1.2)
How to reduce your risk of catching swine flu	183 (74.4)	43 (17.5)	16 (6.5)	1 (0.4)	3 (1.2)
How swine flu might affect chest problems	202 (81.5)	35 (14.1)	8 (3.2)	1 (0.4)	2 (0.8)
Whether people with chest problems are more likely to catch swine flu than others	170 (69.1)	53 (21.5)	18 (7.3)	3 (1.2)	2 (0.8)
Whether the families of people with chest problems are more likely to catch swine flu than others	128 (52.7)	67 (27.6)	35 (14.4)	7 (2.9)	6 (2.5)
Whether people with chest problems are more likely to develop complications or die from swine flu	192 (78.4)	35 (14.3)	14 (5.7)	2 (0.8)	2 (0.8)

continued

TABLE 18 *Importance of information topics – patients, (n = 253) (continued)*

	Very important	→			Not at all important
Information topic	**1**	**2**	**3**	**4**	**5**
Whether treatments for swine flu are safe for people with chest problems	187 (76.0)	39 (15.9)	15 (6.1)	2 (0.8)	3 (1.2)
Whether treatments for swine flu can interfere with treatments for chest problems	181 (74.2)	42 (17.2)	15 (6.1)	4 (1.6)	2 (0.8)
Where to get information, help or support (e.g. if worried or want to know more about swine flu)	164 (66.7)	60 (24.4)	14 (5.7)	4 (1.6)	4 (1.6)

Most items had some missing data; figures in parentheses = valid percentage.

TABLE 19 *Importance of information topics – family members, (n = 101)*

	Very important	→			Not at all important
Information topic	**1**	**2**	**3**	**4**	**5**
What swine flu is and what it does to your body	71 (70.3)	21 (24.8)	5 (5.0)	0 (0)	0 (0)
Whether swine flu is different from ordinary flu	57 (56.4)	35 (34.7)	5 (5.0)	4 (4.0)	0 (0)
How serious swine flu is and the outlook for people who catch it	74 (73.3)	22 (21.8)	4 (4.0)	1 (1.0)	0 (0)
Whether there is a vaccine available for swine flu yet and who will get it	72 (72.0)	22 (22.0)	3 (3.0)	3 (3.0)	0 (0)
The treatments available for swine flu and how effective they are	70 (70.0)	23 (23.0)	6 (6.0)	1 (1.0)	0 (0)
What the symptoms of swine flu are	77 (76.2)	20 (19.8)	4 (4.0)	0 (0)	0 (0)
How to recognise if you might have swine flu	83 (83.0)	14 (14.0)	3 (3.0)	0 (0)	0 (0)
What to do if you think you have swine flu	77 (77.8)	18 (18.2)	2 (2.0)	2 (2.0)	0 (0)
Recognising complications and what to do about them	80 (80.8)	16 (16.2)	3 (3.0)	0 (0)	0 (0)
How likely it is that you will catch swine flu	50 (50.0)	31 (31.0)	18 (18.0)	1 (1.0)	0 (0)
How to prevent the spread of swine flu	74 (74.7)	16 (16.2)	8 (8.1)	1 (1.0)	0 (0)
How to reduce your risk of catching swine flu	72 (72.2)	22 (22.2)	5 (5.1)	0 (0)	0 (0)
How swine flu might affect chest problems	86 (86.0)	12 (12.0)	2 (2.0)	0 (0)	0 (0)
Whether people with chest problems are more likely to catch swine flu than others	78 (78.0)	18 (18.0)	4 (4.0)	0 (0)	0 (0)
Whether the families of people with chest problems are more likely to catch swine flu than others	56 (56.6)	27 (27.3)	15 (15.2)	0 (0)	1 (1.0)

TABLE 19 *Importance of information topics – family members, (n = 101) (continued)*

	Very important → Not at all important				
Information topic	**1**	**2**	**3**	**4**	**5**
Whether people with chest problems are more likely to develop complications or die from swine flu	80 (79.2)	15 (14.9)	6 (5.9)	0 (0)	0 (0)
Whether treatments for swine flu are safe for people with chest problems	81 (81.0)	14 (14.0)	4 (4.0)	1 (1.0)	0 (0)
Whether treatments for swine flu can interfere with treatments for chest problems	78 (78.0)	16 (16.0)	5 (5.0)	1 (1.0)	0 (0)
Where to get information, help or support (e.g. if worried or want to know more about swine flu)	61 (61.6)	29 (29.3)	8 (8.1)	1 (1.0)	0 (0)

Most items had some missing data; figures in parentheses = valid percentage.

TABLE 20 *Sources of information about swine flu for patients (n = 253) and family members (n = 101)*

Information source	**Patients**	**Family members**
Leaflet delivered to my home	125 (49.4)	55 (54.5)
Leaflet picked up somewhere else	29 (11.5)	17 (16.8)
Poster displayed at work	16 (6.3)	21 (20.8)
Poster displayed at GP surgery	109 (43.1)	37 (36.6)
Poster displayed at hospital	58 (22.9)	19 (18.8)
Internet – NHS Choices (www.nhs.uk)	22 (8.7)	9 (8.9)
Internet – Government website (www.direct.gov.uk/pandemicflu)	26 (10.3)	15 (14.9)
Internet – health-care organisation or health-care charity website	8 (3.2)	4 (4.0)
Internet – other website	6 (2.4)	6 (5.9)
NHS Direct (telephone line)	17 (6.7)	7 (6.9)
The Swine Flu Information Line (phone line, recorded information)	16 (6.3)	8 (7.9)
Other telephone helpline (e.g. health-care charity)	4 (1.6)	3 (3.0)
Friends or relatives	54 (21.3)	23 (22.8)

continued

TABLE 20 *Sources of information about swine flu for patients (n = 253) and family members (n = 101) (continued)*

Information source	Patients	Family members
General practitioner (GP)	75 (29.6)	21 (20.8)
Practice nurse (GP's nurse)	44 (17.4)	14 (13.9)
Receptionist at GP's surgery	13 (5.1)	6 (5.9)
Community pharmacist (chemist)	12 (4.7)	4 (4.0)
Specialist nurse (hospital or community)	18 (7.1)	7 (6.9)
District nurse	4 (1.6)	2 (2.0)
Health visitor	4 (1.6)	3 (3.0)
Hospital consultant/specialist doctor	48 (19.0)	10 (9.9)
Other hospital doctor	10 (4.0)	2 (2.0)
Hospital doctor's secretary or clinic receptionist	2 (0.8)	3 (3.0)
Nurses on hospital wards or at clinics	8 (3.2)	2 (2.0)
Other health professional (e.g. physiotherapist, occupational therapist)	7 (2.8)	2 (2.0)
Minor injuries clinic or walk-in centre	3 (1.2)	1 (1.0)
A&E (casualty) department	1 (0.4)	2 (2.0)
National Pandemic Flu Service (website and telephone line)	18 (7.1)	11 (10.9)
The Health Protection Agency	3 (1.2)	5 (5.0)
Television	116 (45.8)	44 (43.6)
Radio	47 (18.6)	25 (24.8)
Newspaper	91 (36.0)	36 (35.6)
Magazine	25 (9.9)	12 (11.9)
Medical book/journal	9 (3.6)	3 (3.0)
Patient self-help or support group	10 (4.0)	5 (5.0)
Other	9 (3.6)	6 (5.9)

Figures in parentheses = percentage selecting the option; participants could select multiple options.

TABLE 21 *Patients' perceptions of usefulness of information sources in general[a] and likelihood of personally using the source[b] (n = 253)*

	Very useful (definitely use)→Not at all useful (definitely not use)				
Information source	**1**	**2**	**3**	**4**	**5**
Friends/relatives	72 (30.3)	45 (18.9)	67 (28.2)	28 (11.8)	26 (10.9)
	55 (24.4)	*28 (12.4)*	*59 (26.2)*	*43 (19.1)*	*40 (17.8)*
General practitioner (GP)/family doctor	188 (75.2)	42 (16.8)	15 (6.0)	3 (1.2)	2 (0.8)
	197 (81.1)	*25 (10.3)*	*15 (6.2)*	*5 (2.1)*	*1 (0.4)*
Hospital consultant	190 (76.9)	36 (14.6)	17 (6.9)	2 (0.8)	2 (0.8)
	167 (70.2)	*28 (11.8)*	*28 (11.8)*	*9 (3.8)*	*6 (2.5)*
Other hospital doctor	146 (59.3)	64 (26.0)	27 (11.0)	4 (1.6)	5 (2.0)
	102 (43.6)	*57 (24.4)*	*46 (19.7)*	*17 (7.3)*	*12 (5.1)*
Specialist nurse (hospital or community)	150 (61.7)	66 (27.2)	15 (6.2)	6 (2.5)	6 (2.5)
	110 (46.6)	*63 (26.7)*	*38 (16.1)*	*13 (5.5)*	*12 (5.1)*
District nurse	107 (43.9)	78 (32.0)	38 (15.6)	13 (5.3)	8 (3.3)
	68 (29.8)	*57 (25.0)*	*48 (21.1)*	*31 (13.6)*	*24 (10.5)*
Health visitor	99 (40.6)	71 (29.1)	47 (19.3)	17 (7.0)	10 (4.1)
	54 (23.6)	*56 (24.5)*	*59 (25.8)*	*32 (14.0)*	*28 (12.2)*
Nurses on hospital wards/at hospital clinics	119 (48.6)	65 (26.5)	47 (19.2)	6 (2.4)	8 (3.3)
	62 (26.6)	*64 (27.4)*	*65 (27.9)*	*24 (10.3)*	*18 (7.7)*
Practice nurse (GP's nurse)	137 (55.9)	70 (28.6)	29 (11.8)	5 (2.0)	4 (1.6)
	117 (49.4)	*57 (24.1)*	*36 (15.2)*	*18 (7.6)*	*9 (3.8)*
A&E (casualty) department	106 (43.1)	61 (24.8)	55 (22.4)	17 (6.9)	7 (2.8)
	69 (30.1)	*43 (18.8)*	*62 (27.1)*	*26 (11.4)*	*29 (12.7)*
Walk-in centre or minor injuries unit	95 (39.3)	59 (24.4)	56 (23.1)	21 (8.7)	10 (4.1)
	61 (26.8)	*42 (18.4)*	*62 (27.2)*	*37 (16.2)*	*26 (11.4)*
Community pharmacist (chemist)	102 (41.3)	74 (30.0)	47 (19.0)	14 (5.7)	10 (4.0)
	66 (28.8)	*67 (29.3)*	*61 (26.6)*	*21 (9.2)*	*14 (6.1)*
NHS Direct (telephone line)	118 (48.6)	55 (22.5)	36 (14.8)	20 (8.2)	14 (5.7)
	77 (33.5)	*55 (23.9)*	*53 (23.0)*	*22 (9.6)*	*23 (10.0)*
The Health Protection Agency	94 (39.3)	64 (26.8)	51 (21.3)	16 (6.7)	14 (5.9)
	44 (19.5)	*55 (24.3)*	*57 (25.2)*	*32 (14.2)*	*38 (16.8)*
Television	80 (32.5)	70 (28.5)	49 (19.9)	29 (11.8)	18 (7.3)
	49 (21.0)	*53 (22.7)*	*57 (24.5)*	*40 (17.2)*	*34 (14.6)*
Radio	69 (28.3)	69 (28.3)	55 (22.5)	28 (11.5)	23 (9.4)
	34 (14.8)	*51 (22.3)*	*57 (24.9)*	*44 (19.2)*	*43 (18.8)*
Posters or billboards	53 (21.5)	58 (23.6)	68 (27.6)	36 (14.6)	31 (12.6)
	28 (12.1)	*42 (18.2)*	*57 (24.7)*	*53 (22.9)*	*51 (22.1)*
Medical book/journal	54 (22.2)	52 (21.4)	70 (28.8)	41 (16.9)	26 (10.7)
	34 (14.8)	*36 (15.7)*	*55 (24.0)*	*48 (20.9)*	*56 (26.5)*
Magazines	44 (18.0)	51 (20.9)	75 (30.7)	39 (16.0)	35 (14.3)
	19 (8.3)	*42 (18.4)*	*60 (26.3)*	*48 (21.1)*	*59 (25.9)*
Newspapers	65 (26.6)	54 (22.1)	65 (26.6)	36 (14.8)	24 (9.8)
	45 (19.4)	*45 (19.4)*	*52 (22.4)*	*50 (21.6)*	*40 (17.2)*
Leaflets	79 (31.2)	60 (23.7)	63 (25.9)	25 (10.3)	16 (6.6)
	66 (28.7)	*48 (20.9)*	*59 (25.7)*	*30 (13.0)*	*27 (11.7)*

continued

TABLE 21 *Patients' perceptions of usefulness of information sources in general[a] and likelihood of personally using the source[b] (n = 253)*

	Very useful (definitely use)→Not at all useful (definitely not use)				
Information source	**1**	**2**	**3**	**4**	**5**
Government website (www.direct.gov.uk/ pandemicflu)	79 (33.2)	64 (26.9)	56 (23.5)	16 (6.7)	23 (9.7)
	75 (33.8)	*34 (15.3)*	*51 (23.0)*	*25 (11.3)*	*37 (16.7)*
NHS Choices website (www.nhs.uk)	83 (34.9)	60 (25.2)	56 (23.5)	17 (7.1)	22 (9.2)
	61 (27.5)	*44 (19.8)*	*54 (24.3)*	*27 (12.2)*	*36 (16.2)*
Other website	41 (17.5)	41 (17.5)	79 (33.8)	31 (13.2)	42 (17.9)
	27 (12.3)	*31 (14.4)*	*56 (25.5)*	*50 (22.7)*	*56 (25.5)*
Health-related charities	49 (20.2)	43 (17.8)	82 (33.9)	36 (14.9)	32 (13.2)
	29 (12.8)	*27 (11.9)*	*64 (28.3)*	*50 (22.1)*	*56 (24.8)*
Patient support/self-help groups	58 (24.2)	65 (27.1)	73 (30.4)	24 (10.0)	20 (8.3)
	30 (13.3)	*48 (21.3)*	*63 (28.0)*	*37 (16.4)*	*47 (20.9)*
National Pandemic Flu Service	124 (51.0)	51 (21.0)	40 (16.5)	17 (7.0)	11 (4.5)
	90 (39.5)	*46 (20.2)*	*51 (22.4)*	*20 (8.8)*	*21 (9.2)*

a Non-italic text.
b Italic text.
All items had some missing data; figures in parentheses = valid percentage.

TABLE 22 *Family members' perceptions of usefulness of information sources in general[a] and likelihood of personally using the source[b] (n = 101)*

	Very useful (definitely use)→Not at all useful (definitely not use)				
Information source	**1**	**2**	**3**	**4**	**5**
Friends/relatives	29 (29.3)	22 (22.2)	26 (26.3)	16 (16.2)	6 (6.1)
	22 (23.2)	*12 (12.6)*	*26 (27.4)*	*16 (16.8)*	*19 (20.0)*
General practitioner (GP)/family doctor	78 (77.2)	15 (14.9)	6 (5.9)	0 (0)	2 (2.0)
	74 (76.3)	*14 (14.4)*	*5 (5.2)*	*2 (2.1)*	*2 (2.1)*
Hospital consultant	73 (72.3)	11 (10.9)	12 (11.9)	3 (3.0)	2 (2.0)
	58 (60.4)	*14 (14.6)*	*10 (10.4)*	*7 (7.3)*	*7 (7.3)*
Other hospital doctor	47 (47.5)	22 (22.2)	19 (19.2)	6 (6.1)	5 (5.1)
	38 (40.4)	*19 (20.2)*	*20 (21.3)*	*10 (10.6)*	*7 (7.4)*
Specialist nurse (hospital or community)	57 (58.2)	28 (28.6)	9 (9.2)	2 (2.0)	2 (2.0)
	48 (50.5)	*23 (24.2)*	*9 (9.5)*	*9 (9.5)*	*6 (6.3)*
District nurse	46 (47.4)	23 (23.7)	21 (21.6)	7 (7.2)	0 (0)
	36 (38.3)	*16 (17.0)*	*19 (20.2)*	*13 (13.8)*	*10 (10.6)*
Health visitor	41 (41.8)	19 (19.4)	25 (25.5)	8 (8.2)	5 (5.1)
	35 (37.2)	*11 (11.7)*	*23 (24.5)*	*13 (13.8)*	*12 (12.8)*
Nurses on hospital wards/at hospital clinics	45 (45.0)	17 (17.0)	29 (29.0)	5 (5.0)	4 (4.0)
	33 (35.5)	*18 (19.4)*	*20 (21.5)*	*12 (12.9)*	*10 (10.8)*
Practice nurse (GP's nurse)	54 (54.5)	25 (25.3)	17 (17.2)	2 (2.0)	1 (1.0)
	52 (54.2)	*19 (19.8)*	*14 (14.6)*	*10 (10.4)*	*1 (1.0)*
A&E (casualty) department	41 (41.4)	18 (18.2)	26 (26.3)	9 (9.1)	5 (5.1)
	33 (34.7)	*15 (15.8)*	*24 (25.3)*	*7 (7.4)*	*16 (16.8)*
Walk-in centre or minor injuries unit	35 (36.1)	27 (27.8)	27 (27.8)	6 (6.2)	2 (2.1)
	25 (26.6)	*19 (20.2)*	*25 (26.6)*	*11 (11.7)*	*14 (14.9)*

TABLE 22 *Family members' perceptions of usefulness of information sources in general[a] and likelihood of personally using the source[b] (n = 101) (continued)*

	Very useful (definitely use)→Not at all useful (definitely not use)				
Information source	**1**	**2**	**3**	**4**	**5**
Community pharmacist (chemist)	40 (40.4)	26 (26.3)	24 (24.2)	8 (8.1)	1 (1.0)
	34 (35.8)	*26 (27.4)*	*18 (18.9)*	*14 (14.7)*	*3 (3.2)*
NHS Direct (telephone line)	53 (54.1)	20 (20.4)	18 (18.4)	2 (2.0)	5 (5.1)
	40 (43.0)	*19 (20.4)*	*17 (18.3)*	*7 (7.5)*	*10 (10.8)*
The Health Protection Agency	45 (46.4)	19 (19.6)	20 (20.6)	7 (7.2)	6 (6.2)
	29 (30.9)	*22 (23.4)*	*22 (23.4)*	*10 (10.6)*	*11 (11.7)*
Television	31 (30.7)	23 (22.8)	28 (27.7)	14 (13.9)	5 (5.0)
	17 (18.3)	*20 (21.5)*	*19 (20.4)*	*20 (21.5)*	*17 (18.3)*
Radio	25 (25.0)	22 (22.0)	32 (32.0)	14 (14.0)	7 (7.0)
	15 (16.1)	*16 (17.2)*	*22 (23.7)*	*22 (23.7)*	*18 (19.4)*
Posters or billboards	23 (23.5)	20 (20.4)	38 (38.8)	12 (12.2)	5 (5.1)
	14 (15.1)	*14 (15.1)*	*23 (14.7)*	*24 (25.8)*	*18 (19.4)*
Medical book/journal	19 (19.2)	27 (27.3)	32 (32.3)	12 (12.1)	9 (9.1)
	16 (17.2)	*17 (18.3)*	*23 (24.7)*	*19 (20.4)*	*18 (19.4)*
Magazines	20 (20.6)	24 (24.7)	29 (29.9)	16 (16.5)	8 (8.2)
	13 (14.0)	*15 (16.1)*	*21 (22.6)*	*24 (25.8)*	*20 (21.5)*
Newspapers	25 (25.2)	23 (23.2)	30 (30.3)	16 (16.2)	5 (5.1)
	12 (13.0)	*18 (19.6)*	*24 (26.1)*	*18 (19.6)*	*20 (21.7)*
Leaflets	35 (34.7)	30 (29.7)	28 (27.7)	6 (5.9)	2 (2.0)
	26 (28.0)	*26 (28.0)*	*21 (22.6)*	*14 (15.1)*	*6 (6.5)*
Government website (www.direct.gov.uk/ pandemicflu)	45 (45.5)	20 (20.2)	23 (23.2)	6 (6.1)	5 (5.1)
	38 (41.3)	*20 (21.7)*	*18 (19.6)*	*8 (8.7)*	*8 (8.7)*
NHS Choices website (www.nhs.uk)	35 (35.7)	21 (21.4)	24 (24.5)	10 (10.2)	8 (8.1)
	31 (34.1)	*19 (20.9)*	*21 (23.1)*	*9 (9.9)*	*11 (12.1)*
Other website	21 (21.4)	13 (13.3)	35 (35.7)	18 (18.4)	11 (11.2)
	10 (11.1)	*12 (13.3)*	*30 (33.3)*	*21 (23.3)*	*17 (18.9)*
Health-related charities	22 (22.4)	13 (13.3)	39 (39.8)	15 (15.3)	9 (9.2)
	11 (12.2)	*5 (5.6)*	*31 (34.4)*	*22 (24.4)*	*21 (23.3)*
Patient support/self-help groups	30 (30.0)	28 (28.0)	26 (26.0)	10 (10.0)	6 (6.0)
	18 (19.8)	*8 (8.8)*	*28 (30.8)*	*20 (22.0)*	*17 (18.7)*
National Pandemic Flu Service (website and telephone line)	55 (55.0)	26 (26.0)	11 (11.0)	4 (4.0)	4 (4.0)
	50 (52.1)	*16 (16.7)*	*16 (16.7)*	*3 (3.1)*	*11 (11.5)*

a Non-italic text.
b Italic text.
Most items had some missing data; figures in parentheses = valid percentage.

TABLE 23 *Patients' (n = 253) responses to items exploring knowledge of 'facts' and 'myths' regarding swine flu*

Please tell us if you think each of the following statements is *true* or *false*	**True**	**False**
Very young people are the most likely to get swine flu	171	71
False, although high incidence of death and hospitalisation in very young	(70.7)	(29.3)
Wearing a mask will stop me getting swine flu	41	202
False, and not recommended in official UK government advice	(16.9)	(83.1)
People with chest problems are more likely than others to catch swine flu	153	90
False	(63.0)	(37.0)
Washing your hands is very important in preventing the spread of swine flu	240	8
True, per official government advice	(96.8)	(3.2)
The ordinary flu vaccine will protect me from swine flu	19	226
False	(7.8)	(92.2)
People with chest problems are more likely than others to develop complications of swine flu	210	32
True	(86.8)	(13.2)
Older people are the most likely to get swine flu	96	145
False – older people had some residual immunity from previous pandemics	(39.8)	(60.2)
Tamiflu is a vaccine for swine flu	138	107
False	(56.3)	(43.7)
Swine flu may become more of a problem over the winter	218	27
True, per expectations/predictions at commencement of study	(89.0)	(11.0)
People with chest problems are more likely to die from swine flu than others	174	63
True – greater risk of death	(73.4)	(26.6)
It is possible to catch swine flu from eating pork	16	232
False	(6.5)	(93.5)
Using an antibacterial hand wash or gel will stop the spread of swine flu	177	68
True, per official government advice	(72.2)	(27.8)
If your doctor says you need antiviral treatment, you should send someone to collect a prescription for you, rather than going yourself	225	22
True	(91.1)	(8.9)
If someone in a household develops swine flu, all their family can get anti-swine flu treatment (e.g. Tamiflu or Relenza)	138	96
False – prophylaxis only recommended for at-risk close contacts	(59.0)	(41.0)
Swine flu is very contagious	205	33
True, per official government advice	(86.1)	(13.9)
'Swine flu parties' are good way of developing immunity to swine flu	17	227
False	(7.0)	(93.0)
Swine flu is different from ordinary flu	236	12
True	(95.2)	(4.8)

Indication of whether the item is true or false is given in italic text after each statement.
Most items had some missing data; figures in parentheses = valid percentage.

TABLE 24 *Family members' (n = 101) responses to items exploring knowledge of 'facts' and 'myths' regarding swine flu*

Please tell us if you think each of the following statements is *true or false*	**True**	**False**
Very young people are the most likely to get swine flu	64	31
False – although high incidence of death and hospitalisation in very young	(67.4)	(32.6)
Wearing a mask will stop me getting swine flu	15	82
False, and not recommended in official UK government advice	(15.5)	(84.5)
People with chest problems are more likely than others to catch swine flu	67	30
False	(69.1)	(30.9)
Washing your hands is very important in preventing the spread of swine flu	96	1
True, per official government advice	(99.0)	(1.0)
The ordinary flu vaccine will protect me from swine flu	9	88
False	(9.3)	(90.7)
People with chest problems are more likely than others to develop complications of swine flu	89	7
True	(92.7)	(7.3)
Older people are the most likely to get swine flu	44	52
False – older people had some residual immunity from previous pandemics	(45.8)	(54.2)
Tamiflu is a vaccine for swine flu	48	47
False	(50.5)	(49.5)
Swine flu may become more of a problem over the winter	86	10
True, per expectations/predictions at commencement of study	(89.6)	(10.4)
People with chest problems are more likely to die from swine flu than others	71	25
True – greater risk of death	(74.0)	(26.0)
It is possible to catch swine flu from eating pork	8	89
False	(8.2)	(91.8)
Using an antibacterial hand wash or gel will stop the spread of swine flu	68	29
True, per official government advice	(70.1)	(29.9)
If your doctor says you need antiviral treatment, you should send someone to collect a prescription for you, rather than going yourself	92	5
True	(94.8)	(5.2)
If someone in a household develops swine flu, all their family can get anti-swine flu treatment (e.g. Tamiflu or Relenza)	49	46
False – prophylaxis only recommended for at-risk close contacts	(51.6)	(48.4)
Swine flu is very contagious	74	22
True, per official government advice	(77.0)	(23.0)
'Swine flu parties' are good way of developing immunity to swine flu	9	88
False	(9.3)	(90.7)
Swine flu is different from ordinary flu	90	6
True	(93.7)	(6.3)

Indication of whether the item is true or false is given in italic text after each statement.
Most items had some missing data; figures in parentheses = valid percentage.

TABLE 25 *Identification of swine flu symptoms – patients (n = 253)*

Please tell us if you think any of the following might be a symptom of swine flu or not	True	False
Sudden fever (high temperature)	221 (94.8)	12 (5.2)
Sudden cough (in people who don't usually have a cough)	165 (73.7)	59 (26.3)
Worsening of cough (in people who usually have a cough)	164 (74.5)	56 (25.5)
Headache	185 (80.7)	44 (19.3)
Tiredness	174 (77.7)	50 (22.3)
Producing more sputum (phlegm/mucus) than usual	147 (66.2)	75 (33.8)
Chills	164 (72.9)	61 (27.1)
Aching muscles	206 (88.8)	26 (11.2)
Limb or joint pain	182 (78.8)	49 (21.2)
Suddenly becoming breathless (in people who aren't usually breathless)	142 (62.8)	84 (37.2)
Worsening of breathlessness (in people who are usually breathless)	173 (76.5)	53 (23.5)
Dizziness	78 (36.3)	137 (63.7)
Diarrhoea or stomach upset	99 (44.6)	123 (55.4)
Sore throat	181 (78.7)	49 (21.3)
Blurred vision	46 (21.3)	170 (78.7)
Runny nose	146 (65.8)	76 (34.2)
Sputum (phlegm/mucus) turning a different colour than usual	144 (64.9)	78 (35.1)
Loss of memory	10 (4.5)	210 (95.5)
Rash	26 (11.7)	196 (88.3)
Loss of appetite	135 (60.5)	88 (39.5)
Sudden inability to move or control limbs	52 (23.5)	169 (76.5)
Wheezing	139 (60.7)	90 (39.3)

TABLE 25 *Identification of swine flu symptoms patients (n = 253) (continued)*

Please tell us if you think any of the following might be a symptom of swine flu or not	True	False
Confusion	15 (17.2)	183 (82.8)
Sneezing	153 (66.2)	78 (33.8)
Chest pains	87 (38.8)	137 (61.2)

Most items had some missing data; figures in parentheses = valid percentage.

TABLE 26 *Identification of swine flu symptoms – family members (n = 101)*

Please tell us if you think any of the following might be a symptom of swine flu or not	True	False
Sudden fever (high temperature)	92 (96.8)	3 (3.2)
Sudden cough (in people who don't usually have a cough)	65 (71.4)	26 (28.6)
Worsening of cough (in people who usually have a cough)	69 (76.7)	21 (23.3)
Headache	80 (86.0)	13 (14.0)
Tiredness	72 (80.0)	18 (20.0)
Producing more sputum (phlegm/mucus) than usual	55 (61.1)	35 (38.9)
Chills	66 (74.2)	23 (25.8)
Aching muscles	82 (89.1)	10 (10.9)
Limb or joint pain	72 (79.1)	19 (20.9)
Suddenly becoming breathless (in people who aren't usually breathless)	67 (72.8)	25 (27.2)
Worsening of breathlessness (in people who are usually breathless)	68 (75.6)	22 (24.4)
Dizziness	36 (40.4)	53 (59.6)
Diarrhoea or stomach upset	62 (66.0)	32 (34.0)
Sore throat	67 (73.6)	24 (26.4)
Blurred vision	23 (25.6)	67 (74.4)

continued

TABLE 26 *Identification of swine flu symptoms – family members (n = 101)*

Please tell us if you think any of the following might be a symptom of swine flu or not	True	False
Runny nose	58 (64.4)	32 (35.6)
Sputum (phlegm/mucus) turning a different colour than usual	37 (40.2)	55 (58.8)
Loss of memory	10 (11.9)	80 (88.9)
Rash	20 (22.2)	70 (77.8)
Loss of appetite	43 (47.8)	47 (52.2)
Sudden inability to move or control limbs	32 (35.2)	59 (64.8)
Wheezing	37 (40.2)	55 (59.8)
Confusion	23 (25.3)	68 (74.7)
Sneezing	49 (53.8)	42 (46.2)
Chest pains	38 (42.2)	52 (57.8)

Most items had some missing data; figures in parentheses = valid percentage.

TABLE 27 *Impact of worries about swine flu on daily activities – patients (n = 253) and family members (n = 101)*

Because of worries about swine flu I am/have (my family member with chest problems is/has):	Patients (self)	Family members (self)	Family members (for patients)
Stopped or cut down on travelling by public transport (buses, trains, etc.)	43 (17.0)	10 (9.9)	11 (10.9)
Taking things like vitamins or food supplements	19 (7.5)	6 (5.9)	5 (5.0)
Avoiding crowded places (e.g. shops, cinemas, sports events, etc.)	55 (21.7)	11 (10.9)	16 (15.8)
Leaving the house less often	35 (13.8)	5 (5.0)	11 (10.9)
Avoiding contact with friends and family members	9 (3.6)	4 (4.0)	1 (1.0)
Feel(s) that people are worried about being around me/them because of my/their chest problem	12 (4.7)	3 (3.0)	8 (7.9)
Cut down or stopped smoking	15 (5.9)	7 (6.9)	5 (5.0)
Cancelled a holiday/rearranged travel plans	4 (1.6)	0 (0)	2 (2.0)

TABLE 27 *Impact of worries about swine flu on daily activities – patients (n = 253) and family members (n = 101) (continued)*

Because of worries about swine flu I am/have (my family member with chest problems is/has):	Patients (self)	Family members (self)	Family members (for patients)
Keeping windows and doors closed	3 (1.2)	3 (3.0)	0 (0)
More anxious than usual about my/their chest problem	87 (34.4)	39 (38.6)	35 (34.7)
Avoiding contact with children	11 (4.3)	6 (5.9)	6 (5.9)
Will not take my/their medication or use my/their inhaler in a public place, even if really needed	8 (3.2)	N/A	7 (6.9)
Avoiding contact with my family member with chest problems	N/A	2 (2.0)	N/A
Trying to get more exercise	53 (20.9)	14 (13.9)	14 (13.9)
Not leaving the house at all	3 (1.2)	1 (1.0)	4 (4.0)
Feel more self-conscious about my/their chest problem	64 (25.3)	13 (12.9)	17 (16.8)
Avoiding contact with pets/animals	10 (4.0)	1 (1.0)	4 (4.0)
Using my/their inhaler(s) more often	29 (11.5)	N/A	10 (9.9)
Would not wish to travel far within the UK	21 (8.3)	6 (5.9)	6 (5.9)
Eating more healthy foods	38 (15.0)	9 (8.9)	11 (10.9)
Much more aware of my/their chest problem than usual	81 (32.0)	38 (37.6)	23 (22.8)
Not sleeping well	27 (10.7)	8 (7.9)	10 (9.9)
Would not wish to travel abroad	44 (17.4)	10 (9.9)	11 (10.9)
Cut down my/their usual social activities (e.g. going to the pub, eating out, etc.)	24 (9.5)	7 (6.9)	8 (7.9)
Avoiding contact with people who have been abroad	7 (2.8)	2 (2.0)	4 (4.0)
Constantly on the alert for changes in my/their chest problem	89 (35.2)	44 (43.6)	29 (28.7)
Other people are avoiding me/them because of chest problem	5 (2.0)	0 (0)	2 (2.0)
More careful about taking my/their regular medications as instructed	52 (20.6)	N/A	15 (14.9)
Avoiding eating pork/ham/bacon, etc.	3 (1.2)	1 (1.0)	0 (0)
Tried to buy/bought Tamiflu	2 (0.8)	3 (3.0)	2 (2.0)

N/A, not applicable.

TABLE 28 *Previous uptake of annual seasonal influenza vaccination in patients (n = 253) and family members (n = 101)*

	Regularly each year	Occasionally	Never	Don't know/ can't remember	No response
Patients (*n*, %)	198	23	27	1	4
	(78.3)	(9.1)	(10.7)	(0.4)	(1.6)
Family members (*n*, %)	56	9	33	2	1
	(55.4)	(8.9)	(32.7)	(2.0)	(1.0)

TABLE 29 *Intentions regarding uptake this year of annual seasonal influenza vaccination in patients (n = 253) and family members (n = 101)*

	I am now more likely to get the regular winter flu jab:						
	Strongly agree	Tend to agree	Neither agree nor disagree	Tend to disagree	Strongly disagree	Don't know	No response
Patients (*n*, %)	98	37	54	23	28	7	6
	(38.7)	(14.6)	(21.3)	(9.1)	(11.1)	(2.8)	(2.4)
Family members (*n*, %)	29	12	30	15	6	7	2
	(28.7)	(11.9)	(29.7)	(14.9)	(5.9)	(6.9)	(2.0)

TABLE 30 *Help-seeking behaviour in response to specific symptoms – patients (n = 253)*

If you had swine flu, would *you* get help *if you developed* any of the following symptoms?	Yes	No
Fast breathing or feeling much more short of breath than usual	211	23
	(90.2)	(9.8)
Feeling very tired	90	139
	(39.3)	(60.7)
Chest pains	209	27
	(88.6)	(11.4)
Fever (high temperature) that didn't go down after 4 or 5 days	234	5
	(97.9)	(2.1)
Aching muscles	121	107
	(53.1)	(46.9)
Producing more sputum (phlegm/mucus) than usual	150	83
	(64.4)	(35.6)
Worsening of cough or cough that wouldn't go away	194	40
	(82.9)	(17.1)
Drowsiness or confusion	135	91
	(59.7)	(40.3)
Coughing up blood	213	21
	(91.0)	(9.0)
Sputum (phlegm/mucus) turning a different colour than usual	186	46
	(80.2)	(19.8)
Sore throat	115	113
	(50.4)	(49.6)
Feeling more wheezy than usual	181	53
	(77.4)	(22.6)

All items had some missing data; figures in parentheses = valid percentage.

TABLE 31 *Help-seeking behaviour in response to specific symptoms – family members for themselves (n = 101)*

If you had swine flu, would *you* get help *if you developed* any of the following symptoms?	**Yes**	**No**
Fast breathing or feeling very short of breath	82	13
	(86.3)	(13.7)
Feeling very tired	28	63
	(30.8)	(69.2)
Chest pains	80	14
	(85.1)	(14.9)
Fever (high temperature) that didn't go down after 4 or 5 days	88	6
	(93.6)	(6.4)
Aching muscles	37	58
	(38.9)	(61.1)
Producing more sputum (phlegm/mucus) than usual	49	42
	(53.8)	(46.2)
Worsening of cough or cough that wouldn't go away	78	15
	(83.9)	(16.1)
Drowsiness or confusion	57	34
	(62.6)	(37.4)
Coughing up blood	85	8
	(91.4)	(8.6)
Sputum (phlegm/mucus) turning a different colour than usual	67	22
	(75.3)	(24.7)
Sore throat	38	55
	(40.9)	(59.1)
Feeling very wheezy	67	27
	(71.3)	(28.7)

All items had some missing data; figures in parentheses = valid percentage.

TABLE 32 *Help-seeking behaviour in response to specific symptoms – family members on behalf of patients (n = 101)*

If *your family member with chest problems* had swine flu, would you get help *if they developed* any of the following symptoms?	**Yes**	**No**
Fast breathing or feeling much more short of breath than usual	89	5
	(94.7)	(5.3)
Feeling very tired	42	48
	(46.7)	(53.3)
Chest pains	87	8
	(91.6)	(8.4)
Fever (high temperature) that didn't go down after 4 or 5 days	89	6
	(93.4)	(6.6)
Aching muscles	45	49
	(47.9)	(52.1)
Producing more sputum (phlegm/mucus) than usual	74	16
	(82.2)	(17.8)

continued

TABLE 32 *Help-seeking behaviour in response to specific symptoms – family members on behalf of patients (n = 101) (continued)*

If *your family member with chest problems* had swine flu, would you get help *if they developed* any of the following symptoms?	**Yes**	**No**
Worsening of cough or cough that wouldn't go away	87 (93.5)	6 (6.5)
Drowsiness or confusion	68 (75.6)	22 (24.4)
Coughing up blood	86 (92.5)	7 (7.5)
Sputum (phlegm/mucus) turning a different colour than usual	73 (80.2)	18 (19.8)
Sore throat	53 (57.6)	39 (42.4)
Feeling more wheezy than usual	80 (84.2)	15 (15.8)

All items had some missing data; figures in parentheses = valid percentage.

TABLE 33 *Help-seeking – obtaining oseltamivir – patients (n = 253) and family members (n = 101)*

Source/action	**Patients (self) (*n*, %)**	**Family members (self) (*n*, %)**	**Family members (for patient) (*n*, %)**
Go to A&E	8 (3.2)	1 (1.0)	3 (3.0)
Go to GP's surgery	60 (23.7)	15 (14.9)	19 (18.8)
Call GP/health centre	152 (60.1)	58 (57.4)	64 (63.4)
Call a health helpline	62 (24.5)	23 (22.8)	24 (23.8)
Call the National Pandemic Flu Service	62 (24.5)	29 (28.7)	31 (31.7)
Ask a Flu Friend/Flu Buddy	46 (18.2)	21 (20.8)	24 (23.8)
Ask community pharmacist	20 (7.9)	14 (13.9)	12 (11.9)
Look for information on television news programmes	6 (2.4)	3 (3.0)	1 (1.0)
Look for information in newspapers	6 (2.4)	5 (5.0)	2 (2.0)
Listen for information on radio news programmes	10 (4.0)	3 (3.0)	3 (3.0)
Look on news websites	10 (4.0)	6 (5.9)	4 (4.0)
Look on health websites	25 (9.9)	15 (14.9)	8 (7.9)
Look on other websites	2 (0.8)	3 (3.0)	3 (3.0)
Look on unspecified websites	1 (0.4)	0 (0)	1 (1.0)
Contact chest consultant or hospital chest clinic	32 (12.6)	N/A	19 (18.8)
Contact a chest specialist nurse (hospital or community)	15 (5.9)	N/A	6 (5.9)
Already have a supply of oseltamivir	5 (2.0)	2 (2.0)	1 (1.0)
None of these	2 (0.8)	0 (0)	0 (0)
Don't know	12 (4.7)	1 (1.0)	0 (0)
Other	2 (0.8)	1 (1.0)	2 (2.0)

Note: participants could select more than one option.

Influenza A/H1N1v in pregnancy: an investigation of the characteristics and management of affected women and the relationship to pregnancy outcomes for mother and infant

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Abstract

Influenza A/H1N1v in pregnancy: an investigation of the characteristics and management of affected women and the relationship to pregnancy outcomes for mother and infant

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Background: In April 2009 a novel influenza A virus (AHINIv) of swine origin (swine flu) emerged, spreading rapidly and achieving pandemic status in June 2009. Pregnant women were identified as being at high risk of severe influenza-related complications and as a priority group for vaccination against AHINIv. Limited information was available about the maternal and fetal risks of AHINIv infection or of antiviral drug or AHINIv vaccine use in pregnancy.

Objectives: To assess rates of and risk factors for adverse outcomes following AHINIv infection in pregnancy and to assess the adverse effects of the antiviral drugs and vaccines used in prevention and management.

Methods: Prospective national cohort studies were conducted to identify pregnant women who were (1) suspected to be infected with AHINIv or being treated with antiviral medication in primary care; (2) vaccinated against AHINIv; and (3) admitted to hospital with confirmed AHINIv. Characteristics of women with influenza-like illness (ILI) in primary care were compared with those of women without symptoms accepting or declining immunisation. Characteristics of women admitted to hospital with confirmed AHINIv infection in pregnancy were compared with a historical cohort of over 1200 women giving birth in the UK who were uninfected with AHINIv. Outcomes examined in hospitalised women included maternal death, admission to an intensive care unit, perinatal mortality and preterm birth. Risk factors for hospital and intensive care unit admission were examined in a full regression model.

Results: The weekly incidence of ILI among pregnant women averaged 51/100,000 over the study period. Antiviral drugs were offered to 4.8% [95% confidence interval (CI) 4.0% to 5.9%] and vaccination to 64.8% (95% CI 64.7% to 68.9%) of registered pregnant women. Ninety pregnant women with ILI presenting in primary care were reported to the research team, 55 of whom were prescribed antiviral drugs and in 42 (76%) cases this was within 2 days of symptom onset. After comparison with 1329 uninfected pregnant women offered vaccination, pre-existing asthma was the only maternal factor identified as increasing risk of ILI presentation [adjusted odds ratio (OR) 2.0, 95% CI 1.0 to 3.9]. Maternal obesity and smoking during pregnancy were also associated with hospital admission with AHINIv infection. Overall, 241 pregnant women were admitted to hospital with laboratory-confirmed AHINIv infection. Eighty-three per cent of these women were treated with antiviral agents, but only 6% received antiviral treatment before hospital admission. Treatment within 2 days of symptom onset was associated with an 84% reduction in the odds of admission to an intensive therapy unit (OR 0.16, 95% CI 0.08 to 0.34). Women admitted to hospital with

AH1N1v infection were more likely to deliver preterm; a three times increased risk was suggested compared with an uninfected population cohort (OR 3.1, 95% CI 2.1 to 4.5).

Conclusions: Earlier treatment with antiviral agents is associated with improved outcomes for pregnant women and further actions are needed in future pandemics to ensure that antiviral agents and vaccines are provided promptly to pregnant women, particularly in the primary care setting. Further research is needed on longer-term outcomes for infants exposed to AH1N1v influenza, antiviral drugs or vaccines during pregnancy.

Contents

List of abbreviations

AH1N1v	influenza A (H1N1) 2009 virus
aOR	adjusted odds ratio
BMI	body mass index
CDC	Centers for Disease Control and Prevention
CI	confidence interval
CMACE	Centre for Maternal and Child Enquiries
GP	general practitioner
HCP	health-care professional
HPA	Health Protection Agency
ILI	influenza-like illness
IMD	index of multiple deprivation
ITU	intensive therapy unit
MHRA	Medicines and Healthcare products Regulatory Agency
NICE	National Institute for Health and Clinical Excellence
NIHR	National Institute for Health Research
NPIS	National Poisons Information Service
NTD	neural tube defect
OR	odds ratio
PCRN	Primary Care Research Network
RCOG	Royal College of Obstetricians and Gynaecologists
RM&G	research management and governance
UKOSS	UK Obstetric Surveillance System
UKTIS	United Kingdom Teratology Information Service
WHO	World Health Organization

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices, in which case the abbreviation is defined in the figure legend or in the notes at the end of the table.

Executive summary

Background

April 2009 saw the emergence of a novel influenza A virus of swine origin (swine flu), subsequently subtyped (and referred to in this document) as AH1N1v. This spread rapidly, achieving pandemic status in June 2009. Pregnant women were identified as being at high risk of severe influenza-related complications, requiring early assessment and treatment of flu-like symptoms, and as a priority group for vaccination against AH1N1v. There was, however, limited information available about the maternal and fetal risks of AH1N1v infection or of antiviral drug or AH1N1v vaccine use in pregnancy. This study was therefore designed to assess rates of and risk factors for adverse outcomes following AH1N1v infection in pregnancy and to assess the adverse effects of the antiviral drugs and vaccines used in prevention and management.

Objectives

The objectives of this research were to:

1. estimate the incidence of AH1N1v influenza in pregnancy during the 'second wave'
2. determine the effect of AH1N1v infection and/or treatment with neuraminidase antiviral drugs in pregnant women and/or AH1N1v vaccination (timing of use, dose and agent) on pregnancy outcome, including specific adverse or beneficial effects of antiviral treatment or AH1N1v vaccination on eventual maternal and fetal outcome
3. ascertain the influence of demographic or pregnancy characteristics and additional aspects of pregnancy management on outcomes for mother and infant
4. produce guidance on the management of AH1N1v infection in pregnancy: initially following systematic review and updated subsequently by monthly review of emerging data from this study such that outcomes for women and infants could be optimised during the current pandemic.

Methods

Prospective national cohort studies were conducted using different sources to identify women in three specific groups:

1. pregnant women suspected of being infected with AH1N1v or treated with antiviral medication and managed in the community
2. pregnant women vaccinated against AH1N1v
3. pregnant women admitted to hospital with confirmed AH1N1v.

Information about pregnancy management and outcomes was collected directly from health professionals caring for infected women in secondary care settings, and from health professionals as well as women themselves, with consent, where infection was managed in primary care.

Women were identified through the following sources:

1. The UK Teratology Information Service (UKTIS) collected data from general practices within and outside the Primary Care Research Networks (PCRNs), as well as from self-notifications from affected women. Some practices acted as 'sentinel' sites, providing data on all presentations, antiviral prescriptions and vaccinations.
2. The UK Obstetric Surveillance System (UKOSS) collected data through its network of collaborating clinicians in all consultant-led maternity units in the UK.

Characteristics of women with influenza-like illness (ILI) in primary care were compared with those of women without symptoms accepting or declining immunisation. Characteristics of women admitted to hospital with confirmed AH1N1v infection in pregnancy were compared with a historical cohort of over 1200 women giving birth in the UK, identified from the same hospitals as the cohort women and uninfected with AH1N1v.

The incidences of suspected AH1N1v infection, use of antiviral drugs and AH1N1v vaccination were estimated from presentation data provided by sentinel general practices. Characteristics of women with ILI were compared with asymptomatic women who were offered vaccination. Use and timing of antiviral agents and uptake of AH1N1v vaccines were also determined.

The incidence of hospitalisation with confirmed AH1N1v influenza in pregnancy was estimated with 95% confidence intervals (CIs) using the most recently available birth data (2007) as a proxy for September 2009 to January 2010. Outcomes examined in hospitalised women included maternal death, admission to an intensive care unit, perinatal mortality and preterm birth. In addition, risk factors for hospital and intensive care unit admission were examined in a full regression model, which was developed by including both potential explanatory and confounding factors in a core model if there was a pre-existing hypothesis or evidence to suggest that they were causally related to admission with AH1N1v influenza in pregnancy.

Results

The weekly incidence of ILI amongst pregnant women in 24 sentinel practices averaged 51/100,000 over the period of study. In the 23 practices providing these data, antiviral drugs were offered to 4.8% (95% CI 4.0% to 5.9%) and vaccination to 64.8% (95% CI 64.7% to 68.9%) of registered pregnant women.

A total of 90 pregnant women with ILI presenting in primary care were reported to the research team: 55 were prescribed antiviral drugs and in 42 (76%) cases this was within 2 days of symptom onset. After comparison with 1329 uninfected pregnant women who were offered vaccination, the only maternal factor identified as increasing odds of ILI presentation was pre-existing asthma [adjusted odds ratio (aOR) 2.0, 95% CI 1.0 to 3.9]. In this small data set there was no significant effect of other comorbid conditions or of age, racial group, body mass index (BMI), index of multiple deprivation (IMD) or smoking status. The data suggest that vaccination occurred in 56% of pregnant women who were offered it, although information on whether or not vaccination was offered was not always provided.

Overall, 241 pregnant women were admitted to hospital with laboratory-confirmed AH1N1v infection. Eighty-three per cent of women who were hospitalised with AH1N1v influenza were treated with antiviral agents, but only 6% received antiviral treatment before hospital admission.

Women hospitalised with AH1N1v influenza in pregnancy were more likely to be overweight (aOR 1.7, 95% CI 1.2 to 2.4) or obese (aOR 2.0, 95% CI 1.3 to 3.0) than the comparison cohort. They were also more likely to have asthma requiring inhaled or oral steroids (aOR 2.3, 95% CI 1.4 to 3.9), to be multiparous (aOR 1.6, 95% CI 1.1 to 2.2), to have a multiple pregnancy (aOR 5.2, 95% CI 1.9 to 13.8) and to be from a black or other minority ethnic group (aOR 1.6, 95% CI 1.1 to 2.3). Younger smokers had a raised odds of admission with confirmed AH1N1v influenza (aOR 4.2, 95% CI 2.0 to 8.9) when compared with older non-smokers.

Treatment within 2 days of symptom onset was associated with an 84% reduction in the odds of admission to an intensive therapy unit (ITU) (OR 0.16, 95% CI 0.08 to 0.34); women admitted to ITU were more likely to be obese (aOR 3.4, 95% CI 1.2 to 9.2) than women who were not admitted to an ITU.

Sixty-three per cent of hospitalised women had completed their pregnancies at the time of reporting. Women admitted to hospital with AH1N1v infection were more likely to deliver preterm; a conservative estimate accounting for the high proportion of women who are undelivered suggests a three times increased risk compared with an uninfected population cohort (OR 3.1, 95% CI 2.1 to 4.5).

Conclusions

Earlier treatment with antiviral agents is associated with improved outcomes for pregnant women. Further actions are needed in future pandemics to ensure that antiviral agents and vaccines are provided promptly to pregnant women, particularly in the primary care setting.

Maternal obesity during pregnancy is associated with both admission to hospital with confirmed infection and critical illness from AH1N1v infection. This highlights the importance of ongoing work to support obesity prevention at a community level.

Maternal smoking, particularly in younger mothers, is also associated with admission with

AH1N1v infection in pregnancy. Smoking in pregnancy is associated with a number of risks to both mother and fetus and thus prevention programmes continue to be important.

Women with asthma and other comorbidities are more likely to present in primary care or be admitted to hospital with AH1N1v infection in pregnancy. Clinicians should be aware of this association and work to ensure that women with coexisting illnesses in pregnancy are treated appropriately.

Data on outcomes of pregnancy in women admitted to hospital with confirmed AH1N1v influenza are, as yet, incomplete. However, there appears to be a significantly increased risk of preterm delivery, which may impact on service provision in a future pandemic.

Further research is needed on longer-term outcomes for infants exposed to AH1N1v influenza, antiviral drugs or vaccines during pregnancy. This includes studies of the effects of these factors on:

1. fetal development and congenital malformations
2. postnatal development
3. potentially associated conditions, such as childhood leukaemia.

Chapter 1
Background

2009 AH1N1v influenza

April 2009 saw the emergence of a novel influenza A virus of swine origin, subsequently subtyped (and referred to in this report) as AH1N1v. Over the subsequent months, this AH1N1v or swine flu virus spread rapidly among humans, achieving pandemic status on 11 June 2009, as declared by the World Health Organization (WHO). The detection of avian influenza H5N1 in humans less than a year previously had stimulated preparation for a possible influenza pandemic. A document produced in anticipation of such an event by the Centers for Disease Control and Prevention (CDC) in the USA[1] identified pregnant women as being at high risk of severe influenza-related complications. Concerns about the effect of AH1N1v infection in pregnancy were further highlighted following the death of a previously healthy pregnant woman in the USA as the second documented death associated with the 2009 outbreak. In the UK, the Department of Health identified pregnant women as a high-risk group requiring early assessment and treatment of flu-like symptoms at the beginning of the pandemic, and, subsequently, as a priority group for vaccination against AH1N1v.

Influenza in pregnancy

Maternal risks

Reports from previous influenza epidemics, such as the Spanish influenza pandemic of 1918–19, and research on seasonal influenza, have been cited as evidence that pregnant women are at risk of increased maternal mortality and morbidity from influenza infection compared with non-pregnant women.[2]

There are inconsistent data, however, regarding the risk of complications in pregnancy after influenza infection. A hospital database-matched cohort study by Cox *et al.* in the USA[3] identified pregnant women with underlying respiratory conditions as having longer hospital admissions and increased delivery complications during the influenza season than hospitalised pregnant women without comorbid respiratory conditions. An earlier study in the USA by Hartert *et al.*,[4] using a similar design but in which influenza and non-influenza cases were matched for comorbid conditions and trimester of pregnancy, failed to identify a significant difference in mode of delivery, duration of delivery admission, episodes of preterm labour and adverse perinatal outcomes between the two groups. The authors did identify, however, that miscarriages, early neonatal deaths and maternal deaths were not studied, potentially resulting in an underestimate of maternal and perinatal mortality.

Pregnant women, particularly in the third trimester of pregnancy, have been reported as being at a higher risk of developing influenza-associated pneumonia and cardiorespiratory complications.[5,6]

Fetal risks

In addition to the maternal risks, there are concerns about the direct and indirect effects of maternal influenza infection on the fetus. An increased risk of spontaneous abortion[7] and stillbirth[8] have been reported in pregnant women with influenza, and there are inconsistent data to suggest that maternal influenza may be associated with an increased risk of certain congenital malformations, including oesophageal atresia[9] and anophthalmos/microphthalmos.[10] An increased risk of anencephaly was also reported following epidemics of Asian influenza.[11–13]

The Hungarian Case–Control Surveillance of Congenital Abnormalities reported an association between maternal influenza during the second and third month of pregnancy and congenital malformations in the offspring, including cleft lip or palate, neural tube defects (NTDs) and cardiovascular abnormalities.[14] In this study the use of antipyretic drugs reduced the risk of congenital malformations, suggesting that these might be due to fever. Use of folic acid supplements reduced or eliminated the apparent risk associated with influenza during pregnancy.

A further case–control study, involving 363 infants with NTDs and 523 normal newborns, indicated an increased risk of NTDs associated with maternal

influenza. However, in this study, risk was enhanced when antipyretic drugs were used, in contrast with the findings of the Hungarian study described above.[15]

Antiviral therapy during pregnancy

Oseltamivir (Tamiflu®, Roche Products) and zanamivir (Relenza®, GlaxoSmithKline) are neuraminidase inhibitors that are effective in the treatment and prophylaxis of influenza types A and B in adults. AH1N1v has been shown to be susceptible to these agents. These drugs prevent viral release from infected cells and subsequent infection of adjacent cells. The National Institute for Health and Clinical Excellence (NICE) has concluded that both of these agents are clinically effective treatments for influenza in the general population,[16] with no clear distinctions between the two agents on the basis of clinical efficacy, and that both are effective for seasonal or postexposure prophylaxis.[17] Oseltamivir is readily absorbed from the gastrointestinal tract following oral administration, and has significant systemic activity.[18] Zanamivir is administered through inhalation and has lower systemic bioavailability.[19] It may therefore be less suitable for severe systemic illness, but low transplacental bioavailability may reduce risks of adverse fetal effects.

Limited information was available on the safety of neuraminidase inhibitor use during pregnancy prior to the AH1N1v pandemic. A review article cited a total of 61 cases of oseltamivir exposure in pregnancy, collected during postmarketing surveillance.[20] Although complete details of these cases were not provided, the majority of pregnancies were reported to result in a normal baby. Ten abortions (of which six were therapeutic – no further details provided) were reported. There were also single cases of trisomy 21 and anencephaly; in both cases causality was considered as not related to treatment with oseltamivir.

There were no epidemiological studies regarding exposure to zanamivir during human pregnancy. Three pregnancies were reported during preclinical marketing studies carried out by the manufacturer; of these pregnancies, one resulted in the birth of a normal healthy baby, one pregnancy was terminated electively and one resulted in a spontaneous abortion. No other details were available.[21]

Influenza vaccination during pregnancy

Published outcome data on the use of seasonal influenza vaccines during pregnancy have not indicated an association with an increased incidence of congenital malformations.[22–30] However, the majority of reports focused on use during the second and third trimesters of pregnancy, after organogenesis has taken place.

In a prospective cohort study comparing 189 women who were vaccinated with the influenza A vaccine during pregnancy (41 of whom were vaccinated in the first trimester) with a control group of 517 non-vaccinated women, the rate of congenital malformations was within the expected range in both groups.[24] In addition, no increase in perinatal or infant complications was observed following maternal vaccination. A prospective longitudinal, population-based study by the Collaborative Perinatal Project published findings from 650 pregnant women who were given seasonal influenza vaccinations in the first 4 months of pregnancy.[23] After follow-up from birth to 7 years of age, there was no observed increase in risk of stillbirth, congenital malformation, childhood cancer or neurocognitive disability in the offspring.

Other prospectively and retrospectively gathered data have not indicated an increased incidence of adverse pregnancy outcomes in over 4000 pregnant women who received the influenza vaccine during the second or third trimesters of pregnancy.[23–29]

A recent randomised controlled trial found that immunisation of pregnant women against influenza in the third trimester ($n = 172$) reduced the rate of influenza-like illness (ILI) in the mothers and children by 29% and reduced laboratory-proven influenza infections in 0- to 6-month-olds by 63% (95% CI 5% to 85%).[27] The authors did not report any congenital malformations or adverse fetal effects that were attributable to vaccination in the influenza vaccine-exposed infants. The rates of maternal, neonatal and infant mortality were all within the expected ranges.

Review of published and unpublished data from the first AH1N1v influenza wave up to September 2009

Prior to commencing recruitment for this study, a systematic search for information about AH1N1v influenza and its treatment in pregnancy was performed by the research team and has been reported separately.[31] In addition to reviewing data published in the scientific literature, this also considered evidence provided by antiviral manufacturers, teratology information services and drug regulatory bodies. Interpretation of data identified in this systematic review was difficult because important information was often missing or incomplete, and there was overlap of data collected from different sources, the extent of which was uncertain. Pooling of published data from different sources identified reports involving 135 pregnant women with AH1N1v infection.

Mortality

Mortality in this group of 135 women was high, with death occurring in at least 26 of the women involved. However, these reports addressed the characteristics of patients with AH1N1v influenza who were admitted to hospital and/or who died. It is thus likely that this published literature is heavily biased towards reporting of severe or fatal cases. Estimation of mortality from these data is likely to be very misleading.

Comorbidity

Comorbidity was also common amongst these published cases. At least 26 (19.4%) of the 135 pregnant women with swine flu were reported to have coexisting medical conditions. These included asthma, tuberculosis, heart disease, diabetes, hypertension and hyperthyroidism, obesity and Factor V Leiden deficiency. It should be noted that three (50%) out of the six women reported by Jamieson *et al*.[2] to have died had underlying health conditions, as did 8 out of the 16 fatal cases reported by Vaillant *et al*.[32] Although comorbidity is reported in other case series, it is not clear from the data presented whether this correlates with a higher risk of hospital admission or of death. Asthma was the most frequently reported associated chronic illness in these women, in keeping with experience from the study of Hartert *et al*.[4] on seasonal influenza, in which pregnant women with asthma accounted for one-half of all respiratory admissions during influenza seasons.

Trimester of illness

It has been widely quoted that women in the third trimester of pregnancy are at increased risk of hospitalisation due to respiratory illness during the influenza season.[6] With respect to the published literature on the 2009 AH1N1v pandemic, most papers do not report on pregnancy trimester for the women admitted to hospital or who die. Although the numbers are too small to identify a statistically significant difference between hospitalisation rate and case fatality rate by trimester of pregnancy for the cases reported by Jain *et al*.[33] and Jamieson *et al*.,[2] respectively, the absolute number and percentage of women affected in the third trimester is greater than the percentage of women in the first and second trimesters. This may reflect a trend of increased risk to women in the third trimester of pregnancy. It should be emphasised, however, that none of the 16 deaths from AH1N1v infection in pregnancy reported by Vaillant *et al*.[32] was categorised by trimester.

Timing of antiviral treatment

Only two articles provided details of the interval between onset of symptoms and initiation of antiviral treatment.[2,34] Of the 34 women described in the study of Jamieson *et al*.,[2] 17 received treatment with oseltamivir and eight were treated within 2 days of symptom onset. The six women who died received antiviral drugs, a median of 9 days (range 6–15) after symptom onset. No details of antiviral treatment were provided in any of the other studies.

Fetal risks

From the data available thus far, no clear pattern of congenital abnormalities suggestive of teratogenicity due to oseltamivir or zanamivir exposure has emerged. Information on fetal outcome is not available for the majority of AH1N1v infection in pregnancy cases referred to in the published literature, as many of these women were still pregnant at the time of publication. This is in keeping with the lack of outcome data available from the UK and other teratology information services. Interestingly, live born infants were delivered by caesarean section to five of the six fatal cases described by Jamieson

et al.[2] and were doing well with no evidence of influenza infection. The sixth case was associated with a miscarriage at 11 weeks' gestation at the time of maternal death. At the time of writing, it was too early in the pandemic to expect sufficient information regarding congenital malformation rates in babies born to mothers infected with AH1N1v in the first trimester.

Preparation for the AH1N1v (2009) influenza 'second wave'

As the initial peak of the 2009 AH1N1v pandemic subsided in the summer, predictions were made about a second, potentially more virulent, wave of AH1N1v influenza emerging in the autumn of 2009. In anticipation of a second peak, expedited AH1N1v research was identified as a government priority, and the need for evidence-based guidance of the management of AH1N1v (2009) influenza in pregnancy during the second wave was evident. In particular, there was a need to better characterise the adverse maternal and fetal effects of influenza infection involving this new pandemic strain, and to obtain more data on the safety of antiviral therapy during pregnancy. Subsequently, following the licensing of vaccines for AH1N1v, there was a need to collect information on the safety of these vaccines when used in pregnancy.

This study, one of several commissioned by the National Institute for Health Research (NIHR), aimed to collect information on pregnant women during the second wave of the pandemic, with a view to providing interim analyses of the data to inform guidance on the management of AH1N1v infection in pregnancy.

Study objectives

The objectives of this research were to:

1. estimate the incidence of AH1N1v influenza in pregnancy during the second wave
2. determine the effect of AH1N1v influenza infection and/or treatment with neuraminidase antiviral drugs in pregnant women and/or AH1N1v vaccination (timing of use, dose and agent) on pregnancy outcome, including specific adverse or beneficial effects of antiviral treatment or AH1N1v vaccination on eventual maternal and fetal outcome
3. ascertain the influence of demographic or pregnancy characteristics and additional aspects of pregnancy management on outcomes for mother and infant
4. produce guidance on the management of AH1N1v infection in pregnancy: initially following systematic review, updated subsequently by monthly review of emerging data from this study such that outcomes for women and infants could be optimised during the current pandemic.

This report describes study results for the period September 2009 to January 2010, concentrating on clinical outcomes of episodes of influenza in pregnant women. Data collection is continuing and further information on pregnancy and fetal outcomes will be published when this is available.

Chapter 2
Methods

The research described in this report comprises two separate prospective observational cohort studies. In one, information was collected with consent from pregnant women who were recruited in the primary care setting and met the study inclusion criteria. This research was lead by the UK Teratology Information Service (UKTIS). The second study, performed in a secondary care setting, used anonymised data collected by the UK Obstetric Surveillance System (UKOSS) on pregnant women with confirmed influenza who were admitted to hospital. These two studies were intended to provide data on the full spectrum of AH1N1v infection and its management during pregnancy. Information on participants was collected directly from heath professionals caring for these women in secondary care settings, and from health professionals, as well as the women themselves, for women recruited in primary care.

Health professionals were made aware of the study via information on the National Poisons Information Service (NPIS) online database TOXBASE® and websites of the UKTIS, UKOSS, Royal College of Obstetricians and Gynaecologists (RCOG) and Medicines and Healthcare Products Regulatory Agency (MHRA), and via advice provided on AH1N1v influenza by the Health Protection Agency (HPA). Recruitment in primary care was encouraged across the UK and was supported by the Primary Care Research Networks (PCRNs).

Women with suspected AH1N1v infection or antiviral exposure managed in primary care

Case definition

Initially, pregnant women in the UK with confirmed or suspected AH1N1v influenza, or, who were offered antiviral medication for treatment or prophylaxis, were eligible for inclusion in the study. The study protocol was subsequently amended in November 2009 (see details for assessing the full study protocol at the end of the paragraph), following licensing of AH1N1v vaccines, to allow in addition the recruitment of pregnant women offered immunisation against AH1N1v influenza (full study protocol available at www.uktis.org).

Influenza cases were defined as pregnant women with suspected or confirmed AH1N1v influenza. Antiviral exposure cases included women exposed to antiviral medication in pregnancy, either for treatment of suspected swine flu or as prophylaxis. AH1N1v vaccination cases were defined as pregnant women vaccinated with the AH1N1v vaccine. Data were also sought from pregnant women who were offered, but were not subsequently undergoing, vaccination. Data provided in this report include women who had suspected AH1N1v infection or antiviral treatment or were offered immunisation between 7 September 2009 and 29 January 2010.

Data collection

Women presenting in primary care with suspected AH1N1v infection were notified to UKTIS by health professionals when clinical advice was sought from the service, by means of a dedicated UKTIS swine flu reporting line or by reporting form available for download from the UKTIS website. In addition, the MHRA and HPA Regional Microbiology Laboratory Network alerted clinicians to the study when they reported adverse events or sent specimens. Clinicians were then asked to seek consent from patients for their details to be provided to UKTIS. Women were also invited to self-report to UKTIS via the dedicated swine flu reporting telephone line referred to above.

Brief clinical details of women identified by their health professionals or identifying themselves to the research team were collected. Health professionals sought verbal consent from eligible women for the provision of this personally identifiable information to UKTIS, to allow an approach for written consent to participate from the research team.

Potential participants were then sent a participant information sheet and consent documentation, together with an initial data collection sheet that they were asked to complete if they wished to take part. Only women providing written consent were asked to provide further health information.

The reporting health professional was asked to alert the research team should the status of the patient change after initial notification, to avoid the small risk of contacting individuals who might have died or experienced a distressing or adverse pregnancy outcome. In these cases, information was collected from the health professional only when consent to do so had been granted. For cases where women were notified with suspected swine flu, further information on the illness was sought from the participant and health professional 4 weeks after initial contact. Patients who remained unwell from influenza continued to be followed up at 4-weekly intervals until recovery. If the patient had recovered, the next follow-up was planned for approximately 2 weeks after the expected date of delivery, in order to obtain maternal and pregnancy outcome information, again collected from the woman and her health professional. If a completed data collection form was not received back by UKTIS after 3 weeks, a further reminder was sent. Anonymised details of patients declining participation were also notified to UKTIS.

Participants and health professionals were offered the opportunity to report any additional information of relevance to the study (e.g. illnesses, exposures or pregnancy complications) at any point during the study in addition to the planned follow-up intervals.

Virological testing of women with suspected AH1N1v infection

Virological confirmation of infection was not a requirement for participation in the primary care element of the study, but details of those who had not been tested for AH1N1v in a diagnostic setting were forwarded to the HPA North East virology laboratory, with their consent. A self-administered swabbing kit was provided to the participant by post from the UKTIS research team, enclosed with the initial participant information sheet, and consent forms as detailed below. The kit comprised two viral swabs, an instruction leaflet and a prepaid envelope with the necessary transport tubes for return of the sample to the virology laboratory. Given the known difficulties of obtaining informative throat swabs by self-testing, a nasal swab from each nostril was requested. This is thought to achieve an equivalent diagnostic yield. Swabs returned through research testing were processed immediately by the HPA North East virology laboratory to extract and store total nucleic acids and tested for AH1N1v. Testing including extraction, amplification and detection was performed in accordance with the national standard operating procedures for detection of AH1N1v. Samples needing additional testing to clarify status were referred to the HPA Centre for Infections, Colindale, London.

Assessment of incidence in primary care

The incidence of presentation in primary care with ILI and of use of antiviral therapy and vaccination was estimated by collecting all cases from selected general practives agreeing to act as 'sentinel' sites. These practices were asked to submit weekly anonymised data, with null reporting, of all pregnant women consulting with suspected swine flu, prescribed antiviral drugs, offered AH1N1v vaccination and receiving the AH1N1v vaccine over the period of study. Details were also provided of practice list sizes and the numbers of women aged 15–45 years, as well as the numbers of women in the practices who were recorded as being pregnant on 1 December 2009.

Comparison groups

The characteristics of pregnant women with suspected or confirmed AH1N1v influenza were compared with those of pregnant women who did not report influenza-like symptoms and who were not treated with antiviral drugs, but who qualified for inclusion in the study because they were offered vaccination and consented to provide their details to the research team. Information from women receiving AH1N1v vaccination in pregnancy was compared with that collected from participants who were offered vaccination but not vaccinated.

Sample size

The available sample size was dependent on rates of infection, antiviral use or vaccination among pregnant women, the list sizes of participating general practices, the proportion of potential participants who provided consent for data handling and subsequent follow-up, and the UK maternity rate (around 760,000 maternities per year at the outset of the study). With the limited available data from the first wave of AH1N1v influenza and assuming similar rates of presentation, we anticipated identifying 500–1000 affected pregnancies, using the combined UKTIS and UKOSS approach, over the 6-month initial study period.

Statistical analyses

Index of multiple deprivation (IMD) scores were obtained by linking patients' postcodes to small geographical areas referred to as Super Output Areas (SOAs). IMD scores[35] are publicly available continuous measures of compound social and material deprivation, and are calculated using a variety of data including current income, employment, health, education and housing. As the IMD score increases, the level of deprivation increases.

Unadjusted odds ratios (ORs) with 95% confidence intervals (CIs) for women displaying swine flu symptoms compared with women not displaying symptoms nor taking antiviral drugs were estimated for potential risk factors, using unconditional logistic regression and adjusted for putative confounding factors. A full regression model was developed by including both potential explanatory and confounding factors in a core model if there was a pre-existing hypothesis or evidence to suggest that they were causally related to AH1N1v influenza in pregnancy, for example asthma. Potential interactions were tested by the addition of interaction terms between all variables in the model and subsequent likelihood ratio testing on removal. Data for case and comparison women were compared using the chi-squared test – $p < 0.05$ was considered evidence for a significant interaction.

Secondary care hospital admission with confirmed AH1N1v infection in pregnancy

Case definition

Cases were defined as any pregnant women admitted to hospital in the UK with confirmed AH1N1v infection between 1 September 2009 and 31 January 2010. Women with AH1N1v infection in pregnancy who were not admitted to hospital and women with AH1N1v infection diagnosed post partum were excluded from this arm of the study.

Data collection

Cases were identified through the UKOSS network of collaborating clinicians.[36] In view of the need for rapid and ongoing data analysis, clinicians were asked to report, using a web-based rapid reporting system, all pregnant women with confirmed AH1N1v infection who were admitted to their unit, as soon as possible after the woman's admission. In response to a report of a case, clinicians were able to download a data collection form with a unique UKOSS identification number, asking for further detailed information about diagnosis, management and outcomes. If a completed data collection form was not received back by the central team after 3 weeks, a reminder letter was sent. A further reminder was sent 6 weeks after the initial case report, and, if the completed form had not been received after 9 weeks, a further prompt was sent with a new copy of the form to complete.

In addition, every 2 weeks nominated UKOSS reporting clinicians were sent a summary detailing the cases that had been reported from their unit and were asked to confirm that there were no additional cases to report. Clinicians were also asked to return a 'nil report' indicating that there had been no women admitted so that participation could be monitored and the denominator population for the study could be confirmed. The cases included in this report include all data returned up to, and including, 23 February 2010.

All data were double-entered into a customised database. Cases were checked to confirm that they met the case definition and to exclude duplicate reports. Where data were missing or the response invalid, the reporting clinician was contacted by e-mail and asked for the correct information. If the woman was undelivered at the time of discharge following her AH1N1v infection, a further copy of the data collection form was sent to the reporting clinician 2 weeks after the expected date of delivery in order to obtain details of the outcome of pregnancy.

All information collected was anonymous.

Additional case ascertainment

At the end of the data collection period, the Centre for Maternal and Child Enquiries (CMACE) was contacted and provided with information on cases of maternal death in association with AH1N1v infection in pregnancy reported through UKOSS, identifying the hospital and date of death. They were asked to compare the cases they had identified with the cases reported to UKOSS.

Comparison group

Information about comparison women delivering in UK hospitals was obtained from previously collected UKOSS data. The comparison women

were identified by UKOSS reporters as the two women delivering in the same hospital immediately before other UKOSS cases.[37] This cohort was chosen for pragmatic reasons to facilitate rapid comparisons during the epidemic, and, as a historical cohort, to ensure that none of the women could have been infected with AH1N1v.

Statistical analyses

The incidence of hospitalisation with confirmed AH1N1v influenza in pregnancy was estimated with 95% CIs using the most recently available birth data (2007) as a proxy for September 2009 to January 2010.[38]

Data for case and comparison women were compared using the chi-squared test or the Wilcoxon rank-sum test, as appropriate. Figures presented show the percentages of those with data. Unadjusted ORs with 95% CIs were estimated for potential risk and confounding factors using unconditional logistic regression. A full regression model was developed by including both potential explanatory and confounding factors in a core model if there was a pre-existing hypothesis or evidence to suggest that they were causally related to admission with AH1N1v influenza in pregnancy, for example asthma. Continuous variables were tested for departure from linearity, and potential interactions were tested by the addition of interaction terms between all variables in the model and subsequent likelihood ratio testing on removal – $p < 0.05$ was considered evidence for a significant interaction or departure from linearity.

The risk factors for admission to an intensive care unit were examined in a regression model including only women admitted to hospital with confirmed AH1N1v infection. This analysis had 80% power at the 5% level of statistical significance to detect an OR for obesity [body mass index (BMI) of 30 kg/m^2 or greater] in pregnancy of 3.0 or greater.

Interim reporting

During the pandemic, clinical guidance was produced by the Department of Health and RCOG. Rather than issuing potentially confusing additional guidance, the team informed the development of management guidelines through a series of reports to the organisations developing guidance. The data were analysed on an approximately monthly basis from November 2009. Interim reports were produced and made available to the Department of Health, the Influenza Clinical Information Network and the RCOG pandemic influenza working group, as well as to collaborating clinicians, in order to inform development of ongoing clinical guidance during the course of the pandemic. Interim reports were also publicly available on the UKOSS website.[39–41]

Research approvals

This study, and the subsequent protocol amendment allowing the inclusion of pregnant women undergoing vaccination, was approved by the County Durham & Tees Valley 1 Research Ethics Committee (study reference 09/H0905/66). The UKOSS general methodology has previously been approved by the London Research Ethics Committee (study reference 04/MRE02/45).

For the primary care element, research management and governance (RM&G) approval was required from all UK NHS organisations acting as participant identification sites for the original study and, subsequently, for the protocol amendment. This entailed applications to 319 NHS organisations for the original study and 192 organisations for the amendment.

Chapter 3
Results

Women identified in primary care

Incidence of AH1N1v influenza in pregnancy in primary care

Twenty-four general practices, including some linked to the PCRNs in England, Wales, Scotland and Northern Ireland, as well as some non-PCRN practices, provided complete weekly figures to UKTIS, with null reporting, of numbers of pregnant women consulting with suspected swine flu during the study period from 7 September 2009 to 29 January 2010 by the cut-off date of 8 March 2010. These sentinel practices had a combined list size of 216,193 women, including 45,647 who were aged 15–45 and 2431 (1.1%) who were recorded as pregnant as of 1 December 2009. These practices reported 26 consultations involving ILI in pregnant women over the 21 study weeks, giving a mean weekly consultation rate of 51/100,000 amongst pregnant women. As a proportion of all pregnant women, 1.1% (95% CI 0.7% to 1.6%) were reported to have presented with suspected influenza at some point during the study period.

Twenty-three of the practices (combined list size 189,245, with 2061 pregnant women and 40,555 women aged 15–45 years) also provided weekly data on prescribing of antiviral drugs and use of AH1N1v vaccination in pregnant women over the 21-week study period. Antiviral drugs were offered to 100 pregnant women (4.85%, 95% CI 3.98% to 5.89%) and vaccination to 1378 (64.8%, 95% CI 64.7% to 68.9%). Of the pregnant women who were offered vaccination, 520 were reported to have been vaccinated, representing 25.2% (95% CI 23.4% to 27.7%) of all pregnant women and 37.7% (95% CI 35.2% to 40.4%) of those reported to have been offered vaccination.

Recruitment of participants

In total, 159 general practices across the UK forwarded details of at least one pregnant woman who met UKTIS study inclusion criteria and who gave verbal consent for her/their details to be forwarded to the research team. The number of women notified per practice ranged from 1 to 69.

A total of 1587 women were notified to the research team for the period of study. Of these, 1565 were notified with their verbal consent by health professionals and 22 self-reported to the study team. Thirteen notifications from secondary care and 122 retrospective reports (121 health professionals and one self-report) were excluded because pregnancy outcome or an abnormal antenatal result was already known at the time of reporting. There were 1432 health-care reports that met the study inclusion criteria and were included in the current analysis (*Figure 1*).

The health professional reports comprised 90 patients with ILI, 55 of whom were treated with antiviral drugs; 13 patients without symptoms who received antiviral drugs; and 1329 women who were not reported to have influenza symptoms or to have received antiviral therapy but who met the study inclusion criteria because they were pregnant and were offered vaccination.

Of the 13 women reported via secondary care, nine were also included in the UKOSS data set described below, while three cases did not meet the UKOSS inclusion criteria for this study. One case had not been reported to UKOSS, but the information available for this woman was insufficient to determine whether or not she would have met the UKOSS case definition for inclusion in the hospital cohort. None of these women was included in the primary care analysis.

Of the 1565 women consenting verbally to their details being passed to the study team, 234 had provided written consent by the end of the data collection period to allow the study team to collect further information on their pregnancy outcome and infant's health at 6 months. In total, 263 women meeting the study inclusion criteria had completed the initial participant questionnaire; 26 women withdrew from the study during the period of this analysis.

Of the 90 women reported with influenza symptoms, 23 had been tested for AH1N1v at the time of reporting by a health professional. Of these, two swabs were AH1N1v positive, six were

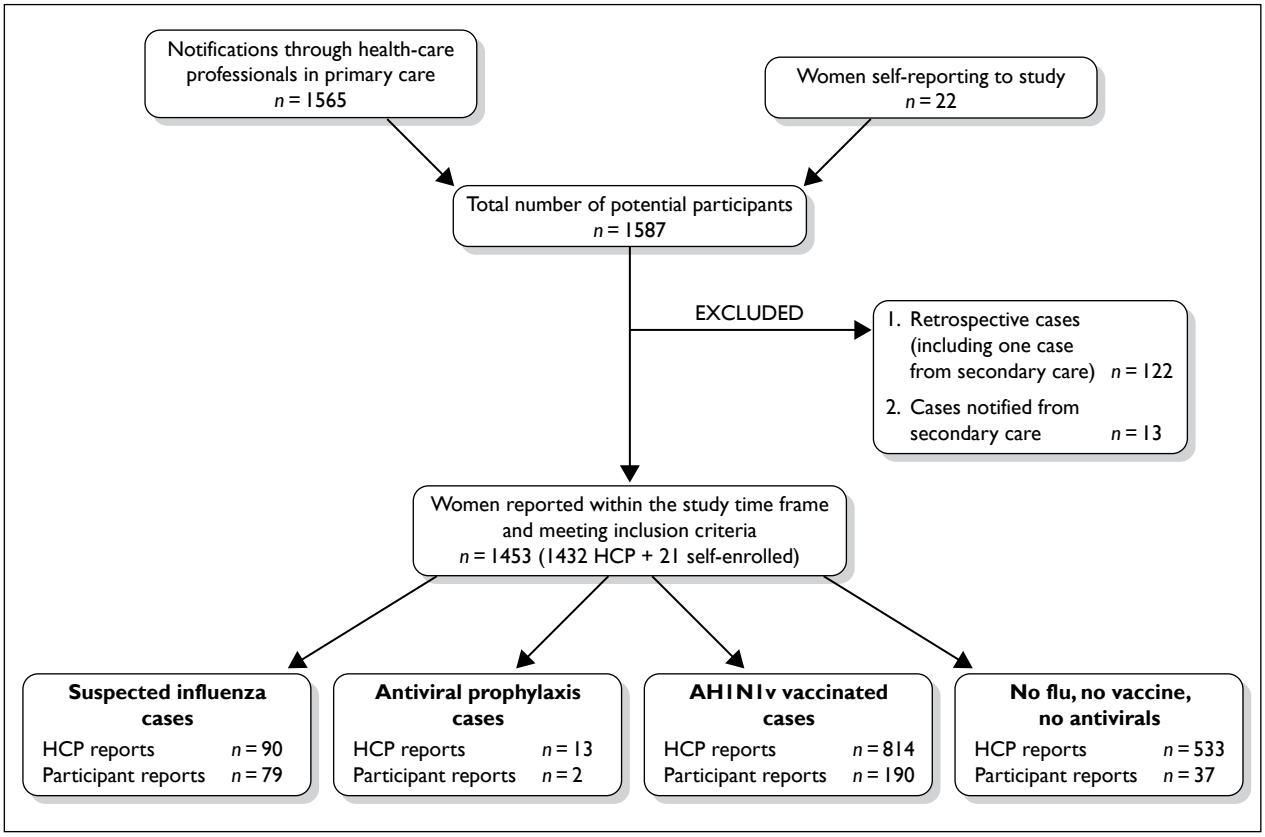

FIGURE 1 *Recruitment in primary care. HCP, health-care professional.*

AH1N1v negative and results were pending for 16 (one women whose initial swab was negative was swabbed again). The study team posted virology swabs to 25 women with suspected AH1N1v influenza or influenza symptoms who had not been tested as part of their routine health care. Of the 25 swabs sent, eight swabs were returned to the virology laboratory: two of these were positive and six were negative for AH1Nv and 17 swabs were not returned. Swabs were not sent to the remaining 42 participants as notification occurred outside the period of illness.

Characteristics of women with ILI

Characteristics of the 90 women reported from primary care with suspected or confirmed AH1N1v infection and those of the comparison cohort are detailed in *Table 1*. Of these, 14 (15.6%) were in their first trimester, 25 (27.8%) in their second trimester and 43 (47.8%) in their third trimester. The trimester was not specified on eight (8.9%) reports.

Factors associated with increased risk of presenting with ILI were assessed by comparing suspected influenza cases with a comparison group of 1329 women without reported symptoms or antiviral treatment offered vaccination. The characteristics of this control group of women are shown in *Table 2*.

The low number of cases limits the power of this analysis to compare the characteristics of pregnant women, described in *Tables 1* and *2*, with an ILI and those who were not ill. Nevertheless, we found a significant association between presentation with an ILI and asthma [adjusted OR (aOR) 2.0, 95% CI 1.0 to 3.9]; there were no statistically significant associations with other comorbid conditions or age (including as a continuous variable), racial group, BMI, IMD score or smoking status (*Table 3*).

Presenting symptoms of pregnant women with an ILI, as reported by their general practitioner (GP) or midwife, are shown in *Table 4*; fever ($n = 64$, 71%), cough ($n = 61$, 68%) and sore throat ($n = 54$, 60%) were the most frequent.

TABLE 1 *Characteristics of women notified with suspected AH1N1v infection in primary care (n = 90)*

			Trimester			
			I	II	III	Unknown
Cases	**All**	**(%)**	**14**	**25**	**43**	**8**
Age						
Unknown	9	(10)	0	5	3	1
< 20	2	(2)	0	2	0	0
20–34	71	(79)	13	16	36	6
≥ 35	8	(9)	1	2	4	1
Ethnicity						
British or white background	48	(53)	6	11	30	1
Black or other ethnic minority	11	(12)	4	0	6	1
Unknown	31	(34)				
Smoking behaviour						
Never smoked	34	(38)	8	7	16	3
Gave up	15	(17)	2	3	10	0
Current smoker	12	(13)	0	2	9	1
Unknown	29	(32)				
Comorbidity						
Asthma	14	(16)	3	3	6	2
Psychiatric illness	3	(3)	0	1	2	0
Diabetes	2	(2)	0	2	0	0
Obesity	4	(4)	1	1	2	0

Note: (a) some women fall into more than one group and (b) reporting forms were not always received from the health-care professional when women self-reported.

The information provided by health professionals indicated that 55 (61%) of women with influenza symptoms were prescribed zanamivir or oseltamivir. In 42 cases (76%) these were prescribed within 2 days of symptom onset (*Table 5*).

Thirty-five (39%) of the symptomatic women did not receive antiviral treatment. In 28 cases reasons were not provided; in the remaining cases reasons were: the antiviral drugs were offered but refused, the GP wanted to see the participant before prescribing treatment, the participant was worried about the effects of the antiviral drugs, symptoms were mild, the symptoms had resolved by the time the participant presented themselves at the surgery, and in two cases participants were prescribed antibiotics instead of antiviral drugs.

The only reported adverse effects attributed to antiviral use were vomiting in one woman taking zanamivir, and nausea and vomiting in one woman who was prescribed oseltamivir.

AH1N1v vaccination in pregnancy

Of the 1432 pregnant women reported to us for this study, 194 (13.5%) were not offered vaccination, often because the report predated availability of the vaccines. A further 406 declined vaccination and 814 women (56.8%) were reported as vaccinated. Other than injection site reactions, health professionals reported adverse effects infrequently (*Table 6*).

Data reported by participants

Data were received directly from 263 participants, 79 of whom had symptoms of ILI. Of these, eight had been tested for AH1N1v, with one positive and one negative result available and the remainder

TABLE 2 *Characteristics of comparison group of women with no influenza symptoms and no antiviral drug exposure (n = 1329)*

			Trimester			
			I	II	III	Unknown
Controls	**All**	**(%)**	**131**	**507**	**576**	**115**
Age						
Unknown	114	(9)	16	40	42	16
< 20	47	(4)	3	21	20	3
20–34	932	(70)	95	340	418	79
≥ 35	236	(18)	17	106	96	17
Ethnicity						
British or white background	743	(56)	78	290	334	41
Black or other ethnic minority	105	(8)	10	43	49	3
Unknown	481	(36)				
Smoking behaviour						
Never smoked	533	(40)	45	209	241	38
Gave up	243	(18)	25	89	119	10
Current	106	(8)	14	39	48	5
Unknown	447	(34)				
Comorbidity						
Asthma	95	(7)	5	36	48	6
Chronic kidney disease	1	(0)	0	1	0	0
Chronic lung disease	1	(0)	0	0	1	0
Chronic liver disease	1	(0)	0	1	0	0
Chronic heart disease	1	(0)	1	0	0	0
Chronic neurological disease	9	(1)	0	4	4	1
Obesity	68	(5)	5	30	33	0
Psychiatric illness	3	(0)	0	0	3	0
Epilepsy	3	(0)	0	2	1	0
Immunosuppression	1	(0)	0	0	1	0
Diabetes	5	(0)	0	2	3	0
Hypertension	4	(0)	0	1	2	1

pending or unreported. The most common reported symptoms were rhinorrhoea ($n = 57$, 72%), sore throat ($n = 56$, 71%), and cough and tiredness (each $n = 57$, 66%). Eighteen women (23%) had been prescribed antiviral drugs, in 16 cases (89%) zanamivir and in two cases (11%) oseltamivir. In five cases (28%) antiviral drugs were prescribed within 2 days of symptom onset. Two women reported adverse effects with zanamivir (nausea, headaches and dizziness, worsening of asthma) and one reported adverse effects with oseltamivir (nausea and nightmares).

