

**Cardiff University  
School of Medicine**

**The development and evaluation of an interactive  
booklet for use in primary care consultations with  
children with respiratory tract infections**

by

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*This work is dedicated to my family, Emma, Megan and Elen. Thank you for your patience, love and support.*

## **Summary (300 words)**

Respiratory tract infections are the most common reason for children to consult, and be prescribed antibiotics, in primary care. Parental anxiety and misinformation can contribute to increased consulting which, combined with perceived expectations for antibiotics, can increase prescribing. Clinicians are exhorted to rationalise antibiotic prescribing, but lack evidence-based tools to achieve this. Patient education using printed materials presented by a healthcare professional has been shown to reduce reconsulting and antibiotic prescribing. I developed an interactive booklet on respiratory tract infections in children for use in primary care consultations, and training in its use. The booklet aims to address unrealistic expectations about symptom duration and antibiotic effectiveness, and increase parental empowerment by prompting clinicians to address parental concerns and expectations, and providing information about treatment options, and features that should prompt reconsultation. Booklet development was guided by behaviour change theories and guidance on developing patient materials. It involved summarising relevant scientific evidence and consulting with parents and clinicians through focus groups, and other professionals (graphic designer and a literacy expert). The intervention (booklet and training in its use) was compared with usual care in a cluster randomised controlled trial. 83 practices were randomised and 61 recruited 557 children with an acute RTI. Reconsulting, antibiotic prescribing, and parental satisfaction, enablement, and other outcomes were assessed via a telephone interview at two-weeks. Use of the intervention resulted in a non-statistically significant reduction in reconsulting, a statistically significant and clinically meaningful reduction in antibiotic prescribing (OR 0.27, 95% CI 0.14 to 0.60), and no statistically significant difference in enablement, satisfaction, reassurance, or consulting over the following year. There was no statistically significant difference in total cost between study arms. Changes in clinicians' beliefs about the importance of rationalising prescribing, and using the booklet as an aide-memoir, and to support a non-prescribing approach, appear to be responsible for the reduction in prescribing.

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## ABBREVIATIONS USED IN THIS THESIS

BNF	British National Formulary
CB	Chris Butler (supervisor)
CI	Confidence interval
CRF	Case report form
DPCPH	Department of Primary Care and Public Health
DPCPH	The Department of Primary Care and Public Health, Cardiff University
FW	Fiona Wood (supervisor)
GP	General practitioner
HSW	Health Solutions Wales
ICC	Intra-cluster correlation coefficient
IGLS	Iterative Generalised Least Squares
IQR	Inter-quartile range
JN	Jacqui Nuttall
KH	Kerry Hood (supervisor)
LHB	Local Health Board
LRTI	Lower respiratory tract infection
MCMC	Monte-Carlo Markov Chain
MQL	Marginal Quasi Likelihood
NF	Nick Francis (the candidate)
NNT	Number needed to treat
OOH	Out of hours
OR	Odds ratio
PAU	Paediatric Assessment Unit
PCRN	Primary Care Research Network
PCT	Primary Care Trust
PQL	Penalised Quasi Likelihood
RTI	Respiratory tract infection
SD	Standard deviation
SE	Standard error
SES	Socio-economic status
SMG	Study management group
SS	Sharon Simpson (supervisor)
TSC	Trial Steering Committee
UCHSC	Unit costs for health and social care
UK	United Kingdom
UKCRN	United Kingdom Clinical Research Network
URTI	Upper respiratory tract infection



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# 1 Introduction

The work in this thesis is about respiratory tract infections (RTI) in children. Throughout the thesis I will use this as a collective term for a group of common infections of the respiratory tract. These include: the common cold, influenza, sore throat, acute tonsillitis, acute sinusitis, acute otitis media, and infections of the airways and lung parenchyma. However, I need to express a note of caution about influenza. Normal seasonal influenza can be difficult to distinguish clinically from other causes of respiratory tract infections in children, and there is no reason to believe that the work in this thesis should not apply to seasonal influenza infections. However, during the period in which this thesis was being written a global influenza pandemic emerged, and it should be made clear that the evidence discussed in this thesis, and indeed the results of the studies in this thesis, cannot be applied to a pandemic situation with any degree of certainty.

## 1.1 Search strategy

I conducted searches of the scientific literature in order to identify evidence relevant to this thesis. First, I conducted a comprehensive search for journal articles about the use of printed educational materials (leaflets, etc.) about RTIs in children (see appendix 1 for search terms). The search was conducted in MEDLINE (1950 – October 2009), All EBM Reviews (Cochrane DSR, ACP Journal club, DARE, CCTR, CMR HTA, NHSEED), EMBASE (1980 – 2008), and PsycINFO (2002 – 2008), using the OVID platform. No restrictions on the type of scientific paper were used (i.e. all study types, review articles, editorials, etc. were included). No language restrictions were applied, but there were no foreign language papers judged to be of such significance to warrant translation into English. This search resulted in 40 papers. 28 of these were excluded because they did not relate to acute RTIs, or were not about the provision of written information. This left 12 papers (9 trials, 2 qualitative studies, and 1 description of the development of a behaviour change intervention). The references of all these papers were reviewed for additional references. In addition, I conducted a secondary search, for journal articles about printed materials *or patient education* about RTIs in primary care (see appendix 1 for search terms), and a number of tertiary (or context) searches (Table 1.1). Search terms used for the main search and secondary search are included in appendix 1. I reviewed

the article titles and abstracts (where relevant) for all search results, and obtained the full text of all articles relating to educating patients or clinicians about acute RTIs, the epidemiology of RTIs in children in primary care, and communication skills training for consultations regarding RTIs or the use of antibiotics in primary care. In addition, review papers on antibiotic prescribing for RTIs in primary care, and antibiotic resistance, were reviewed and their references searched for further relevant papers.

**Table 1.1 Literature searches**

<b>Level</b>	<b>Search</b>
1 – Main search	Printed educational materials about RTIs in children
2 – Secondary search	Patient education or printed materials about RTIs in primary care
3 - Context	Epidemiology (including consulting behaviour) for RTIs in primary care
3 - Context	Antibiotic prescribing for RTIs in primary care
3 - Context	Antibiotic resistance
3 - Context	Consultation / communication skills and RTIs
3 - Context	Behaviour change theories
3 - Context	Developing patient educational materials

## **1.2 Respiratory tract infections in children**

RTIs in children in resource rich countries are problematic in that they are common, and although largely minor, self-limiting illnesses, they are a significant cause of anxiety for parents, primary health care resource use, and widespread (unnecessary) antibiotic use. Rarely, these illnesses can progress rapidly causing serious illness and death.

### **1.2.1 Incidence of respiratory tract infections in children**

Cohort studies from the UK,(1) The Netherlands,(2) Germany,(3) and Australia,(4) have shown how common respiratory symptoms are in children. In a birth cohort in the UK, 100% of children had experienced symptoms by the time they were nearly five years old, and cough, cold, and high fever were among the most common symptoms reported.(1) Other studies have shown that children experience a median of

5 RTIs in the first year of life,(2) and 3.4 and 2.3 episodes per year in the second and third years of life respectively.(3)

### **1.2.2 Consulting and parental anxiety**

Parents manage the majority of symptoms in young children without consulting with a health care professional.(1, 5, 6) However, RTIs frequently result in distress and anxiety for parents. Qualitative studies have shown that parents often perceive acute illnesses as a serious threat to their child's health.(7-9) They worry that they will not be able to recognise the symptoms of serious illness,(9) and worry that their child may die,(9) especially during the night.(8) Fever is a particularly frequent cause of anxiety amongst parents,(10) leading some experts to describe these emotions as 'fever phobia'.(11) Less experienced parents are especially prone to high levels of anxiety about RTIs in their children.(7)

One of the challenges for parents is deciding whether, and at what point, they should consult with a healthcare professional. Respiratory symptoms are the most common reason for children to consult,(1) and children have higher consultation rates for acute RTIs than any other age group, with under fives consulting at more than double the rate of adults.(12) Two analyses from a Dutch birth cohort found that around half of all children consulted for respiratory symptoms during the first year of life.(13, 14) Furthermore, as many as one in every five children who consult for an RTI re-consult during the same illness episode,(15, 16) a figure which has changed little over the past 30 years.(17)

Such high levels of consulting clearly have important implications for health service utilisation, and have costs for parents in terms of time and transportation. Small reductions in consulting (or reconsulting) for such common conditions could result in important savings in the use of primary health care (and parent) resources. In addition, high consultation rates, and in particular high reconsultation rates, suggest that there may be room to help empower parents so that they feel more able to manage these (largely) self-limiting illnesses with confidence at home. Parents with high levels of concern about infectious illnesses are more likely to consult and be prescribed antibiotics for their child,(18) and consultation rates for children tend to decrease as parents become more experienced (have more children).(1) This suggests that

measures to increase parental knowledge and confidence may result in reduced consulting (and prescribing) for these common illnesses.

A further issue is that consulting with a healthcare professional does not necessarily relieve parental anxiety. Indeed, for some parents it results in even greater anxiety, confusion, and frustration.(19) Failure to provide parents with information about the definition, consequences, and treatment of fever has been shown to be associated with increased levels of parental concern.(20)

For some parents, anxiety is related more to misinformation, conflicting messages, and a sense of powerlessness or loss of control,(9, 19) than a reaction to a real threat. A qualitative study of 32 parents from a disadvantaged area, reported parents feeling disempowered and helpless when their children were acutely ill.(19) They worried about their children and wanted to be actively treating them, but were uncertain about how to assess illness severity and what was likely to help their child. They wanted to share their anxiety with a professional but feared 'bothering' the doctor unnecessarily. Concern about 'bothering' the doctor,(5, 21) and feelings disempowerment and anxiety,(22) are themes that have been identified in other studies on this topic.

### **1.2.3 Antibiotics for respiratory tract infections in primary care**

Another major concern regarding the management of RTIs is the widespread use of antibiotics for these illnesses. Most RTIs are caused by viruses,(16) and outcomes are not improved by antibiotics. Evidence for the effectiveness of antibiotics for most common RTIs are summarised in Table 1.2. These show that antibiotics confer minimal or no detectable benefit for most individuals when treating the common cold,(23) sore throat,(24) otitis media,(25, 26) sinusitis,(27) or acute bronchitis.(28) As a result, the recent UK guideline from the National Institute for Health and Clinical Excellence (NICE)(29) recommend not prescribing (or providing a delayed prescription) for most RTIs in adults and children (3 months or older).

Table 1.2 - Summary of Cochrane Reviews of antibiotic use for RTIs

	<b>Number of trials</b>	<b>Number of patients</b>	<b>Adults (A) Children (C) or Both adults &amp; children (B)</b>	<b>Outcome of interest</b>	<b>Risk ratio (95% CI)</b>	<b>Number needed to treat (95% CI)</b>	<b>Reference</b>
Common cold	6	1147	B	Persistence of symptoms	0.89 (0.77 to 1.04)		(23)
Sore throat	27	12835	B	Sore throat and fever at day 3 (greatest benefit)	0.68 (0.59 to 0.79)	6 (4.9 to 7)	(24)
Otitis media	8	2287	C	Pain at day 2-7		15 (11 to 24)	(26)
Sinusitis	5	631	A	Lack of cure or improvement at 7-15 days	0.66 (0.44 to 0.98)		(27)
Acute bronchitis	5	478	B	Limitation in work or activities at follow up	0.75 (0.46 to 1.22)		(28)
Bronchiolitis	1	52	C	Duration of symptoms	Effect size not estimable - no significant difference found		(48)

### **1.2.3.1 Use of antibiotics in primary care**

Despite the evidence of marginal benefit from antibiotic treatment for most RTIs, they continue to be the most common reason for prescribing systemic antibiotics in primary care,(30) with children receiving more antibiotics than any other age group.(31, 32)

The use of antibiotics in the developed world increased year on year up to the mid nineties, when the trend started to reverse.(33) In the United Kingdom, in 1994, 79% of consultations for RTIs resulted in a prescription for an antibiotic,(34) by 2000 it had reduced to 67%.(34) However, despite this overall reduction, prescribing continued to be high for many RTIs. For example, 81% of consultations for ear infections, 60% of consultations for sore throat, and 88% of consultations for 'tonsillitis' still ended with a prescription for an antibiotic.(34)

However, prescribing rates appear to be increasing again. A study examining antibiotic prescribing trends for children in the UK found a decline of 24% between 1996 and 2000, but an increase of 10% between 2003 and 2006. The authors report that this was primarily as a result of increased prescribing for non-specific upper respiratory tract infection.(35)

Similar changes in prescribing have been reported in other countries. Overall antibiotic prescribing, and antibiotic prescribing for RTIs, for children and adolescents decreased between 1989/90 and 1999/2000 in the United States.(36) However, at the end of this period 68% of consultations for acute RTIs still resulted in a prescription for antibiotics, and 80% of these were deemed inappropriate by Center for Disease Control (CDC) criteria.(37) In a study of children in the late 1990's, almost half of those consulting with upper respiratory tract infections were prescribed antibiotics.(38) Using similar data from the nineties, it was estimated that in the United States there were approximately 6.5 million antibiotic prescriptions for upper respiratory tract infections (URTIs) in children issued every year.(39) In Sweden, consultation rates for RTIs declined between 1999 and 2005, but the proportion of patients receiving an antibiotic prescription remained the same.(40) Even in The

Netherlands, which has the lowest level of antibiotic prescribing in Europe,(41) there is considerable room for improving the quality of antibiotic prescribing.(13, 42, 43)

Variation in antibiotic prescribing can be a useful marker of inappropriate use. Some variation can be expected, indeed desired. However, studies have demonstrated that there is wide variation between countries(41, 44) and between practices within countries.(45, 46) Furthermore, not all of this variation can be accounted for by socio-demographic differences,(47) or is associated with variation in outcomes. Variation in antibiotic prescribing also results in confusion and frustration amongst patients and parents.(19)

### **1.2.3.2 Antibiotic resistance**

One of the main concerns regarding the overuse of antibiotics is the public health threat posed by the development of antimicrobial resistance.(49) There is now a strong evidence base linking antibiotic prescribing with the prevalence of resistance. Observational studies have found associations between prescribing and resistance at the level of the country,(41) and general practice.(50) In individuals, recent antibiotic use is associated with resistant isolates found in urine samples.(51) In addition, there is evidence from a randomised controlled trial that taking a macrolide antibiotic is associated with pharyngeal colonisation with macrolide resistant strains of streptococci.(52) In children there is also evidence of an association from observational studies at a regional level,(53, 54) and in individuals.(55) A review of studies linking antibiotic use with resistance and examining for evidence of bias and confounding that was published in 2001 concluded that the association was likely to be causal.(56)

There is also increasing evidence that reducing antimicrobial consumption results in a reduction in antibiotic resistance. Studies from Finland,(57) France,(58, 59) and Belgium(60) have all demonstrated reductions in resistance following campaigns that resulted in reduced antibiotic prescribing. A recent seven year UK study examined resistance to ampicillin and trimethoprim in urinary coliform isolates and found a statistically significant reduction in levels of resistance in practices with the greatest reduction in antibiotic prescribing compared to practices with the least reduction in antibiotic prescribing.(61)

The importance of antibiotic resistance as a public health problem has been recognised by the World Health Organisation,(62) and national governments. A number of important UK governmental reports have highlighted the problem,(63) including a report from the Standing Medical Advisory Committee for the House of Lords which recommended a reduction in antibiotic prescribing in primary care as a key priority.(64) Antibiotic resistance is not only a public health threat, there is now evidence from primary care at an individual level that urinary infections caused by resistant organisms are associated with worse outcomes.(65) However, despite health education campaigns, many primary care patients have limited awareness of antibiotic resistance,(66) limited understanding of the nature and causes of resistance, and low perceptions of the importance of their role in combating the problem.(67, 68)

### **1.2.3.3 The medicalising effect of prescribing**

Unnecessary antibiotic prescribing not only wastes resources, exposes patients to the risk of adverse reactions, and increases antibiotic resistance, it is also associated with increased future consulting. Evidence from studying routinely collected general practice data,(45) and from trials,(69) suggest that prescribing antibiotics for self-limiting infections encourages consulting for similar illnesses in the future, thus further increasing the cycle of consulting and prescribing.

## **1.3 Evidence for reducing consultations for RTIs in children**

I will now review the current scientific evidence about factors that are likely to influence consulting behaviour for RTIs in children, and interventions that have attempted to reduce consulting for RTIs.

### **1.3.1 Factors likely to influence consulting behaviour**

#### **1.3.1.1 Parental knowledge and beliefs**

Many parents lack knowledge about the likely risks and benefits of antibiotic treatment, and the normal duration of respiratory illnesses.(70) Some have beliefs about the causes of RTIs(70-72), the meaning of symptoms(73, 74), and the effectiveness of medications(70, 71, 74-76), that are at odds with accepted biomedical views. For example, in a telephone survey of parents and other adults who had



recently consulted for an RTI, half thought that 'bacteria' or 'bacteria and viruses' were the cause of colds, a quarter thought that getting wet or chilled caused a cold, 12% thought that colds would not resolve on their own, and around 70% thought that vitamin C and steam were beneficial in treating a cold.(70) All of these beliefs are contrary to available evidence.

Mistaken beliefs and a lack of knowledge contribute to anxiety amongst parents and increased levels of consulting. For example, cohort studies have shown that RTIs in children last longer than most parents expect (up to ten days for URTIs,(77) and up to four weeks for a cough(78)), and a parental perception that the illness has lasted longer than expected is an important driver of consulting.(79) However, clinicians seldom discuss likely duration of illness, and when they do they frequently predict it to be brief.(80)

In addition, beliefs about the effectiveness of antibiotics can influence consulting. Parental beliefs about antibiotics and expectations for antibiotics, and the relationship between prescribing and consulting, are explored in section 1.4.1.

### **1.3.1.2 Consultation skills**

Consulting with a healthcare professional can leave parents feeling informed and empowered. However, some consultations leave parents feeling uninformed and uncertain,(19) or create a sense of dependency. In studies that have involved interviewing parents about consulting for RTIs in their children, parents have reported receiving insufficient information, including not being told their child's diagnosis, not being given information about drugs their child was prescribed, and not being given information about non-drug options.(81) They also report feeling excluded from the 'mystique' of professional assessment of their child's illness.(19) The difference between the way parents and clinicians assess children may account for some of the discordance. Mothers tend to judge illness in their children by changes in behaviour that deviate from perceived norms, whereas clinicians tend to look for 'hard' findings and make diagnoses.(82) Clinicians need to draw on a range of general and specific communication skills and adopt an appropriate consulting style (model) in order to achieve best practice.

### **1.3.2 Evaluations of interventions to reduce consulting for RTIs**

No systematic reviews of interventions aimed at reducing consulting for RTIs in children were identified. Evaluations of educational interventions for parents, aimed at reducing consulting, include: face-to-face educational encounters, booklets on minor illnesses sent to homes, a symptom scoring system for infants, and training doctors to provide counselling to parents. In addition, a study evaluating the effect of a leaflet about LRTI in adults on reconsulting was identified. These studies will now be described.

#### **1.3.2.1 Face-to-face educational encounters**

McWilliams et al. evaluated the effect of an educational intervention on acute otitis media (AOM) on consultation rates in the United States.<sup>(83)</sup> Parents of children attending a 15-month well child visit were provided with a 5-10 minute nurse-run educational session (with the aid of PowerPoint slides), backed up by written materials, and a prescription for analgesic eardrops. During the following 12-month period, there was an 80% reduction in emergency department visits for ear pain, a 40% reduction in urgent care visits for ear pain, and a 28% reduction in primary care visits for ear pain in the intervention area. In the control area there were no significant reductions.

A study from the United Kingdom evaluated the effect of an educational visit, and a booklet about minor illnesses in children, delivered to parents of new babies by a nurse educator. Parents who received the intervention displayed an increase in knowledge and confidence, and a reduction in intention to consult, but no difference in health service usage.<sup>(84)</sup>

Another study from the United States examined the effect of providing a four-page educational leaflet on the common cold, along with an adhesive guide about when to call the clinic, and an oral thermometer.<sup>(85)</sup> The materials were provided in a brief educational session run by a health educator for adults attending the clinic for any reason. They found that use of this intervention was associated with a statistically significant 29% reduction in consultations for RTI by family members of the adult who had received the intervention, and a 44% reduction in consultations for RTI that

were deemed to be 'inappropriate'. However, the results of this study must be interpreted with caution as it was limited by non-random allocation and post allocation exclusion of patients.

Finally, a study in a single group practice in the United States allocated parents to either an 'educational interview' on the interpretation and management of fever, and were sent a leaflet on fever two months later, or a control group who receive no intervention. Knowledge about fever increased in both groups, with no difference between groups. The authors also reported a significant reduction in 'inappropriate' consulting in the intervention group. However, the results of this study also need to be interpreted with caution as the trial was not randomised, and the main outcome was not clearly specified at the start of the trial.(86)

### **1.3.2.2 Minor illness booklets sent to patient's homes**

Six studies have examined the effect of sending booklets on RTIs (and other minor illnesses) to patient's homes. Three European studies, conducted in the seventies and eighties, assessed the use of booklets developed by a local general practitioner and evaluated within a single practice(87-89). The booklets evaluated in these studies appear to be very similar (and may have been the same in two of the studies), being between 15 and 16 pages in length, and providing general information about common symptoms (including common symptoms of RTIs, diarrhoea and vomiting, and minor injuries). In each practice families with young children were randomised to be sent the booklet in the post or not, and the main outcome in each study was primary care service use during the follow-up period (six months or one year). Two studies(87, 89) found no difference in health service use. The third(88) found significantly more self-reported self-care and significantly less patient initiated consultations and home visits in the group who received the booklet. However, the effect size was small, and the fact that it was conducted in a single practice, patient outcomes were self-recorded, total consultations were not reported, and the assessment of statistical significance between the groups is not clearly reported, all make it difficult to interpret the significance of these results.

A study from the early nineties in the United States, randomised 14,916 new enrollees in a state-wide health management organisation (HMO) to receive seven self-care

booklets in the post or control (no booklets sent).(90) They found a short-term (one month) reduction in consultations for colds in the month following distribution of the booklet on colds, but this was not sustained. For sore throat, they found that consultations increased in the months following distribution of the sore throat booklet, and hypothesised that discussion of the risk of rheumatic fever in the booklet may have resulted in an increased level of anxiety about sore throat.

In 2001, a further two studies examining the effects of sending self-care booklets to patients on general practice registers were published.(91, 92) These were both British studies, and both examined the provision of a booklet called, “What Should I Do?” which contained information on 40 common health problems and had previously been used in an health education campaign in The Netherlands. One of these studies randomised 20 practices to use one of two booklets; the “What Should I Do?” booklet or a similar booklet, the “Health Care Manual”, which provided information on 50 common conditions and advice about staying healthy.(91) They then randomised a sample of patients in each practice to receipt of the booklet or control (no booklet). The main outcomes were total health service use over the following year and health service use for minor illnesses. No differences in health service use were found in patients who had been sent either booklet compared with control patients. In the other study, 4002 households randomly selected from the registers of 6 practices in one region of England were randomly assigned to one of three groups: Receipt of the, “What Should I Do?” booklet, receipt of a two-sided summary card giving information on self-management of respiratory infections and other common illnesses, and receipt of a one-page leaflet giving surgery times and how to contact the doctor (control group).(92) They found a statistically significant difference in the proportion of patients consulting frequently (2 or more times) for minor illnesses over the following year in both the booklet group (adjusted OR = 0.81, 95% CI 0.67 to 0.99) and the summary card group (adjusted OR = 0.83, 95% CI 0.72 to 0.96). However, there was no significant difference in overall consultations, consultations for respiratory tract infections, or willingness to wait score.

In summary, the six studies evaluating the use of general ‘self care’ booklets sent to patient’s (or parent’s) homes have demonstrated that this approach has little effect on health care service usage. An editorial accompanying the two most recent studies

suggested that it was not surprising that providing illness information outside of the context of being ill or having a consultation did not reduce prescribing, and that providing written information within the context of the consultation was much more likely to be successful.(93)

### **1.3.2.3 Symptom scoring**

‘Baby Check’ is an illness scoring system for babies aged 6 months or less,(94) that has been found to reduce parental anxiety, increase confidence, and increase a sense of empowerment.(95) However, providing the scoring system to parents appears to have no effect health service utilisation. Thomson et al. randomised 997 newly delivered mothers in 13 practices in Glasgow to receive the booklet or not.(96) General practice notes were used to identify the number of consultations over the first 6 months of each baby’s life, and no difference in consultation rates was found.

### **1.3.2.4 Counseling training for doctors**

A study in India evaluated training doctors to provide educational messages about childhood illnesses to mothers.(97) The doctor’s counseling performance improved, the mothers’ appreciation of the need to seek prompt care for severe childhood illnesses improved, but careseeking behaviour did not improve significantly.

### **1.3.2.5 Leaflet on LRTI in adults**

MacFarlane et al. evaluated the use of a simple leaflet (which provided reassurance and advice on when to reconsult) in 1014 previously-well adults with LRTI, recruited by 76 GPs.(98) In this study, use of the leaflet was associated with a statistically significant reduction in the proportion reconsulting with similar symptoms in the first month (14.9% in the leaflet group and 21.4% in the control group;  $p=0.007$ ).

## **1.3.3 Summary**

The evidence for improving consulting behaviour (increasing ‘appropriate’ consulting or reducing overall consulting) from educational interventions aimed at parents is mixed. The evidence from the six studies evaluating sending booklets on minor illnesses to homes suggests that this approach has little, if any, effect on consulting. Use of a symptom score in babies had no effect on consulting, and neither did training doctors in India to counsel parents about childhood illnesses. A simple leaflet on

LRTI, given out at the end of primary care consultations, significantly reduced reconsultations for the same illness episode. However, this was for adults. The approach that appears to be most effective is providing educational materials in the context of a face-to-face encounter. Three of the four studies that evaluated this approach demonstrated a reduction in consulting (although two of these had methodological flaws).

## **1.4 Evidence for improving antibiotic prescribing for RTIs in children**

### **1.4.1 Factors likely to influence antibiotic prescribing**

The decision to prescribe antibiotics involves a complex process that is influenced by factors related to the patient (and / or parent), the clinician, and the situation. Patient (parent) factors include the nature of the illness, age, co-morbidities and other demographics, and direct and indirect pressure to prescribe antibiotics. The latter is influenced by the patient's (parent's) knowledge, beliefs, expectations, and concerns. Clinician factors include their diagnostic abilities (including clinical skills, and availability of useful diagnostic tests and clinical prediction tools), their knowledge and beliefs, and their communication skills. Situational factors include time and other pressures, and the availability of follow-up (i.e. during weekends and holidays).

In addition, given that in most developed countries antibiotics can only be obtained following a consultation with a healthcare professional, unless left-over antibiotics have been stored at home, or obtained from someone else who has not used them, the factors that influence consulting behaviour (discussed in Section 1.3.1) will also have an impact on antibiotic consumption.

#### **1.4.1.1 Parental knowledge and beliefs**

Parental beliefs about the need for antibiotics are often grounded in their perceptions of the severity and impact of the illness (i.e. on sleeping) rather than on the diagnostic category of their child's illness.<sup>(19)</sup> In addition, some parents believe that antibiotics are simply more potent forms of paracetamol or ibuprofen. As a result, clinicians' 'refusal' to provide antibiotics is often seen as illogical by parents and can result in confusion and disharmony in the consultation.<sup>(19)</sup>

### **1.4.1.2 Parental expectations**

Most patients bring expectations about the nature and outcome of a consultation with them when they consult, and mistaken beliefs and a lack of knowledge can increase the expectation for antibiotics.(73) However, these expectations, whether for antibiotics or not, often remain unvoiced, and this can lead to misunderstandings, unwanted prescriptions, non-use of prescriptions, and non-adherence to treatment.(99)

Studies exploring parental expectations for antibiotics come almost exclusively from the US. These studies have shown relatively high proportions of parents expecting antibiotics, ranging from 30%(100) to around 50-70%(73, 101, 102) of parents consulting for 'cold symptoms' in their child and over 90% of parents consulting for otitis media.(103) However, it is not clear whether expectations for antibiotics are as high in other countries. A study from Israel reported that only 24% of parents consulting for a URTI (excluding otitis media) in their child expected an antibiotic,(104) and in Denmark only 19% of parents attending an out-of-hours clinic with a child experiencing fever or RTI symptoms expected antibiotic treatment.(105) In the UK, around a third of the public expect an antibiotic for RTIs,(106, 107) (21) and it appears that parents are more willing to accept non-antibiotic treatment for their children than for themselves.(21)

Studies have shown that patients who expect antibiotics are significantly more likely to receive them.(75, 108) Furthermore, receiving a prescription for antibiotics increases the expectation for receiving antibiotics in the future,(104) potentially creating a self-perpetuating cycle of increasing expectations and antibiotic prescribing. Some patients do not voice their expectations, but use other methods to 'pressure' a clinician to prescribe, including: suggesting a diagnosis, portraying the severity of the illness, and appealing to their life circumstances.(37) However, antibiotics are not necessarily the main expectation that parents have when they consult. In a survey of patients in 8 countries, aspects most wanted when consulting in primary care were: enough time in consultation, being seen quickly for emergencies, confidentiality, and telling patients all they want to know about their illness.(109) The main expectations of parents attending an out-of-hours centre with a febrile child were: a thorough examination (98%), an explanation or diagnosis (79%), and

guidance or treatment (20%).(105) Adult patients have similar expectations; a study of patients over 12 years old with sore throat found that the highest ranking expectations were for: an examination to establish cause (85.5%), something for pain (84.5%), and an explanation of the likely course of the problem (82.7%).(110) Antibiotics were ranked 11<sup>th</sup> out of 13 items, and only expected by 37.6%.(110)

Unrealistic expectations for antibiotics by parents can influence prescribing, but they are not necessarily the main influence. Clinicians are not good at detecting parental expectations,(101, 111) seldom explicitly ask about them during consultations,(21, 112, 113) and often overestimate the expectation for antibiotics.(114) Furthermore, clinicians' perceptions of an expectation for antibiotics are associated with an even greater likelihood of prescribing(115-118), and with inappropriate prescribing,(111) than actual expectations. Indeed one study showed that while patient expectations were associated with a three-fold increase in the likelihood of receiving a prescription, clinicians' perceptions of expectations were associated with a ten-fold increase.(115) Pediatricians in the United States frequently perceive parents as expecting antibiotics, and report that this pressure can lead to them prescribing when they otherwise wouldn't.(119) Interestingly, clinicians may be more likely to perceive that a parent expects antibiotics, and then prescribe antibiotics, when the parent questions the clinician's treatment plan,(111) suggesting that treatment plans that focus on what can be done for the patient, rather than on what is not needed (i.e. antibiotics) may result in a reduction in perceived parental expectations, and thus prescribing.

Finally, some clinicians prescribe antibiotics because they believe it is associated with greater parental satisfaction. However, meeting parental prescribing expectations is not necessarily associated with greater satisfaction.(101, 120-122) When patients consult about an RTI, satisfaction is related to the clinician spending enough time to explain the illness,(120) understanding the clinician's choice of treatment,(120) being carefully examined,(123) and receiving information and reassurance about the illness.(121) And parents who expect antibiotics and do not receive them are more likely to be satisfied if their clinician discusses a 'contingency plan' with them,(114) suggesting that good communication can mitigate loss of satisfaction.



### **1.4.1.3 Clinician knowledge and beliefs**

Some clinicians have beliefs, misunderstandings, or a lack of knowledge about the possible benefits and harms of antibiotic treatment, which are likely to contribute to the overuse of antibiotics. For example, clinicians are much more likely to make a diagnosis of sinusitis,(124) and prescribe antibiotics,(125) when there is discoloured nasal discharge, while the evidence suggests that this sign is associated with only marginal benefit from antibiotic treatment.(23)

General practitioners have described antibiotic prescribing decisions as one of the most difficult prescribing decisions that they make.(126) They often feel conflicted by their sense of obligation to try and do something about antibiotic resistance, and their sense of duty to do their best for their patient and concerns about complications.(127) In a qualitative study exploring attitudes towards sore throat consultations, GP's expressed uncertainty about when to prescribe, and said that these consultations had the potential to generate disagreements. However, many also expressed the view that these were mundane consultations that were a waste of time.(128)

### **1.4.1.4 Consulting skills**

A lack of patient participation in the consultation, and guesses and assumptions on the part of the clinician, frequently result in misunderstandings in consultations in which prescribing decisions are made.(129) Furthermore, decisions are often influenced by factors such as pressure of time, fear of damaging the doctor-patient relationship, avoiding home visits, and defensive medicine.(130)

The role of shared decision-making in consultations that involve antibiotic prescribing decisions has been explored by Butler et al.(131) They describe how these consultations involve decisions where: best treatment is controversial, management is inconsistent, clinicians are not in the best position to evaluate trade-offs between management options without understanding patients' perspectives, and many pressures (apart from patients' agendas) intrude into the consultation. They conclude that the paternalistic model of consulting (which is still commonly employed) cannot be justified and that the shared decision-making model is the only feasible approach for such consultations. This is supported by the results of a discourse analysis of

consultations where there was conflict around the management of upper respiratory tract infections in children, which found that shared decision-making competencies were not exhibited in these consultations(132). There is evidence that clinicians can be helped to develop the skills needed to make their consultations more patient-centred,(133) and evidence that it can lead to a reduced parental desire for antibiotics and increased parental satisfaction.(134) However, preferences for decisional involvement vary, with some patients preferring a more paternalistic approach.(135)

## **1.4.2 Interventions aimed at rationalising antibiotic prescribing for RTIs**

Evidence from an online database of current research evidence on the effects of strategies to improve drug prescribing practice,(136) a published review of systematic reviews on interventions to improve prescribing,(137) a systematic review updating evidence on the same topic,(138) and a Cochrane systematic review focusing specifically on reducing antibiotic prescribing,(139) will be used to summarise the evidence base in this area.

### **1.4.2.1 Systematic reviews of approaches directed at professionals**

Educational outreach visits (academic detailing) and audit and feedback are generally found to be effective at improving prescribing.(136-139) However, as these approaches are often combined with each other, or with other interventions such as patient educational materials, it is not always easy to determine the effect of the individual components. Simple educational meetings appear to be significantly less effective, but the results are mixed.(136, 137, 139) There are also mixed results for the use of computerised and manual reminders at the point of care, with some reviews finding them effective,(137, 139) but others finding less consistent results.(136, 138) Tailored interventions, which include interviews or focus groups with clinicians, and other interventions that have been designed based on identification of local barriers, appear to be effective.(136) The passive distribution of educational materials to professionals does not appear to be effective.(136, 139)

### **1.4.2.2 Systematic reviews of approaches directed at consumers**

The 'Rx for Change' database found that providing information or education for consumers as a single component was generally ineffective at improving clinical

outcomes, but did result in improvements in knowledge and health service use. However, providing patient information and education in combination with other interventions, such as self-management training and counselling, may improve adherence and other outcomes.(136) Grindrod et al. found five systematic reviews that supported the use of patient-mediated interventions (including patient educational materials, telephone calls, and postal reminders), but these were mostly to encourage the use of preventative measures such as immunisations.(137) The Cochrane review found few studies evaluating the effect of patient based interventions alone, and the studies that are included are reviewed below.(139) Mass media campaigns were generally effective at improving appropriate care in the short term, but the effect generally decreases with time, and there is insufficient evidence to determine their effectiveness on prescribing.(136)

#### **1.4.2.3 Educational interventions about antibiotic use for respiratory tract infections that are directed at parents**

Most educational interventions on antibiotic use for RTIs that are directed at parents have involved mass media campaigns or have included the use of leaflets or booklets. The former have been mentioned above, and will not be described in any further detail here, and the latter will be discussed in detail in section 1.5. Evaluations of two other approaches, brief structured advice and educational videos, will be outlined in this section.

