Venkatesan, Sudhir and Myles, Puja Runa and McCann, Gerard and Kousoulis, Antonis A. and Hashmi, Maimoona and Belatri, Rabah and Boyle, Emma and Barcroft, Alan and van Staa, Tjeerd Pieter and Kirkham, Jamie J. and Nguyen-Van-Tam, Jonathan S. and Williams, Timothy J. and Semple, Malcolm G. (2015) Development of processes allowing near real-time refinement and validation of triage tools during the early stage of an outbreak in readiness for surge: the FLU-CATs Study. Health Technology Assessment, 19 (89). pp. 1-132. ISSN 1366-5278

Development of processes allowing near real-time refinement and validation of triage tools during the early stage of an outbreak in readiness for surge: the FLU-CATs Study

Sudhir Venkatesan,[1†] Puja R Myles,[1†] Gerard McCann,[2] Antonis A Kousoulis,[2] Maimoona Hashmi,[2] Rabah Belatri,[2] Emma Boyle,[2] Alan Barcroft,[2] Tjeerd Pieter van Staa,[3] Jamie J Kirkham,[4] Jonathan S Nguyen Van Tam,[1] Timothy J Williams[2] and Malcolm G Semple[4*]

[1]Division of Epidemiology and Public Health, University of Nottingham, Nottingham, UK
[2]Clinical Practice Research Datalink, Medicines and Healthcare products Regulatory Agency, London, UK
[3]University of Manchester, Manchester, UK
[4]Institute of Translational Medicine, University of Liverpool, Liverpool, UK

*Corresponding author
†Joint first authors

Declared competing interests of authors: SV, PRM, GMcC, AAK, MH, RB, EB, AB, TPvS, JJK, JSNVT, JSW and MGS were in receipt of grants from the National Institute for Health Research (NIHR), both for the conduct of this study and others. In addition, PRM reports grants from F. Hoffman La Roche outside the submitted work, and TPvS has participated in expert meetings with GlaxoSmithKline and Boehringer (not related to flu) and has provided methodological advice to Laser (including an observational study on the incidence of flu). The Clinical Practice Research Datalink is a joint venture between the UK Medicines and Healthcare products Regulatory Agency and NIHR.

Published October 2015
DOI: 10.3310/hta19890

Scientific summary

The FLU-CATs Study

Health Technology Assessment 2015; Vol. 19: No. 89
DOI: 10.3310/hta19890

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

During pandemics of novel influenza and outbreaks of other emerging infections, surge in health-care demand can exceed capacity to provide normal standards of care. During surge, workload pressures may limit the time available for clinical decision-making and health-care worker absence because of personal sickness, or caring for dependants, may limit the skill mix. Imaging and laboratory services may also be limited. Health-care workers who are unfamiliar with clinical assessment and admission decision-making may be asked to fulfil 'gatekeeper' roles. In such exceptional circumstances, triage tools may aid decisions in identifying people who are most likely to benefit from higher levels of care.

Provisional UK Emergency Planning Guidance published in 2007 suggested the use of the CURB-65 pneumonia score and the Pandemic Medical Early Warning Score (PMEWS) for hospital triage of adults, but did not address the needs of children. Recognising this gap, a 'toolkit' of national guidance was developed in 2008 by the Department of Health for the UK, which included the newly developed Community Assessment Tools (CATs) for both children and adults in primary and secondary care, and matched hospital care pathways. The validity and utility of using triage tools in the community to aid management decisions during a pandemic remains untested. Both PMEWS and CATs were developed specifically with this purpose in mind and so we aimed to capture the criteria that would allow validation of these tools in this study.

The validity and utility of triage tools needs to be assessed in a large community-based prospective study of patients presenting with influenza-like illness (ILI), to give confidence to general practitioners (GPs) who may be asked to use such tools in the event of surge, and policy-makers who may need to recommend their use to GPs. Validation of a triage tool for use in an outbreak of a novel disease requires rapid research during the early phase of that outbreak. Rapid research should allow refinement and validation of triage tools so that in the event of surge a valid tool is available.

Objectives

1. *In preparation for conducting rapid research in the early phase of a future outbreak* To develop information technology (IT) infrastructure and processes that allow near real-time analysis of GP assessments of people presenting with ILI, and GP management decisions and patient outcomes.
2. *As proof of concept and to test processes* To conduct a pilot study evaluating the performance of the triage tools 'CATs' and 'PMEWS' in predicting hospital admission and death in patients presenting with ILIs to GPs during inter-pandemic winter seasons.
3. To conduct a prospective near real-time analysis of structured clinical assessments for ILI using primary care electronic health records (EHRs) during a pandemic.

This report addresses only the first two objectives, involving preparatory work that would make the third objective feasible in the event of a pandemic.

Methods

Aim

The overarching study aim is to conduct a prospective near real-time analysis of structured clinical assessments of ILI using primary care EHRs during a pandemic. This report covers the preparatory work, that is, IT infrastructure development, user testing and pilot study as 'proof of concept'.