Comparison of the characteristics of the 79 women with symptoms with 182 women without symptoms did not identify significant associations with age, BMI, IMD score, black or ethnic minority group, asthma or trimester of pregnancy, although the conclusions that can be drawn are limited by the very small sample size involved.

Of the asymptomatic participants, two had received antiviral drugs and 212 had been offered vaccination. Of the latter group, 190 (89.6%) had been vaccinated. Adverse effects reported by participants being vaccinated included injection site reactions ($n = 97$, 51%), myalgia ($n = 54$, 28%), fever ($n = 25$, 13%), headache ($n = 19$, 10%) and arthralgia ($n = 8$, 4.2%).

TABLE 3 *Analysis of characteristics of women with suspected AH1N1v influenza in pregnancy and comparison women in primary care*

Characteristic	Case frequency (%[a]), *n* = 90	Comparison group frequency (%), *n* = 1329	Analysis			
			Univariate		Multivariate	
			OR [95% CI]	*p*-value	aOR [95% CI]	*p*-value
Age						
< 20	2 (2)	47 (4)	0.6 [0.1 to1.9]	0.05	0.6 [0.1 to 2.1]	0.08[b]
20–34	71 (88)	932 (77)	1[c]		1[c]	
≥ 35	8 (10)	236 (19)	0.4 [0.2 to 0.8]		0.5 [0.2 to 1.0]	
BMI						
Normal	15 (54)	225 (56)	1[c]	0.84	–[d]	
Overweight	9 (32)	109 (27)	1.2 [0.5 to 2.9]			
Obese	4 (14)	67 (17)	1.9 [0.2 to 2.6]			
IMD score						
IMD < 20	50 (61)	844 (67)	1[c]	0.56	1[c]	0.73[b]
IMD 20–40	23 (29)	311 (25)	1.2 [0.7 to 2.0]		1.2 [0.5 to 2.5]	
IMD > 40	8 (10)	97 (8)	1.4 [0.6 to 2.9]		1.2 [0.7 to 2.1]	
Black or other minority ethnic group						
Yes	11 (19)	105 (12)	1.6 [0.8 to3.1]	0.16	–[d]	
No	48 (81)	743 (88)	1[c]			
Current smoking						
Yes	12 (13)	106 (12)	1.8 [0.9 to 3.2]	0.08	1.3 [0.6 to 2.7]	0.33
No	78 (87)	1223 (88)	1[c]			
Asthma						
Yes	14 (16)	95 (7)	2.4 [1.3 to 4.3]	0.005	2.0 [1.0 to 3.9]	0.04
No	76 (84)	1234 (93)	1[c]			
Trimester						
I	14 (17)	131 (11)	2.2 [1.1 to 4.2]	0.07	–[d]	
II	25 (31)	507 (42)	1[c]			
III	43 (52)	576 (47)	1.5 [0.9 to 2.5]			

a Percentage of those with data.
b *p*-value for the total effect of the variable, not the individual categories.
c Reference group.
d Omitted from multivariable model owing to missing data.

Maternal and fetal outcomes

No maternal deaths of pregnant women with suspected swine flu or cases requiring hospitalisation have been reported in the primary care cohort for this study period. However, the amount of follow-up information available from consenting women is currently very limited.

Further follow-up of women included in the study will take place until 6 months after the latest expected dates of delivery and these data, including maternal and fetal outcomes, will be reported when available.

TABLE 4 *Symptoms reported in pregnant women with suspected AH1N1v infection notified to the research team by primary care health professionals (n = 90)*

			Trimester			
			I	II	III	Unknown
Symptom	**All**	**(%)**	**14**	**25**	**43**	**8**
Aching muscles	22	(24)	4	11	3	4
Breathlessness	24	(27)	3	8	12	1
Chills	31	(34)	6	7	16	2
Cough	61	(68)	12	16	27	6
Diarrhoea	13	(14)	0	5	8	0
Fever (> 38°C)	64	(71)	10	16	31	7
Headache	47	(52)	6	16	23	2
Limb or joint pain	30	(33)	6	8	16	0
Loss of appetite	26	(29)	5	6	14	1
Rhinorrhoea	32	(36)	1	13	14	4
Sneezing	12	(13)	0	7	4	1
Sore throat	54	(60)	3	14	31	6
Tiredness	41	(46)	8	10	20	3
Vomiting	23	(26)	6	8	9	0
Other	17	(19)	3	5	9	0

TABLE 5 *Use of antiviral agents in pregnant women with suspected AH1N1v infection in primary care who were notified to the research team (n = 90)*

			Antiviral agents administered for		Trimester			
	All	**%**	**Treatment**	**Not reported**	**Unknown**	**I**	**II**	**III**
Antiviral agents prescribed								
Zanamivir	50	(56)	30	20	2	10	14	24
Oseltamivir	5	(6)	3	2	1	2	0	2
Both	0		0	0	0	0	0	0
None	35	(39)						
Intervals between first symptoms and prescription								
0–2 days	42	(76)	26	16	2	9	11	20
3–5 days	8	(15)	3	5	0	1	2	5
> 5	1	(2)	1	0	1	0	0	0
Unknown	4	(7)	3	1	0	2	1	1

TABLE 6 *AH1N1v vaccination in pregnant women notified to the research team (n = 1432)*

			Trimester			
Study patients	**All**	**%**	**III**	**I**	**II**	**Unknown**
Immunised (n = 1432)						
Yes	814	(57)	369	70	308	67
No	470	(33)	205	63	164	38
Not offered	194	(14)	86	14	77	17
Refused	406	(28)	172	58	142	34
Not known/reported	98	(10)	5	14	66	13
Reported adverse effects (n = 814)						
Headache	15	(2)	4	2	5	4
Arthralgia	6	(1)	2	2	2	0
Myalgia	26	(3)	10	1	12	3
Reaction at injection site	127	(16)	66	8	48	5
Fever	22	(3)	5	3	9	5

Women admitted to secondary care with confirmed AH1N1v infection in pregnancy

Cases reported

Reports were received from 221 of the 223 hospitals with consultant-led maternity units in the UK (99%). Using the most recently available birth data from the Office for National Statistics (2007), there were an estimated 314,135 maternities (women delivering) during the study period. Thirty-five per cent of hospitals returned negative reports, i.e. hospitals indicated that there had not been any pregnant women admitted with confirmed AH1N1v influenza during the study period. Hospitals reporting cases recorded between 1 and 18 cases, with a median of two cases reported per hospital.

A total of 427 cases were reported, with complete data received for 349 cases (82%) (*Figure 2*). Thirty-four cases were subsequently reported by clinicians as not cases and there were 11 duplicate reports. Data collection forms were received for 304 women. A further 63 women were excluded because on further examination they did not meet the case definition: 48 women were not confirmed to have had AH1N1v influenza on testing, seven were never admitted to hospital, seven contracted AH1N1v, or were admitted to hospital, after delivery; for one woman, dates of symptoms and admission were missing and thus we were unable to confirm that she met the case definition. There was thus a total of 241 women admitted to hospital in the UK with confirmed AH1N1v influenza in an estimated 314,135 maternities, representing an estimated incidence of 7.7 hospitalised cases per 10,000 maternities (95% CI 6.7 to 8.7 per 10,000 maternities).

The women who were not confirmed to have AH1N1v infection had a range of final diagnoses: 14 had an unspecified viral respiratory infection, four had a bacterial chest infection, three had a urinary tract infection and seven had a variety of other diagnoses. The final diagnosis was unknown for 20 women.

Figure 3 shows the distribution of cases by week of hospital admission or start of symptoms if the date of admission was unknown. The peak number of admissions occurred in week 42, the week commencing 12 October 2009. The epidemic was largely over by the end of 2009, with only four reported admissions during January 2010.

Characteristics of cases and risk factors

Of the 241 women admitted with confirmed AH1N1v, 15 (6%) were in their first trimester, 32 (13%) were in their second trimester and 193 (80%) were in their third trimester. For one woman, the

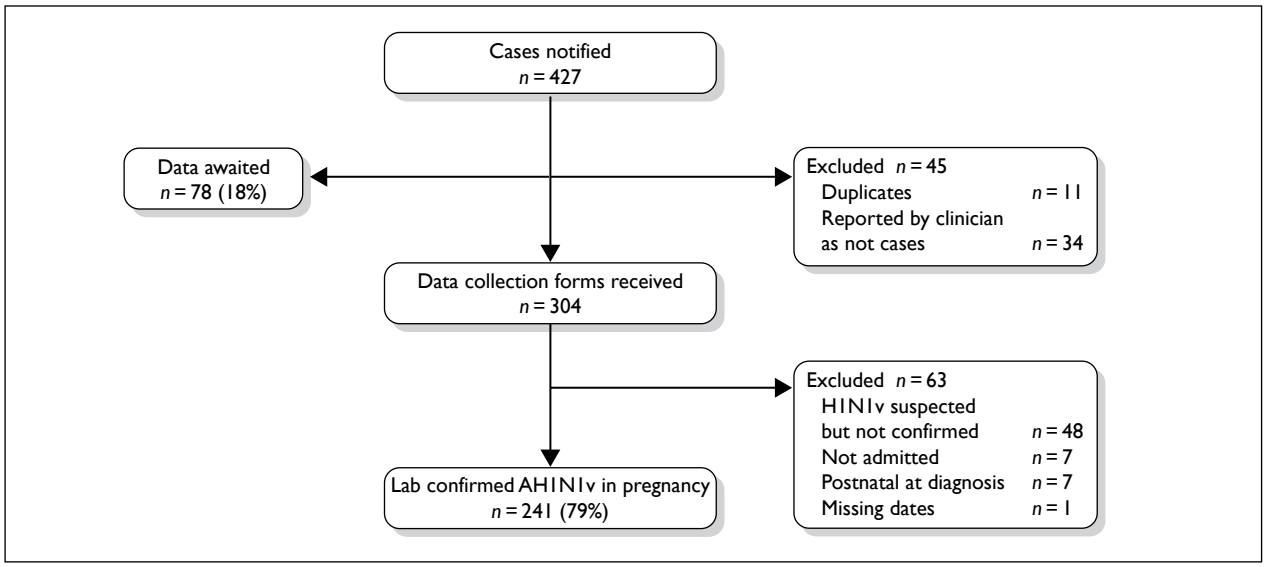

FIGURE 2 *Case reporting and completeness of data collection for women hospitalised with AH1N1v influenza in pregnancy.*

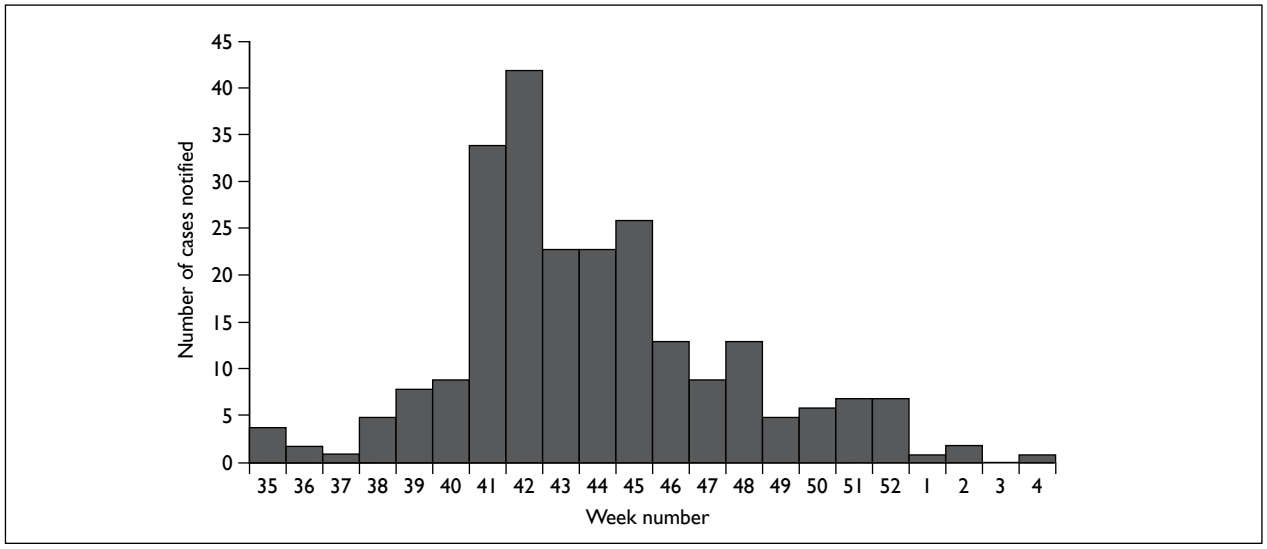

FIGURE 3 *Hospital admissions of pregnant women with AH1N1v by week of hospital admission or start of symptoms (2009–10).*

trimester of admission was unknown. *Table 7* shows the characteristics of women who were admitted with AH1N1v and the comparison cohort. A one unit increase in BMI was associated with a 5% increase in the odds of admission with AH1N1v in pregnancy (95% CI 2% to 8%) after adjusting for potential confounders, thus women admitted with AH1N1v influenza were significantly more likely to be overweight (aOR 1.7, 95% CI 1.2 to 2.4) or obese (aOR 2.0, 95% CI 1.3 to 3.0) than the comparison cohort. They were also more likely to have asthma requiring inhaled or oral steroids (aOR 2.3, 95% CI 1.4 to 3.9), to be multiparous (aOR 1.6, 95% CI 1.1 to 2.2), to have a multiple pregnancy (aOR 5.2, 95% CI 1.9 to 13.8) and to be from a black or other minority ethnic group (aOR 1.6, 95% CI 1.1 to 2.3), although this last association was of borderline statistical significance ($p = 0.03$).

Women hospitalised with AH1N1v influenza in pregnancy were younger than comparison women (unadjusted OR for age less than 20 years = 1.9, 95% CI 1.2 to 3.1; OR associated with a 1-year increase in age OR = 0.94, 95% CI 0.92 to 0.96). After testing for all possible two-way interactions in the adjusted model, there was a statistically significant interaction found between age and smoking ($p = 0.01$, *Table 8*). Amongst non-smokers, a 1-year increase in age was associated with a 6%

TABLE 7 *Characteristics of women hospitalised with AH1N1v influenza in pregnancy and comparison women*

	Characteristic case frequency (%), *n* = 241	Comparison group frequency (%), *n* = 1223	Analysis			
			Univariate		Multivariate	
			OR [95% CI]	*p*-value	OR [95% CI]	*p*-value
Age						
< 20	25 (10)	62 (5)	1.9 [1.2 to 3.1]	< 0.001[a]	–[c]	
20–34	188 (78)	897 (73)	1[b]			
≥ 35	28 (12)	264 (22)	0.5 [0.3 to 0.8]			
BMI						
Normal	84 (40)	563 (53)	1[b]	0.001[a]	1[b]	0.0014[a]
Overweight	70 (33)	306 (29)	1.5 [1.1 to 2.2]		1.7 [1.2 to 2.4]	
Obese	58 (27)	202 (19)	1.9 [1.3 to 2.8]		2.0 [1.3 to 3.0]	
Managerial or professional occupation						
Yes	44 (28)	766 (70)	0.9 [0.6 to 1.3]	0.58	–[d]	
No	112 (72)	334 (30)	1[b]			
Black or other minority ethnic group						
Yes	54 (23)	220 (18)	1.3 [0.9 to 1.8]	0.13	1.6 [1.1 to 2.3]	0.03
No	184 (77)	974 (82)	1[b]		1[b]	
Current smoking						
Yes	55 (23)	258 (22)	1.1 [0.8 to 1.6]	0.53	[c]	
No	180 (77)	940 (78)	1[b]			
Multiparous						
Yes	148 (62)	696 (57)	1.3 [0.9 to 1.7]	0.12	1.6 [1.1 to 2.2]	0.01
No	89 (38)	525 (43)	1[b]		1[b]	
Asthma						
Yes	32 (13)	66 (5)	2.7 [1.7 to 4.2]	< 0.001	2.3 [1.4 to 3.9]	0.001
No	206 (87)	1154 (95)	1[b]		1[b]	
Multiple pregnancy						
Yes	8 (3)	13 (1)	3.3 [1.3 to 8.0]	0.006	5.2 [1.9 to 13.8]	0.001
No	228 (97)	8 (3)	1[b]		1[b]	

a *p*-value for the total effect of the variable, not the individual categories.
b Reference group.
c Entered multivariate model as an interaction term – see *Table 8*.
d Omitted from multivariate model owing to missing data.

decrease in the odds of admission with AH1N1v in pregnancy (95% CI 3% to 9%), among smokers, a 1-year increase in age was associated with a 15% decrease in the odds of admission with AH1N1v in pregnancy (95% CI 8% to 20%). Thus, younger smokers had the highest odds of admission with confirmed AH1N1v influenza (aOR 4.2, 95% CI 2.0 to 8.9) when compared with older non-smokers (*Table 8*).

Women hospitalised with AH1N1v influenza in pregnancy also had a number of other medical problems, although owing to differences in data collection we were unable to compare these formally with the frequency in comparison women in the multivariate model. Forty-two women had other medical problems, but these disorders were very heterogeneous: 10 women had a metabolic disease, 10 women a haematological

TABLE 8 *ORs for admission to hospital with confirmed AH1N1v influenza in pregnancy in different age and smoking groups after adjusting for potential confounders*

Exposure	*n* cases (%)	*n* comparison group (%)	Adjusted OR [95% CI][a]
Age under 20, smoking	13 (6)	25 (2)	4.2 [2.0 to 8.9]
Age under 20, non-smoking	11 (5)	35 (3)	1.8 [0.8 to 4.1]
Age 20 or over, smoking	42 (18)	233 (19)	1.0 [0.7 to 1.5]
Age 20 or over, non-smoking	169 (72)	905 (76)	1[b]

a Adjusted for factors included in multivariate analysis in *Table 7*.
b Reference group.

disorder, five women had chronic lung disease (excluding asthma), four women had cardiac disease, four women had neurological disease, four women had gastrointestinal disease, three women had endocrine disorders, two women had essential hypertension, and nine women had other problems. Seven women had two or more additional medical problems.

Presenting symptoms and prior immunisation

The most frequent presenting symptoms of AH1N1v infection in pregnancy were fever (206 women, 88%) and cough (201 women, 86%) (*Figure 4*). Almost one-half of all women also reported a sore throat, vomiting, headache, lethargy and joint pain. The median number of symptoms experienced was five (interquartile range 3–6). Four women had fever as their sole symptom.

Six women (2%) had been vaccinated before their admission for AH1N1v influenza in pregnancy. These women had been vaccinated a median of 3 days before the onset of symptoms (range 0–9 days) and a median of 7.5 days before the diagnosis of AH1N1v infection was confirmed (range 3–16 days).

Inpatient management

Eighty-three per cent of women hospitalised with AH1N1v were treated with antiviral agents (197 of 237 with known treatment status). The most common first-line antiviral treatment was zanamivir (139 of 196 women where the agent was known, 71%). The route of administration was known for 129 women treated with zanamivir, with 99% (128 women) inhaled (two women, 2% by nebuliser) and 1% (1 woman) intravenous. The remaining 28% of women were given oseltamivir as first line treatment (57 of 196 women), all receiving it orally or by nasogastric tube. Eighteen women who were initially given zanamivir were subsequently switched to oseltamivir. One woman treated initially with oseltamivir was subsequently switched to intravenous zanamivir. Overall, 60% of women received an antiviral agent within the

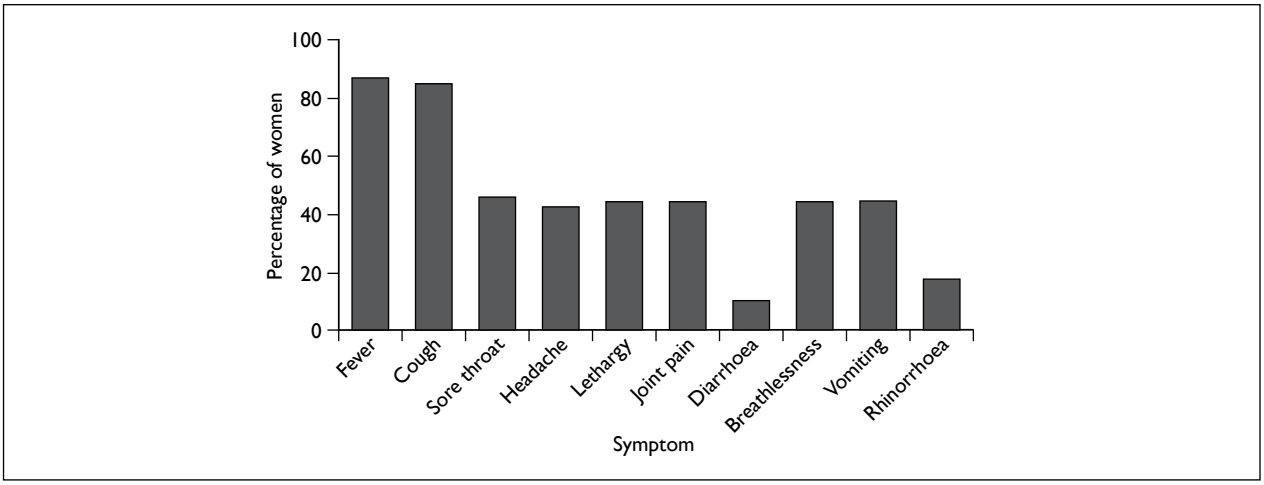

FIGURE 4 *Presenting symptoms of AH1N1v influenza in hospitalised pregnant women.*

recommended 2 days from symptom onset (134 of 224), but only 6% (14 of 224) received antiviral treatment before admission to hospital (a median of 2 days before admission, range 1–5).

In addition, 34 women (14%) were managed with corticosteroids to enhance fetal lung maturation.

Women were admitted for a median of 3 days with 50% of cases in the range 2–6 days. The longest length of stay was 76 days. Twenty-two per cent of women were admitted to an intensive therapy unit (ITU) (51 of 234 women) and eight women (3%) were reported to have received extracorporeal membrane oxygenation. This represents an estimated incidence of 1.6 pregnant women admitted to ITU with confirmed AH1N1v infection per 10,000 maternities (95% CI 1.2 to 2.1 per 10,000 maternities). Forty-four of the women admitted to ITU (86%) were in their third trimester of pregnancy (*Figure 5*). Women admitted to ITU were more likely to report breathlessness as a symptom of AH1N1v infection than those not admitted to ITU ($n = 31$, 62% versus $n = 74$, 41%; $p = 0.01$), but were less likely to report sore throat ($n = 17$, 34% versus $n = 91$, 51%; $p = 0.04$) or joint pain ($n = 14$, 28% versus $n = 89$, 50%; $p = 0.006$). *Table 9* shows the characteristics of women admitted to ITU and those who were admitted to hospital but not to an ITU. Treatment within 2 days of symptom onset was associated with an 84% reduction in the odds of admission to ITU (OR 0.16, 95% CI 0.08 to 0.34); 26% of women (12 of 46) admitted to ITU were treated within 2 days of symptom onset compared with 68% of women who were not admitted to ITU (119 of 174). After adjustment, the only other factor statistically significantly associated with ITU admission was BMI; women admitted to ITU were more likely to be obese (aOR 3.4, 95% CI 1.2 to 9.2) than women not admitted to an ITU; a one-unit increase in BMI was associated with a 9% increase in odds of ITU admission (95% CI 2% to 17%) (*Table 9*).

Maternal outcomes

Four women reported to UKOSS, who met the case definition, died, representing a case fatality of 1.7% of women admitted to hospital with confirmed AH1N1v influenza in pregnancy (95% CI 0.5% to 4.2%). Note that an additional two women who died were reported to UKOSS but did not meet the case definition; one woman did not have virological confirmation of AH1N1v infection and the second had symptom onset after delivery. Maternal deaths were cross-checked with those reported to the Centre for Maternal and Child Enquiries (CMACE); four cases meeting the case criteria had been reported to CMACE. Three of these cases had also been reported to UKOSS; one case was identified uniquely through UKOSS and one uniquely through CMACE, representing a total of five deaths in women hospitalised with confirmed AH1N1v infection in pregnancy in an estimated 314,135 maternities, an estimated 1.6 deaths per 100,000 maternities (95% CI 0.5 to 3.7). Note that this figure does not include deaths in women with a symptom onset in the postpartum period.

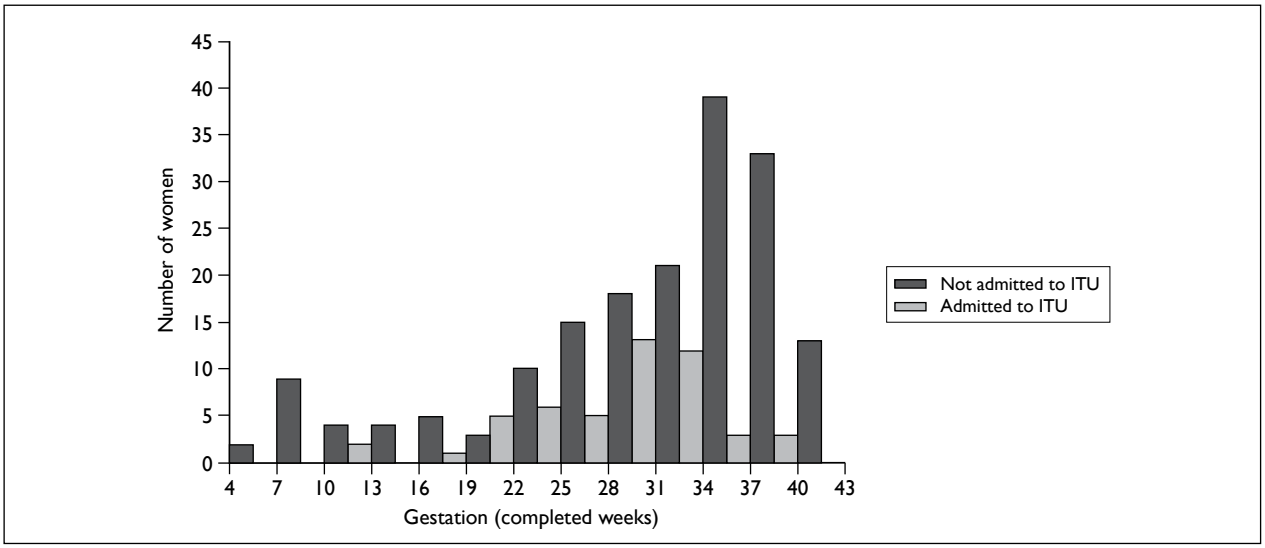

FIGURE 5 *Gestation at admission for pregnant women with confirmed AH1N1v influenza admitted to an ITU and those admitted to hospital but not to an ITU.*

TABLE 9 *Characteristics of women hospitalised with AH1N1v influenza in pregnancy admitted to ITU*

Characteristic	ITU frequency (%), *n* = 51	Non-ITU frequency (%), *n* = 183	Analysis			
			Univariate		Multivariate	
			OR [95% CI]	*p*-value	OR [95% CI]	*p*-value
Age				0.44[a]		0.81[a]
< 20	2 (4)	22 (12)	0.3 [0.1 to 1.3]		0.3 [0.1 to 2.1]	
20–34	44 (86)	139 (76)	1[b]		1[b]	
≥ 35	5 (10)	22 (12)	0.7 [0.3 to 2.0]		0.4 [0.1 to 2.0]	
BMI				0.01[a]		0.008[a]
Normal	11 (25)	71 (44)	1[b]		1[b]	
Overweight	14 (32)	56 (34)	1.6 [0.7 to 3.8]		1.3 [0.5 to 3.5]	
Obese	19 (43)	36 (22)	3.4 [1.5 to 7.9]		3.4 [1.2 to 9.2]	
Managerial or professional occupation						
Yes	9 (29)	35 (28)	1.0 [0.4 to 2.5]	0.95	–[c]	
No	22 (71)	88 (72)	1[b]			
Black or other minority ethnic group						
Yes	7 (14)	47 (26)	0.5 [0.2 to 1.1]	0.08	0.6 [0.2 to 1.8]	0.37
No	43 (86)	134 (74)	1[b]		1[b]	
Current smoking						
Yes	15 (30)	39 (22)	1.5 [0.8 to 3.1]	0.23	2.1 [0.8 to 5.5]	0.14
No	35 (70)	140 (78)	1[b]		1[b]	
Multiparous						
Yes	35 (70)	110 (61)	1.5 [0.8 to 2.9]	0.25	0.8 [0.3 to 1.8]	0.55
No	15 (30)	70 (39)	1[b]		1[b]	
Asthma						
Yes	4 (8)	28 (15)	0.5 [0.2 to 1.4]	0.18	2.2 [0.6 to 9.0]	0.26
No	46 (92)	154 (85)	1[b]		1[b]	
Multiple pregnancy						
Yes	0	8 (4)	–[d]		–[d]	
No	51 (100)	172 (96)				
Treated within 2 days						
Yes	12 (26)	119 (68)	0.2 [0.1 to 0.3]	<0.001	0.1 [0.1 to 0.3]	<0.001
No	34 (74)	55 (32)	1		1	

a *p*-value for the total effect of the variable, not the individual categories.
b Reference group.
c Omitted from multivariate model due to missing data.
d Not calculable due to zero cells.

Pregnancy outcomes

One hundred and fifty-three women (63%) had completed their pregnancy at the time of reporting; the remainder currently have ongoing pregnancies. Among those who have delivered, three pregnancies were miscarried or terminated. There were six stillbirths and 147 live births, representing a perinatal mortality of 39 per 1000 total births (95% CI 15 to 83 per 1000 total births). Forty-five women of the 152 with a known gestation at delivery (30%) delivered preterm at less than 37 weeks' completed gestation, taking into account three women who were admitted after 37 weeks' gestation but for whom we do not have other outcome information. Comparison with the uninfected cohort shows that women admitted to hospital with AH1N1v infection were more likely to deliver preterm (OR 5.5, 95% CI 3.7 to 8.3). Note that, owing due to the large number of ongoing pregnancies, these outcome figures are likely to represent a significant overestimate of the proportion of pregnancies with poor outcomes. If we assume, in order to obtain an estimate not biased by lack of outcome data, that all women who are not yet delivered go on to deliver at term, there is still a significant increase in the odds of preterm delivery associated with admission with AH1N1v infection in pregnancy (OR 3.1, 95% CI 2.1 to 4.5).

These figures are very similar when we consider preterm delivery at less than 32 weeks' completed gestation; 12 women of the 164 with a known gestation at delivery (7%) delivered preterm at less than 32 weeks' completed gestation, taking into account 11 women who were admitted while still pregnant after 32 weeks' gestation, who can be assumed to have delivered after 32 weeks' gestation. Comparison with the uninfected cohort shows that women admitted to hospital with AH1N1v infection are also more likely to deliver very preterm at less than 32 weeks (OR 4.3, 95% CI 2.1 to 8.9). If we assume, in order to obtain an estimate not biased by lack of outcome data, that all women who are not yet delivered go on to deliver at greater than 32 weeks' gestation, there is still a significant increase in the odds of very preterm delivery associated with admission with AH1N1v infection in pregnancy (OR 2.9, 95% CI 1.4 to 6.0).

Chapter 4
Discussion

Management of AH1N1v (2009) influenza in primary care

ILI in primary care

Population data from primary care on the effects of influenza, and, more specifically, AH1N1v (2009) influenza, in pregnancy are lacking. Reports published thus far have focused on cases managed in secondary care and are thus likely to be biased towards the severe end of the spectrum. The primary care element of this study aimed to capture information on the incidence and characteristics of pregnant women with suspected AH1N1v influenza presenting in the community, with a view to identifying factors contributing to adverse maternal and fetal outcomes.

The UKTIS is a service commissioned by the HPA to provide advice on drug and chemical exposures during pregnancy. Details of women on whom we provide advice are held to enable follow-up of pregnancy outcome. During the first wave of the 2009 AH1N1v pandemic we collected details of 259 women with suspected AH1N1v influenza or who had been prescribed antiviral medication during pregnancy as part of our routine surveillance activities. Given these figures, the predicted incidence of AH1N1v infection in the second wave, the adoption of our study as NIHR portfolio research and the support of PCRNs across the UK, we had anticipated that we would recruit around 500 pregnant women with suspected AH1N1v influenza presenting in primary care during this 6-month study period. However, recruitment to the study was significantly less than expected for several reasons. First, the incidence of AH1N1v infection circulating in the community during the study period was not as high as anticipated. Second, fewer GP practices than expected were willing to act as participant identification centres for the study. Concern about high influenza consultation rates and staffing during the pandemic was the most frequently expressed reason for non-participation. Compounding this, data that were provided were often incomplete. Third, while ethical approval was provided within a few days of application, there were delays in obtaining the RM&G approvals required before this expedited research could start locally, especially in some parts of the UK. For individual NHS organisations, intervals to approval ranged from 0 to 141 days, with 55% and 19% providing approval for the original application and amendment, respectively, within 2 days. Fourth, although participants had provided verbal permission for their details to be passed to the research team, the numbers of women eventually providing written consent for active follow-up was lower than anticipated.

The move from laboratory-based AH1N1v diagnosis to the treatment phase of the pandemic on 2 July 2009 meant that virological confirmation of AH1N1v in pregnant women presenting in primary care with ILI was no longer performed as a matter of routine. Although AH1N1v rapidly became the dominant circulating strain in certain regions, this was not true in all regions of the UK. In order to characterise accurately the features of AH1N1v infection in pregnancy in primary care and to compare these with those of seasonal influenza, virological confirmation of influenza cases was sought by the study team. The significant delay in launching this study, as described above, resulted in many cases being reported to the study team several weeks after their acute illness. The situation was further exacerbated by the low return rate of consent for follow-up and of self-swabbing kits by consenting participants (8 out of 25).

Interpretation of the AH1N1v influenza infection data collected in primary care is thus limited by the relatively small sample size ($n = 90$) and low rates of virological confirmation. Nevertheless, the study provides some valuable information about the epidemiology of ILI, although not necessarily AH1N1v influenza, during pregnancy in primary care during the second wave of AH1N1v infection. To put this in context, surveillance data during the same period (weeks 37–53 of 2009) identified that between 15% and 50% of GP consultations for respiratory viral infection in England, and 10% and 34.1% in Scotland, were due to AH1N1v.[42,43]

Data collected from the sentinel sites suggests a mean weekly consultation rate for ILI of 51/100,000 pregnant women over the study period. Although it is not possible to undertake a direct comparison with the non-pregnant female

population, these figures are within the range reported by the RCGP Research & Surveillance Centre[44] for the non-pregnant population over the study period. It should be noted that the National Pandemic Flu Service was in operation throughout the study period. This service, consisting of a website and a network of call centres, was able to assess symptoms and provide antiviral drugs for collection without the need for a GP consultation. Policy, however, was for this service to direct pregnant women to their GP for provision of antiviral therapy, so this was not expected to have a major effect on GP consultation rates for pregnant women.

Comparison of data provided about women presenting with suspected AH1N1v infection with that of pregnant women without features of infection who were being offered vaccination allows assessment of factors that may be associated with infection. The limited numbers of women with suspected infection restrict the power of this comparison. The only factor showing a statistically significant association with an increased risk of AH1N1v influenza in pregnancy in this analysis was maternal asthma. This finding is consistent with reports following the first AH1N1v influenza wave and with data collected in the secondary care arm of this study (see below). Although not statistically significant, our data suggest a similarity in characteristics between women with influenza managed in primary care and the more serious cases requiring hospital admission, with a trend towards women who smoke or who have an IMD score of greater than 20 being at increased risk of influenza when compared with pregnant women who did not report influenza symptoms during the second AH1N1v influenza wave.

Use of antiviral drugs

The proportion of pregnant women with ILI who were prescribed antiviral drugs was 61%, with 76% of these treated within 2 days of symptom onset, when reported by health professionals. In contrast, when reported by participants, 23% were treated with antiviral drugs and only 20% received these within 2 days of symptom onset. The differences may be due to women not taking prescribed antiviral drugs, symptoms being of longer duration than recorded by health professionals or women not seeking antiviral therapy when they develop symptoms. The impact of antiviral therapy on outcomes of influenza during a pandemic would be enhanced by encouraging pregnant women to seek medical advice as soon as possible during their illness and to have facilities for this group to be provided with antiviral drugs at an early stage.

Use of AH1N1v vaccines

The majority of pregnant women were offered vaccination during the study period, with the precise proportion depending on the method of data collection. In the sentinel practices, the data indicate that only 65% of pregnant women were offered vaccination; however, it should be recognised that the vaccines were not available for the initial part of data collection. Much higher proportions were reported by health professionals (86.5%) and by participants (88.5%), although these figures may be inflated by under-reporting of women offered but declining vaccination. Uptake of vaccination was lower, with 37% (sentinel practices), 57% (health professional reports) and 79% (participant reports) of those offered vaccination receiving it. Considering that the vaccines became available only during the study period, the levels of vaccination reported in these cohorts are a considerable achievement by the practices involved. It should be recognised, however, that the UK Chief Medical Officer has reported that as of 3 March 2010 148,000 pregnant women had been vaccinated, which is less than one-quarter of the total.[45] It is important to ensure that all pregnant women without contraindications are offered vaccination and that these women have adequate information available about safety and efficacy of vaccines in pregnancy to make an informed choice.

Pregnancy outcomes

Consenting women will undergo follow-up until 6 months after their expected dates of delivery. Because of the very limited number of women with ILI who have provided consent, it is unlikely that this cohort will provide robust information on adverse maternal effects of influenza in pregnancy or the adverse effects of the use of antiviral drugs. In contrast, the number of women available for follow-up following vaccination is substantially larger, and useful information on the safety of vaccine use in pregnancy will become available in due course. Recruitment into the study is continuing and this will increase the amount of follow-up information eventually available.

Hospitalised women with confirmed AH1N1v influenza in pregnancy

This study has shown that the UKOSS can be used effectively in response to a public health emergency to rapidly collect data on disease incidence, management and outcomes in pregnant women. The UKOSS network of collaborating clinicians is based in all UK hospital consultant-led maternity units, allowing comprehensive surveillance of women admitted to hospital with confirmed AH1N1v influenza in pregnancy. This approach, effectively collecting information on the severe end of the disease spectrum, has been recommended as an appropriate method in the pandemic situation, when surveillance of all cases becomes impractical.[46] The availability of the established UKOSS infrastructure allowed for commencement of surveillance within 4 weeks of the study receiving funding and highlights the importance of maintaining such unique national collaborations, especially in the perinatal field where pregnancy exposures, both infective and pharmaceutical, may have major and long-lasting impacts.

We estimate from this study that eight women were hospitalised with AH1N1v influenza for every 10,000 women delivering in the UK. Other national figures for admission with confirmed AH1N1v influenza in pregnancy have been estimated but use both different numerator and denominator figures. The risk of admission to an ITU with AH1N1v influenza in Australia and New Zealand has been estimated as 1 in 14,600 in women with a gestation of less than 20 weeks and 1 in 2700 for women of 20 weeks' or greater gestation.[47] The authors do not report figures for women hospitalised with AH1N1v influenza in pregnancy. They record 59 women who were pregnant at the time of symptoms of influenza who were subsequently admitted to an ITU during the 3 months of 1 June to 31 August 2009, which we calculate to represent an estimated 6.6 women admitted to ITUs in Australia and New Zealand per 10,000 maternities, based on 2008 birth figures[48,49] (95% CI 5.1 to 8.6). This clearly represents a significantly higher rate of admission to an ITU with confirmed AH1N1v influenza in pregnancy than the 1.6 women per 10,000 maternities we estimate in the UK. These differences may reflect an underascertainment of cases admitted to ITUs in the UK, which we hope to investigate further through collaboration with the Intensive Care National Audit and Research Centre, or it may represent a difference in hospital practice or health-care systems between the three countries, for example in access to health care and hence delay in treatment resulting in greater disease severity. It may also reflect a difference in population characteristics between the countries; for example, indigenous ethnicity was an important factor associated with critical illness due to AH1N1v influenza in pregnancy in Australia and New Zealand, clearly not a factor that would impact on illness in the UK. In addition, the Australian and New Zealand data were collected during the peak 3 months of the first wave of the epidemic, whereas our data were collected over 5 months during the second wave; averaging of admissions over a longer period of time may also lead to an apparently lower admission rate, and also there is a possibility that the properties of the circulating virus may have changed over time.

Comprehensive data have recently been reported from the US state of California,[50] documenting 94 pregnant women who were admitted to hospital with confirmed AH1N1v between 3 April and 5 August 2009, a period with an estimated 188,383 live births. This represents an estimated 5.0 admissions per 10,000 live births (95% CI 4.0 to 6.1). The UK data expressed with the same denominator represent an estimated 7.5 admissions per 10,000 live births (95% CI 6.6 to 8.5).[38] This observed difference is likely to be explained entirely by differential case ascertainment in areas with different epidemic characteristics. Disease incidence is known to vary widely across regions;[51] the US study obtained case reports for pregnant cases from jurisdictions representing only 79% of the population, whereas this UK study covered 98.6% of the population of women giving birth.

The date of the peak of admissions with AH1N1v influenza in pregnancy corresponds directly with the peak of infections reported in the UK by the HPA.[52] Only six women hospitalised with AH1N1v influenza in pregnancy had received specific immunisation against the infection; all of these women were infected well within the 3 weeks following vaccination, which it is suggested is required to achieve 98% seroconversion.[53] Note that the main vaccination programme in the UK was rolled out after the peak of hospital admission in this series and these secondary care data are not therefore useful to assess the efficacy of the vaccine.

Risk factors for hospitalisation with AH1N1v influenza in pregnancy

This study has identified a number of factors associated with admission with confirmed AH1N1v infection in pregnancy. The comparison group we used was a historical cohort of women delivering in UK hospitals, and thus the risks documented may represent a raised risk of infection with AH1N1v or a raised risk of hospitalisation following infection, or a combination of both. In order to obtain estimates of the risk factors associated with hospitalisation, we had planned to compare the hospitalised cohort with a cohort of pregnant women with confirmed AH1N1v infection who were not admitted to hospital. Unfortunately, because of difficulties encountered in collecting information about this community cohort, we have not been able to undertake this comparison. Retrospective case identification of community cases is ongoing, and we may be able to undertake this comparison in the future.

We identified that younger maternal age was associated with an increase in the odds of admission with AH1N1v infection in pregnancy; this is likely to reflect a higher infection rate in this group, as national data on AH1N1v infection has demonstrated higher rates of infection amongst younger (aged 16–24) than older adults (aged 25–44).[54] Similarly, parity as a factor is unlikely to be related to an increased severity of illness, but may be a reflection of an increased infection rate among multiparous women who are more likely to have increased exposure to infection through contact with children than nulliparous women. Children have been shown to have the highest rates of infection with AH1N1v.[54] In contrast, obesity has been noted to be a risk factor for severe illness with AH1N1v in both the pregnant[47] and non-pregnant populations.[55] We found a linear increase in risk of hospital admission with AH1N1v in pregnancy with increasing BMI, as well as a linear increase in the risk of admission to an ITU once hospitalised. This increase in risk of admission may be associated with co-existing medical conditions that are known to be more frequent in the obese population;[56] owing to data collection differences we were not able to account for these in our multivariate model. However, there was no difference in the proportion of women with co-existing medical conditions admitted to ITUs when compared with those admitted to hospital but not to an ITU, thus it would appear that obesity per se may be causally related to disease severity.

In common with other studies,[50] we identified asthma – treated with regular inhaled or oral steroids – as a risk factor for admission to hospital with AH1N1v influenza in pregnancy; the proportion of women with asthma among those admitted with AH1N1v influenza in pregnancy was more than double that in the comparison group. Furthermore, this is likely to be an underestimate of the risk of hospitalisation associated with asthma, as the condition was defined differently in each group; in the AH1N1v group, we collected data on all women with asthma treated with regular inhaled or oral steroids, whereas in the comparison group we had collected data on all women with a diagnosis of asthma irrespective of their current treatment. This will therefore be an overestimate of the proportion of comparison women using regular steroid treatment. It has been suggested in other studies that other co-existing illnesses are also over-represented amongst those admitted with AH1N1v infection, whether pregnant or not.[2,47,50,54,55] Our data support these observations; excluding asthma, 17% of women admitted had other co-existing illnesses.

We observed that admission to hospital with AH1N1v infection in pregnancy in the UK was associated with black or other minority ethnicity, although this was of borderline statistical significance. Indigenous women were over-represented amongst those admitted to ITUs in Australia and New Zealand, and pregnant women admitted with AH1N1v infection in pregnancy in California were more likely to be Hispanic than non-pregnant women with AH1N1v infection.[47,50] Ethnic minority women in the UK have been shown to be at risk of other severe illness in pregnancy,[37] hypothesised to be due to pre-existing medical factors or to differences in access to care. Both of these explanations may account for the observed increase in the risk of admission with AH1N1v in pregnancy. Pre-existing illness has been shown to be associated as noted above; in addition, delayed access to care, and particularly to antiviral treatment, whether through a language or other barrier, may increase the risk of hospitalisation with AH1N1v in pregnancy among ethnic minority women. Similar factors have been linked to a higher attack rate of AH1N1v influenza amongst indigenous populations in general.[57]

Smoking has not been reported in the US and Australasian series as associated with hospitalisation or ITU admission with AH1N1v influenza in pregnancy,[47,50] although it was not specifically

examined as a factor in either of these studies. We noted an interaction between smoking and age, such that younger smokers were over-represented amongst women hospitalised with AH1N1v. Again, it may be hypothesised that this represents an increased risk of infection in association with smoking or an increased risk of hospitalisation, both of which are biologically plausible. Why this effect varies with age is less clear, perhaps the most likely explanation is that the lack of an observed association in older women is a reflection of low study power to detect this, owing to the smaller number of older women admitted. It is also possible that smoking in younger women is associated with other unmeasured risk behaviours and lifestyle factors not seen in older women and is therefore acting as a proxy measure for a different factor.

Four-fifths of women admitted with AH1N1v influenza in pregnancy were in their third trimester of pregnancy. The trimester of pregnancy clearly represents a risk factor for hospital admission with confirmed AH1N1v influenza in pregnancy, as less than one-third of pregnant women at any one time would be expected to be in the third trimester. This may not necessarily reflect an increased risk of disease severity amongst women in the third trimester, but may reflect admission for fetal considerations in association, for example, with an increased risk of preterm labour in conjunction with maternal fever. However, were this the case, we would expect a lower proportion of women who were admitted in their third trimester to be admitted to an ITU than the proportion of women admitted in the first and second trimester. We did not observe this to be the case; the proportions of women admitted in each trimester who were subsequently admitted to ITUs were very similar. We also noted an association between admission with AH1N1v infection and multiple pregnancy, which may also reflect either fetal or maternal considerations. None of the women admitted with AH1N1v who had a multiple pregnancy were subsequently admitted to ITU, which could be interpreted to mean that this association does reflect pregnancy concerns rather than an increased severity of maternal illness, although this observation should be treated with caution due to the small numbers involved.

Factors associated with admission to an ITU

For every one unit increase in BMI, there was a 9% increase in the odds of admission to an ITU with confirmed AH1N1v infection in pregnancy, independent of age, ethnicity, smoking, parity, asthma or early treatment. Obese women are known to be at risk of a number of complications of pregnancy;[56] this study has identified a further risk of both hospital admission and critical illness associated with AH1N1v influenza, highlighting the importance of public health actions to address obesity prevention. Treatment with antiviral agents within 2 days of symptom onset was associated with an 84% decrease in the odds of admission to an ITU; the association between a delay in treatment and severe disease or death in pregnancy has also been suggested by other studies.[2,47,50] This observation is particularly important given our observation that only 60% of women were treated within 2 days of symptom onset, and, perhaps more importantly, only 6% of women had received antiviral treatment prior to hospital admission. This suggests that further actions may be needed in future pandemics to ensure that antiviral agents are provided promptly to pregnant women, particularly in the primary care setting.

In this analysis, obesity and delayed antiviral treatment were the only factors statistically significantly associated with ITU admission. However, even although this is a national study covering more than 300,000 women giving birth, the power of this analysis is limited due to the rarity of ITU admission. A raised odds of both smoking and asthma treated with inhaled or oral steroids was observed amongst women admitted to ITUs; although this was not statistically significant, it is possible that this also represents a clinically important association.

Maternal outcomes

The number of reported deaths in this series is very small and consequently the conclusions that can be drawn are limited. Maternal death with confirmed AH1N1v influenza is clearly rare, and the estimated maternal death rate from confirmed AH1N1v in pregnancy of 1.6 per 100,000 maternities needs to be seen in the context of the most recent estimated all-cause maternal mortality rate in the UK of 14 per 100,000 maternities.[58] The outcomes of infection for most women are good. There were, however, no reported maternal deaths from influenza between 1997 and 2005 in the UK,[58–60] suggesting that pandemic AH1N1v influenza has had a significant impact on maternal death in the UK in comparison with seasonal influenza.

Pregnancy outcomes

Fewer than two-thirds of women hospitalised with AH1N1v influenza in pregnancy between September 2009 and January 2010 in the UK have completed their pregnancies. Pregnancy outcome data are therefore at this point incomplete and it is thus difficult to draw definitive conclusions as the women for whom we have outcome data undoubtedly represent a biased subset. Hence our figure for perinatal mortality is likely to represent an overestimate. Similarly, using current figures, the risk of preterm delivery and very preterm delivery we estimate is high. However, by assuming that all women not yet delivered deliver at term, we can estimate the lowest likely risk of preterm delivery associated with hospitalisation with AH1N1v infection in pregnancy. Using even this conservative estimate suggests at least a threefold increase in risk; the true risk is likely to lie between this figure and the fivefold increase suggested from our current data. The conservative estimate for very preterm birth suggests a similar estimated threefold increase in risk. These estimates show that AH1N1v infection in pregnancy has an important fetal as well as maternal impact.

We have followed up infants only as far as the mother's hospital discharge. Exposures during the perinatal period are known to be associated with both short- and long-term impacts into childhood and beyond. Maternal history of influenza or pneumonia has been associated with the occurrence of childhood leukaemia,[61] and maternal influenza infection has been hypothesised to be associated with schizophrenia in later life, although a recent meta-analysis of data following the 1957 pandemic does not support this hypothesis.[62] As perhaps one of the most comprehensive cohorts of women hospitalised with AH1N1v infection in pregnancy, it is important to consider whether the infants of these women should be followed up over a prolonged period in order to investigate further some of these longer-term impacts.

Comparison of primary and secondary care data

Incidence

By extrapolating from the data obtained from primary care sentinel practices and UK population data,[38] we can estimate that there were approximately 650,000 pregnant women in the UK at the time the study was conducted. Assuming that the pattern of presentation with ILI in pregnant women in these practices was similar to that in the UK as a whole, this suggests that nationally approximately 7000 pregnant women (1.1%) presented with illness. The secondary care data indicate that 241 women were admitted to hospital with confirmed AH1N1v influenza, an estimated 3.5% or 1 in 29 of those presenting to the GP with ILI.

Risk factors

Although the risk factor data are limited by the low number of cases identified from primary care, there are several points worth noting. The only factor noted to be both a risk factor for presentation with ILI in primary care in pregnancy and admission to hospital with confirmed AH1N1v influenza was asthma. This emphasises the importance of influenza vaccination in this subgroup of pregnant women. Given the high proportion of pregnant women reported to have declined immunisation, almost one-third, it is important that these risks are highlighted by clinicians when counselling pregnant women with asthma about influenza vaccination.

Obesity was noted to be a factor significantly associated with both hospital admission with confirmed AH1N1v influenza in pregnancy and with subsequent admission to intensive care. We were, however, unable to investigate this as a factor associated with ILI presenting in primary care due to the large amount of missing data; BMI data were available for fewer than one-third of the women reported. A number of other risks, maternal and fetal, and both short- and long-term, associated with obesity in pregnancy have been reported.[63] Recording of BMI early in pregnancy is important to allow tailored care for women who are at increased risk of pregnancy complications. In many cases, BMI information and other information was not provided. This may be because women were not present with their hand-held notes when reporting forms were completed, but further investigation is needed to assess whether the poor recording of BMI in the reports from primary care reflects that it is not being routinely recorded as part of pregnancy care.

Several elements of this study suggest that inequalities in health, documented across many disease spectra in the UK[64] may also be evident when considering ILI and AH1N1v infection in pregnancy. Although there was no statistically significant association between deprivation and presentation with ILI in pregnancy in primary care, the observed trend towards women who

present with ILI being more likely to come from deprived areas is worthy of further exploration to see whether this is also observed in other population groups with AH1N1v influenza. The observed increased odds of hospitalisation with AH1N1v infection in young pregnant smokers may contribute to an inequality between different socioeconomic groups, as smoking rates and socioeconomic status are known to be associated.[65] Additionally, we observed an association between admission to hospital with confirmed AH1N1v and black or other minority ethnicity, which needs to be further investigated in the context of addressing health inequalities.

Chapter 5

Further and ongoing research

There is a need to obtain better data on longer-term pregnancy outcomes following AH1N1v infection, treatment with antiviral drugs and vaccination. Although limited numbers of women with AH1N1v infection or treated with antiviral drugs were identified in primary care, as of 9 March 2010 the research team has been provided with details of over 1200 women who have undergone vaccination against AH1N1v, and almost 700 women who have declined vaccination. Over 400 of these women have consented to detailed follow-up of pregnancy outcome and this information will be collected over the next few months. Data collection is continuing and the research infrastructure is in place to collect information during a third wave of infection, should that occur.

UKTIS also received notification of over 300 women with suspected AH1N1v infection during the first wave and efforts will be made to obtain pregnancy outcome information for these women as part of the routine surveillance activity of the service.

The remainder of the hospitalised cohort will also be followed up through UKOSS to ensure that we have a complete picture of the pregnancy outcomes for these women.

Chapter 6
Conclusions

The data currently available, including the research reported here, suggest that pregnant women with AH1N1v infection appear to have worse clinical outcomes than the non-pregnant population. This is evidenced by the higher than expected proportion of pregnant women who are admitted to hospital or require admission to an ITU. Interpretation of published data is difficult because there is limited information available on the numbers of pregnant women who have been infected compared with the non-pregnant population, and the likely under-reporting of women who are pregnant and have had favourable outcomes. There is also evidence that AH1N1v infection has been more severe in younger adults than in older people[66,67] and this may also contribute to the apparently higher proportion of pregnant women with adverse outcomes following infection. Risks of adverse outcomes appear to be increased in pregnant women who have comorbidities, especially asthma and obesity.

The evidence from this report, together with other published data, strongly supports early treatment with antiviral drugs for all pregnant women with influenza symptoms, ideally within 48 hours of onset of symptoms, particularly for those in the third trimester of pregnancy and those with comorbidities. There is, however, currently insufficient evidence, either published or unpublished, to justify a change in the current UK recommendations on choice of antiviral drug. There are limited data available on the safety of antiviral medication use in pregnancy; existing data do not provide strong evidence of a teratogenic risk, but further data collection will be important.

The higher rate of adverse clinical outcomes in pregnant women with AH1N1v infection emphasises the importance of vaccination in this group. According to the limited information collected as part of this research, only a minority of women who were pregnant during the study period were vaccinated and more women will have become pregnant since the previous intensive efforts were made to vaccinate pregnant women. In view of the risk of a third wave of infection, efforts should be made to increase the proportion of pregnant women who have been vaccinated.

Chapter 7

Key points

- Earlier treatment with antiviral agents is associated with improved outcomes for women, yet few women were treated with antiviral drugs prior to admission to hospital. Further actions may be needed in future pandemics to ensure that antiviral agents are provided promptly to pregnant women, particularly in the primary care setting.
- Maternal obesity is associated with both admission to hospital with confirmed AH1N1v infection in pregnancy and critical illness from AH1N1v in pregnancy. This highlights the importance of ongoing work to support obesity prevention at a community level.
- Maternal smoking, particularly in younger mothers, is also associated with admission with AH1N1v infection in pregnancy. Smoking in pregnancy is associated with a number of risks to both mother and fetus and thus prevention programmes continue to be important.
- Women with asthma and other comorbidities are more likely to be admitted to hospital with AH1N1v infection in pregnancy. Clinicians should be aware of this association and work to ensure that women with co-existing illnesses in pregnancy are treated appropriately.
- Data on outcomes of pregnancy in women admitted to hospital with confirmed AH1N1v influenza are, as yet, incomplete. However, there appears to be a significantly increased risk of preterm delivery which may impact on service provision in a future pandemic. Further research on longer-term outcomes for infants exposed to AH1N1v influenza in the perinatal period may be warranted.
- AH1N1v vaccination should continue to be offered to pregnant women in light of the probability that AH1N1v will remain the predominant circulating influenza strain in autumn/winter 2010–11.

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Sally Stephens (Assistant Head of Teratology, UKTIS) contributed to the management, data collection and data analysis of the primary care element of the study, and assisted with editing of this part of the report.

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All authors contributed to and approved this report.

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Appendix 1
Study protocol

Study Protocol

Influenza A/H1N1v in pregnancy: An investigation of the characteristics and management of affected women, A/H1N1v vaccination in pregnancy and the relationship to pregnancy outcomes for mother and infant

1 Research Objectives

a) To conduct a systematic review to summarise existing evidence on the effects of influenza and its treatment, demographic and pregnancy characteristics and additional pregnancy management strategies on pregnancy outcomes.

b) To determine:

i) the incidence of influenza A/H1N1v in pregnancy

ii) the effect of H1N1 Influenza infection and/or treatment with neuraminidase antiviral drugs in pregnant women and /or H1N1 vaccination (timing of use, dose and agent) on pregnancy outcome, including specific adverse or beneficial effects of antiviral treatment or H1N1 vaccination on eventual maternal and fetal outcome

iii) the influence of demographic or pregnancy characteristics and additional aspects of pregnancy management on outcomes for mother and infant

c) To produce guidance on the management of H1N1v infection in pregnancy initially following systematic review updated subsequently by monthly review of emerging data from this study such that outcomes for women and infants are optimised during the current pandemic.

2 Existing Research

Influenza infection during pregnancy is associated with adverse maternal and fetal outcomes, including probable increases in the risk of maternal pneumonia and possible increases in risks of certain congenital malformations[1-6]. Recent US H1N1 pandemic experience as well as data from previous influenza pandemics indicates higher morbidity and mortality among pregnant women[7, 8], however, detailed epidemiological studies investigating risks in subgroups of pregnant women and the impact of pregnancy management strategies on outcomes are currently lacking

The neuraminidase inhibitors oseltamivir and zanamivir are effective for prophylaxis and treatment of H1N1 influenza. Neither is licensed for use in pregnancy, but current UK guidance recommends use in pregnancy when indicated. Oseltamivir is an oral treatment *with* limited transplacental bioavailability. Approximately 150 outcomes have been reported following oseltamivir exposure during pregnancy and provide no evidence of specific harms.[9, 10] Because of this, in the USA and Canada, oseltamivir is recommended as first line treatment in women with established H1N1 infection and for prophylaxis. Zanamivir is an inhaled treatment and the amount crossing the placenta is therefore small. For this reason it is preferred in the UK as the first line option in pregnancy, although experience of use in pregnancy is

limited, with only 4 cases published and a further 50 reported to regulatory authorities.[10-12] UK guidance also acknowledges that the benefits of oseltamivir outweigh potential risks during pregnancy.

This inconsistency in guidance between the UK and USA/Canada arises from the paucity of data on the safety of these antiviral drugs during pregnancy, especially relating to zanamivir. The data available are inadequate to exclude a clinically important increase in risk of congenital malformation or neonatal problems. This research is therefore designed to collect further experience of neuraminidase use in human pregnancy on which to base future guidance. The anticipated increase in numbers of cases of H1N1 in the second half of 2009 offers a unique opportunity to collect these data.

H1N1 influenza vaccination

There are currently two vaccines for H1N1 influenza available in the UK; Pandemrix® and Celvapan®. Pandemrix® is adjuvanted with AS03 (squalene, DL α tocopherol, polysorbate 80) and contains thiomersal (a mercury containing compound) as a preservative. Celvapan® is unadjuvanted and does not contain thiomersal. There are no specific safety data on the use of adjuvanted vaccines in pregnancy.

A study from 1973 of over 2000 pregnant women who received influenza vaccine demonstrated no associated adverse fetal effects.[13] There is no evidence of risk from vaccinating pregnant women, or those who are breast-feeding, with inactivated viral or bacterial vaccines or toxoids.[14] Expert scientific advice is clear that thiomersal-containing vaccines do not present a risk to pregnant women or their offspring, however published studies on the use of thiomersal containing vaccines in pregnancy are limited.

The Department of Health, UK has recommended that all pregnant women should be vaccinated as they are at increased risk of complications from swine flu. JCVI recommended that pregnant women should be given Pandemrix since a one-dose schedule with this vaccine appears to generate adequate levels of antibodies and thereby confer more rapid protection than would be afforded by a two-dose schedule. Once again, however, guidance as to which vaccine to recommend in pregnancy differs between countries, highlighting the lack of data regarding efficacy and safety of these vaccines in pregnant women.

2.1 Justification for research proposal

Preliminary data, particularly from the United States and Mexico, suggest that pregnant women are more susceptible to complications of influenza A/H1N1v infection[15, 16], and worldwide data suggest that younger people, including women of reproductive age are at increased risk of infection. This research will identify, through two existing reporting systems, the UK Teratology Information Service (UKTIS) and the UK Obstetric Surveillance System (UKOSS), all pregnant women hospitalised with confirmed influenza A/H1N1v in the UK, as well as pregnant women with the illness or requiring prophylactic antiviral therapy in the community. We will collect information on their demographic and pregnancy

characteristics as well as management, including use, mode and timing of any antiviral therapy. In addition, we will collect data on the incidence of complications of both influenza and pregnancy, and the outcomes for both women and their infants. We will investigate the relationship between demographic, pregnancy characteristics, management and outcomes in order to generate immediate recommendations for changes in practice to improve outcomes for this vulnerable group.

Data on pregnant women exposed to neuraminidase inhibitors is currently being collected by UKTIS as part of a routine surveillance program commissioned by the Health Protection Agency. Voluntary reporting is, however, known to under ascertain cases. Ascertainment of such cases is reliant on ad hoc reporting by busy health professionals who are primarily requesting advice. Studies using these data are therefore subject to case selection bias and are insufficient to enable scientifically valid conclusions to be drawn regarding the effects of H1N1 infection and/or neuraminidase inhibitor treatment in pregnancy on maternal and fetal outcome. At present, follow up of selected cases only is possible.

UKOSS is an existing network of collaborating obstetricians, midwives and obstetric anaesthetists in all 226 hospitals with consultant-led maternity units in the UK, through which selected studies of severe complications of pregnancy can be conducted[17]. The system has been used to conduct a number of studies of severe morbidities, resulting in improvements in the care of pregnant women throughout the UK[18-23]. The current paper-based system, however, does not allow a sufficiently rapid response to collect data for rapid analysis and production of guidance for clinical management of H1N1v infected women in the current pandemic.

We propose to extend these systems to allow rapid web-based reporting and analysis, together with conducting follow-up and testing of women with suspected influenza infection in pregnancy, to allow us to develop guidance on the management of H1N1v infection in pregnancy and hence improve outcomes for women and their infants.

Vaccination of pregnant women may significantly alter the impact of AH1N1v infection during pregnancy for the remainder of this pandemic, and hence our study period. Information about the AH1N1v and seasonal influenza vaccination status of pregnant women is thus paramount to interpreting the data collected on AH1N1v Influenza and antiviral use during this study. Furthermore, GSK and Baxter (manufacturers of the AH1N1v vaccines available in the UK) are under obligation to the EMEA (European Medicines Agency) to collect data on the effects of AH1N1v vaccination in pregnancy and have approached UKTIS to establish a registry of AH1N1v vaccination in pregnancy in order to collect this data. Given that we are already collecting information on swine flu and its treatment

in pregnancy, and that vaccination against swine flu may impact on the findings of our research, extension of the study to include collection of data on AH1N1v vaccination in pregnancy will enhance our study.

3 Methods – Systematic review

3.1 Research question

How is influenza H1N1v managed in pregnancy and what factors influence disease outcome for mother and infant?

3.2 Search strategy

A literature search will be performed to identify reports of influenza infection and/or treatment with the neuraminidase inhibitors oseltamivir or zanamavir during pregnancy using MEDLINE and EMBASE databases, as well as web search engines. Search terms will include pregnancy, influenza, neuraminidase inhibitors, oseltamivir and zanamavir in various permutations. Further data on H1N1 and neuraminidase inhibitor exposure in pregnancy will be ascertained by personal communication with manufacturers and non-UK teratology organisations including the European Network of Teratology Information Services (ENTIS), European Teratology Society (ETS), Organization of Teratology Information Specialists (OTIS, USA), and Motherisk (Canada).

Studies will be included if these include cases or case series of influenza or antiviral exposure in pregnancy and where data on maternal or fetal outcome has been collected prospectively.

3.3 Outputs

Included studies will be reviewed to identify factors influencing the outcomes of H1N1v infection in pregnancy for mother and infant. The results will be used to develop guidance for clinicians to improve the management and outcomes of infected pregnant women.

4 Methods – cohort study

4.1 Research design

This will be a prospective observational cohort study using several different sources to identify women in order to conduct a comprehensive national study. Information about pregnancy management and outcomes will be collected directly from heath professionals caring for infected women in secondary care settings and from health professionals as well as women themselves, with consent, where infection is managed in a primary care setting.

4.2 Identification of infected women

The cohort will be all pregnant women in the UK identified with confirmed or suspected influenza H1N1v , who have been offered treatment with antiviral medication (e.g. as prophylaxis) or who are offered immunisation against AH1N1v. The denominator population will be all women giving birth in the UK. The cohort will be identified through the following sources:

i. The UK Teratology Information Service (UKTIS). Women will be notified by health professionals when clinical advice is sought from the service, by means of a dedicated Swine Flu reporting line (0191 2606197) and also through a reporting form available for download from the UKTIS website (Appendix 1). Women will be asked for verbal consent for their contact details and initial clinical information to be provided to the research team. This information will then be passed to the research team by telephone, secure fax or where neither of these options is possible by post.

ii. Active notification with null reporting to UKTIS by research midwives through the Reproductive Medicine and Childbirth Research Network and a cohort of GP practices that have agreed to undertake pandemic flu research at short notice through the primary care network. It is anticipated that these practices will provide complete case ascertainment for the accurate estimation of incidence in their practice populations.

iii. The HPA Regional Microbiology Laboratory Network will alert clinicians who have sent specimens to the fact that the study is taking place and will ask them to seek consent for patient details to be provided to the research team

iv. Self reporting by patients to UKTIS via a dedicated patient reporting telephone line and a novel secure website that allows women to enter their details directly onto an online form designed to facilitate easy, rapid and accurate input of data into a database, hence reducing research staffing demands.

v. Active negative surveillance through the UKOSS collaboration of over 700 reporting obstetricians, midwives and anaesthetists in all 226 consultant-led maternity units in the UK through a new web-based reporting system.

Health professionals will be made aware of the study through the research networks, via information on the NPIS on-line database TOXBASE® and the UKTIS website and via advice provided on H1N1 influenza by the HPA. Eligible women will be made aware by information in antiviral distribution centres and via the UKTIS website.

4.3 Virological confirmation of H1N1

Details of pregnant women who have not been tested for H1N1v in a diagnostic setting will, with their consent, be forwarded to the HPA virology laboratory North East. Women recruited to the study who have not already had this will undergo H1N1 testing. This will be arranged by provision of a self administered swabbing kit by post from the UKTIS research team. This will be enclosed with the initial participant information sheet and consent forms. The self swabbing kit for H1N1v testing is already validated and is currently used by NHS Direct in conjunction with the HPA Centre for Infections (CFI). The kit comprises of 2 viral swabs, an instruction leaflet for patients explaining how to obtain optimal samples and a prepaid

envelope with the necessary transport tubes for return of the sample to the virology laboratory. This method of approach is important because reliability of identification of influenza viruses from nasal swabs is highest within 3 days of symptoms. Current routine practice in the UK entails collecting both a nasal and nasopharyngeal throat swab to optimise H1N1 diagnosis. Given the known difficulties of obtaining informative throat swabs by self testing, a nasal swab from each nostril will be requested instead. This is thought to achieve an equivalent diagnostic yield. Swabs returned through research testing will be processed immediately by the HPA virology lab in Newcastle to extract and store total nucleic acids. H1N1 testing will then be carried out at a later date in batched runs to minimise staffing and consumable costs. Testing including extraction, amplification and detection will be performed in accordance with the national standard operating procedures (SOP) for detection of H1N1v. Samples needing additional testing to clarify status will be referred to CFI, Colindale London.

It will be made clear to the patient that not all viral samples collected as part of this research will be analysed for H1N1 and that where testing is performed there is no guarantee that these results will be fed back to the patient or their referrer.

4.4 Data collection

1. Women identified by their health professionals or identifying themselves to the research team will be sent the participant information sheet and consent documentation, together with an initial data collection sheet that they are asked to complete if they agree to take part (Appendix 2). The GP/midwife reporting will be asked to alert the research team should the status of the patient change after initial notification, to avoid the small risk of contacting individuals who may have died. Four weeks after initial contact further information is sought from the participant (Appendix 3) and health professional (Appendix 4). If the patient has recovered, the next follow up will be of maternal and pregnancy outcome two weeks after birth, again collected from patient (Appendix 5) and health professional (Appendix 6). The final follow up questionnaire will be to request information on the baby's health at six months of age (Appendix 8). Patients who remain unwell from influenza will be followed up at four weekly intervals (using the forms in Appendices 3 and 4) until recovery and as above, four weeks after the estimated delivery date. The final follow up questionnaire will be to request information on the baby's health at six months of age (Appendix 8).

For practices that are not associated with a research network, the GP or midwife will identify participants and provide follow up information available from the medical records on two occasions (four weeks after the initial illness/exposure and after delivery). Consent and recruitment will be performed by the research team at UKTIS. For patients identified by the Primary Care Research Network or the Reproductive Medicine and Childbirth Research Networks, identification, recruitment, consent and follow-up may be delivered through GPs or research midwives. Anonymised details of patients declining participation will also be notified to UKTIS (Appendix 6) to allow accurate estimation of incidence. The details of research network involvement are currently being finalised.

Patients will be offered the opportunity to report additional illnesses, exposures or complications during their pregnancy at any point as well as at the planned follow up intervals through the a novel web-based reporting system, or by telephone. If a completed data collection form is not received back by UKTIS after three weeks, a further reminder will be sent out.

2. Nominated UKOSS reporting clinicians will be asked to report all pregnant women with confirmed or suspected H1N1v infection admitted to their unit. In view of the need for rapid and ongoing data analysis and production of guidance, we will set up a specific web-based rapid reporting and data collection system for this study to enable UKOSS nominated clinicians to report cases as they occur. In addition, nominated clinicians will be sent a standard UKOSS reporting card each month to further enhance case ascertainment. On receiving a case report, the central team will ask the clinician to complete an electronic data collection form, asking for further detailed information about diagnosis, management and outcomes. Women will be identified using a unique UKOSS number supplied by the central team. If a completed data collection form is not received back by the central team after three weeks, a further reminder will be sent out. If there is still no response after a further three weeks, the clinician will be contacted by telephone.

4.5 Identification of comparison women

Information about comparison women managed in hospitals will be obtained from previously collected UKOSS data. The UKOSS database contains detailed demographic, pregnancy and delivery information about a cohort of over 1200 women giving birth in the UK identified from the same hospitals as cohort women. Comparative information on several thousand women exposed to other medicines during pregnancy is available from the UKTIS pregnancy outcome register.

4.6 Monitoring ascertainment

The Confidential Enquiry into Maternal and Child Health (CEMACH) will be contacted at the end of the study and provided with information on cases of maternal or perinatal death in association with influenza in pregnancy, identifying the hospital and date of death. They will be asked to compare the cases they have identified with cases reported through UKTIS and UKOSS.

Ascertainment in primary care will be studied by comparing recruitment nationally with that achieved by network-associated practices reporting intensively.

4.7 Study Size

The primary objective of this study is to determine the incidence of H1N1v infection in pregnancy. The study size will therefore be dependent on the infection rate among pregnant women, together with the UK maternity rate (currently 760,000 maternities per year). With the limited available data, we anticipate

identifying 500-1000 affected pregnancies during the 6 month initial study period. Information on 1200 comparison women is available from existing UKOSS data. A study of this size will have 80% power at the 5% level to detect a doubling of the risk of any adverse outcome (severe maternal morbidity or mortality, preterm delivery, congenital malformation or perinatal death) in women with influenza or treated for influenza compared with comparison women.

4.8 Statistical Analysis

Incidence rates with 95% confidence intervals will be calculated and outcomes (maternal death, other major complication, preterm birth, congenital anomaly, perinatal death) compared between women with influenza and comparison women. Odds ratios with confidence intervals will be calculated and adjusted for confounders (age, parity, marital status, ethnicity, smoking status, socioeconomic status, previous preterm delivery, previous perinatal death) using logistic regression. In addition, outcomes will be explored in different subgroups according to demographic and pregnancy characteristics, timing, agent and dose of antiviral treatment, the use of additional treatments in pregnancy, timing and mode of delivery.

4.9 Outputs

The study data will be analysed on an ongoing basis in order to update guidance for management of women with H1N1v in pregnancy on a monthly basis.

4.10 Consent

4.10.1 UKTIS/UKOSS data collection from health professionals

All data collection will either involve anonymised information or will be performed with patient consent. In order to describe the incidence of H1N1v in pregnancy, some data must be collected on ALL cases occurring in the populations in which an accurate estimate of incidence is being made. These are (a) hospital inpatients and (b) people with swine flu infection or exposure identified in the community via specific research network practices. It is not practicable to obtain individual patient consent for all patients. Some potential participants will decline to participate, which may lead to a biased estimate of incidence. Therefore there is a need to pass some anonymised information to the research teams without consent.

Recruitment in the community (UKTIS):
For patients identified in the community, verbal consent will be sought by the responsible health professional for the provision of personal identifiable information to UKTIS, to allow an approach for written consent to participation. In practices where incidence is being measured (i.e. Sentinel Practices), anonymised information will be provided about patient characteristics for women who decline to give verbal consent. These practices will be expected to fax a report to UKTIS on a weekly basis, including ‘null

reporting' if no cases have been identified for that week. Subsequently, only women in the community providing written consent will be asked to provide further health information.

UKTIS is permitted to store patient data on the existing database under Section 60 of the Health and Social Care Act 2001 to enable surveillance and follow up of pregnancy outcomes of cases where exposure to a potential teratogen in has been reported. This data is obtained from health care professionals involved in the patient's care. UKTIS does not offer counselling or advice directly to members of the public.

Recruitment in hospitals (UKOSS):
The hospital based component of the research is a non-interventional (descriptive) study only. UKOSS collects only anonymised information and accordingly the central team will not seek to collect any names, addresses, dates of birth, hospital or NHS numbers in order that none of the participants are individually identifiable. Duplicate cases will be identified by comparing a woman's year of birth, reporting hospital and expected date of delivery and follow-up with reporting clinicians. Patients will be managed by their usual clinical team and will receive the usual management for their hospital of delivery. Information will be collected from the clinical team responsible for each patient after the initial diagnosis. The management of each woman participating will not be altered in any way by participation in the study. The anonymised information will be used to calculate incidence rates and identify means to further improve patient care. This UKOSS methodology has received the approval of the London Multi-centre Research Ethics Committee (study reference 04/MRE02/45). The National Information Governance Board (formerly Patient Information advisory Group, PIAG) has judged that collection of information only, for the purpose of studying incidence and identifying means to improve patient care, which is not individually identifiable and does not lead to any change in management for the individual patient is acceptable without requiring individual patient consent[24].

4.10.2 Patient testing and follow-up

Women self reporting or reported through their GPs will be provided with written information about the study, and will be given the opportunity to discuss any concerns they may have or to ask questions about the study. For most participants, these discussions will be by telephone with the research team at UKTIS. In some network-associated practices, informed consent may be obtained directly by local health professionals. Potential participants will be made aware that participation in the study is voluntary, that they may withdraw from the study at any point and that these decisions will not affect their routine clinical care. It will also be made clear at the point of enrolment that 1 in 7 pregnancies miscarry and 2 to 3 out of every 100 children are born with a birth defect, and that the study does not imply that influenza infection and/or antiviral treatment during pregnancy is causative of either of these outcomes.

The GP/midwife will be asked to alert the research team should the status of the patient change after initial notification, to avoid the small risk of contacting individuals who may have died. Similarly, pregnancy outcome will be confirmed through the GP practice or obstetric unit involved before contacting the patient regarding pregnancy outcome.

H1N1 testing will be offered on a research basis to women who have not been tested as part of their routine care. Women will be advised that not all swabs will be analysed, and that the test result will be used for research purposes only, and not to inform individual patient clinical care. There will be no guarantee that the result of these tests is fed back to the participating women or their referrer, or of a timescale within which testing will occur. Consent will be sought to store the sample for future tests to further characterise influenza viruses that may be present.

All advertising of the dedicated participant's telephone line will clearly state that the service is purely to enable women to self-report influenza or antiviral exposure in pregnancy and will not offer a medical assessment or give advice. A pre-recorded message at the start of the call will direct callers who are seeking medical advice to NHS Direct (England and Wales) or NHS 24 (Scotland).

5 Project timetable and milestones

5.1 Timetable

Aug-Sept 2009	Obtain necessary approvals, develop web-based reporting systems
Sept 2009	Systematic Literature Review
Sept 2009 −Jan 2010	Data collection.
Oct 2009−Feb 2010	Ongoing data analysis, production of management guidance and dissemination.
Nov 2009	Commence data collection on AH1N1v vaccination
Jan-Feb 2010	Report– outcomes of H1N1v infection in pregnancy
April 2010 – Feb 2011	Ongoing data collection on infant outcome at six months
Feb – April 2011	Data analysis and report of outcomes for A H1N1v vaccination in pregnancy

5.2 Milestones

Sept 2009	Approvals completed, data collection commenced
Oct 2009	Systematic Review completed, first guidance for clinicians
Nov 2009	First data analysis, revised guidance issued
Dec 2009	Ongoing data analysis, revised guidance issued
Feb 2010	Final report and guidance: Management and outcomes of H1N1v infection in pregnancy

6 Expertise

The research team has the necessary expertise to carry out this comprehensive national study, including clinical pharmacology and pharmacoepidemiology (SHLT), teratology (SHLT, LY, SS), public health (ELF, MK, JK), systematic reviewing (MK, JK, PB), congenital malformations (JK) perinatal epidemiology and statistics (MK, JK, PB), obstetric surveillance (MK), guideline development (JK, PB) and obstetrics (PB).

UKTIS is experienced in this type of research; it is actively providing information on antiviral use during the current H1N1 pandemic and has drafted national guidance for management of H1N1 infection or exposure during pregnancy. This guidance already prompts health professionals to report affected pregnancies to UKTIS. The infrastructure is thus already in place for recording pregnancy details and fetal outcomes collected by letter or telephone, as are the necessary ethical approvals for the relevant databases and current methods of data collection.

The National Perinatal Epidemiology Unit (NPEU) has a national and international reputation for conducting studies which change policy, influence practice and improve the care of women and their babies. MK developed and launched UKOSS and led the initiative from its inception; since its establishment in 2005, UKOSS has generated evidence to improve prevention and management of a range of severe pregnancy complications in the UK involving a network of over 700 collaborating clinicians at 226 hospitals throughout the UK. The infrastructure is thus in place to allow rapid identification of women hospitalized with H1N1 infection in pregnancy through an established active surveillance system.

In addition the project benefits from a wide range of collaborations. The study will be co-adopted by the Reproductive Health and Childbirth Network and the Primary Care Research Network. It has been discussed with both National leads of the Reproductive Health and Childbirth Network (Prof Steve Robson and Prof Steve Thornton) and Prof Wallace of the Primary Care Research Network. Each network will be involved in recruitment, and the subsequent consent and follow up of any patients accrued within the respective network. Collaboration with the HPA Virology Laboratory North East (Prof John McGee, Dr Manoj Valappil, Dr Andrew Sails) to undertake H1N1 testing on a research basis, provide expert virological opinion and act as lead laboratory of the HPA Regional Microbiology Laboratory Network (RMN) on this study has been agreed. The feasibility of a postal self testing system for H1N1 has been fully considered and discussed with the HPA laboratory in Colindale who are currently operating such a system for community influenza surveillance and who have agreed to share their expertise in this area. Links with the RMN will also ensure that any H1N1 positive samples are forwarded to Colindale for further analysis according to current surveillance practice, and that swabs for which an equivocal result is

obtained are also tested by one of the other HPA laboratories in order to ensure an accurate result and continue monitoring of possible viral mutation.

Dr Phillip Bryan of the Medicines and Healthcare Regulatory Agency (MRHA) will provide expertise on interpreting adverse reactions reported during this study, and assist with supplying information on adverse reactions associated with neuraminidase exposure in pregnancy reported via the MRHA.

Collaboration with non-UK Teratology organisations including the European Network of Teratology Information Services (ENTIS), European Teratology Society (ETS), Organization of Teratology Information Specialists (OTIS, USA), and Motherisk (Canada) will be formalised if the study is funded with a view to producing a meta analysis of the data collected by each of these centres.

Lastly, access to information on background congenital abnormality rates for the period of this study will be obtained from the British Isles Network of Congenital Anomalies Registers (BINOCAR) in collaboration with Dr Judith Rankin who also has extensive expertise in maternal and perinatal health.

We informed the manufacturers of both Oseltamivir (Roche) and Zanamivir (GSK) of our proposed study and are keen to work effectively with them on this project.

7 Service users

Within the timescale of the current pandemic, extensive consultation with service users has not been possible during the development of the project protocol. The planned project has been discussed with the NPEU advisory group, which includes both lay and professional representatives, and, if funded, lay representatives from UKOSS and UKTIS Steering Groups will be consulted about the development and acceptability of information and other materials.

8 Justification of support requested

The additional resource specified from the University of Newcastle is being sought for (a) additional information scientist/nursing staff for systematic review and to allow the logging and processing of data (1 wte, 6 months, £24k) (b) the development of a website to allow patients to enter and edit their own data directly (£14k), (c) funds to cover travel and administrative costs for collaborative work with other European Centres (£5k) and (d) Further publicity of the study with relevant health professionals (£5k) (e) statistical analysis costs (£5k). Note costs are approximate and include overheads.

At the time of submission of our expression of interest, H1N1 testing had been routinely carried out on all patients with suspected swine flu. As a result of the subsequent move from the containment to treatment phase by the Department of Health, diagnosis of H1N1 influenza is being made on clinical grounds. With the approach of autumn, it will become increasingly difficult to accurately differentiate between cases of

H1N1 and seasonal flu using clinical markers only. A further £30k is therefore being sought for H1N1 testing on a research basis.

Costs from the University of Oxford are sought to cover administration of UKOSS data collection (£4.5k), programming and database management (£3.5k) and website design (£3k). In addition, funds are sought to cover the data analysis and clinical guidance development and review (£15k) together with printing and mailing of monthly cards and data collection forms, telephone and stationery costs (£2k). Estates and indirect costs are sought at the standard University rate.

Please note that this proposal is the result of a collaboration formed after each organisation had submitted separate expressions of interest for the call for research, both of which were shortlisted for submission as full proposals. The costs included therefore reflect the combined costs of the two projects, and therefore show an increase over the amounts in both the individual expressions of interest (submitted by Prof Thomas and Dr Knight), although we have been able to make cost savings by combining the projects as well as enhancing the scope of the proposed research.

NHS Service support costs are requested to cover clinician time completing the data collection forms, providing women with study information and obtaining consent to participate.

No additional funding for the protocol amendments is being sought from the NIHR. GlaxoSmithKline (GSK) and Baxter have agreed to provide resources for the AH1N1v vaccination arm of the study via the Newcastle Hospitals NHS Foundation Trust. This additional funding will be used to employ an additional information scientist for processing of data and producing reports; a study administrator; funds to cover postage, administrative costs, further advertising of the study and stationary; statistical analysis costs and funding to update the database with the additional data fields and to produce six month infant follow-up forms.

The CLRN have agreed to provide the required NHS Service Support costs for the requested protocol amendment.

9 Research Ethics Committee Approval

The original proposal was given favourable opinion by the County Durham and Tees Valley 1 Research Ethics Committee.

The protocol amendment relating to AH1N1v vaccination in pregnancy has been submitted for ethical review.

10 Project Management

The overall conduct of the study will be monitored by a Management Group consisting of the Co-Applicants, Information Scientist, Researcher, Project Programmer, Statistician and other external members as considered necessary for the project.

11 Research Governance

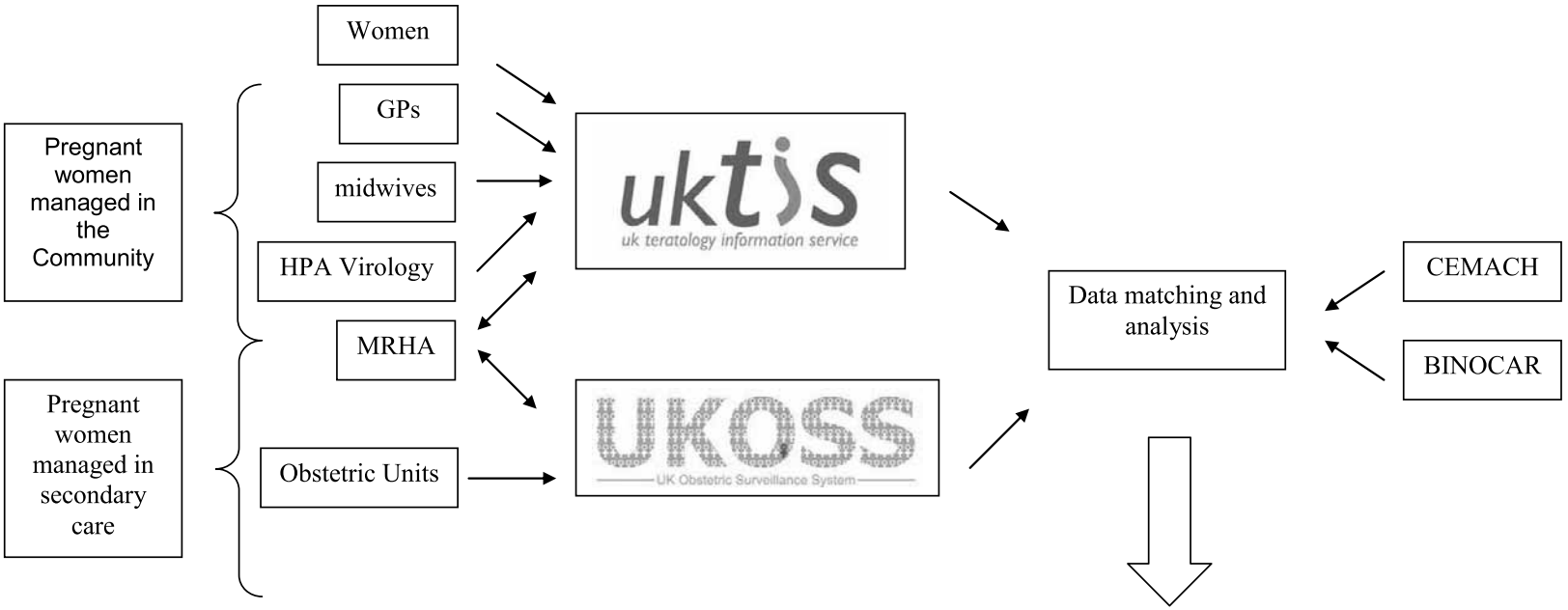
The Newcastle Upon Tyne Hospitals NHS Trust has agreed to sponsor the study.