##### ***1.4.2.3.1 Brief structured advice***

Pshetizky et al. recruited 81 children with acute otitis media presenting to two primary care clinics in Israel. All parents were provided with a delayed prescription for antibiotics, but were randomised to receive brief structured verbal information about the nature of the illness, management of symptoms, and likely outcomes with and without antibiotics, or usual care. Use of the intervention was associated with statistically significantly fewer parents administering the antibiotics (37%) compared with the control arm (63%).(140)

##### ***1.4.2.3.2 Educational videos***

Three studies from the United States have evaluated the use of videos promoting the judicious use of antibiotics along with provision of a leaflet on the same subject. In

the first, 499 parents of children under 2 years of age were recruited during a consultation for any condition. Parents (and their children) were randomised to receive the CDC booklet on judicious use of antibiotics (“Your Child and Antibiotics”) and exposure to a five-minute videotape highlighting the key messages from the booklet, or a set of booklets on injury prevention as a control. The authors found that use of the intervention modified parental attitudes in the direction of favouring more judicious use of antibiotics,(141) but failed to result in differences in consultations for RTIs or prescriptions for antibiotics over the following year.(142) In the second, 206 parents attending pediatric clinics were randomised to a video and leaflet or usual care.(143) No significant difference in parental knowledge, beliefs, or behaviours was observed. The third study was a prospective cohort study that included 771 parents.(144) The leaflets, which were left in the waiting room, were read by less than 2% of the parents. Parents who watched the video were significantly less likely to say they expected antibiotics, but the video was only viewed by around 50% of parents, and the authors did not report the overall effect on expectations. No change in prescribing was found.

#### **1.4.2.4 Other approaches**

Delayed prescribing has consistently been found to safely reduce antibiotic use when compared with ‘immediate prescribing’.(136, 145) Use of a C-reactive protein near patient test reduced antibiotic prescribing for adults with LRTI in a study in the Netherlands.(146)

Clinical prediction rules have the potential to help target prescribing at those most likely to benefit. A rule to predict complications from acute cough in children has been developed,(147) but a validation assessment was not able to confirm its value.(148) A prediction rule for Group A streptococcal infections in adults and children presenting with sore throat has been shown to have reasonable sensitivity and specificity,(149) and been validated,(150) but prompts to use the rule in a primary care setting in Canada did not result in any reduction in antibiotic prescribing.(151)

Many studies have used multifaceted approaches that employ a range of strategies. Using this type of approach may be more effective than the use of single

approaches,(137, 139) although there is insufficient evidence from direct comparisons to draw clear conclusions.(136)

## **1.5 Evidence for the use of leaflets about RTIs**

Sections 1.3 and 1.4 described some of the factors that influence consulting behaviour and antibiotic prescribing for RTIs, as well as studies evaluating interventions aimed at reducing consulting and rationalising antibiotic prescribing for these illnesses. One approach to addressing some of these factors (parental knowledge and beliefs, clinician knowledge and beliefs, and the ways in which information is shared between clinicians and parents) is the use of information leaflets or booklets. Indeed, a number of the studies reviewed in the previous sections evaluated the use of leaflets or booklets, either alone or as one of a number of components of the intervention. This section of the thesis will describe the rationale for using leaflets to address the problems associated with RTIs in children, and will summarise the studies that have used this approach, including the studies mentioned above, and other relevant studies.

### **1.5.1 Rationale for using leaflets**

Health literacy, which encompasses the range of skills and competencies that people develop to seek out, comprehend, evaluate, and use health information and concepts to make informed choices, reduce health risks, and increase quality of life,(152) is an essential ingredient for patient engagement in healthcare. Increasing patient engagement in healthcare has been shown to improve knowledge, patient experience, use of health services, health behaviour, and health status.(153) Lack of, or poor quality, information has been identified as a key barrier to evidence-based patient choice.(154)

Patient information leaflets are widely used in primary care, and as part of public health campaigns, but are often of poor quality.(155, 156) In the primary care setting, they can be used as a source of additional information, to reinforce or act as a reminder of information that was discussed in the consultation, or to act as an aide-memoire, or prompt, during the consultation. Providing a leaflet during the consultation has been shown to improve information retention by up to 50%.(157) Patients report that they want, use, and value written information in primary care consultations.(158) More than four-fifths of the population rely on information from

their GP, and over half use leaflets from their surgery or pharmacy.(159) Furthermore, a survey conducted for the policy group Developing Patient Partnerships found that nearly three-quarters of respondents would be less likely to visit their general practitioner if they had more information about managing minor ailments.(159)

Parents have expressed a need for a range of accessible and specific information to help them manage acute illnesses in their children (typically acute RTIs)(19), and providing written information has been shown to increase satisfaction, compliance, and parental knowledge, for a range of conditions.(160)

### **1.5.2 Evaluations of leaflets to improve the management of RTIs**

Leaflets can be sent directly to patients' homes, distributed passively through healthcare or other facilities, provided to patients at the end of a consultation, used interactively within a consultation, or provided as part of some other face-to-face educational activity. There is considerable evidence that leaflets are more effective when delivered interactively as part of a consultation or educational activity.(22, 160, 161) In addition, leaflets can form the only or main part of the intervention, or they can be one of many components of a multifaceted intervention.

Most studies that have used leaflets in the management of RTIs have been evaluations multi-faceted interventions, where the leaflet is one of many parts.(162-179)

Although a number of these studies have shown an impact on antibiotic prescribing, it is difficult to determine the independent effect of the leaflet, and therefore they will not be discussed further.

#### **1.5.2.1 Using leaflets within the consultation**

The use of leaflets on RTIs within the consultation has not been widely evaluated. Three studies, all in patients with LRTI, have evaluated the use of a leaflet within primary care consultations. None involved encouraging 'interactive' use of the leaflet.

The first involved the effect of a leaflet for adults with LRTI on reconsulting, and was discussed in section 1.3.2.4.

The second included adults with LRTI who were assessed by their GP as not needing immediate antibiotics.(180) They were provided with a delayed prescription and randomised to be provided with a leaflet or not. The leaflet gave reassurance, and advice about the normal duration of symptoms, managing symptoms, and when to consider using the antibiotics. Patients randomised to receive the leaflet were significantly less likely to use antibiotics (RR 0.76, 95% CI 0.59 to 0.97).

The third evaluated the use of a leaflet as well as the use of three ‘prescribing strategies’ in 807 children (3 years or older) and adults with acute cough and one or more symptoms suggesting a lower respiratory tract infection (but excluding those with pneumonia).(181) Patients were randomised to one of six groups using a factorial design; leaflet or no leaflet as the first factor, and antibiotic prescribing strategy (immediate antibiotics, no antibiotics, or delayed antibiotics) as the second factor. Comparisons of the leaflet versus no leaflet groups found that use of the leaflet was associated with an increase in reattendance within the first month (RR 1.63, 95% CI 1.07 to 2.47,  $p=0.02$ ), and no difference in use of antibiotics, belief in the effectiveness of antibiotics, or satisfaction.

### **1.5.2.2 Provision as part of an educational initiative**

Four studies have examined using leaflets as part of an educational intervention, involving face-to-face education, but outside the context of the consultation. All of these were aiming to impact on consulting and were reviewed in section 1.3.2.1.

### **1.5.2.3 Sending booklets to patients homes**

Six studies have evaluated sending booklets on managing minor illnesses to patients’ homes, and all were described in section 1.3.2.2, and none found important differences in consulting as a result of the intervention.

### **1.5.2.4 Leaflet and symptom kit**

Kelley et al. evaluated the distribution of leaflets, other educational materials, and ‘symptom kits’ (containing chicken soup, lozenges, tissues, thermometer, etc.) to three practices in the United States.(182) The clinicians in these practices had previously been provided with some training related to antibiotic resistance and treatment guidelines, and were encouraged to distribute the symptom kit and other

materials in place of prescribing antibiotics. The purpose of the evaluation was to assess the feasibility of such an approach, and they concluded that the approach was feasible and that the clinicians who used them valued the materials.

### **1.5.3 Summary of evidence for using leaflets**

There are good theoretical reasons for using well-produced leaflets to try and improve the health literacy of parents, and the use of leaflets is valued by patients and has been shown to increase information retention. I was not able to find any studies that evaluated the use of leaflets in consultations for children with RTIs, or studies that evaluated encouraging or training clinicians to use leaflets about RTIs ‘interactively’ in consultations. Three studies evaluating the effect of leaflets to patients consulting with LRTI have had mixed results; two demonstrated beneficial effects (reduced reconsulting(98) and antibiotic prescribing(180)), and one found no reduction in prescribing and an increase in reconsulting.(181) Sending booklets to patients homes seems to have little effect, but providing leaflets as part of an educational initiatives may be effective. Three of the four studies evaluating this approach found beneficial effects, with one study demonstrating a reduction in consulting for ear pain of up to 80%.(83)

The role of leaflets in the management of RTIs in children remains unclear. However, it would appear that the use of a leaflet as part of an educational interaction, within or outside of the consultation, is more likely to be associated with a reduction in consulting than a more passive approach.

## **1.6 Enhancing communication in consultations**

Another approach to improving the management of respiratory tract infections is attempting to improve communication in consultations by providing clinicians with communication skills training. There is growing evidence that adopting a patient-centred approach, including developing a better understanding of patient beliefs, concerns, and expectations, can improve the appropriate use of antibiotics, as well as enhancing patient related outcomes. (183, 184) One of the keys to such an approach is good communication skills within the consultation.



### **1.6.1 Evaluations of communication skills training**

Welschen et al. randomised 12 peer review groups in The Netherlands to an intervention consisting of group education and communication skills training, feedback on prescribing, training for assistants, and patient educational materials.(170) The training was based around exploring patients' worries and expectations, and informing them about the natural course of the illness, self medication, and alarm symptoms. The leaflet also covered the self-limiting nature of the illnesses, self-medication, and alarm symptoms, but was not used in the consultation (left in the waiting room). The intervention resulted in a 4% absolute risk reduction (from 27% to 23%) in antibiotic prescribing. However, as the prescribing rate in the control group increased during the same time period, the mean difference in change (adjusted for clustering) was -10.7%, 95% CI -20.3% to -1.0% (i.e. a 10% reduction from use of the intervention).

Altiner et al. conducted a similar study, although the unit of randomisation was the individual GP, and the condition of interest was limited to acute cough. The intervention in this study was a visit from a group of 'GP Peers' who provided training in 'exploring the phenomenon of antibiotic misunderstanding in the consultation'. The training encouraged GPs to explore expectations, demands, and anxieties, and to make antibiotic prescribing a subject of discussion in the consultation. The analyses in this study were complicated by an imbalance in baseline prescribing rates (36.4% intervention, 54.7% control), an increase in prescribing during the study period in the control group, and confounding by differences in disease severity over time. The crude antibiotic prescribing rates in the intervention group did not change much (36.4% at baseline, 29.4% at 6 weeks, and 36.7% at one year). However, when compared with the control group, and when the above complexities and study design were taken into account in the modelling, the authors concluded that there was a relative reduction in prescribing of ~60% at six weeks and ~40% at one year.

Briel et al. recruited 45 general practitioners, the first 30 of which all received guidelines on RTIs presented in a two-hour seminar, and were randomised to receive additional communication skills training or not.(185) The remaining 15 did not

receive guidelines or communication skills training. The communication skills training was based around, “How to understand and modify patients’ concepts and beliefs about antibiotics”, and included practising active listening, responding to emotional clues, and tailoring information for patients. Participating clinicians recruited 837 eligible adults with an acute RTI. Antibiotic prescribing was assessed through community pharmacies and other outcomes were assessed by telephone interviews at days 7 and 14. No differences between either randomised group or the control group were found for total antibiotic prescribing, antibiotic prescribing according to guidelines, consultations within 14 days, or satisfaction.

Two recent studies have evaluated communication skills training for ‘RTI consultations’. Cals et al. used a factorial design to evaluate the use of a near patient test (C-Reactive Protein) and communication skills training for consultations in which adults presented with symptoms suggestive of a lower respiratory tract infection.(146) A novel training approach was adopted which involved the use of simulated patients consulting (without identifying themselves) in routine surgery sessions, seminar-based group work, and reflection on transcripts of their own, and others, consultations. The training was based on the elicit-provide-elicite framework,(186) which has its origins in motivational interviewing and has been adapted for use in primary care, and like the studies mentioned above, emphasised the importance of eliciting expectations and worries and discussing the role of antibiotics. Both interventions in this study were found to be effective, with an antibiotic prescribing rate of 27% in the group who had received the training compared with 54% in the no training group ( $p < 0.01$ ). Finally, Butler et al. developed a blended learning program (on-line learning, a practice based seminar, and context bound learning) about antibiotic prescribing, for use in general practices.(187) The program, which is based on Social Learning Theory, is being evaluated in a cluster randomised controlled trial. Preliminary analysis suggests the intervention has been effective in reducing prescribing. [Personal communication]

### **1.6.2 Summary of evidence about communication skills training for RTI consultations**

There is good evidence from the above studies that providing clinicians with training in enhanced communication skills can reduce antibiotic prescribing for RTIs in

primary care. However, none of the above studies specifically involved consultations with children, none evaluated the effect on consulting, and it is not clear whether the benefit of enhanced communication is additive with other educational interventions, such as use of a leaflet.

## **1.7 Chapter summary**

This chapter has outlined the burden of respiratory tract infections in children. Although these infections are generally mild and have a low rate of complications, their frequency, and the challenges involved in assessing diagnosis, severity of illness, and likely prognosis, and in effectively dealing with uncertainty, anxiety, and the desire to ‘do something’, contribute to a number of challenges. In particular; how to protect the precious resources of primary healthcare consultations and effective antibiotics, while appropriately dealing with parental concerns and not compromising patient safety? Clinicians are frequently instructed to rationalise their antibiotic prescribing, but although there have been a large number of studies evaluating many approaches to improving the management of respiratory tract infections, there are a limited number of easily adoptable, effective, tools for clinicians to draw from. Approaches based on identifying and addressing the barriers to change are likely to be more effective. Some of the barriers to change include gaps and misunderstandings in parental knowledge and beliefs about RTIs, gaps and deficiencies in clinicians’ knowledge and skills, and problems in communication between parents and health care professionals. Educational interventions aimed at patients (and parents), including the use of printed information, have the potential to fill some of these gaps through informing and empowering patients (parents), and helping to make consultations more patient-centred. However, evaluations of the use of leaflets for these illnesses have had mixed results. Many studies have used leaflets as one part (often a small part) of a multi-faceted intervention and it is difficult to determine the effectiveness of the leaflet. Only three studies have evaluated use of a leaflet at the time of consulting for an RTI, and these were all in patients (mostly adults) with LRTI. Two of these found that leaflets were helpful in reducing reconsultations, and antibiotic consumption, but in the third, where the study was evaluating the use of prescribing strategies as well, no beneficial effect was found. Sending booklets of information to households appears to have little effect on consulting, but face-to-face educational interventions that use leaflets are much more effective. There is good

evidence that training clinicians in enhanced communication is effective at reducing antibiotic prescribing for RTI consultations.

Taken as a whole, the evidence summarised in this chapter suggest that there is scope for improving the management of RTIs in children, in terms of consulting behaviour, antibiotic prescribing, and parental empowerment, through the use of an information leaflet for parents. However, such a leaflet is more likely to be effective if used interactively in the consultation, and if, in combination with training in its use, it can facilitate enhanced communication in the consultation. Furthermore, easy-to-understand, accessible, and comprehensive information about RTIs in children is something that parents have expressed a need for. To date, there have been no evaluations of the interactive use of an information leaflet on RTIs in children within the consultation.

## **1.8 Aims and objectives**

### **1.8.1 Aims**

The aims of the research described in this thesis are:

1. To develop a complex intervention consisting of an interactive booklet about respiratory tract infections in children designed for use in primary care consultations, and training in its use for clinicians.
2. To evaluate the effect of this complex intervention in routine general practice.

### **1.8.2 Objectives**

To address these aims, the following objectives have been identified:

1. To develop a booklet about respiratory tract infections in children for use in primary care consultations that:
  - a. Is based on current scientific evidence.
  - b. Is based on parents and primary care clinicians needs and perceived barriers to change.
  - c. Is underpinned by behaviour change theories
  - d. Addresses key gaps in information-sharing in these consultations; namely, discussing likely duration of illness, evidence regarding the benefits and harms of antibiotic treatment for these infections, and

features which should prompt reconsultation, and eliciting and addressing parental expectations and concerns.

- e. Is designed to be used within the consultation, as an aide-memoir, and to facilitate communication.
2. To develop training for clinicians in use of the booklet within the consultation.
3. To evaluate the effect of using this complex intervention in routine primary care consultations on reconsultations, antibiotic prescribing, parental satisfaction, parental enablement, and other outcomes.
4. To gain a greater understanding of how the intervention was used, the study participants (parents and clinicians) impressions of it, and which components of it may have led to the trial findings, through a qualitative process evaluation.
5. To describe the 'costs' and 'consequences' of using such an intervention through an economic evaluation.

## **2 Intervention development**

### **2.1 Introduction**

This chapter will describe the process of developing the study intervention; a booklet (initially called a leaflet but given its final length it was termed a booklet and will be referred to as such throughout the rest of this thesis) on respiratory tract infections in children, designed for use in primary care consultations, and training in its use for primary care clinicians. The development of this intervention followed the outline suggested for the development and evaluation of complex interventions by the Medical Research Council.(188) This includes a theoretical phase and a modelling phase prior to pilot and then definitive trials. The bulk of this chapter focuses on the modelling phase. However, the theories that informed the development of the intervention (phase 1) will be outlined first.

### **2.2 Theoretical perspective**

Eccles et al. argue that one of the reasons why complex interventions often have poor take-up in routine practice is that the interventions are inadequately based on theoretical constructs.(189) A key aim of the research in this thesis is to change behaviour: the behaviour of the clinicians (towards prescribing less antibiotics) and the behaviour of the parents (towards consulting less). Therefore, the development of the intervention was informed by theories of behaviour change. Behaviour change theories help us understand the factors that are likely to influence a change in behaviour. Applied to this field, they can help inform the approaches taken to try and change the behaviour of patients and parents (consulting, implicit or explicit requests for antibiotics) and clinicians (consulting style, prescribing). There are a large number of behaviour change theories, many of which overlap and some of which are conflicting. Two theories that are of particular relevance and have gained widespread use in behaviour change interventions in healthcare, are the Theory of Planned Behaviour, developed by Ajzen(190), and Social Cognitive Theory, developed by Bandura(191). Taken together, these theories emphasise that change is more likely when both the 'Why' of change (attitudes and subjective norms / outcome expectations) and the 'How' of change (perceived behavioural control / efficacy expectations) are addressed.(192) These concepts formed the basis of the intervention

and were woven into the design and content of the booklet, and the training in using it within consultations.

## **2.3 Developing a draft leaflet**

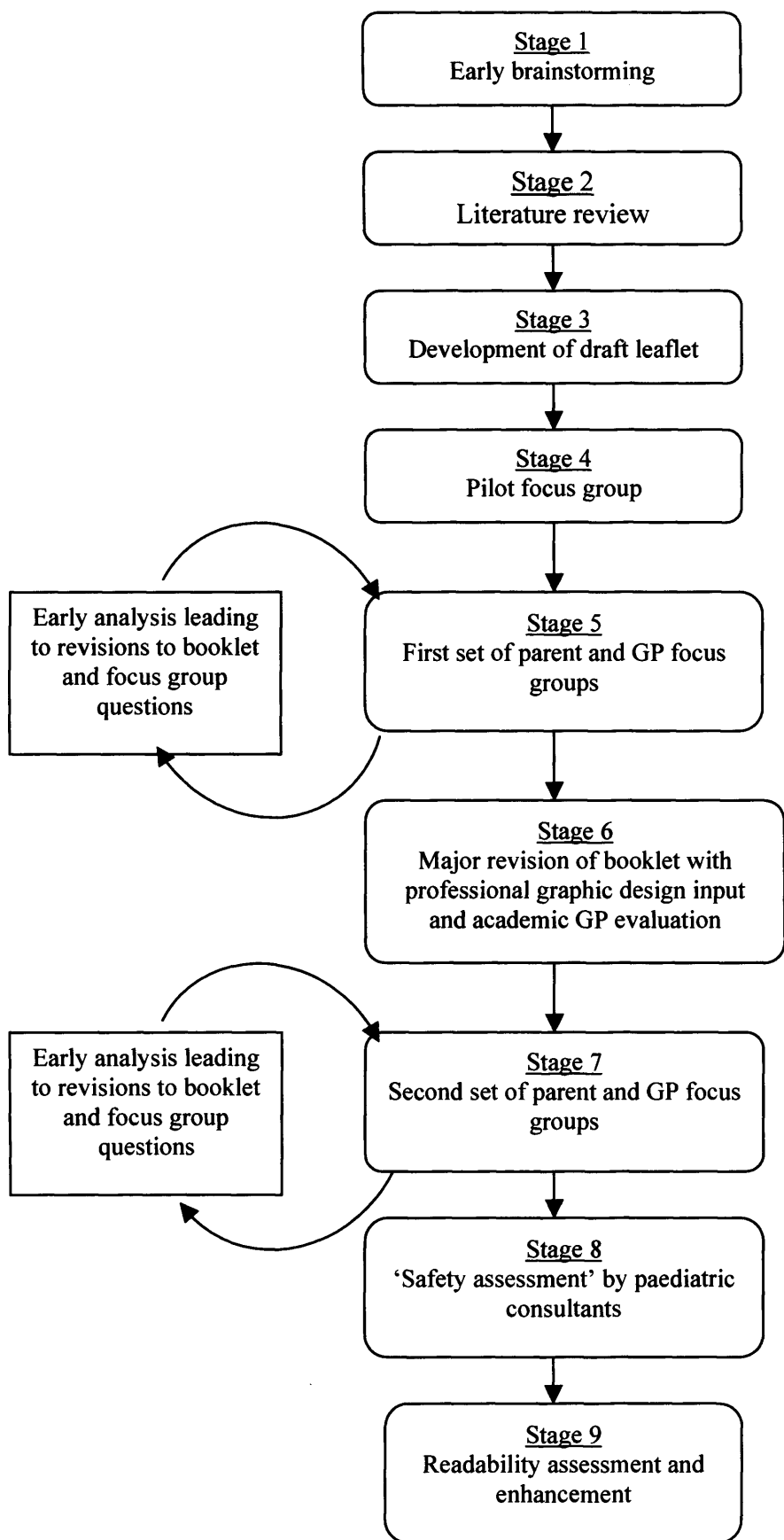
Development of the booklet involved a nine-stage process, which is outlined in Figure 2.1.

### **2.3.1 'Brainstorming' meetings**

A key aim in the leaflet (booklet) development process was to have input from stakeholders (primarily parents and general practitioners) at an early stage. However, the study team decided that these stakeholders would be able to play a more valuable role if they were provided with a clear remit and a draft leaflet on which they could base their comments. In order to achieve this, a booklet development group (NF, CB, KH, SS) was established to decide on the aims and objectives of the booklet, to review the relevant literature and to develop a draft narrative for the booklet. Outside experts were also brought in to inform this process. As a result of these meetings the group decided that the leaflet should:

- Be discussed by the practitioner with the parent (and / or child) within the consultation and be designed to facilitate such use;
- Include natural history data on colds and coughs as a main focus, with the aim of being able to assist the practitioner in giving the parent a clear understanding of the likely prognosis for their child;
- Include information on when to re-consult;
- Contain information on the effectiveness of antibiotics and the downsides to antibiotic use;
- Include information on self-help measures.

**Figure 2.1 Outline of booklet development process**





### **2.3.2 Review of guidance on producing patient information**

In addition to advice from members of the study group and outside experts, local library resources and the internet (using Google) were searched to identify guidance on the production of patient information resources. A number of resources were identified and reviewed, and two were found to be particularly helpful and used extensively. Dunman(193) has developed a guide called 'Producing patient information: how to research, develop and produce effective information resources', and the Department of Health has produced a 'Toolkit for producing patient information' .(194) Both of these guides emphasise the need to approach the development of patient information in a systematic way, and the importance of consulting with the intended users of the resource. Dunman highlights a number of important processes including: having clear aims and objectives for the project, planning the development, collecting the evidence, considering content and presentation, piloting, dissemination, and evaluation. He suggests that seeking the views of patients and carers, and clinicians, is as important as reviewing the clinical evidence. Both resources also provide valuable guidance on writing style, improving readability, and issues of presentation such as typeface, use of images, colour, page size, etc. I will refer to these later in the section on finalising the booklet.

### **2.3.3 Review of existing patient information leaflets**

Existing patient information leaflets about RTI in children or the use of antibiotics were reviewed. Prodigy, an online clinical information resource for NHS practitioners (which has subsequently been replaced by Clinical Knowledge Summaries), was the main source for evidence based patient information leaflets in the UK at the time of development. Four relevant patient information leaflets were identified from this source ('Coughs and Colds in Young Children', 'Upper Respiratory Tract Infections', 'Flu and Flu-like Illnesses' and 'Why No Antibiotic?'). Another reputable source of health information for consumers, Patient UK ([www.patient.co.uk](http://www.patient.co.uk)), was also searched, but no new leaflets were identified. The general practice in which I work was searched for additional information leaflets, and one additional leaflet on meningitis from the Meningitis Trust was found.

### **2.3.4 Content literature review**

The literature relating to the natural history of respiratory tract infections in children and the effectiveness of antibiotics and other treatments was identified and reviewed. A study outlining the natural history of URTI in children (77) was used for natural history data on 'the common cold' as was a paper examining the natural history of cough in children.(78) Systematic searches of Medline using the terms ('Respiratory Tract Infections/' OR 'Cough/' OR 'Common Cold/') AND ('Prognosis/' OR 'natural history.mp' OR 'duration.mp') AND ('Child/') did not identify any other papers relating to natural history of these infections in children.

A systematic search of reviews in Medline and the Cochrane Library was conducted to identify evidence on the effectiveness of antibiotics and other treatments for RTIs in children. Cochrane reviews (latest versions at the time of development) on the use of antibiotics for the common cold,(23) sore throat,(24) otitis media,(26) and acute bronchitis, (28) were used.

Other systematic reviews were identified which provided evidence on the use of other treatments such as antihistamines(195) and vitamin C (196). However, as there was no evidence that these interventions had any beneficial effects they were not included in the draft leaflet.

The results of a study looking at the signs and symptoms of early meningococcal disease were seen at a scientific meeting (and subsequently published in the Lancet(197)) and provided valuable information on features (leg pains, cold hands and feet, and abnormal skin colour) to be included in the advice on when to seek help.

### **2.3.5 Preparation of draft booklet**

The draft booklet was first written in outline format using the notes from the brainstorming sessions, the evidence from the literature, and the guidance of writing style and content. This was then developed into a two-page draft booklet, which was formatted to be folded in thirds and double-sided. Some clip-art images were added to give it greater appeal. A graphical representation of the natural history data was included in the leaflet and other possible ways of representing the same data were developed and included on a separate sheet to be shown to the focus group

participants. Other members of the study team (CB, KH, SS) then reviewed the draft booklet and suggested revisions. The sections in the earliest draft were: 'What is a respiratory tract infection?', 'What is this leaflet for?', 'What can help?', 'Will antibiotics help?', 'If antibiotics might help a little, why not take them?', 'How long is this likely to last?', 'When should I seek further help?', and 'Contacts'. An example of this can be seen in Appendix 2.

## **2.4 Focus groups**

In order to test ideas, generate new ideas, and assess the relevance and acceptability of the draft leaflet, as well as the plans for its interactive use in the consultation, a series of focus groups were arranged with parents and general practitioners. In order to ensure that ideas and opinions from the early focus groups could be reviewed by later focus groups the meetings were conducted in two distinct stages with sufficient time between to allow for a significant revision of the draft leaflet.

### **2.4.1 Justification for using focus groups**

A number of methods have been used to seek the views of relevant stakeholders during the development of patient materials including questionnaires (198, 199), interviews (200), the Delphi technique (201) and focus groups (198, 200, 202, 203). Focus groups were selected because they allow for the sharing and comparing of ideas amongst group members, which then facilitates the evaluation and interpretation of those ideas and the identification of group norms.(204)

### **2.4.2 Methods**

#### **2.4.2.1 Preparation**

Prior to commencing the focus group work I met with two members of the study team (FW and SS), who are both experienced qualitative researchers, in order to develop my understanding and skills regarding the role of focus groups, planning and developing questions, recruiting participants, moderating, and analysing data. I also reviewed published resources on conducting focus groups.(204)

### **2.4.2.2 Pilot**

Following the preparatory work, a pilot focus group was arranged with clinicians and staff in the DPCPH. The purpose was to test the proposed format of the focus group, the focusing exercises, the materials, and the procedures, and to provide an opportunity for me to practice my moderation skills. The meeting was audio-recorded and then transcribed and another researcher agreed to act as an assistant during the meeting and take notes. Three focusing exercises (discussion around a case scenario, review of a draft version of the leaflet, and review of a number of different ways of graphically representing the natural history data) had been devised and these were tested in the pilot meeting. Although the intention of the meeting was not to generate data, some observations and suggestion about the leaflet were felt to be valuable and these were taken forward to the parent focus groups for further discussion.

### **2.4.2.3 Recruitment**

#### ***2.4.2.3.1 Parent focus groups***

Purposive sampling was used in order to obtain a maximum variation sample. Parents from lower social status groups have been shown to have greater concern about infectious illnesses, and this is associated with higher levels of consulting and prescribing.(18) For this reason, parents were recruited from both areas with higher and lower levels of socio-economic deprivation. Parental experience was also felt to be an important factor that was likely to have a significant influence, so the recruitment methods selected were designed to ensure that both ‘less experienced’ parents (parents with only pre-school age children) and ‘more experienced’ parents (Parents with at least one school aged child) were included. A description of how each focus group was recruited, the type of socio-economic area from which the group was drawn and the number of participants (two planned focus groups became interviews when only one participant attended) are shown in Table 2.1.

Table 2.1 Description of focus groups and interviews

<b>Meeting</b>	<b>How recruited</b>	<b>High or low level of deprivation</b>	<b>Number of participants</b>
<b>Parent meetings</b>			
FG* 1	Recruited opportunistically by a health visitor	Low	4
FG* 2	Consenting parents from a parent-toddler group	High	8
FG* 3	Consenting parents from a parent-toddler group	High	8
FG* 4	Parents recruited opportunistically by a general practitioner	High	6
I* 1	Recruited from a health visitor's baby clinic	Low	1
I* 2	Parents recruited opportunistically by a general practitioner	High	1
FG* 5	Parents recruited opportunistically by a general practitioner	Low	7
<b>GP meetings</b>			
GP FG* 1	Consenting GPs working in a number of practices in one large health centre	High	7
GP FG* 2	Invited general practitioners registered as honorary lecturers in the Department of General Practice at Cardiff University	Mixed	5
* FG = Focus group. I = Interview			

#### ***2.4.2.3.2 General practitioner focus groups***

Purposive sampling was used to recruit the general practitioners for the focus groups. For similar reasons to the parent focus groups, the level of social deprivation in the area where the GP practiced was considered to be an important factor and therefore participants working in deprived as well as non-deprived areas were selected. We invited participants from both larger and smaller practices as practice list size is known to be related consultation length,(205) reported availability,(206) and range of services offered.(207) Table 2.1 summarises how members of each of the GP focus groups were recruited and the number of participants in each group.

#### **2.4.2.4 Focus group format and questions**

##### ***2.4.2.4.1 Parent focus groups***

Parent focus group meetings were conducted at or close to the general practices or parent-toddler groups from which they were recruited. Participants all provided written informed consent. All meetings were facilitated by the candidate and three of the parent meetings were also attended by an assistant who recorded notes about the meeting and paid particular attention to group dynamics and non-verbal communication. Three focusing exercises were used in all the meetings as discussed above. All focus groups were digitally recorded and subsequently transcribed. All participant data were anonymised and kept confidential.

One of the main aims of the focus groups was to seek the participants' opinions of the draft leaflet, and to modify and improve it. However, it was also recognised that it would be valuable to explore parental experiences, beliefs, attitudes, fears and expectations about respiratory tract infections in children, the use of primary care services for these infections, and their beliefs about the use of antibiotics.

The full parent focus group topic guide is given in appendix 3.

##### ***2.4.2.4.2 General practitioner focus groups***

The first general practitioner focus group was conducted in a combined health centre that housed all the involved practices. The second meeting was conducted in a

meeting room in the DPCPH. Both meetings were moderated by the candidate, and an assistant was present for the first meeting to take notes. Focusing exercises were similar to those used in the parent focus groups (see appendix 4 for the topic guide).

#### **2.4.2.5 Analysis**

Development of the booklet was guided iteratively by the experiences and views of the participants. Thus, data collection and analysis occurred in tandem. A preliminary analysis was conducted after each meeting so that the materials and prompts used in subsequent meetings could be modified in order to test the ideas that had been generated.

A more detailed analysis was subsequently conducted using a thematic approach.(208) Thematic analysis is a commonly used, accessible approach to qualitative analysis that is not tied to a particular theoretical framework. It is an ideal approach for this analysis as it allows for the description of various patterns or themes within the data, and interpretation of these themes, but does not require the detailed and technological knowledge of some approaches, and is therefore feasible as a relatively small component of a larger project.(208)

The data from GP and parent groups were analysed concurrently, but different coding frameworks were developed for each type of group. Following an initial familiarisation with the data, three researchers (NF, FW, SS) reviewed one parent focus group transcript and identified themes were used to develop an initial coding framework. All transcripts were then examined and coded on a line-by-line basis using a qualitative software package (QSR NUD\*IST). Three of the five focus group transcripts were double coded by two researchers (NF and FW) to assess reliability, and inconsistencies were discussed and resolved. A process of constant comparison was used to generate new themes, re-classify themes, and incorporate themes within other themes. This was an iterative process, which was revisited many times during the analysis. A similar process was undertaken for the GP focus groups, with one of the two GP focus group transcripts dual coded. The end result was a hierarchy of identified themes for each set of groups (parents and GPs).

## 2.4.3 Focus group results

### 2.4.3.1 Parent focus groups

#### 2.4.3.1.1 Group characteristics

Seven parent focus groups had been planned but two of these meetings were attended by only one participant and therefore were regarded as single interviews. This resulted in a total of five focus groups with a median of 7 (range 4 to 8) participants per group, and two interviews. There were a total of 35 participants, all of who had data about their gender available. Other demographics were obtained via a questionnaire sent to participants in the post, which was returned by 24 participants. The characteristics of the parent focus group participants are given in Table 2.2.

Table 2.2 - Characteristics of parent focus group participants

Age (mean)	30 years
Female	34/35 (97%)
Only have one child	11/24 (46%)
New parent (no children over 2 yrs)	8/24 (33%)
Single parent	7/24 (29%)
Employment status*	
Unemployed	16/24 (67%)
Social class V	1/24 (4%)
Social class III-N	3/24 (13%)
Social class II	4/24 (17%)
* Classified according to the National Statistics Socio-Economic Classification (NS-SEC)	

#### 2.4.3.1.2 Concerns, experiences, and beliefs

##### Parental concerns

When talking about respiratory tract infection in their children, the parents in our focus groups described them as, “scary”, “frustrating”, and “exhausting”. The main fears were of something serious developing. Meningitis, breathing problems, and febrile seizures were the main serious complications that were mentioned, but many



parents had a more general fear of “something serious”. Many parents expressed concern about specific symptoms and others were confused and frustrated by a lack of understanding of the meaning of symptoms. Common examples of such symptoms were: the colour of nasal discharge, ‘chesty’ sounding coughs, large tonsils, and fever (including the degree and duration of fever). Some parents expressed concern about ear infections. These were interpreted as serious, because the doctor always checked for it and almost always prescribed antibiotics for it, and yet elusive, because only the doctor could check for them. One parent talked about her fear of ear infections in her son and said it was the main reason she consulted.