Design

The proof-of-concept study involved setting up and piloting a prospective near real-time analysis of structured clinical assessments and anonymised linkage to data from EHRs. User (GP) experience was evaluated by semistructured interviews. Processes were also developed for retrospective validation of outcome events using Hospital Episode Statistics (HES) and Office for National Statistics (ONS) mortality data.

Setting

Thirty GPs in England, Wales and Scotland participating in the Clinical Practice Research Datalink (CPRD) using the Vision® version 3.01 (In Practice Systems Ltd, London, UK) EHR.

Participants

All people presenting with ILIs to participating GPs.

Interventions

None.

Main outcome measures

Study outcome is proof of concept through demonstration of data capture, appropriateness of data definitions and near real-time analysis. Primary patient outcomes are hospital admission within 24 hours and death (all causes) within 30 days of GP assessment. Secondary patient outcomes included GP decision to prescribe antibiotics and/or influenza-specific antivirals and/or refer to hospital, need for higher levels of care if admitted, and length of hospital stay.

Data sources

Linked anonymised data from a study-specific web-based structured clinical assessment and primary care patient EHRs. Retrospective validation of hospital admission was planned using HES, and mortality data validation was planned using ONS data.

Results

In the 24 months prior to April 2015, data from 704 adult and 159 child consultations to 30 GPs were captured. Influenza activity during these two winter seasons was low. GPs decided to refer 11 (1.6%) adults and 6 (3.8%) children to hospital. There were 13 (1.8%) deaths among adults and 2 (1.3%) among children. There were too few outcome events from which to draw any conclusions regarding the performance of the triage tools; however, the data captured allowed testing of almost all analytical algorithms and demonstrated proof of concept.

Data relating to each GP consultation were uploaded on to the CPRD database every night. The CPRD team then collated these data and sent weekly data to researchers based at the Universities of Nottingham and Liverpool. Additionally, on a monthly basis, the CPRD team sent background data (comorbidities, prescriptions, death, etc.) sourced from the EHRs for all patients with captured consultations. Each subsequent data instalment comprised the cumulative data acquired since the initiation of the study. Validation of outcome events with HES and ONS data was not possible for inclusion in this interim report because of a moratorium on provision of this data by the Health and Social Care Information Centre.

Six participating GPs agreed to be interviewed about their user experience. The main finding that emerged from these interviews was that the Local Eligibility Patient Identification Software (LEPIS) and web-based electronic Case Report Forms (eCRFs) were easy to use. The simplicity of the eCRFs encouraged GPs to participate in the study despite there not being any financial incentive for participation.

The GPs reported that the triage process of the consultation was quite easy to conduct and did not interfere with the routine GP consultation. Several GPs felt that a monetary incentive, even if small, would be necessary to increase GP participation in the study unless there was a statutory requirement to systematically collect data on all possible influenza cases during a pandemic. All interviewed GPs agreed that the FLU-CATs eCRF, with a few modifications, was ready to be used in a pandemic scenario. However, the setting up of the LEPIS system to enable data collection for the study was fraught with technical difficulties and not compatible with other EHR systems in use in the UK. Both these points are important limitations that would prevent a rapid national level rollout beyond the 650 plus practices currently using the Vision® EHR platform. Any decision aid based on the validated criteria could better be delivered separately on an open web-based platform or mobile phone 'app'.

Lessons learnt from the data analysis included that up to 74% of some clinical measurements (blood pressure in adults in this instance) were not recorded as part of GP's routine assessment of an adult person presenting with ILI. We would question the utility and adoption of triage tools that depend upon a clinical measurement that is not used in the routine assessment of ILI for use in a time-pressured pandemic situation.

Conclusions

The use of EHRs linked to study-specific data capture forms increased the comprehensiveness, validity and usability of data; pre-prepared analytical processes allowed near real-time analysis of GP assessments, management decisions and patient outcomes on a weekly basis. The processes are dynamic and should allow refinement of triage criteria in the early stages of a future outbreak.

Future work

We will test the effect of minimal remuneration on recruitment in future seasons, develop processes to include other EHR systems, attempt linkage to data on influenza surveillance and maintain processes in readiness for a future outbreak.

Study registration

This study is registered as ISRCTN87130712 and UK Clinical Research Network 12827.

Funding

The National Institute for Health Research Health Technology Assessment programme. MGS is supported by the UK NIHR Health Protection Research Unit in Emerging and Zoonotic Infections.

Health Technology Assessment

HTA/HTA TAR

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 5.116

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: nihredit@southampton.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the *Health Technology Assessment* journal

Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers 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.

HTA programme

The HTA programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It 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 journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

For more information about the HTA programme please visit the website: http://www.nets.nihr.ac.uk/programmes/hta

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 11/46/22. The contractual start date was in January 2013. The draft report began editorial review in June 2015 and was accepted for publication in August 2015. 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 reviewers 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.Should the study progress further, the full report will be published in the HTA journal.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).