12 Dissemination and publication

It will be important to feedback the outcomes of the study to the clinicians who participated in providing information. This will be done through monthly guidance for management and a final report. The results will also be reported to the Scientific Advisory Committee of the RCOG, the Royal College of Midwives, the Royal College of General Practitioners and the Obstetric Anaesthetists Association. In the academic arena, the findings will be presented at specialist conferences, such as the British Maternal and Fetal Medicine Society and the Annual Conference of the Faculty of Public Health. The findings of this study will also be submitted for publication in peer-reviewed journals such as the British Journal of Obstetrics and Gynaecology. The NPEU reports directly to the UK Department of Health and has a distinguished record for influencing health policy both in the UK and worldwide.

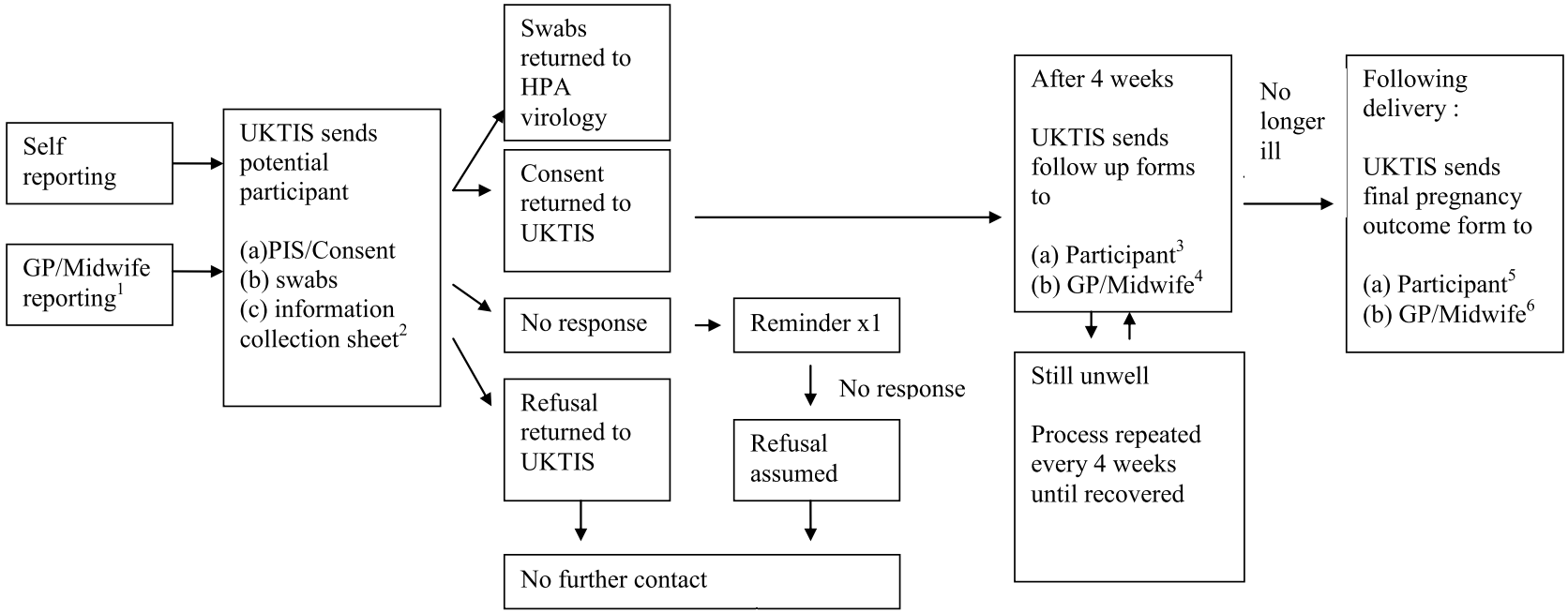
13 Flow Diagrams

(a) Overall study structure



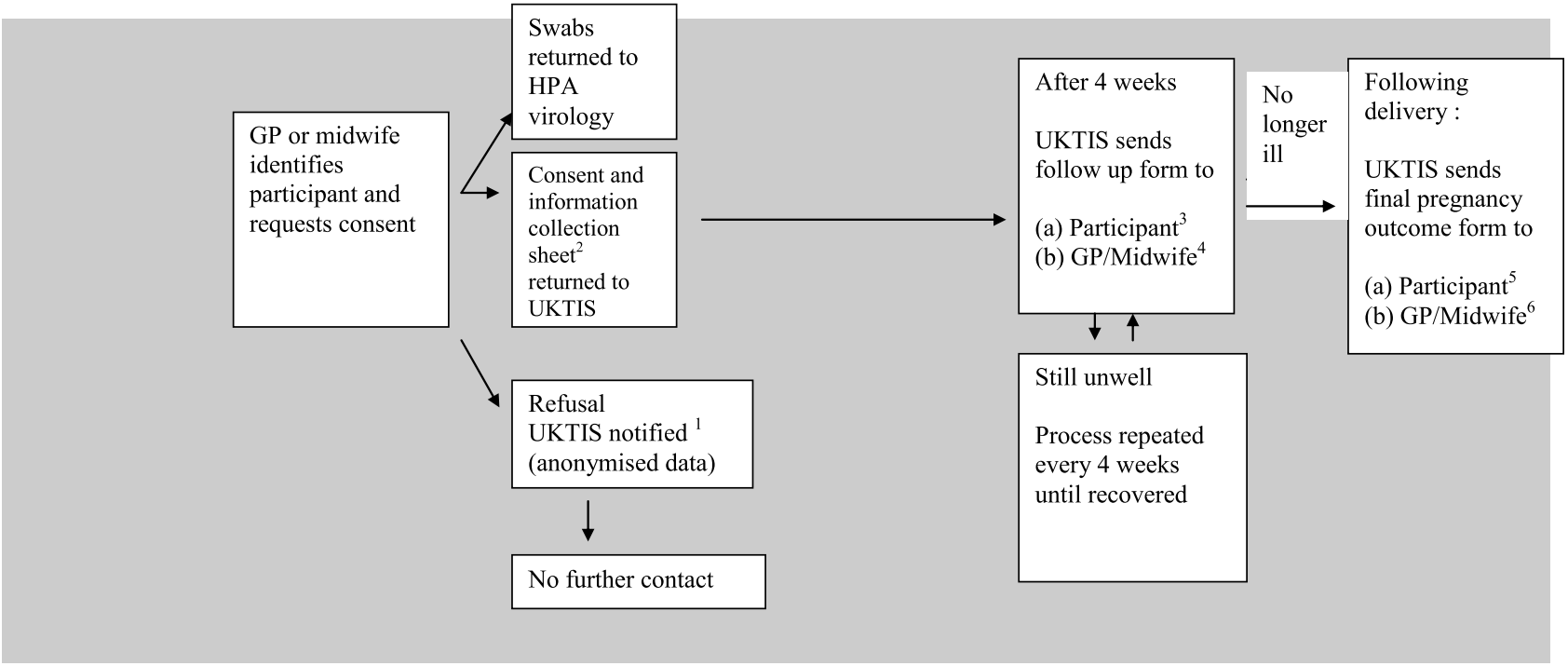
- **Oct 09 – Dec 09 Monthly review of emerging data to produce guidance on H1N1 management in pregnancy**
- **Feb 2010: Final report and guidance: Management and outcomes of H1N1v infection in pregnancy**

(b) Non-network recruiting in primary care



[1] Notification made using "UTKIS Antiviral Exposure in Pregnancy – Patient Reporting Form" (Appendix 1), [2] Initial information collection sheet - participant[Appendix 2], [3]Four week update form – participant [Appendix 3], [4] Four week update form – health professional [Appendix 4], [5] Final pregnancy outcome form – participant [Appendix 5], [6]Final pregnancy outcome form – health professional [Appendix 6]

(c) Network recruiting in primary care (provisional)



[1] Declined consent form (Appendix 7), [2] Initial information collection sheet [Appendix 2], [3]Four week update form – participant [Appendix 3], [4] Four week update form – health professional [Appendix 4], [4] Final pregnancy outcome form – participant [Appendix 5], [5] Final outcome form – health professional [Appendix 6]

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The impact of communications about swine flu (influenza A H1N1v) on public responses to the outbreak: results from 36 national telephone surveys in the UK

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Abstract

The impact of communications about swine flu (influenza A H1N1v) on public responses to the outbreak: results from 36 national telephone surveys in the UK

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Objectives: To assess the association between levels of worry about the possibility of catching swine flu and the volume of media reporting about it; the role of psychological factors in predicting likely uptake of the swine flu vaccine; and the role of media coverage and advertising in predicting other swine flu-related behaviours.

Design: Data from a series of random-digit-dial telephone surveys were analysed. A time series analysis tested the association between levels of worry and the volume of media reporting on the start day of each survey. Cross-sectional regression analyses assessed the relationships between likely vaccine uptake or behaviour and predictor variables.

Setting: Thirty-six surveys were run at, on average, weekly intervals across the UK between 1 May 2009 and 10 January 2010. Five surveys (run between 14 August and 13 September) were used to assess likely vaccine uptake. Five surveys (1–17 May) provided data relating to other behaviours.

Participants: Between 1047 and 1173 people aged 16 years or over took part in each survey: 5175 participants provided data about their likely uptake of the swine flu vaccine; 5419 participants provided data relating to other behaviours.

Main outcome measures: All participants were asked to state how worried they were about the possibility of personally catching swine flu. Subsets were asked how likely they were to take up a swine flu vaccination if offered it and whether they had recently carried tissues with them, bought sanitising hand gel, avoided using public transport or had been to see a general practitioner, visited a hospital or called NHS Direct for a flu-related reason.

Results: The percentage of 'very' or 'fairly' worried participants fluctuated between 9.6% and 32.9%. This figure was associated with the volume of media reporting, even after adjusting for the changing severity of the outbreak [$\chi^2(1) = 6.6$, $p = 0.010$, coefficient for log-transformed data = 2.6]. However, this effect only occurred during the UK's first summer wave of swine flu. In total, 56.1% of respondents were very or fairly likely to accept the swine flu vaccine. The strongest predictors were being very worried about the possibility of oneself [adjusted odds ratio (aOR) 4.7, 95% confidence interval (CI) 3.2 to 7.0] or one's child (aOR 8.0, 95% CI 4.6 to 13.9) catching swine flu. Overall, 33.1% of participants reporting carrying tissues with them, 9.5% had bought sanitising gel, 2.0% had avoided public transport and 1.6% had sought medical advice. Exposure to media coverage or advertising about swine flu increased tissue carrying or buying of sanitising hand gel, and reduced avoidance of public transport or consultation with health services during early May 2009. Path analyses showed that media coverage and advertising had these differential effects because they raised the perceived efficacy of hygiene behaviours but decreased the perceived efficacy of avoidance behaviours.

Conclusions: During the swine flu outbreak, uptake rates for protective behaviours and likely acceptance rates for vaccination were low. One reason for this may in part be explained by was the low level of public worry about the possibility of catching swine flu. When levels of worry are generally low, acting to increase the volume of mass media and advertising coverage is likely to increase the perceived efficacy of recommended behaviours, which, in turn, is likely to increase their uptake.

Contents

List of abbreviations

aOR	adjusted odds ratio
ARIMA	autoregressive integrated moving average
CI	confidence interval
GP	general practitioner
OR	odds ratio
SARS	severe acute respiratory syndrome

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices, in which case the abbreviation is defined in the figure legend or in the notes at the end of the table.

Executive summary

Background

During the 2009 influenza A H1N1v (swine flu) pandemic, the UK government urged members of the public to adopt several behaviours in order to reduce the effects of the outbreak. A major communications campaign was launched in which people were asked to clean their hands regularly, use tissues appropriately and use automated telephone numbers or websites if they wished to check whether they might have swine flu. Later on in the outbreak, selected population groups were advised to have the new swine flu vaccination, with the possibility raised that the vaccine might eventually be offered to most people.

In order to understand the public's attitudes and knowledge relating to swine flu, the Department of Health, England commissioned a series of 40 telephone surveys, each of which contacted a new, randomly selected sample of between 1047 and 1173 members of the public across the UK. All participants were aged 16 years or over and spoke English. Surveys occured on average once per week, and over a 3-day time period. Response rates for each were in the range of 8–11%, which is usual for this type of research. Quota sampling ensured that each sample was demographically representative of the UK population.

We analysed the data from 36 of these surveys, covering the period between 1 May 2009 and 10 January 2010. Data for the last four surveys were still being finalised when we conducted our analyses. We used the data to assess the impact of the government's communications campaign on uptake of recommended behaviours, on behaviours that had not been recommended and on likely uptake of the swine flu vaccine. We also assessed possible psychological factors that might have mediated any associations between exposure to information and behaviour. Because we were interested in how public responses changed over time, we examined how responses to five survey questions concerning perceptions of the outbreak altered over time, and whether any changes correlated with changes in the amount of media reporting about swine flu.

Our overall approach was guided by a psychological theory that suggests that higher levels of worry about a hazard, coupled with perceiving a specific action to be effective in protecting against the hazard, increases the likelihood of an individual performing that action.

Objectives

1. To assess whether changes in the volume of media reporting about swine flu were associated with changes in the percentage of people who reported being worried about the possibility of catching swine flu or with other changes in the way the outbreak was perceived.
2. To assess how many members of the UK public would have accepted the swine flu vaccine had it been offered to them, and to identify whether likely acceptance was predicted by worry about the possibility of catching swine flu, perceptions about the outbreak or the amount or type of information heard about the outbreak.
3. To assess whether being more likely to have the seasonal flu vaccine as a result of the swine flu outbreak was predicted by worry about the possibility of catching swine flu, perceptions about the outbreak or the amount or type of information heard about the outbreak.
4. To assess what percentage of the public had performed recommended and non-recommended behaviours in the early stages of the outbreak.
5. To assess whether people who had been exposed to media coverage or advertising about swine flu were more likely to perform recommended or non-recommended behaviours, and to assess whether effects of media coverage or advertising were due to changes in knowledge about swine flu, levels of worry about the possibility of catching swine flu or perceptions about the efficacy of different protective actions.

Methods

Because the questions included in the surveys changed over time, different surveys were used to address the different objectives. Three studies were conducted.

- *Study 1* used data from all 36 surveys to address Objective 1. Percentages of people in each survey who reported the following were documented: being fairly or very worried about the possibility of catching swine flu; being very or fairly satisfied with the amount of information available to them about swine flu; having heard a great deal or a fair amount in the past week about swine flu; tending to agree or strongly agree that 'too much fuss is being made about the risk of swine flu'; and believing that the government was very well prepared, or fairly well prepared, for a swine flu pandemic. Specialist media monitoring software was used to search 11,132 UK-based news sources for articles that mentioned the words swine flu, 'H1N1' or 'pandemic' in their opening paragraphs. Additional searches identified the number of stories that also included terms in their headlines relating to children or deaths. Time series analyses were used to investigate whether changes in the aggregate survey data were associated with changes in the total volume of media reporting relating to swine flu or changes in the volume of reporting that also mentioned children or deaths. These analyses adjusted for the number of new hospitalisations from swine flu per week, to control for the fact that changed levels of reporting and worry might reflect the changing severity of the outbreak.
- *Study 2* assessed Objectives 2 and 3, with analyses for Objective 2 using data from five surveys ($n = 5175$, data collection from 14 August to 13 September) and analyses for Objective 3 using data from 20 surveys ($n = 20{,}999$, 8 May to 13 September). All data were collected prior to the start of the swine flu vaccination campaign. Participants were asked how likely, if at all, they were to take up a swine flu vaccination if offered it, and whether, as a result of swine flu, they were now more likely to get the seasonal flu vaccination. Possible predictors included demographic variables, worry about the possibility of oneself or one's child catching swine flu, perceiving that too much fuss had been made about the risk of swine flu, perceptions of government preparedness, amount of information heard about swine flu in the past week, level of satisfaction with the information available and specific aspects of information that had been heard.
- *Study 3* assessed Objectives 4 and 5, using data from the first five surveys ($n = 5419$, 1–17 May). Participants were asked whether they had carried tissues with them, bought sanitising hand gel or avoided using public transport since the beginning of the outbreak. Carrying tissues and using hand gel were behaviours endorsed by the government. Avoiding public transport was not endorsed by the government. Participants were also asked whether they had been to see a general practitioner (GP), visited a hospital or telephoned NHS Direct in the past 2 weeks because of flu-related reasons. As levels of flu in the community were low at the time of these surveys, participants responding 'yes' to these questions were unlikely to have had flu. Predictor variables for these four outcomes were demographic variables, self-reported exposure to media coverage or advertising relating to swine flu, knowledge about swine flu, perceptions of the information available, worry about the possibility of catching swine flu, and perceptions of the efficacy of hygiene-related behaviours or avoidance of other people as ways of preventing the spread of swine flu.

Results

Study 1: The influence of the media on levels of worry in the community

The percentage of people who were satisfied with the amount of information available or who thought that the government was well prepared for a pandemic ranged from 77.6% to 88.4% and from 66.4% to 81.7% respectively. Levels of worry about the possibility of catching swine flu showed larger fluctuations in the first half of the data collection period, rising from initially low levels (9.6–16.6% during May) to 19.3% in mid-June following the declaration of a full pandemic by the World Health Organization, with a second peak of 32.9% in mid-July at the height of the summer wave of the outbreak. Following the summer wave, levels of worry then remained more stable from the end of August onwards, although smaller increases coinciding with the start of the winter wave of the outbreak and the start of the vaccination campaign were observed. Reports of the amount heard about swine flu showed the most dramatic changes, from initially high levels, with over 90% of respondents reporting that they had heard 'a lot' or a 'a moderate amount', dropping to 11.4% having

heard 'a great deal' or 'a fair amount' by early January 2010.

Across the whole pandemic, the percentage of people reporting worry about the possibility of catching swine flu correlated with the number of hospitalisations recorded that week [likelihood ratio test: $\chi^2(1) = 8.2$, $p = 0.004$] and the total volume of reporting relating to swine flu, after adjusting for hospitalisations [$\chi^2(1) = 6.6$, $p = 0.010$]. The relationship between reporting and worry changed over time. Prior to community transmission of swine flu becoming established in the UK, very high levels of media reporting about the disease were observed but these were accompanied by low levels of worry. During the summer wave of swine flu, an association appeared between levels of reporting and worry [$\chi^2(1) = 6.8$, $p = 0.009$]. This relationship was not observed in the second (winter) wave of the outbreak. Adjusting for hospitalisations and for the total amount of reporting about swine flu, the amount of reporting about deaths from swine flu or about children and swine flu was not associated with any of the survey variables.

Study 2: Factors predicting likely acceptance of vaccination against swine or seasonal flu

A total of 31.7% of respondents reported being very likely to accept the swine flu vaccine if offered it, 24.4% were fairly likely, 19.4% were not very likely, 20.8% were very unlikely and 3.7% said they did not know. Overall, 16.7% of respondents strongly agreed that as a result of swine flu they were now more likely to get the seasonal flu vaccine – 12.9% tended to agree, 15.3% neither agreed nor disagreed, 27.9% tended to disagree, 26.1% strongly disagreed and 1.1% did not know.

Controlling for personal and health-related factors, the following variables were associated with being very or fairly likely to accept the swine flu vaccine: having higher levels of worry about the possibility of one's child catching swine flu [adjusted odds ratio (aOR) 8.0, 95% confidence interval (CI) 4.6 to 13.9]; having higher levels of worry about the possibility of personally catching swine flu (aOR 4.7, 95% CI 3.2 to 7.0); disagreeing that too much fuss had been made about the risk of swine flu (aOR 2.2, 95% CI 1.9 to 2.7); perceiving the government to be well prepared for swine flu (aOR 1.6, 95% CI 1.3 to 1.8); and knowing someone who had had swine flu (aOR 1.2, 95% CI 1.0 to 1.3). All of these variables, except for perceptions about government preparedness and knowing someone who had had swine flu, were also associated with being more likely to accept the seasonal flu vaccine as a result of swine flu.

Only two out of eight information-related variables that were available in the relevant surveys were associated with being more likely to accept the swine flu vaccine if offered it: being satisfied with the amount of information available about swine flu (aOR 1.5, 95% CI 1.2 to 1.9) and having recently heard that the number of deaths from swine flu had increased (aOR 1.3, 95% CI 1.0 to 1.6). Eleven information-related variables were available in the surveys which included likelihood of having the seasonal flu vaccine as an outcome. Of these, only satisfaction with the amount of information available about swine flu (aOR 1.5, 95% CI 1.1 to 2.0) and believing, incorrectly, that the seasonal flu vaccine would protect against swine flu (aOR 2.4, 95% CI 2.1 to 2.7) were associated with being more likely to get the seasonal flu vaccine as a result of swine flu.

Study 3: The effects of advertising and media coverage on behavioural change during the early stages of the swine flu outbreak

In total, 33.1% of respondents reported carrying tissues with them, 9.5% reported having bought sanitising gel, 2.0% reported avoiding public transport and 1.6% reported having visited a GP or hospital or phoning NHS Direct for flu-related reasons. Path analyses demonstrated that exposure to media reporting or advertising coverage was associated with greater likelihood of carrying tissues or buying sanitising gel, and lower likelihood of avoiding public transport or using NHS services. These effects occurred mainly because media or advertising exposure increased variables associated with perceived knowledge about swine flu, increased the perceived efficacy of hygiene strategies and decreased the perceived efficacy of avoidance strategies. Exposure to advertising or media reporting also tended to reduce levels of worry about the possibility of catching swine flu, which also helped to reduce avoidance of public transport and use of NHS services.

Conclusions

Implications for practice

1. Uptake of recommended behaviours during the swine flu outbreak was low. Maximising the impact of communications campaigns

that promote protective behaviours during future pandemics is therefore important. Our results show that psychological processes are important to consider when designing these campaigns.

2. Rapid-turnaround surveys can be useful as part of a public health response to evaluate whether communications campaigns have had an effect on behaviour and to identify what factors mediated this process. However, in order to get the most out of analysing such data, it is important that the most appropriate constructs are measured using wording and response options that maximise reliability and validity of measurement. This is true both of psychological predictors and of self-report measures of behaviour. Seeking early advice from behavioural scientists on these issues is recommended in any future outbreak. It is also recommended that a model template for such a survey be designed in advance of a future pandemic.
3. During a future outbreak, raising levels of worry about the possibility of catching a disease from low levels is likely to increase uptake of behavioural recommendations. However, it is also likely to increase uptake of non-recommended behaviours. Conversely, attempts to reassure the public about their chances of becoming ill during a future infectious disease outbreak are likely to reduce rates of behaviour change. How to steer the best course in the face of these conflicting influences requires the application of general principles to the specifics of any particular situation.
4. Emphasising the efficacy of recommended behaviours in any future campaign should help to maximise the campaign's impact on those behaviours. Importantly, although increasing levels of worry might increase rates of all protective behaviours, regardless of whether they had been recommended or not, our results suggest that communicating the efficacy of a specific behaviour may have an impact on that behaviour alone.

Research recommendations

1. While our results suggest that successfully communicating information about the efficacy of protective behaviours will increase the uptake of these behaviours, we are unable to specify the best techniques for providing information about efficacy. Additional research on this topic would help to guide future communications campaigns.
2. Across all of the behavioural outcomes that we assessed, there was evidence that people from particular demographic groups were more inclined to engage in behavioural change. Our results showed that ethnicity, age, household size, health status, socioeconomic status and gender all played a role in determining whether someone engaged in a given behaviour or not. The mechanisms underlying these effects are likely to be complex and may have important implications for the way in which messages for these groups should be framed. Additional research to understand the reasons for and implications of these effects would be of value.
3. Since the cross-sectional analyses reported in studies 2 and 3 were completed, additional data from the surveys have become available. These include potential outcome variables such as hand-washing data and actual, rather than intended, vaccine uptake. We recommend further analysis of this data set, focusing on these variables. Similarly, the database would also allow a more detailed analysis of the content of media reporting to be used as a predictor of worry during the outbreak.
4. The perception that too much fuss was being made about the risk of swine flu was high throughout the outbreak, and was associated with reduced uptake of recommended behaviours. It is unclear how people's experiences during the swine flu outbreak have affected their perceptions of health warnings produced by scientists, the media or the government, what impact this might have on their response to future warnings about a potentially more severe pandemic or how best to ameliorate any scepticism. Additional research addressing these areas is warranted, informed by evidence-based theories of behaviour change.
5. For the foreseeable future, telephone surveys are likely to remain the only pragmatic way to obtain rapid, quantitative data with which to inform policy decisions during public health incidents. Additional research to improve the validity of this technique is therefore warranted. As a first step, testing the validity of self-report measures of different types of behaviour would be of value.

Chapter 1
General introduction

How members of the public react when informed about the outbreak of a novel infectious disease can play a large role in determining the outbreak's health,[1] social[2] and economic[3] impact. Depending on the disease and the cultural context, governments often recommend that members of the public adopt protective behaviours, such as wearing masks,[1] avoiding social events,[4] washing their hands more frequently,[1] taking prophylactic medication[5] or receiving a vaccination.[6] Other actions that members of the public sometimes take, such as avoiding economically important activities that are perceived to be risky,[3] shunning particular social groups[2] or unnecessarily seeking medical care,[7] are often discouraged by governments as causing more harm than good.

Levels of compliance with these official recommendations are rarely perfect.[5,8,9] As well as information received from public health campaigns, information from social contacts or the media and previous experiences with similar incidents can influence how people react during an outbreak, or if they will react at all. One important task that public health bodies can perform during any major incident is to assess how the public responds to the novel threat and what factors are important in influencing those responses.[10,11] Armed with this information, communication campaigns can be designed or fine-tuned to target those factors, with the aim of improving uptake of recommended behaviours and reducing the rates of other, less helpful, actions. Measuring and analysing public responses using theoretical frameworks of behaviour change strengthens this process; it provides greater understanding of the psychological mechanisms through which communication campaigns translate into behaviour and it informs us about the behaviour change techniques that are likely to be effective.[12]

The influenza A H1N1v pandemic of 2009–10, commonly referred to in the UK as the 'swine flu' outbreak, saw the UK government make several behaviour recommendations to the public using an extensive multimedia campaign. After the first cases of swine flu were confirmed in the UK on 27 April 2009, the government's messages focused on the importance of hygiene behaviours, such as hand-washing and tissue use, as ways to reduce the spread of the virus, and the appropriate use of NHS health services by people who were concerned that they might have caught swine flu. Later in the outbreak, the government also recommended that those who were believed to be at heightened risk from swine flu should receive the newly available vaccination against it. Consideration was also given to offering this vaccine to the UK population more generally. However, although this policy was widely discussed, it was never put into practice.

In order to assess the impact of the government's communications campaigns, the Department of Health, England commissioned a series of 40 telephone surveys in which randomly selected members of the public were asked about the information they had heard regarding swine flu and about a range of cognitive, emotional and behavioural responses to the outbreak. As well as providing data that were of immediate relevance in informing policy, the surveys also provided an opportunity to gather data to improve communication strategies in future influenza pandemics or in outbreaks of other forms of infectious disease.

In this report, we present three studies that used unweighted data drawn from the first 36 of these surveys, which took place between 1 May 2009 and 10 January 2010. Data for the final four surveys were still being checked and finalised at the time of our analyses. In the first study we assessed how public perceptions relating to the swine flu outbreak changed over time, with a particular focus on levels of self-reported worry about the possibility of catching swine flu. Because media reporting is an area that official agencies may be able to influence during an outbreak, we also assessed the association between changes in the volume of media attention devoted to swine flu and changes in public perceptions.

In the second study, we used data from 20 of the surveys that were conducted before, during and after the UK's summer wave of swine flu in order to assess how many people would have accepted the swine flu vaccine, had it been offered to

them. Using cross-sectional analyses of the survey data, we also assessed whether the amount of information people had heard about the outbreak or their level of satisfaction with that information was associated with likely acceptance of the vaccine, and whether other factors that could be targeted by future communications campaigns were associated with likely acceptance, such as worry about the possibility of catching swine flu.

In the third study, we analysed data from the first five surveys that were conducted during May 2009, prior to any large-scale community spread of swine flu occurring in the UK. We assessed the percentage of people who had complied with official recommendations to carry tissues, had bought sanitising gel in order to clean their hands, avoided public transport (a behaviour that was not recommended by the UK government) and unnecessarily used NHS resources for a flu-related reason. We also assessed whether exposure to advertising or media coverage about swine flu influenced whether or not people had engaged in these behaviours, and whether this influence was because exposure altered the amount of knowledge they had regarding swine flu, their perceptions about the information available to them about swine flu, their perceptions about the efficacy of different protective actions or their level of worry about the possibility of catching swine flu.

These studies therefore assessed changes in the survey data over time (study 1) and the cross-sectional associations within the survey data at specific points during the outbreak (studies 2 and 3). Our approach to these analyses was informed by existing psychological models suggesting that worry about a health risk and perceptions about the efficacy of protective behaviours are important factors determining whether an individual will perform a given behaviour in response to a health threat.[13]

Our research arose from collaborative work between the Department of Health's Communications Directorate and the Behaviour and Communications subgroup of the UK's Scientific Pandemic Influenza Committee, which reported to the Scientific Advisory Group in Emergencies during the outbreak (see Appendix 1 for our initial protocol). Analyses were led by the research team of psychologists and a statistician, with regular consultations with colleagues in the Department of Health's Communications Directorate.

Chapter 2

Study 1: The influence of the media on levels of worry in the community

Key points

- Members of the public get much of their information about health risks from the mass media. How the media report a given health risk therefore has the potential to affect how the public perceive it.
- Using aggregate data from 36 UK national telephone surveys, this study demonstrated a correlation between the volume of media reporting about swine flu at any given time point and the number of people worried about the possibility of catching it. However, this association was only observable during the first wave of the outbreak during the summer of 2009. No such associations existed before swine flu had become established in the UK or during the second (winter) wave of the outbreak.
- In future outbreaks involving a prolonged risk to the public's health, attempting to keep the media's attention focused on the outbreak is unlikely to maintain public concern about the risk over the medium to long term and hence their motivation to adhere to recommended protective behaviours. Other strategies may need to be used to maintain the public's motivation.

Introduction

Members of the public are regularly exposed to health-related information from multiple sources, including friends and family, the internet, commercial advertising and health-care professionals. Most of the health-related information that people receive, however, is obtained from television, radio and the print media.[14,15] Reporting by these news sources has long been recognised as a key factor that can affect people's health-related behaviours and have both positive and negative consequences for the public's health.[16–22]

One way in which the media exert these effects is by 'setting the agenda'. The theory of agenda setting suggests that the more coverage an issue receives, regardless of the nature of that coverage, the more important it becomes to members of the public.[23,24] Where the issue is a health risk, an extension to the theory suggests that the more coverage the risk receives then the more concerned about it the public will become, regardless of the nature of the coverage.[25] Numerous studies have demonstrated a link between greater exposure to media reports about a health issue and concern, worry or anxiety about it: examples include anxiety about breast cancer,[26] disquiet about genetically modified foods,[27] fear of avian influenza[28] or worry about a cryptosporidiosis outbreak.[29] Whether such effects persist during a sustained period of reporting is less certain. Two previous studies have assessed the impact of media coverage about severe acute respiratory syndrome (SARS) or the 2001 US anthrax attacks on distress or behaviour change.[9,30] In both studies, while media coverage in the early stages of the incident strongly predicted emotional or behavioural responses, media coverage in the later stages had little impact.

The content of media reporting about a risk may also affect how the public reacts to it. The theories of 'second-level agenda setting' and the closely related concept of 'framing'[31] suggest that those attributes of an issue that are made particularly salient by the media, or which are used to place an issue in context, can affect how people perceive it.[24] For health risks, there is a tendency for the media to make salient those attributes that are known to cause greater concern among the public or to reduce the perceived credibility or competence of the government. Examples of such attributes are a hazard's adverse effects on children, its fatal consequences, and disagreement or uncertainty among scientific experts about the nature of the risk.[32–34] Conversely, portrayal of a risk as having been deliberately exaggerated by politicians, scientists or the media may increase scepticism among the public as to the true importance of the issue and result in decreased levels of concern.[35,36]

The 2009 outbreak of swine flu was accompanied by extensive reporting by the UK news media.[36,37]

In this study, we assessed whether the quantity of media reporting over the period of the outbreak was associated with changes in the number of people who reported being worried about the possibility of catching swine flu. We also sought to assess whether the amount of media reporting that specifically related to children, deaths, scientific uncertainty or disagreement, or which portrayed swine flu as an overexaggerated risk, was associated with levels of worry. Because swine flu was portrayed as a particular risk to children, we also conducted subgroup analyses to examine the relationship between media reporting and worry for survey respondents who had children in their households. As secondary outcomes, we assessed whether media reporting was associated with being satisfied with the amount of information available about swine flu, having heard a lot recently about swine flu, believing that too much fuss had been made about the risk of swine flu or believing that the government was well prepared for a swine flu pandemic.

Methods

The telephone surveys

Thirty-six telephone surveys were conducted between 1 May 2009 and 10 January 2010 by the Ipsos MORI Social Research Institute on behalf of the Department of Health, England. Each collected data over a 3-day period. The first five surveys were run with less than 2 days between them. Subsequent surveys were run weekly and then fortnightly. Random digit dialling and proportional quota sampling were used to ensure that each sample was demographically representative of the UK population, as determined by the most recent census data, with quotas based on age, gender, geographical region and social grade.[38] To be eligible for a survey, respondents had to be 16 years or over and speak English. Each survey was introduced to respondents as being 'a national survey covering a variety of subjects'. Any other subjects were covered after the flu-related questions had been asked. The questions included in the surveys changed as the pandemic progressed, with time for completion ranging from 8 to 15 minutes.

The first survey (1–3 May 2009) had a sample size of 1173. All others had sample sizes of between 1047 and 1070. These sample sizes provided a sampling error of about plus or minus 3% for each survey. The total sample size for all 36 surveys was 38,182. Response rates for each survey, calculated as the number of completed interviews divided by the total number of people spoken to regardless of eligibility, were in the region of 8–11%. This is typical for surveys of this nature.[35,39,40]

Survey questions

Participants in all surveys were told that 'Swine flu is a form of influenza that originated in pigs but can be caught by, and spread among, people' and were then asked 'How worried, if at all, would you say you are now about the possibility of personally catching swine flu?' Possible answers were 'very worried', 'fairly worried', 'not very worried' and 'not at all worried'.

Participants were also asked 'How satisfied or dissatisfied are you with the amount of information available to you about swine flu, from any source?' Responses of 'very satisfied', 'fairly satisfied', 'neither satisfied nor dissatisfied', 'fairly dissatisfied' or 'very dissatisfied' were recorded.

Participants were asked 'Please tell me whether you agree or disagree with the following statement: too much fuss is being made about the risk of swine flu.' Responses of 'strongly agree', 'tend to agree', 'neither agree nor disagree', 'tend to disagree' and 'strongly disagree' were allowed.

Perceptions of governmental preparedness were assessed by asking 'How well prepared do you think the government is for a swine flu pandemic?' Possible responses were 'very well prepared', 'fairly well prepared', 'not very well prepared' and 'not at all well prepared'.

In five surveys conducted between 1 May and 17 May 2009, participants were asked 'How much have you heard about swine flu?', with possible responses being 'a lot', 'a moderate amount', 'a little' or 'nothing at all'. A similar question was then introduced in 22 surveys between 24 July 2009 and 10 January 2010, in which participants were asked 'How much have you heard about swine flu in the past week?', with responses of 'a great deal', 'a fair amount', 'not very much' or 'nothing at all' being allowed. For these later surveys, participants who reported having heard anything about swine flu in the past week were asked where they had heard this information. Responses were coded as relating to advertising (in newspapers or on television), news coverage (in local or national newspapers, on television or on radio), via a general practitioner (through a GP's surgery or a letter from the GP), on the internet, from friends/family or at work.

In addition to a range of other personal and demographic questions, all participants were asked to state how many, if any, children under the age of 16 years were in their household.

All questions allowed participants to give a response of 'don't know'. 'Don't know' responses accounted for no more than 1% of responses to the 'worry' and 'how much have you heard' items in any given survey, and no more than 3% for the 'too much fuss' and 'satisfaction with the amount of information available' items. The item relating to government preparedness was the hardest for participants to answer, with between 4% and 13% of respondents replying 'don't know' in each survey. We excluded 'don't know' responses from all analyses.

Media coverage

We assessed media coverage using software supplied by Meltwater News (http://meltwaternews.com). All searches were restricted to the internet sites of 11,132 UK-based news sources. These sources included a mix of national and regional newspapers, magazines, trade journals, television and radio stations and internet news providers. Searches were performed for the start dates of the 36 surveys.

As an indicator of the total amount of coverage devoted to swine flu we searched for any stories that contained the words swine flu, 'pandemic' or 'H1N1' in their opening paragraph. To assess the number of stories in which children were specifically linked to swine flu, we added a requirement that stories must include a word such as 'child', 'baby', 'pupil' or 'school' in the title. Similarly, to identify stories that discussed deaths relating to swine flu we added a requirement that the story must include a word such as 'death', 'dies' or 'dead' in its title. Stories relating to uncertainty or disagreement were identified as those which included the following terms, or common variations, in their title: 'contradiction', 'muddle', 'disagree', 'uncertain', 'controversy', 'debate', 'doubt', 'argument', 'confusion', 'inconsistent' or 'critic'. Stories relating to the exaggeration of swine flu were identified as those that included variations on the following terms in the title: 'alarmist', 'hype', 'hysteria', 'exaggerated', 'overplayed', 'overreacting', 'over the top', 'overstated', 'overblown', 'embellished', 'inflated' or 'sensationalised'. The exact searches used are given in Appendix 2.

In order to describe the type of reporting occurring on the start date for each survey, we also conducted a separate search using the Nexis database (www.lexisnexis.com/uk/nexis) to identify all UK-based national or regional newspaper stories with the terms swine flu, 'H1N1' or 'pandemic' in their title. A random sample of 30 stories was selected for each day to generate a short synopsis of the main aspects of media reporting.

Potential confounders

Because any association between public concern about swine flu and media reporting of it might simply reflect the changing severity of the outbreak, we obtained data on hospitalisations from swine flu in England as an objective marker of outbreak severity. These data were obtained from the Health Protection Agency[41] and reflected the number of new patients admitted to hospital with suspected swine flu over a 7-day period.

Analyses

All media variables had a large positive skew, because of a small number of dates on which there was an unusually high level of media reporting. For our analyses, we transformed these data by adding 1 and taking the natural log. For the survey data we grouped together participant responses of 'very worried' and 'fairly worried' about the possibility of catching swine flu, 'strongly agree' and 'tend to agree' about too much fuss having been made, answers that the government was 'very well prepared' or 'fairly well prepared', and answers that the participant was 'very satisfied' or 'fairly satisfied' with the amount of information available about swine flu. For worry, although responses of 'very worried' might have reflected qualitatively different underlying mechanisms than responses of 'fairy worried', in practice the data for these two responses showed similar changes over time.

A consistent time interval between the data was required for our analyses. We therefore excluded results from the second and fourth surveys, and from the last three surveys to ensure that those surveys that were included had a gap of roughly 1 week between them. Most analyses were therefore based on data from 31 surveys. We excluded all of the May results for the question relating to the amount heard about swine flu, because excluding the second and fourth surveys left only three results for May followed by a lengthy gap until the question was reintroduced in July. This variable was

therefore analysed for 19 surveys. Results from all surveys were plotted on the figures given below.

For the associations between survey data and hospitalisation or media data, we used regression models with autoregressive moving average disturbances. Here the dependent variable is regressed on the independent variable(s) as in a normal regression model but an autoregressive integrated moving average (ARIMA) model is fitted to the residuals to take into account the time series nature of the data. Although some of the variables are non-stationary, the residuals broadly meet the required assumptions, allowing this approach. For each dependent variable, diagnostic plots were examined and suggested low-order autoregressive modes with either one or two terms. The final model was selected based on the lowest Akaike's information criterion: a first order autoregressive [AR(1)] model was the best fitting for all of the variables. Associations between the survey variables were then assessed using a likelihood ratio test comparing an AR(1) model with no independent variable and an AR(1) model with a survey variable as the independent variable. Associations between the media variables were tested using Kendall's non-parametric correlation.

Subgroup analyses were conducted for worry data obtained from people who had children aged under 16 years of age in the household (between 21.7% and 27.9% of respondents in each survey).

Results

Changes in outcome measures over the course of the outbreak

Figure 1 shows the percentages of people within each survey who reported being worried about the possibility of catching swine flu, agreed that too much fuss had been made about the risk of swine flu, felt that the government was well prepared for a pandemic, were satisfied with the amount of information available about swine flu and reported having heard a lot or a moderate amount about swine flu.

The percentage of people who were satisfied with the amount of information available or who felt that the government was well prepared for a pandemic ranged from 77.6% to 88.4% and from 66.4% to 81.7% respectively. Levels of worry showed larger fluctuations in the first half of the data collection period, rising from initially low levels (9.6–16.6% during May) to a peak of 19.3% in mid-June immediately following the declaration of a full pandemic by the World Health Organization, and a second peak of 32.9% in mid-July at the height of the summer wave of the outbreak. Following the summer wave, levels of worry then remained more stable from the end of August onwards, although smaller increases coinciding with the start of the winter wave of the outbreak and the start of the vaccination campaign were observed. Reports of the amount heard about swine flu showed the most dramatic changes, from initially high levels with over 90% of respondents reporting that they had heard 'a lot' or a 'a moderate amount' dropping to 11.4% having heard 'a great deal' or 'a fair amount' by early January 2010. Three noticeable peaks in 'how much heard' were observed in late September, late October and late November. These appeared to coincide with the winter wave of swine flu, the start of the swine flu vaccination campaign and the extension of the vaccination campaign to young children, respectively.

Table 1 shows the associations between the aggregate survey data. Overall, a higher level of worry about the possibility of catching swine flu tended to occur at the same time as lower satisfaction with the amount of information available about swine flu and having heard more about swine flu. Higher levels of belief that the government was very or fairly well prepared for a pandemic were associated with greater satisfaction with the amount of information available.

Participants who had heard something about swine flu had mostly received their information from the mainstream news media ($n = 13{,}581$, 74.7%), followed by friends, family or work ($n = 3579$, 19.7%), advertisements ($n = 1959$, 10.8%), the internet ($n = 1426$, 7.8%) and GPs ($n = 846$, 4.7%).

Changes in media reporting and hospitalisations

The general themes in media reporting on the start dates of each survey are summarised in Appendix 3. Overall, the media were consistent in characterising swine flu as a mild illness for most people. More specific themes changed over time. Throughout most of May, media reports about UK cases of swine flu typically described their connection to Mexico or the USA, either as a result of travel or through contact with a returned traveller. This trend was no longer apparent by early June, as the number of tertiary cases or cases with no known history of travel or contact with

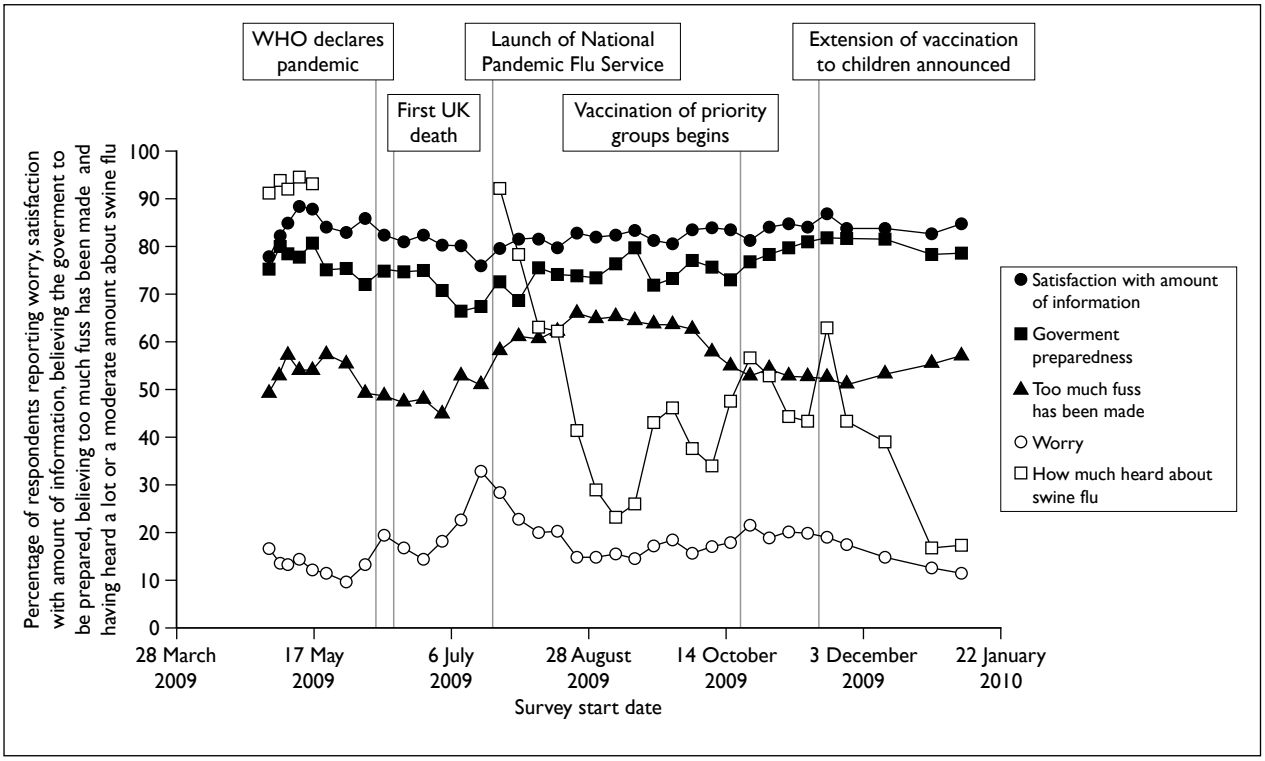

FIGURE 1 *Changes over time in survey data. WHO, World Health Organization.*

a traveller increased. Initial reports focused on 'firsts', such as the first cases occurring in local areas or the first instance of person-to-person transmission in the UK. As cases increased during the summer wave of the outbreak, media reporting started to focus on issues relating to government strategy, the capacity of the NHS, the suitability of the newly set up National Pandemic Flu Service, and the safety and efficacy of antiviral medications. From the start of August, the issue of swine flu vaccination became more prominent, with concerns raised about the vaccine's safety, efficacy and availability, the information given about the order in which it would be provided to different sections of the population, and the apparently low uptake of the vaccine.

TABLE 1 *Associations between the aggregate survey data*

	Dependent variable			
Predictor variable	**Very or fairly worried about the possibility of catching swine flu**	**Strongly agree or agree that too much fuss has been made about swine flu**	**Believe that the government is very well prepared or fairly well prepared for a pandemic**	**Very satisfied or fairly satisfied with the amount of information available about swine flu**
Too much fuss	$\chi^2(1) = 3.2$, $p = 0.074$, coeff. = –0.3			
Government preparedness	$\chi^2(1) = 2.0$, $p = 0.2$, coeff. = –0.3	$\chi^2(1) = 0.1$, $p = 0.8$, coeff. = 0.1		
Satisfaction with amount of information available	$\chi^2(1) = 12.1$, $p < 0.001$, coeff. = –0.8	$\chi^2(1) = 3.6$, $p = 0.058$, coeff. = 0.4	$\chi^2(1) = 5.1$, $p = 0.024$, coeff. = 0.6	
Heard a lot about swine flu	$\chi^2(1) = 22.5$, $p < 0.001$, coeff. = 0.2	$\chi^2(1) = 1.1$, $p = 0.3$, coeff. = 0.0	$\chi^2(1) = 2.1$, $p = 0.1$, coeff. = –0.1	$\chi^2(1) = 1.9$, $p = 0.2$, coeff. = 0.0

coeff., coefficient.

Figure 2 shows the changes in media reporting over time in terms of the total number of stories relating to swine flu and the number relating to children, death, uncertainty or exaggeration. *Figure 2* also shows the changes in the number of new hospitalisations from swine flu reported to the Health Protection Agency. The total volume of media reporting started at a high level on 1 May, but decreased rapidly. After a small spike in reporting, which related to the World Health Organization's declaration of a full pandemic on 11 June, two main peaks in reporting were observed, which largely coincided with the increased prevalence of swine flu during the summer and winter months. There was relatively little reporting that specifically focused on children or deaths. Those reports mentioning death showed a similar pattern to the total volume of coverage, with increases coinciding with the peaks of the outbreak. Articles mentioning children showed two main peaks: on 5 May 2009 following the reporting of the closure of two schools in London and on 7 August 2009 during discussions on whether or not to vaccinate school children. Levels of reporting relating to uncertainty or exaggeration were too low to be analysed and were dropped from all further analyses.

The association between survey outcomes and media reporting

Table 2 shows the associations between the survey and hospitalisation data, and between the survey and media data adjusting for hospitalisations.

Across the whole epidemic, the percentage of people reporting worry about the possibility of catching swine flu correlated with the number of hospitalisations recorded that week [$\chi^2(1) = 8.2$, $p = 0.004$, coefficient = 0.04], the total volume of reporting relating to swine flu after adjusting for hospitalisations [$\chi^2(1) = 6.6$, $p = 0.010$, coefficient = 2.6] and the total number of stories relating to death after adjusting for hospitalisations [$\chi^2(1) = 4.3$, $p = 0.038$, coefficient = 1.0]. Restricting the worry data to that obtained from participants with children in the house did not affect the pattern of results. There was no effect of the volume of reporting relating to children adjusting for hospitalisations [$\chi^2(1) = 0.9$, $p = 0.3$, coefficient = 0.8].

Adjusting for hospitalisations, lower volume of reporting about swine flu was associated with greater satisfaction with the amount of information available [$\chi^2(1) = 6.0$, $p = 0.014$, coefficient = –2.0], and fewer stories relating to death was associated with more frequent perceptions that too much fuss had been made about the risk of swine flu [$\chi^2(1) = 4.7$, $p = 0.030$, coefficient = –1.0]. How much someone had heard about swine flu in the past week was associated with the number of hospitalisations for swine flu [$\chi^2(1) = 7.7$, $p = 0.006$, coefficient = 0.19].

The significant associations we identified between the survey data and reporting relating to children or death might have reflected the fact that both reporting relating to children ($\tau_b = 0.53$, $p < 0.001$)

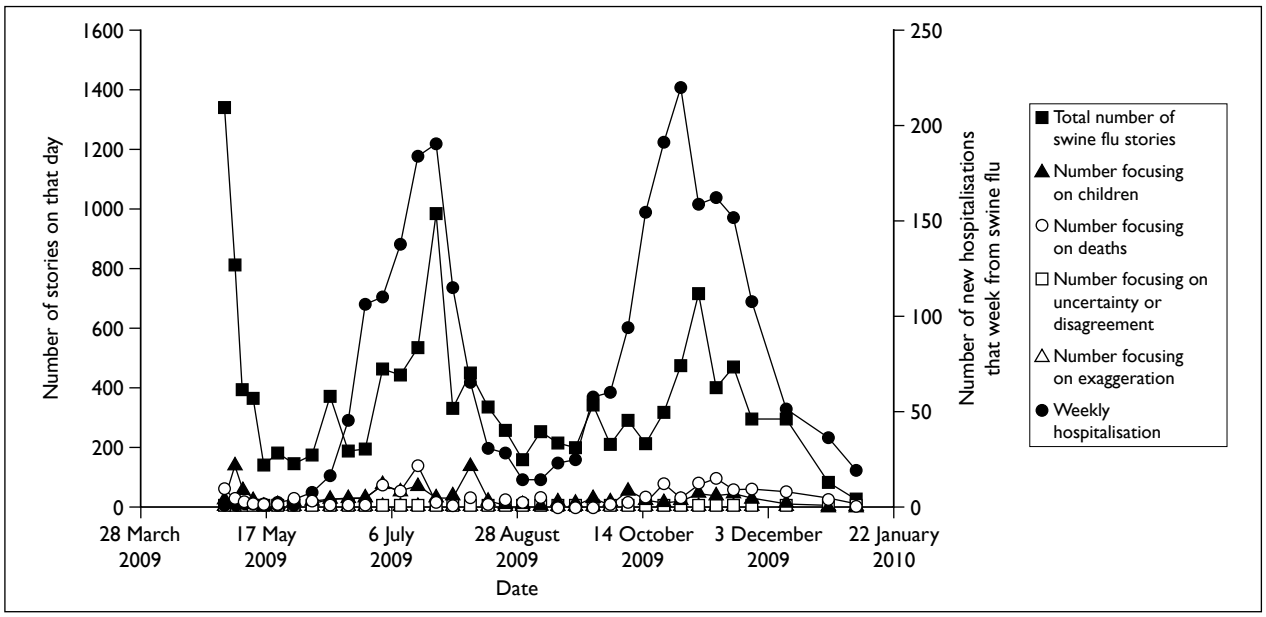

FIGURE 2 *Media reporting and number of new hospitalisations from swine flu.*

TABLE 2 *Associations between survey data and number of hospitalisations from swine flu or media reporting about swine flu*

	No. of new hospitalisations that week from swine flu	Total no. of stories[a]	No. of stories relating to children[a]	No. of stories relating to death[a]
Worry about the possibility of catching swine flu	$\chi^2(1) = 8.2$, $p = 0.004$, coeff. = 0.04	$\chi^2(1) = 6.6$, $p = 0.010$, coeff. = 2.6	$\chi^2(1) = 0.6$, $p = 0.4$, coeff. = 0.0	$\chi^2(1) = 4.3$, $p = 0.038$, coeff. = 1.0
Too much fuss is being made about the risk of swine flu	$\chi^2(1) = 0.3$, $p = 0.6$, coeff. = –0.01	$\chi^2(1) = 0.8$, $p = 0.4$, coeff. = –1.1	$\chi^2(1) < 0.1$, $p = 0.8$, coeff. = 0.1	$\chi^2(1) = 4.7$, $p = 0.030$, coeff. = –1.0
Perceptions of government preparedness	$\chi^2(1) < 0.1$, $p = 0.9$, coeff. = 0.00	$\chi^2(1) = 0.1$, $p = 0.8$, coeff. = 0.3	$^2(1) < 0.1$, $p = 0.9$, coeff. = 0.1	$\chi^2(1) < 0.1$, $p = 0.9$, coeff. = 0.0
Satisfaction with amount of information available	$\chi^2(1) = 0.2$, $p = 0.6$, coeff. = 0.00	$\chi^2(1) = 6.0$, $p = 0.014$, coeff. = –2.0	$\chi^2(1) = 1.4$, $p = 0.2$, coeff. = –0.7	$\chi^2(1) = 1.0$, $p = 0.3$, coeff. = –0.4
How much have you heard about swine flu in the past week?	$\chi^2(1) = 7.7$, $p = 0.006$, coeff. = 0.19	$\chi^2(1) = 0.7$, $p = 0.4$, coeff. = 4.9	$\chi^2(1) = 0.2$, $p = 0.7$, coeff. = –1.1	$\chi^2(1) = 3.0$, $p = 0.083$, coeff. = –4.5

coeff., coefficient.
a Adjusting for number of hospitalisations.

and to death ($\tau_b = 0.51$, $p < 0.001$) were correlated with the total volume of reporting. We investigated this by calculating additional models to test whether adjusting for the total volume of reporting affected the relevant associations shown in *Table 2*. With worry about the possibility of catching swine flu as the dependent variable, adding the number of stories relating to death to a model that already included the total number of stories did not significantly add to the effect [$\chi^2(1) = 1.6$, $p = 0.2$]. Similarly, with perceptions of too much fuss as the dependent variable, adding the number of stories relating to death to a model that already included the total volume of reporting as an independent variable did not significantly improve the model [$\chi^2(1) = 3.8$, $p = 0.053$].

Figure 3 shows changes over time in worry about the possibility of catching swine flu, hospitalisation and the total amount of reporting. On the basis of visual inspection, we split the data into three periods: a first period in which a large volume of media reporting existed but without any substantial spread of swine flu in the community and two further periods reflecting the two peaks of the outbreak (see *Figure 3*). Although there were insufficient data to assess the relevant associations in the first period, the total volume of media reporting was positively associated with worry about the possibility of catching swine flu in the second and third periods (*Table 3*). After adjusting for the number of hospitalisations, however, this association remained only in the second period [$\chi^2(1) = 6.8$, $p = 0.009$, coefficient = 6.9].

Discussion

Our results show that public worry about the possibility of catching swine flu remained at relatively low levels throughout the outbreak. These levels showed some fluctuation, however, and were generally associated with the amount of media reporting about swine flu even after controlling for the potentially confounding influence of the changing nature of the outbreak.

The influence of total volume of reporting

The data relating to the outbreak's summer wave were largely consistent with a theory suggesting that the total volume of reporting plays an important role in predicting levels of public concern.[25] Indeed, across the outbreak as a whole, quantitative changes in more specific aspects of media reporting, such as coverage relating to children or to deaths, were not associated with changes in worry about the possibility of catching swine flu after we adjusted for the severity of the outbreak and for the total volume of reporting. Although previous research has suggested that the personal relevance of a news story is a key factor in determining whether someone will pay attention to it,[42] this lack of effect for specific aspects of reporting held true even for the effects of child-related reporting on participants who had children in their household.

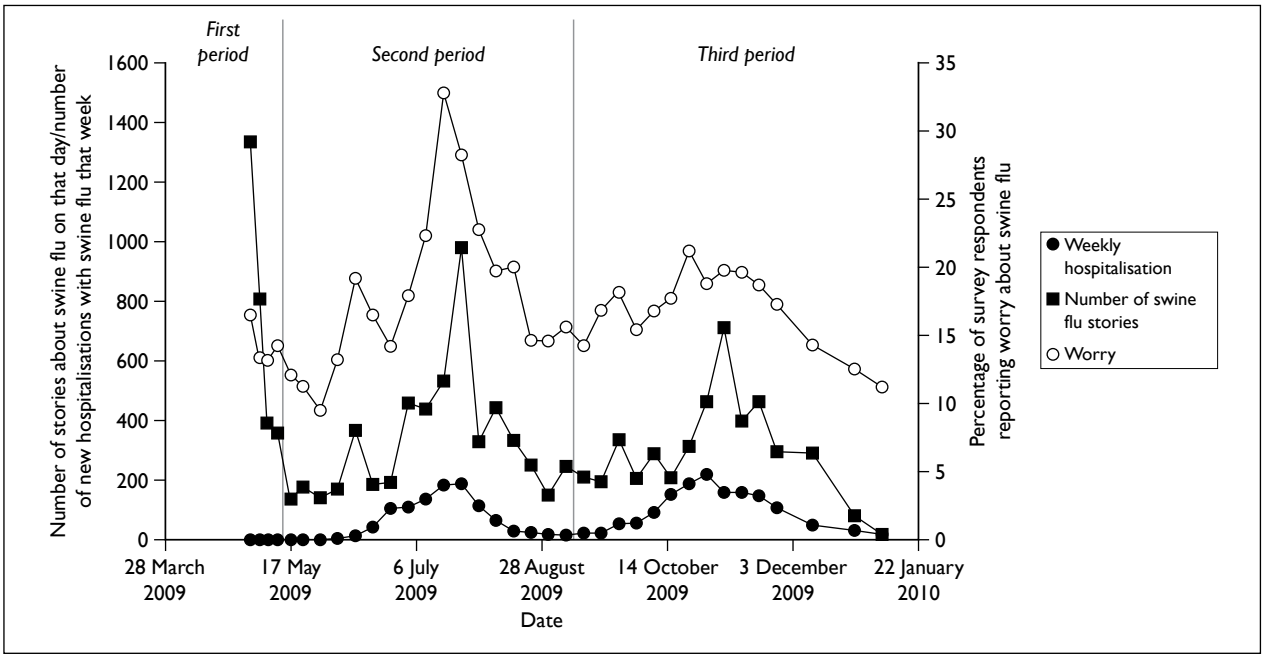

FIGURE 3 *Changes over time for hospitalisations, media reporting and worry.*

This support for the quantity of coverage theory did not hold for every stage of the outbreak, however. In particular, it was notable that the earliest stage of the outbreak had the highest levels of media reporting yet relatively low levels of worry about the possibility of catching swine flu. One possible explanation for the apparent lack of association during this period is that at the time media reporting did not contain many examples of people in the UK being affected by swine flu unless they had some form of contact with the outbreak in Mexico.[43] This may have led many members of the public to conclude that swine flu was unlikely to be a risk to them. Previous research has suggested that a degree of geographical proximity may be required before people feel that a risk applies to them.[44] This may be particularly true for media coverage relating to infectious disease outbreaks, as the UK press has a history of reporting emerging infectious diseases, such as avian influenza, SARS and Ebola fever, which subsequently failed to become a risk to most people in the UK.

Levels of worry about the possibility of catching swine flu during the winter wave of the swine flu outbreak also failed to show any robust association with the total volume of media reporting. In part, this may reflect the fact that by the time the winter wave had arrived, members of the public had already built up a coherent understanding of the illness and of the outbreak, something that additional reporting did little to change. The decreased level of worry during the second wave suggests that the public had become habituated to flu-related messages and/or that their experience had demonstrated that worst-case scenarios had not occurred. It may also be that changes in the nature of the media reporting were responsible for this lack of an association, with a large proportion of the swine flu-related coverage during the winter

TABLE 3 *Association between worry data and total volume of reporting during the summer (period 2) and winter (period 3) waves of the outbreak*

	Total no. of stories	**Total no. of stories[a]**
Worry about the possibility of catching swine flu (period 2)	$\chi^2(1) = 13.1$, $p < 0.001$, coefficient = 11.0	$\chi^2(1) = 6.8$, $p = 0.009$, coefficient = 6.9
Worry about the possibility of catching swine flu (period 3)	$\chi^2(1) = 5.2$, $p = 0.023$, coefficient = 3.2	$\chi^2(1) = 1.4$, $p = 0.2$, coefficient = 1.1

a Adjusting for the number of hospitalisations.

period discussing the risks, benefits and roll-out of the swine flu vaccination rather than the impact of the disease itself.

The influence of key events

Although the total volume of media reporting did not show any clear association with worry about the possibility of catching swine flu during the winter period, examination of where changes in survey data occurred suggested that specific developments in the pandemic, such as the start of the winter wave of infections, the start of the vaccination campaign and discussions about the vaccination of children, did appear to be associated with an increase in the proportions of people who had recently heard information about swine flu and who were worried about the possibility of catching it. Even several months into the pandemic, key events were still able to generate increased concern.

One event that did not seem to trigger an increase in worry about the possibility of catching swine flu was the first death in the UK. This is inconsistent with reports from other countries.[45] It is possible than any genuine effect of this event was masked by a greater effect produced by the World Health Organization's statement that a full pandemic had begun 4 days previously. Alternatively, any effect of the first death may have subsided over the 4-day interval which occurred before data collection began for the next survey wave. Other notable events that might be expected to trigger increased worry, such as the UK's first case of swine flu, the move by the World Health Organization to phase 5 of its pandemic alert system, and the first case of swine flu in the UK resulting from transmission within the community, occurred either before or on the start date of the first survey, preventing us from examining their effects.

Changes in non-worry variables

Aside from worry about the possibility of catching swine flu and the amount of information heard about swine flu, the other survey data were notable for their relative stability. Satisfaction with the amount of information available about swine flu and belief that the government was well prepared for a pandemic showed little fluctuation and remained at relatively high levels throughout. It may be that this stability reflected the general lack of worry about the outbreak, which restricted any fluctuation in these variables to the minority of people who were worried. With little motivation to actively seek out information, it makes sense that most people were satisfied with the amount of information available to them. It is also understandable that most people were not overtly critical of governmental preparedness for a swine flu pandemic, given that they themselves did not believe swine flu to be particularly concerning. Perceptions that too much fuss had been made were also relatively stable, although some reductions that coincided with the summer and winter waves of the outbreak were observed. The relative stability of this variable suggests that this perception was determined by factors that were not readily amenable to change, for example an already established scepticism regarding the credibility of health warnings issued by the media or the government.[46]

Methodological limitations

Several methodological limitations should be borne in mind when considering these results:

- First, and most importantly, because they were based on aggregate data, our analyses ran the risk of falling prey to the ecological fallacy.[47] While our results indicate that periods of high reporting tended to coincide with high levels of worry about the possibility of catching swine flu among the community, this does not necessarily imply that the same correlations existed on an individual level.
- Second, our measures of the quantity of media reporting were not ideal. It is likely that we missed some coverage, particularly for news stories that were broadcast on television or radio. Many of these stories will not have been catalogued by the database we used for our searches. Given that television and radio are widely used, this will have reduced the accuracy of our media measures. We were also unable to produce a metric to represent the amount that each story had been viewed, listened to or read. This would have resulted in a more accurate estimate of the effect of media coverage than simply calculating the total number of stories present on any given day. A more detailed content analysis of reporting by specific UK newspapers, coupled with individual-level data on the newspaper-reading habits of the survey participants, will allow a more fine-grained analysis to be conducted at a later date.
- Third, our use of hospitalisation data as an objective marker of outbreak severity was limited. As well as being influenced by the number of people with swine flu, this measure may also have been affected by changes in

doctor and patient behaviour as a result of changing information, perceptions or concerns about the illness.[48] However, alternative measures, such as the volume of calls to a telephone helpline or the number of GP consultations relating to influenza-like illness, were even more likely to be affected by levels of worry in the community,[7,45] whereas the number of deaths from swine flu were too low to be a useful marker.

- Fourth, the power of our analyses was restricted by the number of surveys that we were able to include. In particular, this may have had implications for those analyses that were restricted to data collected during the winter period of the outbreak. These analyses were based on only 12 surveys.
- Fifth, the generalisability of our findings to other countries or other, more severe, outbreaks cannot be assumed. It is conceivable, for example, that at higher levels of threat and worry, the association between media coverage and worry might disappear, or even reverse. Similarly, in situations where media reporting diverges more dramatically from the official government position, it is possible that media reporting will have a larger impact on levels of uncertainty or worry among the public. Cross-cultural difference in terms of patterns of media use or perceptions of the trustworthiness of the media may also limit the generalisability of our findings.

Conclusions

Despite these methodological caveats, our results suggest that once a new risk has arrived in a country, the volume of media reporting about it will help to determine changes in the level of concern among members of the public. Once the risk has become more familiar, however, this association may be weakened. Given that worry about a risk is an important factor that motivates people to take protective actions[13] and that the use of recommended protective actions can fade over time during an infectious disease outbreak,[49] maintaining a degree of public concern about a new risk might be an important medium-term strategy for public health bodies that wish to promote the use of particular protective behaviours. Our results imply that attempting to influence the volume of media reporting about a new risk may become a less productive way of achieving this as public familiarity with the risk grows. Nonetheless, the occurrence of key events may continue to trigger increased levels of worry and, potentially, uptake of protective behaviours, even several months after a new risk has emerged.

In terms of the aspects of media reporting that might be the most important to engage with or monitor in any future infectious disease outbreak, our results suggest that the traditional news media remain the source most used by the public in obtaining information about public health incidents. About 75% of survey respondents who had heard anything about swine flu reported having heard this information via local or national newspapers, television or radio. In comparison, despite a growing interest in the use of the internet to convey information to the public,[50] only 8% of the public reported having seen information on the internet. While 70% of UK households have internet access,[51] there is clearly some way to go before this can become the main route of information transmission between the government and the public during a public health emergency.

Chapter 3

Study 2: Factors predicting likely acceptance of vaccination against swine or seasonal flu

Key points

- Within the UK, vaccination against swine flu was restricted to specific priority groups. Although wider vaccination of the general public was discussed, it was never implemented.
- Analysis of survey data collected prior to the start of the swine flu vaccination campaign suggested that only 56.1% of the general population were likely to have accepted the vaccine if offered it. Strong predictors for being likely to accept it were being worried about the possibility of personally catching swine flu, or being worried about the possibility of one's children catching it, and disagreeing that too much fuss had been made about the risk of swine flu. Predictors for being more likely to accept the seasonal flu vaccine as a result of swine flu were similar, but also included the misperception that the seasonal flu vaccine would protect against swine flu.
- If a vaccine needs to be given to the general public during a future infectious disease outbreak, messages that highlight people's concerns or worries about the outbreak may be effective in improving uptake. Communications that emphasise the effectiveness of the vaccine in protecting against the disease are also likely to be effective.

Introduction

Within the UK, vaccination against swine flu began to be provided to priority groups from 21 October 2009. These groups consisted of frontline health and social care staff, people in clinical at-risk groups for seasonal influenza, pregnant women and household contacts of people with compromised immune systems. Other members of the public were also considered for vaccination at a later date,[52] although this policy was never put into practice. At the time, efforts to increase the uptake of the seasonal flu vaccine were also renewed.[53]

Maximising the uptake of either vaccine would have reduced the health and economic impact of influenza during the pandemic,[54] but it is unclear what uptake rates would have been possible. In the UK, uptake of the seasonal flu vaccine for people aged 65 or over was 74.1% in 2008, close to World Health Organization targets;[55] whether the focus on swine flu during 2009 increased this rate is currently uncertain. Given that swine flu was a relatively mild illness for most people, it is possible that had the swine flu vaccine been offered to the general public, its uptake would have been relatively low.[56,57] Furthermore, while confidence in the government's handling of the outbreak appears to have been high[35] and might be expected to have improved compliance with official recommendations concerning vaccination,[58] the perception by some members of the public that journalists, scientists and other commentators had overexaggerated the risks of swine flu may have partly counteracted this effect.[35,59]

Specific perceptions concerning the nature of the swine flu outbreak may also have affected desire for vaccination. For example, research conducted during the SARS outbreak of 2003 suggested that changes in media reporting relating to the incidence, prevalence and location of cases had an effect on levels of anxiety and other health-related behaviours.[9,19,60] Although the impact of mass media campaigns on vaccine uptake has previously been documented,[20,61] few studies have assessed whether the way in which an infectious disease outbreak is reported or perceived affects desire for vaccination.[21]

In this study, we analysed data from the telephone surveys commissioned by the Department of Health, England to identify variables associated with the 2009 swine flu outbreak that might encourage people to receive vaccination. We assessed the extent to which worry about the possibility of catching swine flu, perceptions of government preparedness for swine flu and perceiving that too much fuss had been made about the risk of swine flu predicted self-reported likelihood of accepting an offer of vaccination against swine flu. We also assessed whether the amount and type of information heard about swine flu, and satisfaction with the amount of information

available predicted likely uptake. Because we were also interested in whether the 2009 outbreak might encourage people to receive the seasonal flu vaccine, we assessed whether any of these variables were associated with a self-reported increase in the likelihood of accepting the offer of vaccination against seasonal flu as a result of swine flu.

Methods

The surveys

Twenty of the telephone surveys contained relevant data for these analyses. These surveys were conducted between 8 May 2009 and 13 September 2009. Their sample sizes varied between 1047 and 1070.

Likely vaccine uptake

Likely uptake of the swine flu vaccine was measured in five surveys conducted between 14 August and 13 September 2009. Participants were asked: 'The government announced recently that a swine flu vaccination programme will be rolled out across the UK starting this autumn. How likely, if at all, are you to take up a swine flu vaccination if offered it?' Possible answers were 'very likely', 'fairly likely', 'not very likely' and 'not at all likely'. These were divided into 'likely' and 'not likely' for our analyses.

Likely uptake of the seasonal flu vaccine was measured in all 20 surveys from 8 May to 13 September. Participants were asked whether they agreed or disagreed that 'as a result of swine flu, I am now more likely to get the regular winter flu jab'. Possible answers were 'strongly agree', 'tend to agree', 'neither agree nor disagree', 'tend to disagree' and 'strongly disagree'. For our analyses, responses were dichotomised into 'agree' versus 'disagree'. Because the question would have been hypothetical for some respondents, particularly those who would not usually expect to be offered the seasonal flu vaccine, we felt that responses of 'neither agree nor disagree' might have indicated either a participant's uncertainty about being vaccinated or the fact that they did not feel the question was applicable to them. Rather than conflate these two groups, we chose to exclude responses of 'neither agree nor disagree'.

Worry and perceptions

All participants were asked 'How worried, if at all, would you say you are now about the possibility of personally catching swine flu?' Possible answers were 'very worried', 'fairly worried', 'not very worried' or 'not at all worried'. In four surveys (conducted from 21 August to 13 September), parents of children aged under 16 years were also asked how worried they were about the possibility of their child or children catching swine flu. Participants in all surveys were asked 'How well prepared do you think the government is for a swine flu pandemic? Would you say very well, fairly well, not very well, or not at all well prepared?' They were also asked whether they agreed or disagreed that 'Too much fuss is being made about the risk of swine flu.' Finally, in six surveys (7 August to 13 September), participants were asked whether they, or anyone they knew, had caught swine flu.

Information heard about swine flu

Participants in eight surveys (24 July–13 September) were asked 'How much have you heard about swine flu in the past week?', with possible responses being 'a great deal', 'a fair amount', 'not very much' and 'nothing at all'. Those who had heard anything were asked to describe what they had heard. We categorised responses to this open-ended item as relating to: increased number of deaths; increased number of new cases; decreased number of new cases; information about vaccines or priority groups for vaccination; information about antiviral drugs or hygiene measures; and suggestions that the number of cases would rise later in the year. Three true or false items were included relating to vaccines or immunity: 'Currently, there is no vaccine to protect against swine flu' (true: 14 surveys, 8 May–2 August), 'If swine flu breaks out, most people will have some natural immunity to it' (false: three surveys, 8–17 May) and 'The ordinary flu vaccine will protect me from swine flu' (false: 14 surveys, 8 May–2 August). All participants were asked about their satisfaction with the amount of information available to them about swine flu ('very satisfied', 'fairly satisfied', 'neither satisfied nor dissatisfied', 'fairly dissatisfied', 'very dissatisfied').

Personal and health-related variables

Personal data collected included: gender, age, social grade,[38] working status, ethnicity, parental status and household size (the number of adults or children living at home, including self). For ethnicity, although 16 categories were included, the sample sizes for many of our analyses prevented

us from comparing between these categories. We therefore separated the 16 categories into 'white' and 'ethnic minority' groups. All participants were asked whether their health in general was very good or good, fair, or poor or very poor, and whether they had any 'long-standing illness, disability or infirmity'. Participants were also asked in which region of the UK they lived.

Analyses

We used binary logistic regressions to calculate the univariate associations between personal and health-related variables and likely uptake of vaccination. We calculated a second set of regressions for each personal or health-related variable, which adjusted for the effects of all other personal or health-related variables. In order to assess whether coming from a region that had been heavily affected by the outbreak affected these associations, we recalculated these regressions using data from participants who lived only in England and adjusting for whether a participant lived in one of the two regions of England with the highest prevalence rates of swine flu (London and the West Midlands).[41] This did not noticeably alter any of the aORs and is not discussed further.

We used two sets of binary logistic regressions to assess the univariate associations between other variables and likely uptake of vaccination, and to assess the multivariate associations adjusting for those personal or health-related variables that were found to have significant univariate associations with the outcome measure.

Finally, in order to assess the potential role of worry in mediating any of the effects that we identified, we calculated another set of logistic regressions for any variable that showed a significant multivariate association with vaccination uptake, including worry about the possibility of personally catching swine flu as one of the variables for which we adjusted.

We maximised the statistical power for these analyses by combining data from all surveys that included the relevant questions. As different questions were used in different weeks, the sample sizes for each analysis differed. While the frequencies for individual variables obtained for these surveys changed over time, we assumed that the associations between variables would remain constant. In order to check this, we identified three periods during the data collection period that, we judged, might be qualitatively different in terms of public perceptions relating to swine flu. Two periods (May to July and August to mid-September) reflected relatively low levels of activity in media reporting, internet searches in the UK for the phrase swine flu[62] and GP consultations for influenza like-illnesses.[41] The other period (July to August) reflected higher activity in all three parameters. For any univariate analysis that drew on data from two or more of these periods, we calculated the equivalent odds ratios (ORs) for that analysis using only the individual surveys closest to the midpoints of the respective periods. Wald tests were used to compare the regression coefficients obtained for these individual surveys. Six associations were found to differ significantly over time (data not shown). In all cases but one, these differences reflected relatively small changes in the strength of the association. An association between ethnicity and being more likely to accept the seasonal flu vaccine as a result of swine flu appeared to display larger changes over time. Plotting the relevant OR from each individual survey over time showed no readily interpretable pattern.

In all analyses, we counted responses of 'don't know', 'unsure' or 'neither agree nor disagree' as missing data: such responses typically had low frequencies for the predictor variables. For six surveys in which the relevant question was asked (7 August 2009 to 13 September 2009), we excluded participants who reported that they had already had swine flu (2–3% of participants in each survey).

Results

Likely vaccine uptake

Out of 5175 eligible respondents questioned between 14 August 2009 and 13 September 2009, 1642 (31.7%) reported being very likely to accept the swine flu vaccine if offered it, 1263 (24.4%) were fairly likely, 1005 (19.4%) were not very likely and 1074 (20.8%) were very unlikely; 191 (3.7%) said they did not know. Out of 20,999 eligible participants interviewed between 8 May and 13 September, 3506 (16.7%) strongly agreed that as a result of swine flu they were now more likely to get the seasonal flu vaccine, 2700 (12.9%) tended to agree, 3219 (15.3%) neither agreed nor disagreed, 5865 (27.9%) tended to disagree and 5475 (26.1%) strongly disagreed; 234 respondents (1.1%) did not know.

Association with personal and health-related variables

Tables 4 and *5* show the association between personal or health-related variables and vaccine-related outcomes. After adjusting for all other personal or health-related variables, the following groups reported being most likely to accept the swine flu vaccine if offered it: participants aged 16–24 (aOR versus those aged 65 or more: 1.6, 95% CI 1.1 to 2.4); people from ethnic minority groups (aOR 1.9, 95% CI 1.4 to 2.5); people from households of six individuals or more (aOR versus those who lived alone: 2.1, 95% CI 1.2 to 3.6); people who rated their health as fair (aOR versus those with good or very good health: 1.4, 95% CI 1.1 to 1.7); and people with long-standing illnesses or disabilities (aOR 1.5, 95% CI 1.3 to 1.7). The same groups also reported being more likely to accept the seasonal flu vaccine as a result of swine flu. In addition, participants aged 65 or more, people from social groups C2DE (that is, manual or unskilled workers, or those dependent on state welfare),[38] and participants who rated their health as poor or very poor were also more likely to accept the seasonal flu vaccine (see *Table 5* for ORs).

Association with worry and perceptions

Controlling for personal and health-related factors, the following variables were associated with being more likely to accept the swine flu vaccine if offered it (*Table 6*): having higher levels of worry about the possibility of your child catching swine flu (aOR 8.0, 95% CI 4.6 to 13.9); having higher levels of worry about the possibility of personally catching swine flu (aOR 4.7, 95% CI 3.2 to 7.0); disagreeing that too much fuss had been made about the risk of swine flu (aOR 2.2, 95% CI 1.9 to 2.7); perceiving the government to be well prepared for swine flu (aOR 1.6, 95% CI 1.3 to 1.8); and knowing someone who had had swine flu (aOR 1.2, 95% CI 1.0 to 1.3). All of these variables except for perceptions about government preparedness and knowing someone who had had swine flu were associated with being more likely to accept the seasonal flu vaccine as a result of swine flu (*Table 7*).

Association with information heard about swine flu

Tables 8 and *9* show the associations between information heard about the outbreak and likely vaccine uptake. Adjusting for personal and health-related variables, only two variables were associated with being more likely to accept the swine flu vaccine if offered it: being satisfied with the amount of information available about swine flu (aOR 1.5, 95% CI 1.2 to 1.9) and having recently heard that the number of deaths from swine flu had increased (aOR 1.3, 95% CI 1.0 to 1.6). Once personal variables and health were controlled for, only satisfaction with the amount of information available about swine flu (aOR 1.5, 95% CI 1.1 to 2.0) and believing that the seasonal flu vaccine would protect against swine flu (aOR 2.4, 95% CI 2.1 to 2.7) were associated with being more likely to get the seasonal flu vaccine as a result of swine flu.

Adjusting for worry about the possibility of catching swine flu

Controlling for worry about the possibility of personally catching swine flu did not substantially alter the strength of association for any of the significant non-worry-related predictor variables (results not shown), other than reducing to insignificance for the predictor 'having heard that the number of deaths from swine flu had increased' (aOR 1.0, 95% CI 0.6 to 1.6).

Discussion

The usefulness of vaccination as a means of reducing the overall impact of influenza depends on the willingness of members of the public to be vaccinated.[54] At the time of our data collection (14 August to 13 September 2009), only 56.1% of respondents reported being likely to accept the swine flu vaccination if offered it. While this figure may have altered following the start of the Department of Health's vaccine-related communications campaign, this pre-campaign baseline suggests that ample scope existed for interventions to improve uptake. Our identification of demographic and psychological predictors for increased likelihood of accepting both swine and seasonal flu vaccines suggests possible ways of developing effective communication campaigns in future, and suggests that the same messages delivered as part of a single vaccine-related communications campaign may be effective in improving the uptake of both types of vaccine.

By far the strongest predictors were worry about the possibility of personally catching swine flu and, for parents, worry about a child catching swine flu. Similar associations between emotional and behavioural responses to an infectious disease outbreak have been observed before.[35,60,63] Focusing on the more worrying aspects of catching flu, be

TABLE 4 *Association between personal or health variables and being likely to take up swine flu vaccine*

Variable levels	*n* (%)	*n* (%) likely to accept vaccine	OR (95% CI)	aOR (95% CI)[a]
Sex				
Female	2957 (59.3)	1747 (59.1)	1.1 (1.0 to 1.2)	1.1 (1.0 to 1.3)
Male	2027 (40.7)	1158 (57.1)	Reference	Reference
Age – years				
16–24	435 (8.7)	308 (70.8)	1.5 (1.2 to 1.9)	1.6 (1.1 to 2.4)
25–34	578 (11.6)	360 (62.3)	1.0 (0.8 to 1.3)	1.2 (0.8 to 1.6)
35–54	11,677 (33.6)	884 (52.7)	0.7 (0.6 to 0.8)	0.7 (0.5 to 1.0)
55–64	927 (18.6)	511 (55.1)	0.8 (0.6 to 0.9)	0.8 (0.7 to 1.1)
≥65	1367 (27.4)	842 (61.6)	Reference	Reference
Social grade				
C2DE	2225 (44.6)	1334 (60.0)	1.1 (1.0 to 1.3)	1.0 (0.9 to 1.1)
ABC1	2759 (55.4)	1571 (56.9)	Reference	Reference
Working status				
Housewife	241 (4.8)	143 (59.3)	1.2 (0.9 to 1.5)	1.0 (0.7 to 1.4)
Unemployed	173 (3.5)	106 (61.3)	1.3 (0.9 to 1.7)	1.0 (0.7 to 1.5)
Retired	1633 (32.8)	985 (60.3)	1.2 (1.1 to 1.4)	1.0 (0.8 to 1.3)
Student	242 (4.9)	162 (66.9)	1.6 (1.2 to 2.1)	0.9 (0.6 to 1.3)
Other (including disabled)	167 (3.4)	102 (61.1)	1.3 (0.9 to 1.7)	1.0 (0.7 to 1.5)
Working full or part-time	2528 (50.7)	1407 (55.7)	Reference	Reference
Ethnicity				
Other ethnicity	357 (7.2)	260 (72.8)	2.0 (1.6 to 2.6)	1.9 (1.4 to 2.5)
White	4627 (92.8)	2645 (57.2)	Reference	Reference
Parental status				
Has child 16 years or under	947 (23.9)	529 (55.9)	0.9 (0.8 to 1.1)	1.0 (0.8 to 1.2)
Has older child or no children	3022 (76.1)	1730 (57.2)	Reference	Reference
Household size				
Six people or more	97 (2.0)	73 (75.3)	2.1 (1.3 to 3.4)	2.1 (1.2 to 3.6)
Three to five people	1660 (33.5)	978 (58.9)	1.0 (0.9 to 1.2)	1.1 (0.9 to 1.4)
Two people	1802 (36.4)	1017 (56.4)	0.9 (0.8 to 1.0)	0.9 (0.8 to 1.1)
One person	1395 (28.2)	823 (59.0)	Reference	Reference
General health status				
Poor or very poor	350 (7.0)	231 (66.0)	1.5 (1.3 to 1.8)	1.1 (0.9 to 1.5)
Fair	766 (15.4)	507 (66.2)	1.5 (1.2 to 1.9)	1.4 (1.1 to 1.7)
Very good or good	3855 (77.5)	2159 (56.0)	Reference	Reference
Does participant have any long-standing infirmity or illness?				
Yes	1477 (29.7)	960 (65.0)	1.5 (1.3 to 1.7)	1.5 (1.3 to 1.7)
No	3496 (70.3)	1938 (55.4)	Reference	Reference

a Adjusting for all other personal or health-related variables.

TABLE 5 *Association between personal or health variables and being more likely to get seasonal flu vaccine as a result of swine flu*

Variable levels	*n* (%)	*n* (%) more likely to accept vaccine	OR (95% CI)	aOR (95% CI)[a]
Sex				
Female	10,283 (58.6)	3720 (36.2)	1.1 (1.0 to 1.2)	1.0 (0.9 to 1.2)
Male	7263 (41.4)	2486 (34.2)	Reference	Reference
Age – years				
16–24	1584 (9.0)	649 (41.0)	0.5 (0.5 to 0.6)	0.7 (0.5 to 1.1)
25–34	2082 (11.9)	517 (24.8)	0.3 (0.2 to 0.3)	0.4 (0.3 to 0.6)
35–54	5982 (34.1)	1269 (21.2)	0.2 (0.2 to 0.2)	0.3 (0.2 to 0.4)
55–64	3219 (18.3)	1109 (34.5)	0.4 (0.4 to 0.4)	0.5 (0.4 to 0.7)
≥65	4679 (26.7)	2662 (56.9)	Reference	Reference
Social grade				
C2DE	7773 (44.3)	3497 (45.0)	2.1 (2.0 to 2.3)	1.5 (1.3 to 1.7)
ABC1	9773 (55.7)	2709 (27.7)	Reference	Reference
Working status				
Housewife	773 (4.4)	269 (34.8)	1.8 (1.5 to 2.1)	1.1 (0.7 to 1.6)
Unemployed	701 (4.0)	247 (35.2)	1.8 (1.6 to 2.2)	1.2 (0.8 to 1.8)
Retired	5547 (31.6)	2989 (53.9)	4.0 (3.7 to 4.2)	1.1 (0.9 to 1.5)
Student	837 (4.8)	359 (42.9)	2.5 (2.2 to 2.9)	1.2 (0.8 to 1.9)
Other (including disabled)	636 (3.6)	277 (43.6)	2.6 (2.2 to 3.1)	1.2 (0.8 to 1.9)
Working full or part-time	9052 (516)	2065 (22.8)	Reference	Reference
Ethnicity				
Other ethnicity	1277 (7.3)	585 (45.8)	1.6 (1.4 to 1.8)	2.5 (1.9 to 3.4)
White	16,269 (92.7)	5621 (34.6)	Reference	Reference
Parental status				
Has child 16 years or under	832 (24.7)	216 (26.0)	0.6 (0.5 to 0.7)	1.0 (0.7 to 1.2)
Has older child or no children	2542 (75.3)	959 (37.7)	Reference	Reference
Household size				
Six people or more	378 (2.2)	169 (44.7)	1.0 (0.8 to 1.3)	2.2 (1.3 to 3.4)
Three to five people	5801 (33.3)	1565 (27.0)	0.5 (0.4 to 0.5)	1.0 (0.8 to 1.3)
Two people	6295 (36.1)	2266 (36.0)	0.7 (0.7 to 0.8)	0.9 (0.7 to 1.1)
One person	4944 (28.4)	2160 (43.7)	Reference	Reference
General health status				
Poor or very poor	1338 (7.7)	719 (53.7)	2.6 (2.3 to 2.9)	1.5 (1.2 to 1.9)
Fair	2733 (15.6)	1316 (48.2)	2.1 (1.9 to 2.3)	1.5 (1.2 to 1.9)
Very good or good	13,422 (76.7)	4145 (30.9)	Reference	Reference
Presence of any long-standing infirmity or illness				
Yes	5264 (30.1)	2428 (46.1)	1.9 (1.8 to 2.1)	1.3 (1.0 to 1.5)
No	12,224 (69.9)	3756 (30.7)	Reference	Reference

a Adjusting for all other personal or health-related variables.