### **Experience of consulting with healthcare professionals**

Parents frequently talked about their experience of consulting with healthcare professionals, and in particular, the difficulties they experienced in trying to decide when to consult. Parents talked about a fear of going too early, as this would be a waste of time, may result in them appearing overly-anxious, and lead to the doctor not taking them seriously in the future, and they worried about attending too late, as this may result in harm for their child, or at least postpone them receiving appropriate treatment. These problems were often compounded by difficulties obtaining an appointment at short notice. In describing their experience of consulting, some parents described very positive experiences, but many described feeling dismissed or ‘fobbed off’, and this problem was compounded by what parents described as very brief consultations. A number felt that if more time had been spent explaining to them what they should watch out for and what they can do for their child, then they would consult less often in the future. Other issues that were raised included; receiving conflicting advice from different healthcare professionals, problems understanding the language used by the healthcare professional, and a fear of asking for clarification.

### **Beliefs about antibiotics**

The parents in our groups were divided in their beliefs about antibiotics, with many believing that they were wonder drugs and berating the fact that ‘you have to battle with the doctor to get them’, and others concerned about their use and feeling that doctors, ‘dish them out too easily’. A number of parents felt that the decision to prescribe seemed quite arbitrary and some described being given conflicting advice about the treatment of similar symptoms. This increased the sense that doctors

prescribing decisions were often based on factors other than what was in the best interest of their child, and some felt that antibiotics had been withheld on the grounds of cost, and others that they had been given antibiotics in an attempt to brush them off. Some parents expressed concern about antibiotic resistance, although there was often confusion about the exact nature of the problem with some believing that antibiotic use affected their child's immune system. Others expressed the belief that their child should not be denied the benefit of antibiotics in order to try and achieve some possible benefit for future generations.

### ***2.4.3.1.3 Influence on booklet development***

#### **Thirst for information**

Almost all parents expressed a belief that having a leaflet or booklet on respiratory tract infections in children would be valuable, and most had a very positive overall impression of the draft booklet. The main emerging theme was the desire for more information, and as a result the draft grew (from two sides of A4 paper) into an eight-page A5 size booklet. A number of parents had questions about the interpretation of symptoms, and found that these were not adequately addressed in the draft booklet that was organised around conditions (common cold, sore throat, ear ache, etc.) As a result, sections were added that dealt with symptoms such as, 'discoloured nasal discharge,' 'large tonsils,' and 'noisy sounding chests.' The early draft included information on topics identified in previous research as causing parental anxiety, for example: fever, cough, and the signs of meningitis. While most participants commented on the value of this information, others wanted still more.

*"Have you got anything in there if they go into fits? For temperature fits I'm on about now. Because some people with a high temperature ... they can experience fits cant they? Cos my niece did. I don't know anything about em ... what to do, what to do with an attack of fits"* (Parent focus group 3, high deprivation area)

As a result, sections were added on febrile seizures and croup, information on recognising dehydration in a child, and images of a septicaemia rash. The section on febrile seizures provides an example of the value of conducting a series of focus groups. Following the addition of information about this condition, two subsequent focus groups (one parent and one GP) suggested changing the advice about managing

a new seizure in a febrile child (changed from ‘call for an ambulance if the fit has not stopped after 5 minutes’ to ‘call immediately for an ambulance’). Finally, members of a further parent group endorsed inclusion of this section, with one parent saying:

*“I have to say though, in this leaflet, that’s the best thing is these febrile seizures. That’s the first time I’ve ever seen anything in a leaflet about that”*  
(Parent focus group 5, low deprivation area)

### **Don’t discourage consulting**

A section of the booklet was designed to provide parents with information about signs and symptoms in their children that should prompt them to seek further help. While many parents commented on the value of this section, a number expressed anxiety about possibly deterring a worried parent from consulting.

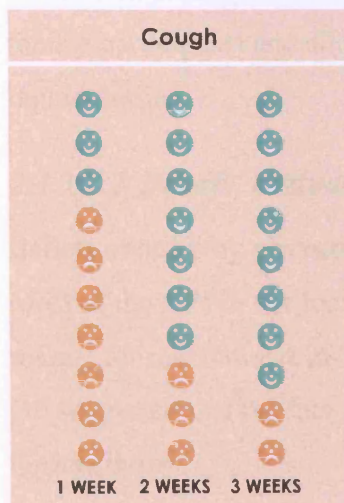
*“It should say something about the parent’s discretion or something because if there is something serious and they’ve read this and you know it could be a bit of a problem ...”* (Parent interview 2, high deprivation area)

As a result, a highlighted sentence was added to the booklet that advised parents to re-consult if they are still worried after reading the booklet.

### **Natural history data**

In keeping with guidance on explaining risks to patients,(209) an attempt was made to present the natural history data in graphical format for ease of understanding. The focus groups assessed the acceptability of a variety of ways of presenting this data, including: bar graphs, line graphs, pie charts, pictographs (with smiling and sad faces), and textual information. There was no single favourite format. However, the format that seemed to convey the information most clearly, to most people, was the face pictograms (see Figure 2.2 Example of face pictographs).

Figure 2.2 Example of face pictographs



### Language, design, and organisation

Although we had set out to avoid jargon, the participants identified a few examples and the wording was subsequently changed. An example of this was a change to the booklet title from, “Respiratory tract infections in children” to “When should I worry? – Your guide to coughs, colds, earache & sore throats”.

Early drafts of the booklet were divided into sections by topic (‘What can be done to help them feel better?’, ‘How long is it likely to last?’, ‘Will antibiotics help?’, etc.) Some parents commented that this resulted in them having to search through the booklet in order to ‘pick out’ the pieces of information relevant to a specific illness. As a result, almost half of the information was grouped by illness or symptom. Some ‘topic’ sections were felt to be applicable to most of these illnesses and so were retained. Examples of this include, ‘What can I do?’, ‘Why not take antibiotics?’, and ‘When should I seek further help?’

Design improvements suggested by parents included the addition of a fridge magnet with key points written on it that could be used to stick the booklet to the fridge.

### 2.4.3.2 General practitioner focus groups

#### 2.4.3.2.1 Group characteristics

Seven GPs participated in the first focus group and five in the second. There were two female participants and all of the participants reported consulting with children on a regular basis.

#### **2.4.3.2.2 Beliefs, attitudes and concerns**

##### **Beliefs about why parents consult**

Most of the GPs in our focus groups expressed the belief that parents consulted mainly for reassurance, and that their main worry was of a serious complication. One GP suggested that parents wanted not just reassurance, but an opportunity to share the responsibility.

*“ ... they want someone else to take a bit of the responsibility ... and as long as it's safe, and as long as you say that you've got a chance of seeing that child again. And as long as you can explain to them that sometimes, most times, kids will fight it off on their own, but occasionally they may get worse, and if they do they need to see somebody again.” (GP focus group 1)*

A few GPs felt that parents consulted because they had unresolved worries, and that therefore they were always 'right' to consult, as these worries needed to be addressed. These GPs remarked that since parents spend more time with their children than the GP, their 'gut feelings' were often right and should not be dismissed lightly.

##### **Beliefs about parental expectations**

A number of clinicians talked about parents who were believed to have unrealistic expectations about what could be done for their children. They described parents who had unrealistic expectations for antibiotics as well as those with unrealistic expectations for home visits. There was widespread agreement that dealing with these expectations was often very challenging. This was especially so if the child had been seen previously for this illness, or if the parents had past experience of either receiving antibiotics for a similar problem or of not receiving antibiotics and the child becoming more unwell. However, it was also acknowledged that verbalising the expectation might make it easier to deal with.

*“I think that’s the difficulty isn’t it. Is when they come in and they’ve got that expectation. Although I suppose, if they are up front about what that expectation is, in some respects, that makes it easy because you know, once you’ve made up your mind what you are going to do, how you need to try and channel it.” (GP focus group2)*

### **Challenges for GPs**

Some GPs expressed uncertainty about making an accurate diagnosis and anxiety about preventing complications and deciding when antibiotics were likely to be effective. This uncertainty seemed to be heightened when seeing febrile children. One doctor expressed that he would be surprised if his diagnostic accuracy even approached fifty percent.

The GPs admitted that many challenges were attributable, at least in part, to the medical profession. Patients’ previous experience of being prescribed antibiotics and conflicting messages from different clinicians contributed to uncertainty, confusion, and increased expectations. Having clear practice policies and a consistency of approach was seen as important.

Other challenges that were described included dealing with outside pressures, such as media coverage of scare stories, the fear of missing a more serious complication with its subsequent effects on their doctor-patient relationship, their judgement and the medico-legal implications, concerns about changes in service delivery (losing continuity of care both in and out of hours), and concerns expressed in the medical literature about the association between lower prescribing and increased complications.

*“The only problem is that if, supposing somebody ends up with a meningitis. And the news is in the newspaper, and on the television, then what is going to happen? The prescribing rate for the antibiotic will go ten times.” (GP focus group 1)*

#### **2.4.3.2.3 Influence on booklet development**

## **Endorsement**

There was a fairly mixed reaction from the GPs about the use of a booklet on respiratory tract infections in children. Some thought that it would be a practical and useful tool while others expressed some reservations, saying that they did not think patients would read it. A couple of GPs expressed some concern about maintaining a steady supply of booklets, indicating that they were more used to printing patient materials now.

*“... that would be my concern is how ... is ensuring regular use ... a regular supply of them. And, I don't know, more and more as we get the computers to print these things, we haven't ... we seem to have less and less use for ready printed material.” (GP focus group 2)*

## **Safety-netting**

One of the main roles the GPs fulfilled during focus groups was in clarifying the wording to ensure that the messages were clear and were not likely to cause confusion. For example, concern was expressed about a statement giving advice about re-consulting for a child who had lost weight during a respiratory tract infection.

*“... it's not very practical, because, do we expect the parents to weigh them ... twice within a week? And also it's age related ... weight loss in younger, infants, you know, is quite significant, you know, older children ... is quite different.” (GP focus group 1)*

After some discussion it was suggested that the advice should be made more age specific. Similarly, re-wording was suggested for advice about persistent coughing. Some GPs were concerned that the advice to consult if a cough had persisted for more than three weeks may result in some children with asthma not being seen for this length of time. A caution was added indicating that the booklet should not be used for children with asthma, and the advice around persistent cough was amended to suggest that a child becoming breathless more easily, or with a family history of asthma, should be seen earlier. Similar wording modifications were made to sections on

febrile seizures, croup, discoloured nasal secretions, and weight loss. The GPs, like the parents, wanted to ensure that the booklet did not discourage worried parents from consulting.

### **Use of the booklet**

Unlike the parents who wanted the booklet expanded considerably, some GPs in both focus groups thought the booklet was too long. Some were concerned that parents would not read it, but the main concern was that use of the booklet would lengthen the consultation.

*“My concern is, if this is going to be used as a tool in the consulting room, and to be a realistic tool, we want it to be something that you can get through fairly quickly. And I can’t see me getting through to that end section.” (GP focus group 2)*

However, other GPs believed that having clear sections would enable them to just go through the relevant parts, and that this would be feasible within a normal consultation. Most GPs agreed that having some training on how to use the booklet within the consultation would be acceptable, and were happy for the booklet to include prompts which encourage exploration of concerns and expectations.

## **2.5 Other aspects of booklet development**

### **2.5.1 Developing the ‘interactivity’ of the booklet**

Evidence that written educational materials are more likely to be effective if used within the context of a face-to-face interaction was presented in chapter 1.(160, 161) Therefore, a key aim during the booklet development process was to ensure that it included elements to promote its use within the consultation. Early ideas were generated in the brainstorming meetings (see section 2.2.1) and included; having a space to personalise the booklet by writing the child’s name on it, having ‘tick boxes’ to facilitate the highlighting of information discussed or considered particularly relevant by the clinician, having a graph or chart depicting the natural history which could be used to visually demonstrate the child’s likely duration of illness and having a ‘checklist’ of tasks for the clinician to work through. Most of these ideas were well received by the focus groups. However, the checklist of tasks was dropped because



although it was perceived as a ‘good thing’ by most parents, a number expressed reservations about how realistic it was to expect a GP to run through it within a normal consultation. Furthermore, the study group felt that most of the ‘tasks’ could be prompted by the section headings and provided to the clinicians as part of their training in using the booklet (see section 2.5.3). As a result, the ‘task list’ was dropped and was replaced by two communication skills prompts. These prompts covered important aspects of communication (exploring the patient’s (parent’s) main concerns and addressing expectations), which have been shown to be important in these consultations,(131, 133, 134, 146, 170, 178) and were not covered by other aspects of the booklet. The prompts were worded in such a way that they could be used to prompt parents to raise the topics or prompt clinicians to address them within the consultation.

### **2.5.2 Academic GP review**

Following the first set of focus groups (four parent focus groups and one GP focus group) the study team decided to seek the views of a number of practicing academic GPs prior to the major revision of the booklet. Six academic GPs reviewed the booklet and provided valuable feedback relating to clarity of content, ease of use, and design issues. Many of these suggestions were incorporated into the draft booklet, which was taken into the second round of focus groups.

### **2.5.3 Booklet safety check**

The focus group process was ideal for identifying the needs of the intended consumers (parents of children suffering from a respiratory tract infection). It allowed us to test ideas, modify the booklet and then re-test it with end users, and therefore meant the final booklet was more likely to fulfil parents’ needs. Furthermore, the GP focus groups had allowed us to ensure the booklet was something that clinicians thought was useful, useable, correct and not misleading. As a final safety check we asked two practicing paediatricians to review the booklet with a particular emphasis on patient safety issues. Two potential safety issues (as well as a few other minor suggestions) were identified by the paediatricians. The first was to avoid advising that steam can be used in the management of croup. They cited a lack of evidence and concerns about potential burns from steam as reasons for leaving this advice out. It was subsequently removed. The other was with regard to advice about assessing

dehydration in children. Following requests from parents in the focus groups, fairly extensive advice on recognising signs and symptoms of dehydration in children had been included in the draft booklet. One of the paediatricians expressed concern that the assessment of skin turgor was difficult for health professionals and that suggesting that parents assess skin turgor may lead to confusion. As a result, the advice on assessing skin turgor was removed (although the rest of the advice on assessing dehydration was left in).

#### **2.5.4 Graphic design**

It has been argued that considering the design of information materials, particularly with regard to how it impacts on the reader's attention and comprehension, is an essential element of the development of such materials.(210) Guidance on producing patient educational materials and data from the focus groups both fed into the design of the booklet. However, in order to ensure that the booklet was attractive and appealing, and that its design facilitated its use within, and beyond, the consultation, a professional graphic designer was hired to design the final booklet. A series of meetings were arranged with the designer and these were used to discuss the aims of the booklet, its target audience, and design ideas. Draft designs were reviewed by members of the study team in an iterative process that led to the final design.

#### **2.5.5 Improving readability**

There are a number of 'tools' available for assessing readability. However, a reading age 'score' is not in itself a reliable indicator of readability.(193) Therefore, a 'basic skills' professional was employed to assess readability and to make recommendations for enhancing accessibility by those with low literacy levels. The booklet was initially assessed as having an average SMOG (simplified measure of gobbledygook)(211) score of approximately 15, which indicated that a large proportion of the UK adult population would have some difficulties reading it. The basic skills professional provided a four-page report containing detailed advice on word choice, sentence structure, and design features. A large number of the recommended changes were possible without any change to the meaning, and as a result the final booklet had an average SMOG score of approximately 10, which according to the National Literacy Trust suggests readability by most people.(212) An example of the final study booklet is included as appendix 5.

## **2.6 Developing the training website**

### **2.6.1 Introduction**

Training in study procedures (recruitment, consent, data collection, etc.) needed to be developed for all participating clinicians. In addition, in order to facilitate use of the booklet within the consultation, training in use of the booklet within the consultation was developed for intervention clinicians. Such training could be provided face-to-face, or using a multimedia website. Potential advantages to online training include:

- Allows for ease of recruitment of practices over a wide geographic area
- Savings in time and cost of travel to practices
- Allows practitioners to complete at a time and in a place (assuming they have a home computer) that is convenient to them, and at their own pace
- Allows for monitoring of progress and completion

However, these advantages need to be weighed against the cost of developing the site and the loss of face-to-face contact, which makes it more difficult for the research team to establish good relationships with participating clinicians, and may have an adverse impact on recruitment. For this study, in consultation with my supervisory team, I made a decision to use online training.

### **2.6.2 Overview of the website**

The website had three aims:

1. As a source of information about the study to aid in study recruitment
2. As a training resource on study procedures for all clinicians taking part in the study.
3. As a training resource on use of the booklet for clinicians in practices randomised to use of the intervention.

As such the site had pages that were accessible to all visitors, that described the study and what was required of clinicians who participated, gave pros and cons of participating (from the clinician's perspective) and provided details on how to contact that study team. The site also allowed users to 'log in' using a unique username and password. Requiring users to 'log in' allowed control over access to certain sections of the site (allowing only those in practices randomised to the intervention arm access

to the training on use of the booklet), and provided a way of monitoring usage of the site (pages accessed and time spent accessing them).

### **2.6.3 Developing the training on use of the intervention**

The aims of the training on use of the booklet were:

- To provide some background to the problem
- To describe the sections of the booklet
- To describe the seven tasks that clinicians should aim to achieve during each consultation. These tasks are:
  1. Conduct a thorough history and examination;
  2. Introduce the booklet during the consultation;
  3. Ask about and then address the parent's (and child's) concerns;
  4. Discuss the natural history of any symptoms the child has that are covered in the booklet;
  5. Explore the parent's (and child's) expectations;
  6. Discuss self-help options;
  7. Discuss signs and symptoms that should prompt re-consultation.

These aims were developed from the main aims of the study and are largely based on the theoretical underpinnings discussed in section 2.2 and the contents of the booklet.

#### **2.6.3.1 Developing the audiovisual material**

The use of multimedia in online training is associated with greater appeal,(213) and therefore may increase its effectiveness. We developed a number of videos that demonstrated each of the seven tasks being conducted, and some audiovisual 'flash' elements (moving diagrams with audio dialogue). We also included a number of relevant images to enhance the visual appeal of the site.

In order to develop the videos I contracted a video production unit, wrote the video scripts, hired actors and arranged for volunteer actors, developed and dressed the set and helped edit the videos.

### **2.6.3.2 Website production**

The website was developed by a professional web development team. I wrote the content in line with the aims and objectives, and it was then modified through a series of meetings with members of the study team. A number of meetings were then arranged with the web developers in order to discuss the aims and objectives and technical requirements for the site. The development became an iterative process with many reviews of the emerging site and subsequent modifications. The final site was reviewed by members of the study team and then by clinicians participating in the pilot study. Only minor modifications were made following the pilot. The study website can be viewed at [www.equipstudy.com](http://www.equipstudy.com)

## **2.7 Summary**

The intervention being tested in this study includes an interactive booklet and training in its use within the consultation. Leaflets and booklets come in many different forms, and are often of poor quality. An important aspect of this study was that the booklet be developed to a high standard; using both established methods (literature review, development of patient information, and focus groups with both parents and GPs), as well as novel approaches (personalisation of the booklet, using it to facilitate communication within the consultation, and training in use of the booklet). In this chapter I have described the development of both aspects of the intervention (booklet and training in its use). A publication, describing the development of the booklet, and outlining a framework for good practice in the development of materials designed for interactive use in the consultation, is included as appendix 6.

### **3 Trial Methods**

The trial methods were published as a protocol paper prior to data analysis. This paper can be found in appendix 7.

#### **3.1 Design**

A two-arm, cluster randomised controlled trial, comparing use of the intervention with usual care, was selected as the trial design.

##### **3.1.1 Reasons for choice of design**

Randomised controlled trials (RCT) are the design of choice for evaluating interventions. The most common type of RCT is the individually randomised trial. This type of design usually involves the randomisation of individual patients into one of two or more treatment arms. However, sometimes randomisation into treatment arms is done at the level of a group (or cluster). This type of study is known as cluster randomised trial. Individually randomised trials are generally preferable to cluster randomised trials, as the cluster design is a less efficient design that requires more patients for the same degree of power.(214) This is because the responses of patients within a cluster tend to be more similar than the responses of individuals within different clusters.(214) Furthermore, the design needs to be taken into account at every stage of the study, in particular in the sample size calculation, analysis, and consideration of potential bias. However, there are situations in which a cluster design is the preferred (or only) option. The main reason for choosing a cluster design rather than an individually randomised design is the need to avoid contamination.

In this study, a cluster design was chosen in order to try and avoid treatment contamination. The intervention was directed in part at the clinicians, with clinicians in the intervention arm receiving online training in using the booklet within consultations. This training provided them with background information about the issues the trial was aiming to address, reviewed the contents of the study booklet, and discussed and encouraged the use of certain communication skills. The study booklet contained information on respiratory tract infections in children that some clinicians might not know, or at least might not be completely familiar with. Furthermore,

reading through the booklet and discussing it with patients (parents) may change their knowledge or beliefs about these infections, or change the dialogue they have with parents about these illnesses. It is not feasible to imagine that a clinician who had completed this training, and had used the booklet with some parents, would be able to switch back to their untrained state at will.

Contamination can also occur in terms of patients sharing the intervention. If this study randomised individual patients, parents who had received the booklet could have shared it (or shared knowledge gleaned from it) with parents whose children had been randomised to the control arm. The possibility of this occurring exists in a cluster RCT, but the risk would be greater in an individually randomised study where participants in different treatment arms are in the same practice and are therefore more likely to know each other. Nevertheless, this type of contamination is unlikely to have occurred to a large degree and would not in itself have been justification enough for a cluster design.

One potential problem with cluster RCTs is increased risk of selection bias. This can occur if the cluster (a general practice in this study) is aware of their study allocation prior recruiting patients. The possibility of selection bias and the steps taken to minimise and measure it are discussed in 3.9.1.

### **3.1.2 Trial arms**

Practices were randomised to use of the intervention (which involved providing practices with a supply of study booklets and training on use of the booklet within consultations) or usual care. The intervention has been described in detail in chapter 2.

### **3.1.3 Justification for comparison group**

‘Usual care’ was chosen as the study comparison group. Other comparisons were considered including provision of a booklet on another topic (such as healthy eating) and provision of a very basic leaflet on RTI. The use of an alternative booklet or leaflet as a comparator would have helped control for ‘placebo’ effect from receiving a booklet. However, the main aim of this trial was to assess the effectiveness of the booklet in routine practice. As such, a comparison with usual care is the best approach

to identify the likely effect should this intervention be introduced into routine care. If an alternative ‘best practice’ approach existed then it would have been reasonable to use this as a comparator. However, although some interventions, such as delayed prescribing, have been shown to reduce consultations and antibiotic prescribing, there are no interventions that have been accepted as standard ‘best practice’ or that have been shown to improve parental satisfaction, reassurance and enablement, as well as prescribing and consulting, for these conditions.

## **3.2 Outcomes**

### **3.2.1 Primary outcome**

Reconsultation with a primary care provider for the same illness episode, within two weeks of the index consultation, was chosen as the primary outcome. Previous studies have shown that around 20% of children who consult for a RTI will reconsult for the same illness episode.(15-17) Such a high proportion seems likely to be unnecessary for a group of conditions that are generally self-limiting and not associated with a high incidence of complications. Reconsulting not only contributes to increased use of healthcare resources and costs for parents and children, it provides an additional opportunity for antibiotic prescribing and may increase the expectation for antibiotics. Re-consultation was therefore seen as an important, and potentially modifiable, primary outcome.

### **3.2.2 Secondary outcomes**

The following were selected as secondary outcomes:

- Antibiotics prescribing at the index consultation
- Antibiotic prescribing and antibiotic consumption during the two weeks following recruitment
- Parent’s intention to consult in the future should their child develop a similar illness
- Parental satisfaction with the care provided at the index consultation
- Parental reported level of reassurance following the index consultation
- Parental enablement
- Parental rating of the ‘usefulness of any information received’ during the index consultation



- Length of the index consultation
- Consultations for respiratory tract infections over the following year

A number of other outcomes were measured which related to the economic evaluation (see chapter 6). These included:

- Parental time off work and occupation
- Time off school
- Travelling expenses related to consultations occurring during the two weeks following the index consultation.

Any hospital admissions or serious complications were recorded and for hospital admissions the number of nights admitted, whether the parent believed the admission was related to the illness the child had presented with when enrolled into the study, and notes on the admission, were recorded.

### **3.2.2.1 Choice of secondary outcomes**

Concerns about the widespread use of antibiotics to treat these infections have been discussed in the introductory chapter. Therefore, antibiotic prescribing during the index consultation is an important outcome that was considered as a primary outcome. However, reconsulting was selected as the only primary outcome for the following reasons: we decided to select a single primary outcome in order to keep the specified sample size feasible, and we had good data on expected rates and an ICC (intracluster correlation coefficient) for reconsulting and less good data for prescribing, and a reduction in reconsulting would be likely to result in a reduction in overall antibiotic use. Antibiotic use within the two-weeks following the index consultation, and antibiotic consumption (as reported by parents) are also important measures of antibiotic use.

Future consulting intentions is an important intermediary that is likely to be related to the number of consultations over the following year. If consulting intentions are affected by the intervention, but actual consultations are not, it would suggest that the intervention had an immediate effect on consulting intentions but that this was not sustained. Satisfaction and reassurance are important patient-centred constructs. These were both measured using Likert scales that the study team felt had face

validity. Measuring the ‘value of the information provided’ was suggested during piloting of questionnaire, and a decision was made to include this question as a single item using a five-point Likert scale. However, none of these scales were subjected to any form of validation assessment.

Enablement is a concept developed by Howie and colleagues that is related to, but different to satisfaction.(215) The concept draws on the themes of patient centeredness and empowerment, and on the patient’s perceived changes in understanding, coping, and confidence. We adapted the Patient Enablement Instrument (PEI) for use with parents about the care of their children. This involved mainly minor changes in wording, but did require the item examining impact of the consultation on ‘ability to cope with life’ to be dropped as this seemed inappropriate when talking about a consultation involving a third party (the child). No formal validation of this adaption was conducted. However, its use was found to be acceptable in the pilot.

Length of the index consultation is important to measure both because it relates to the cost that use of the intervention has and because it relates to the applicability of the intervention (an intervention that results in a considerable lengthening of consultations is unlikely to be widely adopted). Hospital admissions and other serious adverse events are important to monitor for safety reasons.

### **3.3 Sample size specification**

The sample size calculation was based around a reduction in the primary outcome, the proportion of children reconsulting in primary care in the first 14 days, from 20% to 10%. In previous studies it has been shown that around 20% of children reconsult following their initial presentation.(15-17) It is not clear what the optimum level of reconsulting is, but it is reasonable to assume that a degree of reconsulting is necessary. In Macfarlane’s trial of a simple leaflet on LRTI, reconsulting over the next four weeks was reduced from 21.4% in the intervention group to 14.9% in the control group. Considering that most RTI in children are upper respiratory tract infections, and as such are generally less severe than LRTI, and that we were providing parents with a much more comprehensive booklet and that clinicians were receiving training in its use, my supervisors and I considered that a reduction in

reconsulting to 10% seemed feasible. Furthermore, a reduction of this magnitude (a halving on the proportion reconsulting) was considered to be a clinically important reduction.

### 3.3.1 Accounting for cluster design

As has already been mentioned, cluster randomised trials are not as efficient as individually randomised trials, and this needs to be taken into account in the sample size calculation. The most commonly used measure of the degree of similarity of responses within a cluster is the intraclass (intracluster) correlation coefficient (ICC). The ICC is a measure of the proportion of total variance that is attributable to between cluster variance. In other words it is the between-cluster component of variance divided by the product of the between-cluster component of variance and the within-cluster component of variance (figure 3.1).

Figure 3.1 Intraclass correlation coefficient

$$\rho = \sigma^2_A / (\sigma^2_A + \sigma^2_W)$$

Where:  
 $\rho$  is the ICC  
 $\sigma^2_A$  is the between-cluster component of variance  
 $\sigma^2_W$  is the within-cluster component of variance  
Reference (217)

The ICC for this trial was calculated using data from a primary care trial of an intervention for children with a respiratory tract infection.(15) Although this was not a cluster RCT, it was possible to use this data as patients were recruited by a number of practices, and the proportion reconsulting was recorded as an outcome. Using this data an ICC of 0.04 was calculated.

### 3.3.2 Sample size calculation

The software package nQuery was used to calculate a sample size required to show a difference in the proportions 0.2 and 0.1, using a two-sided test without the continuity correction, with a significance of 0.05 and 80% power for an individually randomised

trial. This calculation indicated that a sample of 199 in each group would be required. Rounding this up to a sample of 400, and using an ICC of 0.04, the formula in figure 3.2 was used to calculate a number of possible combinations of corrected sample size and number of clusters. Possible combinations are given in Table 3.1.

**Figure 3.2 Formula to inflate sample size to account for clustering**

$$N = \frac{nK(1 - \rho)}{K - n\rho}$$

where:  
 N is the corrected sample size  
 n is the uncorrected sample size  
 K is the number of clusters  
 ρ is the ICC  
 Note: K must be greater than nρ

**Table 3.1 Possible combinations of number of clusters and sample size**

<b>Number of clusters</b>	<b>Average cluster size</b>	<b>Total sample size</b>
20	96	1920
30	27.43	823
40	16	640
50	11.29	565
60	8.73	524
70	7.11	498

As can be seen from this table, a small increase in the number of clusters can result in quite a large reduction in the total sample size required. From these possible sets of sample size and number of clusters, 524 patients from 60 practices was judged to be the most feasible in terms of the potential to recruit practices and patients and logistics. In order to allow for loss to follow-up and missing data the total sample size was inflated to 600, which meant a target of ten participants for each of the 60 practices.

### **3.4 Potentially discardable pilot**

The trial procedures and materials were piloted through a potentially discardable pilot in two practices. The first two practices recruited into the study were randomly assigned, one to intervention and one to control, by the study statistician. Two participating clinicians in one practice, and one clinician in the other practice, were interviewed after recruiting at least two patients each. No major problems were identified as a result of these interviews and therefore the data from these practices was included in the main dataset and the trial was expanded to include other sites. However, comments from these interviews did lead to a number of changes to the information provided to clinicians about recruitment procedures, and to the training website.

### **3.5 Recruitment of practices**

General practices were recruited from Wales and England. All practices that were willing to participate were considered eligible. The initial plan was to recruit practices in South Wales and English counties bordering South Wales. These regions were chosen in order to facilitate travel to practices for training purposes (as the research team was based in Cardiff). However, during the development of the study intervention the study team decided to provide all training to practices through the study website. As a result, it became feasible to recruit practices throughout England and Wales. Practices in Wales were contacted initially by a written invitation (flyer) sent through the post. Another trial dealing with the management of respiratory tract infections in primary care was about to begin recruiting practices at around the same time as this trial. Following discussions with the other study team we decided that the two studies were not compatible in that each may influence the results of the other. The teams therefore decided to randomly divide the practices in each Local Health Board (LHB) to be approached first by one study or the other. Practices that declined participation in one study were then invited to participate in the other study. A decision was made to first approach practices in LHBs where English was the first language for the majority of the population (as we did not have study materials in Welsh). Following the postal invitation, attempts were made to contact a general practitioner or practice manager in each practice by telephone. Practices where one or more clinicians expressed an interest in participating were asked to provide the names

of interested clinicians, further contact details, and their practice list size, and were sent a practice agreement to complete. This agreement outlined the terms of participation, and asked for permission to obtain the practice's antibiotic prescribing rate for 2005/06 from either Health Solutions Wales or the Local Health Board or Primary Care Trust (PCT) for the practice. Practices who returned a signed agreement were randomised. Practices who failed to return an agreement were contacted by telephone at least two further times in order to discuss any concerns and / or remind them to return their agreement.

Practices in England were recruited using different methods. A number of general practice research networks were in operation at the start of the trial, and helped to recruit practices. Furthermore, during the recruitment period a national research network, Primary Care Research Network (PCRN), part of the United Kingdom Clinical Research Network (UKCRN), was established and this study was accepted onto its portfolio and promoted amongst participating networks. Network co-ordinators provided practices with details of the study and passed the details of interested practices on to the study team. These practices were then contacted, and if still interested, sent a practice agreement.

### **3.6 Randomisation of practices**

Practices were randomised using block randomisation with random block sizes between 4 and 6. Block randomisation helps ensure an even distribution of certain characteristics (practice characteristics in this case) between the two treatment groups. Keeping the block sizes random helps to maintain allocation concealment by making it more difficult to predict the next allocation.

#### **3.6.1 Stratification variables**

The practice characteristics (stratifying variables) selected were: country in which practice is located (Wales or England), practice list size, and practice antibiotic prescribing rate. There are a number of demographic and health service related differences between Wales and England, and therefore stratification by country is important. Practice list size is known to be related consultation length,(205) reported availability,(206) and range of services offered.(207) In addition, larger practices are more likely to have a practice nurse or nurse practitioner consulting with patients with

minor illnesses, and nurses have been shown to consult differently to GPs.(216-218) Practice list size was compared with the mean list size for Wales (6,169). This was provided by Health Solutions Wales (HSW), an NHS Wales organisation that collects and holds Welsh health data, and was based on 2005 data. The average list size for practices in England was calculated using data from the Department of Health website. The calculated value (6,148) was so similar to the value for Wales that the former was used as the cut-point for all practices. Practice antibiotic prescribing rate was selected because antibiotic prescribing was one of the main outcomes of interest. In Wales, practice level prescribing data is held by HSW. Following the registration of a new practice in Wales an email request was sent to HSW requesting data about the practice's antibiotic prescribing rate (British National Formulary Chapter 5.1 items per 1000 registered patients) for the financial year 2005/06. HSW compared each rate with the median rate for Wales (700 items per 1000 patients) and indicated whether the practice was above or below this median. For practices in England, the antibiotic prescribing rate (using the same criteria as for Welsh practices) was requested from a prescribing advisor within each practice's PCT. These rates were then compared with the mean prescribing rate for practices in England in the same year (617.8 items per 1000 patients), which was obtained from the Prescription Pricing Authority division of the NHS in England under the Freedom of Information Act (they were not able to provide a median).

A potential stratifying variable that was considered was the socio-economic status (SES) of the area in which a practice is based. SES is likely to have an influence on the outcomes of interest (re-consulting and antibiotic prescribing). However, the antibiotic prescribing rate of the practice is clearly a more direct marker of the tendency to prescribe antibiotics, and antibiotic prescribing is correlated with SES, and therefore balancing for antibiotic prescribing should result in a degree of balance in SES. Furthermore, there are a number of potential problems in using practice-level markers of SES. Practice deprivation indices are often based on the geographical location of a practice, and this not always a good indicator of the SES of the practice population. In addition, many practices have patients coming from a range of socio-economic classes, and therefore it is difficult to assign a summary statistic for the practice as a whole. Therefore, we decided to include antibiotic prescribing rate and to not include SES as a stratifying variables.

### **3.6.2 Randomisation procedure**

The study statistician prepared eight allocation tables (one for each combination of the three stratifying variables). These were kept as spreadsheets on a server, which was accessible only to the study statistician and her assistant. Random block sizes were used to decrease the chance of predicting the next allocation based on previous allocations. Once a signed practice agreement was received the study statistician (or her assistant) was provided with the practice ID number and the three stratifying variables for that practice. Practice allocation was then communicated to the study team and recorded on the study database and the relevant allocation table. Therefore, allocation concealment was maintained from the study team during the practice recruitment procedure.

### **3.7 Clinician training**

Two types of training were provided to participating clinicians. An overview of the study and training in study procedures was provided to all clinicians, and training in use of the intervention was provided to clinicians in practices randomised to use of the intervention. Both types of training were provided via a dedicated study website ([www.equipstudy.com](http://www.equipstudy.com)).

A description of how the website was developed and an outline of training in use of the intervention are included in section 2.6. The following section describes the ‘study overview’ and ‘training in study procedures’, which all participating clinicians were asked to complete.

#### **3.7.1 Study overview and training in and study procedures**

All participating clinicians were asked to complete two brief web modules (study overview and study procedures) prior to recruiting patients. The study overview gave a brief background to the study, the study aims, and what participating in the study involved for clinicians. The training in study procedures consisted of:

- Information about the study materials that they were to receive
- Suggestions on remembering the study and recruiting participants during a busy surgery, and information on the importance of approaching all eligible patients and not being selective.
- Reminder of the study inclusion and exclusion criteria



- A suggested recruitment process –reception staff to provide study information sheets to all potential participants and a discussion about eligibility to be held with the parent by the participating clinician.
- Information about informed consent, and in particular obtaining assent from children when possible.
- Information about how to complete the Case Report Form (CRF)
- Information about conducting the consultation (intervention practices reminded to complete intervention training, control practices told to conduct consultation as they normally would).
- Information about sending the CRF to the study team
- Information about the importance of accuracy in data collection, and
- Information about how the patient will be followed-up for study purposes.

### **3.8 Recruitment of patients**

#### **3.8.1 Inclusion / Exclusion criteria**

Patients eligible for inclusion were children aged 6 months to 14 years of age (up to but not including those who had reached their 15<sup>th</sup> birthday) who had been ill for 7 days or less, and had been diagnosed by their primary care clinician as having an acute respiratory tract infection. This included children suspected of having both upper and lower respiratory tract infections, and viral or bacterial infections, and those with sore throat, otitis media and sinusitis.

The following exclusions were applied. Children:

- With suspected pneumonia
- Who had been formally diagnosed with asthma or who are currently taking or in need of oral or inhaled steroids or inhaled bronchodilators
- Judged to need immediate admittance to hospital or with serious / concerning features
- With serious concomitant illness (i.e. malignancy, cystic fibrosis)
- Whose carer was unable to comply with the study protocol
- Who had been seen previously for this illness episode
- Who had been previously recruited into the trial (each child can only be recruited into the trial once)

- Who had a sibling who has been recruited into the trial (each family can only be recruited into the trial once)

### **3.8.2 Justification for inclusion / exclusion criteria**

#### **3.8.2.1 Age criteria**

Children less than 6 months of age can have different clinical features (for example, are less likely to develop fever) and are at greater risk of serious complications than older children.(219) As one of the main aims of the study was to encourage parents to self-manage these illnesses in their children, it was judged to be inappropriate to include very young children who may be at greater risk from this approach. Older children are less likely to consult,(12) and to be prescribed antibiotics,(31) than younger children, and are therefore less likely to benefit from use of the intervention. Furthermore, older children start to play an increasing role in the decision-making around their illnesses and therefore an intervention aimed at teenagers would likely be more effective if it was targeted more specifically at them. Our intervention had been designed to be used by older children as well as parents, but was primarily aimed at parents. For these reasons we chose an upper age limit of 14years.

#### **3.8.2.2 Other illness exclusions**

Asthma, as a condition that affects the respiratory tract, is known to influence the presentation and course of respiratory tract infections in children. Asthma and wheezing in children are common, and therefore including them in the study would have increased the study's generalisability. However, the management of children with asthma is considerably more complex and the study team decided that to expand the booklet to include information about the management of asthma would make the booklet too long and potentially confusing.

The study intervention was largely aimed at enhancing home management and therefore children who required immediate hospitalisation were not enrolled. Children with serious concomitant illnesses are likely to have a different illness course and be at greater risk of complications and were therefore also excluded.

### **3.8.2.3 Other exclusions**

Parents needed to be able to follow the study protocol and read the study materials (including the booklet if in the intervention arm). The study materials were only provided in English and therefore those who did not have adequate English language reading skills were excluded. As the intervention was largely directed at the recruited child's parent(s) recruiting siblings would have resulted in contamination in that the parents would have already been exposed to the intervention and this may have influenced outcomes.

### **3.8.3 Recruitment process**

Participating clinicians were given information about how to recruit participants, and advice about an approach to recruitment that might aid the process. This information was largely provided via the study website but was also reinforced through written study materials and verbal communication with practices.

#### **3.8.3.1 How to recruit participants**

Clinicians were told that participants were to be invited during routine surgery sessions. Potentially eligible participants could be identified by others (see below) and given information about the study, but that the responsibility for assessing eligibility was with the participating clinician. The clinician was asked to discuss the study with the parent or carer of all potentially eligible children and to record information about all those who were not able to participate, declined participation, or were not invited. They were also instructed that the parent or carer of all children invited to participate should be provided with a study information sheet, be given adequate time to read it and consider participation, and to sign a consent form if they are happy to participate. Furthermore, clinicians were asked to assess the competency of the children, and where a child was deemed to be Fraser competent (i.e. understands the implications of the proposed study), to provide them with an information sheet specifically designed for young people, and to ask them to sign an 'assent' form in addition to the parent signing a consent form.

#### **3.8.3.2 Recruitment suggestions**

In order to try and facilitate recruitment during a busy surgery session, and to ensure that parents have adequate time to consider their participation, we suggested that

information packs (which included the adult study information sheet, the young persons information sheet, the parent consent form, and the young persons assent form) were provided to potential participants by reception staff. In most general practice surgeries patients report their arrival to a member of the reception staff. Posters for the waiting room or reception area that informed patients about the study, and guidance for reception staff on identifying potentially eligible patients, were provided to all participating practices. Practices were advised to ask their reception staff to identify potentially eligible patients and to provide their parents with an information pack when they first arrived in the surgery. In many instances this would give the parent time to read through the study information prior to entering the consultation room. Although clinicians would still need to discuss the study, answer questions, assess eligibility, and obtain informed consent during the consultation, allowing the parents to read the study information prior to entering the consultation room was likely to make this process more efficient. Clinicians choosing this recruitment approach were advised to keep participant information packs in their consulting room as well so that eligible patients that had not been identified by the reception staff could still be approached.

### **3.9 Data collection**

#### **3.9.1 Patients not recruited**

In order to assess for potential selection bias, practices were asked to recruit sequential eligible patients, and to record non-identifiable information about all those ‘potentially eligible patients’ who:

- Were subsequently deemed ineligible
- Declined participation
- Were not invited to participate

‘Potentially eligible patients’ included all those who had been identified as potentially eligible by a practice receptionist, and all those with whom the study had been discussed by the participating clinician.

The following data was collected on all ‘potentially eligible participants (including those who were recruited):

- Date of consultation
- Duration of illness (in days)
- Age (in years)
- Gender
- Whether the patient was recruited or not and the reason for non-recruitment if not
- And the presence or absence of the following symptoms:
  - Cough
  - Sore throat
  - Fever
  - Earache
  - Runny nose
  - Appears unwell (subjective assessment by the clinician)

### **3.9.2 Case report form (Patient Encounter Sheet)**

The case report form (CRF) (which was titled ‘Patient Encounter Sheet’ during the study) was used to collect the above information about both recruited and non-recruited patients, and to provide further information about recruited patients (and their parents). The following additional information was provided for recruited patients:

- Child’s date of birth
- Parent(s) name(s)
- Address for parent(s)
- Telephone number(s) for parents

Participating clinicians were asked to fax completed CRFs (both for recruited and non-recruited patients) to the study team at the end of each surgery session. An example of CRF can be found in Appendix 8.

### **3.9.3 Two-week follow-up**

Outcomes were measured primarily through a telephone-administered questionnaire with the child’s parent or guardian at two weeks.

### **3.9.3.1 Contacting parents / guardians**

The study database was set-up such that the consultation date for each recruited participant was used to identify the date for the two-week telephone call. Using these dates the database was used to prepare a daily list of participants due for their two-week follow-up call. The telephone number(s) provided on the CRF were used to attempt to contact the child's parent(s). Attempts to contact the parent(s) were made at least once each day for at least three days. Where the number provided was found to be incorrect the practice was contacted and asked to provide an alternative number. If an alternative number could not be provided (or was also incorrect) then attempts were made to obtain the number using on-line directory enquiries. Where a correct number could not be identified or when attempts to contact the parent(s) for at least three days were unsuccessful, then a letter and a paper-based questionnaire were sent to the parent(s). The letter asked the parent(s) to either telephone the study team with a new contact number or to complete the written questionnaire (see section 3.9.3.3) and return it in the postage-paid envelope provided.

### **3.9.3.2 Telephone-administered questionnaire**

The questions for the telephone questionnaire were included as a form on the study database. In most instances the database was open during the interview and the responses were recorded directly into the database. On occasion it was necessary to contact participants outside regular working hours, and in order to allow this a paper version of the questionnaire was developed. When this was used the responses were recorded on the paper and entered into the database by the researcher who conducted the interview, at the earliest opportunity. I conducted the majority of telephone questionnaires. However, one other member of the study team conducted the telephone questionnaires during my annual leave. The name of the person conducting the questionnaire was recorded on the database.

The questions and possible responses for the telephone questionnaire can be found in appendix 9.

### **3.9.3.3 Paper questionnaire**

Participants for whom telephone contact could not be achieved were sent a paper questionnaire. In order to encourage completion of this questionnaire it was an abridged version of the telephone-administered questionnaire, covering only the main outcomes (reconsulting and antibiotic prescribing). A copy of this questionnaire can be found in appendix 10.

### **3.9.4 One-year follow-up**

Participating practices were asked to search the primary care record of each patient enrolled in the study for the one-year period following their date of enrolment. For each practice, one year after the date on which they recruited their last patient, a letter reminding them about collecting one-year follow-up data and a form for completion were sent. The following data was requested for each participating patient:

Reconsultation data:

- Total number of surgery consultations
- Total number of telephone consultations
- Total number of home visits
- Total number of primary care out-of-hours consultations
- Number of surgery consultations for a RTI
- Number of telephone consultations for a RTI
- Number of home visits for a RTI
- Number of primary care out-of-hours consultations for a RTI

And, data about the length of the consultation in which the patient was enrolled (the index consultation), including:

- Start and end times, or
- Length in minutes

The information provided to practices informed them that they could choose to summarise the information themselves and write the numbers on the form provided, or send print-outs of the primary care records for participating children for the relevant time periods. The form provided to them listed the name, date of birth, date of consultation, and recruiting clinician for each enrolled patient. It also provided

them with space to in which to record the requested data. The information provided to the practice also gave guidance about what would be considered as a respiratory tract infection (RTI). An example is included in appendix 11.

### **3.10 Data management**

#### **3.10.1 Data handling**

A Microsoft Access database was developed to store all study data. This database was stored on a shared server owned by Cardiff University that all members of the study team had access to and that was backed-up daily by Cardiff University Information Services.

Faxed CRFs were collected by a study administrator, entered into the study database, and then stored in a locked cabinet. The database was designed such that fields had limited response options or limited acceptable ranges, as appropriate. This was to help minimise errors in data entry. Similarly, the database form for the telephone questionnaire had field restrictions that helped to minimise errors in data entry. Furthermore, entering the data directly into the database during the administration of the questionnaire helped minimise copying errors, and errors related to recall. Returned paper questionnaires were entered into the database and then stored in a locked cabinet.

Once the collection of two-week data had been completed a copy of the database was exported into STATA version 9 for data cleaning. Data from the one-year follow-up continued to be entered into the main study database. This was exported into STATA version 9 as a separate file, following collection of this data.

#### **3.10.2 Data cleaning**

##### **3.10.2.1 CRF double entry**

A ten percent sample (65) of all CRFs (including non-recruited patients) was randomly selected for double entry. Eight errors were detected giving a cell-wide error rate of 0.95% (8/845 cells), which is less than the 2% error rate that was considered to be acceptable. The most frequent error was 'age' which had been



recorded in decimal form or in months by some investigators and yet could only be recorded in the database in whole years. Therefore, I conducted more extensive validation of the age data (see below) and a calculated age, using the participant's date of birth and the date of the consultation, was used for recruited participants.

### **3.10.2.2 Missing data, range, and validity checks**

For all variables that had been obtained from the CRFs, missing data were identified and checked against the original CRF. Range checks were used to identify values outside the expected ranges. Duration of illness had been recorded as '0' when it was missing – these values were identified, checked, and corrected. Symptoms were identified on the CRF by placing a mark in a box to indicate the presence of a symptom and to leave it blank if a symptom was not present. Eight patients were found to have no symptoms indicated. Examining these patient's CRFs resulted in one or more symptom being recorded for four patients. A decision was made to change all symptoms to 'missing' for the other four. All patients with a recorded age of less than two were identified so that those whose age had been provided in months could have this re-entered as a decimal age in years. A 'calculated age' was created using the patient's date of birth and consultation date, where available. Age, date of birth, and consultation date were all checked against the paper CRF for all patients where the calculated age and the age from the form differed by one year or more. The calculated age was used as the default age and the age from the CRF was used if calculated age was missing (i.e. date of birth and / or date of consultation were missing).

### **3.10.3 One year and consultation length data**

Where practices had provided computer print-outs, I reviewed them and extracted the relevant data onto the one-year data collection form for that practice. This form was then used to enter the information into the study database. For practices that had summarised the data on to the one-year data form, an administrator in the South East Wales Trials Unit entered this information directly into the study database. The relevant information was extracted from the database and examined in Stata.

The data were examined for occurrences of:

- Consultations for RTI exceeding all consultations, in each of the four categories (surgery, telephone, home visits, out of hours)

- Missing values. Where there were missing values for RTI consultations and zeros for ‘all consultations’, the missing values were replaced with zeros. Other missing values were assessed by examining the form to see if it was likely that they were intended to be zeros instead of missing.

For consultation length data, where a start and end time for the consultation had been given these were used to calculate a consultation length. Other participants had a consultation length provided by the practice. Consultation lengths of zero minutes were changed to missing. All consultations over 30 minutes were identified and the source records were examined. Three participants from one practice had consultation lengths that were clear outliers and on the one-year data form a note beside these three participants indicated that they had been conducted, “in a student clinic”. After discussion with the study team these three participants were excluded from analyses that involved the time of the consultation.

A 10% sample (6 practices with 57 participants) was double-entered to assess for data entry errors. The cell-wide error rate was  $1/570 = 0.18\%$ , which is less than the 2% error rate that was considered to be acceptable.

### **3.11 Analysis**

Analysis was conducted using Stata version 9 and MLwiN version 2.11. Analysis (and data cleaning) in Stata was conducted by developing executable ‘Do’ files for each stage of data manipulation and analysis. Each stage of analysis was recorded in a ‘Log’ file, and the resultant data set was saved as a new file. Therefore each stage of the process was carefully recorded and could easily be returned to. A spreadsheet was maintained which identified all data files, Do files, and Log files.

The main analyses were conducted by fitting a two-level (practice and patient) random intercept logistic regression model using MLwiN version 2.11. A separate model was fitted for each main outcome, with the outcome as the response variable and study arm as the only explanatory variable. Iterative Generalised Least Squares (IGLS) was used to estimate the models. For discrete response multilevel models MLwiN uses quasi-likelihood methods to transform the model into a linear model.(220) Two types of approximation (Marginal Quasi Likelihood (MQL) and

Penalised Quasi Likelihood (PQL)) are available and either 1<sup>st</sup> order terms or up to 2<sup>nd</sup> order terms can be included. As recommended in the MLwiN user guide,(220) I used 1<sup>st</sup> order MQL approximation first, followed by 2<sup>nd</sup> order PQL approximation. The 1<sup>st</sup> order MQL is a more crude approach that can lead to biased estimates, but it is more stable than using 2<sup>nd</sup> order PQL which can lead to convergence problems.(220) Running the 1<sup>st</sup> order MQL first allows for starting values to be obtained, which can then be used to run a 2<sup>nd</sup> order PQL procedure in order to avoid convergence problems and provide more accurate estimates.(220)

### **3.11.1 Descriptives**

Standard descriptive statistical methods were used to describe the dataset at both the practice and individual levels. For continuous variables (age and prior duration of illness) the standard deviations were inflated to account for clustering. I achieved this by calculating an ICC for each variable and using this to calculate an inflation factor ( $IF = 1 + (\bar{m} - 1)\rho$ , where  $\rho$ =ICC and  $\bar{m}$  = average cluster size). For each continuous variable, the standard deviation was converted to variance, multiplied by the inflation factor, and then converted back to a standard deviation.

### **3.11.2 Primary analysis**

The primary analysis was an intention to treat analysis conducted by fitting a two-level (practice and patient) random intercept logistic regression model using MLwiN version 2.11 as described above. Prior to examining the data a clear outcome definition was developed and agreed by the study team. The agreed definitions for the two main outcomes are shown in Box 3.1.

#### **Box 3.1 - Main outcome definitions**

##### **Re-consultation**

The proportion of patients who report re-consulting in a face-to-face consultation with a primary care practitioner in the two week period from the date of registration.

##### **Antibiotic prescription**

The proportion of patients who report being given a prescription for antibiotics (either for immediate use or as a delayed prescription) during the consultation in which they were registered for the study.

New binary variables were created for the main re-consultation outcome and the main antibiotic prescribing outcome. Two-level logistic regression models were fitted in MLwiN as described above.

### **3.11.3 Secondary analyses**

#### **3.11.3.1 Future consulting intentions**

Intention to consult in the future was recorded as a binary outcome. This was analysed by fitting a two-level logistic regression model as described above.

#### **3.11.3.2 Satisfaction**

Satisfaction had been measured on a five-point Likert scale. After examining the distribution of responses, and considering face validity, it was converted to a binary variable (satisfied or very satisfied versus neutral, dissatisfied or very dissatisfied).

This binary variable was then modelled by fitting a two-level logistic regression model as described above.

#### **3.11.3.3 Reassurance**

Reassurance had been measured using a three-point Likert scale. After examining the distribution of responses and considering the implications of the responses the study team made a decision to convert this to a binary outcome ('very reassured' versus 'a little reassured' and 'not reassured'). This binary variable was then modelled by fitting a two-level logistic regression model as described above.

#### **3.11.3.4 Value of information received**

Value of information received had been measured on a five-point Likert scale that was similar to the scale used for satisfaction. For similar reasons, this was converted to a binary variable with the same cut-point as the satisfaction variable, and modelled in the same way.

#### **3.11.3.5 Enablement**

Enablement scores were calculated in the standard way (score of 0 to 2 for each item). However, as one item had been dropped the scores ranged from 0 to 10 (instead of 0

to 12). The distribution of the scores was examined and found to be skewed.

Therefore, a decision was made to convert enablement to a binary outcome using a mid range cut point of five. This was then modelled using logistic regression as for the other outcomes.

### **3.11.3.6 Long-term (one year) follow-up**

There were a number of possible ways in which the one-year follow-up data could be analysed and so it was important to define a main (or primary) one-year follow-up outcome. The main aim of the study was to reduce face-to-face consultations for respiratory tract infections. Therefore, after discussion with members of the study team, I decided that the main outcome for this analysis would be all primary care face-to-face consultations for respiratory tract infections (including surgery consultations, home visits, and out of hours consultations, but excluding telephone consultations). The data was then modelled in MLwiN using Poisson regression. The following secondary one-year follow-up analyses were conducted in a similar way:

- Total number of face-to-face consultations for any condition
- Total number of consultations for RTI (including telephone consultations)
- Two or more face-to-face consultations for RTI (binary outcome)

Two or more consultations for RTIs was selected as an indicator of frequent consulting, as this was more than the median in each group.

All the secondary analyses were conducted in MLwiN, with count data fitted using Poisson regression and the binary outcome fitted using logistic regression.

### **3.11.3.7 Consultation length**

Consultation length was analysed using a complete case analysis (missing cases were excluded). Following an examination of the distribution of consultation length data, which was found to follow a normal distribution fairly closely, a decision was made to analyse this data using linear regression in a two-level model (patients nested within practices) using MLwiN.

### **3.11.4 Sensitivity analyses**

In order to explore the validity of the main results a series of sensitivity analyses were conducted. For the two main outcomes, patient age, prior duration of illness, the practice stratification variables (practice size, historical practice antibiotic prescribing status, and country in which practice is located), and symptoms which were found to be statistically significant at the 10% level in univariate analyses were included in the models. These analyses were conducted as described above (using IGLS), and using Monte-Carlo Markov Chain (MCMC) estimation in MLwiN.(220) The latter allowed for calculation of a Deviance Information Criterion (DIC), which allowed for comparison of model fit.

### **3.11.5 Exploratory analyses**

#### **3.11.5.1 Subgroup analyses**

Following the main analyses the effect of the intervention on re-consulting and antibiotic prescribing was explored in a number of subgroups. The intervention included specific information on the likely duration of cough and on the management of fever and therefore I considered it feasible that use of the intervention may have a greater impact on reconsulting in participants with one of these clinical features. In addition, prior duration of illness, patient's age, receiving an antibiotic prescription at the index consultation, and the practice stratification variables (size of practice, antibiotic prescribing rate, and country in which the practice is located), were all considered to be factors which could potentially impact on the effectiveness of the intervention at reducing reconsulting. In order to assess for subgroup effects, each of these factors were added to the basic model one at a time. A similar process was followed for the main antibiotic prescribing outcome, with duration of illness, patient age, practice stratification variables (size of practice, antibiotic prescribing rate, and country in which the practice is located), and the presence of each of the six clinical features recorded (runny nose, cough, fever, sore throat, ear ache, appearing unwell) each being included as grouping variables. An argument could be made for why the intervention might be expected to have a differential effect in each of these groups. For each analysis the intervention effect, the grouping variable, and the interaction between the intervention and the grouping variable were included in the model. The models were analysed in MLwiN with two-level logistic regression modelling using

IGLS and MCMC estimations as described above. For the sub-group analyses the significance of the interaction coefficient was examined.

### **3.11.5.2 Variations in main outcome definitions**

The two main outcomes (re-consultation and antibiotic prescribing) could both be defined in a number of ways. Prior to the main analysis definitions of these two outcomes were agreed (see 11.2 above). However, analyses using a variety of other outcome definitions were conducted as exploratory analyses. New outcome variables were generated by combining outcomes in a number of ways (see Table 3.2 and Table 3.3). Binary outcomes were modelled in MLwiN using the approach described under section 3.11 above. Count outcomes (number of consultations occurring in the two week follow-up period) were modelled in a similar way, using Poisson regression instead of logistic regression.

**Table 3.2 Secondary reconsultation outcomes**

Any consultation with a primary care provider (GP, practice nurse or OOH) including face-to-face and telephone consultations
Any consultation with a primary care provider (as above) or an A&E department
Total number of face-to-face consultations with a primary care provider (GP, practice nurse, OOH) excluding telephone consultations
Total number of primary care consultations (face-to-face and telephone)
Total number of consultations (primary care and A&E, face-to-face and telephone)

**Table 3.3 Secondary antibiotic outcomes**

Prescription for antibiotics for immediate use at index consultation (excluding delayed prescriptions)
Prescription for antibiotics (immediate or delayed) either at the index consultation or at any point in the two-week follow-up period

## **3.12 Trial approvals, monitoring, and NHS costs**

### **3.12.1 Ethics approval**

The study was approved by the South East Wales Local Research Ethics Committee (Ref: 04/WSE04/109).

### **3.12.2 Sponsorship**

The study was sponsored by Cardiff University.

### **3.12.3 NHS research governance approval**

Approval was gained from the research governance officer (or committee) for each LHB and PCT in which practices were recruited.

### **3.12.4 Study Management Group**

A study management group was convened and met on a regular basis throughout the period of recruitment and follow-up to discuss progress and challenges. The membership of the SMG consisted of six members (CB, KH, SS, FW, JN, NF)

### **3.12.5 Trial Steering Committee**

An independent trial steering committee was convened to provide an independent perspective and oversight of the study. The committee had three independent members (IR-chair, JR, SL-lay representative) and met six-monthly during recruitment and annually thereafter.

### **3.12.6 NHS service support and excess treatment costs**

Service support and excess treatment costs were sought and obtained from the Welsh Office for Research and Development in social and health care (WORD) to pay for general practice time for participating in the study. Practices were paid £400 for recruiting ten patients (£200 after recruiting five patients and a further £200 for the next five). In addition, practices were paid £100 for each of the next five patients recruited, up to a total of £400 for recruiting 20 patients. These payments were to compensate for clinical time spent identifying and recruiting eligible patients, and the time of the clinician or a designate, for local management of the study, faxing study forms, and collecting follow-up data from the practice notes.



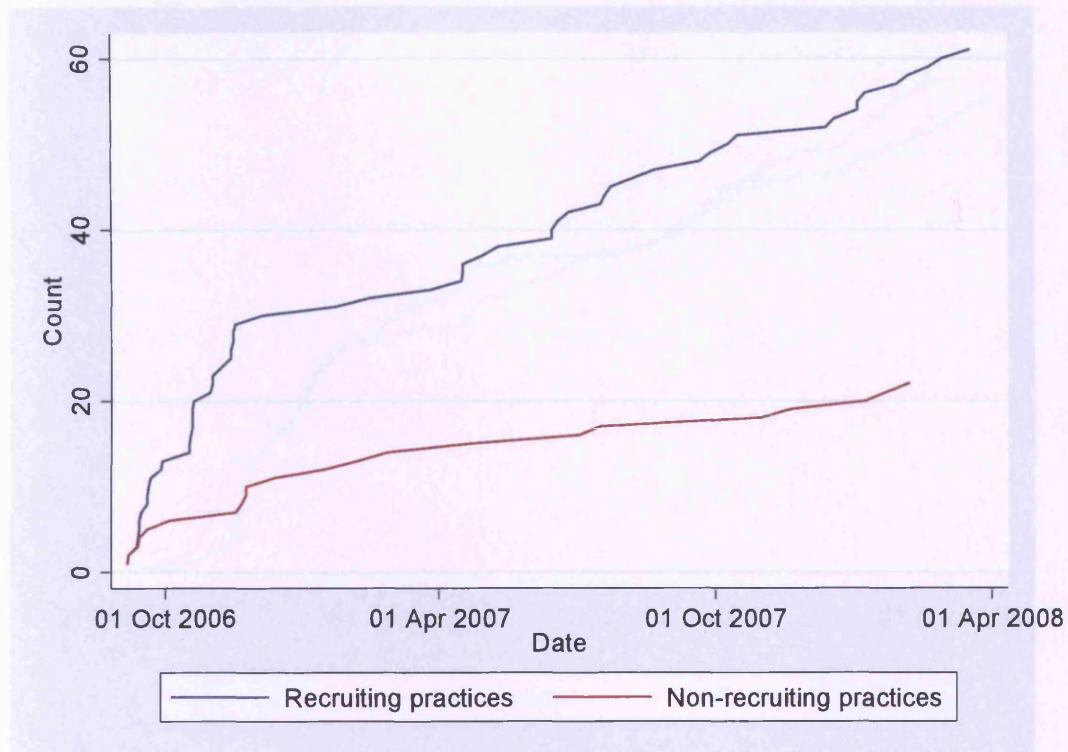
## **4 Trial Results**

### **4.1 Recruitment**

#### **4.1.1 Practice recruitment**

Practices were recruited into the trial between September 2006 and March 2008. Nine local health boards in Wales, with a total of 147 practices, were identified as being in primarily English speaking areas. Half of the practices in each of these local health boards were randomly selected to be sent information about the study (our research group was conducting another randomised controlled trial assessing a related intervention and the other practices were sent information about that study). This procedure was followed by attempts to contact a general practitioner or practice manager in each practice. Telephone contact with a general practitioner or practice manager was successful for 81 practices in Wales. 62 of these practices agreed to take part, although only 49 returned a practice agreement and were subsequently randomised. Of the 49 randomised practices, 36 recruited study participants. In England, four primary care research networks agreed to help recruit practices. The total number of practices approached in these networks is not available. However, 38 practices in England verbally agreed to take part, 34 of these returned a practice agreement and were randomised, and 25 of the randomised practices recruited participants. Practices (including those who went on to participate and those who did not recruit any patients) were recruited at a fairly consistent rate throughout the study period (Figure 4.1).

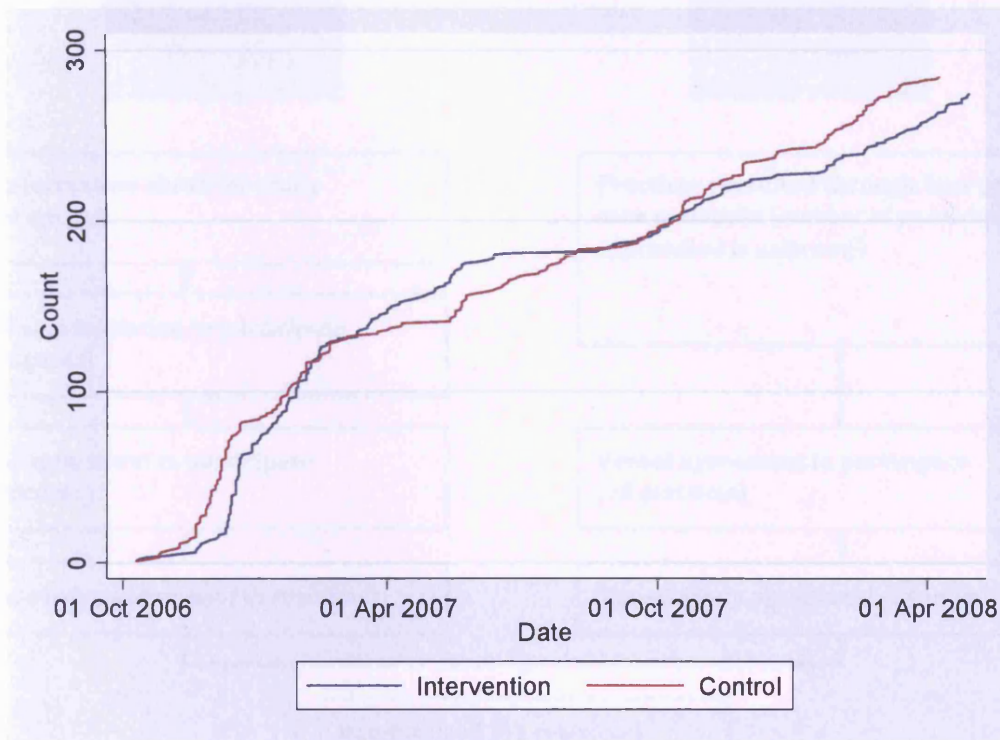
Figure 4.1 Practice recruitment



#### 4.1.2 Patient recruitment

Patients were recruited between October 2006 and April 2008. Patient recruitment also occurred at a fairly steady rate throughout the trial period (Figure 4.2). The recruitment rate increased during the first winter period (as expected given the increased incidence of RTI during the winter). No increase in recruitment was seen during the second winter period. No obvious reason for this was identified. As can be seen from the figure, recruitment in the two arms of the trial progressed at a similar rate.

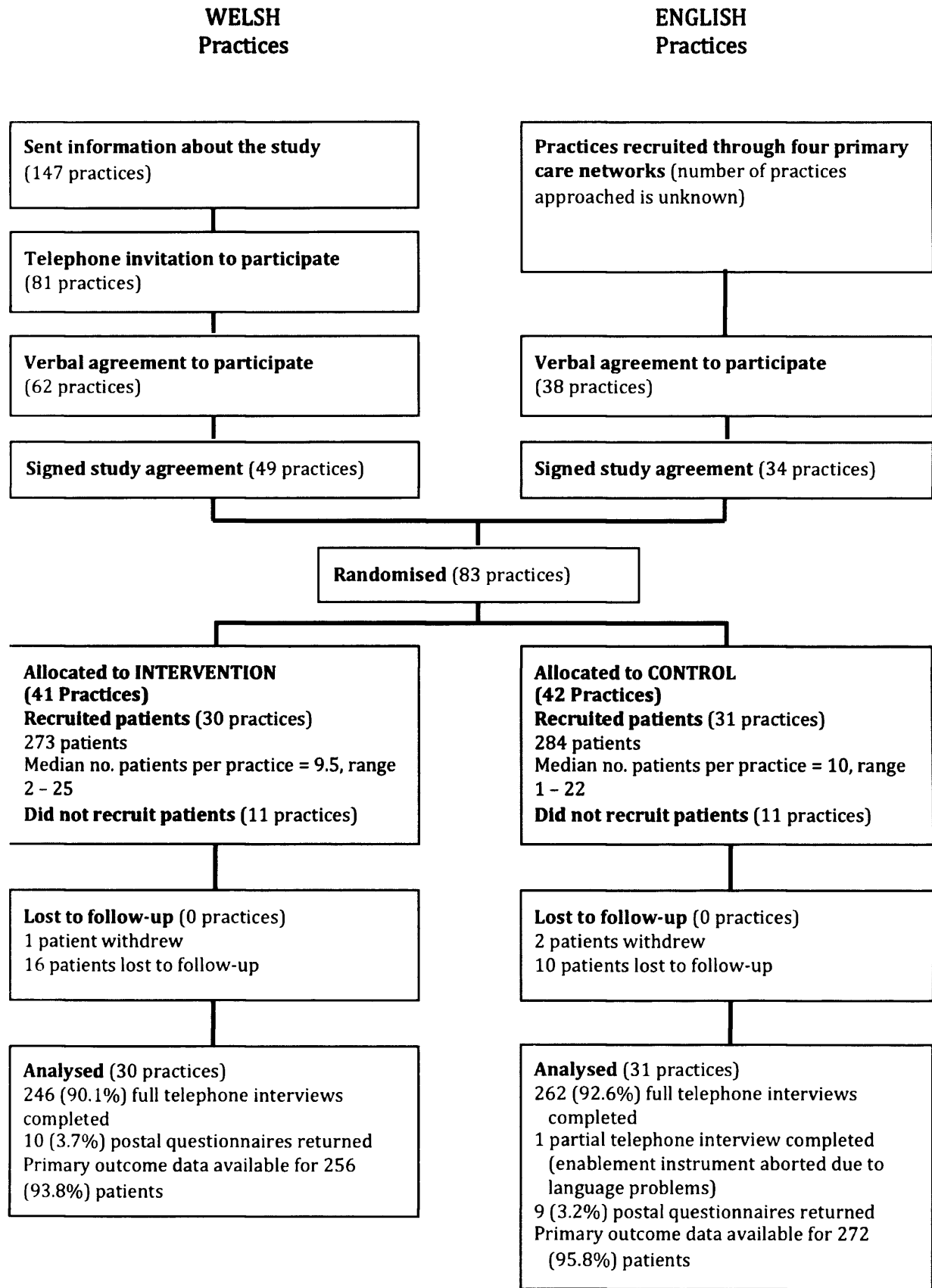
Figure 4.2 Patient recruitment by trial arm



### 4.1.3 Flow of participants

The flow of practices and patients through the study is shown in the CONSORT diagram (Figure 4.3). No participating practices (practices who had recruited one or more patients) withdrew from the study, and only 1 (0.4%) patient in the intervention arm and 2 (0.7%) patients in the control arm withdrew. 17 (6.2%) patients in the intervention arm and 10 (3.5%) patients in the control arm were lost to follow-up. Main outcome follow-up data was available for 93.4% and 95.8% of patients in the intervention and control arms respectively. However, 19 (3.4%) of these patients had completed a postal questionnaire instead of a telephone interview, and therefore only data on the main outcomes were available for these patients.

Figure 4.3 CONSORT flow diagram



\*One patient from the control group was subsequently found to have longstanding asthma and was therefore determined (after consultation with the trial steering committee) to have been 'recruited in error' and has not been included as a recruited patient.