TABLE 6 *Association between psychological variables and being more likely to take up swine flu vaccine if offered it*

Variable levels	*n* (%)[a]	*n* (%) likely to accept vaccine	Unadjusted OR (95% CI)	aOR (95% CI)[b]
Worry about self catching swine flu				
Very worried	177 (3.6)	143 (80.8)	5.1 (3.5 to 7.5)	4.7 (3.2 to 7.0)
Fairly worried	624 (12.6)	498 (79.8)	4.8 (3.9 to 5.9)	4.9 (4.0 to 6.2)
Not very worried	1916 (38.6)	1233 (64.4)	2.2 (1.9 to 2.5)	2.3 (2.0 to 2.6)
Not at all worried	2246 (45.3)	1014 (45.1)	Reference	Reference
Worry about child catching swine flu				
Very worried	180 (19.1)	148 (82.2)	9.7 (5.7 to 16.4)	8.0 (4.6 to 13.9)
Fairly worried	301 (32.0)	187 (62.1)	3.4 (2.2 to 5.3)	3.3 (2.1 to 5.3)
Not very worried	328 (34.8)	149 (45.4)	1.7 (1.1 to 2.7)	1.7 (1.1 to 2.7)
Not at all worried	133 (14.1)	43 (32.3)	Reference	Reference
Too much fuss is being made about the risk of swine flu				
Disagree	1351 (29.8)	952 (70.5)	2.1 (1.9 to 2.4)	2.2 (1.9 to 2.5)
Agree	3178 (70.2)	1679 (52.8)	Reference	Reference
How well prepared is the government for swine flu?				
Well prepared	3423 (75.4)	2100 (61.3)	1.4 (1.2 to 1.6)	1.6 (1.3 to 1.8)
Not well prepared	1118 (24.6)	590 (52.8)	Reference	Reference
Has anyone you know been ill with swine flu?				
Yes	1600 (32.1)	976 (61.0)	1.2 (1.0 to 1.3)	1.2 (1.0 to 1.3)
No	3384 (67.9)	1929 (57.0)	Reference	Reference

a Responses of 'don't know', 'not sure' or 'not applicable' excluded.
b Adjusting for age, working status, social grade, ethnicity, household size, general health status and chronic illness.

they financial, social or health, may be one way of increasing vaccination rates. However, it should be noted that this will depend on the baseline level of worry in any population and that there are individual differences, so that increasing worry may have negative consequences for some members of the population. At the levels of worry present during this pandemic outbreak, messages intended to reassure people about the risks from swine flu are unlikely to have a positive impact on vaccine uptake.

Conversely, perceiving that too much fuss had been made about the risk of swine flu was associated with decreased likelihood of accepting either form of vaccine. This corresponds well with earlier work showing that people who felt that the risks from swine flu were being exaggerated were less likely to adopt recommended behaviours such as increased hand-washing.[35] From a policy perspective, no easy short-term answer exists to this. Providing an appropriate level of warning and advice to members of the public while not being perceived as 'making too much fuss' is inevitably difficult.[64] At a minimum, giving sufficient assurances to the public that the necessary plans and resources are in place to deal with the situation does appear to be helpful, with respondents who expressed confidence in government preparedness being more likely to accept vaccination.

Consistent with studies that have previously examined how information provision that specifically relates to a particular vaccine can affect its uptake,[20,61,65,66] this study identified the importance of vaccine-specific information. We found an association between believing, incorrectly, that the seasonal flu vaccine is effective against swine flu and being more likely to accept the seasonal flu vaccine as a result of swine flu. Less research has assessed the effects of information about the course of an infectious disease outbreak on desire for vaccination, although at least one study has suggested that media reporting about

TABLE 7 *Association between psychological variables and being more likely to get seasonal flu vaccine as a result of swine flu*

Variable levels	*n* (%)[a]	*n* (%) more likely to accept vaccine	Unadjusted OR (95% CI)	aOR (95% CI)[b]
Worry about self catching swine flu				
Very worried	714 (4.1)	441 (61.8)	4.0 (3.4 to 4.7)	4.5 (3.0 to 6.9)
Fairly worried	2372 (13.6)	1203 (50.7)	2.6 (2.3 to 2.8)	3.2 (2.5 to 4.1)
Not very worried	6835 (39.1)	2359 (34.5)	1.3 (1.2 to 1.4)	1.8 (1.5 to 2.1)
Not at all worried	7544 (43.2)	2154 (28.6)	Reference	Reference
Worry about child catching swine flu				
Very worried	164 (19.8)	79 (48.2)	5.3 (2.9 to 9.5)	3.4 (1.8 to 6.4)
Fairly worried	257 (31.0)	67 (26.1)	2.0 (1.1 to 3.5)	1.7 (0.9 to 3.1)
Not very worried	289 (34.8)	51 (17.6)	1.2 (0.7 to 2.2)	1.1 (0.6 to 2.0)
Not at all worried	120 (14.5)	18 (15.0)	Reference	Reference
Too much fuss is being made about the risk of swine flu				
Disagree	6398 (39.6)	2479 (38.7)	1.3 (1.2 to 1.4)	1.5 (1.3 to 1.8)
Agree	9776 (60.4)	3255 (33.3)	Reference	Reference
How well prepared is the government for swine flu?				
Well prepared	12,221 (73.9)	4309 (35.3)	1.0 (0.9 to 1.0)	1.2 (1.0 to 1.4)
Not well prepared	4308 (26.1)	1554 (36.1)	Reference	Reference
Has anyone you know been ill with swine flu?				
Yes	1583 (31.6)	518 (32.7)	0.8 (0.7 to 0.9)	0.9 (0.8 to 1.1)
No	3425 (68.4)	1327 (38.7)	Reference	Reference

a Responses of 'don't know', 'not sure' or 'not applicable' excluded.
b Adjusting for sex, age, working status, social grade, ethnicity, parental status, household size, general health status and chronic illness.

the unexpected severity of a flu outbreak played a larger role in driving uptake of the vaccine than vaccine-specific reporting.[21] Several studies have suggested that media reporting about features of an outbreak, such as the number of cases or deaths, might influence key health behaviours.[9,19,60,67] However, we found no evidence to suggest that how much people had heard about swine flu in the past week affected likely vaccine uptake or that specific aspects of what they had heard had any substantial impact. The only exception was a weak association between having heard that the number of deaths from swine flu had increased recently and greater likelihood of accepting the swine flu vaccine. Given the large number of statistical tests we calculated, it is possible that this solitary finding reflects a type 1 error rather than a genuine effect.

One explanation for this discrepancy between our findings concerning the role of receiving information about the outbreak and those of previous studies[9,19,60,67] is that information may have a different effect on vaccine intentions depending on the stage of the outbreak. While the spread of information during the study period had no impact on likely vaccine uptake, stronger associations might have been observed earlier in the swine flu outbreak when members of the public were less certain about the transmission or nature of the illness. By the time of our study, it is possible that most members of the public had already formed a stable understanding of the severity and prevalence of swine flu and the most effective ways of preventing it, which additional information did little to alter.

The role of personal variables

Several personal variables were found to predict greater likelihood of vaccine uptake. Those people in groups prioritised to be offered the swine flu vaccine first or who are regularly offered the

TABLE 8 *Association between knowledge or beliefs and being likely to take up swine flu vaccine if offered it*

Variable levels	*n* (%)[a]	*n* (%) likely to accept vaccine	Unadjusted OR (95% CI)	aOR (95% CI)[b]
How much have you heard about swine flu this week?				
A great deal	684 (13.7)	388 (56.7)	1.0 (0.8 to 1.2)	1.0 (0.8 to 1.2)
A fair amount	1139 (22.9)	695 (61.0)	1.2 (1.0 to 1.4)	1.2 (1.0 to 1.4)
Not very much	1939 (39.0)	1131 (58.3)	1.1 (0.9 to 1.2)	1.1 (0.9 to 1.3)
Nothing at all	1215 (24.4)	687 (56.5)	Reference	Reference
How satisfied are you with the amount of information available?				
Satisfied	4024 (90.9)	2437 (55.0)	1.4 (1.1 to 1.7)	1.5 (1.2 to 1.9)
Not satisfied	403 (9.1)	212 (52.6)	Reference	Reference
What have you heard?				
Number of cases increased				
Heard	454 (12.3)	290 (63.9)	1.3 (1.0 to 1.6)	1.2 (1.0 to 1.5)
Not heard	3243 (87.7)	1882 (50.9)	Reference	Reference
Number of cases decreased				
Heard	740 (20.0)	1767 (59.8)	0.8 (0.7 to 1.0)	0.9 (0.7 to 1.0)
Not heard	2957 (80.0)	405 (54.7)	Reference	Reference
Number of deaths increased				
Heard	370 (10.0)	238 (64.3)	1.3 (1.0 to 1.6)	1.3 (1.0 to 1.6)
Not heard	3327 (90.0)	1934 (58.1)	Reference	Reference
Anything about vaccination				
Heard	375 (10.1)	228 (60.8)	1.1 (0.9 to 1.4)	1.1 (0.9 to 1.4)
Not heard	3322 (89.9)	1944 (58.5)	Reference	Reference
Anything about antiviral agents or hygiene				
Heard	433 (11.7)	258 (59.6)	1.0 (0.8 to 1.3)	1.0 (0.8 to 1.3)
Not heard	3264 (88.3)	1914 (58.6)	Reference	Reference
Number of cases will rise later in year				
Heard	153 (4.1)	84 (54.9)	0.8 (0.6 to 1.2)	1.0 (0.7 to 1.4)
Not heard	3544 (95.9)	2088 (58.9)	Reference	Reference

a Responses of 'don't know', 'not sure' or 'not applicable' excluded.
b Adjusting for age, working status, social grade, ethnicity, household size, general health status and chronic illness.

seasonal flu vaccine reported being more likely to accept either (e.g. those with long-standing illnesses, worse general health or aged 65 years and over). People from social groups C2DE (manual or unskilled workers, or those dependent on state welfare),[38] ethnic minority groups or large households were also found to be more likely to be willing to accept vaccination. The explanation for higher likely uptake in these groups is unclear. While adjusting for worry about the possibility of catching swine flu did not alter the associations, other variables that we did not measure, such as a stronger tendency to follow health advice or less concern about potential side effects,[68] may be relevant.

Methodological issues

Three methodological issues in particular should be borne in mind with this study. First, as is common in research of this type, the need for data to be collected quickly in order to inform policy meant that conventional epidemiological methods involving random probability sampling and attempts to recontact initial non-responders could not be used.[11] Instead, rapid-turnaround telephone

TABLE 9 *Association between knowledge or beliefs and being more likely to get seasonal flu vaccine as a result of swine flu*

Variable levels	*n* (%)[a]	*n* (%) more likely to accept vaccine	Unadjusted OR (95% CI)	aOR (95% CI)[b]
How much have you heard about swine flu this week?				
A great deal	1665 (24.7)	603 (36.2)	1.0 (0.9 to 1.2)	0.9 (0.7 to 1.2)
A fair amount	1862 (27.6)	791 (42.5)	1.3 (1.1 to 1.5)	1.0 (0.8 to 1.3)
Not very much	2080 (30.8)	743 (35.7)	1.0 (0.9 to 1.2)	0.9 (0.7 to 1.1)
Nothing at all	1145 (17)	410 (35.8)	Reference	Reference
How satisfied are you with the amount of information available?				
Satisfied	14,337 (89.6)	5154 (35.9)	0.9 (0.8 to 1.0)	1.5 (1.1 to 2.0)
Not satisfied	1656 (10.4)	644 (38.9)	Reference	Reference
There is no vaccine for swine flu				
True	5873 (50.4)	1963 (33.4)	0.9 (0.9 to 1.0)	0.9 (0.8 to 1.0)
False	5774 (49.6)	2013 (34.9)	Reference	Reference
Most people have some natural immunity to swine flu				
True	1501 (62.8)	451 (30.0)	1.2 (1.0 to 1.5)	1.2 (1.0 to 1.5)
False	889 (37.2)	231 (26.0)	Reference	Reference
The ordinary flu vaccine will protect me from swine flu				
True	1787 (15.6)	966 (54.1)	2.7 (2.5 to 3.0)	2.4 (2.1 to 2.7)
False	9636 (84.4)	2903 (30.1)	Reference	Reference
What have you heard?				
Number of cases increased				
Heard	1215 (22.0)	470 (38.7)	1.0 (0.9 to 1.1)	1.1 (0.8 to 1.5)
Not heard	4297 (78.0)	1631 (38.0)	Reference	Reference
Number of cases decreased				
Heard	809 (14.7)	282 (34.9)	0.8 (0.7 to 1.0)	0.9 (0.7 to 1.1)
Not heard	4703 (85.3)	1819 (38.7)	Reference	Reference
Number of deaths increased				
Heard	765 (13.9)	303 (39.6)	1.1 (0.9 to 1.3)	1.2 (0.9 to 1.6)
Not heard	4747 (86.1)	1798 (37.9)	Reference	Reference
Anything about vaccination				
Heard	459 (8.3)	164 (35.7)	0.9 (0.7 to 1.1)	1.0 (0.7 to 1.4)
Not heard	5053 (91.7)	1937 (35.1)	Reference	Reference
Anything about antiviral agents or hygiene				
Heard	680 (12.3)	244 (35.9)	0.9 (0.8 to 1.1)	1.0 (0.8 to 1.4)
Not heard	4832 (87.7)	1857 (33.7)	Reference	Reference
Number of cases will rise later				
Heard	169 (3.1)	49 (29.0)	0.7 (0.5 to 0.9)	1.0 (0.6 to 1.5)
Not heard	5343 (96.9)	2052 (38.4)	Reference	Reference

a Responses of 'don't know', 'not sure' or 'not applicable' excluded.
b Adjusted for sex, age, working status, social grade, ethnicity, parental status (if available), household size, health status and chronic illness.

surveys with quota sampling were used to ensure that the eventual samples were demographically representative of the UK population. Inevitably, this meant that the response rates for these surveys were low, although not unusually low.[35,39,40] Whether participants were psychologically representative of the general population is uncertain.

Second, while we have speculated about potential causal links between the predictor and outcome measures, the data that we have relied on are correlational. It is possible that some third variable, such as general civic-mindedness or trust in the government, could have been responsible for some of the associations that we identified. Experimental studies are required to confirm the causal nature of the associations that we found.

Third, given the number of statistical tests that we conducted it is possible that some of the significant associations that we identified were type 1 errors. However, given the correlated nature of our predictor variables, applying a Bonferroni correction to our results would have been too conservative. It is therefore appropriate to consider those results that achieved only marginal significance as exploratory.

Conclusions

If uptake of vaccines is to be encouraged during this or any future pandemic, communication campaigns should focus on factors shown to be associated with intended uptake. Our results suggest that, while providing information that relates to the outbreak is unlikely to increase uptake, messages that highlight people's concerns and worries about the illness in question may be effective. In addition, highlighting the efficacy of vaccination may also be an effective way to increase uptake. In this study, people who incorrectly believed that the seasonal flu vaccine would be effective against swine flu were more likely to say that they would accept it.

Chapter 4

Study 3: The effects of advertising and media coverage on behavioural change during the early stages of the swine flu outbreak

Key points

- During the early stages of the swine flu outbreak, government communications focused on encouraging people to adopt specific respiratory and hand hygiene behaviours in order to reduce the spread of swine flu. People were also encouraged to use remote facilities to access NHS advice if they were concerned that they might have swine flu. Other behaviours, such as avoiding public transport, were not encouraged.
- Telephone surveys conducted between 1 and 17 May 2009 suggested that 33.1% of the public were carrying tissues with them as advised, 9.5% had bought sanitising hand gel to help clean their hands, 2.0% had avoided public transport and 1.6% had visited a GP or hospital or called NHS Direct for flu-related reasons.
- Path analyses suggested that exposure to advertising and media coverage about swine flu was associated with performance of these four behaviours and that they had broadly similar effects. Exposure to either advertising or media coverage appeared to promote the carrying of tissues and purchasing of sanitising gel, and discourage avoidance of public transport or unnecessary use of NHS services. These effects partly occurred because exposure to both advertising and media coverage increased the perceived efficacy of hygiene-related behaviours and decreased the perceived efficacy of avoidance-related behaviours.
- In future outbreaks, messages that emphasise the efficacy of recommended behaviours may help to promote their uptake, without promoting the uptake of other behaviours.

Introduction

Immediately after the emergence of swine flu, the UK government launched a major advertising campaign to encourage people to engage in a set of behaviours intended to reduce the effects of the outbreak. This campaign included a leaflet that was sent to every household in the country and extensive television, radio, internet, print and poster advertising.[69] The campaign conveyed basic facts about swine flu, provided information about the government's level of preparedness, and stressed the importance of using and disposing of tissues for coughs and sneezes, and regularly cleaning hands with soap and water or sanitising gel. In order to reduce the spread of swine flu, people who had just returned from an affected country and who had developed flu-like symptoms were asked to stay at home, to check their symptoms using an internet site or an automated telephone system, and to telephone their GP or NHS Direct, a national telephone advice line 'if [they had] taken these steps and [were] still concerned'.[69] These messages were reinforced by commercial advertising for tissues, hand sanitisers and other products, which regularly repeated the official hygiene slogan of 'Catch it, Bin it, Kill it'.

At the time that this campaign began, traditional news media and internet sources devoted large amounts of coverage to the unfolding events. While some commentators accused the media of 'scaremongering',[70] others[36,37] noted that 'the mass media coverage of the H1N1 outbreak has […] been balanced and rational'.[36]

The extensive advertising and media coverage during this initial period of the pandemic might have influenced people's behaviour through several mechanisms. For example, levels of worry about a disease outbreak, perceptions about how effective preventative measures are and perceptions about how well the government is coping can all affect how people behave in response to a disease outbreak.[35,56,58,63] Similarly, how much a person thinks they know about a given hazard, their satisfaction with how much they know and how well informed they actually are might also help to determine whether or not people feel at risk and what, if any, action they decide to take.

These mechanisms are consistent with a literature review of the determinants of protective behaviours during a pandemic, and with several explanatory models of how people react to a health threat, for example the Protection Motivation Theory and the Health Belief Model.[71]

In practice, what impact the advertising and media coverage actually had on behavioural change, and via what mechanism, is unknown. In this study we tested the association between exposure to advertisements or media coverage during the first 3 weeks of the swine flu outbreak and four self-reported behaviours. Two of these behaviours were encouraged by the government's advertisements: namely carrying tissues and buying sanitising gel. A third behaviour, avoiding public transport, represented a preventative strategy known to be used by some members of the public[35] but was not specifically recommended. The fourth behaviour, contacting the health services for a flu-related reason, was discouraged except for rare cases of flu-like illness among travellers returning from an affected country. However, GPs and NHS Direct both reported a sharp increase in consultation rates for influenza-like illness during May 2009.[41,72] We also assessed several potential mediators between exposure to advertising or media coverage and behaviour: knowledge about swine flu, the perceived efficacy of various preventative behaviours, perceptions about the government's level of preparedness for a pandemic and levels of worry about the possibility of catching swine flu.

Methods

Design

The first five cross-sectional telephone surveys commissioned by the Department of Health, England contained data that were relevant to these analyses. These surveys began data collection on 1 May 2009 and ended on 17 May 2009. Sample sizes for each varied between 1058 and 1173.

Behavioural outcomes

Respondents were asked 'Have you done any of the following since the beginning of the swine flu outbreak?' Eleven behaviours were specified, of which three were analysed here. These were 'carried tissues with me', 'bought antibacterial gel' and 'avoided using public transport'.

Respondents were also asked whether they had been to see a GP, visited a hospital, called NHS Direct or the Swine Flu Information Line or visited www.nhs.uk for flu-related issues in the last 2 weeks. Participants who reported having visited their GP or a hospital or having called NHS Direct (or a related telephone service for Northern Irish, Scottish or Welsh participants) because of flu-related issues were counted as health-care users.

Exposure to advertising and media coverage

Participants were asked whether they recalled having seen or heard any advertising or media coverage on the subject of swine flu and, if so, where. Responses were categorised as relating to media coverage or advertising.

Information-related variables

Participants were asked how much they had heard about swine flu, with responses dichotomised into 'a lot or a moderate amount' versus 'a little or nothing at all'. Perceived knowledge was assessed by asking 'how much do you think you know about swine flu' with responses dichotomised as 'a lot or a moderate amount' versus 'a little or nothing at all'. Participants were asked how satisfied or dissatisfied they were with the amount of information available to them about swine flu, from any source; responses to this item were dichotomised as 'very satisfied or fairly satisfied' versus 'fairly or very dissatisfied'. A middle option ('neither satisfied nor dissatisfied') was excluded from our analyses. Participants were also asked what additional information they would like to receive about swine flu, with responses grouped thematically and categorised as 'wanting additional information' and 'does not want additional information'. To assess actual knowledge, six true or false statements were presented, with responses summed to produce a knowledge score of 0–6. The statements were: 'currently, there is no vaccine to protect against swine flu' (true); 'there are ways to help slow the spread of swine flu' (true); 'if swine flu breaks out, it is likely that most people will have some natural immunity to it' (false); 'the ordinary flu vaccine will protect me from swine flu' (false); 'it is possible to catch swine flu from eating pork' (false); 'thousands of people worldwide have died from swine flu' (false). Finally, participants were asked to state how well prepared they thought the government was for a swine flu pandemic, with responses dichotomised as 'very well prepared or fairly well prepared' versus 'not very well prepared or not at all well prepared'.

Worry about the possibility of catching swine flu

A single item asked participants to state how worried, if at all, they were about the possibility of personally catching swine flu. Responses were dichotomised into 'very worried or fairly worried' versus 'not very or not at all worried'.

Efficacy of preventative actions

Participants were asked to rate eight actions on a scale from 1 ('it will make no difference at all') to 10 ('it is vital') in terms of how effective it would be in preventing the spread of swine flu. The eight actions were: 'washing hands frequently with soap and water', 'covering nose and mouth with a tissue when sneezing and coughing', 'disposing of dirty tissues promptly and carefully in a bin or bag', 'avoiding non-essential travel whenever possible', 'avoiding large crowds whenever possible', 'cleaning hard surfaces such as kitchen worktops and door handles frequently', 'getting the yearly flu jab' and 'wearing a surgical/hygienic facemask'. Factor analysis using principal axis factoring and direct oblimin rotation suggested that two factors were present in the data, accounting for 57.8% of the variance. The first factor, which we labelled 'hygiene efficacy', was loaded on by hand-washing, use of tissues, disposal of tissues and cleaning hard surfaces. The second factor, 'avoidance efficacy', was loaded on by avoidance of crowds and avoidance of public transport. Scores on these factors were calculated by taking the mean score for the relevant items. Neither the yearly flu jab item nor the surgical facemask item loaded on either factor. These items were dropped from subsequent analyses. Because scores on the hygiene and avoidance efficacy scales were skewed, we dichotomised them, based around the median score for each scale.

Personal variables

Personal data collected included: gender, age, social grade,[38] ethnicity and household size. Participants were asked whether their health in general was very good or good, fair, or poor or very poor, and whether they had any 'long-standing illness, disability or infirmity'.

Analyses

We assessed univariate associations between the categorical predictor variables and the four behavioural outcomes using binary logistic regressions adjusting for all personal or health-related variables. In order to assess whether coming from a region that had been heavily affected by the outbreak affected the associations between exposure to advertising or media coverage and any of the four outcome variables, we recalculated these regressions using only data from participants who lived in England and adjusting for whether a participant lived in one of the two regions of England with the highest prevalence rates of swine flu (London and the West Midlands).[41] This did not noticeably alter any of the aORs and is not discussed further. We assessed univariate associations between the actual knowledge score and each outcome variable using *t*-tests.

We hypothesised pathways linking exposure to media coverage or advertising and behaviour (*Figure 4*). We hypothesised that personal variables would predict exposure to advertising or media coverage. We further hypothesised that exposure to advertising or media coverage would predict the information-related variables, which, in turn, would predict the worry- and efficacy-related variables. The behavioural outcomes were placed at the end of this causal chain. We assumed that any of the variables might be directly influenced by any other variable at the same level as it in *Figure 4*, or at any of the preceding levels. In order to test this path diagram, each information, worry, efficacy and behaviour variable was used as a dependent variable in a binary logistic regression or multiple regression, as applicable. These regressions used any variables at the same or preceding levels as predictor variables. Associations that were identified as significant at $p < 0.05$ were plotted on a revised path diagram.

We chose not to use structural equation modelling to analyse the path diagrams. Structural equation modelling is appropriate as a confirmatory technique when one is able to specify a model. Here, we were limited by the variables available to us and did not expect to be able to specify a complete model. We thus took a more exploratory approach and the results should be interpreted in that context.

Results

In total, 5419 people took part in the surveys: 1793 (33.1%) reported carrying tissues with them, 513 (9.5%) reported having bought sanitising gel, 111 (2.0%) reported avoiding public transport and 88 (1.6%) reported having visited a GP or hospital or phoning NHS Direct for flu-related reasons.

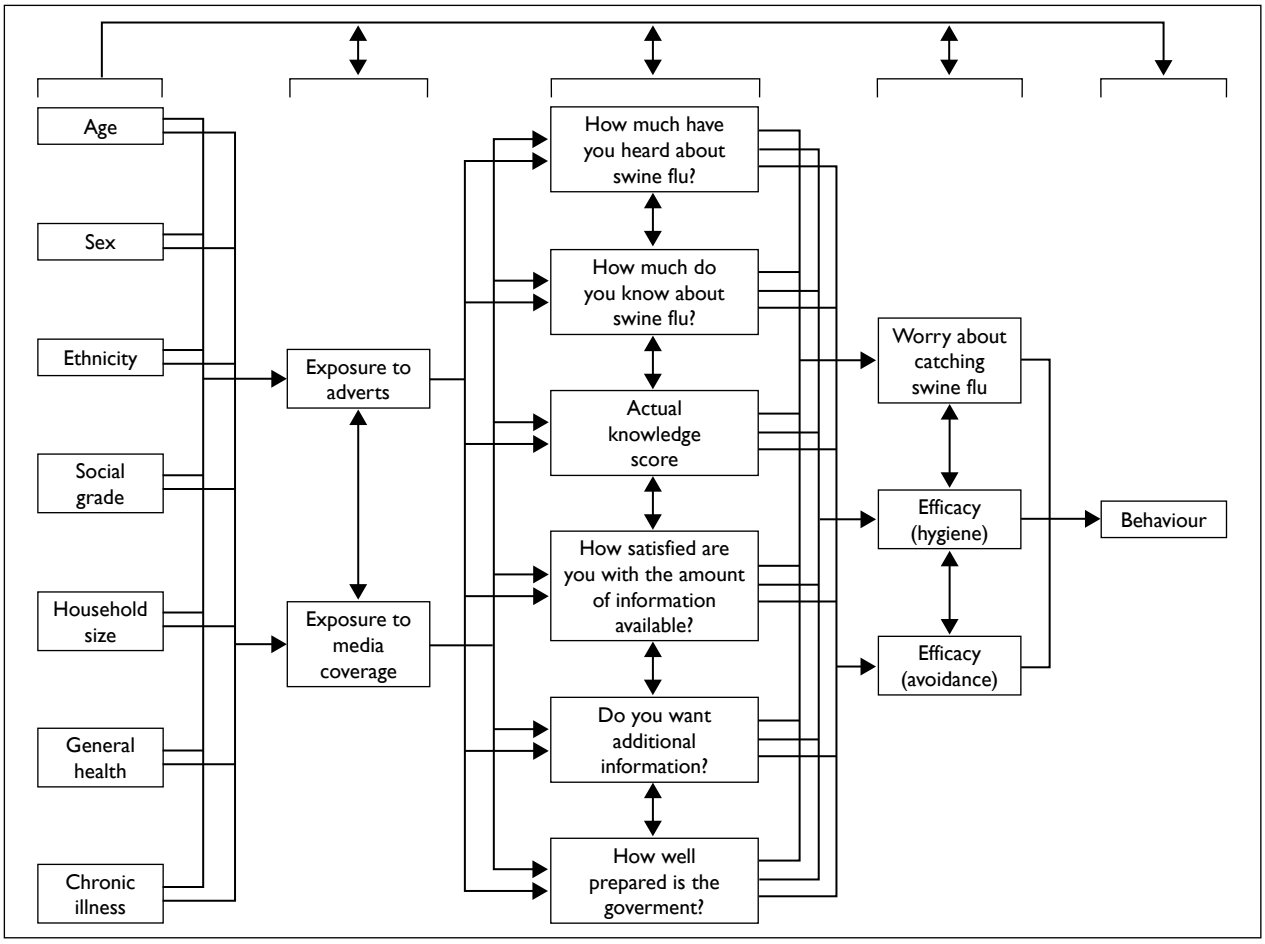

FIGURE 4 *Input path diagram specifying the hypothesised pathways between exposure to advertising or media coverage and behaviour. Each variable may have been predicted by any other variable from the same level or from any preceding level of the diagram.*

Personal characteristics

Tables 11–14 in Appendix 4 show the association between each personal characteristic and the four behavioural outcomes. Adjusting for all other personal variables, women (aOR 2.1, 95% CI 1.8 to 2.3), ethnic minority participants (aOR 1.8, 95% CI 1.4 to 2.3) and participants with poor or very poor health compared with those with good or very good health (aOR 1.3, 95% CI 1.02 to 1.7) were more likely to carry tissues, whereas those aged 25–34 (aOR 0.7, 95% CI 0.6 to 0.9) or 35–54 (aOR 0.8, 95% CI 0.7 to 0.96) were less likely than those aged 65 or more to carry tissues.

Women (aOR 2.4, 95% CI 2.0 to 3.0), participants aged 16 to 54 (aOR 95% CIs for these three categories ranged from 1.2 to 3.4), ethnic minority participants (aOR 1.5, 95% CI 1.1 to 2.0), participants from households of two or more people (aOR 95% CIs for these three categories ranged from 1.02 to 3.5) and participants with poor or very poor health (aOR 1.6, 95% CI 1.1 to 2.4) were more likely have bought sanitising hand gel. Participants from ethnic minority groups (aOR 4.1, 95% CI 2.5 to 6.8) and those with poor or very poor health (aOR 2.6, 95% CI 1.3 to 5.1) were more likely to have avoided public transport. People from ethnic minority groups (aOR 2.2, 95% CI 1.2 to 4.2), those from households of six people or more (aOR 3.3, 95% CI 1.2 to 9.1) and people with poor or very poor health (aOR 2.6, 95% CI 1.3 to 5.5) were more likely to have visited a GP or hospital or to have telephoned NHS Direct for flu-related reasons.

Exposure to advertising and media coverage

Overall, 4167 participants (76.9%) reported having seen media coverage of swine flu, while 2735 (50.5%) reported having seen advertising relating to swine flu. *Tables 15–18* in Appendix 4 show the associations between exposure to advertising or media coverage and each behavioural outcome.

Adjusting for personal variables, participants who had been exposed to advertising were more likely to have carried tissues (aOR 1.2, 95% CI 1.05 to 1.3), to have bought sanitising hand gel (aOR 1.4, 95% CI 1.2 to 1.7) and were less likely to have avoided public transport (aOR 0.7, 95% CI 0.4 to 0.99). Participants exposed to media coverage were less likely to have contacted a GP, hospital or NHS Direct for flu-related reasons (aOR 0.6, 95% CI 0.4 to 0.9).

Information about swine flu

A total of 4817 people (92.9%) had heard a lot or a moderate amount about swine flu, 3808 (73.6%) felt they knew a lot or a moderate amount about swine flu, and 4462 (91.0%) were very or fairly satisfied with the amount of information available about swine flu, while 1998 (36.9%) still had one or more specific pieces of information that they wanted to know. *Table 10* shows the specific types of information that they wanted. In total, 4014 participants (78.3%) felt that the government was very or fairly well prepared for a swine flu pandemic. The mean number of correct answers on the six knowledge questions was 4.2 (standard deviation 1.2).

The association between the information-related variables and the behavioural outcomes are given in *Tables 15–18* in Appendix 4. Adjusting for all personal variables, participants who thought that they knew a lot or a moderate amount about swine flu (aOR 1.2, 95% CI 1.03 to 1.4) and those who wanted more information about swine flu (aOR 1.4, 95% CI 1.3 to 1.6) were more likely to carry tissues. Those who wanted more information were also more likely to have bought sanitising hand gel (aOR 1.5, 95% CI 1.3 to 1.9). Participants were less likely to avoid public transport if they thought they had heard a lot or a moderate amount about swine flu (aOR 0.4, 95% CI 0.2 to 0.6), if they thought they knew a lot or a moderate amount about swine flu (aOR 0.6, 95% CI 0.4 to 0.99) or if they were very or fairly satisfied with the amount of information available to them (aOR 0.4, 95% CI 0.2 to 0.7). They were more likely to avoid public transport if they wanted more information (aOR 2.8, 95% CI 1.9 to 4.2).

There were no significant differences in knowledge between participants who had or had not contacted the health services, bought sanitising gel or carried tissues (all p values > 0.09). Avoiding public transport was associated with less knowledge (mean difference 0.4, $t(5417) = 3.8$, $p < 0.001$).

TABLE 10 *Additional information requested by participants about swine flu*

What additional information would you like to receive?	No. of participants (%) ($n = 5415$)[a]
None	3138 (58.0)
Details on symptoms	594 (11.0)
Advice on prevention	440 (8.1)
Advice on treatment	417 (7.7)
Wants to receive the Government leaflet	212 (3.9)
Regular/up-to-date updates	156 (2.9)
Outbreaks in local area	124 (2.3)
Advice for people who might need more tailored information, such as those with pre-existing conditions	112 (2.1)
Availability of medicine/vaccine	69 (1.3)
How any affected/where	69 (1.3)
Travel advice	58 (1.1)
How it is spread	50 (0.9)
What other countries are doing	34 (0.6)
Other	607 (11.2)
Don't know	281 (5.2)

a Four participants had missing data.

Worry about the possibility of catching swine flu

In total, 757 participants (14.0%) reported being very or fairly worried about the possibility of catching swine flu. Adjusting for personal variables, worry was significantly associated with carrying tissues (aOR 1.7, 95% CI 1.5 to 2.0), buying sanitising gel (aOR 2.3, 95% CI 1.9 to 2.9), avoiding public transport (aOR 4.1, 95% CI 2.7 to 6.2) and contacting health-care services for flu-related reasons (aOR 2.3, 95% CI 1.4 to 3.4).

Response efficacy

Median efficacy scores were 6 (interquartile range 4.0 to 8.0) for the avoidance efficacy scale and 9 (7.75 to 10.0) for the hygiene efficacy scale. Participants who perceived avoidance measures to be highly effective were more likely to have avoided public transport (aOR 4.1, 95% CI 2.5 to 6.8) and to have carried tissues (aOR 1.2, 95% CI 1.1 to 1.4). Those who perceived hygiene measures to be highly effective were more likely to have carried tissues (aOR 1.6, 95% CI 1.4 to 1.8) and to have bought sanitising gel (aOR 1.8, 95% CI 1.5 to 2.2).

Path analyses

Figures 5–8 show the significant associations identified within our path diagrams. These associations adjusted for all personal variables and for all predictor variables at the same or preceding levels as in *Figure 4*. The initial stages of each figure are identical. Overall, exposure to advertising or media coverage was associated with believing hygiene behaviours to be more effective. According to the path diagram, this was the result of higher perceived knowledge about swine flu and increased satisfaction with the amount of information available about swine flu, together with greater perceptions of government preparedness, and a direct effect of exposure to advertising. In contrast, exposure to advertising or media coverage was associated with believing avoidance behaviours to be less effective. For exposure to advertising, this was due to a direct effect, whereas for exposure to media coverage the effect was due to increased satisfaction with the amount of information available and thus reduced desire for more information. Exposure to either advertising or media coverage reduced worry about the possibility of catching swine flu, with exposure to advertising having this effect by increasing perceived and actual knowledge levels, whereas exposure to media coverage had an effect by increasing satisfaction with the amount of information available and therefore reducing desire for more information.

Extending the pathways to include carrying tissues (*Figure 5*) and buying sanitising gel (*Figure 6*) revealed identical patterns of results. By increasing the perceived efficacy of hygiene behaviours, both exposure to advertising and media coverage increased the likelihood of people engaging in these behaviours. A direct effect of advertising on carrying tissues or buying sanitising gel was also observed. These effects were partly offset by the fact that exposure to advertising or media coverage reduced worry about the possibility of catching swine flu and desire for more information, both of which had positive associations with the two behaviours.

Every pathway leading from exposure to advertising or media coverage tended to reduce avoidance of public transport by reducing worry about the possibility of catching swine flu, increasing the amount heard about swine flu, reducing the perceived efficacy of avoidance measures and reducing the desire for more information (*Figure 7*).

Exposure to advertising or media coverage decreased health-care service use by reducing worry about the possibility of catching swine flu and by a direct effect of exposure to media coverage (*Figure 8*).

Discussion

In the early stages of the swine flu outbreak, the numbers of people in the UK who reported carrying tissues (33.1%) or having bought sanitising hand gel (9.5%) were low, despite both measures having been promoted by the government.[69] These low rates suggest that the government's advertising campaign and the attendant media coverage failed to convince most people to make changes to their daily routine that were intended to reduce the spread of infection. This finding tallies with the results of other studies conducted during this period.[35]

Rates of behaviours that had not been recommended by the government were lower. Only 2.0% of participants reported having avoided public transport, a proportion consistent with that identified by another survey.[35] Although previous outbreaks of an emerging infectious disease have

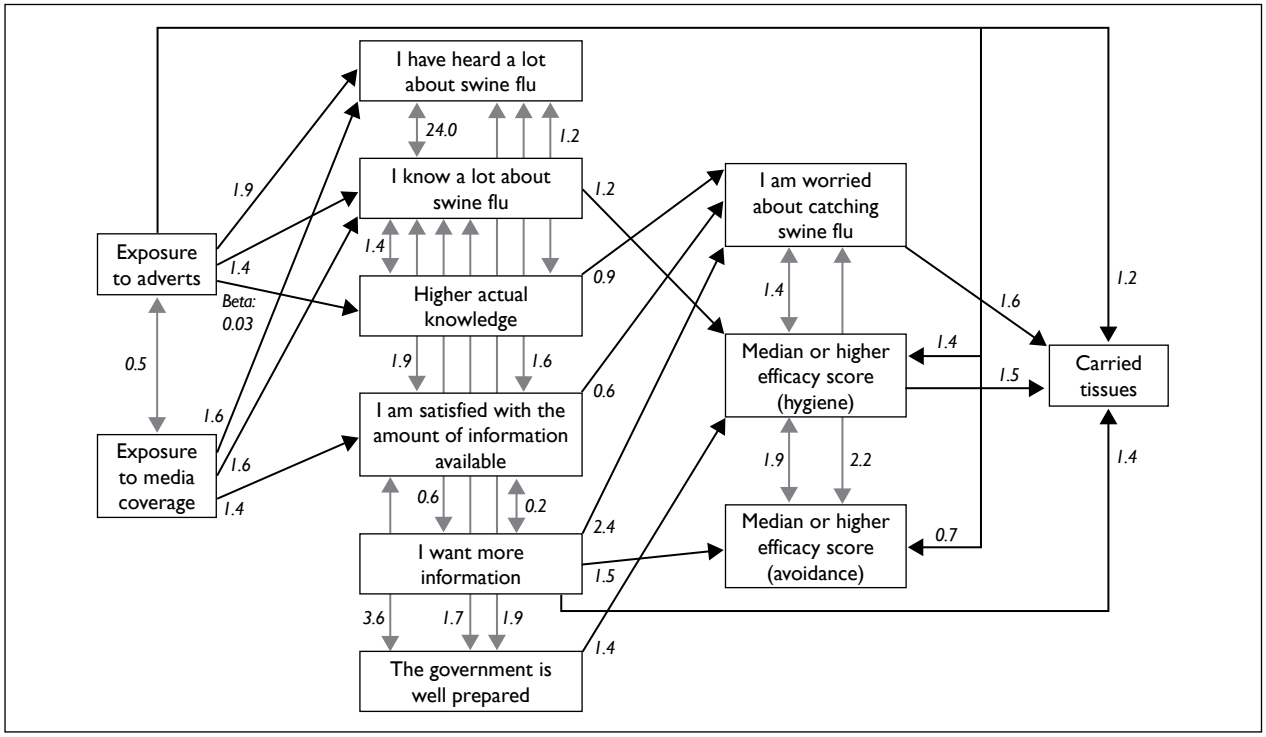

FIGURE 5 *Path diagram showing the significant paths ($p < 0.05$) between the information-related, efficacy and worry variables, and whether participants carried tissues. Unless stated otherwise, all numbers are ORs adjusting for all personal and health-related variables, for all other variables at the same level as the outcome variable and for all other variables at preceding levels. For clarity, significant associations with personal or health-related variables have been omitted.*

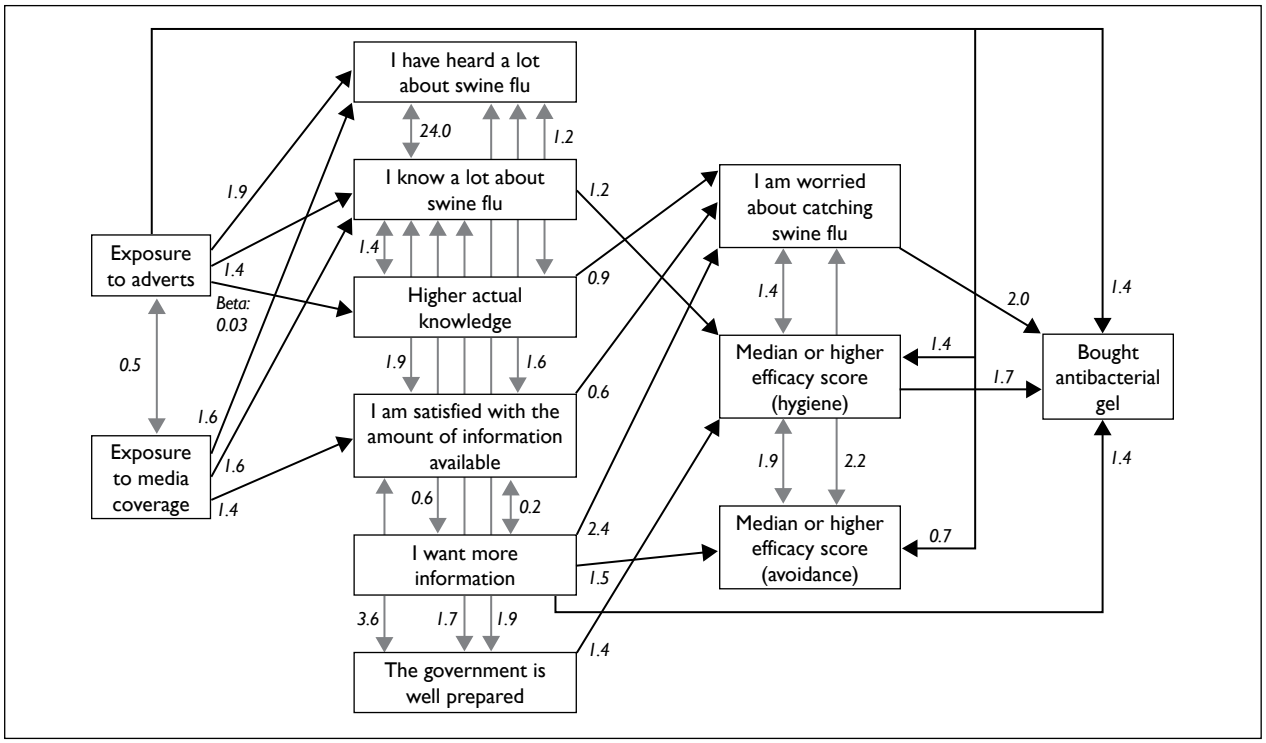

FIGURE 6 *Path diagram showing the significant paths ($p < 0.05$) between the information-related, efficacy and worry variables, and whether participants had bought sanitising ('antibacterial') hand gel. Unless stated otherwise, all numbers are ORs adjusting for all personal and health-related variables, for all other variables at the same level as the outcome variable and for all other variables at preceding levels. For clarity, significant associations with personal or health-related variables have been omitted.*

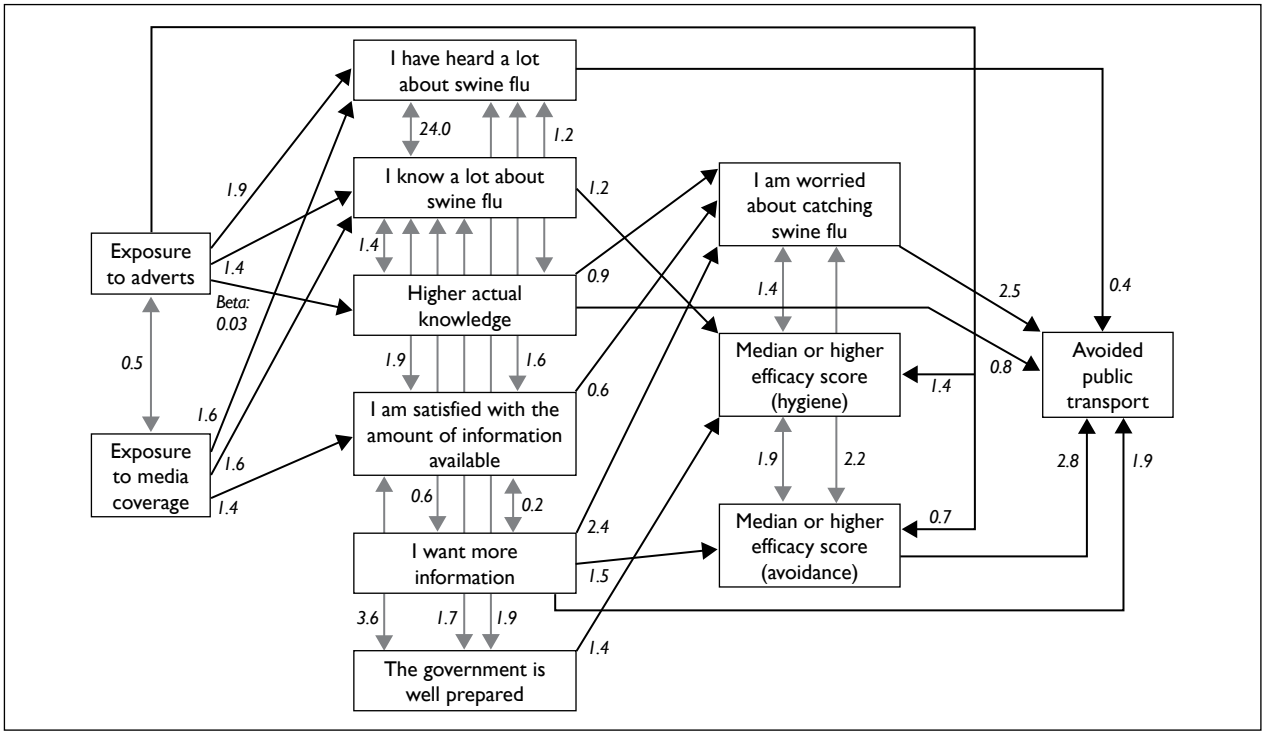

FIGURE 7 *Path diagram showing the significant paths ($p < 0.05$) between the information-related, efficacy and worry variables, and whether participants had avoided public transport. Unless stated otherwise, all numbers are ORs adjusting for all personal and health-related variables, for all other variables at the same level as the outcome variable and for all other variables at preceding levels. For clarity, significant associations with personal or health-related variables have been omitted.*

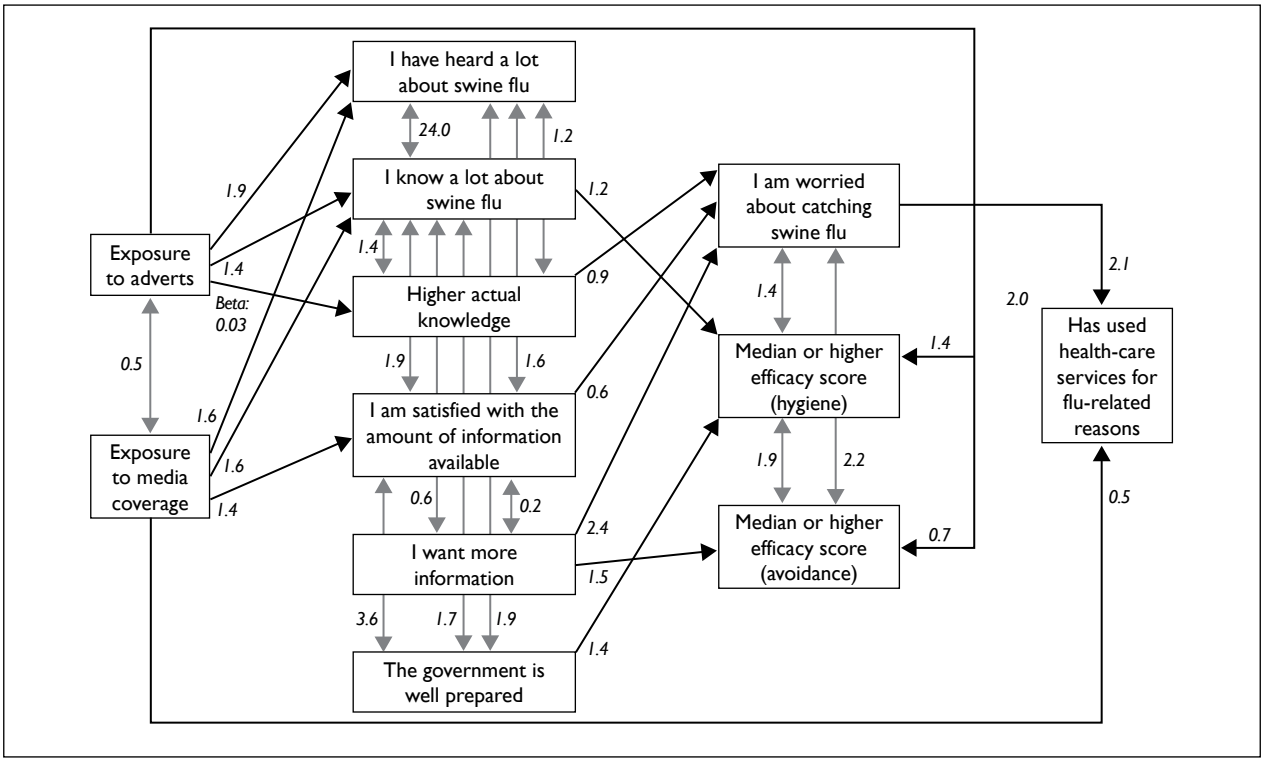

FIGURE 8 *Path diagram showing the significant paths ($p < 0.05$) between the information-related, efficacy and worry variables, and whether participants had contacted the health services for a flu-related reason. Unless stated otherwise, all numbers are ORs adjusting for all personal and health-related variables, for all other variables at the same level as the outcome variable and for all other variables at preceding levels. For clarity, significant associations with personal or health-related variables have been omitted.*

occasionally been accompanied by a high level of avoidant behaviour among members of the public, this did not occur in the UK during the swine flu outbreak. Similarly, only 1.6% of participants reported having visited a GP or hospital or phoning NHS Direct for a flu-related reason. Although small, this proportion reflects a large volume of consultations for the health-care services and is therefore of more concern,[72] particularly as the increase above seasonal norms for flu-related consultations during this period is unlikely to have reflected a genuine increase in rates of infection in the community,[41] and is more likely to have been caused by social or psychological factors.[7]

Our results also suggest that both advertising and media coverage had beneficial effects on people's behaviours, both in terms of increasing recommended behaviours and reducing behaviours that were not recommended. As a result of the direct and indirect pathways identified in our path analyses, exposure to either form of information provision tended to result in increased rates of tissue carrying and purchasing of sanitising gel, and decreased rates of public transport avoidance or health-care use. Only 76.9% of respondents reported having been exposed to any media coverage relating to swine flu, while only 50.5% reported having seen any advertising. While maintaining media interest and increasing the visibility of an advertising campaign requires time and resources, our results suggest that this approach may have a beneficial effect on public behaviour during any future outbreak.[22]

As well as increasing the quantity of advertising or media articles, ensuring that their content reflects factors shown to improve adherence to behavioural recommendations would also be beneficial. Our path analyses suggest two factors that may be particularly relevant. First, worry about the possibility of catching swine flu was an important variable that was associated with increased rates of all of the behaviours that we examined. A link between worry or anxiety and behaviour change has been observed before in the context of the swine flu outbreak.[35,63] According to some psychological models, a degree of fear is an important precondition if someone is to be encouraged to engage in a behaviour designed to protect them from a hazard.[13] However, while a certain amount of public concern may be helpful in any future outbreak, our results suggest that deliberately increasing worry may cause people to adopt both desirable behaviours (e.g. carrying tissues) and undesirable behaviours (e.g. avoiding public transport). Targeting variables that are more specifically associated with recommended behaviours is likely to be preferable.

A second factor suggested by our analyses may provide this more targeted way of encouraging behaviour change. Our path analyses demonstrated that the perceived efficacy of behaviours was associated with their uptake, and that this followed a logical pattern, with the perceived efficacy of hygiene behaviours being associated with tissue carrying and buying sanitising gel, while the perceived efficacy of avoidance behaviours was associated with avoidance of public transport. This finding, which has been observed before,[71] fits with psychological theories of how behaviour change can be brought about in people faced with a potential threat.[13] Importantly, exposure to media coverage or advertising had the effect of increasing the perceived efficacy of hygiene behaviours while decreasing the perceived efficacy of avoidance behaviours. A useful strategy in future outbreaks will be to ensure that advertising and media coverage focus on the efficacy of recommended behaviours, while also highlighting, where relevant, the reasons why other behaviours are not effective.

In addition to effects that were mediated by worry about the possibility of catching swine flu and by perceived efficacy, exposure to advertising also had the direct, unmediated effect of increasing tissue carrying or purchasing of sanitising gel, while exposure to media coverage had a direct effect of reducing health-care use for flu-related reasons. It is likely that the influence of advertising reflects a 'mere exposure' effect, in which higher levels of familiarity with an advertised product result in more favourable attitudes towards it.[73] It is also possible that other variables we did not measure, such as perceptions of the capacity of health-care services, the severity of swine flu, or the mechanisms through which swine flu can be contracted, acted as mediators for these effects.

Our path analyses suggested that the mechanisms linking exposure to media coverage or advertising and behaviour were largely similar. Exposure to either form of information tended to increase knowledge, perceived knowledge and satisfaction with the amount of information available, which then affected levels of worry about the possibility of catching swine flu and perceptions of efficacy, and hence behaviour. The similarity between the effects of media and advertising exposure may reflect the fact that information from the government influenced not only its own advertising, but also

the coverage given to swine flu by the media, with many media stories including information from government briefings or press releases.[36,37] Some differences between the effects of advertising and the effects of media coverage were observed, however. In particular, while the effects of media exposure were largely mediated by the information-related variables that we assessed, advertising had additional effects on perceptions of efficacy and on behaviour that were not mediated by knowledge or information-related perceptions. Additional research to explore the reason for these direct effects is warranted. In terms of practical implications for future outbreaks, it may be that in situations where knowledge or worry are difficult to alter, advertising can still play an important role in producing behaviour change via these other mechanisms.

Methodological issues

In addition to the caveats raised in study 2 concerning the sampling strategy and response rates for these surveys, six methodological issues should be considered with respect to the analyses presented in this study. First, although we specified causal pathways linking our variables, these pathways remain hypothetical. Given the correlational nature of our data, other interpretations are possible. For example, although we specified that exposure to advertising or media coverage would affect information-related variables and that these, in turn, would affect worry, alternative conceptualisations are possible, including a reversal of this pathway[74] or the influence of some other factor that was not measured.

Second, we assumed that the behaviours we assessed were largely driven by the swine flu outbreak. In terms of buying sanitising hand gel and avoiding public transport, this seems a reasonable assumption as these are usually relatively uncommon behaviours. In contrast, it is likely that some of our respondents would have used health-care services for flu-related reasons or would have carried tissues even if the swine flu outbreak had not occurred. This would weaken any association we observed between these outcomes and our predictor variables and thus increase our confidence that the associations we observed for these variables are robust.

Third, the outcome variables that we could include in these analyses were restricted by the questions that were asked in the surveys. The absence of any questions relating to hand-washing presented difficulties. Not only was this one of the behaviours that was most heavily promoted by the government, but also it was also closely tied to communications relating to sanitising hand gel: washing hands or using gel were presented as equally effective alternatives. Had we been able to construct a variable that indicated whether a participant had used sanitising gel or had washed their hands more often than normal as a result of the outbreak, we might have observed a stronger link with media reporting or advertising.

Fourth, because of the need to collect data quickly in order to inform policy, the surveys relied on self-reported behaviour, rather than observed behaviour. The validity of the self-reports of the four outcome measures used in this study is uncertain. For clear-cut behaviours that an individual either has or has not exhibited, such as carrying tissues, having bought sanitising hand gel or speaking to NHS Direct, it is possible that self-reports are reasonably accurate. Avoidance of public transport may be harder for people to quantify, however, as the word 'avoid' may be open to interpretation. The role of social desirability in affecting how participants responded to each of these items is also unclear. Further research on the validity of such self-report measures may help to inform the design of future surveys.

Fifth, we assumed that recall for exposure to advertising and media coverage relating to swine flu was an accurate indicator of actual exposure. However, self-reports for such exposures may be poor, largely as a result of poor memory for exposure to news sources.[75,76] Given that our participants were categorised as having been exposed to media coverage and/or advertising based on their recall of where they had heard information about swine flu, it is likely that some misclassification may have occurred for this variable, potentially blurring any distinction between the effects of media coverage and the effects of advertising.

Finally, our analytical approach assumed that exposure to advertising might be expected to have qualitatively different effects from exposure to media reporting. In practice, during the swine flu outbreak the content of both types of information were largely driven by government communications, either directly, in the case of advertising, or through the influence of press releases, official announcements, quotes from official spokespeople or interviews with

government experts in the case of media coverage. In future incidents, the impact of these two forms of information might differ more dramatically.

Conclusions

During the early stages of the swine flu outbreak, less than one-third of the public complied with official recommendations relating to hygiene behaviours, while the proportions that avoided public transport or approached the health-care services for flu-related advice were even lower. Exposure to media coverage or advertising relating to swine flu was associated with higher uptake of recommended behaviours and lower performance of non-recommended behaviours, largely as a result of changes in the perceived efficacy of these actions. Exposure was also associated with lower rates of worry about the possibility of catching swine flu, contradicting previous suggestions that media coverage during the early stages of the outbreak had been unnecessarily alarmist or scaremongering.[70,77] In future outbreaks, maximising the reach of any advertising campaigns and ensuring that they explicitly mention the efficacy of any recommended behaviours may help to improve public compliance with key recommendations.

Chapter 5
General discussion

Public reactions to the swine flu outbreak

Contrary to speculation that a new influenza pandemic would be accompanied by panic,[43,78] the UK public displayed relatively little concern about swine flu throughout the 10 months covered by our data collection period. Even at the height of the first wave of the outbreak, less than one-third of survey respondents reported being worried about the possibility of catching the disease. For most of the outbreak, this figure fluctuated between 10% and 20%. Similarly, most people did not appear to have made any substantial changes to their daily lives as a result of the outbreak, even when we considered relatively cost-free activities that were being heavily promoted by the government – carrying tissues, for example. Prior to the start of the government's vaccination campaign, willingness to be vaccinated against swine flu was also low, with only 56% of the public saying that they were likely to accept the vaccine if it was offered to them. Meanwhile, perceptions that too much fuss had been made about the risk of swine flu were high, with roughly one-half to two-thirds of respondents endorsing this statement in any given survey.

These results illustrate the challenges that can be faced by public health communicators during an infectious disease outbreak. It is inevitably difficult to improve rates of compliance with behaviours intended to reduce the impact of an outbreak in the face of general scepticism about the importance of the outbreak. In this regard, it is possible that the perception that too much fuss was made about the risk of swine flu will adversely affect how the public respond to government recommendations during the early stages of the next major infectious disease outbreak. If the credibility of official health warnings was eroded by people's experiences during this flu pandemic, encouraging members of the public to adopt precautionary behaviour may prove even harder at the start of the next pandemic. This makes it all the more important that the impact of any future communications campaign is maximised by ensuring that it draws on scientific evidence concerning the factors that influence behaviour during an infectious disease outbreak; the three studies presented in this report provide lessons from the swine flu outbreak, which can assist with this. Key findings from this work relate to the central role of worry and response efficacy as variables that determine behaviour, and to the role of media reporting and information provision in affecting this process.

The role of worry

Worry about the possibility of catching swine flu was strongly associated with increased likelihood of performing each of the protective behaviours that we examined. This was true regardless of whether these behaviours were endorsed by the government (being vaccinated, carrying tissues, buying sanitising gel), were portrayed as unnecessary (avoiding public transport) or were explicitly discouraged (consulting NHS staff for flu-related reasons). That worry about the possibility of catching a disease should act as a non-specific motivator for people to take action is consistent with psychological models of behaviour change, such as the Extended Parallel Process Model.[13] This proposes that fear about a given health threat increases the likelihood of someone altering their behaviour in response to it, and that this effect is increased if paired with information about what can be done to reduce the threat.

In the context of communicating about a novel public health threat, the practical implications of this finding may be limited. During the early stages of a major incident, when there is pervasive uncertainty as to how severe the incident will prove to be, describing a reasonable worst-case scenario in order to encourage members of the public to take protective action might be acceptable.[64] However, if the worst-case scenario does not occur, this strategy risks damaging the credibility of future warnings and recommendations.[79] Once a reasonably clear picture has emerged as to the true nature of the risk, compliance with recommended behaviours will be increased by communicators being honest with the public about the nature of the health threat.[22] If this increases worry, this will not have a detrimental effect on compliance, unless the nature of the threat, and hence level of worry, is substantially higher than that previously studied. A corollary to this is that explicit attempts to reassure

the public rather than to inform them about the level of risk that they face may also be ill advised. Not only can such attempts make the public distrustful as to why reassurance is being given out,[40] but also our results suggest that successful reassurance will reduce uptake of behaviours that might protect against the risk. Providing clear information about the true level of risk faced by the public, based on the best available scientific evidence, is important if the public's trust in official agencies is to be maintained.[71]

The role of efficacy

While our research showed worry about the possibility of catching swine flu to be a motivator for taking action, perceptions about the efficacy of protective strategies were more specific in the way in which they predicted behaviour. Our path analyses in study 3 demonstrated that perceiving avoidance strategies to be effective ways of reducing the spread of swine flu was associated with avoiding public transport, but not with carrying tissues or buying sanitising hand gel, while the opposite was true for the perceived efficacy of hygiene strategies. Study 2 demonstrated that believing, incorrectly, that the seasonal flu vaccine was effective against swine flu was associated with greater likelihood of having the seasonal flu vaccine. Again, these findings fit with the Extended Parallel Process Model,[13] which suggests that while worry or fear about a risk can increase a person's motivation to take action, it is the perceived efficacy of protective actions that determines what action someone will take. Our results therefore suggest that communications campaigns during any future infectious disease outbreak should seek to emphasise the efficacy of any protective behaviours that are being recommended. This suggestion is also supported by previous research in this field.[71] How best to emphasise the efficacy of a protective action is an important question that requires further study.

The role of media reporting and information provision in influencing behaviours

Given that worry appears to act as a motivator for taking protective action, maintaining a degree of public concern throughout any future disease outbreak is likely to assist in promoting uptake of recommended behaviours. This may be particularly relevant during 'slow burn' incidents, in which levels of concern are liable to wane along with the rates of behaviours such as hand-washing,[49] and in future pandemics when separate waves of infections may require the public to renew their protective activities after periods in which any threat appears to have died away. To a certain extent, it may be possible for communicators to keep an issue in the public eye by scheduling press events, briefing journalists, or putting forward experts or patients for interview. The results of study 1 suggest that once a new risk has become familiar to the public, slow and steady attempts to increase the volume of attention that the media devote to it may have limited, if any, effect on levels of worry in the community. Larger events, such as the introduction of a new vaccine or announcements concerning the beginning of a new wave of infection, may be required before elevations in worry are observed.

During the summer wave of swine flu, the total volume of media reporting was associated with higher levels of worry about the possibility of catching swine flu in the population. From this, it might be expected that at an individual level, increased exposure to information about swine flu during this period would be associated with greater uptake of protective behaviours. Yet in study 2, although likely uptake of vaccination between May and September was strongly predicted by greater worry about the possibility of catching swine flu, it showed no association with the amount of information that a person had heard recently about swine flu. Similarly, in study 3, although exposure to media coverage or advertising about swine flu was associated with increased uptake of recommended behaviours, these effects were largely mediated by the impact of exposure on perceptions of response efficacy. In fact, exposure to media coverage or advertising appeared to reduce, rather than increase, worry about the possibility of catching swine flu. In part, these seemingly contradictory results may reflect a methodological artefact. The surveys on which study 3 was based were conducted at the start of the outbreak, at a time when a high level of media reporting did not result in a high level of worry. A different relationship between exposure to media reporting and worry might have been observed in study 3 had these surveys been conducted later. A more fundamental difference between the studies also needs to be considered. While the cross-sectional studies assessed the impact of media exposure or amount of information heard on worry about the possibility of catching swine flu, behaviour or likely behaviour, the time series analysis used in study 1 assessed whether changes in the volume of media reporting were associated with changes in the number of people who were

worried. It is possible that, for the majority of people in any given survey who were worried about the possibility of catching swine flu, their worry reflected reasons that were unrelated to media reporting. At the same time, media reporting may have played a large role in determining worry for a minority of people. Under such circumstances, changes in reporting would predict changes in the number of people who are worried over time, as seen in study 1, even although at any given point in time the amount of reporting that survey respondents had been exposed to would show a poor association with whether or not an individual respondent was worried. Extrapolating from the aggregate data used in the time series analysis to the individual-level data, as used in the cross-sectional analyses, may not be valid.[47]

Methodological limitations

Although the specific methodological limitations relating to our three individual studies are discussed in the relevant chapters, one more general limitation that has not yet been raised affected the findings of all three. This relates to the questions included in the surveys we analysed. The surveys were primarily intended to track awareness of, and attitudes to, swine flu. Therefore, many variables that might have been of interest as predictors of behaviour were not included. For example, the surveys did not include items relating to perceived susceptibility to or severity of swine flu, the perceived self-efficacy of people in performing the various behaviours we assessed, perceptions about what other people would like the participant to do or absolute levels of trust in the government, all factors that might have been pertinent.[71] In addition, they did not include questions relating to some behaviours that were important from a public health perspective, such as hand-washing. Although our analyses have identified some factors that may be associated with behaviour change in a future outbreak, these are unlikely to be the only psychological variables that are relevant.

Chapter 6
Conclusions

The conclusions of each study are presented in Chapters 2–4. Overall, our results lead to several broad conclusions regarding recommendations that can be made for practice and for future research.

Implications for practice

1. Our results showed that uptake of recommended behaviours during the swine flu outbreak was low. Maximising the impact of communication campaigns during future pandemics is therefore important. Our studies demonstrated that psychological processes are important to consider when designing these campaigns. Although such campaigns often need to be designed quickly, seeking evidence-based advice from behavioural scientists as to how best to incorporate psychological principles into these campaigns is likely to strengthen them.
2. Our results also demonstrate that rapid-turnaround surveys can be used to improve communications campaigns by identifying factors that mediate between communication and behaviour. These surveys are often considered to be an integral part of the public health response to a major incident, given that they can help policy-makers to design and fine tune their communication strategies. Conducting informative analyses of this type of data requires that appropriate questions and response options for both rates and predictors of behaviour are used. Again, although such surveys often need to be commissioned very quickly, seeking timely advice from behavioural scientists as to what questions to ask, and how, is very worthwhile. We also suggest that efforts are made to design such surveys ahead of time.
3. More specifically, our results suggest that deliberately raising levels of worry about the possibility of catching a disease from low levels among the public is likely to increase uptake of behavioural recommendations during future infectious disease outbreaks. However, doing this without regard to the true nature of the risk faced by the public might erode levels of trust in public health communicators. In addition, our results showed that elevated worry may result in the uptake of behaviours that are not desirable. Caution should therefore be exercised in deciding how to implement this finding.
4. Conversely, given the importance of worry about the possibility of catching swine flu in motivating uptake of protective behaviours, it is likely that attempts to reassure the public about their chances of becoming ill during a future infectious disease outbreak will reduce rates of behaviour change. Reassuring the public on the one hand, while recommending protective behaviours on the other, may also give out mixed messages and affect the impact and credibility of these communications.
5. During any major public health incident certain events will inevitably occur which increase worry and motivation to take action. The time period surrounding these events may therefore be good times to provide the public with information encouraging the uptake of protective actions. We suggest that predicting, and planning responses to, these events should therefore be a focus for public health organisations.
6. The results of studies 2 and 3 suggest that emphasising the efficacy of recommended behaviours in any future campaign will help to maximise the campaign's impact on those behaviours. Importantly, although increasing levels of worry might increase rates of all protective behaviours, regardless of whether they have been recommended or not, our results suggest that communicating the efficacy of a specific behaviour may have an impact on that behaviour alone.

Research recommendations

1. While our results suggest that successfully communicating information about the efficacy of protective behaviours will increase the uptake of these behaviours, we are unable to say what the best techniques are for providing information about efficacy. Additional research on this topic would help to guide future communications campaigns.

2. Across all the behavioural outcomes that we assessed, there was evidence that people from particular demographic groups were more inclined to engage in behavioural change. As with previous studies, our results showed that ethnicity, age, household size, health status, socioeconomic status and gender all played a role in determining whether someone engaged in a given behaviour or not.[71] The mechanisms underlying these effects are likely to be complex and may have important implications for the way in which messages for these subgroups should be framed.[80] Additional research to understand the reasons for and implications of these effects might help in the design of more effective communications campaigns in future pandemics. Exploring differences within each of these subgroups is also recommended. For example, differences are likely to exist in terms of the concerns of, and most appropriate messages for, people from different ethnic subgroups or with different underlying health conditions.
3. Since the cross-sectional analyses reported in studies 2 and 3 were completed, additional data from the surveys have become available. These include potential outcome variables, such as hand-washing data and actual, rather than intended, vaccine uptake. We recommend further analysis of this data set focusing on these variables. Similarly, the database would also allow a more detailed analysis of the content of media reporting to be used as a predictor of worry during the outbreak.
4. The perception that too much fuss was being made about the risk of swine flu was relatively high throughout the outbreak, but showed low levels of fluctuation as the outbreak developed. It may be that experience with previous health scares and outbreaks was the key factor influencing this perception. It is unclear how people's experiences during the swine flu outbreak have affected their perception of health warnings produced by scientists, the media or the government, what impact this might have on their response to future warnings, or how best to ameliorate any scepticism. Additional research addressing these areas is warranted.
5. For the foreseeable future, telephone surveys are likely to remain the only pragmatic way to obtain rapid, quantitative data with which to inform policy decisions during public health incidents. Additional research to improve the validity of this technique is therefore warranted. As a first step, testing the validity of self-report measures of different types of behaviour would be of value.

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Contribution of authors

Susan Michie (Professor of Health Psychology) and Henry Potts (Lecturer, Health Informatics) had the original idea for the analysis and developed the analytical design with James Rubin (Research Fellow, Psychology as Applied to Medicine). The main statistical analyses were conducted by James Rubin, who also wrote the first draft of the report. All authors contributed to further drafts and had full access to all of the data.

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Appendix 1

Protocol (original grant application)

Project title: Public responses to swine flu communications: a longitudinal analysis

Planned investigation

Research objectives

1. To analyse the Department of Health (DH) swine flu public attitudes and behaviour survey to examine how far behaviour can be understood in terms of specific beliefs and emotional responses.
2. To assess how far behaviour, beliefs and emotional responses vary with socioeconomic and other demographic variables, geographic area, and over time.
3. To assess the effect of NHS/DH communication initiatives and media/new media coverage on behaviour, beliefs and emotional responses.

Existing research

The influenza pandemic is an important ongoing health problem. The second most effective method of preventing the spread of flu, after provision of vaccines, involves behaviours, such as hand and respiratory hygiene behaviours, taking up vaccines and staying at home when ill. They are also key to limiting the severity of illness by, for example using the National Pandemic Flu Service or taking antivirals as prescribed. Data from the Health Protection Agency shows that about a third of schoolchildren given antivirals did not complete the course. Effective communication requires targeting specific behaviours central to preventing ill health and influencing attitudes and beliefs that are determinants of those behaviours. Moreover, we have an unprecedented opportunity in this pandemic to build up knowledge about public attitudes to pandemics and similar health threats more generally. This is important to prepare for the next pandemic, something that remains an ongoing threat, particularly in the context of avian flu and emerging zoonoses.

Existing research on preventative behaviours (e.g. hand-washing, respiratory hygiene, vaccine uptake), avoidant behaviours (e.g. staying at home) and management behaviours (e.g. uptake of antivirals) relevant to flu has been identified and summarised in consultation with the Behaviour & Communications (B&C) Group of the Scientific Pandemic Influenza Advisory Committee (SPI) in June 2009. This literature has been drawn from a range of countries, populations, infections (e.g. SARS, avian flu, swine flu, pandemics) and designs (e.g. hypothetical scenarios). The literature search focused on studies of associations between demographic characteristics, attitudes and behavioural measures, either reported, intended or actual behaviour.

The studies found are of variable quality, with some carried out in the middle of the outbreak, while others investigate intentions to behave in the event of an outbreak (see list of references). We can extract some broad principles from the current evidence. Perceptions about the diseases in question are more important predictors of behaviour than perceptions about the behaviours required. The research shows that perceived susceptibility to the disease and its perceived severity are important, as are issues of trust in authorities. There is also evidence that general levels of anxiety can influence the adoption of protective behaviours. As might be expected, belief in the effectiveness of recommended behaviours to protect against the disease can also predict behaviour. Generally, being older, female, non-white or more educated are associated with a higher chance of adopting the behaviours. *Figure 1* shows an example of one of the conceptual maps of the predictors of preventative behaviour; we have also developed similar maps for avoidant and management behaviours.

Most research in this area lacks an explicit theoretical framework, partly as the studies were carried out in rapid response to the emerging pandemic threats of SARS and avian flu. Few use multivariate analyses, where the relative contribution of factors to the reported behaviour can be examined. Most are cross-sectional in design.

Only one study, Rubin *et al*. (2009), was carried out exclusively in the UK and focused on perceptions of swine flu at the very beginning of the outbreak.

This cross-sectional study found that people were more likely to follow recommended behaviour if they perceived swine flu to be severe, that they are likely to catch it, that the outbreak will last a long time, that the authorities can be trusted, that good information has been provided and that people can control their risk of catching swine flu and that specific behaviours are effective in reducing the risk. Being uncertain about the outbreak and believing that the outbreak had been exaggerated were associated with a lower likelihood of change. Because of its cross-sectional design, it is difficult to have a clear idea of causality or to study the mediating effect of attitudes and beliefs on the association between media and government communication and behaviour.

What is currently needed is an investigation of the extent to which determinants identified in other situations are relevant to the current swine flu outbreak. We will draw on both the specific literature identified above, but also the more general health psychology literature to identify appropriate theoretical frameworks. Despite this substantial literature on public health attitudes and beliefs, little past research has been sufficiently resourced to track public attitudes longitudinally in such detail as the DH's weekly tracking survey is currently doing, or has studied as significant a health event as this.

Public attitudes are influenced by multiple information sources, including but not limited to official advice from the DH/NHS or the Government more generally. The literature on risk perception (Adams 1995) has established that public concerns about risk are higher with novel threats and when individuals do not feel in control of the risk, both factors with the flu pandemic. How individuals interpret information depends on their prior knowledge and attitudes. A substantial literature has demonstrated how illness perceptions predict health behaviours (Hagger and Orbell 2003). Illness perceptions are the cognitive representations individuals have about an illness. These may be discordant with professional advice. Faced with a new threat, individuals build a mental model of the threat (Petrie and Weinman 1997, 2006), which, in turn, elicits an emotional reaction, which drives behaviours relating to that threat. The illness perception literature provides a theoretical model to understand attitudes. However, most illness perception research has been concerned with individuals with chronic diseases rather than large threats to public health.

Since the last influenza pandemic in 1968–9, there have been huge changes in media and communication technologies; in approaches to public health psychology; and in polling methodology and statistical analysis. Even since the near pandemic of SARS in 2002–3, there have been significant changes in media and communication technologies. The rise of internet technologies such as Twitter have already been recognised as having significant sociopolitical implications, while traditional media, like local newspapers, continue to decline. Such changes have impacted on health care too (Potts 2006). We have moved from a paternalistic model of health care, with patients being the target of education, to models of shared decision-making and patient choice. Our understanding of large-scale polls has matured, and the range of statistical tools to analyse the resulting data is larger. We have the expertise in our team to consider these changes in the proposed research.

Research methods

The DH's Communications Directorate has commissioned MORI to conduct a weekly public attitudes tracking survey. Telephone interviews selected from a set of 40 questions are conducted with a representative sample of > 1000 members of the general public to monitor changes in awareness of swine flu communications, trust in information sources, perceptions of swine flu (e.g. severity, controllability), worry about swine flu, perceived efficacy of a variety of preventative behaviours (e.g. hand-washing) and avoidant behaviour (e.g. avoiding travel), and predicted engagement in flu management behaviours (e.g. telephoning Swine Flu Information, staying at home).

The survey started on May 1 and is planned to continue for the next 6 months. There is thus a wealth of data that can be analysed to influence policy and practice. Although DH is analysing these figures as they are produced, the B&C Sub-Group of the SPI Advisory Committee is keen to commission a broader piece of analysis looking at the associations between recalled government and other media communications, cognitive and emotional determinants of behaviours, and reported behaviours. Understanding these will enhance the B&C Group's ability to make recommendations to DH on these issues.

This research will be shaped, supported and informed by the SPI B&C Sub-Group. The SPI Sub-Group is represented on the Government's Scientific Advisory Group for Emergencies, and

is working closely with the DH Communications Directorate who manage the public attitudes tracking survey. The academic partners will be UCL's Health Psychology Unit (led by SM), Health Behaviour Research Centre (RW) and Centre for Health Informatics and Multiprofessional Education (HP). We will have a commercial media monitoring partner, such as Meltwater News, to be decided in consultation with the DH Communications Directorate.

Data analysis will be from May 1 and cover the period for which the SPI modelling group have estimated that peak infections of the current outbreak may occur (September 2009 to February 2010).

Work stream 1: Review of survey content and methods for event monitoring

The cumulative survey data will be reviewed and the literature review of behavioural determinants carried out by the B&C group will be updated and considered in the broader context of work on public attitudes. The results of these will be used to ascertain whether any items should be added and/or dropped from the survey. This will be fed back to the DH and MORI as soon as possible. The method for monitoring and identifying key government and DH communications will be finalised and the electronic media monitoring search strategy agreed.

Government/DH communications

Elizabeth Bailey, Head of Planning, Briefing & Messaging, will arrange for regular alerts of all significant DH communications or other noted events that may influence attitudes and behaviour. We will also seek to liaise with DH/NHS over web access statistics pertinent to swine flu (e.g. page hits, search terms). DH estimates of cases and deaths each week will also be collated.

Media monitoring: DH and electronic

An overnight update for swine flu is produced by the DH duty press officer and wider media monitoring services, daily media briefings and broadcast summaries are commissioned through the Central Office of Information Media Monitoring Unit. In addition, one-off specialist monitoring is commissioned as needed.

Electronic media monitoring will be provided, subject to consultation with DH Communications Directorate, by Meltwater News (http://meltwater.com/mnews), an established and highly regarded company serving academic research, government and 'third sector' organisations and companies. A bespoke search strategy will produce weekly reports of printed media, frontline websites and blog coverage tailored to the key cognitions (e.g. perceived risk and severity, trust in government sources), emotions (e.g. anxiety, anger) and behaviours (e.g. staying away from work, hand hygiene). Printed media and website coverage represent key channels through which government advice is transmitted to the public; blogs will assess the ways in which the public interpret and act (or not) on advice, information and misinformation. The search strategy can be tailored by time (e.g. the last 2 days), national versus geographical region, and type of media (e.g. tabloids versus quality). It also can be changed week by week to reflect new issues as they arise. Analysis can be qualitative (e.g. tonal quality) as well as quantitative. We will have an individual consultant assigned to the project to adapt the search strategy according to need. The monitoring output will be reported in chart formats and in spreadsheets for statistical analysis by the research team.

Work stream 2: data analysis

The weekly cross-sectional data sets will be analysed multivariately to investigate associations between communication events, behavioural determinants and reported behaviours and to identify any mediators of association between these. Methods will include time series and structural equation modelling. Variations across region (mapped against outbreaks), socioeconomic status and other demographic characteristics will be described and their effects in modifying relationships between communication events and attitudes, worry and reported behaviours will be investigated. Analyses will be conducted, reported and discussed with DH on a monthly basis (more frequently if required).

The goal will be to arrive at a parsimonious model that accounts for as much cross-sectional variance in key target behaviours as possible in terms of emotional responses and specific beliefs. Changes over time in key elements of the model will then be explored in relation to DH communications and media coverage of events. It is recognised that in a fast moving situation, even weekly surveys may not be sufficiently frequent to disentangle the effects of different events and also that some of the effects may be cumulative or lagged. Therefore, it is not possible to state at the outset what kinds of answer will emerge from the data.

Conceptual framework

Mass media campaigns are more likely to be effective if principles of campaign design are adhered to; one of the key principles is to use relevant theories of behaviour change as a conceptual framework, since it will suggest important determinants around which to develop messages (Noar 2006). Data analysis will be informed by two conceptual frameworks in order to identify determinants to inform DH communication and campaigns.

The first is a synthesis of empirical data about the determinants of three categories of behaviour relevant to protecting health within the context of outbreaks of infectious disease (SARS, avian flu and swine flu). This was carried out for the SPI B&C group to guide the DH in designing the survey so as to be maximally useful to policy and planning. This synthesis is summarised and illustrated as a series of 'conceptual maps' (see *Figure 1*), linking attitudinal determinants and other predictors with three key sets of behaviours: preventative (e.g. washing hands with soap), avoidant (e.g. staying at home when ill) and management (e.g. using the National Flu Service when symptoms are detected). A mapping exercise between MORI items and relevant evidence has been conducted by the B&C group to inform discussions with the DH about items to add to the current data set.

The second conceptual framework will be PRIME Theory of motivation (West 2006). This aims to provide an overarching model into which diverse aspects of motivation can be fitted. It pulls together decision-making theories, learning theory, theories of self-regulation and identity, and theories regarding the influence of drives and emotional responses to arrive at an account of the moment-to-moment control of behaviour. It proposes that deliberate actions arise from the strongest of competing feelings of 'want' (involving anticipated pleasure or satisfaction) and 'need' (involving anticipated relief from mental or physical discomfort or drive states). Beliefs about what is beneficial or harmful, and intentions concerning future actions will only influence behaviour if they generate sufficiently strong immediate wants or needs at the time. The model proposes that identity (self-descriptions including personal rules) are potentially powerful sources of want or need that need to be considered when predicting many behaviours. In relation to responses to the flu pandemic, anticipated relief from anxiety and extent to which identity involves following rules will prove important drivers of particular behaviours.

The study's ability to inform policy will be shaped by the survey questions included within the DH attitudes survey. It will be limited by the timing of the results; whilst they will not be able to inform response to an autumn flu peak, they will be able to inform policy in relation to the pandemic in the New Year. This proposal will also constitute a dummy run from which we have the opportunity to learn lessons for the future and a possible more severe form of a pandemic flu outbreak.

Statistical analysis

Time series analyses will consider variation over time in key survey responses since May 1 and how these relate to key events (DH activity or media). Analyses will be repeated at both a regional and national level. Data on cases and deaths, key DH communication activity and media/new media activity will be investigated as predictors of public attitudes. Analyses will consider that such relationships may, in turn, vary by demographic factors (e.g. the effect of different media/communication sources may vary by age given known differences by age in use of traditional and online information channels).

Cross-sectional analyses using structural equation modelling will combine data over multiple weeks on a bimonthly basis. This will give a very large statistical power to investigate associations between demography, beliefs, knowledge, attitudes and behaviour. This analysis will be performed three times over the 6 months' period to investigate whether the associations between variables also change over time.

Data interpretation

The results will be interpreted within the context of the literature review that the B&C group is currently conducting of effective communication and other interventions to change flu preventative and management behaviours.

Work stream 3: dissemination and advice on communication strategy

Dissemination will be guided by Richard Bowyer, Deputy Director of Strategy, Planning & Insight, DH Communications Directorate, and SM, who is a member of the Scientific Advisory Group in Emergencies (SAGE) and therefore is informed on a weekly basis of policy and planning needs. The survey analyses will be discussed on a regular basis by relevant members of the pandemic flu team within the DH Communications Directorate and by the B&C Group (of which SM is Chair) that reports to SAGE. The B&C group is charged

with providing scientific advice to underpin policy in communication strategy and in behavioural management, a key aspect of reducing infection transmission and illness severity.

Ethical arrangements

Since the proposed study is to analyse anonymous survey data that is already being collected by the DH, no further ethics/governance permissions are required. The possibility of data being identifiable from demographic variables is very low, but all data will be securely stored.

We are conscious that merely asking a question on beliefs about flu has the potential to spread false information, and will thus carefully discuss survey wording with MORI.

Project timetable and milestones

In an emerging and unpredictable context, we offer an approach that is flexible enough to capture ongoing developments, and robust enough to produce valid conclusions. A detailed Gantt chart will be constructed outlining weekly targets for the duration of the project.

The applicants (SM and HP) will meet with the researcher employed on the study at least once a week to review past week's work and plan the next week's. We will plan for a fast turnaround for analysis to allow the research and the tracking surveys to respond to developments, but we will also reserve time for more detailed analysis. There will be fortnightly contact with the B&C Group of the SPI and the DH's Communications Directorate to ensure that the findings are influencing policy and practice in a timely and effective manner. Both of these organisations are central to the management of the project. Meetings/teleconferences with our assigned advisor from the media monitoring organisation will be as and when needed.

The timeline for this research is:

- *October* Review of survey content and methods for monitoring of DH communications and media and linking to data set; setting up working partnerships; begin analysis of past data.
- *November* Data analysis and first report; dissemination and advice to DH on communication strategy.
- *December* Refined and repeated data analysis and reports, dissemination and advice to DH on communication strategy.
- *December/January* Final report for DH.
- *February & March* Further analysis, dissemination and advice to DH on communication strategy; at least one and probably two journal articles (one addressing first two objectives and one addressing third). Timing of article submission for publication will be coordinated with the DH timetable for publishing the data.

Milestones

- Oct 14
  - Data analysis protocol developed for Objectives 1 and 2.
  - Initial meeting with DH representatives to discuss DH's needs re. monitoring communication events, desirability of adding items to survey and key questions to be addressed by analyses.
  - Initial meeting with Meltwater News to agree search and reporting strategy.
- Nov 1
  - Initial data analyses run on past data.
  - Summary of media and other event monitoring by DH.
  - Data analysis protocol for Objective 3.
- Nov 14
  - First data analysis report addressing all three objectives.
  - Presentation of report to DH communications team.
- Dec 1
  - Refined and repeated data analysis and reports.
- Dec 14
  - Final report for DH of analyses addressing three objectives.
- Jan 14
  - Meeting with DH to discuss future analyses that will inform work at this stage of the pandemic.
- Feb 1
  - Draft of Paper 1.
- Feb 14
  - Meeting with DH to present results of subsequent analyses. Data analysis plan for final 6 weeks.
- Mar 1
  - Draft of Paper 2.
  - Discussion with DH Communications about possible future research to inform their communication design, output and evaluation.

- Mar 14
  - Submission of Paper 1, assuming DH publication of data.
- Mar 31
  - Final report to DH of findings from agreed subsequent analyses.
  - Submission of Paper 2, assuming DH publication of data.

Expertise

Susan Michie is Professor of Health Psychology leading the Health Psychology Unit in UCL's Division of Psychology and Language Sciences. She is known internationally for her work on understanding health-related behaviours and applying psychological theory to designing interventions to change behaviour. She works at the interface of science and policy, acting as part-time consultant to the DH's Health Improvement Directorate to advise on several communication and behavioural intervention programmes. She is a member of the Government's SPI Advisory Committee and SAGE, chairing its B&C group.

Henry Potts is a health informaticist and statistician in UCL Medical School. He brings to the team expertise in statistical analysis for a health psychology context. He is also a recognised expert on new information and communication technologies and their role in health care, including non-traditional media and social networking.

Robert West (collaborator) is Professor of Health Psychology leading a team of researchers within the Health Behaviour Research Centre in UCL's Department of Epidemiology and Public Health. He brings to the team expertise in human motivation, having recently published a comprehensive theory that describes how beliefs and emotions interact with environmental events to generate behaviour. He also runs a longitudinal study of beliefs, emotional responses and behaviours relating to smoking (the Smoking Toolkit Study), which tracks responses on a monthly basis and involves similar kinds of analyses to those proposed here.

Meltwater News is a global specialist in online media monitoring, working with more than 15,000 companies and academic and other organisations to track critical information published online. They provide unlimited and filtered results for research purposes, and analysis is provided including topic, timeline, sources and geographical cross-section.

Service users

The analyses and their dissemination will be guided by SM in collaboration with Richard Bowyer, Deputy Director of Strategy, Planning & Insight, DH Communications Directorate. They will feed directly into the DH Communications Directorate and the B&C Group (of which SM is Chair) that reports to SAGE. The B&C group is charged with providing scientific advice to underpin policy in communication strategy and in behavioural management, a key aspect of reducing infection transmission and illness severity.

Justification of support required

We will require 5% of SM's time to oversee the project and report writing, liaise with the DH and the B&C group and manage the researcher. We will require 10% of HP's time to oversee the statistical analyses and write the statistical parts of the report.

We are asking for the cost of a postdoctoral researcher to conduct the analyses, draft reports and give administrative support to the project. SM, HP and the researcher will meet with the identified DH communications team members. The researcher will need a computer, statistical software and printer. We will require the cost of teleconferences and inner London travel. Finally, we are asking for a small budget to cover casual assistance, which will be provided, as needed, by Alison Bish, a health psychologist providing support to SPI's B&C group.

TABLE 1 *Mapping of items currently included in the MORI survey with evidence-based determinants of behaviour and behavioural responses*

	Evidence that predicts behaviour	**No evidence that predicts behaviour**
Included in MORI poll	Q3 Heard of swine flu (*knowledge*) Q4 How much heard Q5 How much do you know (*4 and 5 possibly more perception than actual knowledge*) Q7 Worry* Q10 No vaccine?* (*sort of knowledge/sort of severity*) Q11 There are ways to slow down spread (*knowledge/severity*) Q12 Natural immunity? (*knowledge/severity*) Q13 Flu vaccine will protect me (*knowledge/severity*) Q14 Catch from pork? (*knowledge)* Q15 Thousands died? (*knowledge/severity)* Q16 Washing hands with soap effectiveness* (*effectiveness of behaviour)* Q17 Covering nose and mouth effectiveness* (*effectiveness of behaviour)* Q18 Disposing of tissues effectiveness* (*effectiveness of behaviour)* Q19 Avoiding travel effectiveness (*effectiveness of behaviour)* Q20 Avoiding crowds effectiveness (*effectiveness of behaviour)* Q21 Cleaning surfaces effectiveness (*effectiveness of behaviour)* Q23 Wearing masks effectiveness (*effectiveness of behaviour)* Q27 Satisfied with amount of information* (*communication)* *Q29* Government prepared?* (*communication*) Q33 Too much fuss being made* (*communication)* Q36 What is pandemic flu/How is it different from normal flu* *(knowledge)* Q37 Pandemic flu is more severe than swine flu* *(severity/knowledge)* Q38 Pandemic flu is the same as swine flu but more widespread* *(severity/knowledge)* Age* Ethnicity* Gender* Children under 16* Marital status*	QA NHS number QB Where to find it *(however, these 2 items are clearly important administratively)* Q1 General health* Q2 Longstanding disability* Q8 Source of information Q9 Websites used Q26 Who trusted Q28 What extra information is required *(although important to know this)* Q30 How to get Tamiflu* Q31 (a) receipt of leaflet (b) TV advert awareness (c) radio advert awareness (d) radio advert awareness (e) newspaper advert awareness Q34 Where expect to receive information from: working status home ownership car ownership job status Which newspaper read Whether self, friends, family work for NHS (*useful markers of social class)* Geographical region (important as at the moment some areas are more affected than others)

continued

TABLE I *Mapping of items currently included in the MORI survey with evidence-based determinants of behaviour and behavioural responses (continued)*

	Evidence that predicts behaviour	**No evidence that predicts behaviour**
Not included in MORI poll	Perceived severity for the individual in various ways e.g. financially, medically – although some items touch on this	
	Perceived susceptibility in terms of feeling at risk/feeling vulnerable/likelihood of catching it	
	Perceived behavioural control and self-efficacy	
	Level of trust (rather than just who is trusted)	
	State anxiety	
	Social pressure/social norms	
	Educational level	
	Income level	
	Presence of symptoms/cues to action	
	Illness perceptions, e.g. beliefs about pandemic flu – its time course (how long are you ill for?), severity (including likelihood of death), what causes it (a virus? a bacterium?), how is it spread (through the air? through food? through contact with another person? from surfaces?)	
	Have you had swine flu?	
	Do you know personally anyone who has had swine flu?	

TABLE 1 *Mapping of items currently included in the MORI survey with evidence-based determinants of behaviour and behavioural responses (continued)*

Behavioural responses included in MORI poll	**Behavioural responses not included in MORI poll**
Q6 Been to see GP/hospital/Called NHS Direct	Avoided crowds
Q24/Q25 Intentions to seek help if symptomatic (*Q25 unprompted*)	Avoided work
call doctor	Taken antiviral agents
call helpline	Used National Flu Line
go to GP	Washed hands more frequently
call swine flu information	Cleaned surfaces
stay at home and self-treat	Coughed into tissues
visit NHS website	Worn mask
go to A&E	Made flu friend plans
visit pharmacist	Used antibacterial gel
speak to family and friends	
go to walk in centre	
take medication	
ask doctor to come to house	
keep away from people	
stay at home	
call A&E	
call pharmacy	
inform my employers	
Q32 Done any of the following since the outbreak	
carrying tissues	
bought antibacterial gel	
looked for information online	
avoided eating pork/ham/bacon	
avoided public transport	
visited GP	
telephoned GP	
rearranged travel	
visited A&E	
tried to buy Tamiflu	
telephoned NHS Direct	

Italicised words in brackets indicate the concept covered.
* Included in scaled down MORI poll.

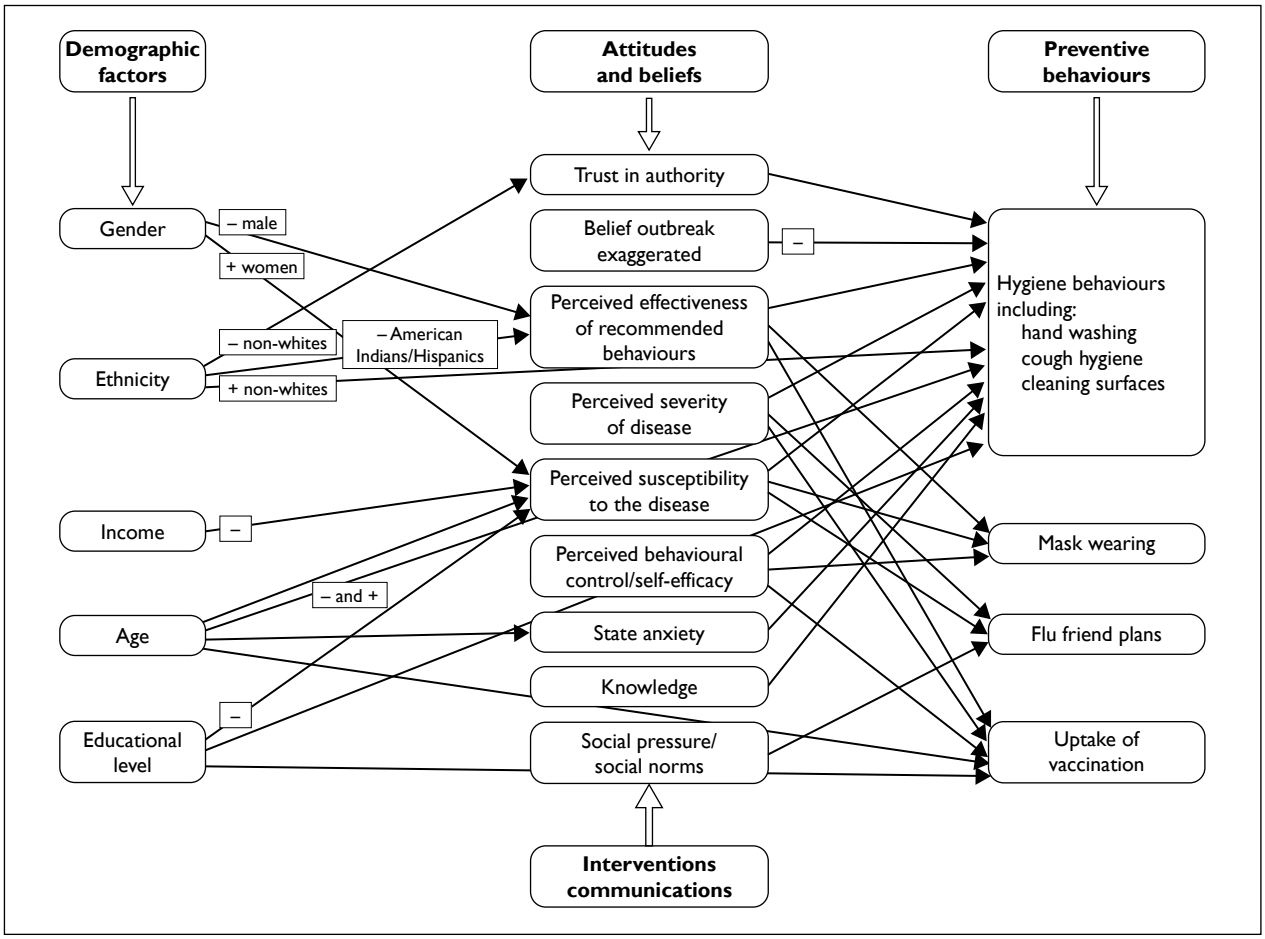

FIGURE I *Example of conceptual maps of predictors of preventative behaviours.*

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Appendix 2

Searches used to identify media stories relating to specific aspects of swine flu

Children-related search

(ingress:“H1N1” or ingress:“swine flu” or ingress:“pandemic”) and (title:“children” or title:“child” or title:“kids” or title:“baby” or title:“babies” or title:“babe” or title:“tots” or title:“tot” or title:“toddler” or title:“toddlers” or title:“school” or title:“nursery” or title:“infant” or title:“infants” or title:“pupil” or title:“pupils” or title:“schools” or title:“nurseries”)

Death-related search

(ingress:“swine flu” or ingress:“H1N1” or ingress:“pandemic”) and (title:“death” or title:“deaths” or title:“dead” or title:“die” or title:“fatality” or title:“kill” or title:“kills” or title:“killed” or title:“killer” or title:“deadly” or title:“lethal” or title:“fatal”)

Exaggeration-related search

(ingress:“swine flu” or ingress:“H1N1” or ingress:“pandemic”) and (ingress:“alarmist” or ingress:“alarmism” or ingress:“overstate” or ingress:“overstated” or ingress:“over the top” or ingress:“hype” or ingress:“hyping” or ingress:“hyped” or ingress:“over hyped” or ingress:“overhyped” or ingress:“hysteria” or ingress:“hysterical” or ingress:“exaggerate” or ingress:“exaggerated” or ingress:“exaggerating” or ingress:“exaggerates” or ingress:“overplay” or ingress:“overplayed” or ingress:“over-react” or ingress:“overreact” or ingress:“over react” or ingress:“over reacts” or ingress:“over reacting” or ingress:“over reacted” or ingress:“over blown” or ingress:“sensationalised” or ingress:“sensationalism” or ingress:“embelished” or ingress:“embelish” or ingress:“inflated”)

Uncertainty or disagreement-related search

(ingress:“H1N1” or ingress:“swine flu” or ingress:“pandemic”) and (title:“uncertain” or title:“uncertainties” or title:“controversy” or title:“controversies” or title:“debate” or title:“debates” or title:“doubt” or title:“doubts” or title:“query” or title:“queries” or title:“argument” or title:“arguments” or title:“confusion” or title:“confusions” or title:“confusing” or title:“contradiction” or title:“contradictions” or title:“contradictory” or title:“muddle” or title:“muddles” or title:“disagree” or title:“disagrees” or title:“disagreement” or title:“disagreements” or title:“inconsistent” or title:“inconsistencies” or title:“critic” or title:“criticism” or title:“critics”)

Appendix 3

Key themes identified in media reporting for the start date of each survey

Survey start date	Main themes in that day's media reporting (key dates of other events recorded in parentheses)
01/05/09	Reporting focuses on news of a UK citizen who contracted swine flu in the UK, the first time community transmission has been recorded. Several local newspapers quote council or local NHS trust spokespeople as saying that local agencies are well prepared for a large-scale outbreak. Reports describe swine flu as still mild, but highlight concerns that it might mutate at some stage in the future. Official advice about respiratory and hand hygiene measures are repeated
05/05/09	Reports of local cases still predominate in the local press. The closure of two large private schools in London and distribution of Tamiflu to the pupils is reported. Official spokespeople are quoted giving advice about respiratory and hand hygiene measures. The illness is typically described as mild by most papers. Initial people who caught it are described as coming out of quarantine and returning to normal life
08/05/09	Although still reporting swine flu to be mild, concerns are voiced that the vaccine might mutate at some point in the future. Some stories report that the response to swine flu may have been an over-reaction. An MP is quoted as saying it is good for people to catch the virus now 'whilst it's still relatively weak'. Warnings about online scams involving fake medication are given
12/05/09	Local cases of swine flu continue to be reported. Some discussion over the use of 'hyperbole' by journalists and scientists occurs. While some new schools are closed, previously closed schools are reported as reopening. Comparisons are made with the 1957 pandemic, as a result of a newly recent study
17/05/09	Limited amount of reporting occurs, describing the impact of swine flu on tourism to Mexico now that the Foreign Office is no longer advising against travel to the region, and some new cases occurring among members of the public
22/05/09	Local newspapers report the first cases occurring in their area. Victims of swine flu are being treated with antiviral drugs. Local and national health officials and ministers are quoted as saying that it is right to prepare for a pandemic, that the health services are working well to contain the spread of disease, and that there is no cause for public alarm
29/05/09	Most articles focus on the closure of a famous private school and a breakthrough in the development of a vaccine. Several stories about swine flu spreading faster in UK than in the rest of EU and the first report of a life-threatening UK case
05/06/09	Reports focus on the geographical clustering of cases (particularly in Scotland and Birmingham). There are also stories about first cases in particular counties within the UK
12/06/09	The majority of stories cover the fact that the World Health Organization has now declared swine flu to be a global pandemic. Focus is also on the use of a containment strategy to control the spread and the provision of Tamiflu to at-risk groups as a prevention measure (World Health Organization declares a full pandemic – 11 June)
19/06/09	Stories focus on the possible overdiagnosis of swine flu by GPs and indicate that there will be greater reliance on lab testing now (first UK death occurs – 15 June)
26/06/09	A coming rise in cases during autumn and winter is suggested as well as reinforcement of advice about hand hygiene and who to contact if ill. Several stories about a surge in people calling NHS Direct worried they may have swine flu. The largest 1-day increase in cases since the outbreak began is reported. Tamiflu is now only being given to those who are ill, rather than contacts
03/07/09	The media suggest that cases cannot be contained. There is talk of 100,000 new cases a day by August. There has been a move to a treatment rather than containment phase. People are warned not to go to work if they're feeling ill and to be cautious of counterfeit drugs. First mention of 'swine flu parties' (government announces a change in strategy from containment of swine flu to treatment – 2 July)
10/07/09	Some papers talk about a potential plan to let people stay off work for 14 days without needing a GP's note in order to ease the burden on GPs and to help prevent the spread of the disease. Talk of business resilience plans. A leaked government memo is reported as saying that the country is 'not ready' to deal with an epidemic

Survey start date	Main themes in that day's media reporting (key dates of other events recorded in parentheses)
17/07/09	Immunisation programme is set to begin in the autumn and the National Pandemic Flu Service (NPFS) helpline will soon be launched. Lots of stories about the death toll rising, but the spread slowing due to the end of the school year
24/07/09	Stories stress that pandemic plans have been in place for years and the country is prepared. There was huge demand as soon as the NPFS website was launched. Impossible to accurately calculate the number of cases since the beginning of the outbreak as swabbing and testing is no longer done (NPFS goes live – 23 July)
31/07/09	Cases may have plateaued for the moment. Reports of Tamiflu side effects in children taking it (nausea and nightmares). Pregnant women described as particularly at risk from swine flu and four times more likely to be admitted to hospital. Vaccine trials have begun
07/08/09	Concerns are raised about the safety of fast-tracking the vaccine. Reminders of hand hygiene and tissue use are issued. Decreasing number of cases for now but warnings of a second wave when schools go back. Worry that the NHS won't get enough doses of the vaccine before the possible second wave of cases. No evidence the virus is mutating or getting stronger. Health workers and pregnant women to take priority for vaccination. Worry about 'unqualified' swine flu advisors on the NPFS helpline
14/08/09	Mass immunisation is to begin in the autumn. Clarifications in many articles in terms of at-risk groups and the order in which people will be vaccinated. Travel companies report losing business. Warnings are given to people who are ill that they should try to avoid public events
21/08/09	Launch of an awareness campaign about what to do if you have swine flu, as well as a leaflet ('Worried about swine flu'). Focus on the difficulty of predicting when the second wave could hit. Only an estimated 1 in 10 people who sought treatment really have swine flu
28/08/09	Swine flu rates continue to fall even in 'hotspots'. Reinforced messages of not panicking and that most deaths have had underlying complications. First batches of vaccine have been delivered to government but won't be used until October. Businesses holding swine flu seminars to raise awareness and help stop spread
04/09/09	UK businesses told to prepare for staff absences of up to 50%. Deaths could actually be less than half those of the normal flu. Criticism that the government overexaggerated the severity of swine flu. Discussion of practicalities surrounding vaccine administration, such as how much GPs should be paid
11/09/09	Some experts say Tamiflu should not be given to children because of severe side effects. The next wave of swine flu predicted to peak between late August and late September
18/09/09	A Northern Irish pig farm has tested positive for swine flu. Cases have increased again over the past week – lots of talk of the 'return of swine flu'
25/09/09	Continued rise in cases. Regulators approve swine flu vaccine for use in UK. Vaccine tests to be done on young children. Alcohol-based hand gels banned in prisons after inmates drink it. Plans are under way to set up vaccination centres
02/10/09	Continues to be a steady increase in cases but is still mild in severity for most people. Reiteration of the symptoms and what to do if ill. Increase in number of people admitted to hospital with swine flu who have no underlying health conditions. Seasonal flu campaign begins
09/10/09	A drop in cases is happening again, but further increases said to be likely – other papers report increases in cases calling it the beginning of the second wave. Preliminary evidence showing there may be a link between obesity and swine flu complications. Reminder messages about good hygiene
16/10/09	UK death toll passes 100. Pregnant women urged to get vaccine after a pregnant woman and her baby die from swine flu. National vaccination programme to begin from 21 October. Postal strike could disrupt the sending out of letters by GPs to vaccine candidates

Survey start date	Main themes in that day's media reporting (key dates of other events recorded in parentheses)
23/10/09	Four people in Scotland die within 24 hours. Children in special schools to be vaccinated as a priority. Vaccination programme is under way – US vaccination facing delays. Concern about the proportion of younger people dying. NHS may soon struggle to cope with the demand on hospital services. Invention of first 'swine flu wipe' (vaccination starts – 21 October)
30/10/09	Reminder of symptoms. Second wave appears to be slow moving, although a number of articles talk about 50% increase in cases. Encouragement to take up the vaccination offer. Pharmaceutical companies report increased profits. GP clinics still don't have the vaccine so there is confusion about when people can get vaccinated. A celebrity duo may have swine flu. Launch of TV ad campaign to 'catch it, bin it, kill it'
06/11/09	Four people die in the West Midlands. Statement issued saying that all school children may potentially be vaccinated. Only a 'small increase' in cases overall this week. Poor school attendance rates in Ireland
13/11/09	Some Irish papers report that the worst of the outbreak has passed. All priority groups to be vaccinated by Christmas. Cases seem to be falling in England and Ireland but still slowly rising in Scotland. Death of another pregnant woman and urges for at-risk groups to get vaccinated
20/11/09	Healthy children under 5 are to be vaccinated against swine flu. Deaths from swine flu still increasing – 21% of deaths have been under-14-year-olds. Concern that parents will not allow their children to get the vaccination (extension of vaccination programme to children is announced – 19 November)
27/11/09	Decrease in cases, but an increase in number needing hospital treatment. More deaths in Scotland. Calls for parents to get children vaccinated. Review to come in terms of whether NPFS needs to continue. A drug-resistant strain of swine flu identified
11/12/09	Swine flu to be a 'slow burn' until spring rather than a huge outbreak. Only about one-quarter of people in risk groups have opted to get the vaccination. A medical study suggests there is no clear evidence that Tamiflu cuts risk of complications. Some GPs claim they are underpaid for administering the swine flu vaccine. Death rate lower than was originally feared
28/12/09	Another rise in Scottish cases. Vaccination for children under 5 has begun. Overall number of cases has been lower than expected
08/01/10	Diagnosis levels have fallen and the worst may be over but people are encouraged to remain vigilant. Vaccination in children under 5 continues. EU governments are scaling back their orders for vaccine

Appendix 4

Tables relating to study 3

TABLE 11 *Association between personal variables and carrying tissues*

Variable	Variable levels	*n* (%)	*n* (%) carrying tissues	OR (95% CI)	aOR (95% CI)[a]
Sex	Female	3101 (57.2)	1229 (39.6)	2.0 (1.8 to 2.3)	2.1 (1.8 to 2.3)
	Male	2318 (42.8)	564 (24.3)	Reference	Reference
Age – years	16–24	518 (9.6)	173 (33.4)	0.9 (0.7 to 1.1)	0.9 (0.7 to 1.1)
	25–34	662 (12.2)	206 (31.1)	0.8 (0.7 to 0.97)	0.7 (0.6 to 0.9)
	35–54	1917 (35.4)	608 (31.7)	0.8 (0.7 to 0.9)	0.8 (0.7 to 0.96)
	55–64	979 (18.1)	320 (32.7)	0.9 (0.7 to 1.0)	0.9 (0.7 to 1.04)
	≥ 65	1343 (24.8)	486 (36.2)	Reference	Reference
Social grade	C2DE	2268 (41.9)	755 (33.3)	1.0 (0.9 to 1.1)	0.9 (0.8 to 1.1)
	ABC1	3151 (58.1)	1038 (32.9)	Reference	Reference
Ethnicity	Other ethnicity	361 (6.7)	153 (42.4)	1.5 (1.2 to 1.9)	1.8 (1.4 to 2.3)
	White	5010 (93.3)	1616 (32.3)	Reference	Reference
Household size	Six people or more	105 (2.0)	36 (34.3)	1.0 (0.7 to 1.6)	1.1 (0.7 to 1.7)
	Three to five people	1806 (33.7)	599 (33.2)	1.0 (0.9 to 1.1)	1.1 (0.9 to 1.3)
	Two people	1943 (36.3)	636 (32.7)	1.0 (0.8 to 1.1)	1.0 (0.9 to 1.2)
	One person	1502 (28.0)	501 (33.4)	Reference	Reference
General health status	Poor or very poor	407 (7.5)	165 (40.5)	1.4 (1.2 to 1.8)	1.3 (1.02 to 1.7)
	Fair	841 (15.6)	279 (33.2)	1.0 (0.9 to 1.2)	1.0 (0.8 to 1.1)
	Very good or good	4153 (76.9)	1346 (32.4)	Reference	Reference
Does participant have any long-standing infirmity or illness?	Yes	1522 (28.2)	557 (36.6)	1.2 (1.1 to 1.4)	1.2 (0.995 to 1.4)
	No	3874 (71.8)	1228 (31.7)	Reference	Reference

a Adjusting for all other personal or health-related variables.

TABLE 12 *Association between personal variables and buying sanitising gel*

Variable	Variable levels	*n* (%)	*n* (%) buying sanitising gel	OR (95% CI)	aOR (95% CI)[a]
Sex	Female	3101 (57.2)	383 (12.4)	2.4 (1.9 to 2.9)	2.4 (2.0 to 3.0)
	Male	2318 (42.8)	130 (5.6)	Reference	Reference
Age – years	16–24	518 (9.6)	77 (14.9)	2.7 (2.0 to 3.8)	2.3 (1.6 to 3.4)
	25–34	662 (12.2)	83 (12.5)	2.2 (1.6 to 3.1)	1.9 (1.3 to 2.8)
	35–54	1917 (35.4)	203 (10.6)	1.8 (1.4 to 2.4)	1.7 (1.2 to 2.2)
	55–64	979 (18.1)	69 (7.0)	1.2 (0.8 to 1.6)	1.2 (0.8 to 1.6)
	≥65	1343 (24.8)	81 (6.0)	Reference	Reference
Social grade	C2DE	2268 (41.9)	214 (9.4)	1.0 (0.8 to 1.2)	1.1 (0.9 to 1.3)
	ABC1	3151 (58.1)	299 (9.5)	Reference	Reference
Ethnicity	Other ethnicity	361 (6.7)	53 (14.7)	1.7 (1.3 to 2.3)	1.5 (1.1 to 2.0)
	White	5010 (93.3)	456 (9.1)	Reference	Reference
Household size	Six people or more	105 (2.0)	17 (16.2)	3.0 (1.7 to 5.2)	1.9 (1.02 to 3.5)
	Three to five people	1806 (33.7)	230 (12.7)	2.3 (1.8 to 2.9)	1.7 (1.3 to 2.3)
	Two people	1943 (36.3)	173 (8.9)	1.5 (1.2 to 2.0)	1.4 (1.1 to 1.9)
	One person	1502 (28.0)	91 (6.1)	Reference	Reference
General health status	Poor or very poor	407 (7.5)	45 (11.1)	1.2 (0.9 to 1.7)	1.6 (1.1 to 2.4)
	Fair	841 (15.6)	80 (9.5)	1.0 (0.8 to 1.3)	1.3 (0.97 to 1.7)
	Very good or good	4153 (76.9)	387 (9.3)	Reference	Reference
Does participant have any long-standing infirmity or illness?	Yes	1522 (28.2)	137 (9.0)	0.9 (0.8 to 1.1)	1.0 (0.8 to 1.3)
	No	3874 (71.8)	375 (9.7)	Reference	Reference

a Adjusting for all other personal or health-related variables.

TABLE 13 *Association between personal variables and avoiding public transport*

Variable	Variable levels	*n* (%)	*n* (%) avoiding public transport	OR (95% CI)	aOR (95% CI)[a]
Sex	Female	3101 (57.2)	65 (2.1)	1.1 (0.7 to 1.5)	1.1 (0.7 to 1.6)
	Male	2318 (42.8)	46 (2.0)	Reference	Reference
Age – years	16–24	518 (9.6)	16 (3.1)	1.4 (0.8 to 2.7)	1.5 (0.7 to 3.2)
	25–34	662 (12.2)	11 (1.7)	0.8 (0.4 to 1.5)	0.8 (0.4 to 1.8)
	35–54	1917 (35.4)	45 (2.3)	1.1 (0.7 to 1.7)	1.3 (0.7 to 2.2)
	55–64	979 (18.1)	10 (1.0)	0.5 (0.2 to 0.96)	0.5 (0.3 to 1.1)
	≥65	1343 (24.8)	29 (2.2)	Reference	Reference
Social grade	C2DE	2268 (41.9)	51 (2.2)	1.2 (0.8 to 1.7)	1.0 (0.7 to 1.6)
	ABC1	3151 (58.1)	60 (1.9)	Reference	Reference
Ethnicity	Other ethnicity	361 (6.7)	24 (6.6)	4.1 (2.6 to 6.6)	4.1 (2.5 to 6.8)
	White	5010 (93.3)	85 (1.7)	Reference	Reference
Household size	Six people or more	105 (2.0)	6 (5.7)	2.6 (1.1 to 6.4)	1.4 (0.5 to 3.8)
	Three to five people	1806 (33.7)	36 (2.0)	0.9 (0.5 to 1.4)	0.8 (0.4 to 1.3)
	Two people	1943 (36.3)	34 (1.7)	0.8 (0.5 to 1.2)	0.8 (0.5 to 1.3)
	One person	1502 (28.0)	34 (2.3)	Reference	Reference
General health status	Poor or very poor	407 (7.5)	16 (3.9)	2.3 (1.3 to 4.0)	2.6 (1.3 to 5.1)
	Fair	841 (15.6)	23 (2.7)	1.6 (0.99 to 2.6)	1.6 (0.96 to 2.8)
	Very good or good	4153 (76.9)	72 (1.7)	Reference	Reference
Does participant have any long-standing infirmity or illness?	Yes	1522 (28.2)	36 (2.4)	1.2 (0.8 to 1.8)	1.0 (0.6 to 1.6)
	No	3874 (71.8)	75 (1.9)	Reference	Reference

a Adjusting for all other personal or health-related variables.

TABLE 14 *Association between personal variables and visiting a GP or hospital or phoning NHS Direct for flu-related reasons.*

Variable	Variable levels	*n* (%)	*n* (%) using health care services	OR (95% CI)	aOR (95% CI)[a]
Sex	Female	3101 (57.2)	53 (1.7)	1.1 (0.7 to 1.7)	1.1 (0.7 to 1.8)
	Male	2318 (42.8)	35 (1.5)	Reference	Reference
Age – years	16–24	518 (9.6)	13 (2.5)	1.7 (0.8 to 3.4)	1.2 (0.5 to 2.9)
	25–34	662 (12.2)	10 (1.5)	1.0 (0.5 to 2.2)	0.9 (0.4 to 2.2)
	35–54	1917 (35.4)	32 (1.7)	1.1 (0.6 to 2.0)	0.9 (0.5 to 1.8)
	55–64	979 (18.1)	13 (1.3)	0.9 (0.4 to 1.8)	0.9 (0.4 to 1.8)
	≥65	1343 (24.8)	20 (1.5)	Reference	Reference
Social grade	C2DE	2268 (41.9)	43 (1.9)	1.3 (0.9 to 2.0)	1.1 (0.7 to 1.8)
	ABC1	3151 (58.1)	45 (1.4)	Reference	Reference
Ethnicity	Other ethnicity	361 (6.7)	13 (3.6)	2.5 (1.4 to 4.5)	2.2 (1.2 to 4.2)
	White	5010 (93.3)	74 (1.5)	Reference	Reference
Household size	Six people or more	105 (2.0)	6 (5.7)	3.7 (1.5 to 9.3)	3.3 (1.2 to 9.1)
	Three to five people	1806 (33.7)	39 (2.2)	1.4 (0.8 to 2.3)	1.6 (0.8 to 2.9)
	Two people	1943 (36.3)	18 (0.9)	0.6 (0.3 to 1.1)	0.6 (0.3 to 1.1)
	One person	1502 (28.0)	24 (1.6)	Reference	Reference
General health status	Poor or very poor	407 (7.5)	13 (3.2)	2.5 (1.3 to 4.5)	2.6 (1.3 to 5.5)
	Fair	841 (15.6)	20 (2.4)	1.8 (1.1 to 3.0)	1.7 (0.9 to 3.1)
	Very good or good	4153 (76.9)	55 (1.3)	Reference	Reference
Does participant have any long-standing infirmity or illness?	Yes	1522 (28.2)	31 (2.0)	1.4 (0.9 to 2.2)	1.2 (0.6 to 2.0)
	No	3874 (71.8)	56 (1.4)	Reference	Reference

a Adjusting for all other personal or health-related variables.

TABLE 15 *Association between media and advertising exposure, information and worry-related variables and carrying tissue*

Variable	Variable levels	*n* (%)	*n* (%) carrying tissues	OR (95% CI)	aOR (95% CI)[a]
Exposure to media coverage	Exposed	4167 (76.9)	1387 (33.3)	1.0 (0.9 to 1.2)	1.0 (0.9 to 1.2)
	Not exposed	1251 (23.1)	405 (32.4)	Reference	Reference
Exposure to advertising	Exposed	2735 (50.5)	942 (34.4)	1.1 (1.01 to 1.3)	1.2 (1.05 to 1.3)
	Not exposed	2683 (49.5)	850 (31.7)	Reference	Reference
How much have you heard about swine flu?	A lot or a moderate amount	4817 (92.9)	1618 (33.6)	1.2 (0.97 to 1.5)	1.3 (0.99 to 1.6)
	A little or nothing	366 (7.1)	107 (29.2)	Reference	Reference
How much do you know about swine flu	A lot or a moderate amount	3803 (73.6)	1308 (34.4)	1.2 (1.05 to 1.4)	1.2 (1.03 to 1.4)
	A little or nothing	1365 (26.4)	416 (30.5)	Reference	Reference
How satisfied are you with amount of information?	Very or fairly satisfied	4462 (91.0)	1520 (34.1)	1.0 (0.8 to 1.2)	1.0 (0.8 to 1.2)
	Very or fairly dissatisfied	441 (9.0)	155 (35.1)	Reference	Reference
Do you want more information?	Yes	1998 (36.9)	775 (38.8)	1.5 (1.3 to 1.7)	1.4 (1.3 to 1.6)
	No	3417 (63.1)	1016 (29.7)	Reference	Reference
How well prepared is the government?	Very or fairly well prepared	4014 (78.3)	1347 (33.6)	1.1 (0.95 to 1.3)	1.1 (0.97 to 1.3)
	Not very or not at all well prepared	1113 (21.7)	351 (31.5)	Reference	Reference
How worried are you about swine flu?	Very or fairly worried	757 (14.0)	348 (46.0)	1.9 (1.6 to 2.2)	1.7 (1.5 to 2.0)
	Not very or not at all worried	4642 (86.0)	1441 (31.0)	Reference	Reference
Hygiene efficacy score	Median or higher	2827 (52.2)	1095 (38.7)	1.7 (1.5 to 1.9)	1.6 (1.4 to 1.8)
	Lower than median	2588 (47.8)	698 (27.0)	Reference	Reference
Avoidance efficacy score	Median or higher	2728 (50.5)	989 (36.3)	1.3 (1.2 to 1.5)	1.2 (1.1 to 1.4)
	Lower than median	2674 (49.5)	801 (30.0)	Reference	Reference

a Adjusting for all other personal or health-related variables.

TABLE 16 *Association between media and advertising exposure, information and worry-related variables and buying sanitising gel*

Variable	Variable levels	*n* (%)	*n* (%) buying sanitising gel	OR (95% CI)	aOR (95% CI)[a]
Exposure to media coverage	Exposed	4167 (76.9)	394 (9.5)	1.0 (0.8 to 1.2)	1.1 (0.8 to 1.3)
	Not exposed	1251 (23.1)	118 (9.4)	Reference	Reference
Exposure to advertising	Exposed	2735 (50.5)	308 (11.3)	1.5 (1.3 to 1.9)	1.4 (1.2 to 1.7)
	Not exposed	2683 (49.5)	204 (7.6)	Reference	Reference
How much have you heard about swine flu?	A lot or a moderate amount	4817 (92.9)	469 (9.7)	1.3 (0.9 to 1.9)	1.4 (0.9 to 2.1)
	A little or nothing	366 (7.1)	28 (7.7)	Reference	Reference
How much do you know about swine flu	A lot or a moderate amount	3803 (73.6)	380 (10.0)	1.2 (0.95 to 1.5)	1.2 (0.97 to 1.5)
	A little or nothing	1365 (26.4)	117 (8.6)	Reference	Reference
How satisfied are you with amount of information?	Very or fairly satisfied	4462 (91.0)	439 (9.8)	1.0 (0.7 to 1.3)	0.9 (0.7 to 1.3)
	Very or fairly dissatisfied	441 (9.0)	45 (10.2)	Reference	Reference
Do you want more information?	Yes	1998 (36.9)	249 (12.5)	1.7 (1.4 to 2.0)	1.5 (1.3 to 1.9)
	No	3417 (63.1)	264 (7.7)	Reference	Reference
How well prepared is the government?	Very or fairly well prepared	4014 (78.3)	372 (9.3)	0.9 (0.7 to 1.1)	0.9 (0.7 to 1.1)
	Not very or not at all well prepared	1113 (21.7)	115 (10.3)	Reference	Reference
How worried are you about swine flu?	Very or fairly worried	757 (14.0)	145 (19.2)	2.8 (2.2 to 3.4)	2.3 (1.9 to 2.9)
	Not very or not at all worried	4642 (86.0)	366 (7.9)	Reference	Reference
Hygiene efficacy score	Median or higher	2827 (52.2)	339 (12.0)	1.9 (1.6 to 2.3)	1.8 (1.5 to 2.2)
	Lower than median	2588 (47.8)	174 (6.7)	Reference	Reference
Avoidance efficacy score	Median or higher	2728 (50.5)	274 (10.0)	1.1 (0.9 to 1.4)	1.2 (0.99 to 1.5)
	Lower than median	2674 (49.5)	239 (8.9)	Reference	Reference

a Adjusting for all other personal or health-related variables.

TABLE 17 *Association between media and advertising exposure, information and worry-related variables and avoiding public transport*

Variable	Variable levels	*n* (%)	*n* (%) carrying tissues	OR (95% CI)	aOR (95% CI)[a]
Exposure to media coverage	Exposed	4167 (76.9)	82 (2.0)	0.8 (0.6 to 1.3)	0.9 (0.6 to 1.4)
	Not exposed	1251 (23.1)	29 (2.3)	Reference	Reference
Exposure to advertising	Exposed	2735 (50.5)	44 (1.6)	0.6 (0.4 to 0.9)	0.7 (0.4 to 0.99)
	Not exposed	2683 (49.5)	67 (2.5)	Reference	Reference
How much have you heard about swine flu?	A lot or a moderate amount	4817 (92.9)	85 (1.8)	0.3 (0.2 to 0.5)	0.4 (0.2 to 0.6)
	A little or nothing	366 (7.1)	20 (5.5)	Reference	Reference
How much do you know about swine flu	A lot or a moderate amount	3803 (73.6)	65 (1.7)	0.6 (0.4 to 0.9)	0.6 (0.4 to 0.99)
	A little or nothing	1365 (26.4)	40 (2.9)	Reference	Reference
How satisfied are you with amount of information?	Very or fairly satisfied	4462 (91.0)	81 (1.8)	0.4 (0.2 to 0.6)	0.4 (0.2 to 0.7)
	Very or fairly dissatisfied	441 (9.0)	21 (4.8)	Reference	Reference
Do you want more information?	Yes	1998 (36.9)	72 (3.6)	3.2 (2.2 to 4.8)	2.8 (1.9 to 4.2)
	No	3417 (63.1)	39 (1.1)	Reference	Reference
How well prepared is the government?	Very or fairly well prepared	4014 (78.3)	73 (1.8)	0.6 (0.4 to 0.9)	0.7 (0.5 to 1.1)
	Not very or not at all well prepared	1113 (21.7)	33 (3.0)	Reference	Reference
How worried are you about swine flu?	Very or fairly worried	757 (14.0)	49 (6.5)	5.1 (3.5 to 7.5)	4.1 (2.7 to 6.2)
	Not very or not at all worried	4642 (86.0)	62 (1.3)	Reference	Reference
Hygiene efficacy score	Median or higher	2827 (52.2)	63 (2.2)	1.2 (0.8 to 1.8)	1.2 (0.8 to 1.9)
	Lower than median	2588 (47.8)	47 (1.8)	Reference	Reference
Avoidance efficacy score	Median or higher	2728 (50.5)	89 (3.3)	4.3 (2.6 to 6.9)	4.1 (2.5 to 6.8)
	Lower than median	2674 (49.5)	21 (0.8)	Reference	Reference

a Adjusting for all other personal or health-related variables.

TABLE 18 *Association between media and advertising exposure, information and worry-related variables and visiting a GP or hospital or phoning NHS Direct for flu-related reasons*

Variable	Variable levels	*n* (%)	*n* (%) using health services	OR (95% CI)	aOR (95% CI)[a]
Exposure to media coverage	Exposed	4167 (76.9)	57 (1.4)	0.5 (0.4 to 0.8)	0.6 (0.4 to 0.9)
	Not exposed	1251 (23.1)	31 (2.5)	Reference	Reference
Exposure to advertising	Exposed	2735 (50.5)	43 (1.6)	0.9 (0.6 to 1.4)	0.9 (0.6 to 1.5)
	Not exposed	2683 (49.5)	45 (1.7)	Reference	Reference
How much have you heard about swine flu?	A lot or a moderate amount	4817 (92.9)	77 (1.6)	3.0 (0.7 to 12.1)	3.6 (0.9 to 14.9)
	A little or nothing	366 (7.1)	2 (0.5)	Reference	Reference
How much do you know about swine flu	A lot or a moderate amount	3803 (73.6)	63 (1.7)	1.5 (0.9 to 2.7)	1.8 (0.99 to 3.2)
	A little or nothing	1365 (26.4)	15 (1.1)	Reference	Reference
How satisfied are you with amount of information?	Very or fairly satisfied	4462 (91.0)	70 (1.6)	0.6 (0.3 to 1.1)	0.6 (0.3 to 1.2)
	Very or fairly dissatisfied	441 (9.0)	12 (2.7)	Reference	Reference
Do you want more information?	Yes	1998 (36.9)	45 (2.3)	1.8 (1.2 to 2.8)	1.5 (0.97 to 2.3)
	No	3417 (63.1)	43 (1.3)	Reference	Reference
How well prepared is the government?	Very or fairly well prepared	4014 (78.3)	65 (1.6)	0.9 (0.6 to 1.6)	1.3 (0.7 to 2.0)
	Not very or not at all well prepared	1113 (21.7)	19 (1.7)	Reference	Reference
How worried are you about swine flu?	Very or fairly worried	757 (14.0)	27 (3.6)	2.8 (1.8 to 4.4)	2.3 (1.4 to 3.4)
	Not very or not at all worried	4642 (86.0)	61 (1.3)	Reference	Reference
Hygiene efficacy score	Median or higher	2827 (52.2)	52 (1.8)	1.4 (0.9 to 2.1)	1.5 (0.9 to 2.4)
	Lower than median	2588 (47.8)	35 (1.4)	Reference	Reference
Avoidance efficacy score	Median or higher	2728 (50.5)	49 (1.8)	1.3 (0.8 to 1.9)	1.3 (0.8 to 2.0)
	Lower than median	2674 (49.5)	38 (1.4)	Reference	Reference

a Adjusting for all personal or health-related variables.

The impact of illness and the impact of school closure on social contact patterns

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Abstract

The impact of illness and the impact of school closure on social contact patterns

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Background: Mathematical models, based on data describing normal patterns of social mixing, are used to understand epidemics in order to predict patterns of disease spread and plan interventions and responses. However, individuals who are ill show behavioural changes that affect their social mixing patterns and predictive models should take into account these changes if they are to be effective.
Objectives: To describe and quantify the changes in (1) social contact behaviour experienced by individuals when they are ill with pandemic H1N1 influenza (swine flu) and (2) mixing patterns of school children that take place as a result of swine flu-related school closures.
Methods: For the first part of the study, a self-completed questionnaire-based study was carried out in the autumn/winter of 2009–10. The study population was individuals who had been diagnosed with swine flu and who received a swine flu antiviral prescription from an antiviral distribution centre (ADC). It consisted of an initial survey to be filled in when participants were symptomatic with swine flu and a follow-up survey to be filled in when they had recovered. Each part of the questionnaire had two sections: patient details and a contact diary. The second part of the study was adapted to quantify the difference in mixing patterns of pupils between the school term and the half-term holiday as school closures did not occur during the study period. Eight schools participated and questionnaire packs were distributed to them, containing two surveys: one to be filled in during the school term and one during the spring half-term holiday.
Results: For the patient study, approximately 3800 surveys were distributed by 31 ADCs. Overall, 317 responses to the initial survey were received and 179 participants returned the follow-up survey. For all types of a contact, except contacts made at home, there were highly significant differences in contact behaviour (Wilcoxon signed-rank test, $p < 0.001$). Individuals made substantially fewer contacts when they were ill than when they were well. Analysis showed that returning to work was the most significant predictor of increased numbers of contacts. Also, the greater the change in the number of symptoms reported, the greater the change in the number of contacts. For the school study, approximately 1100 questionnaire packs were distributed and 134 responses were received, with 119 paired contact diaries. Pupils reported on average 18.51 contacts each day during term time and 9.24 during the half-term holiday – a reduction of over 50% and a highly significant change (Wilcoxon signed-rank test, $p < 0.0001$).
Conclusions: The evidence from this study suggests that ill individuals make substantial changes to their social contact patterns. These changes are strongly linked to absence from work and the severity of the reported illness. Epidemiological modellers should therefore consider the implications of illness-related behavioural changes on model predictions. Future studies to measure the extent of behavioural change in a broader cross-section of infected cases could be valuable, along with more detailed studies of the social contact patterns of school children, focusing on differences between school terms and school holidays.

Contents

List of abbreviations

ADC	antiviral distribution centre	NPFS	National Pandemic Flu Service
IQR	interquartile range	SD	standard deviation

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices, in which case the abbreviation is defined in the figure legend or in the notes at the end of the table.

Executive summary

Background

Mathematical models are increasingly used to understand epidemics, to predict future patterns of disease spread, and to plan interventions and responses. Models of epidemic spread rely heavily on the assumptions that they make about patterns of mixing within the population of interest. In recent years, high-quality data have been collected to describe 'normal' patterns of social mixing. However, while such data give good information about healthy individuals, they tell us very little about the behaviour of individuals when they are ill. If, as seems likely, there are significant behavioural changes that take place as a result of illness – such as taking time off work or avoiding social gatherings – we would expect changes in mixing patterns; for predictive models to be effective, they should take into account these changes.

Objectives

- To describe and quantify the changes in social contact behaviour experienced by individuals when they are ill with pandemic H1N1 influenza (swine flu).
- To describe and quantify the changes in mixing patterns of school children that take place as a result of school closures.

Methods

A self-completed questionnaire-based study was designed and carried out in the autumn/winter of 2009–10. The study population was individuals who had been diagnosed with swine flu and who received a swine flu antiviral prescription from an antiviral distribution centre (ADC). The study aimed to quantify changes in participants' social contact behaviour.

The study consisted of two parts: the *initial survey* was designed to be filled in when participants were symptomatic with swine flu; the *follow-up survey* was designed to be filled in once they had recovered. Each part was returned by post in a provided prepaid envelope.

Each part of the questionnaire had two sections.

The first section collected information about the participant (age, sex, household size and composition), their health status (symptoms list, a measure of their current health, date of symptom onset, antiviral use), their behaviour (work/school/college attendance, public transport use), and the impact of their illness on their activities (time off work, receiving care from others). This section also asked participants for their name and address so that the follow-up survey could be sent to them.

The second section was a contact diary in which participants were asked to list all the people they met over the course of a day. A meeting was defined as 'either talking face-to-face or skin-to-skin contact (e.g. a handshake, a kiss, contact sports)'. Participants were asked to give some information about each person whom they reported meeting:

- age (or age range)
- gender
- whether there was skin-to-skin contact (such contacts will be referred to as 'physical' contacts below)
- how long the encounter lasted (participants were asked to tick one of the following: under 5 minutes, 5–10 minutes, 10 minutes to 1 hour, 1–4 hours, over 4 hours)
- where the encounter occurred (participants were asked to tick one or more of the following: home, work/school/college, travel, leisure activity, other)
- how often they normally met this person (participants were asked to tick one of the following: daily or almost daily, once or twice weekly, once or twice monthly, less than monthly, never met before).

Contact diaries contained space for details of 33 contacts to be recorded. Participants were asked whether they had included everyone whom they met during the day and, if not, were asked how many 'additional' people they met.

The follow-up survey was posted to participants approximately 2 weeks after they completed and returned the initial survey; it was hoped that this

time interval would be long enough that most participants would have recovered and resumed their normal activities, but not so long that they would have lost interest in taking part. Those individuals who had not returned their follow-up survey within a further 2 weeks were sent a reminder. Survey forms were coded with a unique identification number that allowed us to match up an individual's initial and follow-up surveys.

The intention was that each participant would record their social contact behaviour once when they were ill with swine flu and once when they had recovered.

A covering letter explaining the purpose of the study and instructions for filling in the forms was included with each survey.

The initial survey was distributed along with antiviral prescriptions at antiviral distribution centres (ADCs) in all parts of England.

Approximately 3800 surveys were distributed by 31 ADCs. Overall, 317 responses to the initial survey were received, and, of these, participants, 179 also returned the follow-up survey.

It was intended that a similar study should take place to look at the impact of swine flu-related school closure on the social contact patterns of school children. However, as swine flu related closures did not occur during the autumn of 2009, this study could not take place. Instead, the methodology was adapted to attempt to quantify the difference in mixing patterns between the school term and the half-term holiday. Eight schools were recruited to take part, and approximately 1100 questionnaire packs were distributed, containing two surveys similar to those described above: one to be filled in during the school term and one during the spring half-term holiday. A total of 134 responses were received, with 119 completed contact diaries.

Results

Swine flu antiviral patient study

We explored changes in each participant's reported contact data. Because of the repeated sampling of participants, we have paired data (i.e. two completed contact diaries) from each participant.

The completed contact diaries contained a great deal of detail about contact behaviour, and there was therefore a multitude of different comparisons that could be attempted; for the sake of simplicity and clarity we restricted ourselves to the following key measures:

- *all* number of contacts listed on the contact diary
- *all plus additional* contacts listed on the contact diary plus any 'additional' contacts
- *physical* total number of physical (skin-to-skin) contacts reported
- *home* total number of home contacts recorded
- *work* total number of work/school/college contacts recorded
- *other* total number of contacts recorded in travel/leisure/other settings
- *long duration* total number of contacts recorded that lasted over 1 hour
- *short duration* total number of contacts recorded that lasted less than 10 minutes
- *frequent* total number of contacts recorded who were encountered once a week or more
- *infrequent* total number of contacts recorded who were encountered less than once a month.

In each case, we sought to explore the extent to which the numbers of these different types of social contacts differed between the initial and the follow-up surveys.

There were indeed noticeable changes in contact behaviour, although contacts taking place at home did not vary. For all types of a contact, except contacts made at home, the differences are highly significant (Wilcoxon signed-rank test, $p < 0.001$). There was no significant change in the number of home contacts.

However, when viewing the sample, and whichever measure of contact we used, we could see that individuals made substantially fewer contacts when they were ill than when they were well. Contacts made by ill participants tended to take place at home (with very few in the workplace or in other settings); they were generally with people whom they met often and for long periods of time, and they often included physical contact.

We postulated that changes in social mixing patterns would be associated with age, gender, changes in health status, returning to work/school/college, household size, and change in day of the week (for instance, from weekday to weekend or vice versa).

These factors were analysed using a linear regression model. Several factors emerge as significant: returning to work/school/college,

change in number of symptoms, age and household size.

Returning to work/school/college was associated with a large increased change in the number of contacts reported, being a significant factor in the change in all-plus-additional contacts ($p < 0.001$), all contacts ($p < 0.001$), frequent contacts ($p < 0.001$), long-duration contacts ($p = 0.003$), short-duration contacts ($p = 0.007$), contacts in 'other settings' ($p = 0.013$) and (unsurprisingly) work/school/college contacts ($p < 0.001$).

The change in the number of symptoms reported was also associated with an increased change in numbers of social contacts, being a significant factor in the change in all contacts ($p = 0.022$), infrequent contacts ($p < 0.001$), physical contacts ($p = 0.015$) and short contacts ($p = 0.007$).

Older age was associated with a reduced change in number of contacts: younger adults reported a larger change in their number of infrequent contacts ($p = 0.041$), whereas older adults reported a smaller change in their number of physical contacts ($p = 0.017$ for ages 45–59, $p = 0.034$ for ages over 60) and long-duration contacts ($p = 0.006$ for ages 30–44, $p = 0.002$ for ages 45–59, $p = 0.045$ for ages over 60).

A larger household was associated with a smaller change in the number of infrequent contacts ($p = 0.041$) and physical contacts ($p = 0.032$).

Being infected with diagnosed swine flu had a considerable impact on the social contact patterns of those who participated in our study. Infected participants generally took time away from work/school/college and from social activities, and therefore made considerably fewer contacts when they were ill than when they had recovered. Participants made approximately two-thirds fewer contacts when they were unwell.

The distribution of social contacts changed when people were unwell; unwell people made approximately two-thirds of their social contacts at home, falling to one-quarter when they had recovered, although the reported absolute number of contacts made at home stayed almost constant. Not surprisingly, work/school/college contacts and contacts made in other settings (travel, leisure, other) fell dramatically when people were ill.

There was an observed tendency for the more transient contacts (infrequent contacts and contacts not involving physical contact) to be more influenced by illness than stronger contacts (frequent contacts and physical contacts). This again is unsurprising, as stronger contacts are more likely to be made in the home.

The analysis made clear the important role played by the workplace (or school, or college) on social contacts – returning to work was by some distance the most significant predictor of increased numbers of contacts.

The seriousness of infection also played a role; the greater the change in the number of symptoms reported, the greater the change in the number of contacts.

Differences between age groups emerged, with those in younger age groups tending to have a greater change in their contact patterns; this can be explained by the differences in social mixing patterns between schools and workplaces, with older individuals appearing to mingle in smaller groups than younger individuals.

School closure

A similar paired survey carried out in schools to compare mixing patterns during the half-term holiday with those during school term observed large changes in social contact behaviour. Pupils who completed the survey reported, on average, 18.51 contacts each day during term time and 9.24 during the half-term holiday – a reduction of over 50%. The change in number of contacts was highly significant (Wilcoxon signed-rank test, $p < 0.0001$).

Conclusions

The evidence from this study suggests that ill individuals make substantial changes to their social contact patterns. Participants in the study made substantially fewer social contacts when they were ill compared with when they had recovered. The changes in contact patterns were strongly linked to absence from work and the severity of the reported illness, with age and household size also playing a role. Epidemiological modellers should therefore be wary of using data about 'normal' contact patterns to parameterise mathematical models of disease spread, and should consider the implications of illness-related behavioural changes on model predictions.

This study highlights areas for future research. First, a more detailed study that aims to recruit a representative sample of cases would be

particularly valuable; the study here, owing to its sampling methodology and the time constraints under which it took place, almost certainly ended up with a sample population that was experiencing relatively severe symptoms. Although such people are of interest, they are likely to display greater behavioural change than the average infected case. It would be of value to carry out studies, perhaps during forthcoming seasonal flu seasons, which measure the extent of behavioural change in a broader cross-section of infected cases.

Second, as it was clear that children played a dominant role in the swine flu pandemic, and that they might be expected to do so in future pandemics, and as it was apparent from the UK incidence data that normal patterns of school holidays had a significant impact on transmission, we advocate more detailed studies of the social contact patterns of school children, particularly focusing on differences between school terms and school holidays. Our experience is that for school-based studies to be successful the researcher must be prepared to make a substantial investment of time and energy – such studies are therefore best conceived as long-term projects achieving high levels of engagement with participating schools, rather than as rapid exercises.

Chapter 1
Introduction

The spread of infectious diseases is, in many cases, determined by patterns of mixing between individuals in a population. In the case of human-to-human transmission, social contact behaviour is the key to understanding the dynamics of a wide range of common infections, such as measles, influenza and the common cold.[1–15] The response to the 2009 H1N1 influenza (termed swine flu throughout) pandemic illustrated the requirement for well-parameterised mathematical models of the spread of infection.[5,9,16–17] Governments required modellers to provide guidance on likely scenarios, to aid planning and to give advice on vaccination strategies.[3,18–19] Over recent years, more and more research has been devoted to measuring and understanding human social contact patterns. Studies have ranged from detailed analyses of social networks within contained communities[8,20–22] and small-scale detailed surveys,[23] to large-scale population-based surveys of mixing patterns.[4,15,24] The most notable such study (POLYMOD), involving over 7000 individuals across Europe, consisted of self-completed contact diaries in which participants noted details of all the individuals with whom they came into contact over the course of a day.[15] The POLYMOD study allowed a quantitative comparison of contacts made, say, at home and at work, or of long- and short-duration contacts; it also allowed more complex quantities to be evaluated, such as the fraction of contacts made at home that lasted over 1 hour, and included skin-to-skin contact.

As a representation of normal social behaviour, the POLYMOD study is unsurpassed and its results have already been used to parameterise numerous models of infectious disease spread.[3,7,10,13,18] The flaw is that this and other studies are designed to measure only 'normal' behaviour; while this gives us important information, it does not tell us all that we need to know – in particular, it gives us little information about the behaviour of infectious individuals. If, as seems certain, social contact behaviour changes when we are sick, then models based on normal behaviour are in danger of reaching the wrong conclusions. Furthermore, ad hoc attempts to correct this by, for instance, assuming a halving of contacts when ill, are fraught with danger. Would home contacts and work contacts fall by the same amount? Would ill people reduce their interactions with people they normally meet only occasionally to the same extent as those with people whom they normally meet every day?

To shed light on these issues, therefore, in the study described here we aimed to measure changes in social contact behaviour that took place as a result of illness. Using methodology similar to that developed in the POLYMOD study,[15] participants completed contact diaries to describe their contact patterns over the course of a day. In our study, however, participants completed two separate contact diaries: one when they were unwell and one when they had recovered.

The study took place during the 2009–10 swine flu pandemic. This new variant of influenza was first identified in April 2009 in the Americas, and was soon introduced into the UK.[3,19,25] Originally appearing as sporadic cases associated with travel to Mexico and the USA, swine flu soon established itself in the UK, with large numbers of cases occurring in July 2009.[3,25] Antiviral medication was made available in the UK to those with probable/suspected swine flu. Initially, prescriptions were generally issued by GPs, but in mid-July a telephone- and internet-based system [the National Pandemic Flu Service (NPFS)] was launched, whereby reporting a list of symptoms allowed individuals to be issued with an antiviral prescription. Ill individuals were encouraged to seek the assistance of a 'flu friend' to collect their prescription for them.

Cases were concentrated in children, and incidence fell once schools closed for their summer break.[25–31] However, it was expected, and indeed it came to pass, that a second wave of cases would be seen in the autumn once schools reopened.

In order to measure changes in social contact behaviour that took place as a result of illness, a questionnaire-based study was designed and carried out in the UK in autumn/winter 2009.

A second study was carried out to measure changes in school children's contact behaviour as a result of school closure.

Chapter 2
Methods

Survey design

The questionnaire had two parts; the *initial survey* was designed to be filled in when participants were symptomatic with suspected swine flu; the *follow-up survey* was designed to be filled in once they had recovered. Each part was returned in a provided prepaid envelope.

Each part of the questionnaire had two sections: the first section collected information about the participant (age, sex, household size and composition), their health status (symptoms list, a measure of their current health, a measure of their health on the day that they were most unwell, date of symptom onset, antiviral use), their behaviour (work/school/college attendance, public transport use) and the impact of their illness on their activities (time off work, receiving care from others). This section also asked participants for their name and address so that the follow-up survey could be sent to them.

The second section was a contact diary in which participants were asked to list all of the people they met over the course of a day. A meeting was defined as 'either talking face-to-face or skin to skin contact (e.g. a handshake, a kiss, contact sports)'. Participants were asked to give some information about each person whom they reported meeting:

- age (or age range)
- gender
- whether there was skin-to-skin contact (such contacts will be referred to as 'physical' contacts below)
- how long the encounter lasted (participants were asked to tick one of the following: under 5 minutes, 5–10 minutes, 10 minutes to 1 hour, 1–4 hours, over 4 hours)
- where the encounter occurred (participants were asked to tick one or more of the following: home, work/school/college, travel, leisure activity, other)
- how often they normally met this person (participants were asked to tick one of the following: daily or almost daily, once or twice weekly, once or twice monthly, less than monthly, never met before).

There was sufficient space on the contact diary to give this information about 33 different contacts. Participants were asked whether they had included everyone they met during the day and, if not, they were asked how many other people they met that day; these will be termed 'additional contacts'.

The follow-up survey was posted to participants approximately 2 weeks after they completed and returned the initial survey; it was hoped that this time interval would be long enough to ensure that most participants would have recovered and resumed their normal activities, but not so long that they would have lost interest in taking part. Those participants who had not returned their follow-up survey within a further 2 weeks were sent a reminder. Survey forms were coded with a unique identification number that allowed us to match up an individual's initial and follow-up surveys.

The intention was that each participant would record their social contact behaviour once when they were ill with swine flu and once when they had recovered.

A covering letter explaining the purpose of the study and instructions for filling in the forms was included with each survey. All questionnaire forms can be found in Appendix 1.

The study received ethical approval from the Riverside Research Ethics Committee.

It was intended that a similar study would be undertaken to measure the impact of swine flu-related school closures on the contact patterns of school pupils.[5,10–11,14] However, contrary to expectations, such closures did not occur in autumn 2009. Nevertheless, a small 'half-term' study was carried out in February/March 2010 – see Appendix 2 for further details.

Participant recruitment

Participants were recruited to the study through antiviral distribution centres (ADCs). ADCs (generally pharmacies) were sampled via a stratified random sampling design, in which two ADCs in each region of England were selected

from a list of all ADCs. This allowed us to access individuals with probable swine flu and to achieve a wide geographical spread. It became apparent that many of the sampled ADCs were small and were handling very few cases by the time the survey was under way. Hence, it was decided to supplement the initial sample, by additionally sampling from among the busiest ADCs in each of the sampled regions. This resulted in a total of 31 ADCs being sampled. Questionnaire packs were distributed by ADCs along with antiviral prescriptions. Because of the abnormally heavy workload that these ADCs were experiencing, in many cases, due to the epidemic, and to reduce the demands placed on pharmacy staff, ADCs were not asked to screen potential participants (which would, in any case, have been made difficult by the fact that in many instances prescriptions were collected not by the potential participants themselves but on their behalf by their 'flu friend'). No age restrictions were applied to participation; however, it was suggested in the covering letter that if the individual receiving antiviral medicine was under 16 years of age, then their parent/guardian might prefer to complete the survey on their behalf.

Each questionnaire pack contained a covering letter, instructions for filling in the forms, and the initial survey itself.

On the basis of a power calculation, using a conservative estimate of the expected change in number of social contacts (based on data collected in the POLYMOD study[15]) it was hoped to recruit 800 participants into the study.

Analysis

A database was designed using EPIDATA 3.1, and data entry was carried out in March 2010, once all initial and follow-up surveys had been received.

Analyses were carried out to test whether changes in number of contacts took place, and to explore factors influencing the size of any such changes. Change in number of contacts was defined as 'number of contacts reported in the follow-up survey minus number of contacts reported in the initial survey', where 'contacts' could refer to a number of different measures of interactions – such as contacts at home, or contacts involving skin-to-skin contact.

To test whether the number of contacts changed, a non-parametric Wilcoxon signed-rank test was used. A backwards stepwise linear regression model was used to explore significant contributory factors, the factor with the largest non-significant p-value being removed at each step and the model rerun until all remaining factors were significant ($p < 0.05$).

Statistical analyses were carried out using STATA 11.

Capping contacts

A few participants used the 'additional contacts' section of the contact diary to report that they had contact with many hundreds of people in a day (for instance, by working as teachers or in a busy shop); to avoid skewed results generated by such outliers a cap of 33 contacts (the number of rows on the contact diary) was applied to contacts listed, and a cap of 66 was applied to the total number of contacts (i.e. all listed on the contact diary plus the number reported as additional contacts).

The application of this cap affected only a small number of contact diaries (the option of reporting numbers of additional contacts without needing to record extra details about each of these contacts was not required by most participants – it was used three times in the initial contact diary and 12 times in the follow-up contact diary) and does not qualitatively alter our conclusions.

Study population

Participating ADCs

During mid-October 2009, 31 ADCs were recruited to take part in the study, distributing questionnaire packs along with antiviral prescriptions. Depending on their size, ADCs were given between 25 and 300 questionnaire packs to distribute, with some requesting additional packs.

In total, 4265 questionnaire packs were sent to ADCs, of which approximately 3795 were distributed along with antiviral prescriptions. Distribution of questionnaire packs by ADCs began on the 10 November 2009 and continued until approximately 9 January 2010. Details of the spatial distribution of ADCs can be found in *Table 1*.

Participants

Overall, 317 initial surveys were returned and 308 follow-up surveys were sent out (nine participants did not provide an address). A total of 179 follow-up surveys were eventually returned (45 of which

TABLE 1 *Spatial distribution of the study sample and response rate*[a]

Region	ADCs recruited	Approximate no. of questionnaires distributed	Initial response (rate) (*n*, %)	Follow-up response (rate) (*n*, %)
East of England	5	566	46 (8.1)	30 (65.2)
East Midlands	1	200	5 (2.5)	2 (40.0)
London	2	300	19 (6.3)	11 (57.9)
North East	3	619	73 (11.8)	34 (46.8)
North West	3	350	16 (4.6)	10 (62.5)
South East Coast	3	200	14 (7.0)	9 (64.3)
South Central	3	412	45 (10.9)	26 (57.8)
South West	4	252	32 (12.7)	20 (62.5)
West Midlands	4	384	41 (10.7)	22 (53.7)
Yorkshire and the Humber	3	512	26 (5.1)	15 (57.7)
Total	*31*	*3795*	*317 (8.4)*	*179 (56.5)*

a Follow-up surveys were issued to only those who returned the initial survey; the follow-up response rate is therefore defined as the fraction of initial respondents who also returned a follow-up survey.

had received a reminder). The interval between completing the initial and the follow-up surveys had a median of 19 days and an interquartile range (IQR) of 14 to 30 days. The overall response rate was disappointingly low – see below for further discussion (see Chapter 4 – Discussion). The rest of this report will describe the results provided by these 179 participants, which will be referred to as the 'study population'.

The spatial distribution of participating ADCs and of participants is shown in *Table 1*. In some cases, participating ADCs were unable to confirm exactly how many initial surveys they distributed; in such cases we have assumed that all of the initial surveys that were sent to them were given out.

Population characteristics

The study population was not evenly split by gender (40.2% male, 59.8% female). The median age of the study population was 47 (IQR 27 to 56). The demographic characteristics of the sample are shown in *Table 2*. Within our sample, young adults are under-represented and older adults over-represented. It is not possible to calculate the response rates from different groups. Also included in *Table 2* are the characteristics of those individuals who returned the initial survey but not the follow-up survey; those returning only the initial survey tend to be younger and to live in larger households.

TABLE 2 *Study population demographic summary*[a]

	Completed initial survey only (*n* = 138)	Completed both surveys (*n* = 179)	UK population
Female (%)	62.9	59.8	50.9
Age 0–14 (%)	20.6	16.8	17.5
Age 15–29 (%)	22.8	11.2	20.0
Age 30–44 (%)	24.3	17.9	21.1
Age 45–69 (%)	20.6	34.6	19.2
Age ≥ 60 (%)	11.8	19.6	22.1
Mean household size	3.1	2.7	2.4

a Including those who completed only the initial survey and those who completed both the initial and the follow-up survey (UK population characteristics included for comparison).

Within our sample of interest (those who returned both surveys), 117 (65%) reported that they would normally attend work/school/college on the day of their initial survey, while 22 (12%) respondents reported that they would normally use public transport on the day of their initial survey.

The mean household size in the study population was 2.7, with a median of 2 and an IQR of 2 to 4. As might be expected by the observed age distribution of the sample, a large fraction of households contained only one or two people.

Chapter 3
Results

Describing infection – initial survey

As anticipated, the vast majority [169 (94.4%)] of the study population reported that they were unwell with swine flu on the day that they completed the initial questionnaire. Ill individuals were asked to report which symptoms they had from a list of 14 possibilities. The fraction of individuals reporting each symptom is shown in *Figure 1*. On average, ill individuals reported 7.8 symptoms. Tiredness, cough, headache, fever and blocked/runny nose were the most common symptoms, being reported by over 70% of respondents.

Individuals were also asked to record how ill they felt, on a scale of 0–10, with 0 being the 'worst imaginable health state' and 10 the 'best imaginable health state'. The distribution of initial health states of those individuals who reported that they were unwell with swine flu when they completed the initial survey is shown in *Figure 2*. The mean reported health state was 3.38 [standard deviation (SD 1.66)]. For comparison, those individuals who completed only the initial survey had a mean reported health state of 3.61 (SD 1.95) – these two sets of reported health states were not significantly different.

The mean reported health state of individuals on the day that they felt most ill was 1.98 (SD 1.23).

Describing recovery – comparing initial and follow-up questionnaires

Of those 169 individuals who were unwell with swine flu when they completed the initial questionnaire, 146 (86.4%) had recovered by the time they filled in the follow-up questionnaire. The median duration of infection of those who had recovered was 9 days (IQR 6 to 14 days), and 32 (21.9%) of participants reported that they were ill for over a fortnight.

As anticipated, there were large changes in health state between the initial and follow-up survey reports of those who reported that they were no longer unwell when they completed the follow-up survey (*Figure 3*). We see, in most cases, that

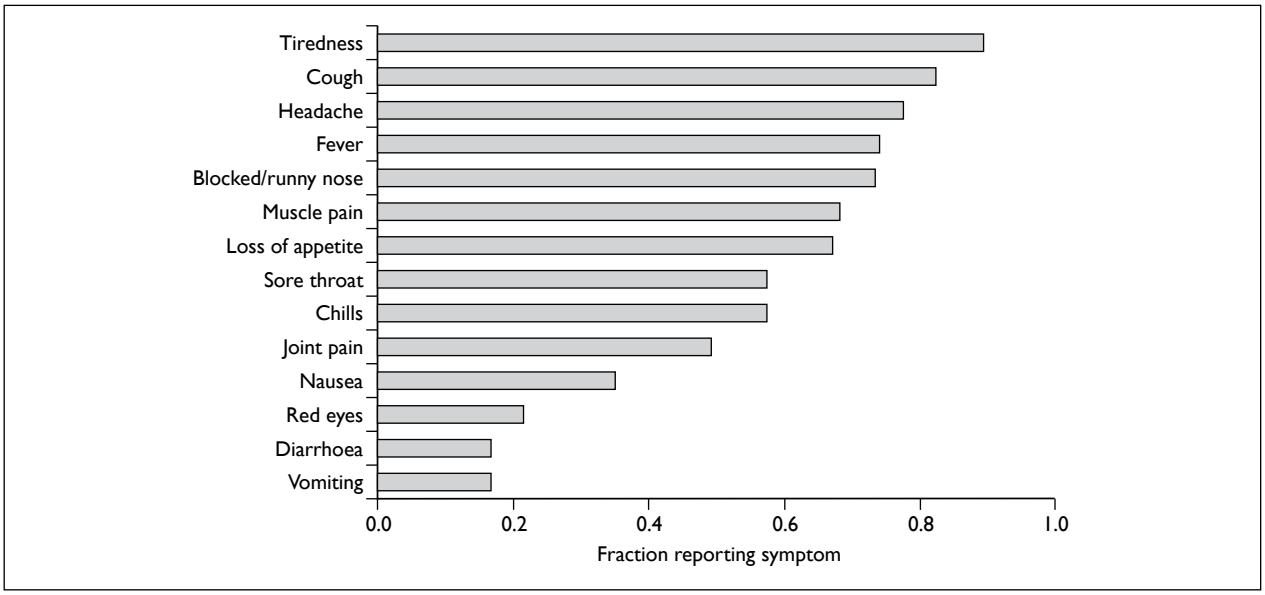

FIGURE 1 *Fraction of individuals reporting each symptom from the symptoms list.*

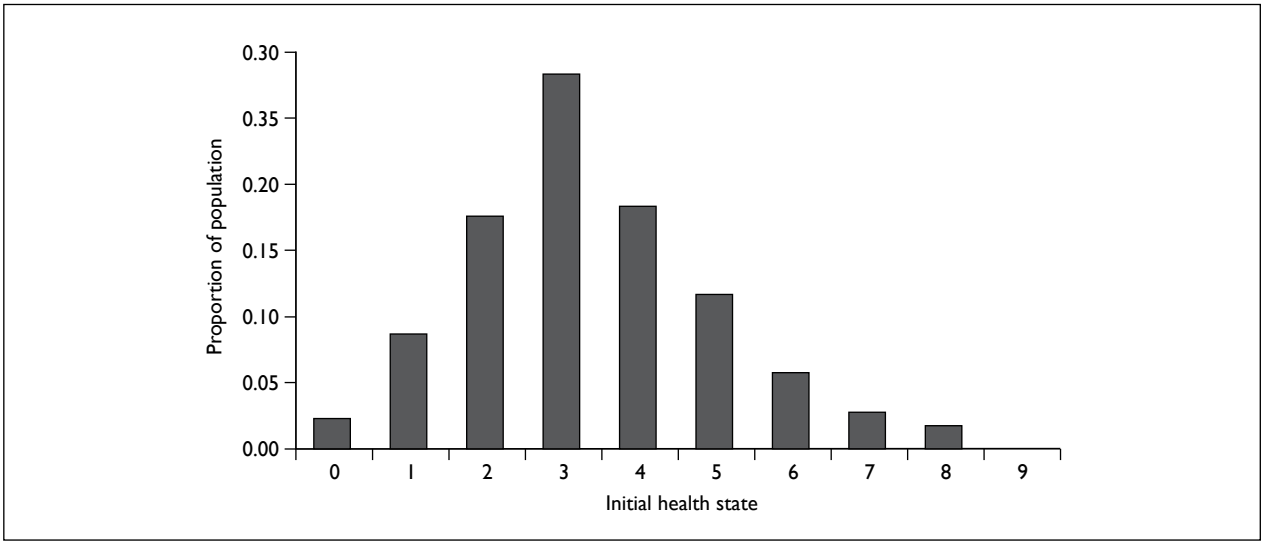

FIGURE 2 *Distribution of initial health states reported by individuals unwell with swine flu (measured on a scale of 0 – the 'worst imaginable health state' – to 10 – the 'best imaginable health state').*

participants reported a substantial change in their health state (mean change 4.92, SD 1.83, $p < 0.001$, one-sample *t*-test).

Participants were asked whether they took time off work/school/college/child-care group/social activities because of their illness; 74.1% of the 162 participants who answered reported that they did take time off. The median length of time off was 6 days (IQR 4 to 8 days) and six (5.0%) respondents reported that they took over a fortnight away from work/school/college/child-care group/social activities.

Overall, 59 individuals (33.0%) reported that they did not attend work/school/college on the day that they completed the initial survey, but that they did attend work/school/college on the day that they completed the follow-up survey.

Contact patterns

Baseline behaviour – comparison with POLYMOD

The most extensive survey to date of normal contact patterns took place in the POLYMOD

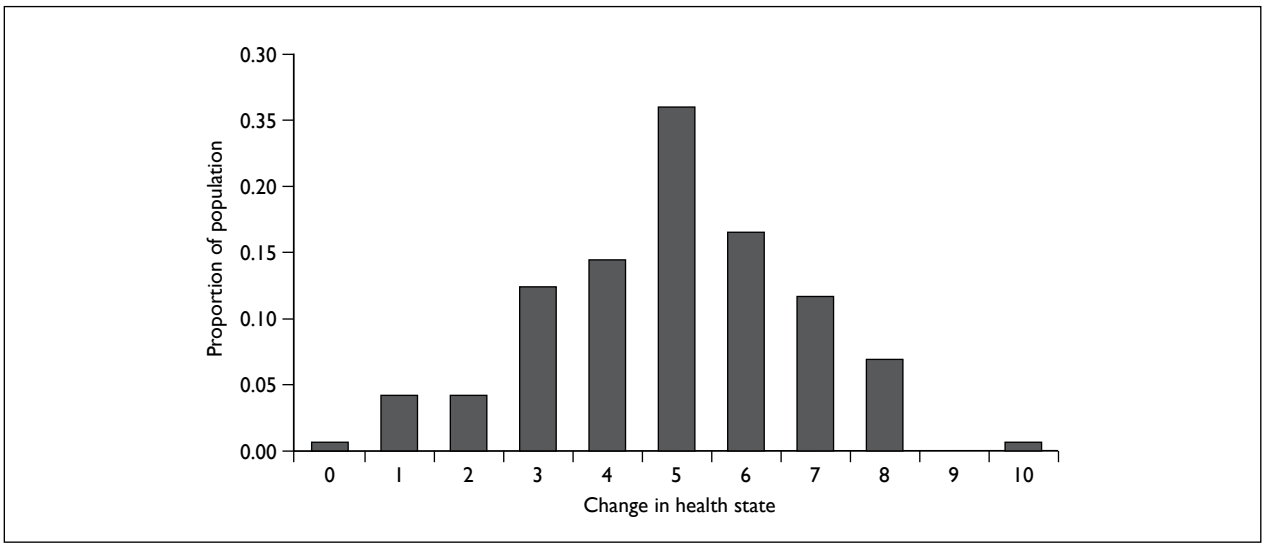

FIGURE 3 *Change in health state of people who recorded that they were unwell when they filled in the initial survey but had recovered when they filled in the follow-up survey (n = 146).*

study in 2005–6.[15] The POLYMOD study sampled 7290 people around Europe, with 1012 in the UK; POLYMOD participants completed a contact diary very similar to that applied in this project. In order to check the reasonableness of our results, we will briefly compare them with those produced by POLYMOD.

POLYMOD sampled 1012 individuals from the UK, whose responses we compare with the 155 participants in our survey who reported that they were well on the day that they completed the follow-up survey; from these 155 individuals, 144 useable contact diaries were obtained.

POLYMOD reported that respondents from the UK named a mean of 11.74 contacts (SD 7.67); our results are broadly similar, with a mean of 10.30 contacts (SD 8.51); our study found that approximately 25% of contacts took place at home, while POLYMOD reported that 23% of contacts occurred at home. Our study found that approximately 40% of contacts involved skin-to-skin contact, which is consistent with POLYMOD (in which the proportion of contacts involving skin-to-skin contact ranges from about 35% in the workplace to 75% at home; our study found that approximately 25% of work/school/college contacts and 72% of home contacts involved skin-to-skin contact). Our study reported more contacts taking place at work/school/college (47% compared with 35%).

Our study and POLYMOD are therefore in broad agreement about 'normal' social contact behaviour. Differences, such as they are, may well be explained by differences in the sample population demographics – our study population contained more older adults – but seasonal differences may also have played a part (POLYMOD took place mainly in the spring, our study in the autumn/winter).

Changes in contact behaviour

The primary aim of this study was to measure the impact of illness on contact patterns. Here, therefore, we explore changes in each participant's reported contact data. Because the methodology involved repeated sampling of participants, we have paired data (i.e. two completed contact diaries) from each participant.

The completed contact diaries contain a great deal of detail about contact behaviour, and there is therefore a multitude of different comparisons that could be attempted; for the sake of simplicity and clarity, and to avoid overanalysing a small database, we restricted ourselves to the following key measures:

- *all* number of contacts listed on the contact diary
- *all plus additional* contacts listed on the contact diary plus any 'additional' contacts
- *physical* total number of physical (skin-to-skin) contacts reported
- *home* total number of home contacts recorded
- *work* total number of work/school/college contacts recorded
- *other* total number of contacts recorded in travel/leisure/other settings
- *long duration* total number of contacts recorded that lasted over 1 hour
- *short duration* total number of contacts recorded that lasted less than 10 minutes
- *frequent* total number of contacts recorded who were encountered once a week or more
- *infrequent* total number of contacts recorded who were encountered less than once a month.

In each case, we seek to explore the extent to which the numbers of these different types of social contacts differed between the initial and the follow-up surveys.

We expected the most marked behavioural changes in those people who were unwell at the time of the initial survey and had recovered by the time of the follow-up survey. When restricting our attention to this subsample ($n = 146$), we see that there were, indeed, noticeable changes in contact behaviour (*Figure 4*), although contacts taking place at home did not vary between the initial and follow-up surveys. The differences between the initial and follow-up surveys are shown in *Table 3*. For all types of a contact except contacts made at home the differences are highly significant (Wilcoxon signed-rank test, $p < 0.001$). There was no significant change in the number of home contacts.

The bump on the right of some plots in *Figure 4* is the result of the capping of the number of contacts permitted, as described above.

Very similar patterns are seen when the sample is not restricted to those who recovered between completing the initial and the follow-up surveys (see *Figure 5* and *Table 5*, Appendix 3). The only notable difference between *Figures 4* and *5* is that, as we would expect, there are more individuals in *Figure 5* who reported no change in their contact behaviour.

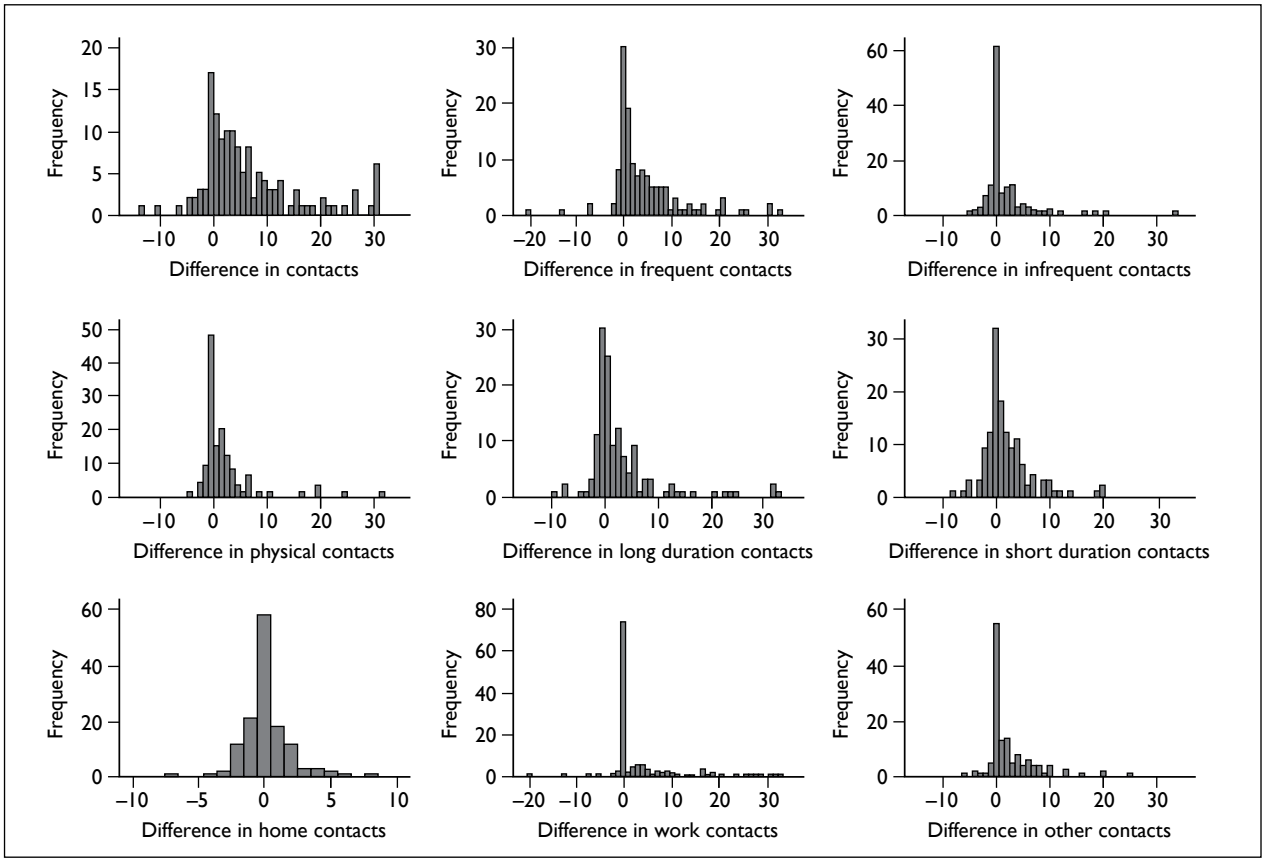

FIGURE 4 *Change in number of contacts reported in the initial and follow-up surveys by those participants who reported that they were unwell on the day of the initial survey and had recovered by the time they completed the follow-up survey; for each of the participants who completed a useable contact diary for both the initial and the follow-up survey (*n *= 135), the change in number of contacts of the relevant type is defined as the number recorded in the follow-up survey minus the number recorded in the initial survey.*

TABLE 3 *The number of contacts reported in the initial and follow-up surveys by those individuals who reported that they were unwell during the initial survey and recovered by the time they completed the follow-up survey*[a]

			Difference ($n = 135$)			
Type of contact	**Initial survey ($n = 141$): mean (SD)**	**Follow-up survey ($n = 138$): mean (SD)**	**Mean (SD)**	**Relative difference (percentage of follow-up mean)**	**Median (IQR)**	***p*-value (median ≠ 0)**
All	3.58 (3.75)	10.30 (8.51)	6.82 (9.01)	66	4 (1 to 10)	< 0.0001
All plus additional	3.58 (3.75)	12.72 (14.80)	9.30 (15.45)	73	4 (1 to 11)	< 0.0001
Frequent	2.91 (3.48)	7.33 (7.15)	4.49 (7.63)	61	2 (0 to 7)	< 0.0001
Infrequent	0.52 (0.11)	2.08 (4.42)	1.61 (4.74)	77	0 (0 to 2)	0.0003
Physical	1.77 (1.75)	4.10 (5.10)	2.36 (5.01)	58	1 (0 to 3)	< 0.0001
Long duration	2.02 (2.29)	5.42 (6.63)	3.45 (6.86)	64	1 (0 to 4)	< 0.0001
Short duration	1.01 (1.45)	2.94 (4.18)	1.99 (4.43)	68	1 (0 to 4)	< 0.0001
Home	2.38 (1.54)	2.58 (2.12)	0.19 (1.81)	7	0 (–1 to 1)	0.5317
Work/school/college	0.73 (3.35)	4.57 (7.92)	3.90 (8.39)	85	0 (0 to 5)	< 0.0001
Other	0.48 (1.16)	3.01 (4.57)	2.59 (4.62)	86	1 (0 to 4)	< 0.0001

a 'Difference' refers to the difference in the number of contacts reported by those participants who returned a contact diary for both the initial and the follow-up questionnaires ($n = 135$). Mean, SD, median and IQR of the difference are shown. The median difference is tested for significant difference from zero, and the *p*-value shown.