## **4.2 Description of participants**

### **4.2.1 Randomised practices**

Eighty-three practices were randomised into the trial and of these 61 recruited one or more participant(s). Data about practice location (Wales or England), list size and antibiotic prescribing rate (above or below average) were collected. Practice list sizes ranged from 1,800 to 16,700, and the number of participating clinicians in each practice ranged from 1 to 9. There were no meaningful differences between the characteristics of practices randomised to intervention or control arms, or between practices that did and did not recruit patients into the study (Table 4.1).

Table 4.1 Characteristics of randomised practices by participation and study arm

	Participating Practices			Non-participating Practices			All Randomised Practices		
	Intvn.	Control	Total	Intvn.	Control	Total	Intvn.	Control	Total
<b>N</b>	30	31	61	11	11	22	41	42	83
<b>List size - mean (SD)</b>	7012 (3711)	6636 (3093)	6821 (3388)	7610 (4062)	7342 (3132)	7476 (3542)	7173 (3766)	6821 (3081)	6995 (3420)
<b>Above average prescribing - No. (%)</b>	9 (30.0)	10 (32.3)	19 (31.2)	5 (45.5)	3 (27.3)	8 (36.4)	14 (34.2)	13 (31.0)	27 (32.5)
<b>Located in England</b>	14 (46.7)	11 (35.5)	25 (41.0)	3 (27.3)	5 (54.6)	9 (40.9)	17 (41.5)	17 (40.5)	34 (41.0)
<b>Enrolled clinicians - median (IQR)</b>	2 (1, 4)	2 (1, 5)	2 (1, 4)	1 (1, 3)	1 (1, 2)	1 (1, 3)	2 (1, 3)	2 (1, 4)	2 (1, 4)

## 4.2.2 Participating clinicians

A total of 218 clinicians in the 83 randomised practices registered to participate in the study. The median numbers of registered clinicians per practice, in each study arm, are shown in Table 4.2. Just over half of these did not participate at all. A total of 103 clinicians recruited patients into the study, and a further 5 contributed data on non-recruited patients. 16 (15.5%) of the participating clinicians were practice nurses or nurse practitioners, with the remainder being general practitioners. The distribution of nurses (and subsequently the proportion of patients recruited by a nurse) was not evenly distributed between the two trial arms (Table 4.2). The possible implications of this are explored in the discussion chapter.

Table 4.2 Clinician registration and participation in the trial

<b>Clinicians who:</b>	<b>Intervention</b>	<b>Control</b>	<b>Total</b>
Registered for study	105	113	218
Contributed to data collection - including data on non-recruited patients (proportion of registered)	55 (52.4%)	53 (46.9%)	108 (49.5%)
Recruited participants (proportion of registered)	51 (48.6%)	52 (46.0%)	103 (47.2%)
Did not recruit participants (number and proportion who were nurses)	54 (6 nurses, 11.1%)	61 (6 nurses, 9.8%)	115 (12 nurses, 10.4%)
Nurses who recruited (proportion of recruiting clinicians)	5 (9.8%)	11 (21.2%)	16 (15.5%)
Proportion of patients recruited by a nurse	11.7%	20.1%	16.0%

## 4.2.3 Patients

Children recruited into the study ranged in age from 6 months to 14.5 years. The average duration of illness prior to being seen was 3.3 days (S.D. 1.7 days). Cough was the most common symptom with 61% of recruited children having a cough. Other symptoms were fever (38%), sore throat (36%), runny nose (33%), and sore ear (26%). Around 15% of children were judged by their clinician to 'appear unwell'.

Children recruited by practices in the two study arms were similar in terms of age, gender, duration of illness and symptoms (Table 4.2).

**Table 4.3 Participant baseline characteristics**

	<b>Intervention (N= 274)</b>	<b>Control (N = 284)</b>
<b>Age(yrs) – mean (s.d.)*</b>	5.1 (4.1)	5.3 (4.0)
<b>Male gender</b>	45.3%	53.5%
<b>Duration of illness - days (s.d)*</b>	3.2 (2.0)	3.3 (2.1)
<b>Clinical features – No. (%) with feature</b>		
<b>Cough</b>	173 (63.4)	167 (58.8)
<b>Earache</b>	74 (27.1)	69 (24.3)
<b>Runny nose</b>	85 (31.1)	97 (34.2)
<b>Sore throat</b>	89 (32.6)	112 (39.4)
<b>Fever</b>	103 (37.7)	109 (38.4)
<b>Looks unwell</b>	36 (13.2)	48 (16.9)

\* Standard deviations inflated to account for clustering

## **4.3 Main outcomes**

### **4.3.1 Re-consultation**

One or more re-consultations in primary care, within the two weeks following enrolment, occurred in 12.9% and 16.2% of children in the intervention and control arms respectively (Table 4.4). However, the difference was not statistically significant either when examined at a univariate level using the Chi-squared test ( $p=0.29$ ), or using multilevel modelling (odds ratio (OR) 0.75, 95% CI 0.41 to 1.38). The absolute difference equates to a number needed to treat (NNT) of 30 (95% CI 11 to -37). In other words, we can be 95% confident that the intervention effect lies somewhere between reducing one reconsultation for every 11 consultations in which the intervention is used to increasing one reconsultation for every 37 consultations in which to intervention is used.



### **4.3.2 Antibiotic prescribing**

A total of 30.5% of children were prescribed an antibiotic at the index consultation. By study arm, 19.5% of children in the intervention arm, and 40.8% in the control arm received a prescription for antibiotics at the index consultation (Table 4.4). The difference was highly statistically significant at the univariate level ( $p < 0.001$ ) and using multilevel modelling to account for clustering (OR 0.29, 95% CI 0.14 to 0.60). The equivalent NNT is 5 (95% CI 4 to 7), which means that we can be 95% confident that the intervention effect lies somewhere between a reduction of one antibiotic prescription in every four consultations in which the intervention is used, to a reduction of one antibiotic prescription in every seven consultations in which the intervention is used.

Table 4.4 Effect of the intervention on patient outcomes

Outcome	Number (%) experiencing outcome		OR from multi-level modelling (95% CI)
	Intervention (n=256)	Control (n=272)	
<b>Outcomes with data collected from telephone administered and postal questionnaires</b>			
<b>Primary outcome</b> Primary care re-consultation within the first two weeks* (ICC <sup>†</sup> = 0.06)	33 (12.9)	44 (16.2)	0.75 (0.41 to 1.38)
<b>Secondary outcome</b> Antibiotic prescribed in index consultation (ICC <sup>†</sup> = 0.24)	50 (19.5)	111 (40.8)	<b>0.29 (0.14 to 0.60)</b>
<b>Outcomes with data collected from telephone administered questionnaire only</b>			
<b>Secondary outcomes</b> Parent intends to consult if their child has a similar illness in future	136 (55.3)	201 (76.4)	<b>0.34 (0.20 to 0.57)</b>
Antibiotics taken any time in two-week follow-up period	55 (22.4)	113 (43.0)	<b>0.35 (0.18 to 0.66)</b>
Parental enablement score (≥ 5)	99 (40.2)	94 <sup>‡</sup> (35.9)	1.20 (0.84 to 1.73)
Satisfaction <sup>§</sup>	222 (90.2)	246 (93.5)	0.64 (0.33 to 1.22)
Reassurance <sup>**</sup>	177 (72.0)	198 (75.3)	0.84 (0.57 to 1.25)
Usefulness of information received <sup>††</sup>	210 (85.4)	224 (85.2)	1.01 (0.60 to 1.68)
<b>Statistically significant results in bold</b>			
* Parental report that the child attended a face-to-face consultation with a primary care clinician in their general practice or with an out of hours provider, in the two weeks following registration.			
† Intra-cluster correlation coefficient			
‡ n=262 for this group as one parent was unable to complete enablement questions due to language problems.			
§ Proportion of parents who reported being 'very satisfied' or 'satisfied' with the consultation.			
** Proportion of parents who reported feeling 'very reassured' or 'a little reassured' following their consultation.			
†† Proportion of parents who reported that information they received in the consultation was 'very useful' or 'useful'.			

#### 4.4 Secondary outcomes

The results of the secondary outcomes are summarised in the lower half of Table 4.4.

#### **4.4.1 Future consulting intentions**

55.3% and 76.4% of parents in the intervention and control arms respectively said that they would consult with a GP or nurse should their child develop a similar illness in the future. This 21% difference, which equates to a NNT of 5, is statistically significant at the univariate level ( $p < 0.001$ ) and using multilevel modelling (OR 0.34, 95% CI 0.20 to 0.57).

#### **4.4.2 Antibiotics taken**

There was a 20% reduction (NNT = 5) in the proportion of patients who took an antibiotic (as reported by the parent) at any time during the two-week follow-up period in the intervention group compared with the control group ( $p < 0.001$ ). Using multilevel modelling an odds ratio of 0.35 (95% CI 0.18 to 0.66) was calculated.

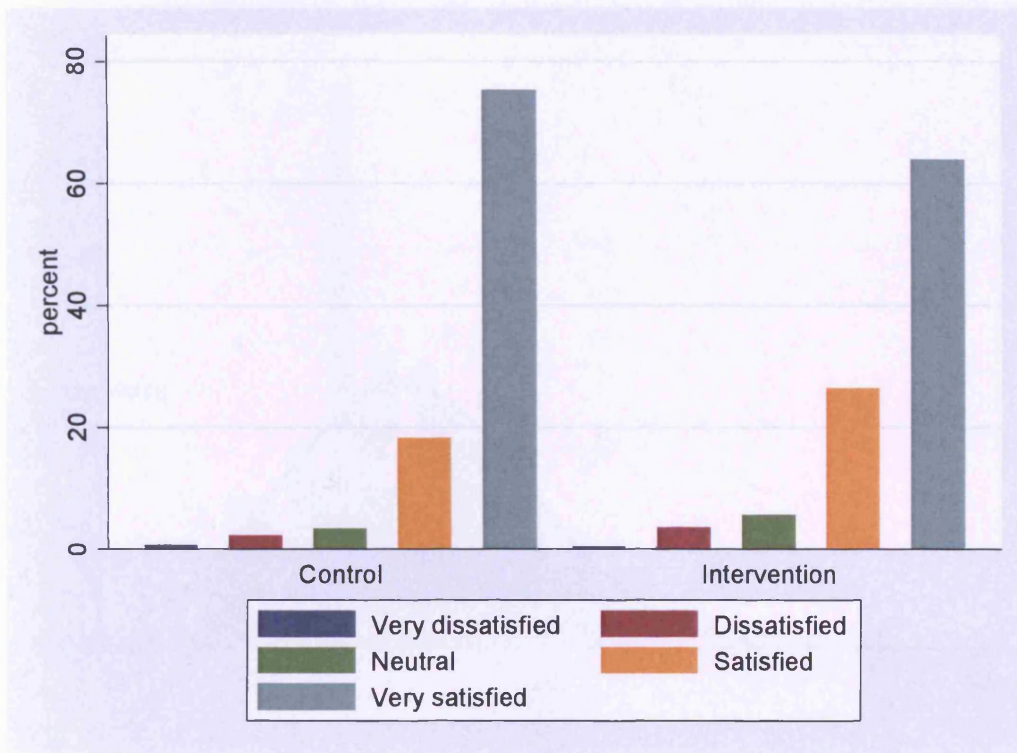
#### **4.4.3 Enablement**

Enablement scores were calculated as described in section 3.11.3.5. The mean enablement score for parents in both trial arms was the same (3.0). After dichotomising the enablement scores we found that 40.2% and 35.9% of parents in the intervention and control arms respectively had enablement scores of five or more. The difference in these proportions was not statistically significant at a univariate level ( $p = 0.31$ ), or using multilevel modelling (OR 1.20, 95% CI 0.84 to 1.73).

#### **4.4.4 Satisfaction, reassurance, usefulness of information**

The proportion of parents who reported being 'satisfied' or 'very satisfied' with the index consultation, who reported feeling 'very reassured' following the index consultation, and who reported finding the information received in the index consultation to be 'useful' or 'very useful' in the intervention and control groups, are shown in Table 4.4. Over 90% of parents in both study groups reported being 'satisfied' or 'very satisfied' (Figure 4.4). Parental rating of the level of reassurance from the consultation and the 'usefulness' of the information received in the consultation were also relatively high, with around three-quarters of parents in both groups saying they felt 'very reassured' and over 85% saying they found the information 'useful' or 'very useful'. No statistically significant differences between the study groups were found for any of these three outcomes.

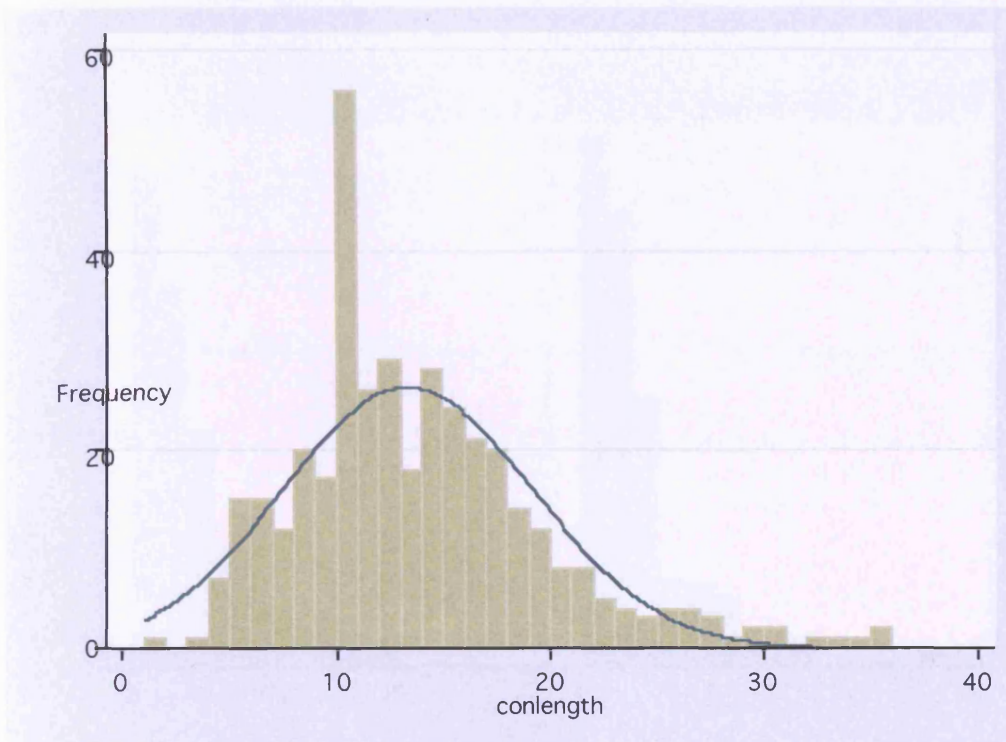
Figure 4.4 Satisfaction scores in Control and Intervention practices



#### 4.4.5 Length of index consultation

Data on the length of the index consultation was only available for 385 participants. The length of the index consultation (in minutes) was only slightly skewed to the right (Figure 4.5). There was a peak at ten minutes, suggesting that some practices recorded 10 minutes for consultations because this was the booked length of their consultations. Mean consultation lengths (and standard deviations) for consultations in the intervention and control arms were 15.7 (6.5) and 12.1 (5.1) minutes respectively. Using linear regression in a multilevel model to account for clustering, a statistically significant difference in means of 2.8 (95% CI 2.5 to 4.8) minutes was calculated.

**Figure 4.5 Distribution of index consultation lengths**



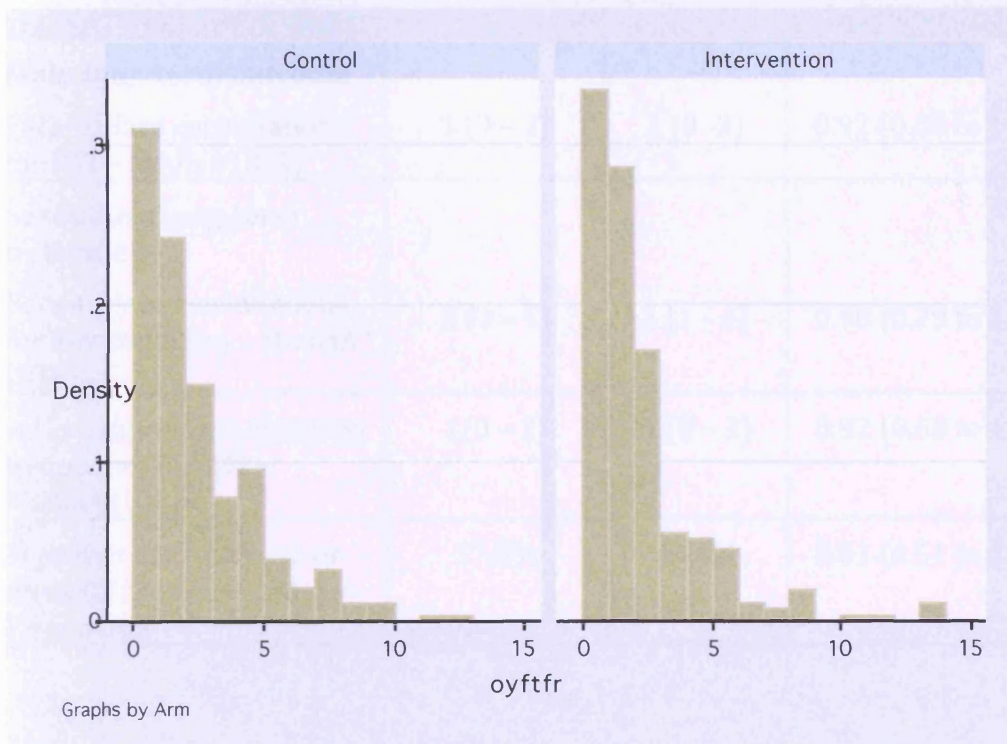
#### **4.4.6 Consultations over the following year**

One year follow-up data was obtained from all participating practices and for 549 (98.6%) participants. Three participants (0.5%) had withdrawn from the study, and five participants (0.9%) had left their practices and no follow-up data was available.

##### **4.4.6.1 Main long-term outcome**

The main outcome for the one-year follow-up was the number of face-to-face consultations in primary care for a respiratory tract infection. As can be seen from Figure 4.6, the data are highly skewed with a median of 1 consultation in both arms. The results of Poisson regression using multilevel modelling are shown in Table 4.5. No statistically significant difference between the groups was found using this approach.

**Figure 4.6 Distribution of face to face consultations for RTIs over one year follow up by study arm**



#### 4.4.6.2 Other long-term outcomes

The results of the secondary long-term follow-up data are shown in Table 4.5. The median number of face-to-face consultations for any condition and consultations for RTIs (including telephone consultations) were the same in the two study arms, and the confidence intervals for the rate ratios obtained from multilevel modelling included one (i.e. not statistically significant). 37.9% of children in the intervention arm consulted two or more times for an RTI compared with 44.6% of children in the control arm. This difference was not statistically significant when analysed using logistic regression in a multilevel model.

Table 4.5 One year follow-up outcomes

<b>Outcome</b>	<b>Intervention</b>	<b>Control</b>	<b>Rate ratio / Odds ratio (95% CI)</b>
<b>Main long-term outcome</b> Face-to-face consultations for RTI - Median (IQR)	1 (0 - 2)	1 (0 - 3)	0.92 (0.68 to 1.25)
<b>Secondary long-term outcomes</b> Face-to-face consultations for any condition - Median (IQR)	3 (2 - 5)	3 (1 - 6)	0.98 (0.79 to 1.20)
All consultations (including telephone) for RTI - Median (IQR)	1(0 - 2)	1 (0 - 3)	0.92 (0.68 to 1.25)
Frequent consulters (2 or more RTI consultations) - Proportion	37.9%	44.6%	0.81 (0.51 to 1.28)

## 4.5 Sensitivity analyses

### 4.5.1 Varying main outcome models

In order to explore the validity of the main results a number of sensitivity analyses were conducted. These analyses involved adding covariates to each of the main outcome models (as described in section 3.11.4). The results of these analyses for the main re-consultation outcome and for the main antibiotic prescribing outcome are given in Table 4.6 and Table 4.7 respectively. For both of these outcomes the additional covariates led to some improvement in model fit. However, there was no meaningful change in effect size (or significance) for either outcome (i.e. there continued to be a non-statistically significant reduction in re-consultations and a statistically significant reduction in antibiotic prescribing with use of the intervention).

Table 4.6 Sensitivity analyses - main reconsultation outcome

<b>Covariates included</b>	<b>Intervention coefficient (s.e)</b>	<b>Equivalent OR (95% CI)</b>	<b>DIC (model fit)</b>
Basic model	-0.279 (0.289)	0.76 (0.43 to 1.33)	437.8
Duration of illness and age	-0.343 (0.317)	0.71 (0.38 to 1.32)	425.4
Practice stratifying variables	-0.239 (0.275)	0.79 (0.46 to 1.35)	440.4
Symptoms significant at 10% level (runny nose and fever)	-0.252 (0.278)	0.78 (0.45 to 1.34)	436.8
Duration of illness, age and stratifying variables	-0.289 (0.35)	0.75 (0.38 to 1.49)	425.1
Duration of illness, age and symptoms	-0.348 (0.375)	0.71 (0.34 to 1.47)	423.9
Duration of illness, age, stratifying variables and symptoms	-0.258 (0.343)	0.77 (0.39 to 1.51)	423.1



Table 4.7 Sensitivity analyses - main antibiotic prescribing outcome

<b>Covariates included</b>	<b>Intervention coefficient (s.e.)</b>	<b>Equivalent OR (95% CI)</b>	<b>DIC (model fit)</b>
Basic model	-1.281 (0.384)	0.28 (0.13 to 0.59)	561.1
Duration of illness and age	-1.21 (0.383)	0.30 (0.14 to 0.63)	556.7
Practice stratifying variables	-1.358 (0.386)	0.26 (0.12 to 0.55)	560.2
Symptoms significant at 10% level (cough, runny nose, ear ache and appearing unwell)	-1.422 (0.415)	0.24 (0.11 to 0.54)	523.1
Duration of illness, age and stratifying variables	-1.244 (0.35)	0.29 (0.15 to 0.57)	556.7
Duration of illness, age and symptoms	-1.352 (0.44)	0.26 (0.11 to 0.61)	514.8
Duration of illness, age, stratifying variables and symptoms	-1.35 (0.408)	0.26 (0.12 to 0.58)	515.3

## 4.5.2 Three level model

Models for the two main outcomes were developed as three-level models (Patients within clinicians within practices) but no important differences in the significance or magnitude of results was found. Furthermore, the profession of clinician (doctor or nurse) was not associated with either of the main outcomes at the univariate level, and no important differences in results were found when clinician profession was added as a covariate to the three level model.

## 4.6 Exploratory analyses

### 4.6.1 Subgroup analyses

#### 4.6.1.1 Main re-consultation outcome

The results of subgroup analyses using multilevel modelling, for the main re-consultation outcome, are given in Table 4.8. No statistically significant effect was

found for any of the subgroups examined (practice prescribing history, practice country, practice list size, patient age, prior duration of illness, cough present, fever present, received antibiotic prescription).

**Table 4.8 Subgroup analyses - main reconsultation outcome**

<b>Model</b>	<b>Intervention coef. (s.e.)</b>	<b>Covariate coef. (s.e.)</b>	<b>Interaction coef. (s.e.)</b>	<b>DIC</b>
Basic	-0.279 (0.289)			437.8
Higher prescribing practices	-0.271 (0.402)	-0.086 (0.488)	-0.161 (0.739)	439.1
English practices	-0.615 (0.367)	-0.679 (0.455)	1.077 (0.638)	440.1
Larger than average list size practices	-0.728 (0.506)	0.192 (0.424)	0.739 (0.613)	436.5
Prior duration of illness (days)	0.136 (0.59)	0.215 (0.092)	-0.124 (0.146)	434.5
Age of child (yrs)	0.127 (0.465)	-0.082 (0.052)	-0.128 (0.088)	427.0
Cough present	-0.634 (0.502)	0.485 (0.326)	0.457 (0.576)	434.2
Fever present	-0.241 (0.4)	0.683 (0.359)	-0.133 (0.533)	434.6
Received antibiotic prescription	-0.25 (0.345)	0.06 (0.352)	-0.021 (0.581)	440.1

#### **4.6.1.2 Main antibiotic prescribing outcome**

The results of subgroup analyses using multilevel modelling, for the main antibiotic prescribing outcome, are given in Table 4.9. The only subgroup effect found to be statistically significant was a greater reduction in prescribing in higher prescribing practices compared with lower prescribing practices. The coefficients from this model have been used to calculate the probability of receiving a prescription for antibiotics for patients consulting a higher or lower prescribing practice in each of the intervention and control arms (Table 4.10).

Table 4.9 Subgroup analyses - main antibiotic prescribing outcome

Model	Intervention coef (s.e.)	Covariate coef (s.e.)	Interaction coef (s.e.)	DIC (model fit)
Basic model	-1.281 (0.384)			561.1
Higher prescribing practices	-0.722 (0.436)	1.561 (0.456)	<b>-1.492 (0.74)</b>	561.5
English practices	-1.305 (0.499)	0.559 (0.54)	-0.047 (0.768)	561.0
Larger than average list size practices	-0.324 (0.443)	-0.254 (0.592)	0.833 (0.951)	562.7
Prior duration of illness (days)	-1.612 (0.66)	0.038 (0.105)	0.105 (0.141)	562.3
Age of child (yrs)	-1.03 (0.539)	0.082 (0.041)	-0.041 (0.061)	559.2
Cough present	-1.104 (0.5)	-0.856 (0.311)	-0.25 (0.496)	548.1
Runny nose present	-1.576 (0.43)	-1.096 (0.348)	0.968 (0.541)	553.9
Earache present	-1.451 (0.444)	1.317 (0.381)	0.29 (0.55)	533.7
Fever present	-1.283 (0.415)	-0.26 (0.32)	0.156 (0.492)	563.7
Sore throat present	-1.106 (0.404)	0.403 (0.296)	-0.411 (0.484)	562.2
Child appears unwell	-1.098 (0.363)	0.9 (0.403)	-1.028 (0.707)	559.7

Table 4.10 Effect of practice prescribing history and study intervention on the calculated probability of being prescribed an antibiotic

		Practice antibiotic prescribing history	
		Higher	Lower
Study arm	Intervention	16.3 %	15.4 %
	Control	64.1 %	27.3 %

## 4.6.2 Outcome definition variations

### 4.6.2.1 Re-consultation outcomes

A definition of the main re-consultation outcome had been agreed prior to any analysis of trial data. Following the main analyses a number of other re-consultation outcomes were examined (Table 4.11). No statistically significant difference between treatment arms was found for any of these outcomes.

**Table 4.11 Effect of intervention on a range of reconsultation outcomes**

<b>Outcome</b>	<b>Coefficient (s.e.)</b>	<b>Equivalent odds ratio (95% CI)</b>
Main re-consultation outcome (any face-to-face consultation with a GP, practice nurse or OOH provider) *	-0.287 (0.309)	0.75 (0.41 to 1.38)
Any consultation with a primary care provider (GP, practice nurse or OOH) including face-to-face and telephone consultations*	-0.196 (0.64)	0.82 (0.23 to 2.88)
Any consultation with a primary care provider (as above) or an A&E department*	-0.16 (0.621)	0.85 (0.25 to 2.88)
Total number of face-to-face consultations with a primary care provider (GP, practice nurse, OOH) excluding telephone consultations <sup>†</sup>	-0.303 (0.276)	0.74 (0.43 to 1.27)
Total number of primary care consultations (face-to-face and telephone) <sup>†</sup>	-0.218 (0.255)	0.80 (0.49 to 1.33)
Total number of consultations (primary care and A&E, face-to-face and telephone) <sup>†</sup>	-0.139 (0.255)	0.87 (0.53 to 1.43)
* Multilevel modelling using binomial logistic regression with IGLS using second order PQL		
<sup>†</sup> Multilevel modelling using poisson regression with IGLS using second order PQL		

#### **4.6.2.2 Antibiotic outcomes**

A comparison of the main antibiotic prescribing outcome with two other antibiotic prescribing outcomes is given in Table 4.12. These analyses suggest that a similar reduction in antibiotic prescribing from use of the intervention is found whether the outcome of interest is all antibiotic prescribing or just antibiotic prescribing for immediate use (excluding delayed prescribing) and whether we consider just antibiotic prescribing at the index consultation or antibiotic prescribing at any point in the first two weeks.

**Table 4.12 Effect of the intervention on a range of antibiotic prescribing outcomes**

<b>Outcome</b>	<b>Coefficient* (s.e.)</b>	<b>Equivalent odds ratio (95% CI)</b>
Main antibiotic outcome (immediate or delayed prescription for antibiotics at index consultation)	-1.244 (0.373)	0.29 (0.14 to 0.60)
Prescription for antibiotics for immediate use at index consultation (excluding delayed prescriptions)	-1.334 (0.44)	0.26 (0.11 to 0.62)
Prescription for antibiotics (immediate or delayed) either at the index consultation or at any point in the two-week follow-up period	-1.153 (0.342)	0.32 (0.16 to 0.62)

\* Multilevel modelling using binomial logistic regression with IGLS using second order PQL.

#### **4.7 Safety data – hospitalisations and adverse events**

Seven participating patients were assessed in Paediatric Assessment Units (PAU) at some point during the two-week follow-up period, and four of these were admitted to hospital for one night or more (Table 4.11). Two members of the study team (at least one of whom was clinically qualified) reviewed details of all hospital assessments. Hospitalisations were considered to be Serious Adverse Events where either the parent or one of the study team members thought that taking part in the study was likely to have contributed to the development or progression of the condition that led to the hospitalisation. The same criteria were used for any other ‘adverse events’ that were reported to the study team but did not result in a hospitalisation. None of the hospital assessments were assessed as being related to participation in the study. There was one ‘adverse event’ reported by one of the participating clinicians. The full text of the email detailing the event can be found in the appendix 12. In summary, the clinician experienced a ‘dysfunctional’ consultation with the parent of a child who was being enrolled into the study. The parent apparently became upset after the clinician suggested that antibiotic treatment was not needed, and this occurred in two separate consultations on two different days. The clinician was especially concerned as he had what he described as an interest in communication skills and was used to winning the trust and confidence of his patients. He wondered whether cultural barriers (or differences) may have contributed to the problem. However, he also wondered whether by focusing on the ‘tasks’ that had been suggested in the intervention training, his ‘antennae’ (awareness of the parents non-verbal cues) may

have been disrupted and whether the booklet suggested a presumption of ‘non-prescribing’ which could result in increased pressure not to prescribe. This event was discussed in detail by both the study management group and the trial steering committee. Neither group considered this to be a ‘Significant Adverse Event’. However, as a result of this correspondence the following steps were taken:

- The booklet was reviewed to ensure there was no implicit or explicit suggestion that antibiotics not be prescribed.
- In order to identify whether other clinicians were experiencing similar encounters following use of the booklet, we added a section to the study newsletter (sent to all participating clinicians) asking them to report all remarkable incidents (positive or negative) that occur in consultations where patients are being recruited into the study.
- The issue of conflict about antibiotics in the consultation was added to the topic guide for the process evaluation.
- The planned response was fed back to the relevant clinician and he was invited to participate in the process evaluation (which he subsequently did).

This event did not result in any changes to the study procedures. However, the clinician in question’s comments are included in the process evaluation.

**Table 4.13 Details of hospital assessments / hospitalisations**

<b>Length of admission (nights)</b>	<b>Details of admission</b>	<b>Study arm</b>
1	Parents took the child to hospital the day following study enrolment because of an ongoing 'high' temperature. He was admitted overnight and diagnosed with a urinary tract infection.	Control
Not admitted	Patient was sent to the PAU for assessment because of persistent vomiting. Assessed for a few hours in the PAU and then sent home	Control
2	Patient had a febrile convulsion. Had a past history of febrile convulsions associated with RTIs. Also had a history of cerebral palsy.	Intervention
Not admitted	Seen in PAU for breathing problems. Treated with a nebuliser and metered-dose inhalers. Discharged later the same day. No diagnosis given.	Intervention
Not admitted	Patient assessed in the PAU. Parents told that child was dehydrated. Discharged later that day.	Control
2	Patient was a known asthmatic who developed an 'asthma attack' following the initial consultation. As the patient was a known asthmatic they were ineligible for the study. Following a discussion in the TSC this participant was re-classified as 'recruited in error' and was removed from any analysis.	Control
1	Patient was diagnosed as having an ear infection at the index consultation and was prescribed antibiotics. The following day the mother felt the child was worse and noticed that the child had cold hands and feet. As this was mentioned as possible concerning feature in the intervention booklet the mother arranged an immediate re-consultation with the GP. At this time the patient was found to have an O <sub>2</sub> saturation of 89% and was immediately admitted. The parent was unsure of the final diagnosis – she was told that it was a 'chest infection' by one clinician and 'tonsillitis' by another. The child made a full recovery.	Intervention

## **4.8 Summary of results**

557 children (and their parent(s)), recruited from 61 general practices throughout Wales and England, participated in this cluster randomised controlled trial, and follow-up for the primary and main secondary outcomes was achieved for 94.8% of participants. 12.9% and 16.2% of children in the intervention and control arms

respectively reconsulted within two weeks of the index consultation. Using logistic regression in a multilevel model to account for clustering, there was no statistically significant difference in the odds of reconsulting between the intervention and control groups (OR = 0.75, 95% CI 0.41 to 1.38). 19.5% and 40.8% of children in the intervention and control arms respectively received a prescription for antibiotics at the index consultation. This difference was statistically significant using logistic regression in a multilevel model to account for clustering (OR = 0.29, 95% CI 0.14 to 0.60). There was also statistically significantly less self-reported antibiotic consumption (OR = 0.35, 95% CI 0.18 to 0.66), and intention to consult with a similar illness in the future (OR 0.34, 95% CI 0.20 to 0.57). No statistically significant differences in parental enablement, satisfaction, reassurance, or value of information received, were detected. The index consultation (the consultation in which the booklet was used in intervention practices) was statistically significantly longer by a mean of 2.8 minutes (95% CI 2.5 to 4.8) in the intervention arm. No statistically significant differences in primary care consulting in the year following the index consultation were found. Analysis of interaction coefficients to look for subgroup effects demonstrated a greater effect of the intervention on antibiotic prescribing in higher prescribing practices. No significant adverse events related to use of the intervention were identified.

The results from the two-week follow-up were written up as a scientific paper (I was the lead author) and subsequently published in the *British Medical Journal*\*. This paper is included as appendix 13.

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\* The paper in the *BMJ* identifies 558 participants (instead of 557). This is because, following the publication of the paper, it was identified that one of the participants that appeared to have been lost to follow-up was actually a participant who had been entered onto the database twice. This 'participant' did not have any outcome data contributing to the analyses. However, their removal from the denominator did result in small changes to some results, none of which altered the statistical significance, or had any meaningful impact on the clinical importance, of the results.



## **5 Process Evaluation**

### **5.1 Introduction**

The intervention evaluated in this thesis is a complex intervention that is made up of a number of components, each of which may have contributed to the findings, either individually or in combination. Process evaluations form an important part of the evaluation of complex interventions by exploring the implementation, receipt, and setting of an intervention.(221) They help in interpreting the outcome results by exploring how the intervention is used, which elements of the intervention may have led to any findings, and how acceptable the intervention is to those delivering it and those receiving it,(221) and can help with implementation by exploring how use of the intervention can be normalised into routine practice.(222) This chapter details a process evaluation of the trial described in chapters 3 and 4. Both quantitative and qualitative approaches have been used to assess process measures.