However we view the sample, and whichever measure of contact we use, we can see that individuals made substantially fewer contacts when they were ill than when they were well. Contacts made by ill participants tended to take place at home (with very few in the workplace or in other settings); they were generally with people whom they met often and for long periods of time and they often included physical contact.

The distribution of social contacts changed when people were unwell; unwell people made approximately two-thirds of their social contacts at home, falling to one-quarter when they had recovered, although the reported absolute number of contacts made at home stayed almost constant. Not surprisingly, work/school/college contacts and contacts made in other settings (travel, leisure, other) fell dramatically when people were ill.

We note, for comparison, that individuals who completed only the initial survey reported 3.98 contacts on average when they were ill (SD 3.90); this is not significantly different from the number of contacts reported in the initial survey by those who completed both the initial and the follow-up survey (two sample t-test, $p = 0.58$).

We postulated that changes in social mixing patterns may be associated with age, gender, health status, attendance at work/school/college, household size and public transport use. However, because very few participants (6.7%) reported that their public transport use differed between the two questionnaires we exclude considerations of public transport use from the analysis that follows.

An initial simple regression analysis was carried out, suggesting that the following factors might have an influence on the observed changes in contact patterns:

- age group (reference group: age 0–14)
- gender
- returning to work/school/college

TABLE 4 *Regression analysis results for factors related to changes in number of contacts reported by those individuals who reported that they were unwell during the initial survey and recovered by the time they completed the follow-up survey, and who returned a completed contact diary from both the initial and the follow-up survey (n = 135)*[a]

Contact type	Factor	Coefficient	95% confidence interval	*p*-value	r^2
All plus additional	Returning to work	11.00	5.91 to 16.09	<0.001	0.15
All	Returning to work	8.12	5.27 to 10.98	<0.001	0.24
	Change in no. of symptoms	0.70	0.10 to 1.29	0.022	
Frequent	Returning to work	6.76	4.31 to 9.21	<0.001	0.18
Infrequent	Change in no. of symptoms	0.66	0.33 to 1.00	<0.001	0.10
	House size	–0.57	–1.12 to –0.02	0.041	
	Age 15–29	2.05	0.09 to 4.02	0.041	
Physical	House size	–0.96	–1.84 to –0.08	0.032	0.13
	Change in no. of symptoms	0.47	0.09 to 0.84	0.015	
	Age 45–59	–3.21	–5.83 to –0.59	0.017	
	Age over 60	–3.46	–6.65 to –0.27	0.034	
Long duration	Returning to work	3.70	1.32 to 6.07	0.003	0.15
	Age 30–44	–4.85	–8.29 to –1.42	0.006	
	Age 45–59	–4.96	–8.10 to –1.81	0.002	
	Age over 60	–3.92	–7.75 to –0.08	0.045	
Short duration	Returning to work	2.06	0.56 to 3.56	0.007	0.10
	Change in no. of symptoms	0.43	0.12 to 0.75	0.007	
Home	No significant factors				
Work	Returning to work	9.09	6.55 to 11.63	<0.001	0.27
Other	Returning to work	–2.04	–3.64 to –0.44	0.013	0.05

a Analysis includes only factors with p-value < 0.05. 'Work' should be interpreted as covering work, school and college.

- change in health (measured as a binary unwell/well, or as change in number of symptoms reported, or as change in self-assessed health status recorded on a 10-point scale)
- household size (the number of people in the participant's household, not including the participant)
- change in day of the week (from weekday to weekend or vice versa).

These factors were included in a backwards, stepwise regression model, with the factor with the largest non-significant p-value being removed at each step and the model rerun until all remaining factors were significant ($p < 0.05$). Results are shown in *Table 4*. The data set contains a small number of outliers, and therefore the confidence intervals should be treated with caution.

As we can see, although there is a great deal of variation that is not explained by the model, several factors emerge as significant: returning to work/school/college, change in number of symptoms, age and household size.

Returning to work/school/college was associated with a large increased change in the number of contacts reported, being a significant factor in the change in all-plus-additional contacts ($p < 0.001$), all contacts ($p < 0.001$), frequent contacts ($p < 0.001$), long-duration contacts ($p = 0.003$), short-duration contacts ($p = 0.007$), contacts in 'other settings' ($p = 0.013$) and (unsurprisingly) work/school/college contacts ($p < 0.001$).

The change in the number of symptoms reported was also associated with an increased change in numbers of social contacts, being a significant factor in the change in all contacts ($p = 0.022$), infrequent contacts ($p < 0.001$), physical contacts ($p = 0.015$) and short contacts ($p = 0.007$).

Older age was associated with a reduced change in number of contacts: younger adults reported a larger change in their number of infrequent contacts ($p = 0.041$), whereas older adults reported a smaller change in their number of physical contacts ($p = 0.017$ for ages 45–59, $p = 0.034$ for ages over 60) and long-duration contacts ($p = 0.006$ for ages 30–44, $p = 0.002$ for ages 45–59, $p = 0.045$ for ages over 60).

A larger household was associated with a smaller change in the number of infrequent contacts ($p = 0.041$) and physical contacts ($p = 0.032$).

School closure

A similar paired survey carried out in schools to compare mixing patterns during the half-term holiday with those during school term observed large changes in social contact behaviour (see Appendix 2 for further details). Pupils who completed the survey reported, on average, 18.51 contacts ('All' contacts, in the terminology above) each day during term time and 9.24 during the half-term holiday, a reduction of over 50%. The change in number of contacts was highly significant (Wilcoxon signed-rank test, $p < 0.0001$).

Chapter 4
Discussion

Being infected with diagnosed swine flu had a considerable impact on the social contact patterns of those who participated in the study. Infected participants generally took time away from work/school/college and from social activities, and therefore made considerably fewer contacts when they were ill than when they had recovered. Participants made approximately two-thirds fewer contacts when they were unwell.

There was an observed tendency for the more transient contacts (infrequent contacts and contacts not involving physical contact) to be more influenced by illness than stronger contacts (frequent contacts and physical contacts). This again is unsurprising, as stronger contacts are more likely to be made in the home.

The regression analysis made clear the important role played by the workplace (or school, or college) on social contacts – returning to work was, by some distance, the most significant predictor of increased numbers of contacts.

The seriousness of infection also appeared to play a role, again confirming our intuition; the greater the change in the number of symptoms reported, the greater the change in the number of contacts.

Differences between age groups emerged, with those in younger age groups tending to have a greater change in their contact patterns; this can be explained by the differences in social mixing patterns between schools and workplaces, with older individuals appearing to mingle in smaller groups than younger individuals.

The results of the study were highly statistically significant, and the changes in measured contact behaviour were large. However, the study suffered from a number of limitations.

There was an apparently extremely low response rate; almost 3800 questionnaires were distributed along with antiviral prescriptions, and only slightly over 300 returned. Although we have no way of verifying that survey forms given to a potential participant's 'flu friend' did in fact reach the potential participant, in the worst case this represents a response rate of only 8.4%. Furthermore, of the 308 follow-up surveys posted to participants who had completed the initial survey, only 179 were returned, of which 146 individuals reported that they were unwell when they completed the initial survey and had recovered by the time they completed the follow-up survey. Not only was this disappointing, but also it was some distance below the response rate obtained by a survey using very similar methodology: a two-part postal questionnaire survey (the EQ-5D study) carried out during the early stage of the 2009 swine flu pandemic received a response rate of 45%.[3] We postulate that, with hindsight, the low response rate was predictable; by the time the study was under way swine flu had been circulating in the UK for several months. After the initial media frenzy and the surge of attention that was generated by the launch of the NPFS, public interest had waned. By the time the sampling took place it was clear that the epidemic was in decline, and far fewer antiviral prescriptions were being distributed than at the epidemic's peak.[25] For example, according to the Health Protection Agency weekly national influenza reports,[26–31] there were an estimated 84,000 new cases in England in the peak week, the final week of October; by the middle of November, weekly incidence had fallen to 53,000 cases and to 22,000 by the end of November. Autumn weekly antiviral issues peaked in the penultimate week of October, had fallen by over 30% by the middle of November, and by over 40% by the end of November. With each passing week there were fewer cases, fewer potential participants, less media and public interest, and therefore a lower ability to sample and a lower likely response rate. Delays of a few weeks made a real difference. Had this study taken place earlier we believe that an improved response rate would have been achieved.

Unfortunately, the sluggish nature of the various stages of approval that the study was obliged to pass through meant that it was not possible to carry out the research in as timely a manner as had been anticipated. Because surveys were distributed at ADCs, some of which were NHS facilities, it was necessary to obtain local approval from each NHS trust within whose area questionnaires were distributed. Despite assurances that these

local approvals would take 2–3 days, in practice, although some were indeed rapid, others took anything up to 2 months (and some never arrived). Clearly there is a need to reform the system of research governance to enable it to respond effectively to the urgent demands of real-time pandemic research if such research is to have a chance of success and of informing policy, as intended.

It is not clear whether or not there were non-response biases within our sample, although we would be surprised if there were not. When comparing individuals who returned both the initial and the follow-up survey with those who returned only the initial survey, we see that the latter group tends to be younger and to live in larger households. However, there was no significant difference between the groups in terms of either their reported severity of symptoms or their number of reported contacts when ill. Thus, though there are demographic differences, in key epidemiological and behavioural ways there is no significant difference between those who completed both surveys and those who completed only the initial survey. However, such comparisons tell us nothing about people who chose not to return the initial survey. What is almost certain is that the sample population was not a random sample of those who were infected with swine flu. Evidence collected from various sources and presented by the Health Protection Agency and other groups worldwide suggests that infection was concentrated in children.[25] Similarly, records collected by the NPFS show that antiviral distributions were also concentrated in younger age groups.[26–31] So, although our sample achieved a good coverage of age groups, it was not a random sample of the population of interest (i.e. those with swine flu).

At the time of the study, antiviral prescriptions were not issued to all individuals with swine flu, only to those who sought medication. Indeed, most participants received their diagnosis via a telephone line or a web page. Thus it may be that some, although reporting relevant symptoms, did not have swine flu. The participants probably ought, therefore, to be thought of as individuals with influenza-like illness rather than swine flu. It seems certain that those seeking antiviral medication were, in general, more ill than those who did not seek antiviral medication. Therefore, our sample is likely to be biased towards those with a more serious infection. This is supported by evidence from the EQ-5D study, carried out by the Health Protection Agency at the start of the pandemic and using similar methods to those used here, which aimed to recruit all cases of pandemic influenza; participants in the EQ-5D study reported an average health state (on a scale of 0–100) of 44 on their day of worst illness (AJ van Hoek, Health Protection Agency, 13 May 2010, personal communication), whereas participants in our study reported an average worst health state (on a scale of 0–10) of 1.98. More seriously ill people would be expected to be more likely to spend time away from their normal activities, and therefore to experience a greater change in their social contact behaviour than those with only mild infections. In this respect it is likely that our sample overestimates the extent of behavioural change. On the other hand, it might be that the principal difference between seriously ill individuals and those with less serious illness is the length of time taken away from work and other activities – the effect of taking time off may not depend on the seriousness of the infection, in which case our results may be more widely applicable.

However, it is not clear that our sample overestimates the behavioural change of those seeking antiviral medication. It might well be the case, for instance, that those who are most ill (and who therefore change their behaviour the most) would not feel in a fit state to fill in a survey. Furthermore, it is possible that those with the largest numbers of social contacts, when recovered, might decide that the contact diary would be too arduous to complete. These factors may lead to our data underestimating the effect of illness on social contact patterns.

Because the survey contains questions about participants' symptoms and the extent to which participants take time off work, it is hoped that we will be able to compare our data with other data sources, when they become available, to assess the extent of biases by level of illness or of work-related behavioural change, thus to allow some corrections of any observed biases to be attempted.

The study took place in England (the only part of the UK in which the NPFS was in operation), therefore it was not possible to assess whether there were different behavioural changes in response to infection in other parts of the UK.

As with any self-reported questionnaire, we cannot be certain that participants answered the questions in the way that was intended. There may have been deliberate misreporting of behaviour, or there may have been misunderstanding of the questions.

However, potential participants were provided with contact details (telephone number, e-mail address and postal address) for the research team and encouraged to make contact with any questions they had; only one query was received.

The brief school survey, although of limited size, gave the first survey-based quantitative measurements of the changes in contact patterns of school pupils occurring during school holiday periods. It is clear that school holidays have a large impact on social contacts, with children making about one-half of their number of term-time contacts during the holiday period. This observation helps explain the change in swine flu incidence that was seen during both the school summer holiday and, to a lesser extent, during the autumn half-term holiday.[25] Despite the low sample size, the measured behaviour change was highly significant. Although, as described, the study contained a range of biases and limitations, we are confident that the results obtained are a significant step forwards towards a more accurate understanding of the impact of illness on contact patterns. This understanding will facilitate more accurate mathematical modelling of epidemics, reduce the need for ad hoc approximations and aid future pandemic planning.

Chapter 5
Conclusions

The evidence from this study suggests that ill individuals make substantial changes to their social contact patterns. Participants in the study made approximately two-thirds fewer social contacts when they were ill compared with when they had recovered. The changes in contact patterns were strongly linked to absence from work and the severity of the reported illness, with age and household size also playing a role.

Epidemiological modellers should therefore be wary of using data about 'normal' contact patterns to parameterise mathematical models of disease spread, and should consider the implications of illness-related behavioural changes on model predictions. Of course, the changes measured here apply to symptomatic individuals, and care should be taken to use these data appropriately in cases when infected individuals may be asymptomatic or when infectiousness begins before symptom onset.

This study highlights areas for future research. Of particular value would be a more detailed study that aims to recruit a representative sample of cases; the study here, owing to its sampling methodology and the time constraints under which it took place, almost certainly ended up with a sample population that was experiencing relatively severe symptoms. Although such people are of interest, they may well display greater behavioural change than the average infected case. It would be of value, perhaps during forthcoming seasonal flu seasons, to carry out studies that measure the extent of behavioural change in a broader cross-section of infected cases.

The brief school study suggested that school children made approximately twice as many social contacts during school term as they do during the school holidays. As it was clear that children played a dominant role in the swine flu pandemic and might be expected to do so in future pandemics, and as it was apparent from the UK incidence data that normal patterns of school holidays had a significant impact on transmission, we advocate more detailed studies of the social contact patterns of school children, particularly focusing on differences between school terms and school holidays. Our experience, in this and other work (KTD Eames, unpublished), is that for school-based studies to be successful the research teams must be prepared to make a substantial investment of time and energy – such studies are therefore best conceived as long-term projects, achieving high levels of engagement with participating schools, rather than as rapid exercises. The presence of a pandemic cannot be taken as a guarantee of high participation.

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Contributions of authors

Dr Ken Eames (mathematical epidemiologist) conceived and designed the study, carried out the analysis, and wrote the report.

Natasha Tilston (mathematical epidemiologist) assisted with the study and carried out the analysis.

Dr Peter White (mathematical epidemiologist) conceived the study and assisted with the study design.

Dr Elisabeth Adams (mathematical epidemiologist) carried out recruitment for the study.

Professor John Edmunds (mathematical epidemiologist) conceived the study and assisted with the study design.

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Appendix 1
Survey forms

Initial survey

The first part of the survey asks for general (background) information. Note: each form was marked with a two-letter code denoting the ADC at which the survey was distributed – each ADC had its own two-letter code. Each returned form had a three-digit code appended to this ADC code, and the resulting compound code was written on the follow-up forms sent to that participant, allowing a participant's initial and follow-up data to be linked.

Contact diary

The same contact diary form was used for both the initial and the follow-up surveys.

Follow-up survey

The follow-up survey contained a shorter background questionnaire, and a second contact diary (identical to the first).

Background questionnaire

This questionnaire is for the person who has been given antiviral medication. If that person is a child then an adult can complete it on their behalf but should answer from the point-of-view of the child.

Today's date _____

Day of the week _____

About yourself (the person receiving antiviral medication)

(a) Age _____

(b) Gender _____

We would like to send you a follow-up questionnaire in about 2 weeks, so we can compare your social contact patterns while you are ill with your social contact patterns once you are feeling better. Your name and address will only be used to send the follow-up questionnaire. They will not be kept or passed on to anyone else.

Name (person to whom the follow-up questionnaire should be addressed):

_____

Address _____

_____

_____

Postcode _____

About your household

(c) How many people (other than you) live in your household? _____

(d) Please list their ages

_____

(e) How many people in your household other than you **currently** have diagnosed swine flu? _____

- How many of them are taking Tamiflu (oseltamivir) or Relenza (zanamivir) antiviral treatment? _____

About your illness

(f) On what date did you first become unwell with swine flu? _____

(g) Are you still unwell today? YES NO (circle one)

- If NO, on what date did you recover? _____
- If YES, which symptoms do you have today (circle all that apply):

Fever	Chills	Nausea
Sore throat	Loss of appetite	Vomiting
Tiredness	Muscle pain	Diarrhoea
Headache	Joint pain	Red eyes
Cough	Blocked/runny nose	

(h) How do you feel today? (Mark a point on the line below)

worst imaginable health state 0---1---2---3---4---5---6---7---8---9---10 best imaginable health state

(i) Have you taken Tamiflu (oseltamivir) or Relenza (zanamivir) antiviral treatment?

YES NO (circle one)

- If YES, then...
  - On what date did you start taking the treatment? _____
  - Are you still taking the treatment? YES NO (circle one)

(j) On what date did you feel most ill with swine flu? _____

(k) How did you feel on that day? (Mark a point on the line below)

worst imaginable health state 0---1---2---3---4---5---6---7---8---9---10 best imaginable health state

(l) Did you spend last night in hospital? YES NO (circle one)

Receiving care from others

(m) Has anyone taken time off work to take care of you whilst you have been ill with swine flu?

YES NO (circle one)

Using public transport

(n) Did you use public transport (bus/train/tram/underground) today?

YES NO (circle one)

(o) Would you normally use public transport (bus/train/tram/underground) today?

YES NO (circle one)

Your daily routine

(p) Do you normally attend work / school / college?

YES NO (circle one)

(q) Have you been to work / school/ /college today?

YES NO NOT APPLICABLE (circle one)

(r) Is your workplace / school / college currently closed due to swine flu?

YES NO NOT APPLICABLE (circle one)

(s) Have you taken time off work / school / college / playgroup / nursery / childcare group / social activities because of your illness?

YES NO NOT APPLICABLE (circle one)

- If YES, then are you off work / school / college / playgroup / nursery / childcare group / social activities **today** because of your illness?

YES NO (circle one)

At the end of the day, once you have completed this background questionnaire and checked all the entries are correct, please return it and the completed contact diary to us using the pre-paid envelope provided.

Contact diary

Please cut off this column before returning the form.

This questionnaire is **for the person who has been given antiviral medication**. If that person is a child then an adult can complete it on their behalf but should respond from the point-of-view of the child.

Today's date _____ Day of the week_____

Name (or description) of contact	Age (or age range)	Gender (Male or Female)	Was there skin to skin contact (Yes or No)?	How long? Over the day, for how long were you with this person (tick one)?					Where? Where did you meet this person (tick all that apply)?					How often? How often do you normally meet this person (tick one)?				
				Under 5 mins	5-10 mins	10mins-1 hour	1-4 hours	Over 4 hours	Home	Work/ School/ College	Travel	Leisure activity	Other	Daily or almost daily	Once or twice weekly	Once or twice monthly	Less than monthly	Never met before

Please turn over if you need more space

Name (or description) of contact	Age (or age range)	Gender (Male or Female)	Was there skin to skin contact (Yes or No)?	How long? Over the day, for how long were you with this person (tick one)?					Where? Where did you meet this person (tick all that apply)?					How often? How often do you normally meet this person (tick one)?				
				Under 5 mins	5-10 mins	10mins-1 hour	1-4 hours	Over 4 hours	Home	Work/ School/ College	Travel	Leisure activity	Other	Daily or almost daily	Once or twice weekly	Once or twice monthly	Less than monthly	Never met before

Did you include everyone you met today? _____

If not, how many other people did you meet today? _____

At the end of the day, once you have completed this contact diary and checked all the entries are correct, please return it and the completed background questionnaire to us using the pre-paid envelope provided.

Background questionnaire [follow-up]

This questionnaire is **for the person who completed the questionnaire that they received with their antiviral medication**; if that person is a child then an adult can complete the questionnaire on their behalf but should answer from the point-of-view of the child.

Today's date _____

Day of the week _____

About your household

(a) How many people in your household other than you **currently** have diagnosed swine flu? _____

- How many of them are taking Tamiflu (oseltamivir) or Relenza (zanamivir) antiviral treatment? _____

About your illness

(b) Are you still unwell with swine flu today? YES NO (circle one)

- If NO, what date did you recover? _____
- If YES, which symptoms do you have today (circle all that apply):

Fever	Chills	Nausea
Sore throat	Loss of appetite	Vomiting
Tiredness	Muscle pain	Diarrhoea
Headache	Joint pain	Red eyes
Cough	Blocked/runny nose	

(c) How do you feel today? (Mark a point on the line below)

worst imaginable health state 0---1---2---3---4---5---6---7---8---9---10 best imaginable health state

(d) Have you taken Tamiflu (oseltamivir) or Relenza (zanamivir) antiviral treatment?

YES NO (circle one)

- If YES, are you still taking the treatment?

  YES NO (circle one)

  - If NO, what date did you stop taking the treatment?

    _____

(e) What date did you feel most ill with swine flu? _____

(f) How did you feel on that day? (Mark a point on the line below)

worst imaginable health state 0---1---2---3---4---5---6---7---8---9---10 best imaginable health state

(g) Did you spend last night in hospital? YES NO (circle one)

Receiving care from others

(h) Did anyone take time off work to take care of you whilst you were ill with swine flu?

YES NO (circle one)

- If YES, then how many days have they taken off so far, including today (only counting days when they would have gone to work)?

  _____

Using public transport

(i) Did you use public transport (bus/train/tram/underground) today?

YES NO (circle one)

(j) Would you normally use public transport (bus/train/tram/underground) today?

YES NO (circle one)

Your daily routine

(k) Have you been to work / school / college today?

YES NO NOT APPLICABLE (circle one)

(l) Is your workplace / school / college currently closed due to swine flu?

YES NO NOT APPLICABLE (circle one)

(m) Did you take time off work / school / college / playgroup / nursery / childcare group / social activities because of your illness?

YES NO NOT APPLICABLE (circle one)

- If YES, then how many days did you take off? _____

At the end of the day, once you have completed this background questionnaire and checked all the entries are correct, please return it and the completed contact diary to us using the pre-paid envelope provided.

Appendix 2
School closure study

In summer 2009, in the early stages of the swine flu pandemic, several schools in the UK closed as a result of swine flu infections. It was expected that such closures would happen again in autumn 2009, either because of large numbers of cases in pupils or because of staff shortages owing to sickness. To help assess the impact of these closures on contact patterns, and therefore on transmission, it was planned to carry out a study similar to that described above, recruiting school children to complete a contact diary once when their school was closed as a result of swine flu and once when the school had reopened. Such a study would have helped us understand the impact of unplanned closures on children's mixing patterns and informed us about the use of school closure as a control policy.

However, the UK swine flu epidemic in autumn 2009 was milder than expected, and school closures did not occur. The planned study could not, therefore, take place. Instead, as the study materials had already been developed, we took the opportunity to carry out a half-term study – asking pupils to complete a contact diary once during their spring half-term holiday and once during term time. This adapted study clearly does not inform us about the effects of unplanned closures, but instead quantifies the impact of school holidays.

Eight schools in London and Sussex were recruited to take part, and approximately 1100 study packs were distributed. All questionnaire forms were contained in the study pack, so participants (or their parents/guardians) needed to keep hold of the follow-up survey forms until the appropriate date. The initial and follow-up surveys were clearly distinguished within the study pack, and clear instructions given to ensure that forms were completed on the correct days (all forms were dated by participants, and forms filled in incorrectly could be excluded from the analysis). This approach enabled us to avoid having to ask for anyone's name or address. In total, 134 forms were completed correctly (a response rate of approximately 12%) and, from these, a total of 119 paired contact diaries (response rate 10.9%) were obtained.

The results provided by those who participated are clear: during term time, participants reported an average of 18.51 contacts (95% confidence interval 17.03 to 20.00), whereas during the school holiday they reported an average of 9.24 contacts (95% confidence interval 8.15 to 10.32). There was a significant difference in the number of contacts reported in term time compared with during the half-term holiday (difference = 9.28; 95% confidence interval 7.77 to 10.79; $p < 0.0001$, Wilcoxon signed-rank test).

The sample is small and perhaps unrepresentative; however, within our sample children made approximately one-half of the number of social contacts during a day in the half-term holiday that they made during term time.

Appendix 3

Contact pattern changes – complete data set

In Chapter 3, *Figure 4* and *Table 3* show the changes in contacts recorded by participants who reported that they were unwell when they completed the initial survey but who reported that they had recovered by the time that they completed the follow-up survey. For completeness, *Figure 5* and *Table 5* show the equivalent data for all participants (i.e. including those who were still unwell when they completed the follow-up survey).

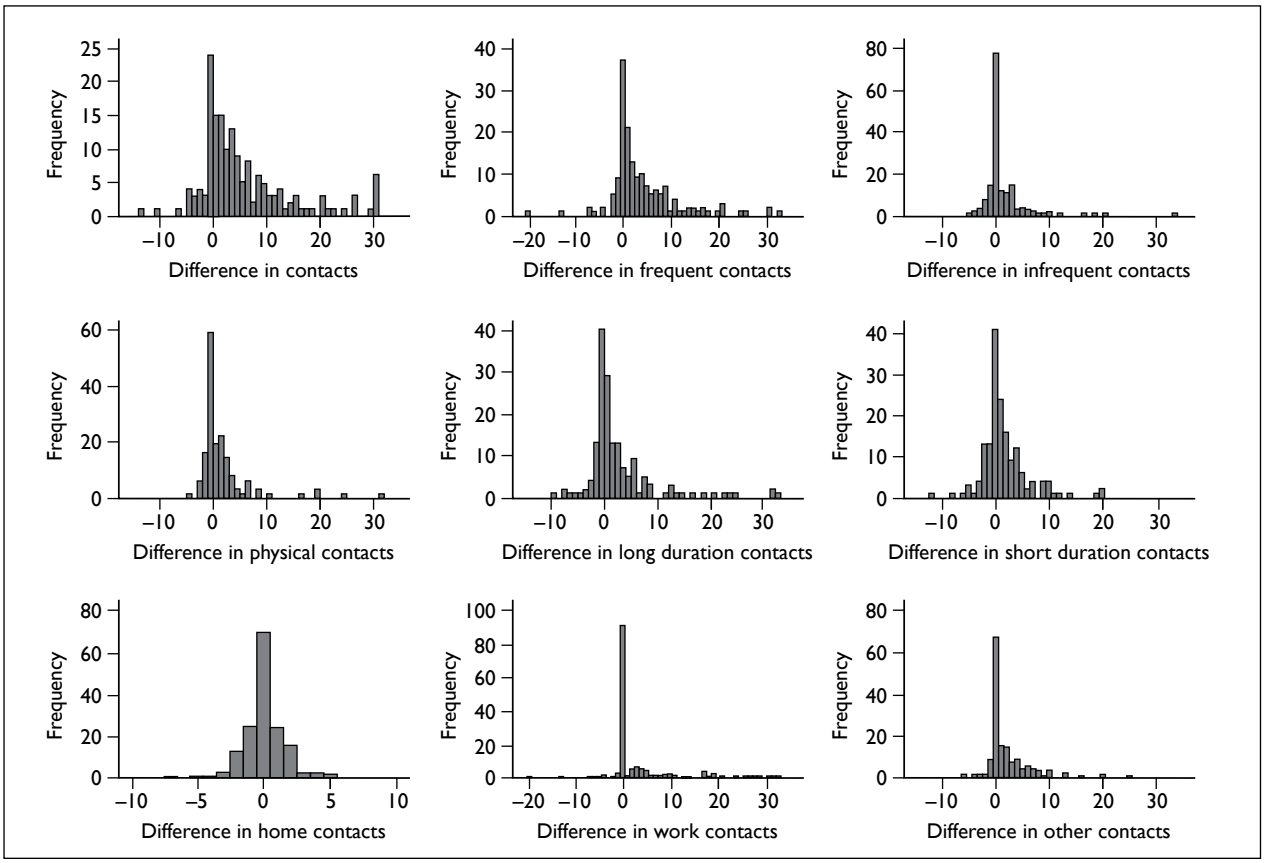

FIGURE 5 *Change in number of contacts reported in the initial and follow-up surveys; for each of the participants who completed a useable contact diary for both the initial and the follow-up survey (n = 165), the change in number of contacts is defined as the number recorded in the follow-up survey minus the number recorded in the initial survey.*

TABLE 5 *The number of contacts reported in the initial and follow-up surveys*[a]

Type of contact	Initial survey ($n = 172$), mean (SD)	Follow-up survey ($n = 168$), mean (SD)	Difference ($n = 165$)			
			Mean (SD)	Relative difference (percentage of follow-up mean)	Median (IQR)	p-value (median $\neq 0$)
All	3.74 (3.76)	9.76 (8.15)	6.08 (8.67)	62	4 (0 to 10)	< 0.0001
All plus additional	4.12 (6.10)	12.10 (14.44)	8.06 (16.04)	67	4 (0 to 9)	< 0.0001
Frequent	3.05 (3.48)	7.12 (6.90)	4.11 (7.31)	58	2 (0 to 7)	< 0.0001
Infrequent	0.49 (1.07)	1.85 (4.06)	1.39 (4.34)	75	0 (0 to 2)	0.0001
Physical	1.72 (1.70)	3.76 (4.80)	2.06 (4.70)	55	1 (0 to 3)	< 0.0001
Long duration	2.07 (2.25)	5.17 (6.38)	3.13 (6.58)	61	1 (0 to 4)	< 0.0001
Short duration	1.06 (1.72)	2.71 (3.97)	1.68 (4.34)	62	1 (0 to 3)	< 0.0001
Home	2.41 (1.61)	2.60 (2.09)	0.16 (1.75)	6	0 (–1 to 1)	0.3740
Work	0.78 (3.20)	4.36 (7.55)	3.64 (7.96)	83	0 (0 to 5)	< 0.0001
Other	0.57 (1.32)	2.71 (4.25)	2.18 (4.41)	80	0 (0 to 3)	< 0.0001

a The 'difference' figures refer to the difference in the number of contacts reported by those participants who returned a contact diary for both the initial and the follow-up survey ($n = 165$). Mean, SD, median and IQR of the difference are shown. The median difference is tested for significant difference from zero, and the p-value shown.

Vaccine effectiveness in pandemic influenza – primary care reporting (VIPER): an observational study to assess the effectiveness of the pandemic influenza A (H1N1)v vaccine

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Abstract

Vaccine effectiveness in pandemic influenza – primary care reporting (VIPER): an observational study to assess the effectiveness of the pandemic influenza A (H1N1)v vaccine

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Objectives: To determine influenza A (H1N1)v vaccine effectiveness (VE) in the Scottish population at an early stage of the 2009–10 H1N1v vaccination programme, using a sentinel surveillance network of 41 general practices contributing to the Practice Team Information (PTI) network.

Methods: Retrospective cohort study using record linkage. Using the Community Health Index (CHI) number, general practice patient-level data were extracted and linked to the Scottish Morbidity Record (SMR) catalogue, containing information on all inpatient hospitalisations in Scotland. The Health Protection Scotland (HPS) data set was also used, consisting of laboratory-confirmed cases of influenza A (H1N1)v from the practices. The study involved a longitudinal evaluation of the aspect of the influenza A (H1N1)v vaccination programme implemented through general practice in autumn/winter 2009.

Results: At 25 December 2009, vaccine uptake estimates for the study population were 12.0% (95% CI 11.9 to 12.1). For those patients in an at-risk group ($n = 59,721$), the uptake rate was 37.5% (95% CI 37.1 to 37.9). Among the 1492 patients swabbed, 467 were positive for H1N1, giving a positivity rate of 31.3% [95% confidence interval (CI) 29.0 to 33.7]. Among those in a clinical risk group who were not vaccinated, 41.3% (95% CI 35.6 to 46.9) tested positive for influenza A (H1N1)v, a significant difference from the H1N1 positivity percentage among patients with no clinical risk ($p < 0.01$). Among those vaccinated and in a clinical risk group, only one patient (5%, 95% CI 0.3 to 23.6) tested after vaccination was positive for influenza A (H1N1)v. By comparing postvaccination swabs in those who were vaccinated with swabs taken in those who remained unvaccinated, the VE was found to be 95.0% (95% CI 76.0 to 100.0). In the study population there were 2739 admissions to hospital, of which 1241 were emergency admissions; all 48 emergency hospitalisations for influenza and pneumonia occurred in patients who did not receive the vaccine. VE for single or combined end points of influenza and pneumonia hospitalisation for all patients was estimated at 100.0% (95% CI ∞ to 100.0). There were 132 hospitalisations in the unvaccinated group versus five in the vaccinated group for cardiovascular-related conditions. There were 193 hospitalisations in the unvaccinated group versus nine in those vaccinated in the group of patients admitted for influenza, pneumonia, chronic obstructive pulmonary disease (COPD) and cardiovascular-related conditions. VE for cardiovascular-related conditions alone, or in individuals with influenza, pneumonia COPD and cardiovascular-related conditions, was 71.1% (95% CI 11.3 to 90.6) and 64.7% (95% CI 12.0 to 85.8) respectively.

Conclusions: Evidence from swabs submitted from patients in the cohort who presented in general practice with influenza-like illness suggests that the introduction of influenza A (H1N1)v vaccine in Scotland during 2009 was associated with a high degree of protection. Influenza A (H1N1)v immunisation in primary health-care settings appears to be both effective and widely acceptable, and should continue to be the mainstay of disease prevention for at-risk patients. A further analysis encompassing the whole influenza season is required to cover more days of vaccination exposure and increase precision.

Contents

List of abbreviations

CHI	Community Health Index
CI	confidence interval
CMO	Chief Medical Officer
COPD	chronic obstructive pulmonary disease
CRH	cardiovascular-related hospitalisation
GP	general practitioner
GROS	General Register Office for Scotland
HPS	Health Protection Scotland
ISD	Information Services Division
OR	odds ratio
PCCIU	Primary Care Clinical Informatics Unit
PTI	Practice Team Information
RR	rate ratio
SMR	Scottish Morbidity Record
VE	vaccination effectiveness

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices, in which case the abbreviation is defined in the figure legend or in the notes at the end of the table.

Executive summary

Objectives

To determine influenza A (H1N1)v vaccine effectiveness (VE) in the Scottish population at an early stage of the 2009–10 H1N1v vaccination programme, using a sentinel surveillance network of 41 general practices contributing to the Practice Team Information (PTI) network.

Methods

The PTI network of general practices covers a 5% sample of the Scottish population ($n = 246,368$). Using the unique Community Health Index (CHI) number, general practice patient-level data were extracted and linked to the Scottish Morbidity Record (SMR) catalogue, which has information on all inpatient hospitalisations in Scotland. We also used the Health Protection Scotland (HPS) data set, which consists of laboratory-confirmed cases of influenza A (H1N1)v from the practices. The study involved a longitudinal evaluation of the aspect of the influenza A (H1N1)v vaccination programme implemented through general practice in autumn/winter 2009. Primary care practices were given financial incentives to record and code additional data electronically, over and above that routinely recorded for clinical care or as part of the PTI project, including: H1N1 vaccination status, age, deprivation status, pregnancy, and, where it was feasible, health worker status. During the study period, we assessed the vaccination uptake in the relevant high-risk populations, i.e. pregnant women, children (< 5 years), health-care workers and patients with at-risk comorbidities. For VE using information from linked virological swab data, a logistic regression model was fitted adjusting for the effects of gender, age, deprivation and being in an at-risk morbidity group. Admission rates to hospital for influenza-related serious morbidity were determined in vaccinated and unvaccinated patients, stratified by at-risk populations, age bands, sex, and socioeconomic status. VE estimates were derived from Poisson regression models, adjusting for gender, age, deprivation and clinical risk group. Influenza-related serious morbidity in vaccinated and unvaccinated patients in the whole population was calculated according to vaccination status for the target groups. An adjustment to the standard error of the estimated effect was made to account for clustering of patients within practices.

Results

At 25 December 2009, vaccine uptake estimates for the study population were 12.0% [95% confidence interval (CI) 11.9 to 12.1]. For those patients in an at-risk group ($n = 59,721$), the uptake rate was 37.5% (95% CI 37.1 to 37.9). Amongst 2203 pregnant women (4.3% of women aged 15–44 years) and 1314 health-care workers (0.8% of working-aged people aged 18–65 years), rates of vaccine uptake were 33.0% (95% CI 31.0 to 34.9) and 26.4% (95% CI 24.0 to 28.8), respectively. More male [odds ratio (OR) 2.67, 95% CI 1.44 to 4.96] health-care workers were vaccinated than female health-care workers. Among the 1492 patients swabbed, 467 were positive for H1N1, giving a positivity rate of 31.3% (95% CI 29.0 to 33.7). Among those in a clinical risk group who were not vaccinated, 41.3% (95% CI 35.6 to 46.9) tested positive for influenza A (H1N1) v. This represented a significant difference from the H1N1 positivity percentage among patients with no clinical risk ($p < 0.01$). Among those vaccinated and in a clinical risk group, only one patient (5%, 95% CI 0.3 to 23.6) tested after vaccination was positive for influenza A (H1N1) v. By comparing postvaccination swabs in those who were vaccinated with swabs taken in those who remained unvaccinated, the VE was found to be 95.0% (95% CI 76.0 to 100.0). There were 2739 admissions to hospital in the study population, of which 1241 were emergency admissions. All 48 emergency hospitalisations for influenza and pneumonia occurred in patients who did not receive the vaccine. VE for single or combined end points of influenza and pneumonia hospitalisation for all patients was estimated at 100.0% (95% CI ∞ to 100.0). There were 132 hospitalisations in the unvaccinated group versus five in the vaccinated group for cardiovascular-related conditions. There were 193 hospitalisations in the unvaccinated

group versus nine in those vaccinated in the group of patients admitted for influenza, pneumonia, chronic obstructive pulmonary disease (COPD) and cardiovascular-related conditions. VE for cardiovascular-related conditions alone, or in individuals with influenza, pneumonia COPD and cardiovascular-related conditions, was 71.1% (95% CI 11.3 to 90.6) and 64.7% (95% CI 12.0 to 85.8), respectively.

Implications for practice

Policy-makers and clinicians should be encouraged that the VE estimates obtained are comparable to those found for seasonal influenza and should strengthen the evidence base for health-care practitioners involved in distributing vaccine in other countries. Influenza A (H1N1)v immunisation in primary health care settings is both effective and widely acceptable, as evidenced by high uptake rates, and should continue to be the mainstay of disease prevention for at-risk patients.

Research recommendations

A further analysis encompassing the whole influenza season is required to encompass more days of vaccination exposure, which will increase precision (with resulting narrower confidence intervals). For pregnant women and under-5-year-olds, a further study using a greater time period of exposure is required to calculate and present meaningful results. A future study that will repeat this data linkage and allow the calculation of longer-term VE (in reducing both morbidity and mortality) should be undertaken later in 2010.

Conclusions

Evidence from swabs submitted from patients in the cohort presenting with influenza-like illness in general practice suggests that the introduction of influenza A (H1N1)v vaccine in Scotland during 2009 was associated with a high degree of protection against influenza A (H1N1)v. In addition, receipt of influenza A (H1N1)v vaccine was associated with a reduction in both admission for cardiac-related conditions and for the combined category of influenza, pneumonia, COPD and cardiac conditions. Policy-makers ought to be encouraged that the VE estimates obtained are comparable to those found for seasonal influenza. Additionally, as the first large-scale demonstration of effectiveness in a UK population, these interim results should help strengthen the evidence base for health-care practitioners involved in distributing influenza A (H1N1)v vaccine in other countries, now that the phased roll-out has been completed in the UK. Influenza A (H1N1)v immunisation in the primary health care setting is both effective and widely acceptable, as evidenced by high uptake rates, and should continue to be a mainstay of disease prevention for at-risk patients. Whether the reduced incidence of severe complications of influenza will persist or a reduction in mortality has occurred will only be apparent when data collected from later in 2010 are analysed.

Chapter 1
Introduction

In the last century, there were three pandemics (global epidemics) of influenza (1918–19, 1957–58, 1968–69), with these resulting in considerable morbidity and mortality; the numbers of deaths in these pandemics have been estimated at 20–40 million, 1 million and 1 million, respectively. The lack of herd immunity to the novel influenza viruses implicated (i.e. H1N1, H2N2 and H3N2) is believed to have been a key factor contributing to these very high numbers of deaths.[1] The influenza A subtype: H1N1 virus, which emerged in Mexico in March 2009, was subsequently declared a pandemic by the World Health Organization in June 2009.[2]

In the light of data that incentivised immunisation programmes delivered in primary health-care settings being shown to be acceptable (as evidenced by high uptake rates) and effective in reducing morbidity and mortality,[3] and evidence that seasonal influenza vaccination has been shown to reduce the risk of hospitalisation and death from pneumonia or influenza by 27% and 48% respectively,[4] the Chief Medical Officer (CMO) for England and the Department of Health instituted a targeted vaccination programme.[5] This was mirrored in Scotland by the CMO (Scotland) and Scottish Government. Production of influenza A (H1N1)v vaccinations began soon after outbreaks in the USA and Europe, with two vaccines being adopted for the UK national immunisation programme: Pandemrix (GlaxoSmithKline), which requires one dose, and Celvapan (Baxter Healthcare), which requires two doses at least 3 weeks apart. The vaccination process in the UK began on 22 October 2009 and was initially offered to frontline health-care workers and pregnant women; those with underlying health conditions that may predispose (and in particular people with respiratory disease) (*Table 1*) who were at increased risk of serious illness or death from influenza-like illness were also targeted in this first phase. In December 2009, phase II of the immunisation programme targeted children aged between 6 months and 5 years to receive the vaccination.

Observational studies can be used to estimate the effectiveness of health-care interventions in situations where it is unethical and/or not feasible to mount more rigorous experimental studies, as is the case in the context of the 2009 HIN1 pandemic.[6] Building on related pilot work,[3] we sought to determine influenza A (H1N1)v vaccine uptake and effectiveness for 2009 in the Scottish population using a sentinel surveillance network of general practices, the Practice Team Information (PTI) network.

Chapter 2
Methods

Overview of methods

The impact of the Scottish 2009 pandemic H1N1 vaccination programme was evaluated using a retrospective cohort design to study vaccination effectiveness (VE). This was achieved by ascertaining the uptake of the influenza A (H1N1)v vaccine by the relevant at-risk populations, i.e. patients with relevant comorbidities and pregnant women, and assessing the reduction in the expected incidence of influenza-related serious morbidity. *Figure 1* gives an overview of the study design and the data sources used.

Setting

The PTI network of 41 general practices covers a 5% broadly representative sample of the Scottish population (n = 246,368). These practices receive an annual financial incentive to record practice data electronically.[7] Data from practices within Scotland have shown to be of high quality and useful for epidemiological research.[8] The completeness of capture of contacts and accuracy of clinical event coding in primary care (using Read codes) has been found to be above 91%.[9] Using the unique Community Health Index (CHI) number, general practice patient-level data were extracted and linked to the Scottish Morbidity Record (SMR) catalogue, which has information on all inpatient hospitalisations within Scotland [as well as information on death certification linked from the General Register Office for Scotland (GROS)].[10] Hospital data are reliable from 1981, with completeness and accuracy rates exceeding 90%.[11] We also used the Health Protection Scotland (HPS) data set, which consists of all laboratory-confirmed cases of influenza A (H1N1)v from the general practices. We determined key characteristics of each identified patient in the cohort: sex, age (0–4, 5–14, 15–44, 45–64, 65–74 and 75+ years), socioeconomic status (Carstairs deprivation category scores[12] expressed as deciles: 1 = most affluent and 10 = most deprived, and quintiles: 1 = most affluent and 5 = most deprived), clinical at-risk groups (i.e. chronic respiratory disease, chronic heart disease, chronic kidney disease, chronic liver disease, chronic neurological disease, immunosuppression and diabetes) and pregnancy

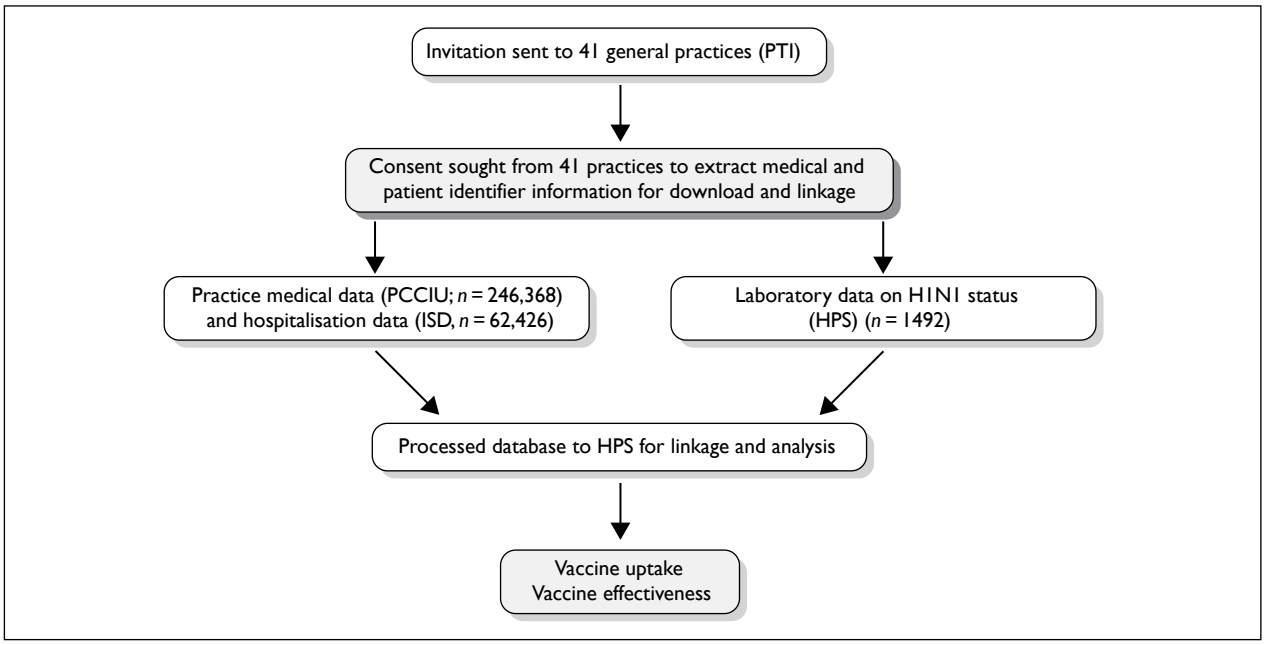

FIGURE 1 *Flow diagram for the VIPER study. HPS, Health Protection Scotland; ISD, Information Services Division; PCCIU, Primary Care Clinical Informatics Unit; PTI, Practice Team Information (network).*

(at start date of H1N1 vaccination). The practices were also asked to collect information on health-care worker status and immunisation (in addition to information routinely recorded as part of usual clinical care).

Interventions

The study involved a quantitative evaluation of the aspect of the H1N1 vaccination programme implemented through general practice during 2009. General practices were given financial incentives to record and code additional data electronically, over and above that routinely recorded for clinical care or as part of the PTI project including: H1N1 vaccination status, age, deprivation status, pregnancy, and, where it was feasible, health-worker status.

Outcome measures

During 2009, swabbing was undertaken to test patients for influenza A (H1N1)v as part of a sentinel swabbing scheme. This was carried out by the practices on a convenience sampling basis, with each practice being encouraged to submit around 10 samples per week from patients presenting with influenza-like illness. To calculate effectiveness, patient swab data were linked to the patient data (from primary and secondary care) using the CHI number.

TABLE 1 *Priority groups for immunisation – Read codes (version 2, 5 byte), medications and hospitalisation outcomes* – International Classification of Disease *(10th revision)*

Disease group	Medical codes
Chronic respiratory disease (including asthma)	Read codes: H33 and below, H3.., H31.., H32.., H34.., H35.., H36.., H37.., H38.., H3y.., H3z.., C370., H40.., H41.., H42.., H43.., H44.., H45.., H46.., H47y0, H48.. H4y.., H4z.., H5410., H55.., H563., H57.., H583., H591. H592., H593., Hyu3., Hyu40, Hyu41, Hyu5.
Chronic heart disease	Read codes: G3 and below, G58 and below, G21 and below, G220. G222., G55 and below, G5yy9, G5yyA, G23 and below, G41 and below, G1 and below, P5 and below, P60 and below, P61 and below, P62 and below, P63 and below, P64 and below, P65 and below, P66 and below, P67 and below, P68 and below, P6W and below, P6X and below, P6y.., P6y0., P6y1., P6y2., P6y3 and below, P6y63, P6y64, P6y6z, P6yy and below, P6z and below, 33BA.
Chronic kidney disease	Read codes: Iz12., Iz13., Iz13. Iz15, Iz16., Iz1B., Iz1C., Iz1D., Iz1E., Iz1F., IZ1G., Iz1H., IZ1J. IZ1K., Iz1L., K01 and below, K02 and below, K0A3 and below, K05 and below, K0D.., 7B00 and below, 7B012, 7B015, 7B063, 8L50., SP083, TB001, ZV420
Chronic liver disease	Read codes: J6…, J61 and below, J62y., J62z., J6353, J6354, J6355, J6356, J63B., PB61 and below, PB63 and below, PB6y1
Chronic neurological disease	G51.., G610., G611., G612., G613., G614., G615., G616., G618., G61X., G61X0, G61X1, G61z.., G63y0, G63y1, G64.., G640. G6400, G641., G6410, G64z., G64z0, G64z1, G64z2, G64z3, G64z4, G66 and below, G6760., G6W..
Immunosuppression	Read codes: PK01., 14N7., 7840 and below, D4154, D4156, 2J30., Drugs: alkylating drugs cytotoxic antibiotics antimetabolites vinca alkaloids and etoposide, other cytotoxix drugs, antagonists, cytotoxic immunosuppressants other immunosuppressants, other antineoplastic agents, leflunomide
Diabetes	Drugs: short-acting insulin preparations, medium/long-acting insulins sulphonylureas, biguanides repaglinide Rosiglitazone pioglitazone nateglinide short with intermediate-acting insulins
Pregnancy	Read code: 62…
Influenza hospitalisation	ICD10: J10,J100,J101,J108,J11,J110,J111,J118
Pneumonia hospitalisation	ICD10: J12,J13,J14,J15,J16,J17,J18
COPD hospitalisation	ICD10:J40,J41,J42,J43,J44,J45,J46,J47,J80,J81,J82,J83,J84,J60,J61,J62,J63,J64,J65,J66,J67,J68, J69,J70,
CRH	ICD10:I05,I06,I07,I08,I09,I10,I11,I12,I13,I15,I20,I21,I22,I23,I24,I25,I26,I27,I28,I30,I31,I32,I33,I34,I35,I36,I37,I38,I39,I40,I41,I42,I43,I44,I45,I46,I47,I48,I49,I50,I51,I52,I60,I61,I62,I63,I64,I65,I66,I67,I68,I69
Trauma (including bone fracture), appendicitis or hernia hospitalisation	ICD10: S, T K35,K36,K37,K38,K40,K41,K42,K43,K44,K45,K46

We assessed the vaccination uptake in the relevant populations, i.e. children (< 5 years), pregnant women, health-care workers and patients with at-risk comorbidities, recorded by general practice prior to 25 December 2009, and influenza, pneumonia, chronic obstructive pulmonary disease (COPD) and cardiovascular-related hospitalisations (CRHs) (both individually and as composite outcomes, for emergency admissions and any admission reason),[13] and, for comparison, hospitalisation for other serious morbidity (e.g. trauma, appendicitis and hernia) in vaccinated and unvaccinated patients (*Table 1*). For patients who remained unvaccinated and who had not been hospitalised, the risk period of interest was 65 days, i.e. from 21 October 2009 (date of first vaccination in the data set) to 24 December 2009 (date of last recorded hospital admission and the study census end point – the vaccination programme continued beyond this time). For those who had been vaccinated, the risk period of interest began 7 days after the vaccination date. [Conventionally, the seasonal influenza vaccine is thought to require 14 days to establish a protective effect; however, there is evidence from ongoing studies (involving HPS and the Health Protection Agency, Colindale) that 7 days is probably sufficient for the influenza A (H1N1)v vaccine.] Hospital admissions before the date of vaccination among those vaccinated were ignored. For those with an admission, the risk period ended on admission. This type of analysis was required so as to ensure that hospitalisations before vaccination could not be attributed to a vaccine effect.

Statistical methods

Odds ratios (adjusted for age, sex and deprivation) were calculated for differences in vaccine uptake rates between groups of patients. For VE using information from linked virological swab data, a logistic regression model was fitted, adjusting for the effects of gender, age, deprivation and being in an at-risk morbidity group. Some of these patients did not receive the influenza A (H1N1)v vaccine, some received the vaccine (but after they were tested) and some received the vaccine before they were tested. We therefore measured VE first by comparing swabs taken after vaccination with swabs taken before vaccination for all vaccinated individuals, and second, by comparing swabs taken after vaccination among those vaccinated with swabs taken among those never vaccinated. A delay of 7 days after vaccination was used to establish a protective effect of the influenza A (H1N1)v vaccine. Confidence intervals for the rate ratio (RR) and tests of the differences between two rates were carried out using the 'MIDP method' in the 'RR' function and rate2by2.test function respectively, using the 'epitools' package in R.[14] For small samples, confidence intervals for the RR were estimated using the EXCEL workbook.[15]

Illness RRs are the ratio of the rate of first admission to hospital in the vaccinated compared with the rate of first admission to hospital among those who did not receive the vaccine. This is a direct measure of VE. The unadjusted estimate of $VE = (1 - RR) \times 100$. Adjusted RRs of VE for prevention of first hospitalisation were derived from Poisson regression models, adjusting for gender, age, deprivation and clinical risk group. An adjustment to the standard error of the estimated effect to account for clustering of patients within practices was carried out using the 'survey' package in R. Statistical analysis was carried out using R version 2.9.0.

Summary of changes to the project protocol

We were unable in this interim analysis to calculate rates of mortality in vaccinated and unvaccinated patients, as only confirmed deaths prior to 30 September 2009 were available. A definitive analysis with a repeat linkage to SMR and HPS records will be required later in 2010.

We planned to use the 'Farrington' method, as detailed in our original project protocol, as we were confident of at least obtaining practice-level vaccination uptake data.[6] We were fortunate, however, to be able to obtain individual patient-level data and so could use the more robust cohort method as described in the statistical methods section above.

Chapter 3
Results

We recruited all 41 PTI practices with a combined list size of 246,368 patients. As only one practice software system, GPASS, was used for the study, the general practitioner (GP) practices in this study are not representative of the spatial distribution of the population of Scotland. There was an under-representation of practices from the north-east of Scotland, in particular Orkney, Grampian and Tayside areas (where practices tend to use other GP software systems). There was also a preponderance of practices in west and central Scotland, which have higher levels of socioeconomic deprivation (*Table 2*).

Overall, 24.2% individuals ($n = 59,721$) were deemed to be in the at-risk category on the basis of existing illnesses; 4.3% ($n = 2203$) of 15- to 44-year-old women ($n = 51,404$) were found to be pregnant and 0.8% ($n = 1314$) of people of working age (18–64 years inclusive, $n = 159,873$) registered with the practices worked for the NHS (*Table 2*).

Vaccine uptake

Influenza A (H1N1)v vaccine uptake estimates for the whole population as obtained at 25 December 2009 were 12.0% (95% CI 11.9 to 12.1) (*Table 2*). These uptake estimates reflect the early stage of the H1N1v vaccination programme, which continued into 2010. For those patients in an at-risk comorbidity group, the uptake rate was 37.5% (95% CI 37.1 to 37.9). Men and younger people (outwith the youngest age group 0–4 years) were less likely to take up the vaccine than women, infants and older adults (*Table 3*). Uptake rates among pregnant women and health-care workers can be found in *Table 2*. More male [odds ratio (OR) 2.67, 95% CI 1.44 to 4.96] and older (45- to 64-years-olds; 1.67, 95% CI 0.87 to 3.19) health-care workers were vaccinated than female and younger (16- to 44-year-old) health-care workers.

Virology

Among the 1492 patients swabbed, 467 were positive for H1N1, giving an influenza A (H1N1)v positive rate of 31.3% (95% CI 29.0 to 33.7). Out of the 1492 patients, 1301 (87.2%; 95% CI 85.5 to 88.9) were never vaccinated, 160 (10.7%; 95% CI 9.2 to 12.3) were swabbed before being vaccinated, and 31 (2.1%; 95% CI 1.4 to 2.8) were tested after vaccination. The ORs in *Table 4* show that during the study period those who were in a clinical risk group had an 82.0% (95% CI 37.0 to 141.0) increase in the odds of being positive for H1N1 compared with those with no clinical risk group. Those in age groups of less than 45 years of age were more likely to test positive for H1N1.

Only one vaccinated patient swabbed after their vaccination tested positive for influenza A (H1N1)v (*Table 5*). For patients not vaccinated during the study period more patients within a clinical at-risk comorbidity group tested positive for H1N1 than those outwith the clinical at-risk groups ($p < 0.01$).

Comparing swabs taken after vaccination with swabs taken before vaccination for all vaccinated individuals, there was a VE of 70.0% (95% CI –58.0 to 98.0). By comparing swabs taken after vaccination among those vaccinated with swabs taken among those never vaccinated, the VE was found to be 95.0% (95% CI 76.0 to 100.0). The former vaccine effect is estimated with much lower precision, as it is based upon fewer cases.

Influenza A (H1N1)v vaccination effectiveness

During the study period there were 2739 admissions to hospital in our cohort, of which 1241 were emergency admissions. All emergency hospitalisations for influenza and pneumonia occurred in patients who did not receive the vaccine (*Table 6*). Patients with an at-risk comorbidity were 12 times more likely to be hospitalised than not-at-risk patients for the composite outcome: influenza, pneumonia, COPD and CRH (0.43 versus 5.18 per 100,000 person-days). Patients who were at risk and vaccinated were less likely than their unvaccinated counterparts to be admitted into hospital for the composite outcome. Vaccinated patients were more likely to be admitted to hospital for trauma.

TABLE 2 *Influenza A (H1N1)v vaccine uptake by groups*

	Total patients (% within category)	No. with at least one at-risk comorbidity group, *n* (%, 95% CI)	Vaccine uptake for not-at-risk comorbidity group, *n* (%, 95% CI)	Vaccine uptake for at-risk comorbidity group, *n* (%, 95% CI)
Sex				
Female	124,177 (50.4)	30,400 (24.5, 24.2 to 24.7)	4823 (5.1, 5.0 to 5.3)	11,557 (38.0, 37.5 to 38.6)
Male	122,193 (49.6)	29,321 (24.0, 23.8 to 24.2)	2356 (2.5, 2.4 to 2.6)	10,840 (37.0, 36.4 to 37.5)
Age group (years)				
0–4	13,245 (5.4)	434 (3.3, 3.0 to 3.6)	384 (3.0, 2.7 to 3.3)	207 (47.7, 43.0 to 52.4)
5–34	25,932 (10.5)	3951 (15.2, 14.8 to 15.7)	288 (1.3, 1.2 to 1.5)	1166 (29.5, 28.1 to 31.0)
35–49	103,888 (42.2)	17,666 (17.0, 16.8 to 17.2)	2674 (3.1, 3.0 to 3.2)	4006 (22.7, 22.1 to 23.3)
50–64	64,823 (26.3)	16,101 (24.8, 24.5 to 25.2)	2571 (5.3, 5.1 to 5.5)	7933 (49.3, 48.5 to 50.0)
65–74	20,625 (8.4)	10,089 (48.9, 48.2 to 49.6)	767 (7.3, 6.8 to 7.8)	4946 (49.0, 48.0 to 50.6)
≥75	17,855 (7.2)	6375 (64.3, 63.6 to 65.0)	495 (7.8, 7.1 to 8.4)	4139 (36.1, 35.2 to 36.9)
Deprivation decile				
1	15,538 (6.3)	3413 (22.0, 21.3 to 22.6)	511 (4.2, 3.9 to 4.6)	1549 (45.4, 43.7 to 47.1)
2	11,594 (4.7)	2277 (19.6, 18.9 to 20.4)	248 (2.7, 2.4 to 3)	694 (30.5, 28.6 to 32.4)
3	12,818 (5.2)	3194 (24.9, 24.2 to 25.7)	572 (5.9, 5.5 to 6.4)	1381 (43.2, 41.5 to 45)
4	11,693 (4.7)	2511 (21.5, 20.7 to 22.2)	222 (2.4, 2.1 to 2.8)	842 (33.5, 31.7 to 35.4)
5	38,742 (15.7)	8996 (23.2, 22.8 to 23.6)	1060 (3.6, 3.4 to 3.8)	3302 (36.7, 35.7 to 37.7)
6	28,558 (11.6)	7281 (25.5, 25 to 26)	963 (4.5, 4.3 to 4.8)	2704 (37.1, 36 to 38.3)
7	43,324 (17.6)	11,318 (26.1, 25.7 to 26.5)	1299 (4.1, 3.8 to 4.3)	4310 (38.1, 37.2 to 39)
8	18,111 (7.4)	4430 (24.5, 23.8 to 25.1)	438 (3.2, 2.9 to 3.5)	1358 (30.7, 29.3 to 32)
9	41,831 (17.0)	10,459 (25, 24.6 to 25.4)	1288 (4.1, 3.9 to 4.3)	3980 (38.1, 37.1 to 39)
10	24,159 (9.8)	5842 (24.2, 23.6 to 24.7)	578 (3.2, 2.9 to 3.4)	2277 (39.0, 37.7 to 40.2)
Pregnant women	2203 (4.3)	360 (16.3, 14.9 to 17.9)	575 (31.2, 29.1 to 33.4)	151 (41.9, 37.0 to 47.1)
Health-care worker	1314 (0.8)	347 (26.4, 24.0 to 28.8)	229 (23.6, 21.0 to 26.4)	118 (34.0, 29.0 to 39.0)

Statistically significant findings consistent with protection in recipients of influenza A (H1N1)v vaccine were evident in the adjusted VE seen for emergency admissions with a CRH alone, or in preventing an emergency admission for any one or more of influenza and pneumonia plus COPD and CRH (for all patients) (*Table 7*).

TABLE 3 *Odds ratios of receiving influenza A (H1N1)v vaccine amongst patients in the at-risk comorbidity group*

	OR	95% CI
Gender		
Females	1.00	
Males	0.96	0.92 to 0.99
Age group (years)		
0–4	1.00	
5–14	0.46	0.35 to 0.60
15–44	0.32	0.24 to 0.43
45–64	1.06	0.76 to 1.47
65–74	1.05	0.71 to 1.54
≥75	0.61	0.42 to 0.90
Socioeconomic status[a]		
Quintile 1	1.00	
Quintile 2	0.93	0.55 to 1.58
Quintile 3	0.86	0.47 to 1.59
Quintile 4	0.84	0.56 to 1.27
Quintile 5	0.92	0.56 to 1.52

a Carstairs deprivation quintiles – 1: most affluent.

TABLE 4 *Adjusted odds ratio of being tested positive for influenza A (H1N1)v virus*

Description	Adjusted OR	95% CI
At-risk comorbidity		
No	1.00	
Yes	1.82	1.37 to 2.41
Gender		
Female	1.00	
Male	1.00	0.79 to 1.27
Age group (years)		
0–4	1.00	
5–14	3.87	2.65 to 5.72
15–44	1.48	1.05 to 2.10
45–64	0.95	0.95 to 1.46
65–74	0.21	0.05 to 0.61
≥75	0.08	0.00 to 0.37
Deprivation quintile		
1	1.00	
2	0.91	0.54 to 1.52
3	1.06	0.67 to 1.69
4	0.92	0.58 to 1.48
5	0.91	0.58 to 1.44

TABLE 5 *Virology result in relation to influenza A (H1N1)v vaccine status and clinical at-risk group*

	Swab test result for H1N1	
Description	**Total tested (*N*)**	**Positive, *n* (%, 95% CI)**
No clinical risk group		
No vaccination	996	323 (32.4, 29.6 to 35.4)
Vaccinated: swabbed after vaccination	11	0 (0.0, 0.0 to 25.9)
Vaccinated: swabbed before vaccination	31	0 (0.0, 0.0 to 11.0)
At least one clinical risk group		
No vaccination	305	126 (41.3, 35.6 to 46.9)
Vaccinated: swabbed after vaccination	20	1 (5.0, 0.3 to 23.6)
Vaccinated: swabbed before vaccination	129	17 (13.2, 8.4 to 20.1)

TABLE 6 *Emergency hospitalisations by at-risk comorbidity group and influenza A (H1N1)v vaccination status*

		Hospitalisation events					
		All patients		Not in at-risk comorbidity group		At-risk comorbidity group	
Hospitalisation	Vaccination status	Rate per 100,000 person-days (*n*)	Crude risk ratio (95% CI)	Rate per 100,000 person-days (*n*)	Crude risk ratio (95% CI)	Rate per 100,000 person-days (*n*)	Crude risk ratio (95% CI)
Influenza	No	0.10 (14)	1.00	0.05 (6)	1.00	0.32 (8)	1.00
	Yes	0.00 (0)	0.00 (0.00 to 7.10)	0.00 (0)	0.00 (0.00 to 49.23)	0.00 (0)	0.00 (0.00 to 3.12)
Pneumonia	No	0.25 (34)	1.00	0.13 (14)	1.00	0.81 (20)	1.00
	Yes	0.00 (0)	0.00 (0.00 to 2.92)	0.00 (0)	0.00 (0.00 to 21.10)	0.00 (0)	0.00 (0.00 to 1.25)
COPD	No	0.39 (53)	1.00	0.03 (3)	1.00	2.03 (50)	1.00
	Yes	0.96 (5)	2.51 (0.86 to 5.71)	0.00 (0)	0.00 (0.00 to 99.47)	1.32 (5)	0.67 (0.23 to 1.53)
CRH	No	0.65 (88)	1.00	0.23 (25)	1.00	2.56 (63)	1.00
	Yes	0.57 (3)	0.93 (0.22 to 2.47)	0.70 (1)	3.50 (0.15 to 16.36)	0.53 (2)	0.22 (0.03 to 0.71)
Influenza and pneumonia	No	0.36 (48)	1.00	0.18 (20)	1.00	1.14 (28)	1.00
	Yes	0.00 (0)	0.00 (0.00 to 2.07)	0.00 (0)	0.00 (0.00 to 14.77)	0.00 (0)	0.00 (0.00 to 0.89)
Influenza, pneumonia and COPD	No	0.75 (101)	1.00	0.21 (23)	1.00	3.17 (78)	1.00
	Yes	0.96 (5)	1.32 (0.46 to 2.92)	0.00 (0)	0.00 (0.00 to 12.84)	1.32 (5)	0.43 (0.15 to 0.96)
Influenza, pneumonia, COPD and CRH	No	1.39 (187)	1.00	0.43 (47)	1.00	5.69 (140)	1.00
	Yes	1.53 (8)	1.13 (0.51 to 2.14)	0.70 (1)	1.87 (0.08 to 8.40)	1.85 (7)	0.33 (0.14 to 0.66)
Trauma-associated emergency admission[a]	No	1.60 (230)	1.00	1.40 (163)	1.00	2.52 (67)	1.00
	Yes	5.18 (30)	3.40 (2.27 to 4.88)	2.09 (4)	1.96 (0.59 to 4.63)	6.36 (26)	2.54 (1.59 to 3.95)
Any emergency admission	No	8.99 (1209)	1.00	6.42 (707)	1.00	20.56 (502)	1.00
	Yes	6.14 (32)	0.69 (0.47 to 0.96)	5.58 (8)	0.89 (0.40 to 1.66)	6.35 (24)	0.31 (0.20 to 0.46)

a Trauma (including fractures), appendicitis and hernia.

TABLE 7 *Vaccine effectiveness in reducing emergency admissions to hospital for all patients*

Description	Unadjusted vaccine effectiveness, % (95% CI)	Adjusted vaccine effectiveness, % (95% CI)[a]
Influenza	100.00 (∞ to 100.00)	100.00 (∞ to 100.00)
Pneumonia	100.00 (∞ to 100.00)	100.00 (∞ to 100.00)
COPD	–144.01 (–526.65 to 4.98)	40.61 (–57.91 to 77.66)
CRH	11.84 (–167.58 to 70.79)	71.11 (11.26 to 90.59)
Influenza and pneumonia	100.00 (∞ to 100.00)	100.00 (∞ to 100.00)
Influenza, pneumonia and COPD	–28.02 (–223.79 to 49.38)	59.46 (–5.79 to 84.46)
Influenza, pneumonia, COPD and CRH	–10.61 (–169.34 to 54.41)	64.69 (12.04 to 85.82)

a Adjusted for age, sex, deprivation and at-risk comorbidity, and clustering of patients within practices.

Chapter 4
Discussion

During the immediate period after the introduction of the influenza A (H1N1)v vaccination, more than one-third of patients registered in primary care with PTI practices and deemed to have an at-risk comorbidity were vaccinated for influenza A (H1N1)v. However, men and younger patients (outwith the 0–4 years age group) were less likely to be vaccinated. Our interim results suggest that during the study period, the vaccine seems to have been particularly effective for people with an at-risk comorbidity. This is reassuring as they were also more likely to be tested positive for having influenza A (H1N1)v (when compared with those not at risk) and to be at much higher rates of hospitalisation for severe complication of influenza. Of the patients tested using swabs after their vaccination, only one tested positive for influenza A (H1N1)v.

Our findings indicate that our estimated influenza A (H1N1)v VE is at least comparable to the seasonal influenza vaccine in preventing hospitalisation admission for: influenza and/or pneumonia (27%),[16] influenza-like illness (27%) in all patients,[4] acute respiratory disease and cardiovascular disease (97%) in high-risk patients,[17] and medically attended acute respiratory illness in children (18% in those aged 18 months to 18 years).[18] As expected, overall uptake rates of vaccine reported in this study were similar to those reported by HPS in similar practices.[19] However, rates of vaccine uptake for health-care workers in occupational settings were lower than those reported by HPS, which relied on occupational health services reporting (as opposed to information captured by the practices). This under-reporting probably reflects a partial success in practices recording of occupational status on patients records, and therefore any inference from the occupational data should be treated with caution. Our findings that females and, outwith the youngest age group (0–4 years), older patients were more likely to be vaccinated is similar to other studies looking at uptake of vaccines by different groups.[20] This is likely to be due to greater levels of perceived susceptibility to, and perceived severity of, influenza A (H1N1)v and a greater belief in the effectiveness of recommended behaviours to protect against the disease. There is also evidence that greater levels of state anxiety and greater trust in authorities are associated with increased vaccine uptake. Our finding that the vaccine seemed to be particularly effective in patients with an at-risk comorbidity endorses the targeted approach advised by the Joint Committee on Vaccination and Immunisation and adopted by the CMOs for England, Northern Ireland, Scotland and Wales and their respective Government Health Departments/Directorates.[5]

There are benefits as well as drawbacks to the evaluation of an influenza vaccine campaign based on just a single postimplementation season. Retrospective ascertainment of vaccination status is less dependable, of course, than prospective clarification, but the use of GP records is more reliable than self-reporting methods,[21] as is the electronic recording of uptake rates in the sample PTI population. Also, the relatively small size of the Scottish population makes it feasible to centrally collate almost all cases of H1N1 disease, allowing for completeness of reporting. Observational studies can be used to assess the effects of health-care interventions without influencing the care that is provided or the patients who receive it;[6] therefore, when used in the assessment of vaccination programmes they have high external validity and broad generalisability. However, non-randomised studies, such as the current evaluation, are limited by the extent to which there may be dissimilarities between vaccinated and non-vaccinated persons, in both their likelihood of receiving vaccination and in their subsequent care and follow-up. Our findings that at-risk patients who received the vaccine were more likely to be admitted for a trauma-associated emergency (and were possibly more likely to be frail, thus leading to negative confounding) than those who did not may mean that there is some underestimate of VE. A further assessment of the possible impact of any bias caused by the preferential receipt of vaccine by relatively healthy individuals will need to be checked, however, outside the influenza season.[22] The results from the single outcome of emergency admission for cardiovascular-related illness or the use of the composite outcome: influenza, pneumococcal disease, COPD and cardiovascular disease should also be treated with some caution

as it may have led to a healthy vaccine effect. For instance, within the high-risk group those at lower risk of heart disease or those who do not smoke (and hence are less likely to have COPD) may be more likely to be vaccinated. However, it is of note that other authors have considered the role of influenza in the generation of cardiac-related conditions and debated its contribution to the excess mortality observed each winter during the annual influenza season.[23–25] The lack of a recorded vaccination amongst health-care workers (which was probably carried out in occupational settings) may have biased the estimation of VE towards zero. The fact that PTI is based on a small sample of practices in Scotland means that the data collected may be subject to fluctuations as a result of any factors that have an impact locally, such as changes to the way that PTI practices manage their services.[9] However, apart from a reduction in precision, it is unlikely that the small sample size, or other associated factors, will have a substantial impact on the overall estimates of VE. A convenience sampling approach was used to collect data on patient H1N1 virological status rather than a more systematic sampling approach. This was adopted in recognition that the implementation of a surveillance programme could not affect routine clinical practice. Conventionally, the seasonal influenza vaccine is thought to require 14 days to establish a protective effect; however, there is evidence from ongoing studies (involving HPS and the Health Protection Agency, Colindale), that 7 days is probably sufficient for the influenza A (H1N1)v vaccine. A sensitivity analysis using the 14-day cut-off period was carried out with similar estimates of vaccine effect being found (results not presented).

Chapter 5
Implications for practice

Policy-makers and clinicians should be encouraged that the VE estimates obtained are comparable to those found for seasonal influenza, which should strengthen the evidence base for health-care practitioners involved in distributing vaccine in other countries.

Influenza A (H1N1)v immunisation in primary health-care settings is both effective and widely acceptable as evidenced by high uptake rates, and should continue to be the mainstay of disease prevention for at-risk patients.

Chapter 6
Research recommendations

Study time constraints resulting from the unexpected 'slow-burn' nature of the second wave of influenza A (H1N1)v and the later than expected roll-out of the vaccine meant that this analysis was limited to studying only the short-term effectiveness of the influenza A (H1N1)v vaccine. A further analysis encompassing the whole influenza season is required to cover more days of vaccination exposure, which will increase precision (with resulting narrower confidence intervals). Also, for pregnant women and under-5-year-olds, a further study using a greater time period of exposure is required to calculate and present meaningful results. We were also unable, in this study, to estimate whether the vaccine was effective in reducing mortality (as only mortality data for the prevaccination period were available). A future study that repeats this data linkage and allows the calculation of longer-term VE (in reducing both morbidity and mortality) should be undertaken later in 2010.

Chapter 7
Conclusions

Evidence from swabs submitted from patients in the cohort presenting with influenza-like illness in general practice suggests that the introduction of influenza A (H1N1)v vaccine in Scotland during 2009 was associated with a high degree of protection against influenza A (H1N1)v. In addition, receipt of influenza A (H1N1)v vaccine was associated with a reduction in both admission for cardiac-related conditions and for the combined category of influenza, pneumonia, COPD and cardiac conditions. Policy-makers ought to be encouraged that the VE estimates obtained are comparable to those found for seasonal influenza, and this possibly reflects the suitability of primary care as a means of delivery. Additionally, as the first large-scale demonstration of effectiveness in a UK population, the results should strengthen the evidence base for health-care practitioners involved in distributing vaccine in other countries. Influenza A (H1N1)v immunisation in primary health-care settings is both effective and widely acceptable, as evidenced by high uptake rates, and should continue to be the mainstay of disease prevention for at-risk patients. Whether the reduced incidence of severe complications of influenza or death will persist will be apparent only when data from later in 2010 are analysed.

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Contribution of authors

Dr Colin Simpson (Chief Scientist Office, Health Services and Health of the Public, Postdoctoral Fellow, Epidemiology) was principal investigator and led the writing of this report. Professor Lewis Ritchie and Professor Aziz Sheikh (Professors of Primary Care) helped design the study and commented on drafts of the paper. Professor Chris Robertson (Professor of Statistics) and Dr Jim McMenamin (Consultant Epidemiologist) helped to design the study, carry out the analyses and write the paper.

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Physical interventions to interrupt or reduce the spread of respiratory viruses: a Cochrane review

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Abstract

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Background: Viral epidemics or pandemics of acute respiratory infections like influenza or severe acute respiratory syndrome pose a world-wide threat. Antiviral drugs and vaccinations may be insufficient to prevent catastrophe.

Objectives: To systematically review the effectiveness of physical interventions to interrupt or reduce the spread of respiratory viruses.

Search strategy: We searched the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2009, issue 2); MEDLINE (1966 to May 2009); OLDMEDLINE (1950 to 1965); EMBASE (1990 to May 2009); and CINAHL (1982 toMay 2009).

Selection criteria: We scanned 2958 titles, excluded 2790 and retrieved the full papers of 168 trials, to include 59 papers of 60 studies. We included any physical interventions (isolation, quarantine, social distancing, barriers, personal protection and hygiene) to prevent transmission of respiratory viruses. We included the following study designs: randomised controlled trials (RCTs), cohorts, case controls, cross-over, before-after, and time series studies.

Data collection and analysis: We used a standardised form to assess trial eligibility. RCTs were assessed by: randomisation method; allocation generation; concealment; blinding; and follow up. Non-RCTs were assessed for the presence of potential confounders, and classified into low, medium, and high risks of bias.

Main results: The risk of bias for the four RCTs, and most cluster RCTs, was high. The observational studies were of mixed quality. Only case-control data were sufficiently homogeneous to allow meta-analysis. The highest quality cluster RCTs suggest respiratory virus spread can be prevented by hygienic measures, such as handwashing, especially around younger children. Additional benefit from reduced transmission from children to other household members is broadly supported in results of other study designs, where the potential for confounding is greater. Six case-control studies suggested that implementing barriers to transmission, isolation, and hygienic measures are effective at containing respiratory virus epidemics. We found limited evidence that N95 respirators were superior to simple surgical masks, but were more expensive, uncomfortable, and caused skin irritation. The incremental effect of adding virucidals or antiseptics to normal handwashing to decrease respiratory disease remains uncertain. Global measures, such as screening at entry ports, were not properly evaluated. There was limited evidence that social distancing was effective especially if related to the risk of Physical interventions to interrupt or reduce the spread of respiratory viruses exposure.

Authors' conclusions: Many simple and probably low-cost interventions would be useful for reducing the transmission of epidemic respiratory viruses. Routine long-term implementation of some of the measures assessed might be difficult without the threat of a looming epidemic.

Contents

Plain language summary

Physical interventions to interrupt or reduce the spread of respiratory viruses

Although respiratory viruses usually only cause minor disease, they can cause epidemics. Approximately 10% to15% of people worldwide contract influenza annually, with attack rates as high as 50% during major epidemics. Global pandemic viral infections have been devastating because of their wide spread. In 2003 the severe acute respiratory syndrome (SARS) epidemic affected ~8000 people, killed 780, and caused an enormous social and economic crisis. In 2006 a new avian H5N1, and in 2009 a new H1N1 'swine' influenza pandemic threat, caused anxiety. Single measures (particularly the use of vaccines or antiviral drugs) may be insufficient to interrupt the spread. Therefore, we searched for evidence for the effectiveness of physical barriers (such as handwashing or wearing masks) in reducing the spread of respiratory viruses, including influenza viruses.

We found 60 studies including randomised controlled trials (RCTs) and observational studies with a mixed risk of bias.

Respiratory virus spread can be reduced by hygienic measures (such as handwashing), especially around younger children. Frequent handwashing can also reduce transmission from children to other household members. Implementing barriers to transmission, such as isolation, and hygienic measures (wearing masks, gloves and gowns) can be effective in containing respiratory virus epidemics or in hospital wards. The more expensive, irritating and uncomfortable N95 respirators might be superior to simple masks. It is unclear if adding virucidals or antiseptics to normal handwashing with soap is more effective. There is insufficient evidence to support screening at entry ports and social distancing as a method to reduce spread during epidemics.

Background

Description of the condition

Pandemic viral infections pose a serious threat to all nations. There have been several recently, including pandemic influenza (one of which is underway at the time of writing) (Jefferson 2009; WHO 2009), and a novel coronavirus causing severe acute respiratory syndrome (SARS) (Shute 2003).

Even non-epidemic acute respiratory infections (ARIs) place a serious burden on the health of nations. In total these cause much of the 7% of total deaths in the world that are attributed to lower respiratory tract infections (representing 4 million deaths worldwide, mostly occurring in low-income countries) (www.who.int/healthinfo/global_burden_disease/estimates_regional/en/index.html). In addition there is a huge burden from ARIs on morbidity, and nations' healthcare systems (www.who.int/healthinfo/global_burden_disease/estimates_regional/en/index.html).

High viral load and infectiousness probably increase the spread of acute respiratory infection outbreaks (Jefferson 2006a). Stopping the spread of virus from person to person may be effective at preventing their outbreaks. This can be achieved in a number of ways. However, single interventions (such as vaccination or antiviral drugs) may be inadequate (Jefferson 2005a; Jefferson 2005b; Jefferson 2005c; Jefferson 2006a).

Description of the intervention

There is increasing evidence (Jefferson 2005a; Jefferson 2005b; Jefferson 2005c; Jefferson 2006a) that single measures (such as the use of vaccines or antivirals) may be insufficient to interrupt the spread of influenza. However, a recent trial showed that handwashing may be effective in diminishing mortality due to respiratory disease (Luby 2005). The possible effectiveness of public health measures during the 'Spanish Flu' pandemic of 1918 to 1919 (Bootsma 2007) in US cities led us to wonder what evidence exists on the effectiveness of combined public health measures such as isolation, distancing and barriers. We also considered the major social implications for any community adopting them (CDC 2005a; CDC 2005b; WHO 2006). Given the potential global importance of interrupting viral transmission, up-to-date, concise estimates of effectiveness are necessary to inform planning and decision making. We could find no previous systematic review of such evidence.

How the intervention might work

Epidemics and pandemics are more likely during antigenic shift in the virus (especially influenza), when the viral genes sufficiently alter to create a new subtype against which there is little circulating natural immunity (Smith 2006). This may happen when viruses cross from animal species such as ducks or pigs to infect humans (Bonn 1997). Minor changes in viral antigenic configurations, known as 'drift', cause local or more circumscribed epidemics (Smith 2006).

High viral load and high viral infectiousness are likely to be the drivers of such epidemics and pandemics (Jefferson 2006a).

Physical means might prevent the spread of virus by aerosol from infected to susceptible people (such as by Physical interventions to interrupt or reduce the spread of respiratory viruses using masks and distancing measures), and by fomites (such as by using handwashing, gloves, and protective gowns). Such public health measures were widely adopted during the 'Spanish Flu' pandemic of 1918 to 1919 (Bootsma 2007).

Why it is important to do this review

Although the benefits of physical methods seem self-evident, they require establishing, and quantifying. Physical methods have several possible advantages over other methods of suppressing acute respiratory infection outbreaks: they can be instituted rapidly and may be independent of any specific type of infective agent including novel viruses.

Objectives

To systematically review the evidence of effectiveness of physical interventions to interrupt or reduce the spread of acute respiratory viruses.

Methods

Criteria for considering studies for this review

Types of studies

We considered trials (individual-level or cluster randomised, or quasi-randomised), observational studies (cohort and case-control designs), and any other comparative design, provided some attempt had been made to control for confounding, carried out in people of all ages.

Types of participants

People of all ages.

Types of interventions

We included any intervention to prevent viral animal-to-human or human-to-human transmission of respiratory viruses (isolation, quarantine, social distancing, barriers, personal protection and hygiene) compared with doing nothing or with another intervention. We excluded vaccines and antivirals.

Types of outcome measures

1. Deaths.
2. Numbers of cases of viral illness.
3. Severity of viral illness in the compared populations. In children and healthy adults we measured burden by consequences of influenza, for example, losses in productivity due to absenteeism by parents. For the elderly in the community, we measured the burden by repeated primary healthcare contacts, hospital admissions, and the risk of complications.
4. Any proxies for these (e.g. clinical symptoms as a proxy for viral illness).

Search methods for identification of studies

Electronic searches

In the first publication of this review we searched the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2006, issue 4); MEDLINE (1966 to November 2006); OLDMEDLINE (1950 to 1965); EMBASE (1990 to November 2006); and CINAHL (1982 to November 2006). The MEDLINE search terms were modified for OLDMEDLINE, EMBASE and CINAHL.

In this 2009 update we searched the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2009, issue 2); Ovid MEDLINE (2006 to May Week 1 2009); OLDMEDLINE (1950 to 1965); Ovid EMBASE (2006 to Week 18, 2009); and Ovid CINAHL (2006 to May Week 1 2009).