### **5.2 Process evaluation aims and objectives**

The aims of the process evaluation are; to explore potential sources of bias, to gain a greater understanding of how the intervention was used, which components of it may have led to the study findings, what the study participants (parents and clinicians) views of the intervention are, and what their wider views on the management of RTIs in children are.

The process evaluation will be divided into three sections: potential sources of bias, parent measures, and clinician measures.

#### **Sources of bias objectives:**

- To explore the role of selection bias by comparing participating children with those who were eligible for participation but not recruited
- To explore whether ascertainment bias may have played a role in the two-week telephone interviews.
- To explore whether late enrolment of clinicians (potentially after they are aware of the allocation of their practice) may have biased the results.

**Parent measure objectives:**

- To explore parents' views of the consultation they had when their child registered to take part in the study, including whether it was what they expected, and what they liked and did not like about it.
- To identify whether parents recalled clinicians employing the consultation 'tasks' that they had been asked to undertake (exploring expectations and addressing concerns), and if so, their views on these components.
- To explore whether parents had been provided with the study booklet, and if so, whether it was used in the consultation or not, and the parents views of how it was presented / used.
- To explore the parents' views of the study booklet, including which sections of it they found useful or did not find useful.
- To describe any use of the booklet after the consultation, including reading through it at home, discussing it with others and using it to help them manage their child's illness, and whether they have kept it for future use.
- To explore their views on ways in which the booklet or the consultation they had on the day they registered for the study has influenced their knowledge or beliefs with regard to RTIs in children.
- To explore their general views on the use of written materials in general practice.

**Clinician measure objectives:**

- To describe their participation in the study, including their use of the on-line training, their use of the booklet in the consultation, and their participation in the other consultation 'tasks' they were asked to perform.
- To explore their views of the online training, including whether they found it helpful, and which aspects of it they liked or did not like.
- To explore their views of the study booklet, including which components they liked or did not like.
- To explore their views on using the booklet within the consultation.
- To explore their perception of how the booklet was received by parents.
- To describe ways in which use of the intervention (training and booklet) has changed their knowledge, beliefs and / or practice with regard to the management of RTIs in children.

- To explore how use of the intervention may have led to the study findings.

### **5.3 Identifying potential sources of bias**

#### **5.3.1 Comparison of participating children with eligible, non-recruited children**

In order to assess for selection bias, in the form of awareness of study arm influencing the recruitment of patients by participating practices, we asked all practices to record anonymous information on all ‘potentially eligible’ patients. This included all children who had been identified by a receptionist or other member of the practice team as potentially eligible, and all patients for whom the recruiting clinician discussed the study with their parent(s). Data were recorded on 50 patients who were subsequently deemed ineligible (28 intervention, 22 control) and 43 patients (24 intervention, 19 control) who were eligible but not recruited for other reasons (declined participation, clinician too busy, etc.). A comparison of the age, prior duration of illness, and clinical features is given in Table 5.1.

As can be seen from this table, there were no important differences between recruited and non-recruited children, or between the non-recruited children in intervention and control arms. The one exception to this was the duration of illness in the ‘ineligible patients’. This is because duration of illness longer than seven days was a common reason for being ineligible to participate. The number of ‘non-recruited’ patients registered by participating clinicians is relatively small. The implications of this will be discussed in chapter 7.

#### **5.3.2 Interviewers**

84.6% of all telephone interviews were conducted by one interviewer (NF). The remaining 15.4% were conducted by one other researcher (JN). The interviewers reported that they remained blind to study arm during 93% of all interviews. No statistically significant associations were found between interviewer and either study arm, or the two main outcomes.

**Table 5.1 Comparison of recruited and non-recruited children**

	Intervention			Control		
	Recruited (N=273)	Did not recruit (N=24)	Ineligible (N=28)	Recruited (N=284)	Did not recruit (N=19)	Ineligible (N=22)
Age* – Median (IQR)	4.0 (1.9, 8.3)	4.0 (2.0, 8.0)	4.0 (1.5, 8.0)	4.3 (2.2, 7.7)	2.0 (1.0, 5.0)	4.5 (2.7, 10.0)
Duration of illness† – Median (IQR)	3 (2, 4)	4 (3, 5)	9.5 (5, 14)	3 (2, 4)	3 (2, 5.5)	10 (5, 12)
Cough‡	172 (63.2)	16 (69.8)	22 (78.6)	167 (58.8)	10 (62.5)	16 (72.2)
Earache‡	74 (27.2)	7 (30.4)	3 (10.7)	69 (24.3)	6 (37.5)	3 (13.6)
Runny nose‡	85 (31.3)	7 (30.4)	7 (25.0)	97 (34.2)	10 (62.5)	10 (45.5)
Sore throat‡	88 (32.4)	6 (26.1)	7 (25.0)	112 (39.4)	2 (12.5)	10 (45.5)
Fever‡	103 (37.8)	6 (26.1)	6 (21.4)	109 (38.4)	5 (31.3)	10 (45.5)
Looks unwell‡	36 (13.2)	2 (8.7)	3 (10.7)	48 (16.9)	1 (6.3)	3 (13.6)
* Age in years † Prior duration of illness in days ‡ Number (%) with clinical feature						

### 5.3.3 Late enrolling clinicians

In this study, a practice could register to participate in the study, and become randomised, as long as at least one clinician was willing to participate. As a result, it was possible for clinicians who were not participating in the study, but were in a practice where one or more clinicians were already participating, to join the study at a later date. This represented a potential source of bias as clinicians joining the study late may be aware of arm of the trial that their practice had been allocated to. In order to identify the potential impact of late joining clinicians, all clinicians who enrolled in the study one week or more after the practice allocation was sent to practice were identified. A total of 26 clinicians (19 doctors and 7 nurses) enrolled into the study late and 12 of these (8 doctors and 4 nurses) recruited one or more patients. The number of late joining clinicians in each arm of the trial are given in Table 5.2.

**Table 5.2 Late enrolling clinicians**

	<b>Intervention</b>	<b>Control</b>
Number of clinicians who joined the study late	20	6
Number of clinicians who joined late and then recruited patients (proportion of participating clinicians)	9 (17.6%)	3 (5.8%)
Professional grouping of late joining clinicians who recruited	7 doctors, 2 nurses	1 doctor, 2 nurses

## 5.4 Parent process measures

### 5.4.1 Design

This component of the study was conducted using qualitative semi-structured interviews with parents who participated in the study and were in the intervention arm of the trial.

### **5.4.2 Rationale for choice of design**

Although a number of quantitative ‘process’ measures were examined in the trial, qualitative methods can explore phenomena, experience, and ideas that are not accessible by quantitative methods.(223) Semi-structured interviews allow for the use of guiding questions which ensure that topics of interest are covered, but also for a degree of flexibility or open-endedness, so that relevant topics that emerge during the discussion can be explored in greater depth.(224) In this study, although the inclusion criteria were based around the demographics and clinical features of the child, the intervention was directed primarily at their parent. Parents are therefore important ‘participants’ to be studied.

### **5.4.3 Sampling framework**

For logistical reasons, and to ensure that the interviews were conducted reasonably soon after the consultation in question, parents were recruited during the final few months of recruitment into the study. Suitable participants were invited between one and four months from the date of recruitment into the study. This was to ensure that their participation did not interfere with the two-week follow-up, and to ensure that the interview occurred within a period in which they were likely to remember the consultation in which their child was recruited. As the aim of the process evaluation was to explore the effects of the intervention, only parents who had consulted in practices in the intervention arm were invited to participate. To ensure that factors that might have influenced the two main outcomes (re-consultation and antibiotic prescribing) were explored, a sampling framework based on these two factors was used (see Table 5.3). The study group discussed the sample size requirements based on the need to balance the importance of achieving theme saturation and the resource requirements for conducting in-depth qualitative analysis.(225) As a result of these discussions, a sample of 20 parents, five from each of the four cells in the sampling framework (Table 5.3), was selected as appropriate for the study objectives. Parents whose children had consulted with clinicians in intervention practices in the defined time period were sent a letter inviting them to participate in the process evaluation, a consent form and a postage-paid envelope in the post. Those who returned completed consent forms were contacted by telephone in order to arrange a mutually convenient time for the telephone interview. Due to insufficient numbers returning consent forms during the early recruitment period a decision was made to ask the ethics committee

for permission to ask parents if they would be willing to participate during the follow-up telephone interview in the trial (at two weeks). The committee gave permission and this allowed for direct telephone contact with parents who had given their permission at this earlier interview. Nevertheless, it was not possible to recruit five participants in each cell and therefore extra participants were recruited from other cells to try to ensure the greatest degree of balance. After recruiting 20 parents, the candidate, along with his supervisors, examined the data and made an assessment that data saturation in the main themes appeared to have been achieved.

#### **5.4.4 Data collection**

Parents providing informed consent were contacted by telephone and either interviewed at that time or arrangements were made to telephone them again at a mutually convenient time. Semi-structured interviews were conducted by using an interview schedule to guide the interview (see appendix 14) but not constraining it to the topics in the guide. All interviews were conducted by the candidate. A digital recorder was used to record the interviews.

#### **5.4.5 Analysis**

All interviews were transcribed verbatim and checked for accuracy. Framework analysis was used to analyse the data.(226) Framework analysis is a systematic approach to qualitative data analysis that allows for easy comparisons between and within cases, facilitates the sharing and discussion of data with other team members, and allows for clear linking / access from the developed themes back to the original data. It is particularly useful when there are a number of clear research aims that have guided the interview questions, while also allowing new themes to emerge from the data that are relevant to the research question.

Framework analysis involves five clear stages, which are outlined below:

1. Familiarisation
2. Creating a thematic framework
3. Indexing
4. Charting
5. Mapping and interpretation

A familiarisation with the data was first achieved by reading through all transcripts. Following this, a thematic framework was developed based on the main research questions and the main themes arising from the data. This is an index of categories or themes that is used to classify the data, and is usually arranged hierarchically. The initial coding framework was modified a number of times following discussions with my supervisory team, and during the coding process. The thematic framework used can be found in Appendix 15. Next, thematic codes were applied to all of the data (Indexing), which then allows data to be sorted, organised, and grouped. Two parent interviews were dual-coded to allow for an assessment of coding validity. Coding was done using the qualitative analysis software package NVivo 8. Following the coding, data coded by theme were retrieved and summarised in a chart. The chart included participants as rows, and the main themes as columns. Each cell then contained a summary of how that theme applied to that participant and / or an indicative quotation from that transcript. The final stage involved interpreting the data by drawing inferences and pulling together relevant themes.

## 5.4.6 Results

### 5.4.6.1 Description of participants

20 parents took part in the process evaluation. Their 20 children had consulted with 11 different participating clinicians from 10 practices in the intervention arm of the trial. Table 5.2 lists the number of parents whose children had received a prescription for antibiotics and who had re-consulted. Seven of the children had consulted with a nurse or nurse practitioner and 13 had consulted with a doctor. Nine of the 11 clinicians that the parents consulted with had completed the study training (accessed the training pages for 10 minutes or more).

**Table 5.3 Parent proces evaluation sampling framework with number of participating parents in each cell**

		Antibiotics received	
		Yes	No
Re-consulted	Yes	5	1
	No	5	9



The descriptions of the children's illnesses overlapped. The most common symptom was cough (11 children), of whom five also had a runny nose, and four also had a temperature. One child had a runny nose with no cough. Six children had predominantly ear pain. One child had just a sore throat and temperature, and one child had a temperature with only non-specific symptoms.

One parent's description of her child's illness (576) suggested that she should not have been entered into the study. She had previously consulted with an ear infection with discharge from the ear, had been on antibiotics, and was re-consulting because the ear was still draining at the time that she was enrolled into the study (duration of illness > 7 days and prior consultation for the same illness were both exclusion criteria).

### **General impressions of consultation**

Most of the parents described the consultation as being broadly what they had been expecting. Six parents expressed a high degree of satisfaction, and three described the consultation as being better than they expected. Two parents described the consultation as worse than expected and reported being not entirely satisfied. When describing their satisfaction with the consultation, most parents talked about the manner of the clinician, and the thoroughness of the examination their child received.

Of the two parents who expressed dissatisfaction, one related this to a sense that the clinician dedicated more time to enrolling her child into the study than dealing with the illness:

*"It was just, 'oh would you like to take part in this?' so I said yes that's fine so then the rest of the time we were there was obviously putting the details together and getting the leaflet together to give me, and give me something to sign. So actually, the bulk of the, I don't know how long I was in there, 10 minutes, 5 minutes I don't know, the bulk of that was actually sorting out the survey for you guys." (parent 556, no antibiotics)*

However, after reflecting on the consultation at home she was more satisfied:

*“I have to say that when I came out I kind of felt fobbed off ... but it wasn't until I got home I thought well actually I am relieved because he has checked his front and his back, he's confirmed it's a cold so I know he doesn't need any antibiotics.”*

(Parent 556, no antibiotic, no reconsultation)

The other dissatisfied parent was a recent immigrant, and her dissatisfaction seemed to be at least in part related to her culturally based beliefs about antibiotics:

*P: ... if it's ear infection and you can't really wait for example 2, 3 days at supervising. Yes they are giving antibiotics, yes.*

*I: Yes okay. Would you think they use antibiotics more in Kazakhstan or ...?*

*P: Yes*

...

*I: So when you took [name] along with his ear infection were you expecting him to have antibiotics, would you say?*

*P: ... probably yes I would expect it because you know antibiotic ... it's infection yes (I: yes) I would rather have you to give him antibiotics so it will clear and everything.*

(Parent 584, antibiotic, no reconsultation)

However, her dissatisfaction also seemed to be related to not being provided with enough information.

*P: I was expected like more detail or just look at his ear ... or just, I don't know, clean it ...*

*I: Do you mean you expected her to ask you more details or you expected her to give you more information?*

*P: To give me more information.*

(Parent 584, antibiotic, no reconsultation)

#### **5.4.6.2 Use of communication strategies in the consultation**

##### **Exploring concerns**

Only eight out of twenty parents recalled specifically being asked about their concerns. None of the parents who had not been specifically asked felt that this was a problem as they said that they had stated their concerns anyway. For example:

- I: Do you remember if she asked you what it was you most worried about?*  
*P: I don't to be honest but I think I would've probably said he's had this cold but listen to this (I: yeah) he's got this terrible cough.*  
*I: So you think you probably would've said anyway (P: oh yes) whether she asked you or not.*
- (Parent 544, no antibiotic, no reconsultation)

A couple of parents were not sure if they had been asked, and a couple thought they had not, but none expressed a feeling that their concerns had not been understood.

### **Expectations**

Only two parents reported being asked specifically about their expectations for the consultation. Seventeen parents said that they were not asked and one parent did not clearly describe if she was asked. The impression from most parents was that they did not think being asked about expectations would have been helpful. The following is an example:

- I: Do you recall whether she asked you what you were expecting from the consultation?*  
*P: I don't think she did ask me that ... she did sort of say you know 'He has got a cough, he has got a cold' umm and she went on to sort of say, 'I wouldn't give him an antibiotic'. I don't know whether she was expecting that I was going to say, 'Well aren't you going to give him antibiotics?', but I know that that's not always the right thing to do.*
- ...
- I: Do you think it would've been helpful if she'd asked you what you were expecting or was it fine the way ...*  
*P: No, I don't, I don't think so really.*
- (Parent 544, no antibiotic, no reconsultation)

### 5.4.6.3 Use of the study booklet in the consultation

Two parents reported that they did not receive a study booklet at all. One of these indicated that the clinician told her she would be given a booklet at the end of the consultation, but then forgot to give it to her, and the other didn't remember being given any written information relating to her child's illness (although she did recall being given information sheets about the study). Of the remaining 18 parents only ten of them report having the booklet discussed with them during the consultation (as had been requested of the clinicians).

Most parents who had the booklet discussed with them said that they found this helpful:

*I: There's some discussion about whether the booklets are more useful if they're kind of discussed with you rather than just given to you*

*P: I think it is, because if not I think it can seem like oh well here's a booklet just read about it. Umm, but you know with sort of being shown the relevant parts, it seems like, umm, they're taking more notice, they've listened to you and they're trying to reassure you more.*

*I: Yes, yes. So, sort of reassuring you that they're not just trying to, sort of job you off with the booklet. (P: yes) Yes okay.*

(Parent 544, no antibiotic, no reconsultation)

Although a couple of parents seemed to think that they would have got as much from it if they had read through it themselves, and one found that she couldn't concentrate on what was being said during the consultation and would have preferred to read it in her own time:

*P: ... yes he did run through it.*

*I: Okay, he ran through it. Do you think that made a difference at all, I mean do you think that was an important part?*

*P: I don't think so. I have a very lively two year old ... and to tell you the truth, umm, I wanted him examined and then to go home. And it*

*lengthened the time I was at the doctors so I didn't take it in. (I: right) But it was quite nice to have it at home.*

...

*I: You were more interested in having him examined.*

*P: Yes, but that doesn't take away from the importance that I found the helpfulness of the booklet. (I: yes) It was just that that was my particular child.*

*I: It was better for you to sort of read it in your own time?*

*P: Yes.*

(Parent 550, no antibiotic, no reconsultation)

Most of the parents who did not have the booklet discussed with them in the consultation thought that this would have been helpful.

#### **5.4.6.4 Views of the study booklet**

Most (15/18) parents had generally positive comments about the booklet, describing it as, “good”, “useful” and “helpful”. However, three parents felt that the material was, “pretty obvious” or that they, “knew most of the stuff in it”. One parent said she did not pay much attention to it because she did not consider it to be from an ‘official’ source. On further questioning, it appeared that this was because of the way the booklet was given to her, which was, ‘as part of a study’, and not reviewed in the consultation or endorsed by her clinician as intended.

Advice about recognising signs of serious illness and information about the usual duration of illness were most frequently mentioned as useful parts of the booklet. The following is an example of the latter:

*The one thing that really stuck in my head is that umm these kind of infections last longer than you think. And his infection was lasting longer than I thought. (I: right) So, yes, and I think he was right because he said, and your booklet was right, ... a couple of days later and [name] was a different child. (I: Right, yes) You know, he was yes, and yes I probably should have waited a couple of days longer for all of it to end.*

(Parent 550, no antibiotic, no reconsultation)

#### **5.4.6.5 Use of the booklet after the consultation**

Of the 18 parents who reported receiving the booklet all but three of them reported reading through the booklet at home. Most of these parents (14/15) also kept the booklet for future reference. Three parents also reported having used the booklet at some point between the index consultation and the process evaluation interview. The following is an example of where the booklet helped the parent identify a serious symptom:

*That evening he'd been ill several times he'd sicked up all his tea ... and I went to the book that I'd been given, the booklet, because he was, his hands and feet and everything were freezing, and he was covered in goose bumps and they'd all changed colour, umm he was very mottled umm and ... and yet his body his torso was very hot and I just thought oh, you know, it's the fear of being a completed hypochondriac, and I thought oh let's have a look at this booklet and see what it says. And I read on a section you know, you should take back to your doctor if the child has very cold limbs and you know his hot body, and what have you, you should contact the doctor. So I did this and ... she said come I'll see him. And she said you know, it just wasn't the child she'd seen the day before. And his sats were low, his sats were 89. [Comment: 'sats' refers to the measured oxygen saturation level, which in a healthy child should be over 95%]*

(Parent 594, antibiotic, reconsulted)

#### **5.4.6.6 Ways in which the intervention may have influenced parents**

A number of parents talked about the booklet giving them more confidence in managing their child's illness and how this would likely result in them being less likely to consult.

*P: Well, I would obviously not be quite so paranoid about when she's not very well ... uhmm ... I would look at the book (I: Yes) or you know, just try and judge for myself a bit more. I do ... obviously worry a little bit too much. I know, I know I do but ... uhmm ... I probably would next time,*

*you know, leave it a little while to see before taking her to the doctor or the nurse practitioner.*

*I: Right ok, so you think it's made you feel a little more confident about it?*

*P: Yes definitely.*

(Parent 518, no antibiotic, no reconsultation)

Two parents also reported increased confidence in these illnesses resolving without the need for antibiotics. One of these said that she was concerned at first that her child had not been given antibiotics. However, her child did recover without antibiotics and within the predicted time scale, and this gave her confidence that antibiotics were not always the best option. The other parent developed a new understanding about the need for antibiotics for RTIs:

*P: ... I was surprised. I didn't think I was going to like it when the doctor give me the leaflet and that. And when I read up on it I was really surprised. I wasn't, I didn't expect half of the stuff.*

*I: Okay. Can you think of what sort of things you were surprised about?*

*P: It's more ... with the ears. I think I was surprised at, they heal up on they're own and you don't need antibiotics. I just assumed that you need antibiotics every time you're ill.*

*I: Right. So you were surprised to learn that they can heal up without antibiotics.*

*P: Yes.*

(Parent 612, antibiotics, no reconsultation)

#### **5.4.6.7 Other factors which may have influenced the main outcomes**

A couple of parents reported re-consulting primarily because they had been told to. One parent, who reported not being given the study booklet, and whose child re-consulted and received a prescription for antibiotics, described how she was told to re-consult after 48 hours to see if the child was improving, and that this was normal practice in her surgery.

*I: Did the doctor say why he wanted to see her again in 48 hours?*

- P: Yes, because he wanted to make sure that it hadn't gone down to a chest infection (I: right) and he wanted to know umm I presumed umm if Calpol and cough medicine would've cleared it or if we needed to go on to antibiotics. (I: right). Which we did in fact have to do.*
- I: So, umm, so your understanding then was that if it was going to clear with the Calpol and the cough medicine, it would clear within 48 hours? (P: yes)*
- I: ... and is that the usual thing then, to get you to come back in 48 hours or, is that what they usually do with, sort of, infection in your children do you think?*
- P: Now she's got older, yes. (I: yes) Not when she was a little, little girl. (I: right) Now she's got older I think that's quite normal.*
- I: And why is that then, why do you think that is?*
- P: Because they don't like to give umm I think it's because antibiotics, they prefer to give after a period of time. As when I was younger, they would've given you antibiotics straight away.*
- ...*
- I: So in the past they would give antibiotics straight away?*
- P: When she was very young, yes.*
- I: When she was younger. And now they tend to, umm, get you to come back in 48 hours? (P: yes) But they didn't say to you, 'see how she is in 48 hours'? They wanted to actually see her again in 48 hours?*
- P: They wanted to see her, yes.*
- (Parent 633, antibiotic, reconsulted)*

The extent of this type of practice is not clear, but if common in a number of general practices this would clearly have an impact on the primary outcome.

#### **5.4.6.8 Parental perception of reason for antibiotic prescription**

A few parents whose children were prescribed antibiotics were asked about their perception of the reasons for the prescription. However, most of them were not very certain about the reasons, although for most it was quite clearly the clinician's decision and not a result of any pressure from the parent:



- I: Okay, umm so can you just explain to me how that happened, because you said he (the doctor) said he didn't necessarily need antibiotics?*
- P: Yes, he said sometimes you don't need antibiotics, sometimes they heal up on their own, but with [child]'s case it was like, he said it was really red, if you know what I mean, I'm just trying to rattle my brain.*
- I: You're just trying to remember; yes it was a little while ago wasn't it. But umm, essentially, as far as you remember, he sort of recommended antibiotics?*
- I: Yes he did. He gave the prescription.*
- I: So it wasn't you asking for them? (P: No) It was him sort of saying I think in [name]'s case they would be a good idea. (P: Yes) Yes, so he sort of said in some cases antibiotics aren't needed. (P: Yes) but I think in [name]'s case they are needed?*
- P: He needed them, yes.*
- I: And did he explain why he felt that they were needed in this case?*
- P: No he didn't explain, and I never thought of asking.*
- (Parent 612, antibiotic, no reconsultation)

#### **5.4.6.9 General thoughts on receiving written information from general practices**

About half of the parents gave their more general thoughts on the use of written materials in primary care. All but two thought it was very useful, and many described picking up leaflets from their general practices or even asking for a leaflet during a consultation. These parents said that having a leaflet helped you remember the information and gave you something to refer to in the future, gave you time to digest the information, backed up what you had been told in the consultation, and often provided more information than was given in the consultation, which as this parent described, appears to be desired by many parents:

*I'm one of those people who is, I have to know everything about, umm, if anyone is diagnosed with anything I have to know everything about it. So I find written information very useful.*

(Parent 550, no antibiotic, no reconsultation)

Of the two parents who were less enthusiastic about written materials, one said that she found it easier to get health information from NHS Direct (either from the website or phone line), although she did agree that written information provided during the consultation may be helpful as well, and the other thought she might lose leaflets given during a consultation, but liked the idea of having an ‘official’ booklet of information given at well-child or other similar clinics.

## **5.5 Clinician process measures**

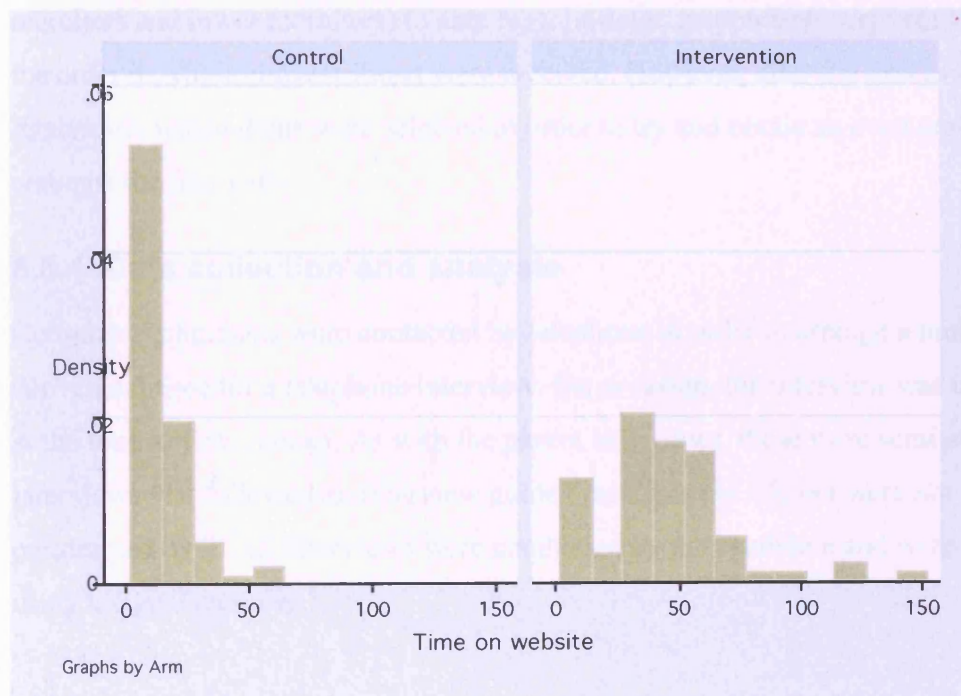
### **5.5.1 Completion of online training**

Details of the time spent completing the study training are given in Table 5.4. In the intervention practices, 67.6% of the 105 clinicians who registered to take part in the study, and 96% of the 51 who recruited patients, accessed the online training. Among those who had accessed the website, the distribution of time spent online was skewed to the left in both arms (Figure 5.1). In the intervention arm, the 71 clinicians who accessed the training spent a median 43 (IQR 30, 53) minutes online. This compares with a median of 11 (IQR 8, 17) minutes for those in the control arm who only had training in study procedures to complete. The difference in these medians, 32 minutes, is the best estimate of the time taken to complete the training in use of the intervention.

**Table 5.4 Completion of online training**

	<b>Intervention</b>	<b>Control</b>	<b>Total</b>
<b>All clinicians -N</b>	105	113	218
<b>Accessed training – N (%)</b>	71 (67.6)	82 (72.6)	153 (70.2)
<b>Time online – Median (IQR)</b>	43 (30, 53)	11 (8, 17)	18 (10, 41)
<b>Clinicians who recruited one or more patients - N</b>	51	52	103
<b>Accessed training – N (%)</b>	49 (96.1%)	51 (98.1%)	100 (97.1)
<b>Time online – Median (IQR)</b>	43 (31, 59)	11 (7, 16)	23.5 (10, 43.5)

**Figure 5.1 Distribution of time spent online in those who accessed online training**



### 5.5.2 Clinician qualitative evaluation

The intervention in this study was not a medicine or ‘treatment’ that the patient could be passively directed to or provided with. Clinicians in the intervention arm of the trial were asked to complete online training in using the intervention, and then to use it interactively within the consultation. Therefore, qualitative semi-structured

interviews were conducted with clinicians who were in the intervention arm of the trial in order to gain a greater understanding of their views of the intervention, use of the intervention, and participation in the trial. The rationale for using semi-structured interviews has been discussed in section 5.4.2 above.

### **5.5.3 Sampling framework**

In April 2008 (during the last month of patient recruitment) a written invitation to participate in the process evaluation was sent to all participating clinicians who were in practices randomised to the intervention arm, and had recruited at least one patient into the study. A consent form and stamped-addressed envelope were included with the invitation, and clinicians were asked to return the signed consent form if they were willing to participate. A sampling framework was employed which aimed to recruit clinicians from practices with above and below average rates of antibiotic prescribing, and clinicians with more and less experience of using the intervention (i.e. higher recruiters and lower recruiters) (Table 5.3). Initially, respondents were contacted in the order in which consent forms were received. However, after the first few interviews, respondents were selected in order to try and obtain an even representation amongst the four cells.

### **5.5.4 Data collection and analysis**

Consenting clinicians were contacted by telephone in order to arrange a mutually convenient time for a telephone interview. On occasion, the interview was conducted at the time of first contact. As with the parent interviews, these were semi-structured interviews that followed an interview guide (see appendix 16) but were not constrained by it. All interviews were conducted by the candidate and were recorded using a digital recorder.

The data from this part of the process evaluation was analysed using the same approach as the parent interviews (Framework analysis), which is described in section 5.4.5 above. The thematic framework can be found in appendix 17. One interview was dual-coded to allow for an assessment of coding validity.

## 5.5.5 Results

### 5.5.5.1 Description of participants

Thirteen clinicians from practices randomised to the intervention arm took part in the process evaluation. Ten of the clinicians were general practitioners, two were nurse practitioners, and one was a practice nurse. The practice nurse had recruited patients whilst working for a control practice and during the course of the study had moved to an intervention practice where she had also recruited patients. The number of clinicians in each cell of the sampling framework is shown in Table 5.3.

**Table 5.3 Number of clinicians participating in the process evaluation from above and below average antibiotic prescribing practices and who were higher or lower recruiters**

Table 5.5 Sampling framework and number of clinicians in each cell for the clinician process evaluation

		Participants recruited by clinician	
		$\geq 6$	$< 6$
Practice antibiotic prescribing rate	Above average	2	3
	Below average	3	5

### 5.5.5.2 Clinicians' accounts of their level of participation in delivering the intervention

Participating clinicians were asked details about the degree to which they undertook the activities they had been asked to as part of the trial. This included: completing the online training, providing participants (or their parents) with the study booklet, providing the booklet within the consultation and not just as a parting gift, personalising the booklet, and using the booklet to facilitate carrying out the consultation tasks as outlined in the training (including, for example, asking the parent about their main concerns and eliciting expectations).

All but one of the clinicians said that they had accessed the online training. The one who had not accessed the training (CL189) was a nurse who moved employment from a control to an intervention practice during the study. She was provided with access to the training after informing the study team that she had changed practices, but failed to access this. One clinician (CL273) accessed the training for over an hour, but said that he did not have sound on his computer and that this limited the usefulness of the training. He acknowledged that he could have accessed the website using a different computer but did not do so. The training website recorded the length of time that participating clinicians accessed the site, and most clinicians participating in the process evaluation had accessed the site for between 29 and 64 minutes (overall mean 43 minutes). However, one clinician (CL264) only accessed the site for 12 minutes, which given that this included time spent accessing the pages describing the study recruitment and other procedures, suggests that this clinician failed to complete the training in use of the intervention in any detail.

Six clinicians (46%) reported using the booklet as a tool within the consultation with all recruited participants. Most of these also reported personalising the booklet although a couple indicated that they did not do this every time they used it. A further five clinicians (38%) used the booklet in the consultation with only some participants or only partially used the booklet as instructed. For example, one clinician reported pointing out relevant sections but not going through them in any detail. One clinician (the nurse who changed practices and did not complete the training) reported not using the booklet at all for the first couple of patients recruited at that practice and not going through it in any detail for the other participants. Another clinician, who had spent an average amount of time on the study website, described only handing out the booklet at the end of the consultation.

### **5.5.5.3 Impressions of the online training**

Four clinicians were very positive about the training, saying that they found it easy to use, nicely designed, useful, and that it improved their use of the intervention within the consultation. One of these said:

*I thought the training was really excellent. The best bit of introduction to study training that I've ever done, umm because it forced you to interact with it. So*

*my initial response to it was, 'this is a bit tedious', but actually I really did feel that I had got the grasp of what I was supposed to be doing by the time I'd done the training, and I thought it was innovative and effective. I enjoyed the training in the end and I still use some of those pieces of information and techniques that came through ... in my clinical practice now.*

(Clinician 98, below avg. prescribing, lower recruiter)

These clinicians were all pleased to have the training online and said they preferred this to face-to-face training. Another five clinicians had no particular complaints about the training but either could not remember much about it, thought it was fairly 'obvious stuff', or simply described it as, 'okay' or 'Useful'. However, one clinician who described it as covering 'obvious stuff' did go on to imply that they had found it a useful learning experience by saying:

*Well, it just takes you back to the learning days doesn't it? Cause sometimes you pick up bad habits ... because you feel like a hamster in a wheel, trying to keep up with everything ... sometimes you take too many shortcuts.*

(Clinician 184, below avg. prescribing, higher recruiter)

None of these clinicians indicated that they would have preferred face-to-face training. One clinician did not remember much about the training but did not feel that they had learnt a lot, and thought face-to-face training might have been better. Another said that the style of the doctor in the videos did not fit with their style of consulting and for this reason they did not find the training very helpful. However, even this clinician thought that it was helpful to have some training on use of the booklet.

#### **5.5.5.4 Impressions of study booklet**

All of the clinicians had a generally positive impression of the booklet, describing it as, 'nicely designed', 'of good quality', 'comprehensive', 'clear', 'patient friendly', 'attractive', 'informative', 'easy to understand', and 'very useful'. Aspects that were described as being useful were the way it was organised into sections so that it was easy to find the information you wanted, and the information on 'when you should bring your child to the doctor':

*I liked the way it was all sectioned off, so that was useful because you didn't spend a lot of time looking for particular bits you wanted. I felt the most useful thing to tell a parent is when you should bring your child to the doctor.*

(Clinician 159, below avg. prescribing, higher recruiter)

However, the section that was most frequently cited as being valuable was the graphical representations of the natural history data (using smiley faces). Other components that were mentioned as being particularly useful were the information about when a child is not eating and drinking as much as normal, and the information about the benefits (or lack thereof) of antibiotic treatment. One clinician thought that the booklet was perhaps a bit too 'erudite' for her patients and that they would not be used to reading a 7-8 page book. Another clinician thought the picture of the 'meningococcal rash' was not needed as parents were constantly getting this, 'thrown at them', and another clinician thought that the picture of a girl on the front might put off some boys and that it would be better to have a boy and a girl on the front.

#### **5.5.5.5 Views on using the booklet in consultations**

Most of the clinicians were very positive about using the booklets within consultations. All clinicians described it as being 'well-received' and 'liked' by parents. It was described as, 'easy to use', and 'easy to introduce into the consultation', 'a good teaching tool', 'useful', it 'helped consultation flow', and was 'something concrete to give to patients to take home'. A number talked about there being a learning curve and that it became easier to incorporate use of the booklet into their consultation style after using it a few times and another stressed the importance of being familiar with the booklet before using it. Most clinicians felt that using the booklet within the consultation made it more valuable than just handing it out at the end of the consultation.