Ovid MEDLINE

1 exp Influenza/
2 influenza.tw.
3 flu.tw.
4 exp Common Cold/
5 common cold.tw.
6 exp Rhinovirus/
7 rhinovirus*.tw.
8 exp Adenoviridae/
9 adenovirus*.tw.
10 exp Coronavirus/
11 exp Coronavirus Infections/
12 coronavirus*.tw.
13 exp Respiratory Syncytial Viruses/
14 exp Respiratory Syncytial Virus Infections/
15 respiratory syncytial virus*.tw.
16 respiratory syncythial virus.tw.
17 exp Parainfluenza Virus 1, Human/
18 exp Parainfluenza Virus 2, Human/
19 exp Parainfluenza Virus 3, Human/
20 exp Parainfluenza Virus 4, Human/
21 (parainfluenza or para-influenza or para influenza).tw.
22 exp Severe Acute Respiratory Syndrome/
23 (severe acute respiratory syndrome or SARS).tw.
24 acute respiratory infection*.tw.
25 acute respiratory tract infection*.tw.
26 or/1-25 (59810)
27 exp Hand Washing/
28 (handwashing or hand washing or hand-washing).tw.
29 hand hygiene.tw.
30 (sanitizer* or sanitiser*).tw.
31 (cleanser* or disinfectant*).tw.
32 exp Gloves, Protective/

33 exp Gloves, Surgical/
34 glov*.tw.
35 exp Masks/
36 mask*1.tw.
37 exp Patient Isolators/
38 exp Patient Isolation/
39 patient isolat*.tw.
40 (barrier* or curtain* or partition*).tw.
41 negative pressure room*.tw.
42 reverse barrier nursing.tw.
43 Cross Infection/pc [Prevention]
44 school closure*.tw.
45 (clos* adj3 school*).tw.
46 mass gathering*.tw.
47 ublic gathering*.tw.
48 (ban or bans or banned or banning).tw.
49 (outbreak* adj3 control*).tw.
50 distancing.tw.
51 exp Quarantine/
52 quarantine*.tw.
53 or/27-49
54 26 and 53
55 (animals not (humans and animals)).sh.
56 4 not 55

The search strategies for, Cochrane Central Register of Controlled Trials (CENTRAL), Ovid EMBASE and EBSCO CINAHL can be found in Appendix 1, Appendix 2 and Appendix 3, respectively.

Searching other resources

There were no language restrictions. Study-design filters designed to retrieve RCTs, cohort case-control and cross-over studies, and before-after and time series trials were used in the original searches but no filters were applied to the searches carried out for this update. We scanned the references of all included studies to identify other potentially relevant studies. We also accessed the archives of the former MRC Common Cold Unit (Jefferson 2005d) as a possible source for interruption of transmission evidence.

Data collection and analysis

Selection of studies

After conducting the searches we scanned the titles and abstracts. If a study appeared to meet our eligibility criteria (or when there was insufficient information to exclude it), we obtained full text articles. We then used a standardised form to assess the eligibility of each study, based on the full article.

Data extraction and management

Two review authors (TOJ, CDM) independently applied inclusion criteria to all identified and retrieved articles. Four review authors (TOJ, EF, BH, AP) extracted data from included studies and checked their accuracy on standard Cochrane Vaccines Field forms. The procedure was supervised and arbitrated by CDM.

For the 2009 update three review authors (EF, LAA, GAA) extracted data independently two review authors (TOJ, CDM) checked the procedure. CDM arbitrated.

Aggregation of data was dependent on study design, types of comparisons, sensitivity and homogeneity of definitions of exposure, populations, and outcomes used. We calculated the I^2 statistic for each pooled estimate to assess the impact on statistical heterogeneity (Higgins 2002; Higgins 2003). Physical interventions to interrupt or reduce the spread of respiratory viruses

When possible, we performed a quantitative analysis and summarised effectiveness as odds ratio (OR) using 95% confidence intervals (CI). We expressed absolute intervention effectiveness as a percentage using the formula intervention effectiveness = 1 - OR, whenever significant. In studies which could not be pooled, we used the effect measures reported by the trial authors (such as risk ratio (RR) or incidence rate ratio (IRR) with 95% CI or, when these where not available, relevant P values).

We contacted one trial author (Dr Michael Broderick) to better understand the risk of bias in his study (Broderick 2008).

Assessment of risk of bias in included studies

A common problem to these studies was a lack of reporting of viral circulation of the reference population, making interpretation and generalisability of their conclusions questionable.

Randomised studies

Three of the four RCTs were poorly reported with no description of randomisation sequence, concealment, or allocation in three studies (Gwaltney 1980; Turner 2004a; Turner 2004b). Satomura 2005 reported the generation of randomisation but the very nature of the intervention (gargling with water with or without

povidone iodine versus standard gargling with no attempt at masking the taste of iodine) made blinding impossible. The design of two trials was so artificial that their results cannot be generalised to everyday situations (Turner 2004a; Turner 2004b). One trial (Satomura 2005) is linked to a subsequent brief report which provides contradictory information difficult to reconcile (Kitimura 2007).

The quality of the cluster randomised trials varied. Only the best reported cluster coefficients, and conducted analysis of data by unit of (cluster) allocation instead of by individuals (Luby 2005; Roberts 2000; Sandora 2005). This practice leads to spuriously narrow confidence intervals around the estimates of effect (Grimshaw 2004). Other frequent problems were a lack of description of randomisation procedure, partial reporting of outcomes, unclear numerators or denominators and unexplained attrition (Carabin 1999; Kotch 1994; Morton 2004; White 2001), and either complete failure of double blinding (Farr 1988a; Farr 1988b) or inappropriate choice of placebo (Longini 1988). Three cluster randomised trials involving the use of face masks (Cowling 2008; Cowling 2009; MacIntyre 2009) by influenza-like illness (ILI) contacts had poor compliance. This shows the difficulty of conducting clinical trials using bulky equipment in the absence of the perception of a real threat. One trial (Cowling 2008) was also conducted in a period of low viral circulation and randomisation was carried out on the basis of two different sequences. The other study (MacIntyre 2009) was underpowered to detect differences in effect between different types of masks.

The other cluster randomised trial (Sandora 2008) is at low risk of bias with careful evaluation of compliance in the intervention arm (hand sanitiser wipes and disinfection of surfaces).

Non-randomised studies

These were assessed for the presence of potential confounders using the appropriate Newcastle-Ottawa Scales (NOS) (Wells 2005) for case-control and cohort studies; and a three-point checklist for controlled before and after and ecological studies (Khan 2000).

Case–control studies

We classified five of the seven case-control studies as having medium risk of bias (Lau 2004a; Seto 2003; Wu 2004; Yin 2004; Yu 2007) and two as at low risk of bias (Nishiura 2005; Teleman 2004), mostly because of inconsistencies in the text and lack of adequate description of controls.

Prospective cohort studies

Six of the 16 prospective cohort studies were classified as at low risk of bias (Agah 1987; Dick 1986; Falsey 1999; Leung 2004; Madge 1992; Somogyi 2004), six as of medium risk (Broderick 2008; Dyer 2000; Kimel 1996; Murphy 1981; White 2003, Yen 2006), and four as of high risk of bias (Makris 2000; Master 1997; Niffenegger 1997; Wang 2007). One was a very brief report of a small study with insufficient details to allow assessment (Derrick 2005).

Retrospective cohort studies

All five retrospective cohort studies had high risk of bias (Doherty 1998; Foo 2006; Isaacs 1991; Ou 2003; Yen 2006). In general, retrospective designs are prone to recall bias.

Time series studies

Six of the 13 controlled before-after studies were at low risk of bias (Hall 1981a; Leclair 1987; Macartney 2000; Pang 2003; Ryan 2001; Simon 2006), two of medium risk (Krasinski 1990; Pelke 1994) and five at high risk (Gala 1986; Hall 1981b; Heymann 2004; Krilov 1996; Snydman 1988).

Measures of treatment effect

Outcome measures varied from incidence of experimentally induced rhinovirus infections, to the incidence of naturally occurring undifferentiated ARIs. This was measured in a variety of ways, including numbers of ARIs per time period, or number of ARIs per household per time period. In some studies the ARIs were replaced by ILI. Other included studies focused on SARS specifically, or respiratory syncytial virus (RSV).

Proxy measures of illness included absenteeism.

Subgroup analysis and investigation of heterogeneity

An a priori subgroup analysis was planned for:

1. pandemic influenza outbreaks;
2. seasonal influenza;
3. other epidemics (for example, SARS).

We had sufficient data to carry out only the last.

Results

Description of studies

See 'Characteristics of included studies' table.

Included studies

See 'Summary of main results' section for a summary table of interventions and types of evidence.

Excluded studies

See 'Characteristics of excluded studies' table.

Risk of bias in included studies

Three RCTs were poorly reported with no description of randomisation sequence, concealment, or allocation (Gwaltney 1980; Turner 2004a; Turner 2004b). The design of two trials by one author means their results may not be generalised to everyday situations. This is due to the artefactual delivery of the interventions tested (see 'Quality issues' in the 'Discussion' section) (Turner 2004a; Turner 2004b).

The quality of the cluster randomised trials varied. Only the highest quality trials (Cowling 2009; Luby 2005; Roberts 2000; Sandora 2005) reported cluster coefficients and conducted analysis of data by unit of (cluster) allocation instead of by individuals. This common problem leads to spuriously narrow CIs around the estimates of effect (Grimshaw 2004). Other common problems were a lack of description of randomisation procedure, partial reporting of outcomes, unclear numerators or denominators and unexplained attrition (Carabin 1999; Kotch 1994; Morton 2004; White 2001), and either complete failure of double blinding (Farr 1988a; Farr 1988b) or inappropriate choice of placebo (Longini 1988).

We classified four of the six case-control studies as having medium risk of bias (Lau 2004a; Seto 2003; Wu 2004; Yin 2004) and two as at low risk of bias (Nishiura 2005; Teleman 2004), mostly because of inconsistencies in the text and lack of adequate description of controls.

Six of the 16 prospective cohort studies were classified as at low risk of bias (Agah 1987; Dick 1986; Falsey 1999; Leung 2004; Madge 1992; Somogyi 2004), four as of medium risk (Dyer 2000; Kimel 1996; Murphy 1981; White 2003), and three as of high risk of bias (Makris 2000; Master 1997; Niffenegger 1997). One was a very brief report of a small study (Derrick 2005) and two recent studies (Broderick 2008; Wang 2007) report insufficient details to allow assessment.

Four retrospective cohort studies exploring the effect of barrier interventions (Doherty 1998; Isaacs 1991; Ou 2003; Yen 2006) and one study reporting on adverse effects of barrier interventions (Foo 2006) had high risk of bias.

Six of the 13 controlled before-after studies were at low risk of bias (Hall 1981a; Leclair 1987; Macartney 2000; Pang 2003; Ryan 2001; Simon 2006), two of medium risk (Krasinski 1990; Pelke 1994) and five at high risk (Gala 1986; Hall 1981b; Heymann 2004; Krilov 1996; Snydman 1988).

The most common problem in all of these studies was a lack of reporting of viral circulation of the reference population, making interpretation and generalisability of their conclusions questionable.

Effects of interventions

We scanned 2958 titles, excluded 2790 and retrieved the full papers of 168 trials, to include 59 papers of 60 studies.

Reported results from randomised studies

Three studies tested the effects of cleaning hands on inactivating the virus and preventing experimental rhinovirus colds. These resulted in either a reduction in the incidence of rhinovirus infection among volunteers treated using different combinations of the acids used for cleaning

($p = 0.025$) (Turner 2004a) or did not reach statistical significance (13% versus 30% with combined denominator of only 60) (Turner 2004b). Using iodine treatment of fingers, one out of 10 volunteers were infected compared to six out of 10 in the placebo preparation arm ($p = 0.06$ with Fisher's exact test) (Gwaltney 1980). One study found that gargling with water or povidone-iodine solution in addition to handwashing is effective in preventing URTIs, but not influenza like illnesses (Satomura 2005).

Three cluster randomised studies tested the effects of virucidal cleaning disposable handkerchief wipes on the incidence and spread of ARIs. One reported a reduced incidence of ARIs in the household over 26 weeks, from 14% to 5% (Farr 1988a). A similar study reported a small non-significant (5%) drop across families (Farr 1988b). However, since the drop in incidence was confined to primary illness, unaffected by tissue use, we might assume they were ineffective. A community trial also reported a non-significant reduction in ARI secondary attack rates (18.7% versus 11.8%) during a time of high circulation of influenza H3N2 and rhinoviruses in the community (Longini 1988). This result is likely to be an underestimate because of any barrier effect of the inert tissue wipes used in controls.

Eight cluster randomised studies tested educational programmes to promote handwashing, with or without the adjunct of antiseptic agents, on the incidence of ARIs either in schools or in households. Because of different definitions, comparisons, lack of reporting of cluster coefficients, and (in two cases) missing participant data (Carabin 1999; Kotch 1994), we judged it improper to meta-analyse the data. Two of these trials reported a lack of effect: RR for the prevention of acute respiratory illness of 0.94 (95% CI -2.43 to 0.66) (Kotch 1994); and 0.97 (95% CI 0.72 to 1.30) (Sandora 2005). Nevertheless, the highest quality trials reported a significant decrease in respiratory illness in children up to 24 months (RR 0.90, 95% CI 0.83 to 0.97), although the decrease was not significant in older children (RR 0.95, 95% CI 0.89 to 1.01) (Roberts 2000); and a 50% (95% CI - 65% to -34%) lower incidence of pneumonia in children aged less than five years of age in a low-income country (Luby 2005). Another study reported a decrease of 30% to 38% in respiratory infections with additional hand-rubbing (RR for illness absence incidence 0.69, RR for absence duration 0.71) (White 2001). One study reported decreased school absenteeism of 43% with the additional use of alcohol gel as well as handwashing (Morton 2004). Two trials reported that repeated handwashing significantly reduced the incidence of colds by as much as 20% (Carabin 1999; Ladegaard 1999). One study found that in households in which interventions (handwashing with or without wearing a facemask) were implemented within 36 hours of symptom onset in the index patient, transmission of RT-PCR-confirmed infection was reduced, an effect attributable to reductions in infection among participants using face masks plus hand hygiene (adjusted odds ratio, 0.33 (95% CI 0.13 to 0.87)) (Cowling 2009).

Reported results from case–control studies

Seven case-control studies assessed the impact of public health measures to curb the spread of the SARS epidemic during February to June 2003 in China, Singapore, and Vietnam. Homogeneity of case definition, agent, settings, and outcomes allowed meta-analysis. Binary data were pooled; none of the comparisons showed significant heterogeneity, so we used a fixed-effect model. Although continuous data were often available, the variables were different and measured in different units with standard deviations usually missing, which prevented their meta-analysis.

Studies reported that disinfection of living quarters was highly effective in preventing the spread of SARS (OR 0.30, 95% CI 0.23 to 0.39) (Lau 2004a); handwashing for a minimum of 11 times daily prevented most cases (OR 0.45, 95% CI 0.36 to 0.57), based on all six studies (Lau 2004a; Nishiura 2005; Seto 2003; Teleman 2004; Wu 2004; Yin 2004); simple mask wearing was highly effective (OR 0.32, 95% CI 0.25 to 0.40), based on five studies (Lau 2004a; Nishiura 2005; Seto 2003; Wu 2004; Yin 2004); two studies found N95 respirator wearing even more effective (OR 0.09, 95% CI 0.03 to 0.30) (Seto 2003; Teleman 2004); glove wearing was effective (OR 0.43, 95% CI 0.29 to 0.65) (Nishiura 2005; Seto 2003; Teleman 2004; Yin 2004); gown wearing was also effective (OR 0.23, 95% CI .14 to 0.37) (Nishiura 2005; Seto 2003; Teleman 2004; Yin 2004); and all means combined (handwashing, masks, gloves, and gowns) achieved very high effectiveness (OR 0.09, 95% CI 0.02 to 0.35) (Nishiura 2005; Seto 2003). Another study from Hong Kong and Guangzhou hospitals wards reported that a minimum distance between beds of less than one meter was a risk factor for transmission (Yu 2007). Disaggregated data were not reported and therefore this study is not pooled

in the meta-analysis. All studies selected cases from hospitals, except for one (Lau 2004a) in which cases were people with probable SARS reported to the Department of Health in Hong Kong.

Reported results from prospective cohort studies

Using an alcohol rub in students' communal residences resulted in significantly fewer symptoms (reductions of 14.8% to 39.9 %) and lower absenteeism (40% reduction) (White 2003). In a much-cited small experimental study, virucidal paper handkerchiefs containing citric acid interrupted the transmission of rhinovirus colds transmitted through playing cards: 42% of re-usable cotton handkerchief users developed colds compared with none using disposable virucidal tissues (Dick 1986).

Few identified studies reported interventions in the daycare setting, either in staff or patients. Perhaps more than the additional portable virucidal hand foam as an adjunct to handwashing, one staff educational programme on handwashing in a daycare centre for adults was effective over the last four years in reducing rates of respiratory infection in daycare patients from 14.5 to 10.4 per 100 person-months to 5.7 ($P < 0.001$), with an accompanying decline in viral isolates (Falsey 1999). This confirmed an earlier report of the effectiveness of a handwashing programme in reducing absenteeism for ILI in a primary school (Kimel 1996).

Two high risk of bias studies reported that education, a handwashing routine, and encouragement for kindergarten children, parents and staff in correct sneezing and coughing procedure were effective, although there were considerable fluctuations in incidence of infections in the control and test centres (Niffenegger 1997); but were not effective in reducing absenteeism caused by ARIs (RR 0.79, $P = 0.756$) (Master 1997).

Dyer and colleagues reported a prospective cluster open-label cross-over cohort study. The study assessed the effectiveness of a hand sanitiser in conjunction with at will soap-and-water handwashing in a private elementary school in California. Use of the sanitiser reduced illness absenteeism by 41.9% (reduction in respiratory illnesses of 49.7% over the 10-week period of the study) (Dyer 2000).

Curiously, an infection-control education programme reinforcing handwashing and other hygienic measures in a nosocomial setting reported reducing the number of organisms present on hands and surfaces, and ARIs, although the data tabled suggested the opposite (an incidence rate of 4.15/1000 patient-days in the test homes versus 3.15/1000 in the control homes) (Makris 2000).

A study found wearing a goggle-mask apparatus in healthcare workers visiting and caring for children aged up to five with respiratory syncytial virus (RSV) and symptoms of respiratory disease was effective (5% illness rate in goggle wearers against 61% in no-goggle controls) (Agah 1987).

Rapid laboratory diagnosis, cohort nursing, and the wearing of gowns and gloves for all contacts with RSVinfected children significantly reduced the risk of nosocomial RSV infection (OR 0.013 to 0.76) (Madge 1992), although another similar study reported no effect of adding the use of both gown and mask to the usual handwashing routine on the development of illness in personnel caring for infants with respiratory disease (4 out of 30 in the handwashing group alone compared to 5 out of 28 in the handwashing, gown, and masking group, $p > 0.20$); although the authors described poor compliance with the barrier protocol (Murphy 1981).

Strict procedures of triage and infection control to stop transmission of SARS from infected children to carers and visitors of a large hospital at the height of the epidemic in 2003 in Hong Kong was reported effective at interruption of transmission as no healthcare worker became ill, in contrast to experiences in other institutions (Leung 2004).

A tiny study comparing the N95 respirator with paper surgical masks in volunteers found that surgical masks, even when worn in multiple layers (up to five), filtered ambient particles poorly (Derrick 2005); this principle was confirmed in another small study of air filtration to prevent droplet spread (Somogyi 2004).

Reported results from retrospective cohort studies

Two studies investigated isolating together children less than three years of age with suspected RSV. In one, transmission was diminished by "up to 60%" (Isaacs 1991), while the statement that nosocomial transmission "was minimised" was not supported

by data in the other study (Doherty 1998). Isolation of cases during the 2003 epidemic of SARS in China was reported to limit transmission only to those contacts who actually had home or hospital contact with a symptomatic SARS patient (attack rate 31.1%, 95% CI 20.2 to 44.4 for carers; 8.9%, 95% CI 2.9 to 22.1 for visitors; 4.6%, 95% CI 2.3 to 8.9 for those living with a SARS case) but not to contacts living in the same building, working with cases, or without contact with SARS cases during the incubation period. This suggests extending quarantine only for contacts of symptomatic SARS cases (Ou 2003).

Another brief report carried out in 2003 during the SARS epidemic, in a military hospital in Taiwan, China and 86 control hospitals, compared an integrated infection-control policy to protect healthcare workers against infection; only two from the military hospital were infected with SARS compared to 43 suspected and 50 probable cases in the control hospitals (Yen 2006).

Reported results from controlled before-and-after studies

Two small studies by the same first author assessed means of nosocomial transmission of RSV in small children and the effects of introducing distancing and barriers: one with low risk of bias reported effective physical distancing and room separation (0 infected out of 14 who sat away from RSV-infected infants compared with five out of seven who cuddled and four out of 10 who touched infected infants) (Hall 1981a). The second with high risk of bias reported no incremental benefits of gowns and masks (32% infection versus 41%) (Hall 1981b). Adding disposable plastic eye-nose goggles to other respiratory infection-control procedures (isolating infected from uninfected people, handwashing) also reduced transmission of RSV (6% versus 42% of controls) (Gala 1986). Screening and subsequent isolation of infected from uninfected people ('cohorting') also reduced nosocomial RSV transmission in older children (from 5.33 infections per 1000/patient days of care to 1.23 infections per 1000/patient days after introduction of screening) (Krasinski 1990). A similar study reported that increased compliance with a policy of glove and gown isolation precautions reduced the high rate of nosocomial RSV transmission on an infant and toddler ward (RR for pre- and post-intervention periods infection rates 2.9, 95% CI 1.5 to 5.7) (Leclair 1987).

A study of protective gowning did not protect neonatal intensive care unit infants from RSV or any other type of infection, or affect mortality (1.21 per 100 patient-days of gowning compared to 1.38 of none), although selection bias was likely with 17% of participating children lost to follow up (Pelke 1994).

A German study conducted over three seasons reported a huge decrease of nosocomial RSV infections, from 1.67/1000 patient-days in the first season to 0.18/1000 patient-days in the last season, after instituting enhanced surveillance and feedback, rapid diagnosis, barriers and isolation, and disinfection of surfaces (Simon 2006). A similar study but with high risk of bias reported a decrease from eight confirmed RSV cases per 1000 patient days to none (Snydman 1988). A better conducted study over eight years implemented a combination of education with high index of suspicion for case-finding (contact precautions), with barriers (but no goggles or masks) and handwashing for patients and staff reduced RSV infections in a hospital in Philadelphia, USA: RR 0.61, 95% CI 0.53 to 0.69 (Macartney 2000).

One small study with serious potential biases assessed training and a sanitary programme (handwashing, disinfection of school buses, appliances and toys) in a special-needs daycare facility for children with Downs Syndrome, a pupil to staff ratio of five or six to one, and reported reductions in: respiratory illnesses from a mean of 0.67 to 0.42 per child per month ($P < 0.07$); physician visits from 0.50 to 0.33 ($p < 0.05$); mean courses of antibiotics prescribed from 0.33 to 0.28 ($P < 0.05$); and days of school missed because of respiratory infections from 0.75 to 0.40 ($p < 0.05$) (Krilov 1996).

A very large study of military recruits reported that a structured top-down programme of handwashing at least five times daily nearly halved the incidence of ARIs. Recruits who handwashed less frequently reported more episodes of ARIs (OR 1.5, 95% CI 1.2 to 1.8), which represents a difference of 4.7 versus 3.2 mean infections per recruit per year, and more hospitalisations (OR 10.9, 95% CI 2.7 to 46.2). However, implementation was difficult (Ryan 2001).

An ecological study analysed the effects of quarantine and port of entry screening on the SARS epidemic in early 2003 in Beijing, China, from data collected centrally. Hospitals were the initial sources of transmission of the SARS

virus. The shape of the epidemic suggests these measures may have reduced SARS transmission although only 12 cases identified out of over 13 million people screened puts in doubt the direct effectiveness of entry port checks at airports and railway stations, and screening was probably more important (Pang 2003).

An Israeli study of 186,094 children aged six to 12 years reported that school closure was temporally associated with a 42% decreased morbidity from respiratory tract infections, a consequent 28% decrease in visits tophysicians and to emergency departments, and a 35% reduction in purchase of medications (Heymann 2004).

Discussion

Quality issues

Several features need consideration before drawing generalisations from these studies. The settings of the studies, conducted over four decades, were heterogeneous and ranged from suburban schools (Carabin 1999; Dyer 2000; Heymann 2004; Niffenegger 1997) to military barracks (Ryan 2001), intensive care units, and paediatric wards (Gala 1986; Leclair 1987) in high-income countries; slums in low-income countries (Luby 2005); and special-needs daycare centres with a very high teacher to pupil ratio (Krilov 1996). Few attempts were made to obtain socio-economic diversity by (for example) involving more schools in the evaluations of the same programme (Dyer 2000). We were able to identify few studies from low-income countries where the vast majority of the burden lies, and where cheap interventions are so critical. Even in high-income countries, such as Israel, the dramatic fall in ARIs subsequent to school closure may have been related to that country's high child population (34%). Additionally, limited availability of over-the-counter medications and national universal comprehensive health insurance provided with consequent physician prescription of symptomatic treatment may limit generalisability of findings further (Heymann 2004).

The variable quality of the methods of these studies is striking. Hasty design of interventions for public health crises, particularly the six case-control studies, is understandable but less so when no randomisation - not even of clusters - was carried out in several unhurried cohort and before-and-after studies. Randomisation could often have involved minimal disruption to service delivery. Inadequate reporting especially made interpretation difficult of before-after studies. Incomplete or no reporting of: randomisation (Turner 2004a), blinding (Farr 1988a; Farr 1988b), numerators and denominators (Carabin 1999; Kotch 1994), interventions, outcomes (White 2003), participant attrition (Makris 2000), CIs (Madge 1992), and cluster coefficients in the relevant trials (Carabin 1999) led to a considerable loss of information. Potential biases (such as cash incentives given to participants (White 2003)) were not discussed. Some trial authors even confused cohort with before-after designs to elaborate conclusions unsupported by their data (Makris 2000). Methodological quality was sometimes eroded by the need to deliver behavioural interventions in the midst of service delivery (Niffenegger 1997).

Nonetheless, even when suboptimal designs were selected, trial authors rarely attempted to articulate potential confounders. A commonly ignored confounder, specific to this area, is the huge variability in viral incidence (Heymann 2004; Isaacs 1991). Sometimes this was addressed in the study design (Falsey 1999), even in controlled before-and-after studies (one attempted correlation between RSV admissions and RSV circulating in the community) (Krasinski 1990). Another attempted linking exposure (measured as nasal excretion) and infection rate in the pre- and post-intervention periods (Leclair 1987).

Inappropriate placebos caused design problems. In some studies the placebo probably carried sufficient intervention effect to apparently dilute the intervention effects (Longini 1988). Two valiant attempts probably failed because placebo handkerchiefs were impregnated with a dummy compound which stung the users' nostrils (Farr 1988a; Farr 1988b).

Some studies used impractical interventions. Volunteers subjected to the intervention hand cleaner (organic acids) were not allowed to use their hands between cleaning and virus challenge, so the effect of normal use of the hands on the intervention remains unknown (Turner 2004a; Turner 2004b). Two per cent aqueous iodine painted on the hands, although a successful antiviral intervention, causes unacceptable cosmetic staining, impractical for all but those at the highest risk of epidemic contagion (Gwaltney 1980).

Compliance with interventions, especially educational programmes, was a problem for several studies despite the importance of many such low-cost interventions.

The evidence

The highest quality cluster randomised trials indicate most effect on preventing respiratory virus spread from hygienic measures in younger children. Perhaps this is because younger children are least capable of hygienic behaviour themselves (Roberts 2000), and have longer-lived infections and greater social contact, thereby acting as portals of infection into the household (Monto 1969). Additional benefit from reduced transmission from them to other members of the household is broadly supported from the results of other study designs where the potential for confounding is greater.

The six pooled case-control studies suggest that implementing barriers to transmission, isolation, and hygienic measures are effective with the use of relatively cheap interventions to contain epidemics of respiratory viruses. We found limited evidence of the superior effectiveness of droplet barrier devices such as the N95 respirator over simple surgical masks. N95 respirators have a 95% filtration capability against non-oily particulate aerosols (Teleman 2004). More expensive and uncomfortable (especially if worn for long periods) than simple surgical masks, they may be useful in very high risk situations.

It is uncertain whether the incremental effect of adding virucidals or antiseptics to normal handwashing actually decreased the respiratory disease burden outside the confines of the rather atypical studies, upon which we reported. The extra benefit may have been, at least in part, accrued by confounding additional routines.

Studies preventing transmission of RSV and similar viruses appeared to be closer to real life and suggest good effectiveness. However, methodological quality concerns of the controlled before-and-after studies, mentioned previously, suggest benefits may have been due to population differences, especially virus infection rates. These were poorly reported in most studies.

Routine long-term implementation of some of the measures assessed in this review would be problematic, particularly maintaining strict hygiene and barrier routines for long periods of time. This would probably only be feasible in highly motivated environments, such as hospitals, without a real threat of a looming epidemic. Most of the trial authors commented on the major logistic burden that barrier routines imposed at the community level. However, the threat of a looming epidemic may provide stimulus for their inception.

A disappointing finding was the lack of proper evaluation of global and highly resource-intensive measures such as screening at entry ports and social distancing. The handful of studies (mostly conducted during the SARS epidemic) do not allow us to reach any firm conclusions.

Summary of main results

	RCT (*n* = 4)	C-RCT (*n* = 15)	Casecontrol (*n* = 7)	Prospective cohort (*n* = 16)	Retrospective cohort (*n* = 5)	Before–after (*n* = 13)
Handwashing	–	3 trials in children effective; 1 trial in households effective if implemented < 36 hours after onset	6 studies OR 0.45 (0.36–0.57)	2 studies found effect and 2 no effect on ARIs	–	1 study in military recruits: > 5 times per day effective
Handwashing with antiseptic	–	3 trials in children: 2 antiseptic more effective; 1 antiseptic = soap	–	2 studies added effect of antiseptic: 1 study no difference	–	–
Handwashing and surface disinfection	–	4 trials in children and families: 2 studies effective	–	–	–	1 study in school effective
Hand disinfection	3 trials effective	–	–	–	–	–
Gargling with iodine	1 trial effective	–	–	–	–	–
Virucidal tissues	–	1 trial small effect; 2 trials non-significant	–	1 study effective	–	–
Disinfection of living quarters	–	–	1 study OR 0.30 (0.23–0.39)	–	–	–
Barriers (masks, gloves, gowns combined)	–	–	2 studies OR 0.09 (0.02–0.35)	1 study: masks + gowns no added effect to handwashing	–	3 studies combined with isolation effective; 1 study: mask and gown added to isolation not effective; 1 study: gowns and gloves effective in paediatric ward
Mask	–	1 trial no effect added to handwashing; 1 trial no effect of P2 mask; 1 trial: added to handwashing effective if implemented < 36 hours after onset of illness	5 studies OR 0.32 (0.25–0.40)	3 studies masks effective (with air filter safer)	1 study harm related to mask wearing	1 study in children's hospital effective

	RCT (*n* = 4)	C-RCT (*n* = 15)	Casecontrol (*n* = 7)	Prospective cohort (*n* = 16)	Retrospective cohort (*n* = 5)	Before–after (*n* = 13)
N95 Respirator	–	–	2 studies OR 0.09 (0.03–0.30)	–	1 study harm related to N95 respirator wearing	–
Gloves	–	–	4 studies OR 0.43 (0.29–0.65)		1 study harm related to gloves	–
Gowns	–	–	4 studies OR 0.23 (0.14–0.37)		1 study harm related to gown wearing	1 study no addedeffect in neonatal ICU
Distancing	–	–	–	1 study no effect in military recruits; 2 studies cohorting in hosp effective	1 study cohorting in paed wards effective; 1 study in military hosp cohorting with handwashing & gowns effective	6 studies: early identification of cases and isolation effective
Quarantine	–	–	–	1 study: isolation of close contacts effective	1 study isolation of close contacts effective	–

Authors' conclusions

Implications for practice

The following effective interventions should be implemented, preferably in a combined fashion, to reduce transmission of viral respiratory disease:

1. frequent handwashing with or without adjunct antiseptics;
2. barrier measures such as gloves, gowns, and masks with filtration apparatus; and
3. suspicion diagnosis with isolation of likely cases.

Special efforts should be focused on implementing the three above interventions in order to reduce transmission from young children, who are generally the most fecund sources of respiratory viruses.

Implications for research

Public health measures can be highly effective, especially when they are part of a structured programme that includes instruction and education and when they are delivered together. There is a clear requirement to carry out further large pragmatic trials to evaluate the best combinations. RCTs with a pragmatic design, similar to the Luby *et al*. trial, should be carried out whenever possible (Luby 2005). Nevertheless, this systematic review of the available research does provide some important insights. Perhaps the impressive effect of the hygienic measures aimed at younger children derives from the children's poor capability with their own hygiene. The variable quality and small scale of some studies is known from descriptive studies (Aiello 2002; Fung 2006; WHO 2006) and systematic reviews of selected interventions (Meadows 2004). More research is needed to evaluate the most effective strategies to implement successful physical interventions in practice, both on a small scale and at a population level.

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Contributions of authors

Ruth Foxlee (RF) and Alex Rivetti (AR) were responsible for constructing the search strategies.

Tom Jefferson (TOJ), Chris Del Mar (CDM) and Liz Dooley (LD) were responsible for drafting the protocol.

TOJ, Eliana Ferroni (EF), Bill Hewak (BH) and Adi Prabhala (AP) extracted study data and Sree Nair (SN) performed the analyses in the original review.

TOJ, EF, Lubna A Al-Ansary (LA), Ghada A Bawazeer (GB), and CDM adjudicated, in data extraction in this 2009 update, and Mieke van Driel (MvD) assisted in the writing, construction of the summary of results table and updating with the most recent trial.

All 2009 review authors contributed to the final report.

Differences between protocol and review

Published notes

In Issue 1, 2010, the title was changed from Interventions for the interruption or reduction of the spread of respiratory viruses to Physical interventions to interrupt or reduce the spread of respiratory viruses.

The original review was subsequently published as Jefferson T, Foxlee R, Del Mar C, Dooley L, Ferroni E, Hewak B, Prabhala A, Nair S, Rivetti A. Physical interventions to interrupt or reduce the spread of respiratory viruses: systematic review. *BMJ* 2008;**336**:77-80.

Characteristics of studies

Characteristics of included studies

Agah 1987

Methods	Prospective cohort study carried out in California hospital during the autumn 1984 to spring 1985 season. The study assessed the efficacy of HCWs wearing goggle-mask apparatus while visiting and caring for children aged up to 5 with RSV and symptoms of respiratory disease compared to do-nothing. Children admitted with a RSV diagnosis were assigned to the 2 arms balanced for age and sex
Participants	168 healthcare workers (HCW) caring for children < 5 years with differential diagnosis of RSV
Interventions	Mask and goggles (sometimes gowns too) versus normal care
Outcomes	RSV illness reduced from 61% (controls) to 5% (intervention) Laboratory: swabs for RSV diagnosis Effectiveness: RSV illness Safety: N/A
Notes	Risk of bias: low Notes: The authors conclude that wearing mask and goggles significantly reduced transmission to HCWs and other children of RSV (61% versus 5% illness rate). Analysis is also given by number of contacts (data not extracted). A reasonably reported if difficult to conduct study. Standard procedures such as handwashing should not have acted as a confounder given 100% coverage among HCWs

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Broderick 2008

Methods	Prospective cohort study carried out in a military recruit training centre during the first 4 weeks of recruit training. Data was collected between February 2004 and March 2005 (duration of recruit training is not reported). It isn't clear how the recruits were assigned to 'experimental' (closed) or control (open). Recruits were assigned to units on the basis of arrival order with no particular allocation scheme. The study assessed if social distancing would reduce the incidence of febrile respiratory illness (FRI). Data were collected over 4 weeks for each new group of recruits. Housing units (*n* = 196 units) were divided into closed units [*n*= 30] (experiment/ intervention) or open units (*n* = 166) (control). For description of how the closed units were selected and geographical position in the training centre see notes. Microbiological samples from physical structures (tables, surfaces, angles of surfaces, handles) of some units were done. However, it is not mentioned if these units were selected from among the closed or open units
Participants	Male military recruits (*n* = 13,114), distributed among 196 housing units (166 open units and 30 closed units) took part in the study. Unit size ranged from 44 to 88 recruits per unit. Reported denominators add up to 13488 recruits not 13114 (closed: 329/2099 versus open: 1586/11389). No exclusions were reported. Dimensions of the units are not described (space/subject or space/unit). The average number of subjects/unit in the closed units was not reported. Ten percent of medical convalescent unit (MCU) subjects (762) and 6% of physical conditioning unit (PCU) subjects (395) were positive for adenovirus 4 by PCR
Interventions	To test the effect of social distancing: Subjects were either assigned (allocation process not clear) to closed or open units. The closed units didn't introduce any new subjects once their personnel had been assigned (socially-distant); sick recruits were removed but if their symptoms did not require placement in the MCU, the recruits returned to their units. The open units accepted recovering subjects after being discharged from MCU and PCU. To test an environmental aetiology: Some of the units, which were vacant after 4 weeks of occupation, were swabbed. The MCU was also swabbed. Then samples were tested by PCR and were cultured
Outcomes	Laboratory: (MicroTest M4 Transport; Remel) polymerase chain reaction (PCR) culture for Ad-4 virus Not used to confirm FRI in all index cases. Adenoviurs was the only microorganism tested for and isolated. Effectiveness: Cases of FRI was defined either by a body temperature of >38°C and 1 respiratory symptom or by the presence of non-febrile pneumonia. Cases were reported as number of cases of FRI per 100 persons per week, averaged over the 4 weeks. Safety: N/A
Notes	The institutional review board of the Naval Health Research Centre classified the protocol of this study as a non-research public health endeavour. Given the flaws of the study design (the disparity between the number of closed and open units, testing 2 different 'etiological' hypothesis using different methodologies and lack of information on how the units were selected), one gets the impression that this study was probably carried out at least retrospectively instead of being carried out as a prospective study as claimed by the authors. The authors conclude that social distancing did not reduce FRI and that environmental contamination rather than person to person transmission is the culprit in the spread of FRI. The method used for social distancing, however, did not exclude those that were little bit sick but did not require placement in the MCU. In other words, sick people were allowed to remain in the closed unit (? as well as in the open units); only apparently healthy recruits were allowed to rejoin the open units after being placed in the MCU and PCU.

	The study put emphasis on the importance of environmental cleaning. In addition to that crowded areas increase the risk of transmission of viruses. In the study, however, it was not clear if open and closed units are similar or different as pathogen reservoir. Also, analysis of closed units according to the population size was not done and information about the location of the closed units (all over the centre or localized in certain (isolated) area) is lacking. Despite these clear limitations this pragmatic study findings may be interpreted in a variety of different ways. Perhaps the most interesting interpretation is that environmental conditions are determinants of adenoviral infectivity but not entry and exit from a community. In other words virological and presumably bacterial agents persist in the environment, they are not "brought" in and do not "arrive" and do not directly and invariably cause one-on-one disease. This hypothesis challenges the current simplistic interpretation of the postulates of Henle-Koch (one agent = one disease and suggests that the presence of microorganism may only be one of the many variables which determine infectious disease. This interpretation is comforted by the relatively small number of isolates found in studies of ILI causes (so called pie studies) The corresponding author provided the following additional information: Each week a new cohort of about 500 recruits arrives at the camp, all of whom arrive by Wednesday. On Thursday the recruits are assigned to 6 platoons (each platoon housed in its own large room - called "housing units" in the article). Each cohort's 6 housing units are numbered from 1 to 6, with no particular distinction between them. Each house is given approximately the same number of recruits. The placement of the recruits into the housing units is based somewhat on the order of their arrival to the camp, but otherwise there are no criteria for placement, although relatives and friends are allowed to be in the same platoon. The recruits at MCRD San Diego tend to be from west of the Mississippi. There's no particular order of arrival at the camp from different regions. The number of the closed housing unit assigned in each cohort varied. In the majority of cases it was 1 or 2. Each building contains 4 wings of 3 floors each. From the sky, the buildings form an H shape. The line in the middle of the H connects the sides of the H, and on each side the half above the middle line is one wing and below the middle line is the other wing. If you go on maps.google.com and type in san diego ca mcrd and zoom in on C you can see how big the buildings are. The housing units for each cohort typically occupy 2 wings one building, but occasionally one housing unit will be in a different building. E.g., if there are 6 housing units in a cohort, the cohort will occupy 3 floors of wing A and 3 floors of wing C. The map gives you an idea of the geography of horizontal distance between each wing, and each floor is about 10 feet high. Although the housing units are relatively close to each other, the platoons do not typically interact with each other. They are large permanent buildings each consisting of 12 large rooms and a hallway.

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Carabin 1999

Methods	Cluster randomised controlled trial carried out in day care centres (DCC) in the Canadian province of Quebec between 1 Sept 1996 and 30 November 1997 (15 months). The aim was to test the effects of a hygiene programme on the incidence of diarrhoea and fecal contamination (data not extracted) and on colds and URTIs. The design included before and after periods analysed to assess the Hawthorne effect of study participation on control DCCs. Unit of randomisation was DCC but analysis was also carried out at classroom and single child level. This is a common mistake in C-RCT analysis. DCCS were stratified by URTI incidence preceding the trial and randomised by location. Cluster coefficients are not reported
Participants	1729 children aged 18 to 36 months in 47 DCCs (83 toddler classrooms). Originally 52 eligible DCCs with 89 classrooms agreed to take part but 5 dropped out (2 closed, 1 was sold, 2 either did not provide data or the data were "unreliable" and 6 classrooms had insufficient data). Forty three children failing to attend DCC for at least 5 days in the autumn were also excluded. ITT analysis was carried out including an additional DCC whose director refused to let staff attend the training session
Interventions	Training session (1 day) with washing of hands, toy cleaning, window opening, sand pit cleaning and repeated exhortations to hand wash
Outcomes	Laboratory: N/A Effectiveness: diarrhoea and coliform contamination (data not extracted) Colds (nasal discharge with at least one of the following: fever, sneezing, cough, sore throat, earache, malaise, irritability) URTI (cold of at least 2 days' duration) Surveillance was carried out by educators, annotating absences or illness on calendars. Researchers also filled in a phone questionnaire with answers by DCC directors Safety: N/A
Notes	Risk of bias: high (no description of randomisation; partial reporting of outcomes, numerators and denominators) Notes: the authors conclude that the intervention reduced the incidence of colds (IRR 0.80, 95% CI 0.68 to 0.93). Confusingly written study with unclear interweaving of two study designs. For unclear reasons analysis was only carried out for the first autumn. Unclear why colds are not reported in the results. Cluster coefficients and randomisation process not described

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Cowling 2008

Methods	Cluster randomised controlled trial carried out in Hong Kong SARS between February and September 2007. The study assessed the effects of non-pharmaceutical interventions on the household transmission of influenza over a 9 day period. ILI cases whose family contacts had been symptom-free for at least 2 weeks rapid tested for influenza A and B were used and randomised to three interventions carried out. Randomisation was carried out in two different schedules (2:1:1 for the first 100 households and subsequently 8:1:1) but it is unclear why and how
Participants	946 index subjects aged 2 years or more in 122 clusters (households). 116 households were included in the analysis, 6 were excluded because subsequent laboratory testing (culture) were negative. There were 350 household contacts in the analysis but there 370 household contacts at randomisation. Attrition is not explained. Index cases were defined as subjects presented with at least two influenza like symptoms of at least 48 hour duration (such as fever more or equal to 38 degrees, cough, headache, coryza , sore throat, muscle aches and pains) and positive influenza A+B rapid test
Interventions	Households were randomised to either wearing face masks with education (as the control group plus education about face mask use) or handwashing with special medicated soap (with alcohol sanitiser) with education (as the control group plus education about handwashing) or education about general healthy lifestyle and diet (control group). The soap was distributed in special containers which were weighed at the start and the end of the study. Interventions visits to the households were done on average 1 day after randomisation of index case household
Outcomes	Laboratory: QuickVue RTI MDCK culture Samples were harvested using NTS, but the text refers to a second procedure from June 2007 onwards testing for non influenza viruses but no data were reported Effectiveness: Secondary attack ratios (SAR): SAR is the proportion of household contacts of an index case who subsequently were ill with influenza (symptomatic contact individuals with at least 1 NTS positive for influenza by viral culture or PCR). Three clinical definitions were used for secondary analysis: Fever more or equal to 38 degrees or at least two of following symptoms, headache, coryza , sore throat, muscle aches and pains At least two of the following S/S: fever more or equal to 37.8 degrees, cough ,headache ,sore throat, and muscles aches and pains Fever of more or equal to 37.8 degrees plus cough or sore throat Safety: No harms were reported in any of the arms
Notes	The authors conclude that "The secondary attack ratios were lower than anticipated, and lower than reported in other countries, perhaps due to differing patterns of susceptibility, lack of significant antigenic drift in circulating influenza virus strains recently, and/or issues related to the symptomatic recruitment design. Lessons learnt from this pilot have informed changes for the main study in 2008". Although billed as a pilot study the text is highly confusing and at times contradictory. The intervention was delivered at a home visit up to 36 hours after the index case was seen in the outpatients. This is a long long time and perhaps the reason for the failure of the intervention. Practically, the intervention will have to be organised before even seeking medical care – i.e. people know to do it when the kid gets sick at home. The choice of season, change in randomization schedules and unexplained dropouts among contacts, the use of QuickVue which proved unreliable, reporting bias on non influenza isolates make this study at high risk of bias

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Yes	Randomisation was computer generated by a biostatistician
Allocation concealment?	Yes	The households of eligible study index patients were allocated to 3 groups in a 1:1:1 ratio under a block randomisation structure with randomly permuted block sizes of 18, 24, and 30 by using a random-number generator. Allocation was concealed from treating physicians and clinics and implemented by study nurses at the time of the initial household visit
Blinding?	No	Participants and people who administered the interventions were not blinded to the interventions, but participants were not informed of the specific nature of the interventions applied to other participating households
Incomplete outcome data addressed?	Yes	Dropout was accounted for. Dropout from randomised population was high: 32% in control group, 37,5% in hand hygiene group and 39.4% in the face masks and hand hygiene group. Reasons for dropout distributed evenly over the 3 groups. Authors report follow up as proportion of patients remaining in the study after initial dropout
Free of selective reporting?	Yes	

Cowling 2009

Methods	Cluster randomised controlled trial
Participants	Households in Hong Kong
	From 45 outpatient clinics in both the private and public sectors across Hong Kong, we enrolled persons who reported at least 2 symptoms of acute respiratory illness (temperature 37.8 °C, cough, headache, sore throat, or myalgia); had symptom onset within 48 hours; and lived in a household with at least 2 other people, none of whom had reported acute respiratory illness in the preceding 14 days. After participants gave informed consent, they provided nasal and throat swab specimens
	2750 patients were eligible and tested between 2 January through 30 September 2008. Included were 407 people with influenza-like illness who were positive for influenza A or B virus by rapid testing (index patients) and 794 household members (contacts) in 331 households
Interventions	Participants with a positive rapid test result and their household contacts were randomly assigned to 1 of 3 study groups: control (lifestyle measures-134 households), control plus enhanced hand hygiene only (136 households), and control plus face masks and enhanced hand hygiene (137 households) for all household members. No detailed description of the instructions given to participants
Outcomes	Influenza virus infection in household contacts, as confirmed by reverse transcription polymerase chain reaction (RT-PCR) or diagnosed clinically after 7 days
	"The primary outcome measure was the secondary attack ratio at the individual level: that is, the proportion of household contacts infected with influenza virus. We evaluated the secondary attack ratio using a laboratory definition (a household contact with a nose and throat swab specimen positive for influenza by RT-PCR) as the primary analysis and 2 secondary clinical definitions of influenza based on self-reported data from the symptom diaries as secondary analyses."
	Statistical analysis: adjusted for clustering
	Results:
	No significant difference in secondary attack ratio between groups in total population. Statistically significant reduction in RT-PCR confirmed influenza virus infections in the household contacts in 154 households in which the intervention was applied within 36 hours of symptom onset in the index patient. Adherence to hand hygiene between 44 and 62%. Adherence of indexpatient to wearing a face mask between 15 and 49%
Notes	"In an unintentional deviation from that protocol, 49 of the 407 randomly allocated persons had a household contact with influenza symptoms at recruitment (a potential co-index patient). We also randomly assigned 6 of 407 persons who had symptoms for slightly more than 48 hours." The authors conclude that "Hand hygiene and face masks seemed to prevent household transmission of influenza virus when implemented within 36 hours of index patient symptom onset. These findings suggest that non-pharmaceutical interventions are important for mitigation of pandemic and interpandemic influenza"

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Yes	Randomisation was computer generated by a biostatistician
Allocation concealment?	Yes	The households of eligible study index patients were allocated to 3 groups in a 1:1:1 ratio under a block randomisation structure with randomly permuted block sizes of 18, 24, and 30 by using a random-number generator. Allocation was concealed from treating physicians and clinics and implemented by study nurses at the time of the initial household visit
Blinding?	No	Participants and people who administered the interventions were not blinded to the interventions, but participants were not informed of the specific nature of the interventions applied to other participating households
Incomplete outcome data addressed?	Yes	Dropout was accounted for. Dropout from randomised population was high: 32% in control group, 37.5% in hand hygiene group and 39.4% in the face masks and hand hygiene group. Reasons for dropout distributed evenly over the 3 groups. Authors report follow up as proportion of patients remaining in the study after initial dropout
Free of selective reporting?	Yes	

Derrick 2005

Methods	Prospective cohort study testing the performance of 1, 2, 3, 4 and 5 surgical masks worn in layers against the droplet filtration capacity of a N95 respirator. The study is described as cross-over trial when all volunteers wore then combinations of layers, but this is not further described
Participants	Six volunteers who wore the masks and had their droplet count taken
Interventions	Pleated rectangular three-ply surgical mask
Outcomes	Laboratory
Notes	Risk of bias: high (report too brief to allow assessment) Notes: The authors conclude that the best combination of five surgical masks scored a fit factor of 13.7, well below the minimum level of 100 required for a half face respirator. The reduction in particle count went from 2.7 for a singe mask to 5.5 for 5 masks worn at the same time. Multiple surgical masks filter ambient particles poorly. They should not be used as a substitute for N95 respirator unless there is no alternative. Cautiously the authors state that they cannot comment on the capacity of five layers of masks to stop infections such as SARS as the infective count of the SARS-CoV is unknown. Fascinating small study with no details of assignment so it was classified as a cohort study. Unfortunately there is no indication of how comfortable 5 masks are to wear in a layer and no description of the volunteers

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Dick 1986

Methods	Prospective cohort study involving men ~ 18 years of age. The objective of the study was to determine whether rhinovirus 16 colds could be stopped from spreading with the use of an highly virucidal paper handkerchief (CMF tissues) containing citric acid and other virucidal ingredients. Twenty to 25 men ~ 18 years of age were inoculated intranasally with a safety tested R16. The laboratory-induced cold was in all aspects comparable to natural colds. Eight of them with the most severe colds (donors) played cards with 12 antibodyfree men (recipients) in a experiment room. Four experiments were conducted, in experiments B and C volunteers used CMS tissues to prevent spreading of R16 colds. In the two control experiments (A and D) volunteers were permitted to use cotton handkerchiefs
Participants	Males ~ 18 years of age with a laboratory-induced R 16 cold (donors) and 12 antibody-free men (recipients)
Interventions	Use of virucidal paper handkerchief (CMF tissues), containing citric acid and other virucidal ingredients to stop the spreading of R16 colds versus normal cotton handkerchiefs
Outcomes	Laboratory: serological evidence (serum samples or viral isolation) Effectiveness: rhinovirus colds
Notes	Risk of bias: low Notes: The authors concluded that the use of CMS tissues has been successful, because it determined a complete interruption of transmission of R16 among participants, stopping the spreading in an environment in which possibilities for transfer of virus were constant, and in which the rate of transmission was predictably high under standard conditions (42% of cotton handkerchief users developed colds, but no user of virucidal tissues did so)

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Doherty 1998

Methods	Retrospective cohort study carried out in North Staffordshire hospital (UK) during two periods: from 1 November 1994 to 31 January 1995 and from 1 November 1995 to 31 January 1996. The study assessed the use at admission of assigning children to a cohort once a rapid enzyme immunoassay or immunofluorescence testing had identified RSV positive patients. The incidence of RSV illness was compared in cohorted and uncohorted children. The authors believed that this procedure would aid clinical management and minimize cross-infection from affected to susceptible patients. Nasopharyngeal aspirates were obtained from infants and young children with an acute respiratory illness. Aspirates were sent for rapid diagnostic testing. RSV positive patients were cohorted into six bedded bays on the paediatric ward. All carers observed standard routines (handwashing and gown wearing)
Participants	Children less than three years of age with an acute respiratory illness on admission. During the study periods a total of 222 patients in 1994 to 1995 and 291 patients in 1995 to 1996 had positive rapid tests
Interventions	RSV diagnosis and cohorting versus normal care
Outcomes	Laboratory: aspirates for RSV diagnosis Effectiveness: RSV illness (developed at least five days since admission) Safety: N/A "RSV infection reduced" (but data tabled do not support this conclusion)
Notes	Risk of bias: high (poor descriptions) Notes: the authors conclude that cohorting has been shown to reduce nosocomial transmission of RSV infections (no OR or other measures of strength are reported: "nosocomial transmission was minimised"). The study presents many inconsistencies between text and table and data were not extracted. The objective of the study is not well defined. Part of the results is in the discussion. Most of all it is unclear who the intervention and controls arms were (i.e. cohorting of RSV infected children to prevent infection in whom?)

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Dyer 2000

Methods	Prospective cluster open-label cross-over cohort study of programmed use of a hand sanitiser in conjunction with at-will soap-and-water handwashing conducted in a private elementary school in California. The aim of the study was to assess the effectiveness of the SAB sanitiser at reducing illness absenteeism in a school setting. Subjects were grouped by classroom without formal randomisation. Seven classes received the instant sanitiser, while the remaining seven classes were assigned to the control group. Male-to-female ratios and age distributions of the two groups did not differ significantly. Prior to study commencement all students participated in an educational program about germs and the importance of handwashing to prevent illnesses. Children in the hand sanitiser group received a spray to use under teacher supervision to supplement normal, at-will handwashing with soap and water. The control group was instructed to wash hands with water and soap, and it was not supervised. Data were collected for 10 weeks. After this period, there was a 2-week wash out period, during which neither group of students used SAB sanitiser. Then SAB sanitiser was distributed to the student group that had previously served as the control and the study proceeded for another 4 weeks
Participants	420 children in a private elementary school in California aged 5 to 12 years; cluster open-label crossover cohort study over 10 weeks
Interventions	Educational programme plus the SAB (surfactant, allontoin and benzal konium chloride) spray hand sanitiser in 1oz bottles fitted with a pump spray top and with at-will soap-and-water handwashing versus nothing
Outcomes	Laboratory: serological evidence: N/A Effectiveness: days of absences from school for respiratory illness (and gastrointestinal illness - data not extracted) Safety: N/A Respiratory illness and gastrointestinal illness: reduced absenteeism by 41.9%; respiratory illnesses by 49.7%
Notes	Risk of bias: medium Notes: The authors conclude that daily use of the SAB instant hand sanitiser with at-will handwashing using soap and water significantly decreased absences due to acute communicable illness. Use of the sanitiser reduced illness absenteeism by 41.9% (reduction in respiratory illnesses of 49.7% over the 10 week period of the study). The authors also described some limitations of the study, as limited socio-economic diversity in the study population, limitation to a single study site and lack of blinding. Further soap-and-water washing was not monitored. Generalisability of the results is questionable as all participants underwent the educational programme

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Falsey 1999

Methods	Prospective cohort study conducted at three adult daycare centers in Rochester, New York. The study assessed the value of a staff educational program combined with the use of a portable virucidal hand foam for the reduction of respiratory infections in daycare participants. The authors report in the same paper an ecological study of the incidence of ILI in 3 previous seasons (1992 to 1996) which does not report numerators and denominators and was not extracted
Participants	In December 1995 when the study started there were centre 1: 69 elderly and 36 staff members; centre 2: 67 elderly and 45 staff members; centre 3: 68 elderly and 16 staff members
Interventions	Addition of virucidal hand foam as a supplement versus normal handwashing and educational programme
Outcomes	Laboratory: serological evidence and virology cultures (Table 1 reports a series of isolated pathogens, with no tie in with actual cases) Effectiveness: viral pathogens: influenza A/B, RSV, coronavirus, parainfluenza, rhinovirus Safety: N/A
Notes	Risk of bias: low Notes: The authors conclude that the educational program for staff was associated with an almost 50% decrease in the infection rate in daycare attendees. The programme was effective only in the last of the four years of the programme (rates of infection in daycare patients fell from 14.5 to 10.4 per 100 person-months to 5.7 per 100 person months, $p < 0.001$). This is a conclusion based on an ecological study of the incidence of ILI in 3 previous seasons which the authors report in the same paper, but which does not report numerators and denominators and was not extracted. The lower infection rate is likely to reflect the combination of interventions and education, which increased staff awareness and more broadly changed behaviour. There was no apparent additional benefit from the virucidal foam. This is one of the few identified studies reporting circulating viruses in the daycare setting, both in staff and patients. The decline in influenza-like illness episodes across the four study years is reflected in the decline in viral isolates, suggesting that aspecific measures such as handwashing are effective against the main respiratory viruses

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Farr 1988a

Methods	The study was a six-month cluster randomised controlled double blind trial of the efficacy of virucidal nasal tissues in the prevention of natural cold, and it was conducted in Charlottesville, Virginia, USA. Many of the families were enrolled, because one or more members worked at the State Farm Insurance Company; the remaining families were recruited from the Charlottesville community by advertisement in a local newspaper. Families were randomly assigned by the sponsoring company to receive boxes of treated tissues, placebo tissues, or no tissues. The randomisation was performed by computer. Study participants and investigators were unaware of the type of tissues which each family was randomised to receive. Blinding efficacy was tested using a questionnaire: the mothers in each family were asked twice if she believed her family was using virucidal or placebo tissues Participants in the treated and placebo groups were instructed to use only tissues received through the study, while families in the additional control group without tissues were allowed to continue their usual practice of personal hygiene. Each family member kept a daily listing of respiratory symptoms on a record card. A nurse epidemiologist visited each family monthly to encourage recording
Participants	186 families, 58 in the active group, 59 in the placebo group and 69 in the no tissues group. A total of 302 families were originally recruited, 116 families who did not comply with the study protocol, lost their surveillance cards, could not complete the protocol were excluded from the analysis
Interventions	Use of virucidal tissues versus placebo tissues versus no tissues. The treated tissues were impregnated with malic and citric acids and sodium lauryl sulfate, while placebo tissues contained saccharin
Outcomes	Laboratory: serological evidence: no Effectiveness: respiratory illness Safety: N/A
Notes	Risk of bias: high (failure of blinding) Notes: the authors conclude that virucidal tissues have only a small impact upon the overall rate of natural acute respiratory illnesses. The total illness rate was lower in families using virucidal tissues than in both of the other two study group, but only the difference between active and placebo groups was statistically significant (3.4 illness per person versus 3.9 for placebo group, $p = 0.04$ and 3.6 for no tissues control group P = 0.2, and overall 14% to 5% reduction). The questionnaire results suggest that some bias may have been present since a majority of mothers in the virucide group believed they were receiving the "active" tissues. Another possible explanation of the low effectiveness of virucidal tissues is poor compliance by children in the use of virucidal tissues. A well designed and honestly reported study

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Farr 1988b

Methods	The study was a six-month randomised controlled double blind trial of the efficacy of virucidal nasal tissues in the prevention of natural cold, and it was conducted in Charlottesville, Virginia. Families were recruited from the Charlottesville community by advertisement in a local newspaper. Families were randomly assigned by the sponsoring company to receive either virucidal tissues, or placebo-treated tissues. Stratified randomisation was performed by computer and the strata were defined by total number in the family. Study participants and investigators were unaware of the type of tissues which each family was randomised to receive. Each family member kept a daily listing of respiratory symptoms on a record card. A nurse epidemiologist visited each family monthly to encourage recording. In addition a study monitor visited each family bimonthly to further encourage compliance and reporting of symptoms
Participants	98 families, 58 in the active group and 40 in the placebo group. Two-hundred and thirty-one families were initially recruited, 222 completed the trial, data of 98 families were analysed. The others were excluded from the analysis since they complained of side effects (sneezing etc) or reported not using the tissues regularly
Interventions	Use of virucidal tissues versus placebo tissues. The treated tissues were impregnated with malic and citric acids and sodium lauryl sulfate, while placebo tissues contained succinin acid. Participants in the treated and placebo groups were instructed to use only tissues received through the study
Outcomes	Laboratory: serological evidence: no Effectiveness: respiratory illness Safety: N/A
Notes	Risk of bias: high (failure of blinding) Notes: the study suggests that virucidal tissues have only a small impact upon the overall rate of natural acute respiratory illnesses. The total illness rate was lower in families using virucidal tissues than in the other study group, but the difference between active and placebo groups was not statistically significant. There was a small non-significant drop in illness rates across families (5%). The tissues appeared ineffective as the drop was confined to primary illness unaffected by tissue use. Placebo (succinin acid) was not inert, and it was associated with cough and nasal burning. This impacted on allocation concealment. A well designed and honestly reported study marred by transparent allocation

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Foo 2006

Methods	Retrospective cohort survey carried out in Singapore to assess the harm associated with the use of the personal protective equipment in healthcare staff working in a "SARS-designated hospital" from March 2003 to middle 2004. Three departments from the hospital were surveyed the National Skin Centre (NSC), Department of Emergency (A&E) and the intensive care unit (ICU) Control group: unclear Control group: none
Participants	Three hundred and forty healthcare staff were surveyed, 322 responded (60 from the NSC, 77 from the TTSH A&E, and 185 from the TTSH ICU)
Interventions	Use of personal protective equipment (PPE), namely, masks, gloves and gowns. Adverse skin reactions to PPE
Outcomes	Laboratory: None Effectiveness: Not applicable Safety: Adverse skin reactions (ASR) from the use of 3 types of PPE [masks (respirator, surgical or paper masks), plastic gloves and disposable gowns] developed with prolonged use (8.4, 9.4 and 8.8 months, respectively)
Notes	The authors conclude that prolonged use of PPEs (N95 respirators, rubber gloves) is associated with high frequency of ASR. The authors reported that there were no significant differences in adverse skin reactions to masks and gloves due to sex, race or profession. Some differences were reported by age as follows: Those who developed acne with masks were younger (mean of 29.5 years) compared with those who didn't (mean of 33.2; $p < 0.001$). Those who developed dry skin with gloves were younger (mean of 28.7 years) compared with those who didn't (mean of 33.2; $p < 0.002$). Those who developed itch with gloves were younger (mean of 29.5 years) compared with those who didn't (mean of 33.2; $p < 0.001$). Survey results show that acne, itach and rash are the most common harms reported after wearing a N95 respirator (59.6%, 51.4% and 35.8%) and that drynskin, itch and rash were reported by (73.4% , 56.3% and 37.5%, respectively) glove users. Other harms were reported by very small numbers of users (4 or below). This study, although a retrospective survey is important as it suggests that barrier intervention-using carries harms and such harms may affect compliance with the intervention

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Gala 1986

Methods	The purpose of this study was to evaluate whether the use of a disposable plastic goggle designed to cover the eyes and nose could help reduce the rate of nosocomial infections during an outbreak of RSV infection. The rates of RSV infection in staff members and infants were determined on an infant and toddler ward during a seven-week. Two 3 week study periods were compared: period 1, during which all staff members used the goggles, and period 2, were no goggles were worn. The respiratory infection control procedures were the same during both periods of study: handwashing, isolation and cohorting. In reality although on report, Gala and colleagues are conducting two studies. The first is a non-concurrent cohort study, in which two different population of children are assessed separated by a 1 week "washout" period and the intervention (goggles) on staff. The play of confounders here is too heavy and uncontrolled to include the data in the study. The second is a controlled before and after on the 40-odd members of staff (32 of whom took part in both periods). Here the play of confounders should be partly reduced. We extracted data relating to the second study only
Participants	74 Children and 40 staff members in period 1; 77 children and 41 staff members in period 2. During the study 151 children were admitted to the ward; their mean age was 12.9 months, 59% were boys. During period 174 infants were examined, 15 were admitted with RSV infections, the remaining 59 constituted the group potentially susceptible to a nosocomial RSV infection. Seventeen infants were hospitalised for sufficient time for a nosocomial infection and in one nosocomial RSV infection was detected. During period 277 babies were studied, 17 of whom were admitted with RSV infection. Of the remaining 60, 39 children were excluded, 21 were considered susceptible, and in 9 of them nosocomial RSV infection was detected. Forty staff members were examined in period 1 and 41 during period 2. During period 2, two of the ward staff were acquired RSV infection and were not considered susceptible
Interventions	Use of a disposable plastic eye-nose goggle and respiratory infection control procedures versus only respiratory infection control procedures (cohorting, isolation and handwashing)
Outcomes	Laboratory: serological evidence Effectiveness: RSV infection (symptoms and laboratory confirmation) Safety: N/A
Notes	Risk of bias: high Notes: The use of the disposable eye-nose goggles appeared to be associated with a significant decrease in nosocomial RSV infections (6% versus 42% of contacts when the goggles were used compared to when they were not). The expense of such goggles will have to be determined and compared with the cost of nosocomial infections. The study has an orgy of confounders, is it difficult to see how such studies can be carried out without disrupting patient care? Why not randomise staff to goggles or standard care?

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Gwaltney 1980

Methods	The study assessed the effectiveness of aqueous iodine applied to the fingers in blocking hand transmission of experimental infection with rhinovirus from one volunteer to another. Healthy, young adult volunteers were recruited from the general population at the University of Virginia, Charlottesville. Volunteers were not informed about the contents of the hand preparation until after the study. Two experiments were conducted to evaluate the virucidal activity of aqueous iodine applied to the fingers immediately before viral contamination. Other two experiments were conducted to determine whether there was sufficient residual activity of aqueous iodine after 2 hours to interrupt viral spread by the hand route. Volunteers who were donors of virus for the hand exposures were challenged intranasally on three consecutive days with strain HH rhinovirus. Recipients were randomly assigned to receive iodine or placebo. The donors contaminated their hands with nasal secretions by finger to nose contact before the exposure. Hand contact was made between a donor and a recipient by stroking of the fingers for 10 sec. Donors and recipients wore masks during the exposure period
Participants	15 and 20 volunteers in two experiments
Interventions	Treatment of fingers with iodine versus placebo. The virucidal preparation used was aqueous iodine (2% iodine and 4% potassium iodide). The placebo was an aqueous solution of food colours
Outcomes	Experimental rhinovirus infection reduced (p = 0.06) Laboratory: serological evidence Effectiveness: rhinovirus infection (based on serology, isolation and clinical symptoms) with high score clinical illness. Score was published elsewhere Safety: N/A
Notes	Risk of bias: High (poor description of randomisation process, concealment, or allocation) Notes: the study suggests that aqueous iodine applied to the fingers was effective in blocking transmission by hand contact of experimental infection with rhinovirus for up to 2 hours after application (1 out 10 volunteers were infected compared to 6 out of 10 in the placebo preparation arm, P = 0.06 with Fisher's exact test). The effectiveness of iodine treatment of the fingers in interrupting viral transmission in volunteers recommends its use for attempting to block transmission of rhinovirus under natural conditions. Although the cosmetic properties of 2% aqueous iodine make it impractical for routine use, it can be used as an epidemiologic tool to study the importance of the hand transmission route and to develop an effective cosmetically acceptable hand preparation. A summarily reported study

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
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Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Hall 1981a

Methods	Cohort study to determine the possible modes of spread a RSV to young adult volunteers working on a paediatric ward who were exposed in different manners to infants with RSV. Volunteers were divided into three groups: "cuddlers", exposed to an infected infant over two to four hours by caring the baby in the usual manner, wearing gowns, but no mask or gloves; "touchers", exposed with the infant out of the room by touching surfaces contaminated with the baby's secretions; "sitters", exposed to an infected baby by sitting at a distance of more than 6 feet from an infant's bed, and they wore gowns and gloves, but no masks. In order to control for possible differences in infectivity among infants, a volunteer from each of the three groups was exposed to each infant, or to this environment in the case of touchers. In addition, volunteers from each group were exposed to more than one infant. After exposure volunteers were followed for 12 days
Participants	31 Volunteers: seven in the cuddler group, 10 in toucher group and 14 in the sitter group
Interventions	Exposure to infants admitted with bronchiolitis or pneumonia during a community outbreak of RSV isolation
Outcomes	Laboratory: serological evidence Effectiveness: RSV infection demonstrated by viral isolation and serology. Clinical symptom diary collected with questionnaires. Symptomatic, asymptomatic and febrile symptomatic data reported separately Safety: N/A
Notes	Risk of bias: low Notes: the authors concluded that the spread of RSV may occur by close contact with direct inoculation of large droplets or by self-inoculation after touching contaminated surfaces. Infections does not appear to occur after more distant contact requiring small particle aerosols (0 infected out of 14 "sitters", those that sat away from RSV infected infants, compared with 5 out of 7 who cuddled and 4 out of 10 who touched the infected infants). Ancillary procedures that may be helpful include the care of contaminated surfaces and gowns, cohorting of staff and infants, and limiting the traffic in and out of the infants' room. With limited facilities, isolation rooms might best be reserved for uninfected infants with underlying disease who, should they acquire nosocomial RSV infection, are at risk for severe disease

Risk of bias table

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Adequate sequence generation?	Unclear	
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Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Hall 1981b

Methods	Controlled before and after study designed to evaluate the efficacy of infection-control procedures with the use of masks and gowns compared with procedures not using mask and gowns on the rate of nosocomial RSV infection in both infants and staff. The study, conducted at Strong Memorial Hospital in Rochester, NY, USA, in 1979, was begun 12 days after the hospital admission of the first infant infected by RSV, and was continued for the next two months. All patients and staff on the ward for children less than three years of age were included. During the first four weeks (period 1) of the study the infectioncontrol procedures for infants with respiratory illness included handwashing and the use of mask and gowns by the staff on entering the room, with a change of gowns between contacts with each infant. After four week the wearing of gowns and masks was discontinued and handwashing alone was used for the final five weeks of the study. Throughout the study handwashing, cohorting and isolation were employed and emphasized. The number of nosocomial infections in patients and staff for period 1 were compared with the period 2 (last four weeks of the study). Infections occurred in the interval week were not counted
Participants	162 patients suspected with RSV infections from infected infants; 78 admitted in the period 1 and 84 in period 2. The age range was 2 weeks to 3 years. 55% were male. Of 78 (period 1), 24 were admitted for RSV infections and the remaining 24 became the contacts. (Due to lack of comparability of children and an unclear text children data were not extracted) 39 ward personnel were included, 30 in the period 1 and 27 of these were also studied during period 2 along with 9 other personnel. Thus a total of 36 staff members were studied during period 2
Interventions	Use of gowns and masks and standard infection-control procedures (handwashing, cohorting, isolation) versus standard infection-control procedures only to prevent transmission of RSV infections from infected infants
Outcomes	Laboratory: serological evidence Effectiveness: RSV infection demonstrated by symptoms, viral isolation and serology Safety: N/A
Notes	Risk of bias: high Notes: The authors concluded that the use of masks and gowns as additional infection-control procedures for RSV infection shows no appreciable benefit in preventing nosocomial spread of RSV to infants or to the ward personnel. The nosocomial infection rate in the two periods was not significantly different in either the infants or staff (32% infection versus 41%). Both of the study periods appeared to be equal in terms of potential for transmission or exposure to RSV. The number of infants admitted during both periods was similar. Furthermore these two groups of contacts were alike in age and types of underlying diseases. The routine use of masks and gowns does not seem warranted in view of the considerable cost. A very poorly reported study with an unclear eligibility procedure and a lack of description of denominators. Why not use randomisation?

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Heymann 2004

Methods	Controlled before and after study to evaluate the effect of school closure on the occurrence of respiratory infection among children ages 6-12 years and its impact on health care services. The study was conducted in Maccabi healthcare services, which has a nationwide network of > 3000 independent physicians connected by a unified computer system. The authors assembled a retrospective cohort of all 6 to 12 year old children comprising 186,094 children. The computerised data were examined for three 2-weeks periods: before school closure, during closure, and after closure. The occurrence of respiratory tract infections was determined according to recorded diagnoses, including cough, upper respiratory tract infection, common cold, sore throat and viral infection
Participants	186,094 children aged 6 to 12 years
Interventions	Effect of a school closure on the occurrence of respiratory infection during an "influenza" outbreak
Outcomes	Laboratory: no Effectiveness: respiratory tract infections Safety: N/A
Notes	Risk of bias: high Notes: The authors concluded that school closure was temporally associated with 42% decreased morbidity from respiratory tract infections, a consequent 28% decrease in visits to physicians and to emergency departments and a 35% reduction in purchase of medications. Limits of this study are: the fact that in Israel 33.8% of the population are children, hence these results may not be applicable to high-income countries with lower per centage of children. In addition there may be a difference in parental attitudes toward respiratory illness symptoms in other cultures that affect health care utilization. Another reason for such a difference may be the basic structure of the health system in Israel, where comprehensive health insurance is universal and provided by the law. Finally there is limited availability of over-the-counter medications, and to obtain symptomatic therapeutic agents children are generally seen by a physician. The biggest limit to this study is not mentioned by the authors: the assumption that the circulation of respiratory viruses is constant throughout the study period. Although in the Discussion the authors mention some surveillance data on national diffusion of an H3N2 epidemic but this took place in Dec 1999 Observed effect may be due to school closure or they may be due to lower circulation of the viruses

Risk of bias table

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Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Isaacs 1991

Methods	Retrospective and prospective cohort study was conducted to evaluate the effectiveness of cohorting and educational program (handwashing) in reducing the incidence of nosocomial respiratory syncytial virus infections Data on all children with RSV infection on any of the paediatric wards in winter of 1986-7 were retrospectively collected. In order to define the population at risk of developing RSV infection it was determined the number of children under 2 years of age hospitalised on the two paediatric wards and the paediatric intensive care unit and the number they spent in hospital. For the next two winters (1987 to 1988 and 1988 to 1989) the same data were prospectively collected. In addition some interventions were made to try to reduce the incidence of hospital acquired RSV infection. Children admitted with suspected RSV infection were nursed in a specific area until the result of an indirect immunofluorescent test. It was not possible to cohort babies on the paediatric intensive care unit. Staff were instructed on the importance of handwashing and this was reinforced on ward rounds. An educational leaflet was prepared and given to the parents of every child admitted with the infection
Participants	Children < 2 years of age: 425 in period 1; 840 in period 2; 552 in period 3
Interventions	Isolation and handwashing versus normal care
Outcomes	Laboratory: indirect immunofluorescence on nasopharyngeal secretions or by culture of secretions Effectiveness: RSV infection Safety: N/A
Notes	Risk of bias: high (poor descriptions) Notes: the authors concluded that handwashing and cohorting reduced at least 66% in the number of hospital acquired infections due to RSV in the two intervention winters. One minor problem with cohorting was that babies could not remain in the accident and emergency department until a diagnosis of RSV was virologically confirmed. Hence they were cohorted on the basis of a clinical diagnosis of bronchiolitis. The authors also underline the importance of a more rapid antigen test for RSV. It is doubtful whether the non-exposed cohort is similar to its hospital peers, especially because there are several cardiac children in the exposed cohort. The biggest limit to this study is mentioned by the authors in the Discussion: the assumption that the circulation of RSV is constant throughout the study period. Exposure however is not the same in the 3 seasons and observed effect may be due to cohorting or to the different viral circulation

Risk of bias table

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Kimel 1996

Methods	Prospective cohort study conducted in a school of Chicago, USA, to evaluate the effectiveness of a handwashing program in reducing the absenteeism caused by flu-like illness. The school was located in a predominantly white, middle to upper middle class suburb. All four kindergarten and five first-grade classes were included in the study. No significant differences were found between participating classes for size, male-female ratio, percentage of lowincome students, or students with chronic health problems. Teachers were surveyed to determine classroom handwashing activities. The influenza season usually occurs during December and January. The handwashing program was planned for presentation just prior to this time. The effectiveness of the program was determined by comparing absentee rates among participants and non-participating classes (the control group). Absentee rates were determined by reviewing the computerized daily school absence logs. Entries that listed flu-like symptoms were counted. A take-home handwashing chart was also given to each student to encourage follow-through with handwashing at home
Participants	199 children of kindergarten and first grade schools
Interventions	Handwashing and educational program versus no intervention
Outcomes	Laboratory: no Effectiveness: flu-like illness Safety: N/A Absenteeism from influenza-like illness was approximately double in the control arm (p = 0.01)
Notes	Risk of bias: medium Notes: The authors concluded that handwashing education can decrease absenteeism even among kindergarten and first grade students. This study did not control for health and hygiene practices at home or exposure to flu-like illness outside of school. Furthermore the student population at the school was generally healthy, probably because families were able to provide adequate health and hygiene resources. Another problem of the study is that flu season was later than usual (February), and this represented a confounding variable. The teacher surveys indicated problems with handwashing facilities

Risk of bias table

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Incomplete outcome data addressed?	Unclear	
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Kotch 1994

Methods	Pair-matched cluster randomised controlled trial conducted in the period 19 October 1988 to 23 May 1989 in 24 child care centres in North Carolina, USA. The trial tested the effects of a handwashing and environment sterilizing programme on diarrhoea (data not extracted) and ARIs. Child day care centres had to care for 30 children or less, at least 5 of whom had to be in nappies and intending to stay open for at least another 2 years. Randomisation is not described, nor are cluster coefficient reported. Centre were matched in pairs and then randomly allocated to either intervention of control programmes
Participants	389 children aged 3 years or less in day care for at least 20 hours a week. There were some withdrawals but the attrition on participants is not stated, only that in the end data for 31 intervention classrooms and 36 control classrooms were available. There were 291 children aged up to 24 months and 80 over 24 months that took part. The text is very confusing as 371 seem to be the total of the number of families that took part. No denominator breakdown by arm is reported and numerators are only reported as new episodes per child-year
Interventions	Structured handwashing and environment (including surfaces, sinks, toilets and toys) disinfecting programme with waterless disinfectant scrub
Outcomes	Laboratory: N/A Effectiveness: ARI (coughing, runny nose, wheezing, sore throat or earache) Safety: N/A
Notes	Risk of bias: high (poor reporting of randomisation; outcomes; numerators; and denominators) Notes: the authors conclude that the fully adjusted RR for prevention of ARIs was 0.94 (-2.43 to 0.66). A poorly reported study

Risk of bias table

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Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Krasinski 1990

Methods	Controlled before and after study conducted in Bellevue Hospital Center, New York, USA, to determine the effectiveness of screening for RSV and assignment to a cohort at admission to reduce nosocomial transmission of RSV infections. Children who were 3 years of age and older were admitted to a paediatric ward that is equipped with private rooms for the control of communicable diseases. Children younger than 3 years of age were admitted to a separate ward without private rooms, where as many as four children shared a room. All paediatric patients hospitalised on or before Dec 31 1986 were regarded as potentially infected with RSV and were constituted as an RSV-infected cohort. A second cohort, free of infection with RSV, was established on the toddlers' ward to segregate high risk patients from RSV-infected patients. Patients requiring hospital admission and assignment to the high risk cohort were screened for evidence of RSV infection by means of a rapid ELISA method. No gloves or masks were used in the RSV cohort
Participants	All hospitalised paediatric patients regarded as potentially infected with RSV
Interventions	RSV screening cohorting and service education programme versus do nothing
Outcomes	The authors concluded that screening and subsequent cohorting reduced RSV infections (from 5.33 infections per 1000/patient days of care to 1.23 infections per 1000/patient days after introduction of screening). There was an attempt at correlation between RSV admissions and RSV community circulation
Notes	Risk of bias: medium Notes: the authors concluded that screening and subsequent cohorting reduced RSV infections (from 5.33 infections per 1000/patient days of care to 1.23 infections per 1000/patient days after introduction of screening). There was an attempt at correlation between RSV admissions and RSV community circulation

Risk of bias table

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Krilov 1996

Methods	Controlled before and after study carried out in a 16 classrooms of special needs school for Down syndrome children in New York State. The study took place between November 1991 to November 1993. The before between Nov 1991 and Oct 1992, followed by a one month washout period during which the intervention was introduced, followed by 12 months of after period (Dec 1992 to Nov 1993)
Participants	Thirty three children aged 6 weeks to 5 years took part in the before and 38 in year 2 (after period). During the study period there were about 110 children in the school but the parents of the majority did not agree to replying to 2 weekly questionnaires, so their children were not entered in the study. In addition 5 sets of questionnaires in the before and 2 in the after periods did not contain sufficient data (6 months' worth) and were excluded. Despite this there were no significant differences between before and after children. The authors also describe viral circulation during the study periods from isolates in the local hospital. All community isolates were constant with the exception of adenovirus which doubled in the after period of the study
Interventions	Training and sanitary programme with handwashing, disinfection of school buses, appliances and toys. In addition a person designated a study monitor carried out intensive monitoring of classroom behaviour and reinforced messages. Disinfection took place with Reckitt & Colman products (sponsors of the study)
Outcomes	Laboratory: viral isolates from surrounding community (non random samples) Effectiveness: ARI (cough, runny nose, sore throat, wheezing or rattling in the chest, ear ache). Vomiting and diarrhoea (data not extracted). Follow up was carried out on the basis of parents' questionnaire Safety: N/A
Notes	Risk of bias: high (disinfectants provided and study sponsored by manufacturer) Notes: The authors concluded that respiratory illnesses decreased from a median of 0.67 to 0.42 per child per month ($p < 0.07$), physician visits, 0.50 versus 0.33 ($p < 0.05$), mean course of antibiotics prescribed 0.33 versus 0.28 ($p < 0.05$) and days of school missed because of respiratory infections 0.75 versus 0.40 ($p < 0.05$). Respiratory illnesses decreased from a median of 0.67 to 0.42 per child per month. Small study with a serious selection bias and generalisability problems

Risk of bias table

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Ladegaard 1999

Methods	RCT with cluster randomisation (they called it "lottery", the same as "clip the coin") to intervention or control. Out of 10 institutions they excluded two because they want institutions comparable in uptake area (that means housing and income). Interventions were given to children, parents and teachers at the institutions
Participants	Children 0 to 6 years old
Interventions	Multifaceted: information, t-shirts to the children with: "Clean hands - yes, thank you", performance of a fairytale "The princess who did not want to wash her hands", exercise in handwashing, importance of clean and fresh air. The aims of the intervention were: to increase the hygiene education of the day care teachers to motivate the children by practical learning to have a better hand hygiene to inform the parents about better hand hygiene
Outcomes	34% decrease in 'sickness', (probably mostly gastroenteritis)
Notes	Risk of bias: limited data only available Notes: the authors conclude that there was a 34% decrease in sickness in the intervention arm, this is probably overall sickness as gastroenteritis is part of the outcomes (data no extracted). Limited data only available from translation by Jørgen Lous

Risk of bias table

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Lau 2004a

Methods	Case-control study carried out in Hong Kong, SAR of China during 4 April to 10 June 2003, at the height of the SARS outbreak. The aim was to describe the defined and undefined sources of SARS cases groups and assess the protective effects of various public health measures Defined sources were classified as being a healthcare worker in a hospital, living in Amoy Gardens (a known focus of infection) having had a contact with a member of the household with SARS of earlier onset, hospital in patients infected with SARS by other hospital inpatients and contacts of SARS cases before the onset of their own symptoms The undefined sources group of cases were all the other categories Cases in general were identified and interviewed on the phone. Households with more than one index case were considered as having two index cases. Of the 1690 identified cases, 1214 from 996 households were enrolled in the study. One hundred and forty cases could not be contacted as they had a wrong phone number, 163 were uncontactable after at least five attempts, 163 refused to take part and 10 did not speak either Chinese or English. Seventeen were further excluded because they were aged less than 16. Twenty two questionnaires were unusable. (This makes 1175, obviously the 17 minors are included in the case-control study, as adding them makes a total of 1192)
Participants	Description of cases: 330 probable cases of SARS selected as follows. From 1192 people with probable SARS reported to the Department of Health in the territory of HK up to 16 May 2003, 1175 were entered in the case-control analysis. SARS cases were defined as RX evidence of pulmonary infiltration consistent with pneumonia with a temperature of > 38 C or a history of such in the previous 2 days and at least 2 of the following: history of chills in the previous 2 days new or increased cough, breathing difficulty, general malaise of myalgia, typical signs of consolidation and known exposure to SARS. The authors say that this definition is the same the WHO's case definition of probable SARS. At interview, risk factors were elicited and identified. There were 727 cases in the defined source category and 347 in the undefined sources category (330 after exclusion of 17 minors) Description of controls: 660 controls of undefined origin and with no description of selection
Interventions	Natural exposure to SARS during a serious epidemic
Outcomes	Community transmission of SARS reduced OR 0.30 (95% CI 0.23 to 0.39)
Notes	Risk of bias: medium (inconsistencies in the text: lack of description of controls) Notes: the authors conclude that community transmission was of less importance than previously thought and public health measures worked. The following risk factors were significantly associated with SARS (matched multivariate analysis OR with 95% CIs): Visit to mainland China 1.95 (1.11 to 3.42) Visited Price of Wales Hospital 7.07 (1.62 to 30.75) Visited other hospitals 3.70 (2.54 to 5.39) Visited Amoy Gardens 7.63 (3.77 to 15.43) The following activities/interventions had a significant protective function: Thorough disinfection of living quarters 0.41 (0.29 to 0.58) Wore a mask in public places frequently 0.36 (0.25 to 0.52) Washed hands 11 or more times a day 0.58 (0.38 to 0.87) Potentially a very interesting study possibly rigorously conducted let down by a very confusingly written text. The biggest problem is lack of clarity as to who the controls were. This may be a reflection of the pressure of carrying out a study in the midst of a serious epidemic

Risk of bias table

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Incomplete outcome data addressed?	Unclear	
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Leclair 1987

Methods	Controlled before and after study conducted in Children's hospital of Boston, USA, to determine whether increased compliance with a policy of glove and gown isolation precautions could reduce the high rate of nosocomial RSV infection on an infant and toddler ward. All patients admitted to the 28-bed infant and toddler medical ward during three consecutive RSV seasons (1982 to 1985) were included in the study. When patients with known or suspected RSV infection were admitted, an attempt was made to place them in single rooms or to group them together, but infected patients were frequently required to share rooms with susceptible patients during the winter months, when the prevalence of RSV on the wards is highest. The RSV season was defined as the 24 weeks each year starting at the beginning of November and continuing through the end of April. All the documented cases of RSV infection occurred during that period, and all the patients and patient-days during that interval on the study ward were recorded. RSV infections were classified as nosocomial if symptoms developed five or more days after the patient's admission to the hospital. All cases of RSV infection were confirmed virologically. During the first half of the study nursing staff wore both gloves and gowns for only 20 of 52 observed contacts. During and after the second compliance survey, compliance rapidly increased: nursing staff wore both gloves and gowns for 73 of 90 of their contacts
Participants	695 patients aged from 5 days to 4 years and 11 months. The distribution of ages was similar in the two periods. Thirty-seven acquired nosocomial RSV infections
Interventions	Infection-control intervention to increase use of gloves and gowns versus no intervention
Outcomes	Laboratory: yes Effectiveness: RSV infection Safety: N/A
Notes	Risk of bias: low Notes: The authors concluded that the incidence of nosocomial RSV infection rose with the intensity of hospital exposure and that this rise was markedly different in the periods before and after intervention. The use of gloves and gowns can reduce the nosocomial transmission of RSV, particularly with increasing exposure to patients shedding the virus (RR for pre and post intervention periods infection rates 2.9, 1.5 to 5.7). Compliance by the staff improved dramatically after the intervention and it continued even after the end of the study, probably because the favourable results of the intervention were well publicized, the head nurse introduced an educational program emphasising the appropriate application of isolation precautions, and gowns and gloves became more accessible to care givers. The study, although prone to selection bias, is better designed than some of it peers as there is an attempt at adjusting for different levels of RSV circulation by sub-analysis by virus shedding days by the infected participants