*I think if you just give it at the end, it wouldn't carry much weight to be honest.*

(Clinician 98, below avg. prescribing, lower recruiter)



A number of clinicians talked about the extra time taken during these consultations. However, most said that the majority of extra time was consumed by the process of registering the patient into the study, and that although use of the booklet did add to the length of the consultation, this improved with practice. Furthermore, some clinicians acknowledged a slight increase in time but considered this a reasonable cost for improving their patients' understanding.

*I: ... but in addition you found that, just using the booklet itself made the consultation longer as well did you or?*

*C: Well, it probably did but then ... I think it was a more useful tool, you know. It was a useful tool, and so it probably made the consultation more constructive.*

(Clinician 17, above avg. prescribing, higher recruiter)

One clinician from a lower prescribing practice thought that providing information was important but that this could be printed out from websites like 'Prodigy' (old name for one of the major NHS health information sites for professionals). This same clinician did not feel that the communication strategies suggested in the online training were helpful as they were no different from what he was doing anyway. He indicated that he did not consider these consultations as challenging. One other clinician liked the booklet but did not feel that the use of it in the consultation added much to its value.

### **5.5.5.6 Barriers to use of the booklet in the consultation**

As discussed in Section 5.4.6.3 and Section 5.5.5.2, the booklet was not always used as intended in consultations. The main reported barriers to use of the booklet within the consultation were time, familiarity with the booklet and its use in the consultation, and discordance between the clinician's treatment plan and the booklet's messages.

#### **5.5.5.6.1 Consultation length**

Most of the clinicians who discussed increased consultation length as a barrier acknowledged that the main consumer of time was the process of registering patients into the study. Nevertheless, use of the booklet was perceived as contributing to a

lengthened consultation, especially when the clinician was not familiar with its use, and when combined with the process of registering the patient into the study this did act as a barrier to its use.

#### **5.5.5.6.2 Familiarity with use of the booklet**

A few clinicians talked about the need to develop a familiarity with both the content of the booklet and use of it. One clinician described giving the booklet out passively within the consultation because he had not become comfortable in using it interactively. Another clinician talked about needing to develop a system for making sure that the booklet was always readily available when appropriate patients consulted.

#### **5.5.5.6.3 Message discordance**

One clinician talked about feeling slightly uncomfortable using the booklet when he was planning on prescribing antibiotics as he felt the message of the booklet was mainly that antibiotics are not helpful. However, he still used the booklet in these circumstances, in fact he indicated that he felt the booklet was helpful for encounters that ended with a prescription for antibiotics.

### **5.5.5.7 Clinicians' perceptions of how booklet was received by parents**

All the clinicians indicated that they thought the booklet was well received by parents, although, as this clinician indicated, most had not received any feedback following the index consultation:

*Yes, I think it was well received. I think people certainly valued having information to take away. But I guess, umm, I mean, I don't recall seeing any parents, you know, a second time and then getting any direct feedback about it.*

(Clinician 135, below avg. prescribing, lower recruiter)

### **5.5.5.8 Effects on clinicians from using the study booklet**

One of the main impacts of the intervention appeared to be on clinicians' knowledge, beliefs and behaviours.

#### **5.5.5.8.1 Clinician knowledge & beliefs**

A number of clinicians felt that their knowledge had improved as a result of reading and using the booklet.

*Understanding the duration of symptoms a bit better than I did at the outset ... you know, that mild symptoms can go on longer.*

(Clinician 173, above avg. prescribing, lower recruiter)

*I think I can more usually describe the signs of possible serious illness.*

(Clinician 184, below avg. prescribing, higher recruiter)

*I found the booklet really, really helpful, and not just for the patients, me too. ... and you know there were little bits in it that I think, I've used since ... to refer to and quote.*

(Clinician 17, above avg. prescribing, higher recruiter)

A couple of clinicians talked about changes to their beliefs around antibiotic prescribing. One talked about having an incentive to cut-down prescribing while the other said:

*I'm more aware of the issues of antibiotic overuse and perhaps umm it's led me to think that, well, parents don't always want antibiotics, they're probably more likely to want reassurance in many of these cases.*

(Clinician 266, below avg. prescribing, lower recruiter)

#### **5.5.5.8.2 Clinician behaviour**

A number of clinicians said that they explained a lot more to the patient (or parent) than they did previously, and some talked about improvements in their consultation style and / or communication skills.

*Having had the training and using the booklet has helped me to consult and to improve my general consulting style in terms of eliciting the patient's agenda and the patient's priorities, umm, and again I think having the booklet there as*

*a resource would be another aid to just generally making the consultation more effective I think.*

(Clinician 53, above avg. prescribing, lower recruiter)

### **5.5.5.9 Other impacts from use of intervention**

A few clinicians talked about the intervention improving patient satisfaction, and one talked about it helping to reinforce the idea that their concerns are being taken seriously and they are not just being ‘fobbed-off’. Another clinician, a nurse practitioner, felt that the booklet helped to give her advice some authority. She found this helpful as she sometimes felt that parents did not accept her advice as readily as they took advice from a doctor. She also found that use of the booklet stimulated discussion, which she found very helpful.

### **5.5.5.10 Ways in which the intervention may have influenced main study outcomes (re-consulting and antibiotic prescribing)**

#### **5.5.5.10.1 Re-consultations**

As discussed above, clinicians felt they were more able to give parents accurate information about the likely duration of illness, and the signs and symptoms that should prompt them to reconsult. Some also felt that parents were more satisfied because they had engaged in more information-sharing as a result of using the booklet. However, there was little direct evidence from the interviews of ways in which the intervention might have reduced consulting intentions. Indeed, one clinician who decreased his prescribing of antibiotics found that he more frequently asked patients to return for follow-up appointments in order to reassure himself that they were recovering.

*C: It did definitely influence my prescribing. Umm, as regards, umm, following up, it maybe, umm, I think about perhaps following up these patients a bit more closely perhaps, for reassurance, and I thought that, umm, if it was really to work, perhaps I would need to review these children after one week or ten days or so, just to see, or even*

*three days, umm, just to see how things are getting on, umm, either face-to-face or even by telephone, to really make it work. These were my thoughts.*

*I: So it made you feel actually more likely to get them to come back?*

*C: I think so yes, yes to umm uh, to kind of check them over yes, yes.*

*I: Right. Can you just go into a bit more detail on that then?*

*C: Umm, I suppose that, umm, one of the reasons you know of prescribing antibiotics and perhaps giving them out, we kind of feel as GPs we were are doing what we can and we are perhaps quite confident and, umm, in the abilities of the antibiotics to work. So we don't tend to give them a definite follow up date, just kind of leave it open as to follow up. But, umm, I suppose when there's a bit of uncertainty as to whether, oh could this be a bacterial infection, and I perhaps, not treating it perhaps, the need to follow up becomes more important.*

(Clinician 266, below avg. prescribing, lower recruiter)

#### **5.5.5.10.2 Antibiotic prescribing**

Use of the intervention may have encouraged clinicians to prescribe more along evidence-based lines:

*I suppose there were times when you have to try and overcome your own clinical prejudices to either go along with the booklet or not ... the booklet was kind of construed, well that mostly antibiotics are not helpful.*

(Clinician 173, above avg. prescribing, lower recruiter)

Natural history advice may encourage parents to, 'hang in a bit longer'.

*Parents may well say, oh well, come on where's that booklet, how long do you have an ear ache before it gets better, oh it's only three days we can hang on in there a bit longer.*

(Clinician 173, above avg. prescribing, lower recruiter)

The impact on clinician beliefs about antibiotic prescribing has already been mentioned. One clinician from a higher prescribing practice who talked about having an 'incentive' to reduce prescribing said that at the end of the study he felt like he 'explained more and prescribed less'.

Other clinicians talked about the booklet backing-up their advice or giving them more authority:

*...it's not always easy when the expectation or perceived expectation is there for antibiotics, umm, just in case. And it's much easier to prescribe than not to prescribe. But if you've got something like that booklet then it kind of gives more backup or authority to reinforce the advice.*

(Clinician 15, below avg. prescribing, higher recruiter)

*I could use it to support why I wasn't giving an antibiotic and by explaining to them, you know, this is normal, part of growing up, umm, the child is going to build up his own immunity.*

(Clinician 159, below avg. prescribing, higher recruiter)

*I do feel that I've got, you know, particularly those little charts, to have something numerical like that ... it's really quite helpful ... to be able to say well look this is work that's been done, this isn't just me trying to save on my prescribing budget, cause some people are a bit suspicious about that these days, ... but this is, this is academic work that's been done.*

(Clinician 17, above avg. prescribing, higher recruiter)

One clinician talked about an increase in confidence in not prescribing as a result of greater knowledge:

*My confidence in not prescribing went up as a result of knowing those pieces of information and I think that if I communicate with that confidence then subliminally the patients register that I'm happy with that and then they take*

*away a bit of that from me, and so if I'm hesitant in my approach then they respond to that, but if I'm confident, I'm sure that that's picked up as well.*

(Clinician 98, below avg. prescribing, lower recruiter)

#### **5.5.5.11 Possible negative impacts from use of the intervention**

One clinician worried that providing printed information could possibly encourage the use of a more of a paternalistic approach rather than a shared decision-making approach. Two clinicians reported each having a somewhat dysfunctional consultation. One of these is the 'dysfunctional' consultation that has previously been discussed in the 'adverse events' section of the chapter on the trial results (Section 4.7). The clinician in question expressed his belief that the problem was that he did not elicit the culturally related expectations of the patient and that his agenda of 'getting through' the booklet distracted him from keeping the patient at the centre of the consultation. It was his belief that if he had been using his usual style he might have identified the problems earlier. However, he stressed that this was the only dysfunctional consultation he had while using the booklet and that his overall impression was that it was an exceptionally useful tool, which he would be keen to use routinely, and feels is best used within the consultation rather than given at the end. The other clinician described a similar situation in which one consultation felt 'slightly dysfunctional'. Again, the clinician wondered whether this had been related to his focus on 'working through the booklet' but did feel that this was likely to improve with more use of the booklet.

#### **5.5.5.12 Views on the format of the printed information**

An issue that had been raised in the booklet development focus groups, and had come up again in these interviews, was whether it was preferable to have a supply of pre-printed booklets (or leaflets) or to print them as needed in the consultation room, either from the internet, from the clinical system, or stored on the computer's hard drive. The main issues raised were fairly consistent; pre-printed booklets are in colour, better quality, more sturdy, and therefore more likely to be kept, while printing material from the computer system is more common, avoids issues of storage and ready access, and allows for a wide range of printed materials to be available that

can readily be printed off as needed. Although there was no clear consensus as to the preferred method, the majority came down in favour of having pre-printed colour booklets, and the main reason for this was that they were perceived to be more likely to be kept. However, a couple expressed a definite preference for having it in an electronic format so that they could print it off.

#### **5.5.5.13 Wider views on the provision of information and the management of RTIs in children**

A number of clinicians emphasised the importance of the problem and the challenges involved in managing these illnesses. These consultations are perceived as challenging because patients, and parents, often come expecting some sort of curative treatment, and effective curative treatment is often not available, and that these consultations are all different and no simple formulaic template can be used.

Some clinicians talked about the importance of investing time in sharing information with parents, and one thought that longer consultations would be helpful. A number of clinicians talked about the damage done by the inconsistency of messages that clinicians give to parents. Inconsistencies included actions, such as varying thresholds for prescribing antibiotics, and communication, such as clinicians giving conflicting advice. In terms of considering interventions for managing these consultations, a consistency of approach was regarded as an important feature.

With regard to the provision of information, three main related themes emerged; the setting in which the information should be provided, the format of the information, and the person providing it. Most participants thought that the provision of information about these illnesses was appropriate within primary care consultations, and indeed that these posed an ideal opportunity for information sharing. A couple of clinicians said that more in-depth information-sharing was not appropriate for this setting and that it could better be achieved away from the consultation. One clinician felt that during an acute illness parents were unlikely to be able to take-on much in the way of information during a consultation. A number of clinicians thought that it would be valuable for *consistent* information to be provided to parents in a number of



settings and by a number of different professionals. Settings and professionals that were mentioned included: during well-baby checks with health visitors, in the 'red book' provided to all new parents, in parent-toddler groups, through NHS direct, and on a dedicated internet site.

The use of the internet was discussed with many participants, both as a resource for clinicians (and a downloadable source of the booklet), and as a resource for parents and older children. Many clinicians indicated that they would be happy to print the booklet from the internet, although the problems with poor quality and lack of colour that have been previously mentioned were raised. One clinician indicated that he sometimes had trouble accessing the information he wanted on the internet and wondered whether clinicians 'of his generation' might have difficulty with this. A number of clinicians thought that internet sites had a useful role to play in the provision of information to patients but a number had concerns about patients accessing 'poor quality' sites. Suggestions for the provision of the information in the booklet included: having a dedicated website, putting it on the NHS direct website, and providing it to surgeries to include on their own websites. One clinician frequently directed patients to websites and highlighted the audio-visual capabilities of websites that printed material does not have. He mentioned a website where parents can listen to the sound of a child with 'whooping cough' and wondered whether there might be opportunities to educate parents in recognising a range of serious and less serious signs and symptoms, and possibly even using a scoring system. Another clinician felt that patients in his practice were more used to receiving messages in video format (such as television messages) rather than in printed format.

## **5.6 Summary**

One interviewer (NF) administered the majority of the two-week telephone-administered questionnaires. However, there is no evidence of interviewer bias. Analysis of 'late-enrolling' clinicians identified that the proportion of participating clinicians who enrolled into the study at a time when they may have been aware of practice allocation was larger in the intervention arm than the control arm. This may indicate a degree of selection bias and is discussed further in Chapter 7.

Participation in the online training by intervention clinicians appears to be good, with 96% of those who recruited participants accessing the website for a median of 43 minutes (estimated 32 minutes completing training in use of the intervention).

Data from the qualitative interviews suggest there may have been some problems with selection bias and intervention fidelity. One patient was found to have been ineligible for inclusion, a number of clinicians reported not using the booklet in consultations (as they had been instructed to), only half the parents remember having a booklet discussed with them in the consultation (two did not receive it at all), and only a minority recall being asked specifically about their main concerns and their expectations (despite the clinicians being instructed to ask them). However, many parents felt that their concerns had been understood even if they had not been specifically enquired about, and most did not seem to think that being asked about their expectations would have been helpful. The possible implications of this are discussed in Chapter 7.

In keeping with the quantitative assessment of satisfaction, most parents reported feeling satisfied with the consultation. The majority of both clinicians and parents thought that the study booklet was a valuable tool, and that it was / would have been helpful to have it discussed in the consultation. Clinicians reported that the booklet was easy to use in the consultation, although some reported a learning curve to using it. Most parents reported reading through it at home and keeping it for future reference. Two components of the booklet stood out as being most valued by parents and clinicians; graphical data on the likely duration of illness, and information on the signs of possible serious illness. Clinicians also reported that information about not eating and / or drinking was helpful, as was information on the likely benefits of antibiotics.

The data suggest that the most likely mechanism for the reduction in antibiotic prescribing described in Chapter 4 was through changes in the clinicians' behaviour. Clinicians described having an increased awareness of the importance of reducing their prescribing (the 'Why' of change), gains in knowledge about RTIs (including the effectiveness of antibiotics, likely duration of illness, signs and symptoms suggestive of serious illness), and using the booklet to help support or reinforce a non-prescribing

approach in consultations where they perceived parental expectations for antibiotics (both of which would help clinicians with the 'How' of change). Clinicians also reported increased information-sharing with parents, which may have also helped to steer the consultation in the direction of a non-prescribing approach. Parents reported a greater belief that their child would recover without antibiotics, and increased confidence in managing their child's illness, and this may have resulted in reduced pressure to prescribe or a greater acceptance of non-antibiotic management by clinicians.

The increase in confidence reported by parents was accompanied by a belief that they would be less likely to consult in the future. This is in line with the quantitative reporting of intention to consult, but does not fit with the non-statistically significant difference in reconsulting in the first two weeks or the lack of difference in consulting in the one-year follow-up. One possible explanation is that some clinicians are actively encouraging parents to reconsult. One clinician reported that they dealt with their anxiety about not prescribing by encouraging parents to reconsult more frequently, and a couple of parents reported being advised to reconsult routinely.

No major concerns or problems were expressed by participants from either group. One GP did not believe he learned anything from the training, and another felt that the booklet was too long and 'erudite' to be of use for her patients. A couple of parents felt that the information in the booklet was 'fairly obvious' and that they did not learn anything from it, and one parent felt the booklet was just about keeping parents away from the surgery. A couple of clinicians had experienced a difficult consultation while using the booklet and wondered whether focusing on use of the booklet in the consultation may distract them from being patient-focused.

## **6 Economic evaluation**

### **6.1 Introduction**

The trial results presented in Chapter 5 help us compare the effects that use of this intervention have in comparison to usual care. However, in order to make decisions about whether an intervention such as this should be adopted, policy makers need information about the costs of the intervention as well as the wider consequences of its use. This chapter describes the economic evaluation of the intervention described in Chapter 2 of this thesis.

### **6.2 Methods**

#### **6.2.1 Preparation**

In order to prepare for the economic evaluation, I consulted with Professor David Cohen (professor of Health Economics) during the trial development phase. These consultations helped inform the development of the data collection tools.

#### **6.2.2 Type of analysis**

There are a number of approaches to economic evaluation, each with its strengths and weaknesses. The approach selected for this analysis was a cost-consequences approach. I will now briefly outline a number of common types of economic evaluations, and give the reasons why a cost-consequences approach was selected.

The most common type of health-economic evaluation is a cost-utility analysis, in which an incremental cost per QALY (quality adjusted life-year) is calculated – unless a dominant result (lower cost, more QALYs) is shown. Such an approach was not suitable for this study because the study aims were primarily about modifying patient management (consulting behaviour and use of antibiotics) and not health states. QALY's are a way of combining changes in health states with survival data, and are therefore useful for comparing interventions that have an impact on health states and / or survival, but not studies aimed at modifying patient management (antibiotic prescribing) or behaviour (consulting). In addition, the instruments used to measure health states that are converted into QALY's have not been validated for use in children. Another possible approach would have been a cost-effectiveness analysis,

with total cost per unit reduction in reconsulting, or total cost per unit reduction in antibiotic prescribing presented as the outcome. However, this type of analysis would not provide information about the full range of outcomes that are relevant to the aims of the study. Finally, a cost-benefit analysis, in which outcomes (consequences) and costs are compared in the same units (usually money), was considered. Such an approach was not feasible because it cannot deal with outcomes that are incommensurable (cannot be measured in monetary units, e.g. parental satisfaction) or intangible (difficult to quantify at all, e.g. potential reductions in antimicrobial resistance as a result of decreased antibiotic consumption).(227)

A cost-consequences analysis is an economic evaluation that presents an array of outcome measures alongside total cost for each group, and allows decision-makers to form their own view of the relative importance of these.(228) Such an approach is idea for a study such as this, that aims to modify intermediate measures (consulting behaviour and antibiotic use) rather than direct health gains, and includes outcomes that are incommensurable and intangible.(227)

### **6.2.3 Viewpoint**

An important decision with respect to an economic evaluation is the viewpoint or perspective taken. I decided to conduct the analysis from a societal perspective. This study involves the delivery of healthcare by the National Health Service and therefore the perspective of the healthcare provider (the NHS) is important. However, common respiratory tract infections in children also have important impacts on families, and as a result, on society at large. Parents often have to take time off work to care for children with respiratory tract infections or to take them to see a doctor or nurse. Attending consultations results in transportation costs, days off work can have impacts for employers as well as employees, and days off school can have implications for schools as well as the child in question. For these reasons a societal approach best describes the important costs and outcomes.

### **6.2.4 Measurement and valuation of costs**

There are three stages to costing; identification, measurement, and valuation.(229) The costs that need to be identified include the resources used in delivering the intervention and any other resources that use of the intervention may impact on.

Decisions need to be made about which resources to include, and these decisions are guided largely by the perspective that has been selected. For this evaluation, a societal perspective dictated that a broad range of costs be considered for inclusion. However, for a cost-consequences analysis there is the opportunity to decide whether resources are included as 'costs or 'consequences'. Resources that are difficult to value may be more usefully included as consequences.

#### **6.2.4.1 Discounting and inflation**

In valuing costs, assessments need to be made about the impact of the timing of those costs. Discounting is the process of making future costs and benefits worth less than those occurring in the present.(230) Discounting is used when there is considerable variation in the timing of costs. It is used because there is an 'opportunity cost' to spending money in the present compared with the future. In this study, the time-period between use of the intervention and the main outcomes is very short and therefore no discounting has been used. Inflation also needs to be considered in the context of valuing costs. If there were significant differences in the timing of costs then an inflation index to increase 'future costs' would need to be used. There was not a large variation in the timing of costs in this study and therefore no inflation factor was required in the cost calculations. The exception to this was in the annuitizing of the cost of clinician training in which a 2% inflation index was used (UK inflation varied between 0.09% and 5.6% in 2008). Finally, it was important to use a consistent time period in terms of valuing, and for this reason, all costs were based on 2008 levels.

#### **6.2.4.2 Intervention costs**

Costing the development of the intervention was based largely on actual receipts for work done and on estimates of time devoted to the project. These costs have been separated into development (one-off) costs and usage (ongoing) costs. The former will not be included in the main analysis because these costs would not be incurred again if the intervention were rolled out. Instead, the cost of developing the intervention will be presented separately.

Table 6.1 lists the items included in the cost of developing, and using, the intervention, as well as the measurements used, and how they were valued. The

clinician training costs were based on the amount of time spent completing the online training. However, only data on the total amount of time spent accessing the site (which included training in study procedures as well as training in use of the intervention) was available. Therefore, the amount of time spent on the intervention training was estimated by subtracting the average amount of time spent online by clinicians in the control arm (who only had study procedure training to complete) from the average time online for clinicians in the intervention group. The training is an investment, the benefits of which are likely to be available over a number of years. Therefore the training cost was annuitized over a two-year period using a 2% interest rate.

#### **6.2.4.3 Other costs**

Table 6.2 lists all costs included in the analysis, including the cost of delivering the intervention, which was calculated as described above. Primary care consulting costs came from 'Unit Costs of Health and Social Care',<sup>(231)</sup> apart from out of hours costs which came from The Primary Care Foundation,<sup>(232)</sup> who collect data on primary care out of hours services and publish an out of hours benchmark. Data on the type of antibiotic prescribed was not available. Therefore, the cost of 100mL (enough for a one-week course) of 'Amoxicillin suspension', the most commonly prescribed first-line antibiotic for RTI in children in the UK, was used as a proxy.

Table 6.1 Intervention costs

<b>Cost</b>	<b>How measured (units)</b>	<b>How valued</b>
<b>Developing the intervention</b>		
Researcher time	Estimated from personal records (hrs)	Calculated from actual salary and estimated annual hours of work
Team meetings	Estimated from personal records (hrs)	Estimate based on the salary scales for the job titles of team members
Focus group materials	Estimated	
Travel to focus groups	Estimated (miles)	Cardiff University mileage rate
Focus group transcription	Number of hours spent on transcribing	Actual hourly rate paid for transcribing
Graphic design	Actual cost	Actual cost
Reading age assessment	Actual cost	
<b>Delivering the intervention</b>		
Booklet printing	Actual cost	Total cost booklet printing
Booklet distribution	Number of randomised intervention practices.	Postage cost for sending a package with a weight equal to the weight of fifteen booklets and packaging. From <a href="http://www.royalmail.com">www.royalmail.com</a>
Web hosting	Length of study recruitment period (mo.)	Cost of hosting per month
GP time completing training	Mean time online for GPs in intervention arm less mean time online in control arm, annuitized over 2 years* (minutes)	Cost of GP time – Unit costs of health and social care
Practice nurse time completing training	Mean time online for nurses in intervention arm less mean time online in control arm, annuitized over 2 years* (minutes)	Cost of nurse time – Unit costs of health and social care
* Intervention time estimated by subtracting average time in control arm from average time in intervention arm. Amount then annuitized over 2 years (see text above).		



**Table 6.2 Costs included in the analysis**

<b>Cost</b>	<b>How measured (units)</b>	<b>How valued</b>
<b>Costs for index consultation and one year follow-up</b>		
Intervention delivery	All participants in intervention arm	See Table 6.1
Length of index consultation	From primary care computer systems* (minutes)	Cost per consultation minute calculated from UCHSC.
Antibiotics prescribed in two weeks following the index consultation	Data from main follow-up telephone interview (No. of courses)	Cost of a course of Amoxicillin suspension (from BNF)
Primary care consultations over year following the index consultation (GP / nurse)	Data extraction from primary care computer record (No.)	Cost per consultation from UCHSC
Primary care telephone consultations over the following year	Data extraction from primary care computer record (No.)	Cost per consultation from UCHSC
Primary care home visits over the following year	Data extraction from primary care computer record (No.)	Cost per consultation from UCHSC
Out of hours consultations over the following year	Data extraction from primary care computer record (No.)	Data obtained from the Primary Care Foundation
Transportation by car cost (to consultations in first two weeks)	Data from main follow-up telephone interview (minutes of driving)	Distance calculated using an average speed of 30mph. Cost calculated using average car costs from the automobile association (AA).
Parking costs (first two weeks)	Data from main follow-up telephone interview (Currency)	-
Other transportations costs (first two weeks)	Data from main follow-up telephone interview (Currency)	-
* Consultation length had to be imputed for a number of subjects (see section 6.2.6.1)		

### **6.2.5 Measurement of outcomes**

Outcomes that were included in the analysis are presented in Table 6.3. They include the outcomes reported in the results chapter as well as some additional outcomes.

Some items appear as both outcomes as well as costs. This does not constitute 'double

counting' as they are included as outcomes as a marker of consequences other than the cost that has been accounted for. For example, consultations have a 'cost' that relates to the health service use, but consulting is also a marker for other consequences (possible anxiety that led to the consultation, parent's time). Outcomes were measured either at the two-week follow-up telephone interview (or postal questionnaire) or through the one-year data collected from practice computer systems.

**Table 6.3 Outcomes included in the analysis**

<b>Outcomes</b>	<b>Units</b>
<b>Outcomes during the first two weeks</b>	
Re-consultations* (included as a proxy for distress and inconvenience caused to parents)	Number who have re-consulted one or more times in the first two weeks
Antibiotics taken during initial two weeks* (included as a proxy for medicalisation of illness, and antibiotic resistance)	Number of children who took antibiotics
Parental satisfaction*	Proportion 'satisfied' or 'very satisfied'†
Parental reassurance from index consultation*	Proportion 'very reassured'†
Parental value placed on information received during index consultation*	Proportion stating information was 'useful' or 'very useful'†
Parental enablement*	Proportion of parents with enablement scores of 5 or more†
Days off school	Number of days
Days off work (parents)	Number of days
<b>Outcomes during the year following registration</b>	
Primary care consultations for respiratory tract infections over the following year (as above, this forms part of the costs but is included as a proxy for parental enablement or confidence in managing their child's illness)	Number of consultations for RTI
Out of hours consultations for RTI	Number
Telephone consultations for RTI	Number
*These outcomes were used in the main trial analysis †The reasons for the categorical splitting choices are discussed in Chapter 3.	

## **6.2.6 Analysis of costs**

Cost were analyses using STATA 9, and MLwiN version 2.11.

### **6.2.6.1 Calculating the cost of the index consultation**

Given the possibility that use of the intervention might increase the length of the index consultation, the cost of the index consultation was based on its recorded length. However, consultation length data was missing for a large number of participants. Although for the primary comparison of consultation length I used a complete case analysis (use of only the available data, see Section 4.4.5), for this analysis excluding all participants who did not have consultation length data would have resulted in a cost analysis that excluded 139 children. Therefore, I explored the use of imputation to estimate consultation lengths for those with missing data.

Regression imputation, using factors correlated with consultation length (study arm, country in which the practice was based, and duration of illness) and simple stochastic imputation were applied independently and compared with the use of a complete case analysis. However, both of these approaches resulted in a marked reduction in variance, and especially between practice variance. A two-stage stochastic imputation approach was attempted, in which stage one involved imputing a practice mean for each practice which had missing data, and stage two involved imputing a value for each individual with missing data from that practice, from a distribution with the imputed mean from stage one. However, the distribution of practice means was not normal and this approach resulted in imputed values that were not feasible (<3 mins). The existing data were skewed to the left and a natural logarithmic transformation resulted in a near normal distribution. Therefore, a simple stochastic approach using a log normal distribution was attempted. Missing values were imputing from the log normal distribution with the same mean and standard deviation as existing data, by trial arm. This approach was the most successful at generating a dataset with properties similar to the existing data. However, this approach does not take into account the clustered nature of the data, and resulted in a reduction in the ICC (see section 6.3.1.2). The implications of this are discussed in section 6.4.

### **6.2.6.2 Main analysis**

A total cost per patient, mean cost in each arm of the trial, and the difference in mean cost, were all calculated in STATA. Calculating cost data from a cluster randomised

trial involves some conceptual complexities, especially with regard to confidence intervals.(233) Resource use and cost data were highly skewed (as expected with cost data). Therefore confidence intervals around the means, for resource use and cost, were calculated using bootstrapping. The data in this study were also clustered. Therefore, linear regression, using a non-parametric bootstrapping approach, was used to explore the impact of the intervention on total cost, while accounting for the clustered and skewed, nature of the data. This approach involved sampling a number of bootstrap replicates (with replacement) from the estimated residuals. Each set of replicates is used to calculate an estimate of the level 2 variance, and this is then used to calculate the estimated downward bias. The ‘bias corrected’ estimate is then used as the starting value for the next simulation. This approach is continued until there is convergence of the estimated level 2 variance.(220)

### **6.2.6.3 Sensitivity analyses**

Two sensitivity analyses exploring alternative intervention delivery costs were calculated. These were conducted because, for the following reasons, the cost of delivering the intervention in the trial setting is likely to be higher than in an implementation setting:

- Results of the process evaluation suggest that the magnet (which accounted for 71% of the booklet production cost) was not highly valued. Therefore, it is unlikely that it would be included in any future use.
- Practices (and clinicians) in the trial were asked to recruit only a very limited number of children (10 per practice) and therefore the cost of training clinicians and postage of booklets per recipient is much greater. If this intervention were implemented into routine practice most clinicians would use the booklet with many more children, and over a much greater period of time, than in the trial.
- Only 60% of the clinicians who completed the training actually recruited any patients. Outside of a trial setting clinicians would not have to recruit patients in order to use the booklet, and therefore the proportion of clinicians receiving training that go on to use the booklet may be higher. However, it is also possible that a lower proportion of trained clinicians use the booklet.

The first sensitivity analysis involved just excluding the cost of the magnet from the intervention cost. The second calculation attempted to represent a more realistic implementation cost. It is based on the following assumptions:

- 100 clinicians (same ratio of nurses to doctors as in this study) in 25 practices complete training;
- 75% of clinicians who complete training use the intervention;
- The 75 clinicians who use the intervention each use it with an average of 100 children over one year (total of 7,500 recipients per year);
- 10% of booklets sent to the practice are lost or not used (therefore each practice supplied with 330 booklets for use with 300 children – total of 8,250 booklets required).

### **6.2.7 Analysis of outcomes**

All patients included in the cost analysis were included in the analysis of outcomes. Reconsultations and antibiotic prescribing in the first two weeks, parental satisfaction, reassurance, value of on information received, and enablement, had been analysed in the main study analysis, and the same approach to analysis was used for these analyses (see section 3.11). However, these outcomes were re-analysed using only the data from patients included in the cost analysis (i.e. those patients for which two-week follow-up data and one-year follow-up data were available).

The data for number of days off school and number of days off work were both skewed and zero inflated. For these data a two-stage analysis was conducted; comparing those who took any time off with those who did not, and comparing the amount of time off in those who took time off. For the first stage of these analyses data are presented as proportions and analysed using multilevel logistic regression modelling to account for clustering at the practice level. For the second stage, which involves the analysis of count data, means will be presented and Poisson regression models fitted in MLwiN version 2.11 will be used to compare the two study arms. Mean proportions and odds ratios (with 95% confidence intervals) from the multilevel modelling will be presented. The data on consultations over the following year were skewed and therefore are presented as means with bootstrapped confidence intervals. Differences are calculated using Poisson regression with parametric bootstrapping, using MLwiN.

## 6.3 Results

### 6.3.1 Costs

#### 6.3.1.1 Intervention delivery cost

Table 6.4 lists the items included in the cost of delivering the intervention. A conservative calculation was used in which the total cost of booklets produced, and the training costs for all clinicians (whether they recruited patients or not), were included.

Table 6.4 Calculation of intervention delivery cost

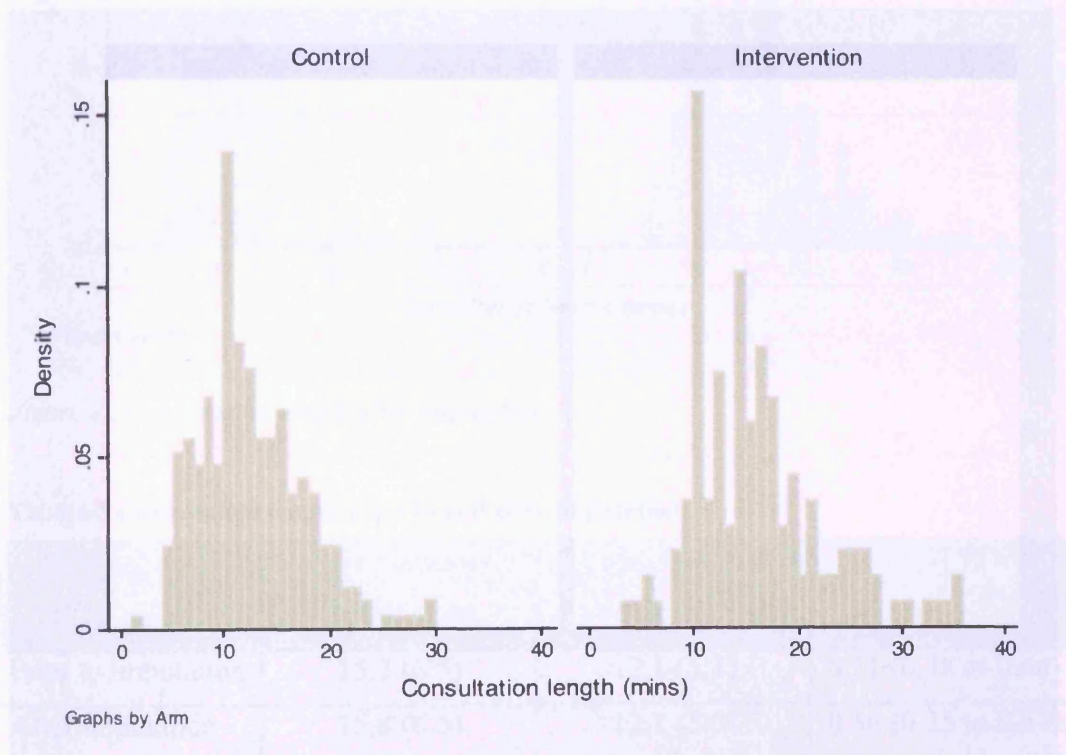
	Unit cost	Resource use	Total
Booklet / magnet printing and assembly*			£1740.50
Postage (pack of 15 sent to practice)	£2.24	83	£185.92
Online training for doctors (Mean 20.5 minutes x 94 doctors)	£52.51 <sup>†</sup>	32.1 hrs	£1685.72
Online training for nurses (Mean 10.6 minutes x 11 nurses)	£12.12 <sup>†</sup>	1.94 hrs	£23.51
Web hosting (per month)	£35	19	£665
Total cost			£4300.65
<b>Cost per recipient (274 recipients)</b>			<b>£15.70</b>

\* Actual amount paid for printing of 1000 booklets and magnets and assembly of magnets onto booklets  
† Cost per hour from Curtis(231) (£104 per hour for doctors, £24 per hour for nurses) annuitized over 2 years at 2% interest.