Risk of bias table

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Leung 2004

Methods	Prospective cohort study conducted during 13 March to 29 June 2003 in the paediatric department of the Price of Wales Hospital at the height of the SARS epidemic in Hong Kong, China. The aim of the study was to test the effectiveness of procedures to stop transmission of SARS from infected children to carers and visitors
Participants	26 HCWs in close contact with probable or suspected SARS and 88 HCWs in contact with patients in other study areas during the study period
Interventions	Triage and UHR-S isolation & strict infection control procedures versus triage and UHR-S isolation and less strict infection control procedures. Healthcare workers were exposed to nine children with probable SARS and 29 with suspected SARS admitted into the Ultra High Risk SARS (UHR-S) areas with a mean age of 8.9 years, 88 children with pneumonia but no SARS contact with a mean age of 8.2 admitted to the isolation cubicle of the Ultra High Risk Infection (UHR-I) area, 227 with febrile illness and normal chest radiograph aged 4.9 years treated in an open cubicle in the UHR-I area and 274 non febrile children with a mean age of 7.5 years admitted into the High Risk (HR) area. The study tested the effectiveness of triage and UHR-S isolation + strict infection control procedures versus triage and UHR-S isolation + less strict infection control procedures Triage at admission aimed at identifying children aged less than 18 who: were febrile or afebrile with a known SARS contact who were admitted to the UHR-S area with a positive CXR and a SARS contact who were admitted to the UHR-S area with CXR changes but no SARS contact who were admitted to the UHR-I area were febrile or afebrile but no SARS contact who were admitted to the HR area Very strict infection control measures were implemented on entry and exit from the UHR-S area (handwashing, gown, caps, goggles, mask, upper and trousers of cloth operating theatre garments and N95 face respirator for HCWs, all measures but no goggles or undergarments for visitors and handwashing and mask for patients Less strict infection control measures were implemented on entry and exit from the UHR-I area (handwashing, gown, goggles, mask, upper and trousers of cloth operating theatre garments and N95 face respirator for HCWs, and handwashing and mask for visitors and patients) Even less strict infection control measures were implemented on entry and exit from the HR area (handwashing, gown, caps, goggles, mask , upper and trousers of cloth operating theatre garments and mask of N95 face respirator for HCWs and handwashing and paper mask for visitors and patients). Enforcement was directed by a police nurse in the UHR areas
Outcomes	Laboratory: laboratory confirmation of SARS Effectiveness: probable or suspected SARS according to WHO definitions Safety: N/A
Notes	Risk of bias: low Note: the authors conclude that the measures worked well as no HCW or visitor became ill. This is a remarkably well-conducted and clearly reported study in the midst of a major infectious disease outbreak with a previously unknown agent. The Prince of Wales Hospital had previously witnessed an outbreak in which an index patient had infected 138 health care workers. All the more remarkable as the paediatric department had not been built as isolation facility and had to be rapidly reorganised

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Longini 1988

Methods	Cluster-controlled double blind randomised trial to assess the efficacy of virucidal tissues in interrupting family transmission of rhinovirus and influenza virus. The study was carried out in the community of Tecumseh, Michigan, USA during the period 25 November 1984 to 28 April 1985. However, the authors only report results for the period 13 January to 23 March 1985, when a high circulation of influenza A H3N2 and rhinovirus was detected
Participants	296 households were enrolled but for "technical reasons" five household were eliminated from the analysis. The analysis was carried out in households with 3 to 5 members. The authors report data on 143 households randomised to virucidal tissues and 148 to placebo tissue. Average age in households was around 22 and the difference between arms was not significant. Randomisation was carried out by the sponsor and tissues were pre-packed in coded boxes with no other identifying features and delivered to households at the beginning of the study period
Interventions	Disposable three-layered virucidal tissues (citric and malic acids with sodium lauryl sulphate in the middle layer) or placebo (succinic acid in the middle layer) tissues. They were used to blow the nose, coughing or sneezing into. Households were also stratified by level of tissue use. Tissue use was significantly higher in the intervention arm (82% versus 71%)
Outcomes	Laboratory: yes - viral culture from nasal and throat swabs from symptomatic participants Effectiveness: ARI (with a proportion of laboratory confirmed diagnosis in non-randomly chosen participants with symptoms lasting 2 days or more) Follow up and surveillance was carried out using a telephone questionnaire Safety: N/A
Notes	Risk of bias: high (inappropriate choice of placebo) Notes: the authors conclude that virucidal tissues were up to 36.9% effective in preventing transmission of ARIs as measured by secondary attack rates (18.7% versus 11.8%). This was not significant but may well have been affected by the lack of do-nothing community controls. This a well-designed, well written study despite the unexplained attrition of 5 families, the lack of reporting of cluster coefficients and the differential in tissue use between the two arms which raises questions about the robustness of double blinding. Particularly notable is the discussion on the low generalisability of results from the study from the placebo arm given that even the inert barrier of the tissues is a likely to have limited spread. Also the lengths to which the authors went to obtain allocation concealment and maintenance of double-blind conditions

Risk of bias table

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Luby 2005

Methods	Partly double blind cluster randomised controlled trial carried out during 15 April 2002 to 5 April 2003 in Karachi, Pakistan. The trial assessed the effects of mother and child handwashing on the incidence of respiratory infections, impetigo (data not extracted) and diarrhoea (data not extracted). Randomisation took place by computer generated random numbers in three phases: 25 neighbourhoods were assigned to handwashing and 11 to standard practice 300 households assigned to using antiseptic soap 300 households assigned to using plain soap 306 households assigned to standard practice 1523 children younger then 15 years assigned to using antiseptic soap 1640 children younger then 15 years assigned to using plain soap 1528 children younger then 15 years assigned to standard practice Soaps were identical weight, colour, and smell and were packed centrally with a coded packing case matched to households containing 96 bars. Neither field workers not participants were aware of the content. Control arm households were visited with the same frequency as intervention household but were given books and pens. Codes were held centrally by the manufacturer and broken after the end of the trial to allow analysis
Participants	Householders of slums in Karachi. Of the 1523 children younger then 15 years assigned to using antiseptic soap 117 dropped out (1 died, 51 were born in and 65 aged out) = 1406; 504 were aged less than 5 Of 1640 children younger then 15 years assigned to using plain soap 117 dropped out (3 died, 44 were born in and 70 aged out) = 1523; 517 were aged less than 5 1528 children younger then 15 years assigned to standard practice 125 dropped out (3 died, 40 were born in and 82 aged out) = 1403; 489 were aged less than 5
Interventions	Instruction programme and antibacterial soap containing 1.2% triclocarban, or ordinary soap to be used throughout the day by householders or standard procedure
Outcomes	Laboratory: N/A Effectiveness: Number of new respiratory illness per person per week Pneumonia (cough or difficulty in breathing with a respiratory rate of > 60 min in children less than 60 days old, > 50 min in those less than 1 year old and > 40 min for those aged 1 to 5 years) Follow up was weekly with household interview and direct observation. Children aged less than 5 were weighed and the report presents stratification of results by child weight Safety: N/A
Notes	Risk of bias: low (cluster coefficients and analysis by unit of randomization provided) Notes: The authors conclude that "handwashing" neighbourhoods has significantly less episodes of respiratory disease than controls (e.g. 50% less cough). "Handwashing" children aged less than 5 had 50% less episodes of pneumonia than controls (-65% to -35%). However there was no difference in respiratory illness between types of soap. The report is confusing, with a shifting focus between children age groups. The impression reading is of an often re-written manuscript. There is some loss of data (for example in the results by weight, i.e. risk group) because of lack of clarity on denominators. Despite this, the trial is a landmark

Risk of bias table

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Macartney 2000

Methods	Controlled before and after study with economic evaluation (data not extracted) carried out over 8 RSV seasons in 1988 to 1996. The study assessed the impact of a programme for the interruption of transmission of RSV in a children hospital in Philadelphia, USA. Analyses are presented both by risk group (exposure to patients by days of viral shedding) and as aggregate. Only for the latter numerators and denominators are provided, whereas for the former figures are presented in bar chart format
Participants	Children with community-acquired RSV infection and the inpatient children exposed to them (1604 in 4 seasons before and 2065 in the "after the intervention" seasons. Children were aged around 1 year and those with risk factors were equally spread (51% versus 54%) in the two periods
Interventions	Education with high index of suspicion for case-finding with barriers (but no goggles or masks) and handwashing for patients and staff with contact precautions for RSV + patients for 2 weeks with isolation (when possible) with cohorting of patients and staff with enhanced surveillance with restriction of visits with discouragement of staff with ARIs from working unprotected in SCBU
Outcomes	Laboratory: ELISA confirmation of RSV infection on all children admitted with respiratory symptoms. In a proportion of cases RSV culture was undertaken, although this had a minimal practical impact as any child with respiratory symptoms was considered as a RSV case Effectiveness: clinically defined RSV cases contracted nosocomially (with symptoms appearing after at least 6 from admission Safety: N/A
Notes	Risk of bias: low Notes: the authors conclude that 10 RSV infections were prevented per season (RR for post-intervention compared to pre-intervention periods 0.61, 95% CI 0.53 to 0.69). The study is well reported and the conclusions appear reasonable, but no information is given on the background rate of infection and the impact of the intervention on HCW morbidity is not analysed

Risk of bias table

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MacIntyre 2009

Methods	Prospective cluster-randomised trial carried out in Sydney, Australia, to assess the use of surgical masks, P2 masks, and no masks in preventing influenza like illness (ILI) in households. The study was carried out during the two winter seasons of 2006 and 2007 (August to the end of October 2006 and June to the end of October 2007). "Gaussian random effects were incorporated in the model to account for the natural clustering of persons in households"
Participants	Two hundred and ninety adults from 145 families; 47 households (94 enrolled adults and 180 children) were randomised to the surgical mask group, 46 (92 enrolled adults and 172 children) to the P2 mask group, and 52 (104 enrolled adults and 192 children) to the no-mask (control) group. Two families in the control group were lost to follow-up during the study. No reason was given for this
Interventions	Use of surgical masks and P2 mask versus no mask. The P2 mask is described as very cumbersome
Outcomes	Laboratory: Serological evidence Effectiveness: Influenza like illness (ILI) (described as fever, history of fever or feeling feverish in the past week, myalgia, arthralgia, sore throat, cough, sneezing, runny nose, nasal congestion, headache However a positive laboratory finding for influenza converts the ILI definition into one of influenza Safety: N/A
Notes	The authors conclude that adherence to mask use significantly reduced the risk for ILI-associated infection, but < 50% of participants wore masks most of the time. We concluded that household use of face masks is associated with low adherence and is ineffective for controlling seasonal respiratory disease. Compliance was by self-report – therefore likely to be an underestimate. The primary outcome was ILI or lab-positive illness. This showed no effect. Sensitivity analysis by adherence showed that under the assumption that the incubation period is equal to 1 day (the most probable value for the 2 most common viruses isolated, influenza [21] and rhinovirus [26]), adherent use of P2 or surgical masks significantly reduces the risk for ILI infection, with a hazard ratio equal to 0.26 (95% CI [confidence interval] 0.09 to 0.77; $p = 0.015$). No other covariate was significant. Under the less likely assumption that the incubation period is equal to 2 days, the quantified effect of complying with P2 or surgical mask use remains strong, although borderline significant; hazard ratio was 0.32 (95% CI 0.11–0.98; $p = 0.046$). The study was underpowered to determine if there was a difference in efficacy between P2 and surgical masks (Table 5). The study conclusion appear to be a posthoc data exploration. Regardless of this the study message is that respirator use in a family setting is unlikely to be effective as compliance is difficult unless there is a situation of real impending risk

Risk of bias table

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Madge 1992

Methods	Prospective cohort study conducted in 4 medical wards of the Royal Hospital for Sick Children in Glasgow, UK, to evaluate the effectiveness of 4 infection control procedures in preventing nosocomial infection with RSV. This is an interruption of transmission study. Every child up to 2, irrespective of clinical presentation, had respiratory secretions tested for RSV antigen within 18 hours of admission. Nosocomial infection was assumed if a child become RSV positive 7 days or more after admission. Children after discharge from hospital were not studied
Participants	No special precaution group 152 (winter 1); gowns/gloves 337 (winter 1 and 2); cohort nursing 265 (winter 1 and 2); cohort nursing and gowns/gloves 310 (winter 1 and 2); 1001 (winter 3)
Interventions	Stepwise intervention programmes: gowns/gloves; cohort nursing + gowns/gloves; cohort nursing, versus no special precautions. The procedures evaluated in the two winter periods were gowns/gloves; cohort nursing + gowns/gloves; cohort nursing, versus no special precautions. In the third year the most effective strategy was introduced into all ward areas and its efficacy in clinical practice was assessed. There was not separate area for managing children with infections
Outcomes	Laboratory: yes - culture, antibodies titres, serological studies Effectiveness: RSV infections (seroconversion within 7 days of admission) Safety: N/A
Notes	Risk of bias: low Notes: the authors conclude that combined with rapid laboratory diagnosis, cohort nursing and the wearing of gowns and gloves for all contacts with RSV-infected children can significantly reduce the risk of nosocomial RSV infection (odds reduced to between 1.27% to 75.6%). One confounding effect that was not accounted for in the study design was a possible "ward effect". For practical reasons, two wards (3 and 4) continued with the same policy over the first 2 years of the study. Since it was also necessary apply policies to whole wards there is a possibility that ward 4 might have been especially effective at implementing their assigned policy

Risk of bias table

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Makris 2000

Methods	Prospective cohort study carried out in 8 private, freestanding long-term care facilities located in New Jersey and Delaware, to determine the impact of an ongoing infection control intervention program in reducing the incidence of nosocomial infections. The 8 facilities were selected on the basis of similarity with respect to admission rate, size, acuity levels, availability of services, overall infection rates, in-house environmental service departments. Resident populations were comparable in terms of age, sex and underlying disease. The 8 facilities were grouped into 4 sets of matched pairs. Within each pair, each home was designated at random as either a test site or a control site. The results was that 4 facilities (2 urban and 2 suburban, with a total of 443 beds), were selected as test sites and another 4 facilities, 2 urban and 2 suburban, with a total of 447 beds, were selected as control sites
Participants	443 beds (patients) in the test group, 447 beds (patients) in the control group. We assumed number of beds as number of participants
Interventions	Infection-control education programme reinforcing handwashing and other hygienic measures versus normal care
Outcomes	Laboratory: no Effectiveness: upper respiratory infections Safety: N/A
Notes	Risk of bias: high (internal inconsistencies) Notes: the authors conclude that infection control education measures that reinforce handwashing and other hygienic measures helps reduce the number of organisms present on hands and surfaces and may have contributed to the non-significant reduction of URTIs (the opposite is reported in the paper: incidence density rate of 4.15/1000 patient days in the test homes versus 3.15/1000 patient days in the control homes) showed in this study. We assumed number of beds as number of participants to the study, but we don't know the characteristics of the patients (age, sex, underlying conditions, etc.). The authors confuse a cohort design with a before and after design and in the report they confusingly use both terms and reach conclusions not supported by the evidence presented

Risk of bias table

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Master 1997

Methods	Prospective cohort study conducted in an elementary school, Detroit, to evaluate the effect of a mandatory scheduled handwashing program on absenteeism due to acute communicable illness (including upper respiratory disease). Classrooms were divided into either control or experimental groups without formal randomisation. Six classrooms were assigned to the handwashing group and eight classrooms were assigned to the control group. Data were collected for 37 school days. Information about absent children was recorded daily by the school secretary. Symptoms were used to classify students as having respiratory or gastrointestinal illness. upper respiratory infections and gastrointestinal symptoms (data not extracted) were not considered mutually exclusive
Participants	14 classrooms including 305 healthy, predominantly upper middle-class children ranging from ages 5 to 12. All grade levels from kindergarten through fifth grade were included. Six classrooms (143 students) were the handwashing group and eight classrooms (162 students) were the control group
Interventions	Handwashing program versus usual practice. Children in the handwashing group were asked to wash their hands after arrival at school, before eating lunch, after lunch recess, and before going home. Children in the control group washed at their normal frequency. All children in both groups washed with the school soap, which was not antibacterial
Outcomes	Laboratory: no Effectiveness: upper respiratory infections (URI) - cough sneeze, pink eye, headache, mononucleosis, acute exacerbation of asthma, sinus trouble, fever alone, bronchitis Safety: N/A
Notes	Risk of bias: high Notes: the authors conclude that handwashing among children can be effective in preventing transmission of disease, but the difference in days of absence is statistically significant only for gastrointestinal symptoms (RR for ARIs 0.79, $p = 0.756$). Limitations in the study design are: use of a discrete population without socio-economically diverse backgrounds, use of a single institution, lack of blind assessment, low specificity of symptoms, and lack of accurate symptom definition

Risk of bias table

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Morton 2004

Methods	Cross-over study to evaluate the effectiveness of an alcohol gel as an adjunct to regular handwashing for decreasing absenteeism among elementary children by reducing specific communicable diseases such cold, flu and conjunctivitis. The study was conducted in an elementary school in New England, US. In the crossover design classrooms in each grade level were randomised to begin as the experimental group (alcohol gel) or the control group (regular handwashing). A study protocol for hand hygiene was introduced following the germ unit education. The handwashing product was a soap and water alternative that is approximately 60% ethyl alcohol. In phase 1 (46 days) children in 9 classrooms were in the experimental group, and children in 8 classrooms were in the control group. After a 1 week washout period when no children had access to the alcohol gel, Phase 2 (47 days) started, and the classroom that had participated before as an experimentalgroup passed in the control group and vice versa. Data were collected by the parents that informed the secretary or the school nurse of the reasons for a child's absence, including symptoms of any illness. Respiratory illnesses were defined by symptoms of URTI
Participants	253 children, 120 girls and 133 boys, from kindergarten to 3rd grade. 32 children dropped out (10 due to skin irritation and 22 because of lack of parental consent)
Interventions	Use of an alcohol gel as an adjunct to regular handwashing and educational program versus regular handwashing and educational program
Outcomes	Laboratory: no Effectiveness: days of absences from school for respiratory illness Safety: N/A
Notes	Risk of bias: high (no description of randomisation; partial reporting of outcomes, numerators and denominators) Notes: the authors conclude that significantly fewer children became ill while using the alcohol gel as an adjunct to regular handwashing than when using regular handwashing only (decreased school absenteeism of 43% with the use of alcohol gel on top of handwashing). The authors also described, as a limitation of the study, the fact that the school nurse served ad the data collector, and this could be perceived as bias in measurement of the outcome variable. Randomisation and allocation are not described, there are no cluster coefficients reported and attrition is not taken into consideration during the analysis. Unit of randomisation and analysis are different. No reporting by arm. No ORs, no CIs reported

Risk of bias table

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Murphy 1981

Methods	Prospective cohort study carried out in the Children's Hospital, Denver, t examine the effect of using gowns, masks and handwashing on the acquisition of symptomatic respiratory infections by medical personnel caring for infants with respiratory disease
Participants	58 people of nursing, medical, respiratory therapy personnel; 30 in the handwashing group, 28 in the handwashing, masks and gowns. Seventy HCWs initially were available for enrolment, 9 refused to take part and 3 withdrew
Interventions	Handwashing versus handwashing, masks and gowns
Outcomes	Laboratory: yes Effectiveness: viral infections (including RSV) Safety: N/A
Notes	Risk of bias: medium Notes: the authors conclude that there was no difference between the two groups with respect to number of viral infections (i.e. 4/30 in the handwashing group versus 5/28 in the handwashing gown and masking group ($p > 0.20$). The findings cannot demonstrate any effect of adding the use of both gown and mask to the usual handwashing routine on the development of illness in personnel caring for infants with respiratory disease. Possible reasons for lack of effect are: the heavy exposure all adults have to respiratory viral illness in the community at large; poor compliance to the study protocol, modes of virus spread which would not be blocked by the use of mask and gown

Risk of bias table

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Niffenegger 1997

Methods	Prospective two-centre cohort study assessing the effects of a handwashing programme in Indiana, USA. Two centres were enrolled for the August to December 1994 (21 weeks) study: a test and a control centre
Participants	Eight teachers and 26 children (aged 3 to 5) in the test group and 12 children and 8 teachers in the control group. According to the authors, age, experience gender and socioeconomic variables were equally distributed between the two groups, but data are not shown. No attrition is mentioned
Interventions	Three weekly cycles of teachings, handwashing routine encouragement for children, parents and staff and correct sneezing and coughing procedure. Follow up was weekly filling in of a teacher report. It is unclear from the text what happened in the control site, or indeed if they were fully aware of the project
Outcomes	Laboratory: N/A Effectiveness: colds and ARIs no better defined Safety: N/A
Notes	Risk of bias: high (wide range of incidence of infections) Notes: the authors conclude that during the first 11 weeks of the study the test centre had double the incidence of colds compared to the control centre this is explained by the author as caused by the influx of new children bringing in new viruses in the test centre. In the second period the reverse was true, explained as the stabilising of the population and the taking effect of the programme. The list of potential confounders and biases is countless. For example there is only a very cursory description of participants in both arms and the role of teachers especially in the control centre is not explained. The test group had significantly less colds than the control group ($p < 0.05$)

Risk of bias table

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Nishiura 2005

Methods	Case-control study carried out during the SARS outbreak (26 Feb 03 to 28 Apr 03) in Hanoi, Vietnam. The study aimed at assessing the relationship between SARS infection and behaviour. The study population was based at the Hanoi French Hospital (HFH) and followed the outbreak during three phases. The first phase (26 Feb to 4 Mar 06) in which an index case and 9 suspected secondary cases were admitted/cared for. The second phase (8 Mar to 11 Mar 03) in which outpatients were closed and staff no longer returned home as the outbreak spread and the third phase (11 Mar 03 to 28 April 03) in which the HFH was closed to all other then SARS cases who were isolated
Participants	Description of cases: 29 surviving people with laboratory confirmed SARS cases either admitted and retained or transferred to other hospitals. Nine cases did not take part (5 died, 1 refused and 3 had relocated). Twenty eight were HCWs employees of the HFH and 1 a relative of a patient. Substantial exposure and behaviour were documented through observation and questionnaires Description of controls: 90 people aged > 20 who provided written consent with substantial SARS exposure, 57 of whom were HFH employees
Interventions	Handwashing before contact with SARS patient Handwashing after contact with SARS patient Masks Gloves Gowns All measures combined Analysis by epidemic stage is reported
Outcomes	SARS infection
Notes	Risk of bias: low Notes: the authors conclude that masks (OR 0.3, 95% 0.1 to 0.7) and gowns (OR 0.2, 95% 0.0 to 0.8) were significantly associated with protection (OR, 95% to) during phase 1 but in Phase 2 masks (OR 0.1, 95% 0.0 to 0.3) and all measures (OR 0.1, 95% 0.0 to 0.3) were associated with protection probably because of the increased awareness of the danger of the outbreak and increase us of measures - this is confirmed by the results of the mathematical model in the second part of the study. A well written and reported study

Risk of bias table

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Ou 2003

Methods	Retrospective cohort study carried out in selected precincts of Haidian district of Beijing, People's Republic of China between March and May 2003 during the epidemic of Severe Acute Respiratory Syndrome (attack rate 19/100,000 population in the period March to July). Precincts were chosen on the basis of the highest number of quarantinees. The study aimed at assessing the risk of acquiring SARS among quarantinees. A better definition of the risk would help in future to identify better candidates for quarantine and target resources accordingly. The study was based on a questionnaire-based survey on the reasons for quarantine. SARS diagnosis for contacts was independently carried out from lists
Participants	171 SARS cases (29% of total) were identified in the precincts and 1210 persons (23%) quarantined from the selected districts (contacts). These were sampled from a total population of 2.24 million, with 5.186 quarantinees. Response rate was 85% (1.028 quarantinees who completed the questionnaire, of which 232 developed probable SARS while in quarantine)
Interventions	Quarantine at home or hospital for 14 days post-exposure (reduced to 10 and then to 3). Quarantine is defined as the separation and or restriction of movement of persons who due to recent exposure to a communicable disease risk acquiring the disease and transmitting to third parties. A contact was defined as: Health care worker not using personal protective equipment (PPE) when caring for/ assessing a SARS case; other persons caring for a SARS case persons sharing accommodation with a SARS case persons visiting a SARS case persons working with a SARS case classmates or teachers of a SARS case persons sharing the same means of public transport with a SARS case All quarantinees were followed-up daily and were admitted to hospital if they developed fever (38 C or more)
Outcomes	Laboratory: no Effectiveness: definition of SARS was based on criteria of Chinese Ministry of Health. Definition was clinical and not based on laboratory isolation of the SARS-CoV Safety: N/A
Notes	Risk of bias: high Notes: the authors conclude that only those quarantinees who actually had home or hospital contact with a symptomatic SARS patient developed the illness (attack rate 31.1, 95% CI 20.2 to 44.4 for carers, 8.9%, 95% CI 2.9 to 22.1 for visitors, 4.6%, 95% CI 2.3 to 8.9 for those who lived with a SARS case) but not those living in the same building or working with them and not contacts of any SARS case during the incubation period. Fever was also not a good reason to quarantine people (attack rate nil). Quarantine also appeared to prevent transmission, although there were numerous cases in which quarantine was not required. There are several limitations to the conclusion of the study. Non -andom basis for the sample, selection bias of the sample and responders, recall bias of responders and the absence of a laboratory confirmed diagnosis may have affected the conclusion one way or another. Overall, not enough denominator data, non exposed data are given to allow data extraction or calculate OR

Risk of bias table

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Pang 2003

Methods	Ecological study describing and analysing the effects of public health measures on the SARS epidemic between 5 March and 29 May 2003 in Beijing, China. Data were collected from centralised notification and close contact databases
Participants	2521 probable SARS cases mostly hospitalised aged around 33 (407 or 16% were HCWs) and 192 of these who died out of a total population of 13.6 million people. The peak took place on 25 April with 173 hospitalised cases
Interventions	SARS was made notifiable on 9th of April and contact tracing commenced a day later. On 18 April 62,363 of the estimated 85,000 Beijing HCWs received training in the management of SARS cases and were issued gowns, gloves, masks. By 17 April, 123 fever clinics were opened, however these were contiguous to hospitals and it is thought that some transmission occurred. By 21 April quarantine of close contacts was underway (these were only allowed to leave quarantine in exceptional circumstances and only wearing a mask) and fever check at airports were begun the day after. By 24 April all schools and universities closed. Two days later public meeting places (bars, libraries etc) were closed. From 27 April all SARS cases were placed in designated hospital wards and by 8 May SARS cases were only sent to designated hospitals. By 1 May a SARS hospital of 1000 beds built in 1 week was opened and received only SARS cases (40% of total cases). The last cases were registered on 26 May. The highest attack rate (14.5%) of quarantined people was those of spouses of SARS cases
Outcomes	Laboratory: laboratory testing for the presence of SARS-CoV was not part of the case definition Effectiveness: Probable SARS cases (close contact of a SARS sufferer with signs and symptoms of febrile respiratory disease and chest X-ray changes, or person visiting of residing in an area with recent SARS activity and with signs and symptoms of febrile respiratory disease and chest X-ray changes and lack of response to antibiotics or person visiting of residing in an area with recent SARS activity and with signs and symptoms of febrile respiratory disease and chest X-Ray changes and normal or decreased WBC count) Safety: N/A
Notes	Risk of bias: low Notes: the authors conclude that in virtue of the shape of the epidemic curve it is likely that the combination of measures taken before the 25th of April helped contain the spread of SARS. Although there may be alternative explanations this appears to be the most likely explanation of the facts. Hospitals were seen early on as sources of transmission of the SARS Co-V. The authors seem to doubt the direct effectiveness of entry port (for example, airports, stations, etc) checks (12 cases identified out of over 13 million people screened). They think screening was more useful to keep away sick people

Risk of bias table

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Free of selective reporting?	Unclear	

Pelke 1994

Methods	Controlled before and after study conducted in a neonatal intensive care unit (NICU) of Kapiolani medical center, Honolulu, Hawaii, to assess the effect of gowning on RSV and other infections, on traffic and handwashing patterns. Alternate 2- months gowning and no-gowning cycles were established in a 24-bed NICU for 8 months. One entire 4-month cycle was repeated to eliminate the potential for seasonal variables and outbreaks. All the people entering into the NICU (physicians, nursing staff, ward clerks, families and visitors) wore gowns. During the no- gowning periods nursing staff wore hospital- issued pantsuit, washed at home through ordinary methods and worn from home. Ward clerks, physicians, hospital staff, families and visitors wore street clothes without gowns. Throughout the entire 8 month period, there was the recommendation for all staff and visitors to enforce initial 2 -minute hand scrub. Nails were cleaned before scrubbing, and a minimum 15-second hand wash between infants or equipment was expected. Surveillance cultures were done weekly on all patients. Without the knowledge of the NICU staff, a neonatal research nurse scheduled observations of traffic patterns, while ostensibly reviewing charts, to determine if a lack of gowning procedures encourage more traffic. Handwashing compliance was studied, again without staff awareness, by 30 minutes direct observation. Follow-up of infection rates was planned through standard infection control surveillance
Participants	230 infants, aged 22 to 42 weeks, with birth a weight of 464-6195 grams. Overall there were 330 infants admitted to NICU during the study period. Thus 17% of participants had no RSV cultures taken. The reasons given are vague (transfer or death)
Interventions	Use of gowns and standard procedures (handwashing) versus standard procedures
Outcomes	Laboratory: serological evidence: yes Effectiveness: RSV infection Safety: N/A
Notes	Risk of bias: medium (17% loss to follow up) Notes: the authors conclude that gowning did not protect NICU infants from any type of infection or affect mortality (1.21 versus 1.38/100 patient-days of gowning and no gowning periods respectively). Gowning procedures did not deter staff or visitors from entering the unit, since traffic was also unchanged between periods. Finally the results showed no change in handwashing patterns between periods. Besides the advantage of eliminating a potentially unnecessary ritual that may be perceived as a psychological barrier to families visiting their infants, other benefits to discontinuing gowning include saving staff tome involved in various gowning procedures and costs. If gowns are eliminated, it is recommended to perform careful follow up. The study conclusions must be taken with caution given the likely selection bias introduced by the missing 17% of children

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Roberts 2000

Methods	Open cluster RCT carried out between March and November 1996 (the southern hemisphere winter season) in 23 child care centres caring for a minimum of 50 children 10 hours a day, 5 days a week in Australia. The study assessed the effects of an Australian national handwashing programme compared to standard procedure. Randomisation was according to a random number table and cluster coefficients are reported
Participants	Children (299 in the intervention arm and 259 in the control arm) aged 3 or younger attending the centres at least 3 days a week. Attrition was 51 children in the intervention arm and 72 children in the control arm due mainly to staff leaving the centres
Interventions	Handwashing programme with training for staff and children. It is unclear whether any extra hand cleansing agents were used, as GloGerm (?) is mentioned when it was used in a preliminary study
Outcomes	Laboratory: N/A Effectiveness: ARI (runny nose, cough and blocked nose) Follow up was via a parental phone interview every 2 weeks Safety: N/A
Notes	Risk of bias: low (cluster coefficients and analysis by unit of randomization) Notes: The authors conclude that although there was no overall decrease in respiratory illness (RR 0.95 95% CI 0.89 to 1.01), but in children up to 24 months the decrease was significant (RR 0.90, 95% CI 0.83 to 0.97). The authors speculated that this was because maximum benefits are likely from this age group because of their limited ability to wipe their nose and hands without a structured programme. Analyses by three compliance levels are also reported. A so-so reported and well conducted trial

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Ryan 2001

Methods	Retrospective and prospective controlled before and after study carried out at the US Navy's Great Lakes recruit training centre, in Illinois. Rates of respiratory disease were retrospectively calculated for recruits undergoing training for 3 periods: 1996, before the implementation of "Operation Stop Cough" and 1997 and 1998. To compare rates of respiratory illness with a similar community the authors also looked at the incidence of respiratory illness in a population of phase II sailors undergoing the second part of their training in the same camp. In addition a compliance questionnaire was also carried out during the latter two years of the study
Participants	Recruits undergoing training (44,797 in 1996; 47,300 in 1997; and 44,128 in 1998) mainly men, aged around 19 to 20 and a control population of phase II training sailors (no precise denominators given but around 10,000 yearly) who did not have a programme of handwashing
Interventions	Structured top-down programme of handwashing at least 5 times daily
Outcomes	Laboratory: N/A Effectiveness: respiratory illness detected from sick parade records and outgoing recruits questionnaire on a sample survey Safety: N/A
Notes	Risk of bias: low Notes: the authors conclude that implementation of the control programme has seen near-halving of incidence of ARIs (based on three stratified samples of recruits infrequent hand washers had more self reported episodes of ARIs (4.7 versus 3.2 per recruit, OR 1.5, 95% CI 1.2 to 1.8) and reported more hospitalisations (OR 10.9, 95% CI 2.7 to 46.2). Despite dramatic results, implementation was and continues to be difficult

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Sandora 2005

Methods	Single-blind cluster randomised controlled trial carried around the Boston area, USA, in the period November 2002 to April 2003. The trial tested the effects of using a hand sanitiser and a programme of instruction on the transmissions of GI infections (data not extracted) and ARIs in families. Units of randomisation were child care centres and were carried out on enrolment by an investigator using random block size generated by computer. Assignment was single blind (i.e. investigator blinded to the status of the centre). Cluster correlation was 0.01
Participants	292 families with 1 or more children aged 6 months to 5 years who were in child care for 10 or more hours a week. There were 155 children in 14 centres allocated to the intervention arm and 137 children in 12 centres allocated to the control arm. The mean age was 3 to 2.7 years. Attrition was respectively 15 (3 lost to follow up and 12 who discontinued the intervention) and 19 (8, lost to follow up and 11 who discontinued the intervention). ITT analysis was carried out
Interventions	Alcohol-based hand sanitiser with bi-weekly hand-hygiene educational materials over 5 months versus bi-weekly educational material on healthy diet
Outcomes	Effectiveness: ARI (two of the following symptoms for 1 day or 1 of the following symptoms for 2 days: runny nose, cough, sneezing, stuffy or blocked nose, fever, sore throat). An illness episode had to be separated by 2 symptom-free days from a previous episode. A secondary illness was when a it followed a similar illness in another family member by 2 to 7 days Follow up was by means of bi-weekly phone calls to care givers Safety: dry skin (71 reports), stinging (11 reports), bad smell (7 reports), dislike (2 reports), allergic reaction (2 reports), slippery feel (1 report) and irritation (20 reports)
Notes	Risk of bias: low Notes: the authors conclude that although the rate of GI illnesses was significantly lower in the intervention group, the incidence rate ratio - IRR was not significantly different for ARIs (0.97; 95% CI 0.72 to 1.30). Compliance and droplet route spread may account for this apparent lack of effect. A well reported trial

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Sandora 2008

Methods	Cluster-randomised, controlled trial carried out in a single elementary school system located in Avon, Ohio, USA to assess the effectiveness of a multifactorial infection-control intervention, including alcohol-based hand sanitiser and surface disinfection, in reducing absenteeism caused by gastrointestinal and respiratory illnesses among elementary school students. The study also aimed to describe the viral and bacterial contamination of common surfaces in the school classroom and to assess the impact of an environmental disinfectant on the presence of selected viruses and bacteria on these surfaces. Clustering was described as 'teams of 3-4 classes depending on the class year"
Participants	A total of 363 students in 15 different classrooms were eligible to participate and received letters about the study. A total of 285 of these students provided written informed consent and were randomly assigned to the intervention group (146) or to the control group (139). No students were lost to follow-up or discontinued the intervention during the study period. Baseline demographic characteristics were similar in the intervention and control groups. Most families were white and non-Hispanic and in excellent or very good health at baseline
Interventions	Alcohol-based hand sanitiser to use at school and quaternary ammonium wipes to disinfect classroom surfaces daily for 8 weeks versus usual handwashing and cleaning practices
Outcomes	Laboratory: Serological evidence: No Swabs for bacteria and viruses from 3 types of classroom surfaces were taken Effectiveness: Respiratory illness defined as days absent as measured by a (blinded) school worked who routinely record reason for absenteeism either for gastrointestinal or respiratory causes Safety: N/A
Notes	The authors conclude that multifaceted intervention that included alcoholbased hand sanitiser use and disinfection of common classroom surfaces reduced absenteeism from gastrointestinal illness among elementary school students. The intervention did not impact on absenteeism from respiratory illness. In addition, norovirus was detected less frequently on classroom surfaces in the group receiving the intervention. The study is good quality with low risk of bias. The authors checked compliance by counting discarded wipes. Reasons given for the apparent lack of effect against ARIs but good effect on GI illness are that disinfecting the classroom surfaces (daily at lunchtime with Alkali) was important – as well as the alcohol wipes. The authors measured the norovirus concentration on surfaces and found this reduced. Other reasons may be that droplets are not affected by this method or that contamination of hands by respiratory infections is likely to be continuous (in orofaecal transmission is mostly at the time of defecation)

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Satomura 2005

Methods	Randomised controlled trial, randomisation was achieved by simple computer-generated random digit. Allocation was concealed using sealed opaque envelopes. Not clear if there was a central randomisation centre. Post hoc exchange of envelopes was prevented by writing both the name of each subject and the number on the envelope he/she drew before breaking the seal. Participants were not blinded to the intervention, however, disease incidence was determined by one study physician who was not informed of the results of assignment. Analysis was done based on the intention-to-treat. The study targeted community healthcare all over Japan and was conducted between Dec 2002 and Mar 2003 for a follow up period of 60 days
Participants	Three hundred and eighty seven participants at 18 sites were recruited. Included in the analysis 384, follow up was completed on 338 participants. Attrition was fully explained for URTI analysis, however, 2 subjects were not accounted for in the ILI analysis. Forty six participants did not complete the follow up due to either discontinuation of diary use (n=9) or contracting influenza like illness (ILI) (*n* = 37). Of the 37 participants with ILI, 11 were in povidone-iodine group, 12 in water group and 14 in control. Analysis was performed on 35 participants (Kitamura 2007)
Interventions	Participants were randomised to one of the following: water gargling, *n* = 122 (20 mL of water for about 15 seconds three times consecutively, at least three times a day); povidone-iodine gargling, *n* = 133 (20 mL of 15 to 30 times diluted 7% povidone-iodine (as indicated by the manufacturer) in the same way as water gargling); and control, *n* = 132 (retain their previous gargling habits). All groups were asked to fill a daily gargling diary (standardised form to record: gargling habits, handwashing and influenza complaints). The frequency of gargling in the water group was higher (3.6), frequency of handwashing was similar between the 3 groups. URTI symptom was classified according to Jackson methods. Diary recording was continued throughout the follow up period and for 1 week after the onset of URTI.ILI were reported separately
Outcomes	Laboratory: None Effectiveness: Primary outcome: Incidence of first URTI. Index cases were defined as all of the following conditions: (1) both nasal and pharyngeal symptoms, (2) severity of at least one symptom increased by two grades or more, and (3) worsening of a symptom of one increment or more for > 3 days. Secondary outcome: Severity of URTI of the incident cases was assessed by grading each symptom during the initial 7 days after the onset of URTI in numeric scores: none = 0, mild = 1, moderate = 2 and severe = 3. ILI was defined as both developing a fever of 38C or higher, and worsening arthralgia in addition to some respiratory symptoms (Kitamura 2007) Safety: No harm was reported. However, 2 patients in the poviodine group switched to water gargling (analyzed in their assignment group)
Notes	The authors conclude that simple water gargling is effective to prevent URTIs among healthy people. However, no significant difference was observed against ILIs. Study was well conducted, blinding would have added to the validity of the results. In addition, the study was not powered enough to detect significant preventative effect against ILI. The study demonstrated that in addition to handwashing, simple gargling even with simple water can reduce URTI but not ILI. However, during periods of endemic influenza, multiple inexpensive and simple modalities (handwashing, masks, gargling) can be utilised together to reduce infection and transmission. Overall, the reporting of the two combined studies together is highly confusing. In the first study (Satomura 2005) the main outcome is URTI defined as fever and arthralgia. The second study, (which is a presentation of further data from the 2005 publication in the guise of a short report) introduces the outcome ILI with a definition similar to that of URTI in the first study but referring to the earlier outcome as common cold. Also of note is reporting of significance without confidence intervals. Overall this potentially important study should be repeated with a larger denominator. Medium risk of bias because of confused reporting and absence of double blinding

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Seto 2003

Methods	Case-control study Hong Kong, China, conducted during the period 15 march to 24 March 2003 in five hospitals. The study aims were to assess the effectiveness of protective procedures for contracting SARS in HCWs exposed to 11 index cases in three of the five hospitals during the SARS epidemic
Participants	Description of cases: 13 HCWs infected with confirmed SARS within 2 to 7 days of exposure with no community exposure, 4 males and 9 females 2 doctors, 6 nurses, 4 healthcare assistants and 1 domestic staff who came into contact with SARS index cases. Only one used no protection measures and all omitted at least one of the protective measures required (handwashing, masks, gloves, gowns). Cases were identified through notification, which has been active since early February. A SARS cases was defined as having fever of 38 C or more, radiological infiltrates, and two of either: new cough, malaise, signs of consolidation Description of controls: 241 staff from the five hospitals who were not infected. The authors report that use of measures was elicited using questionnaires, 365 of which were returned (85% response rate). Non-responders were likely to be on leave or night shift. Data for 102 staff were excluded because they had no exposure to SARS
Interventions	Exposure was defined as coming within 0 to 91 metres (3 feet) of an index case with SARS symptoms when providing care. Recommended measures were handwashing, masks, gloves and gowns
Outcomes	SARS
Notes	Risk of bias: medium (inconsistencies in the text: lack of description of controls) Notes: The authors conclude that the 69 staff reporting use of all 4 measures were not infected, whereas all infected staff had omitted at least one measure. Simple analysis showed that masks, gowns and handwashing (OR 5, 95% CI 1 to 19) were effective but only masks (OR 13, 95% CI 3 to 60) were significant at logistic regression, possibly through lack of power. No blind assessment of cases and control data was carried out and 15% attrition of questionnaires may have introduced bias. The study was published as research letter in the Lancet, so possible lack of space may have affected reporting clarity

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Simon 2006

Methods	Prospective cohort surveillance study conducted in the University Children's Hospital in Bonn, Germany, to assess the global efficacy of a complex intervention programme to contain nosocomial transmission of RSV infections. This is a before-after design, with a multifactorial intervention carried out in one hospital
Participants	6548 paediatric patients admitted at the University Children's Hospital in the period of study (2200 in 1999 to 2000; 2298 in 2000 to 2001; 1959 in 2001 to 2002). 283 RSV infections were documented in 278 hospitalised paediatric patients: 138 in 1999 to 2000, 89 in 2000 to 2001, 56 in 2001 to 2002. Of the general population 244 events were ambulatory RSV infections and 39 nosocomial RSV infections
Interventions	Intervention strategy aimed at increasing vigilance to identify and isolate RSV-infected patients together with enforced contact precautions versus standard procedures. Interventions are not described very well: vigilance + cohorting versus vigilance versus standard practice
Outcomes	Laboratory: All RSV infections were confirmed by antigen detection or cell culture using MS cells Effectiveness: RSV infections no better defined clinically Safety: N/A
Notes	Risk of bias: low The authors conclude that the multi-factorial prevention strategy (early diagnosis, a strict cohorting and contact isolation policy, and prospective surveillance) probably contributed significantly to the reduced risk of nosocomial RSV infections in the hospital. In the pre-intervention period there were 39 cases (13.8%) nosocomial infections with an incidence density of 0.99/1000 patient days; following the introduction of the surveillance and prevention policy there was a 9-fold decrease of the Incidence (1.67 versus 0.18/1000 patient-days)

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Snydman 1988

Methods	Controlled before and after study conducted during the winters of 1983-84 (retrospectively), 1984 to 1985 and 1985 to 1986 (prospectively) to assess whether the introduction of infection control measures halted transmission o RSV in a special nursery in Boston USA. Record review for the retrospective part and prospective study for the two seasons following the introduction of infection control measures
Participants	HCW and patients in the special care baby unit
Interventions	From the 1984 to 1985 season the following were introduced: Active surveillance Extensive cohorting of patients and staff Respiratory precautions on suspicion of respiratory case Gown, mask and gloves used on contact Restricted visiting policy Segregation of cases
Outcomes	Laboratory: RSV culture Effectiveness: RSV cases with symptoms and laboratory confirmation Safety: N/A
Notes	Risk of bias: high Notes: The authors conclude that there were 7 cases in the season "before" and no cases in the following seasons (no transmission per 1000 patient days in the post-intervention period compared 8 per 1000 patient days in the pre-intervention period). No denominators are provided (hence no data can be extracted) and exposure is generically quantified by aggregate patient- days of exposure. It is unclear how the circulation of RSV outside related to the claimed success of the measures, as no information is provided

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Somogyi 2004

Methods	Prospective cohort study of 9 observations (3 each when using 3 different masks). The authors observed and photographed droplet dispersal while a volunteer breathed out 3 times in 3 different types of mask
Participants	1 volunteer
Interventions	Three masks, two without air filter and allowing external exhalation, one with manifold and air filter
Outcomes	Effectiveness: plume of droplets as observed and photographed: masks were poor at preventing droplet spread
Notes	Risk of bias: low Notes: the authors conclude that the mask with manifold and air filter did not allow dispersal of droplets and was far safer in an epidemic such as SARS to contain the spread. Simple, safe and effective study

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Teleman 2004

Methods	Case-control study assessing risk and protective factors in HCWs during the SARS outbreak in Singapore (1 to 22 March 2003)
Participants	Description of cases: 36 HCWs admitted with probable SARS (according to WHO definition) during 1 to 31 March 2003. Six others were too ill to speak and 2 others died
	Description of controls: 50 HCWs working on the same wards who had definite exposure to SARS (physical proximity of 1 metre or less of a patient subsequently diagnosed as having SARS) but did not develop SARS
Interventions	Data on personal details and symptoms and exposure were gathered via a closed phone questionnaire. The 2 groups were comparable for demographic and epidemiological characteristics except that non-Chinese ethnic groups were twice as common among controls
	The following risk factors were assessed:
	Distance from source of infection < 1 meter
	Duration of exposure 60 or more minutes
	Wearing N95 respirator
	Wearing gloves
	Wearing gown
	Touched patients
	Touched patients' personal belongings
	Contact with respiratory secretions
	Performed venepuncture
	Performed or assisted in intubation
	Performed suction of body fluids
	Administered oxygen
	Handwashing after each patient
Outcomes	SARS
Notes	Risk of bias: low
	Notes: The authors conclude that three factors were associated with significant risks or protection:
	Wearing N95 respirator OR 0.1 (95% CI 0.02 to 0.86)
	Contact with respiratory secretions OR 21.8 (95% CI 1.7 to 274.8)
	Handwashing after each patient OR 0.07 (95% CI 0.008 to 0.66)
	A well reported study, let down by the failure to indicate whether assessment of risk factors had been carried out blindly to cases or control status. I wonder how much of the non-significance for certain factors is due to lack of statistical power

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Turner 2004a

Methods	Double-blind randomised controlled trial conducted by Hill Top Research, Inc. Winnipeg, Canada, to assess the efficacy of acids with virucidal activity for the inactivation of virus and prevention of experimental Rhinovirus colds. Subjects in good health, aged 18 to 60, were recruited from Winnipeg and surrounding communities for participation. Qualified subjects were randomised to treatment with vehicle (62% ethanol, 1% ammonium lauryl sulfate, and 1% Klucel), vehicle containing 3,5% salicylic acid or vehicle containing 1% salicylic acid and 3,5% pyroglutamic acid. The volunteers' hands were disinfected and then test product was applied to both hands of each subject. Fifteen minutes after application, the fingerprints of each hand were contaminated with Rhinovirus type 39. The volunteers touched conjunctiva and the nasal mucosa only with the right hand. Viral contamination of the fingers was assessed in the left hands of the volunteers, and viral infection was assessed by culture of nasal lavage specimens and blood samples
Participants	85 volunteers, 31 control group, 27 used vehicle with 3.5% salicylic acid, 27 used vehicle with 1% salicylic acid and 3.5% pyroglutamic acid
Interventions	Use of salicylic acid versus salicylic acid and pyroglutamic acid versus "placebo" substance
Outcomes	Laboratory: yes Effectiveness: rhinovirus type 39 infection Safety: N/A
Notes	Risk of bias: high (no description of randomisation process, concealment, or allocation) Notes: the authors concluded that organic acids commonly used in over-the-counter skin care and cosmetic products have substantial virucidal activity against rhinovirus. These preparations provided effective residual antiviral activity on the hands. The virucidal effect of these hand treatments resulted in a reduction in the incidence of rhinovirus infection in the treated volunteers (p = 0.025). The utility of this observation in the natural setting remains to be determined. The volunteers were not allowed to use their hands in the interval between the hand treatment and the virus challenge, so the effect of normal use of the hands on the virucidal activity of these organic acids is not known. Similarly, the virus challenge method used in these experiments may not simulate the natural setting in all aspects. The effect of nasal secretions that would be transferred with the virus in the natural setting on the activity of the acids or on the transmission of virus was not tested in the model. We are unsure as to the practical significance of this study and the generalisability of its results to the real world. Poorly reported study

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Turner 2004b

Methods	Double-blind randomised controlled trial conducted by Hill Top Research, Inc. Winnipeg, Canada, to assess the residual virucidal activity of a skin cleanser wipe and its effectiveness in preventing experimental Rhinovirus colds. Subjects in good health and from 18 to 60 were recruited from Winnipeg and surrounding communities for participation. The residual activity of a skin cleanser wipe containing 4% pyroglutamic acid formulated with 0.1% benzalkonium chloride was tested. The negative control treatment was 62% ethanol. Benzalkonium chloride had been previously tested and was found to have no virucidal activity. Volunteers were randomly assigned to use the control preparation or the active preparation. The study material was applied to hands with a towelette. Fifteen minutes later, when the fingers were completely dry, the fingertips of each hand of the control subjects and the volunteers in the active treatment group were contaminated with Rhinovirus type 39. An additional volunteer in the active group were challenged with virus 1 hour after application and the final group of volunteers was challenged 3 hours after application. Viral infection was assessed by culture of nasal lavage specimens and blood samples
Participants	122 volunteers, 30 control group, 92 active group (30 tested after 15 minutes, 30 after 1 hour, 32 after 2 hours)
Interventions	Use of a skin cleanser wipe containing 4% pyroglutamic acid formulated with 0.1% benzalkonium chloride versus skin cleanser wipe containing ethanol
Outcomes	Laboratory: yes Effectiveness: rhinovirus type 39 infection Safety: N/A
Notes	Risk of bias: high (no description of randomisation process, concealment, or allocation)

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Wang 2007

Methods	Prospective cohort, surveillance study carried out to indentify risk factors for development of SARS among quarantined persons in Taiwan. Two types of quarantine were implemented during the SARS outbreak in Taiwan: level A and level B quarantine. Level A quarantine was designed for persons who had known and, at times, had close exposure to persons infected with SARS in health care facilities and other community and domestic areas. Level B quarantine was designed for travellers who sat on the same flight within 3 rows of a person infected with SARS or were returning from World Health Organization–designated SARS-affected areas
Participants	During the study period 52,255 persons were placed under level A quarantine and 95,271 persons were placed under level B quarantine
Interventions	Exposure to level A quarantine versus level B
Outcomes	Laboratory: Serological evidence: yes Effectiveness: SARS (definition not reported) Safety: N/A
Notes	The authors conclude that focusing quarantine efforts on persons with known or suspected exposure can greatly decrease the number of persons placed under quarantine, without substantially compromising its yield and effectiveness. This is an important study, as it implies that risk banding can increase effectiveness and efficiency of quarantine procedures. The risk of bias is high as most of the answers to the NOS items are clearly no, however it is very difficult to get answers to a question such as the effectiveness of quarantine using any other design

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

White 2001

Methods	Double blind placebo-controlled cluster randomised trial that took place in 3 schools in California during March to April 1999. The study assessed the incremental value of using an alcohol hand rub together with water & soap handwashing. Both arms had been given an educational programme starting 2 weeks prior to the beginning of the trial. Randomisation was by classroom and the placebo hand rub was indistinguishable from the active ingredient. Details of randomisation are not given
Participants	Of the 72 classes originally recruited, lack of compliance (use of supplementary product at least 3 times a day), reduced the classes to 32 (16 in both arms) with 769 participants aged 5 to 12
Interventions	Pump activated antiseptic hand rub with benzalkonium chloride (SAB) (Woodward Laboratories) or inert placebo that "virtually" looked the same in batches of four colour coded bottles containing both. School staff, parents and participants were blinded
Outcomes	Laboratory: testing of virucidal and bactericidal activity of the active compound Effectiveness: ARI (cough, sneezing, sinus trouble, bronchitis, fever, red eye, headache, mononucleosis, acute exacerbations of asthma) Gastrointestinal and other illnesses (data not extracted) Follow up and observation was carried out by classroom staff and illnesses were described by parents Safety: 7 students dropped out because of mild sensitivity to the rub
Notes	Risk of bias: high (no description of randomisation; partial reporting of outcomes, numerators and denominators) Notes: the authors conclude that addition of the rub led to a 30 to 38% decrease of illness and absenteeism (RR for illness absence incidence 0.69, RR for absence duration 0.71). Very high attrition, unclear randomization procedure, educational programme and use of placebo hand rub make generalisability of the results debatable. No confidence intervals reported

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

White 2003

Methods	Prospective open cohort study carried out at the university of Colorado Boulder campus during eight weeks in the autumn-winter of 2002. The study aimed at assessing the effects of hand hygiene on URTIs and absenteeism. Allocation was by residence hall with 2 halls doing "knowledge studies" being allocated, one to each arm
Participants	430 students aged around 18 mainly females were recruited but only 188 in the intervention cluster and 203 in the control cluster completed at least 3 weeks' follow up. Students were recruited with cash incentives. No reasons for attrition are given
Interventions	Education programme and alcohol gel adjunct to handwashing in residence halls versus standard hygiene
Outcomes	Laboratory: in vitro testing of the antibacterial and antiviral properties of the hand rub Effectiveness: URTI (at least 2 symptoms with one of them lasting at least 2 to 3 days. List of symptoms as follows: sore throat, stuffy nose, ear pain, painful/swollen neck, cough, chest congestion, sinus pain, fever, working days lost). Weekly surveys were carried out before during and after the study Safety: N/A
Notes	Risk of bias: medium Notes: the authors conclude that the intervention resulted in significantly fewer symptoms (reductions of 14.8% to 39.9 %) and absenteeism (40% reduction). Unexplained attrition and unknown effect of cash incentives. Relatively unclear definition of illness with a hint of a sensitivity analysis in the footer to a table

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Wu 2004

Methods	Case-control study carried out on the Beijing SARS outbreak to assess the reasons for the insurgence of SARS cases in people who had no apparent contact with a SARS case
Participants	Description of cases: 94 probable or suspected SARS cases (Ministry of Health of China definitions) hospitalised during the period 28 April 2003 to 9 June 2003, aged 14 or more and non-HCWs with no known or reported no close contact with probably or suspected SARS cases. Fifty percent of cases were males with a median age of 29 years. The definition changed after 3 May to include those with symptoms who travelled to or resided in areas with known recent SARS activity but did not necessarily have contact with an index case. No laboratory confirmation of SARS was included in the definition which was purely practical (i.e. clinical-anamnestic). However antibody titres were taken several weeks after symptoms had abated. Close contacts (which played a part in the earlier case definition) were defined as persons who shared utensils, meals, residence hospital room or transportation vehicle with a suspected SARS or those who visited or came into contact with body fluids up to 14 days prior to the development of the index case's symptoms. Cases and controls were interviewed during the period 3 to 16 June
	Description of controls: 281 controls selected each by telephone random number change of last digits of the cases' phone numbers. This was aimed at providing neighbouring matching. Controls were interviewed by 4 July 2003. Seven controls (two matched sets) were excluded because they were aged less than 14 and seven matched sets were excluded because the case was reclassified as a HCW
	Cases and controls were interviewed for the 2 weeks preceding symptoms
Interventions	Always wearing a mask
	Intermittently wearing a mask
	Washing hands
	Owning a pet
	Visiting a farmer's market
	Visited clinics, eaten out, or taken taxis
Outcomes	SARS
Notes	Risk of bias: medium (inconsistencies in the text: lack of description of controls)
	Notes: The authors conclude that cases were more likely than controls to have chronic pathologies (OR 4.1 95% CI 1.8 to 9.3) or have visited fever clinics (OR 13.4 95% CI 3.8 to 46.7), eaten out (OR 2.3 95% CI 1.2 to 4.5) or taken taxis more than once a week (OR 3.2 95% CI 1.3 to 8.0). In other words, unrecognised sources of transmission were present in the community. Always wearing a mask use was strongly protective (70% reduction in risk, OR 0.3 95% CI 0.2 to 0.7) and even wearing one intermittently with a smaller significant reduction in risk (OR 0.5 95% CI 0.2 to 0.9) and so was always washing hands after returning home (OR 0.3 95% CI 0.2 to 0.7) and owning a pet (OR 0.4, 95% CI 0.2 to 0.9) and visiting a farmer's market (OR 0.4 95% CI 0.2 to 0.8). Of great interest is the role of fever clinics in spreading the disease, probably because of poorly implemented isolation and triage procedures. A fascinating study

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Yen 2006

Methods	Prospective cohort study performed in a 67-bed military hospital in Taiwan to assess the effectiveness of the integrated infection control strategy by comparing the rate of SARS transmission in HCWs in the study hospital with that in other major hospitals in Taiwan without the integrated infection control strategy
Participants	Health care workers (HCWs) of a 67-bed military hospital, that was the study hospital. Eighty-six hospitals were used as comparison hospitals with a total of 746 negative pressure isolation rooms (NPIR beds), caring for SARS patients without the integrated infection control strategy. All HCWs in this group were trained before the SARS epidemic in Taiwan through a national regulation for a standard nosocomial infection control programme, with infectious diseases physicians/infection control nurses available in each regional and tertiary hospital
Interventions	Integrated infection control strategy (consisting of patient traffic into hospital, zone of risks and extensive installation of alcohol dispensers for glove-on hand rubbing) versus standard nosocomial infection control programme
Outcomes	Serological evidence: yes Effectiveness SARS (definition?) Safety N/A
Notes	Risk of bias: high The authors conclude that the integrated infection control strategy appeared to be effective in reducing the incidence of HCWs contracting SARS. Point estimates? 95% CIs. The advantages included rapid implementation without negative pressure isolation rooms, flexibility to transfer patients, and reinforcement for HCWs to comply with infection control procedures, especially handwashing. The efficacy and low cost are major advantages, especially in countries with large populations at risk and fewer economic resources

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Yin 2004

Methods	Case-control study carried out in ten hospitals of Gunandong province, China, comparing the rate of usage of protective measures in HCWs with SARS and without SARS. The rate of exposure to SARS between two groups was similar. The data were obtained by questionnaire. Limited information is available from the abstract and from partial translation of the original text in Chinese
Participants	Description of cases: 77 HCWs who had contracted SARS Description of controls: 180 HCWs who had not contracted SARS Both cases and controls had been working in isolation units and took part in delivering first aid and caring for SARS patients. No significant differences were noted between cases and controls for a series of variables
Interventions	Mouth mask Thick mouth mask (more than 12 layers of cloths) Use one-off paper mouth mask Never use mouth mask Wear eye mask if necessary Protecting for nose and eyes mucosa Wear shoe gloves Wear barrier gown Wear hand gloves Rinse out mouth Take bath and change clothes before home Check mouth mask Intake oseltamivir phosphate orally Never eating and smoking in the ward Handwashing and disinfection Using nose clamp Intake herbal Banlangen (Indigowoad Root) orally
Outcomes	SARS
Notes	Risk of bias: medium (inconsistencies in the text: lack of description of controls) Notes: the authors conclude that the combination of mouth mask, barrier gown, gloves, goggles, footwear, rinse out mouth and take bath and change clothes before provided significant protection and that there was a doseresponse relation with the more interventions used in combination the better the protection. Single measures such as wearing of a mask (OR 0.78 95% CI 0.60 to 0.99), goggles (OR 0.20, 95% CI 0.10 to 0.41) and footwear (OR 0.58 95% CI 0.39 to 0.86) were effective Limited information is available from the abstract and from partial translation of the original text in Chinese

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Yu 2007

Methods	Case control study to analyse the risk factors associated with nosocomial outbreaks of SARS in hospital wards in Guangzhou and Hong Kong, China. The study was designed with the individual hospital wards as the units for data collection and analysis. Case wards were hospital wards in which superspreading events of SARS occurred, and control wards were hospital wards in which patient(s) with SARS were admitted, but no superspreading events occurred. A superspreading event is defined as the development of ≥ 3 new cases of SARS in a ward during the period from 2 to 10 days after the admission of an identifiable index patient or as the development of a cluster of ≥ 3 new cases of SARS in a ward during a period of 8 days but without any known sources of SARS
Participants	Eighty-six wards in 21 hospitals in Guangzhou and 38 wards in 5 hospitals in Hong Kong were included in the study. One ward in Guangzhou and 2 wards in Hong Kong did not participate, and they were excluded from the analysis
Interventions	Information related to 2 factors was collected: (1) environmental and administrative factors and (2) host factors. Environmental and administrative factors included physical factors, procedural or situational factors, and administrative factors pertaining to each ward. Host factors included symptoms, severity or dependency (for activities of daily living and behavior changes), treatment or intervention, and comorbidity of the identified index patient in a case ward or in the first patient with SARS admitted in a control ward
Outcomes	Laboratory: Serological evidence: no Effectiveness: SARS (no definition) Safety: N/A
Notes	The authors conclude that environmental risk factors were significantly associated with the occurrence of a superspreading event (clustering of ≥ 3 cases) included minimum distance between beds of ≤ 1 m and performance of resuscitation in the ward. Use of BIPAP ventilation and use of oxygen were the significant risk factors associated with the host patient. Of the administrative factors, allowing staff with symptoms to work also increased the risk. Providing adequate washing or changing facilities for staff was protective As disaggregate data are not reported we did not extract numeratore/denominator data

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	
Allocation concealment?	Unclear	
Blinding?	Unclear	
Incomplete outcome data addressed?	Unclear	
Free of selective reporting?	Unclear	

Table footnotes

CXR, chest X-ray; GI, gastro-intestinal; HCW, health care worker; HFH, Hanoi French Hospital; ITT, intention-to-treat; MCU, medical convalescent unit; NICU, neonatal intensive care unit; OR, odds ratio; PCU, physical conditioning unit; RSV, respiratory syncytial virus; SCBU, special care baby unit; URTI, upper respiratory tract infection; WBC, white blood cell.

Characteristics of excluded studies

Abou El Hassan 2004

Reason for exclusion	Topic completely extraneous

Amirav 2005

Reason for exclusion	Randomised controlled trial of aerosol treatment

Anderson 2004

Reason for exclusion	Mathematical model with interesting discussion of interaction between public health measures

Anonymous 2002

Reason for exclusion	News item

Anonymous 2003

Reason for exclusion	No data presented

Anonymous 2004

Reason for exclusion	News item

Anonymous 2005a

Reason for exclusion	News item

Anonymous 2005b

Reason for exclusion	News item

Anonymous 2005c

Reason for exclusion	News item

Aragon 2005

Reason for exclusion	Descriptive paper (non-comparative). Has no viral outcomes

Barros 1999

Reason for exclusion	Correlational study between incidence of upper respiratory tract infection (URTI) and factors such as overcrowding

Bell 2004

Reason for exclusion	Has unpublished entry exit screening data and extensive references but no comparative data

Ben-Abraham 2002

Reason for exclusion	Exclude - bacterial illness only

Black 1981

Reason for exclusion	Diarrhoea only outcome

Breugelmans 2004

Reason for exclusion	Description of risk factors in aircraft

Carbonell-Estrany 2008

Reason for exclusion	Immunoglobulin intervention and descriptive review

Carter 2002

Reason for exclusion	News item

Castillo-Chavez 2003

Reason for exclusion	Editorial

Cava 2005a

Reason for exclusion	Survey of quarantinees' views

Cava 2005b

Reason for exclusion	Personal experiences of quarantine

CDC 2003

Reason for exclusion	Case reports

Chai 2005

Reason for exclusion	Letter - about MRSA

Chaovavanich 2004

Reason for exclusion	Case report

Chau 2003

Reason for exclusion	No original retrievable data. Mathematical model fitting expected to observed cases with quarantine in the SAR of Hong Kong

Chen 2007

Reason for exclusion	An assessment of the impact of different handwashing teaching methods. No clinical outcomes

Chia 2005

Reason for exclusion	Knowledge survey

Cowling 2007

Reason for exclusion	Epidemiology, non-comparative non-interventions study

Daugherty 2008

Reason for exclusion	No data free presented

Davies 1994

Reason for exclusion	Antibody titres as outcomes with so many biases that interpretation of study is problematic

Day 1993

Reason for exclusion	No acute respiratory infection outcome data

Day 2006

Reason for exclusion	Mathematical model no new data

Dell'Omodarme 2005

Reason for exclusion	Probabilistic and Bayesian mathematical model of screening at entry

Desenclos 2004

Reason for exclusion	Description of transmission

DiGiovanni 2004

Reason for exclusion	Qualitative study of compliance factors in quarantine

Doebbeling 1992

Reason for exclusion	RCT respiratory data not present. Only 3 viruses isolated in total with no viral typing available

Dwosh 2003

Reason for exclusion	Case series

Fendler 2002

Reason for exclusion	Cohort study badly biased with differential health profiles and healthcare workers dependency in intervention and control semi-cohorts. No attempt at adjusting for confounders was made. No denominators available

Flint 2003

Reason for exclusion	Description of spread in aircraft and non-comparative data

Fung 2004

Reason for exclusion	Non-comparative

Gaydos 2001

Reason for exclusion	Editorial linked to Ryan

Gensini 2004

Reason for exclusion	Interesting historical review

Giroud 2002

Reason for exclusion	Non clinical outcomes

Glass 2006

Reason for exclusion	Mathematical model - no original data presented

Goel 2007

Reason for exclusion	Non-comparative study

Gomersall 2006

Reason for exclusion	Non-comparative study

Gore 2001

Reason for exclusion	Summary of Dyer 2000 (already included)

Gostin 2003

Reason for exclusion	Not an analytical study

Guinan 2002

Reason for exclusion	It would appear that nine classes took part and "acted as their own controls", but it is not clear if there was crossover of classes or not. In addition the outcome is combined gastrointestinal/ respiratory. The clue lies in the presence of a nested economic analysis which shows considerable savings in time for staff and pupils is the soap is used: in other words this is a (covert) publicity study

Gupta 2005

Reason for exclusion	Economic model - no new data

Gwaltney 1982

Reason for exclusion	No breakdown of cases by arm given

Han 2003

Reason for exclusion	Non-comparative

Hayden 1985

Reason for exclusion	This is an RCT with laboratory induced colds, small numbers uncertain numerators but almost certainly because of the unique laboratory conditions (placebo tissues not being a placebo at all) of impossible generalisation. It was a pilot to the far bigger trial by Farr et al (included)

Hendley 1988

Reason for exclusion	Inappropriate intervention

Hilburn 2003

Reason for exclusion	No ARI/viral outcomes (e.g. URTIs)

Hilmarsson 2007

Reason for exclusion	Animal study

Hirsch 2006

Reason for exclusion	Study tested pharmacological interventions

Ho 2003

Reason for exclusion	Descriptive review

Hsieh 2007

Reason for exclusion	Mathematical model

Hugonnet 2007

Reason for exclusion	Letter without any data

Jiang 2003

Reason for exclusion	Two papers probably the same paper in different versions: Jiang SP, Huang LW, Wang JF, Wu W, Yin SM, Chen WX, *et al.* [A study of the architectural factors and the infection rates of healthcare workers in isolation units for severe acute respiratory syndrome]. [Chinese] Chung-Hua Chieh Ho Ho Hu Hsi Tsa Chih [*Chinese Journal of Tuberculosis & Respiratory Diseases*]. **26**(10):594-7, 2003 Oct

Jones 2005

Reason for exclusion	Historical account

Kaydos-Daniels 2004

Reason for exclusion	Not an analytical study

Khaw 2008

Reason for exclusion	Assessing the efficacy of O_2 delivery

Kilabuko 2007

Reason for exclusion	Aetiological study

Kosugi 2004

Reason for exclusion	Non-comparative study

Lam 2004

Reason for exclusion	Outcomes were generic (infection rates). No laboratory data available for viral diagnosis

Lange 2004

Reason for exclusion	No data presented

Larson 2004

Reason for exclusion	Inappropriate outcomes

Larson 2005

Reason for exclusion	Cluster RCT comparing the effects of 2 hand hygiene regimens on infection rates and skin condition and microbial counts of nurses' hands in neonatal intensive care units. Outcomes were generic (for example, pneumonia and microbial counts of participants' skin). No laboratory data available for viral diagnosis

Lau 2004b

Reason for exclusion	Attitude survey

Lau 2005

Reason for exclusion	Herbal remedy effectiveness assessment

Lee 2005

Reason for exclusion	Descriptive study of risk and protective factors of transmission in households. No assignment took place

Lipsitch 2003

Reason for exclusion	Mathematical model fit to evidence

Luckingham 1984

Reason for exclusion	Historical report on Tucson experience during Spanish flu pandemic

Ma 2004

Reason for exclusion	Case-control study of risk factors for SARS

Marin 1991

Reason for exclusion	Viral resistance study

McSweeny 2007

Reason for exclusion	Historical description

Mikolajczyk 2008

Reason for exclusion	No intervention

Monsma 1992

Reason for exclusion	Non-comparative study

O'Callaghan 1993

Reason for exclusion	Letter linked to Isaacs 1991

Olsen 2003

Reason for exclusion	Description of transmission

Ooi 2005

Reason for exclusion	Descriptive study but with interesting organisational chart

Pang 2004

Reason for exclusion	Descriptive study of Beijing outbreak. Some duplicate data in common with Pang 2004

Pittet 2000

Reason for exclusion	Analysis of relationship between handwashing compliance campaign and nosocomial bacterial infections (e.g. MRSA)

Prasad 2004

Reason for exclusion	Letter of retrospective cohort - behavioural

Rabenau 2005

Reason for exclusion	In vitro test of several disinfectants

Reynolds 2008

Reason for exclusion	Describes the psychological effects of quarantine

Riley 2003

Reason for exclusion	Mathematical model fit to evidence

Rosenthal 2005

Reason for exclusion	Outcomes were generic (for example, pneumonia, URTIs). No laboratory data available for viral diagnosis

Safiulin 1972

Reason for exclusion	Non-comparative set of studies with no clinical outcomes

Sandrock 2008

Reason for exclusion	Review

Satter 2000

Reason for exclusion	Experiment assessing virucidal activity of finger tip surface - no clinical outcome data

Schull 2007

Reason for exclusion	Describes the impact of SARS in a Toronto study

Sizun 1996

Reason for exclusion	This is a review, with no original data presented

Stoner 2007

Reason for exclusion	No study data available

Stukel 2008

Reason for exclusion	Impact of the SARS disruption on care/ mortality for other pathologies (for example, acute myocardial infarction). There are no interventions and outcomes are unrelated to acute respiratory infections

Svoboda 2004

Reason for exclusion	Descriptive study with before and after data but shifting denominators

Ueno 1990

Reason for exclusion	Experimental study. No clinical intervention

van der Sande 2008

Reason for exclusion	Laboratory study without any clinical outcomes

Wang 2003

Reason for exclusion	Descriptive study

Wang 2005

Reason for exclusion	Case-control study of susceptibility factors

Weber 2004

Reason for exclusion	Editorial linked to Larson 2004

White 2005

Reason for exclusion	Redundant publication of White 2003

Wilczynski 1997

Reason for exclusion	Clinical trial of the effects of breast feeding

Wilder-Smith 2003

Reason for exclusion	Description of risk factors in aircraft

Wilder-Smith 2005

Reason for exclusion	Descriptive review

Wong 2005

Reason for exclusion	Attitude survey

Yu 2004

Reason for exclusion	Description of transmission

Zamora 2006

Reason for exclusion	Head-to-head comparison of two sets of PPEs with no controls and no clinical outcomes

Zhai 2007

Reason for exclusion	Non-comparative study

Zhao 2003

Reason for exclusion	CCT of SARS treatment

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Data and analyses

Case control studies

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Thorough disinfection of living quarters	1	990	Odds Ratio (M-H, Fixed, 95% CI)	0.30 [0.23, 0.39]
1.2 Frequent handwashing	6	2077	Odds Ratio (M-H, Fixed, 95% CI)	0.45 [0.36, 0.57]
1.3 Wearing mask	5	1991	Odds Ratio (M-H, Fixed, 95% CI)	0.32 [0.25, 0.40]
1.4 Wearing N95 respirator	2	340	Odds Ratio (M-H, Fixed, 95% CI)	0.09 [0.03, 0.30]
1.5 Wearing gloves	4	712	Odds Ratio (M-H, Fixed, 95% CI)	0.43 [0.29, 0.65]
1.6 Wearing gowns	4	712	Odds Ratio (M-H, Fixed, 95% CI)	0.23 [0.14, 0.37]
1.7 All interventions	2	369	Odds Ratio (M-H, Fixed, 95% CI)	0.09 [0.02, 0.35]

Sources of support

Internal sources

- The Cochrane Collaboration Steering Group, UK

External sources

- NHS R&D programme, UK
- NHMRC, Australia competitive funding 2009

Appendices

CENTRAL search strategy

#1 MeSH descriptor Influenza, Human explode all trees
#2 influenza:ti,ab,kw
#3 flu:ti,ab,kw
#4 MeSH descriptor Common Cold explode all trees
#5 "common cold":ti,ab,kw
#6 MeSH descriptor Rhinovirus explode all trees
#7 rhinovirus*:ti,ab,kw
#8 MeSH descriptor Adenoviridae explode all trees
#9 adenovirus*:ti,ab,kw
#10 MeSH descriptor Coronavirus explode all trees
#11 MeSH descriptor Coronavirus Infections explode all trees
#12 coronavirus*:ti,ab,kw
#13 MeSH descriptor Respiratory Syncytial Viruses explode all trees
#14 MeSH descriptor Respiratory Syncytial Virus Infections explode all trees
#15 respiratory syncytial virus*:ti,ab,kw
#16 respiratory syncythial virus*:ti,ab,kw
#17 MeSH descriptor Parainfluenza Virus 1, Human explode all trees
#18 MeSH descriptor Parainfluenza Virus 2, Human explode all trees
#19 MeSH descriptor Parainfluenza Virus 3, Human explode all trees
#20 MeSH descriptor Parainfluenza Virus 4, Human explode all trees
#21 (parainfluenza or para-influenza or para influenza):ti,ab,kw
#22 MeSH descriptor Severe Acute Respiratory Syndrome explode all trees
#23 (severe acute respiratory syndrome or SARS):ti,ab,kw
#24 acute respiratory infection*:ti,ab,kw
#25 acute respiratory tract infection*:ti,ab,kw
#26 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25)
#27 MeSH descriptor Handwashing explode all trees
#28 (handwashing or hand washing or hand-washing):ti,ab,kw
#29 hand hygiene:ti,ab,kw
#30 (sanitizer* or sanitiser*):ti,ab,kw
#31 (cleanser* or disinfectant*):ti,ab,kw
#32 MeSH descriptor Gloves, Protective explode all trees
#33 MeSH descriptor Gloves, Surgical explode all trees
#34 glov*:ti,ab,kw
#35 MeSH descriptor Masks explode all trees
#36 mask*:ti,ab,kw
#37 MeSH descriptor Patient Isolators explode all trees
#38 MeSH descriptor Patient Isolation explode all trees
#39 (barrier* or curtain* or partition*):ti,ab,kw
#40 negative NEXT pressure NEXT room*:ti,ab,kw
#41 "reverse barrier nursing":ti,ab,kw
#42 MeSH descriptor Cross Infection explode all trees with qualifier: PC
#43 school NEXT closure*:ti,ab,kw
#44 (clos* NEAR/3 school*):ti,ab,kw
#45 mass NEXT gathering*:ti,ab,kw
#46 public NEXT gathering*:ti,ab,kw
#47 ("ban" or "bans" or banned or banning):ti,ab,kw
#48 (outbreak* NEAR/3 control*):ti,ab,kw
#49 distancing:ti,ab,kw
#50 MeSH descriptor Quarantine explode all trees
#51 quarantine*:ti,ab,kw
#52 (#27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51)
#53 (#26 AND #52)

Ovid EMBASE search strategy

1 exp Influenza/
2 influenza.tw.
3 flu.tw.
4 exp Common Cold/
5 common cold.tw.
6 exp Human Rhinovirus/
7 rhinovirus*.tw.
8 exp Adenovirus/
9 adenovirus*.tw.

10 exp Coronavirus/
11 coronavirus*.tw.
12 exp Respiratory Syncytial Pneumovirus/
13 respiratory syncytial virus*.tw.
14 respiratory syncythial virus.tw.
15 (parainfluenza or para-influenza or para influenza).tw.
16 exp Severe Acute Respiratory Syndrome/
17 (severe acute respiratory syndrome or SARS).tw.
18 acute respiratory infection*.tw.
19 acute respiratory tract infection*.tw.
20 or/1-19
21 exp Hand Washing/
22 (handwashing or hand washing or hand-washing).tw.
23 hand hygiene.tw.
24 (sanitizer$ or sanitiser$).tw.
25 (cleanser$ or disinfectant$).tw.
26 exp Glove/
27 exp Surgical Glove/
28 glov*.tw.
29 exp Mask/
30 mask*1.tw.
31 patient isolat*.tw.
32 (barrier* or curtain* or partition*).tw.
33 negative pressure room*.tw.
34 reverse barrier nursing.tw.
35 Cross Infection/pc [Prevention]
36 school closure*.tw.
37 (clos* adj3 school*).tw.
38 mass gathering*.tw.
39 public gathering*.tw. (5)
40 (ban or bans or banned or banning).tw.
41 (outbreak* adj3 control*).tw.
42 distancing.tw.
43 quarantine*.tw.
44 or/21-43
45 20 and 44

EBSCO CINAHL search strategy

S26 S10 and S24
S25 S10 and S24
S24 S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22 or 23 or S24
S23 TI outbreak* N3 control* or AB outbreak* N3 control*
S22 TI (school closure* or mass gathering* or public gathering* or ban or bans or banned or banning or
distancing or quarantine*) or AB (school closure* or mass gathering* or public gathering* or ban or bans or
banned or banning or distancing or quarantine*)
S21 TI (patient isolat* or barrier* or curtain* or partition* or negative pressure room* or reverse barrier nursing)
or AB (patient isolat* or barrier* or curtain* or partition* or negative pressure room* or reverse barrier nursing)
S20 TI (glov* or mask*) or AB (glov* or mask*)
S19 TI (handwashing or hand washing or hand-washing or hand hygiene) or AB (handwashing or hand washing
or hand-washing or hand hygiene)
S18 (MH "Quarantine")
S17 (MM "Cross Infection")
S16 (MH "Isolation, Reverse")
S15 (MH "Patient Isolation+")
S14 (MH "Respiratory Protective Devices")
S13 (MH "Masks")
S12 (MH "Gloves")
S11 (MH "Handwashing+")
S10 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9
S9 TI (influenza or flu or rhinovirus* or adenovirus* or coronavirus* or respiratory syncytial virus* or respiratory
syncythial virus* or parainfluenza or para-influenza or para influenza or severe acute respiratory syndrome or
SARS or respiratory viral infection* or viral respiratory infection*) or AB (influenza or flu or rhinovirus* or
adenovirus* or coronavirus* or respiratory syncytial virus* or respiratory syncythial virus* or parainfluenza or
para-influenza or para influenza or severe acute respiratory syndrome or SARS or respiratory viral infection* or
viral respiratory
infection*)TI (influenza or flu or rhinovirus* or adenovirus* or coronavirus* or respiratory syncytial virus* or
respiratory syncythial virus* or parainfluenza or para-influenza or para influenza or severe acute respiratory
(syndrome or SARS or respiratory viral infection* or viral respiratory infection*) or AB (influenza or flu or
rhinovirus* or adenovirus* or coronavirus* or respiratory syncytial virus* or respiratory syncythial virus* or
parainfluenza or para-influenza or para influenza or severe acute respiratory syndrome or SARS or respiratory
viral infection* or viral
respiratory infection*)

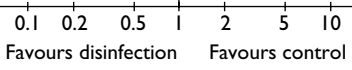
S8 (MH "SARS Virus")
S7 (MH "Severe Acute Respiratory Syndrome")
S6 (MH "Respiratory Syncytial Virus Infections")
S5 (MH "Respiratory Syncytial Viruses")
S4 (MH "Coronavirus+")
S3 (MH "Coronavirus Infections+")
S2 (MH "Common Cold")
S1 (MH "Influenza+")

Graphs

Comparison: 1 Case control studies
Outcome: 1 Thorough disinfection of living quarters

Study or sub-category	Cases n/N	Control n/N	OR MH, Fixed, 95% CI	Weight %	OR MH, Fixed, 95% CI
Lau 2004a	154/330	492/660		100.0	0.30 (0.23 to 0.39)
Total (95% CI)	330	660		100.0	0.30 (0.23 to 0.39)

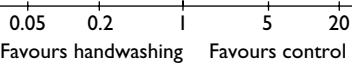
Total events: 154 (Cases), 492 (Control)
Heterogeneity: Not applicable
Test for overall effect: $z = 8.51$ ($p < 0.00001$)



Comparison: 1 Case control studies
Outcome: 2 Frequent handwasling

Study or sub-category	Cases n/N	Control n/N	OR MH, Fixed, 95% CI	Weight %	OR MH, Fixed, 95% CI
Lau 2004a	61/330	222/660		57.3	0.45 (0.32 to 0.62)
Nishiura 2005	15/25	56/90		4.6	0.91 (0.37 to 2.25)
Seto 2003	10/13	227/241		2.5	0.21 (0.05 to 0.83)
Teleman 2004	27/36	46/50		4.6	0.26 (0.07 to 0.93)
Wu 2004	73/94	253/281		13.4	0.38 (0.21 to 0.72)
Yin 2004	28/77	97/180		17.6	0.49 (0.28 to 0.85)
Total (95% CI)	575	1502		100.0	0.45 (0.36 to 0.57)

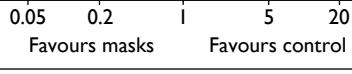
Total events: 214 (Cases), 901 (Control)
Heterogeneity: $\chi^2 = 4.58$, df = 5 ($p = 0.47$); $I^2 = 0\%$
Test for overall effect: $z = 6.56$ ($p < 0.00001$)



Comparison: 1 Case control studies
Outcome: 3 Wearing mask

Study or sub-category	Cases n/N	Control n/N	OR MH, Fixed, 95% CI	Weight %	OR MH, Fixed, 95% CI
Lau 2004a	93/330	388/660		71.9	0.28 (0.21 to 0.37)
Nishiura 2005	8/25	35/90		4.0	0.74 (0.29 to 1.90)
Seto 2003	0/13	51/241		2.1	0.14 (0.01 to 2.34)
Wu 2004	25/94	121/281		17.2	0.48 (0.29 to 0.80)
Yin 2004	68/77	178/180		4.8	0.08 (0.02 to 0.40)
Total (95% CI)	539	1452		100.0	0.32 (0.25 to 0.40)

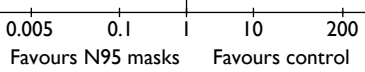
Total events: 194 (Cases), 773 (Control)
Heterogeneity: $\chi^2 = 9.62$, df = 4 ($p = 0.05$); $I^2 = 58\%$
Test for overall effect: $z = 9.52$ ($p < 0.00001$)



Comparison: 1 Case control studies
Outcome: 4 Wearing N95 respirator

Study or sub-category	Cases n/N	Control n/N	OR MH, Fixed, 95% CI	Weight %	OR MH, Fixed, 95% CI
Seto 2003	0/13	92/241		35.6	0.06 (0.00 to 1.02)
Teleman 2004	3/36	23/50		64.4	0.11 (0.03 to 0.39)
Total (95% CI)	49	291		100.0	0.09 (0.03 to 0.30)

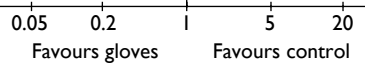
Total events: 3 (Cases), 115 (Control)
Heterogeneity: $\chi^2 = 0.14$, df =1 ($p = 0.70$); $I^2 = 0\%$
Test for overall effect: $z = 3.89$ ($p < 0.0001$)



Comparison: 1 Case control studies
Outcome: 5 Wearing gloves

Study or sub-category	Cases n/N	Control n/N	OR MH, Fixed, 95% CI	Weight %	OR MH, Fixed, 95% CI
Nishiura 2005	8/25	30/90		12.2	0.94 (0.36 to 2.43)
Seto 2003	4/13	117/241		11.4	0.47 (0.14 to 1.57)
Teleman 2004	10/36	22/50		18.3	0.49 (0.20 to 1.23)
Yin 2004	37/77	136/180		58.2	0.30 (0.17 to 0.52)
Total (95% CI)	151	561		100.0	0.43 (0.29 to 0.65)

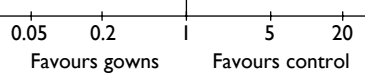
Total events: 59 (Cases), 305 (Control)
Heterogeneity: $\chi^2 = 4.33$, df = 3 ($p = 0.23$); $I^2 = 31\%$
Test for overall effect: $z = 4.07$ ($p < 0.0001$)



Comparison: 1 Case control studies
Outcome: 6 Wearing gowns

Study or sub-category	Cases n/N	Control n/N	OR MH, Fixed, 95% CI	Weight %	OR MH, Fixed, 95% CI
Nishiura 2005	2/25	25/90		12.8	0.23 (0.05 to 1.03)
Seto 2003	0/13	83/241		11.3	0.07 (0.00 to 1.20)
Teleman 2004	5/36	13/50		12.0	0.46 (0.15 to 1.43)
Yin 2004	27/77	128/180		63.9	0.22 (0.12 to 0.39)
Total (95% CI)	151	561		100.0	0.23 (0.14 to 0.37)

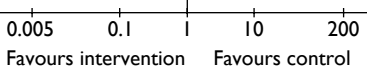
Total events: 34 (Cases), 249 (Control)
Heterogeneity: $\chi^2 = 2.10$, df = 3 ($p = 0.55$); $I^2 = 0\%$
Test for overall effect: $z = 5.99$ ($p < 0.00001$)



Comparison: 1 Case control studies
Outcome: 7 All interventions

Study or sub-category	Cases *n/N*	Control *n/N*	OR MH, Fixed, 95% CI	Weight %	OR MH, Fixed, 95% CI
Nishiura 2005	2/25	44/90		70.6	0.09 (0.02 to 0.41)
Seto 2003	0/13	69/241		29.4	0.09 (0.01 to 1.57)
Total (95% CI)	38	331		100.0	0.09 (0.02 to 0.35)

Total events: 2 (Cases), 113 (Control)
Heterogeneity: $\chi^2 = 0.00$, df = 1 ($p = 0.99$); $I^2 = 0\%$
Test for overall effect: $z = 3.48$ ($p = 0.0005$)



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The Correspondence Page on the HTA website (www.hta.ac.uk) is a convenient way to publish your comments. If you prefer, you can send your comments to the address below, telling us whether you would like us to transfer them to the website.

We look forward to hearing from you.

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