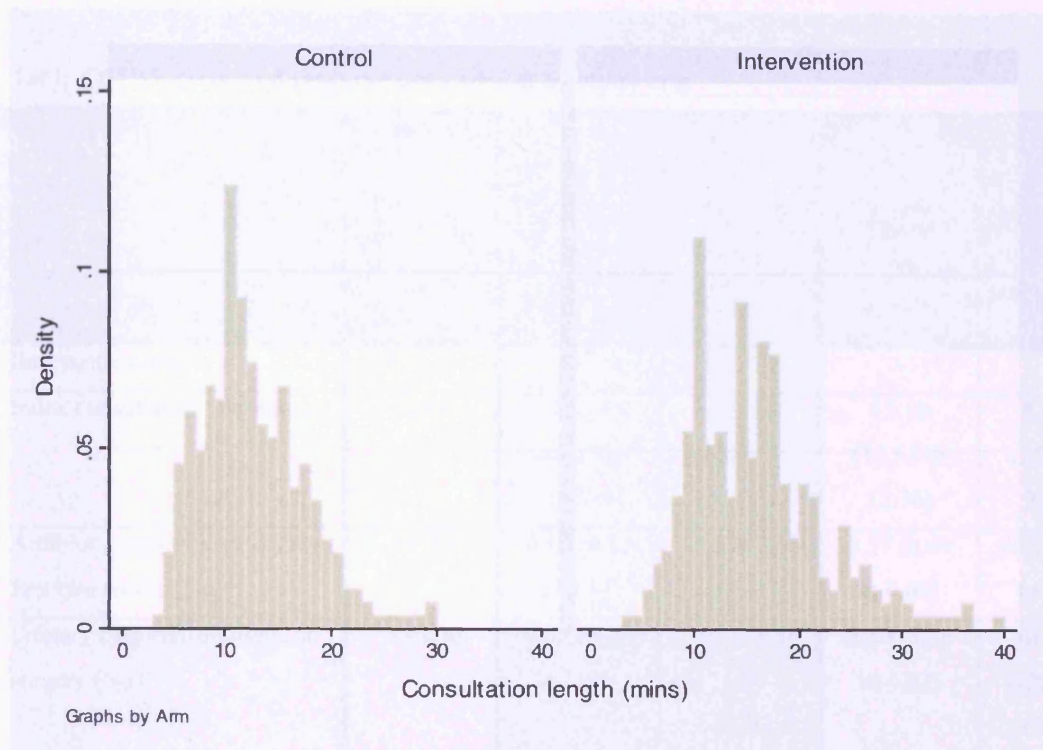
#### 6.3.1.2 Consultation length data

Consultation length data was available for 385 (69.1% of total recruited) children prior to imputation (distribution given in Figure 6.1). For both arms there was a spike at 10 minutes suggesting that some practices recorded the 'booked' consultation length (most commonly 10 minutes in UK general practice) rather than the actual

consultation length. Consultation length data was imputed for 169 children resulting in data being available for 554 children (all participants who had not withdrawn from the study). The distribution of consultation lengths following imputation can be seen in the histograms in Figure 6.2, and mean consultation lengths in each study arm, and ICCs for consultation length prior to and following imputation, are shown in Table 6.5.



**Figure 6.1 Consultation length data prior to imputation**



**Figure 6.2 Consultation length after imputation**

**Table 6.5 Consultation length prior to and after imputation**

	<b>Intervention Mean (sd)</b>	<b>Control Mean (sd)</b>	<b>ICC (95% CI)</b>
Prior to imputation	15.7 (6.5)	12.1 (5.1)	0.51 (0.38 to 0.64)
After imputation	15.8 (6.5)	12.1 (5.0)	0.36 (0.25 to 0.47)

### 6.3.1.3 Main cost analysis

Following imputation of consultation length, cost could be calculated for all participants who had full two-week outcome data (i.e. completed the telephone interview), and had one-year follow-up data. 508 participants (246 Intervention, 262 Control) had full two-week outcome data and 505 (244 Intervention and 261 Control) of those also had one-year data and were included in the economic analyses. This represents 90.7% of the recruited sample of 557 participants. Table 6.6 shows the unit costs, mean (and standard deviation) resource use and cost per resource for each arm of the study, and mean total cost per participant. Total cost per participant ranged from £35.51 to £1219.02 in the intervention arm and £16.67 to £1053.72 in the Control arm (cost distributions are shown in Figure 6.3).

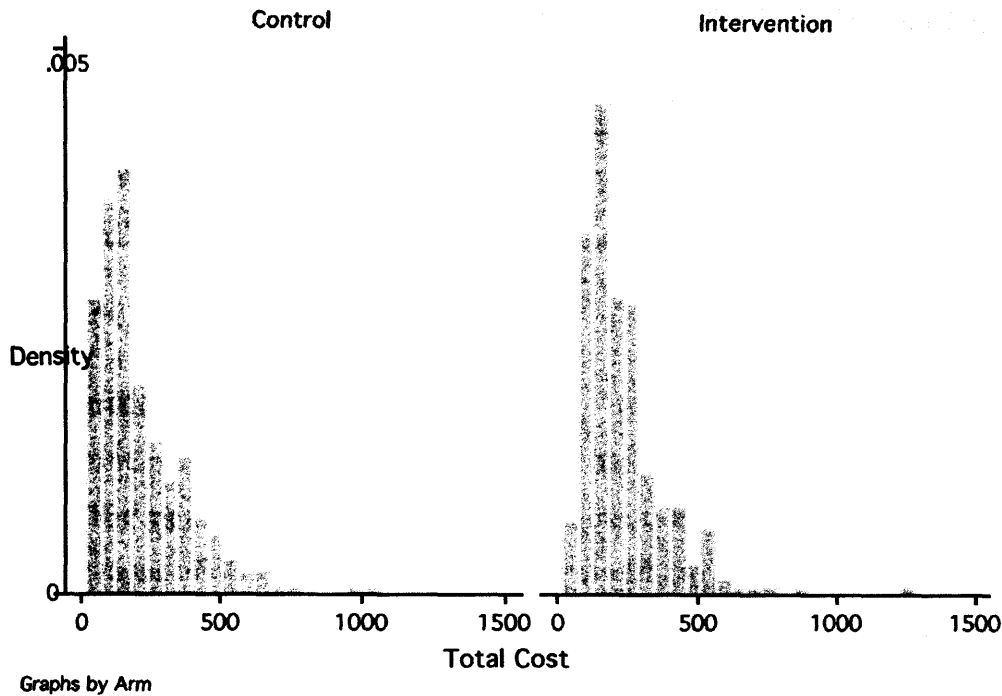


Table 6.6 Unit costs, and resource use and cost by study arm

Resource	Unit cost	Intervention N=244		Control N=261	
		Resource use in units (95% CI)	Cost (95% CI)	Resource use in units (95% CI)	Cost (95% CI)
Intervention delivery	£15.70	-	£15.70	-	-
Index consultation (per min)	£3.08	15.94 (15.15 to 16.74)	£49.11 (46.99 to 51.22)	12.19 (11.63 to 12.76)	£37.55 (35.39 to 39.72)
Antibiotic prescription during first two weeks (No)	£1.27	0.30 (0.22 to 0.37)	£0.37 (0.28 to 0.47)	0.57 (0.49 to 0.66)	£0.73 (0.64 to 0.82)
Primary care consultations at surgery (No)	£36.00	3.58 (3.25 to 3.91)	£128.80 (114.64 to 142.97)	3.80 (3.39 to 4.22)	£136.97 (122.42 to 151.51)
Primary care consultation by telephone (No)	£22.00	0.42 (0.28 to 0.57)	£9.29 (6.21 to 12.36)	0.33 (0.24 to 0.41)	£7.16 (4.92 to 9.41)
Primary care home visits (No)	£58.00	0.02 (0 to 0.05)	£1.43 (0.21 to 2.64)	0.01 (0* to 0.02)	£0.67 (0* to 1.54)
Out of hours consultations (No)	£62.00	0.35 (0.23 to 0.47)	£21.60 (15.30 to 27.89)	0.49 (0.36 to 0.63)	£30.64 (22.32 to 38.96)
Car transport (min)	£0.23	2.11 (1.11 to 3.10)	£0.48 (0.28 to 0.69)	2.39 (0.80 to 3.99)	£0.55 (0.20 to 0.90)
Parking (£)			£0.01 (0 to 0.03)		£0.06 (0 to 0.17)
Other transportation (£)			£0.07 (0 to 0.17)		£0.01 (0 to 0.03)
Total			£226.86 (209.29 to 244.43)		£214.35 (193.72 to 234.97)

\*Lower confidence interval less than zero and therefore set to zero

**Figure 6.3 Distribution of total cost by study arm**



### **Accounting for clustering**

In order to compare the costs in the two study arms, while taking account of the skewed nature of the data, and controlling for clustering, multilevel modelling with non-parametric bootstrapping was used. Graphs of the between practice variance were produced during the modelling in order to assess convergence, and this demonstrated that 10 series of 200 replicates were needed in order to obtain good convergence. The calculated coefficients and their standard errors, along with the between and within practice standard deviations, are given in Table 6.7. Using this approach, the calculated average cost per participant in the control arm was reduced from £214.35 (95% CI 193.72 to 234.97) to £210.80 (95% CI £188.36 to £233.24), and the difference in mean cost per participant in the intervention arm compared to the control arm changed from a non-statistically significant increase of £12.52 (-15.68 to 40.71) to a non-statistically significant increase of £15.46 (95% CI -£15.49 to £46.41).

**Table 6.7 Modelling the effect of intervention on total cost using multilevel modelling with bootstrapping**

<b>Coefficient</b>	<b>Value</b>	<b>Standard error</b>
Constant	210.80	11.45
Intervention effect	15.46	15.79
Between practice sd	33.79	26.28
Within practice sd	154.58	37.58

### **6.3.2 Outcomes**

All 505 participants who contributed to the cost data were included in the outcomes analyses. The number (and proportion) of participants experiencing each outcome, and calculations of difference using multilevel modelling are given in Table 6.8.

There was a statistically significant reduction in reported antibiotic consumption in the intervention arm (OR= 0.34, 95% CI 0.18 to 0.64). There was no statistically significant difference between the study arms for any of the other measured outcomes.

### **6.3.3 Sensitivity analyses**

#### **Sensitivity analysis 1 – Excluding magnet production cost**

The total cost of printing the booklet and magnet, and attaching the magnet to the back of the booklet, in the trial was £1740.50. 71% of this cost related to the production and attachment of the magnets. Therefore without the magnets, the booklet printing cost would have been £499.50. This would have reduced the intervention delivery cost per participant down from £21.82 to £17.29. Given the non-statistically significant difference in total cost with the original (higher) intervention delivery cost, I have not conducted a re-analysis of the total costs using the lower intervention delivery cost.

#### **Sensitivity analysis 2**

The resources used in this calculation, and the calculated cost per recipient, are given in Table 6.9. This shows the dramatic reduction in intervention cost delivery (from £15.70 per recipient to £0.44 per recipient) that results from the more realistic assumptions of bulk printing and spreading the training costs over a larger number of recipients. Again, a full reanalysis of the cost data has not been conducted as the

original difference was non-statistically significant and in this analysis the difference would be smaller.

**Table 6.8 Outcomes by study arm and odds / rate ratio calculated using multilevel modelling**

<b>Outcome</b>	<b>Intervention [N=244] No. (%)</b>	<b>Control [N=261] No. (%)</b>	<b>Odds Ratio* / Rate Ratio† (95% CI)</b>
Reconsulted	32 (13.1)	42 (16.1)	0.77 (0.42 to 1.43) <sup>*</sup>
Antibiotic course taken	54 (22.1)	113 (43.3)	<b>0.34 (0.18 to 0.64)<sup>*</sup></b>
Parent satisfied or very satisfied	220 (90.2)	244 (93.5)	0.64 (0.33 to 1.22) <sup>*</sup>
Parent very reassured	176 (72.1)	196 (75.1)	0.86 (0.58 to 1.27) <sup>*</sup>
Parent reports information received was useful or very useful	209 (85.7)	222 (85.1)	1.04 (0.63 to 1.74) <sup>*</sup>
Parent enablement score $\geq 5$	98 (40.2)	92 (35.4)	1.23 (0.86 to 1.76) <sup>*</sup>
Child took time off school	95 (38.9)	123 (47.1)	0.67 (0.41 to 1.10) <sup>*</sup>
Number of days off school in those who took time off [N=218] – mean (bootstrapped CI)	3.4 (3.0 to 3.9)	3.6 (3.1 to 4.0)	0.91 (0.73 to 1.13) <sup>†</sup>
Parent took time off work	59 (24.2)	63 (24.1)	0.96 (0.62 to 1.49) <sup>*</sup>
Number of days off work in those who took time off [N=122]– mean (bootstrapped CI)	2.7 (2.3 to 3.2)	2.1 (1.7 to 2.5)	1.27 (0.99 to 1.62) <sup>†</sup>
Primary care consultations over following year - mean (bootstrapped CI)	3.6 (3.2 to 3.9)	3.8 (3.4 to 4.2)	0.98 (0.81 to 1.20) <sup>†</sup>
Out of hours consultations over following year - mean (bootstrapped CI)	0.3 (0.3 to 0.4)	0.5 (0.4 to 0.6)	0.75 (0.41 to 1.35) <sup>†</sup>
Telephone consultations over following year - mean (bootstrapped CI)	0.4 (0.3 to 0.6)	0.3 (0.2 to 0.4)	1.18 (0.54 to 2.58) <sup>†</sup>
*Odds ratio for dichotomous outcomes †Rate ratio for count data			

**Table 6.9 Estimated implementation cost of intervention**

<b>Resource</b>	<b>Unit cost</b>	<b>Resource use</b>	<b>Cost</b>
Booklet printing	£0.086	8250	£709.50
Postage (pack of 330 booklets)	£20.00	25	£500.00
GP training (Mean 20.5 minutes x 90 doctors)	£52.51 <sup>†</sup>	30.75 hrs	£1,614.68
Nurse training (Mean 10.6 minutes x 10)	£12.12 <sup>†</sup>	1.77 hrs	£21.41
Web hosting (per month)	£35	12	£420
<b>Total cost</b>			<b>£3265.59</b>
<b>Cost per recipient (7,500 recipients)</b>			<b>£0.44</b>

#### **6.3.4 Cost of developing the intervention**

The resource use (and costs) involved in developing the intervention are given in Table 6.10. The total cost of developing the intervention was £22,214.

Table 6.10 Intervention development costs

Resource	Unit cost	Resource use	Cost
<b>Booklet</b>			
Researcher time developing first draft (hours)	£34	80	£2,720
Researcher time for focus groups (preparation, recruiting, conducting)	£34	100	£3,400
Focus group materials (per group)	£15	7	£105
Travel (miles)	£0.40	175	£70
Audio recording equipment	£150	1	£150
Transcribing (hours)	£84	7	£588
Researcher time analysing focus group data	£34	60	£2,040
Researcher time revising booklet on basis of focus group findings	£34	40	£1,360
Booklet development team meetings (per hour)	£180	3	£540
Reading age assessment and report	£200	1	£200
Graphic design	£400	1	£400
<b>Total booklet development cost</b>			<b>£11,573</b>
<b>Training</b>			
Researcher time developing outline of training programme	£34	40	£1,360
Researcher time writing copy for website	£34	80	£2,720
Team meetings	£180	2	£360
Researcher time writing video scripts	£34	40	£1,360
Actors' fees (per actor)	£470	2	£940
Video filming and editing			£1,000
Website production			£3,900
<b>Total training development cost</b>			<b>£10,641</b>
<b>Total Development Costs</b>			<b>£22,214</b>

### **6.3.5 NHS service support and excess treatment costs**

Participating practices were paid service support and excess treatment costs to compensate them for the time spent identifying and recruiting eligible patients, and the time of the clinician or a designate, for local management of the study, faxing study forms, and collecting follow-up data from the practice notes. Practices were paid £400 for recruiting ten patients (£200 after recruiting five patients and a further £200 for the next five). In addition, practices were paid £100 for each of the next five patients recruited, up to a total of £400 for recruiting 20 patients. Total NHS costs were £20,300.

## **6.4 Discussion**

This cost-consequences analysis has demonstrated no statistically significant difference in mean cost per participant over the year following recruitment. This is not surprising as the cost of delivering the intervention is relatively small (£15.70), there were no statistically significant differences in consulting behaviour, and the one resource where there was a statistically significant difference in use, antibiotic prescribing, is not an expensive resource (£1.27 per course of Amoxicillin). Furthermore, the cost of delivering the intervention will reduce further when its use is considered outside of a trial situation. The sensitivity analysis suggested that the cost of delivering the intervention would reduce dramatically (to around 44 pence per recipient) in an implementation setting.

This analysis suggests that this intervention results in a benefit (reduced antibiotic prescribing) with no statistically significant increase in cost. However, it is important to distinguish between a dominant result (where there is a clear reduction in cost and a clear benefit), from the results of this study where there was no statistically significant difference in cost, a statistically significant benefit in terms of one outcome, and non-statistically significant differences in other outcomes. The confidence interval around the difference in cost suggests that use of the intervention may result in an increase in cost of up to around £44. However, it may also result in a savings of up to £18 (or even more if the reduced intervention delivery costs are used). None of the outcomes other than antibiotic use were statistically significantly different between treatment arms.

The cost of developing the intervention was estimated at £22,214. This is made up largely by the cost of the research (and development) time involved. These development costs have been met by the funders of this project, and would not be incurred again should the intervention be used in its present format.

#### **6.4.1 Strengths and weaknesses**

The cost-consequences approach adopted for this analysis allowed for a clear description of the resource use and cost in each arm of the trial, and for comparison of a variety of outcomes. High rates of follow-up, both at two weeks and at one year, meant that a large proportion of participants were able to be included in the economic analysis. The one exception to this was the consultation length data where 30.9% of the data were missing overall, and 50.6% of the data in the Intervention arm were missing. This problem was dealt with by imputing missing data. No method of imputation is perfect, and there is no way of assessing whether the imputed data is representative of the missing data. A number of imputation approaches were used and gave broadly similar results to a complete case analysis. The stochastic method that was employed resulted in a dataset that appeared similar to the existing data in terms of descriptive statistics, but was less clustered than the original dataset and therefore reduced the ICC. This would have resulted in a slight underestimation of the cost variance. Furthermore, it is possible that practices that did not record consultation length differed in some systematic way from practices that did provide consultation length data. No attempt has been made to determine this, but it is unlikely to have made a significant difference to the results. In addition, there appears to be some inaccuracies in the way consultation length was recorded, with a preponderance of 10 minutes recorded (which is the most common booked consultation time in the UK). Again, this is unlikely to have had an important effect on the results.

The use of symptomatic medicine during the first two weeks was assessed. However, its use was very prevalent in both arms of the trial, no measure of the quantity used was obtained, and its cost is minimal, can be borne by the NHS or the family, and varies in price depending on whether it is prescribed or bought over-the-counter. For these reasons it was not included in the analysis.



The only resources whose use was measured over the follow-up year were consultations (surgery, telephone, and out of hours). There would have been a number of other resource uses that occurred as a result of RTIs in the participating children over the year, including: time off work, time off school, over-the-counter and prescription drug use. However, given that there were no differences in these outcomes over the first two weeks, it is unlikely that there would have been differences in their use over the year. There may also have been hospital admissions, which are so costly that they would have made any other difference in cost inconsequential. It is possible that this intervention, one aim of which is to help parents recognise the early signs of serious illness, could have an impact on hospital admissions. However, this study was underpowered to detect a difference in such a rare outcome.

A number of resource uses included in cost of developing the intervention are estimations based on recorded notes.

#### **6.4.2 Conclusions**

Use of this intervention was not associated with any statistically significant difference in total cost over one year compared with control. A statistically and clinically significant reduction in antibiotic consumption was found in the intervention arm compared to the control arm, but no other statistically significant differences in outcomes were identified. The implications of these findings, in terms of the broader context of the study, will be discussed in Chapter 7.

## **7 Discussion**

### **7.1 Main findings**

The main findings from this thesis are summarised below.

- There is a good evidence base to support the development of an interactive booklet on RTIs in children for use in the consultation as a tool to address high repeat consultation rates and unnecessary antibiotic prescribing.
- With support from my supervisory team, I was able to develop a complex intervention (interactive booklet and training for clinicians on use of the booklet in consultations), based on behaviour change theories, the latest scientific evidence on the management of respiratory tract infections in children, new data on usual duration of illness, evidence and expert opinion on developing printed educational materials for patients, and consultation with the intended users (parents and primary care clinicians) through focus groups.
- In a randomised, controlled evaluation, use of this intervention was associated with a small (3.3%) non-statistically significant reduction in the proportion of children reconsulting in primary care within the following two weeks.
- Use of the intervention resulted in a statistically significant and clinically meaningful two-thirds reduction in antibiotic prescribing compared with ‘usual care’.
- No statistically significant differences in consulting over the following year, or in parental satisfaction, enablement, or reassurance, were found.
- Use of the intervention increased the length of the consultation in which it was used by an average of just under 3 minutes.
- Data from the process evaluation suggest that use of the intervention is feasible, and that parents and clinicians mostly found it a valuable resource. However, there was some evidence that the intervention was not used as intended in up to half of the study consultations.
- The reduction in antibiotic prescribing appears to have been mediated primarily through changes in the clinicians. Increased awareness of the importance of reducing antibiotic prescribing, increased awareness of the evidence relating to the effectiveness of antibiotics, the normal duration of illness, and signs and

symptoms suggestive of serious illness that should be discussed with parents, and use of the booklet to reinforce a non-prescribing approach in consultations where they perceived parental expectations for antibiotics, appear to be the main mechanisms through which change was achieved.

- There was no statistically significant difference in cost over one year between the intervention and control groups from a societal perspective.
- Use of the intervention resulted in no statistically significant differences in the amount of time parents had to take off work or children had to take off school.

## **7.2 Potential sources of bias and study limitations**

### **7.2.1 Intervention development**

Participants of the parent focus groups involved in developing the intervention came from a broadly representative range of backgrounds. Only one father participated, and therefore the views of fathers may not have been captured. However, the majority of childcare is still conducted by mothers, and there is no reason to believe that, when it comes to caring for sick children, the needs of fathers are likely to be substantially different to the needs of mothers.

In the clinician focus groups there was no participation by nurses. Nurses were not ineligible for the focus groups but had not been specifically sought either. Given that nurses are increasingly responsible for the management of acute and 'minor' illnesses, and that 16% of participating clinicians were nurse, this omission may have had an important effect on the booklet development, but it is not clear whether including nurses in the focus groups would have led to changes in the booklet. However, nurses who used the booklet did participate in the qualitative process evaluation. Although they were not specifically asked about how the booklet could be improved, they were asked their views on the booklet, and largely indicated that the booklet was a valuable resource and did not need modifying.

Efforts were made to carefully moderate focus groups so that all participants had an opportunity to express their views. However, although focus group participants made some contribution, it is possible that some participants felt unable to adequately express their views in front of a group. Conducting individual interviews as well as

focus groups may have elicited additional views. However, this was not possible within the time and resource constraints of this project.

Finally, it is possible that additional focus groups would have led to greater refinement of the intervention. Five parent focus groups (and two interviews), and two clinician focus groups were conducted. Most themes arising from the parent focus groups had emerged prior to the final group, suggesting at least a degree of data saturation. However, it is possible that new themes would have emerged from further focus groups. With only two clinician focus groups it is not possible to say with certainty that data saturation was achieved. The results of the focus groups were validated through an assessment of the booklet by a group of academic general practitioners. However, further focus groups may have led to other changes. Again, time and resources limited the possibility of conducting further focus groups. It is nevertheless unlikely that major, materially important issues would have emerged that had not emerged from the two clinician focus groups and the academic general practitioner validation exercise.

### **7.2.2 Quality of the study booklet**

Development of the study booklet was guided by evidence based resources on developing patient information.(234, 235) However, following development of the booklet two tools for evaluating the quality of patient information were identified (DISCERN(236) and EQIP(157)), and if discovered earlier, these may have helped improve the quality of the booklet. Subjecting the booklet subsequently to these tools demonstrated that it met most of the quality criteria in these instruments. However, it did fall down in a few important areas; namely, the aims of the booklet were not described in enough detail at the start of the booklet, and references for sources of information were not included. The first of these is about helping the reader to know whether the leaflet is likely to address their needs, and the latter is largely about allowing the reader to assess the reliability of the material. These are important for leaflets or booklets used as part of routine healthcare, but were considered to be possibly less important in the context of a trial, especially as the booklet was designed to be used interactively in the consultation, and were left off in interests of keeping the length down. However, this may have been an omission and may have led to the booklet not being viewed with as much credibility. Certainly one of the parents in the

focus groups mentioned that they did not feel that the booklet was 'official'. These items should be added to the booklet before it is used in a 'roll-out' situation.

### **7.2.3 Randomised controlled evaluation**

Using the CONSORT extension for cluster randomised trials(237) as a guide, potential sources of error and bias at each stage of the trial have been considered.

#### **7.2.3.1 Selection bias**

Selection bias was possible at all three of the hierarchical levels in this cluster randomised trial – i.e. the practice, the clinician, and the individual level.(238, 239)

##### **Practice level**

Selection bias can occur at the practice level if participating practices are systematically different from non-participating practices, which leads to problems of external validity, or if there systematic differences in the practices that are allocated to each arm of the trial.

In an attempt to ensure that practices were as representative of UK general practices as possible, no practice-level exclusion criteria were used. Indeed, practices were included from many regions in Wales and England, and included a broad range of practice size and antibiotic prescribing history. However, practices that are familiar with participating in research, that are in a research network, or have a particular interest in the management of RTIs or the use of antibiotics, are more likely to have agreed to participate, and these practices may differ in important ways from those who did not agree to participate. Reassuringly, there were no important differences between randomised practices that did, and did not, recruit patients into the study. However, only about a third of practices had an antibiotic prescribing rate above the median, indicating that the population of practices in the study was slightly over-represented by lower prescribing practices. Importantly though, there is no evidence that the intervention was only effective in lower prescribing practices. Indeed, the opposite appears to be true; the intervention had a greater effect on antibiotic prescribing in higher prescribing practices.

In order to ensure that there was no bias in the randomisation procedure, practice allocation was conducted by a third party (independent statistician) only after each practice had agreed to participate. Balance in terms of potentially important factors (country, size, antibiotic prescribing history) was achieved through the use of block randomisation with stratification by these factors. Using random block sizes facilitated concealment of allocation. This approach has been questioned by some,(240) but in a study such as this where the participants (practices in this instance) are at a distance and not known to the researcher, it is likely to be an adequate approach.

Non-participation by randomised practices is another possible source of bias. In this study there were eleven practices in each arm of the trial that did not recruit any participants. No important differences between these non-recruiting practices and the practices that did recruit, or between the non-recruiting practices in the control and intervention arms were identified. This suggests that selection bias at the practice level is unlikely to have had an impact on the internal validity of the results. However, an impact on the external validity cannot be excluded.

### **Clinician level**

At the clinician level, bias could arise from systematic differences between the participating clinicians in the two trial arms, which would have an impact on the internal validity of the results, or materially important differences between participating clinicians and the population of UK primary care clinicians, which would have an impact on the external validity, or generalisability, of the results.

Over 50% of all clinicians agreeing to participate in the study did not recruit any patients. The reasons why such a large proportion did not recruit is unclear. However, it is likely that the method used to recruit and train practices – without any face-to-face contact – played a role. Limited data was collected about clinicians registering to participate in the study, so it is not possible to confidently rule out systematic differences between those who did and did not recruit. Nor is it possible to be confident whether the participating clinicians were sufficiently similar to the general population of primary care clinicians or whether the two trial arms were similar on all important, relevant parameters. The proportion of clinicians who did not recruit was

similar in the two arms, suggesting that lack of participation was not related to trial arm. However, there were a higher proportion of nurses who participated in the control arm (21.2%) compared with the intervention arm (9.8%). This may have resulted from chance. This is supported by the finding that of those clinicians who did not recruit any participants, there were similar proportions of nurses in each arm of the trial (Table 4.2). Furthermore, adding type of clinician (doctor or nurse) to the main outcome models had no effect on the results.

Another way in which systematic differences between the clinicians in the two groups could have occurred was if clinicians elected to take part in the study after knowing which arm of the trial they would be allocated to. Although most clinicians registered for the study prior to allocation of the practice to a study arm, some participating practices recruited additional clinicians subsequent to being allocated to a study arm. In order to explore possible effects of this, the proportion of clinicians who registered for the study a week or more after the date that the practice materials (including allocation assignment) were sent to the practice was calculated for each allocation group. This showed that there was a higher proportion of late-joining clinicians in the intervention arm, which could mean that clinicians who knew that their practice was in the intervention arm may have been more likely to join the trial than those who were in control practices, or may have been a chance finding. However, the number of late-joining clinicians was small (11% of participating clinicians) and therefore unlikely to have made a meaningful difference to the results. In addition, there was no difference in the proportion of late-joining nurses in the two arms, indicating that this was not the reason for the imbalance in nurses.

As with the practices, the numbers of clinicians who did not recruit patients may have affected external validity. Evidence from the process evaluation suggests that the additional time involved in recruiting patients into a trial is likely to be the main factor contributing to non-participation by clinicians. If so, given that this would not be a factor outside of a trial situation, implementation of the intervention outside of a trial situation would be expected to result in good uptake. Clearly, this will need to be evaluated in a pragmatic evaluation of the intervention, where antibiotic use is measured using routinely collected data at a population level.

## **Patient level**

Selection bias at the level of the individual is an important methodological consideration in cluster randomised trials.(239) This can occur if, as occurred in this study, the cluster (practice in this study) needs to recruit participants after they have been allocated to a study arm.

A cluster design was necessary in this study in order to avoid treatment contamination (see section 3.1.1). Some cluster RCTs have asked clusters (sites) to select participants prior to allocation of the practice into treatment arm in order to try and minimise the risk of this type of selection bias. However, in this study participants needed to be recruited at the time of consulting and therefore this approach was not feasible. Given that it was not possible to eliminate the possibility of this type of selection bias, a number of steps were taken to minimise and measure it. First, in order to maintain motivation amongst all participating practices, those clinicians allocated to control were informed that they would be provided with access to the intervention after the trial was completed. Second, all participating clinicians were clearly asked to recruit sequential eligible children, and given guidance about the scientific reasons for this. Finally, participating clinicians were asked to collect data on all 'potentially eligible' children who were not recruited. This included those who were invited to participate but then found to be ineligible, those who declined participation, and those who were not recruited for other reasons (i.e. not enough time).

No important systematic differences were found between recruited and non-recruited patients in this study. The only meaningful difference was duration of illness, but this was not surprising as duration of illness over seven days was a common reason for patients to be deemed ineligible after being informed about the study. However, this data needs to be interpreted with caution. Clinicians only recorded data on 93 children who were not entered into the study, and it is likely that there were many more eligible children who were not recruited. Furthermore, there are limitations to using such an approach to measure selection bias; it relies upon consistent recording of information by clinicians (who are not blinded). Additional evidence that selection bias did not play a large role comes from an examination of the recruitment rates in the two study arms, which were similar. Selection of patients using criteria other than



the broad inclusion criteria, if occurring in only one arm of the study, might be expected to result in different recruitment rates. Similar recruitment rates therefore suggest that selection bias did not occur to an important degree.

### **7.2.3.2 Recall bias**

The primary and many secondary trial outcomes were measured through an interview with parents two weeks after the consultation, and relied upon the ability of parents to accurately recall the events of the consultation and the intervening two weeks. As a method for measuring antibiotic prescriptions and consultations, telephone interviews may have been less accurate than using clinical records. Parents may have failed to accurately recall consultations and antibiotic prescribing decisions, and if this was combined with differential recollection associated with an awareness of the arm of the trial they were allocated to, then this could have biased the results. However, this is unlikely to have played a large role in this study. There is some evidence that patient recall of medical encounters is generally accurate,<sup>(241)</sup> and the main outcomes, antibiotic prescribing and consulting, are concrete outcomes that are unlikely to have been easily forgotten within this time span. Furthermore, there is no reason to believe that parents in the intervention arm would be more or less likely to recall receiving a prescription for antibiotics or having a consultation than parents in the control arm.

It is possible that some parents reported receiving a prescription for antibiotics when in fact they received a prescription for some other medication. However, this is unlikely to have occurred to any important degree because the most likely medicines to be prescribed, other than antibiotics, are paracetamol and ibuprofen, and most parents recognise these as not being antibiotics. Where parents expressed any doubt in the telephone interview about the nature of a medication that their child had been prescribed, the interviewer helped clarify whether the prescription was for an antibiotic or not. Again, there is no reason to believe that such a reporting error would be more likely to occur in one arm of the trial more than the other.

Finally, the use of parent interviews to gather this data, instead of examining the medical records, had certain advantages; it allowed for the measurement of parent-reported outcomes (such as satisfaction, enablement, etc.), allowed for the

measurement of reported antibiotic consumption (rather than just prescribing), and allowed for measurement of consultations that were not in the practice, including out of hours consultations (which may have been missed in a practice notes search).

Obtaining data from clinical records is also subject to error, however small.

### **7.2.3.3 Hawthorne effect**

A potential explanation for the observed difference in antibiotic prescribing found in this study is the Hawthorne effect. This is defined as the unwanted effect on an experiment arising from the act of observing the experiment.(242) In this study, all clinicians were aware that they were participating in a trial, were aware that observations were being made about the patients they were recruiting into the trial, and probably had some idea that one of the objectives of the trial was to modify antibiotic prescribing. As a result, they may have changed their prescribing behaviour towards prescribing fewer antibiotics (as suggested by guidelines and research evidence), in order to put themselves in a favourable light while under academic, external scrutiny. However, in order for this to explain the differential antibiotic prescribing in the two arms of the trial, the Hawthorne effect would have had to have a greater effect on the intervention arm than the control arm. This is possible; clinicians in the intervention arm may have changed their prescribing to a greater degree because of a belief, either conscious or subconscious, that because they have received the intervention, they should change in order to please or appear favourable to the investigators. However, this is less likely. Furthermore, although clinicians were provided with information about the aims of the study, reducing antibiotic prescribing was not identified as the main aim of the study (antibiotic prescribing was listed fourth in a long list of outcome measures). Therefore, it is unlikely that a desire to meet the study objectives was a major cause of the observed change in behaviour. One way of attempting to measure the impact of the Hawthorne effect is to see whether practices near Cardiff, that generally are aware that the local Department of Primary Care and Public Health in Cardiff has an interest in modifying antibiotic prescribing, had a greater intervention effect than more distant practices. No such difference in effect size was found, supporting the conclusion that this was a genuine effect and not simply a result of being observed.

#### **7.2.3.4 Blinding**

Blinding is the process of obscuring allocation from people who are in a position to influence the results in some way. This can include patients, parents, clinicians, observers, and analysers. In this trial the intervention involved participation by both clinicians and parents (and children in some instances), and therefore it was not possible to blind either of these groups. Clinicians took part in training, and a change in their behaviour was both expected and desired, and the participants (parents) were provided with education through receipt (and discussion) of the booklet. Nevertheless, as discussed in the section above on the Hawthorne effect, their behaviour may have been influenced by knowledge about which arm of the trial they were allocated to. One way of achieving clinician blinding might have been to use an alternative training and booklet combination as a comparator, and attempt to completely blind the clinicians to the study aims. However, such an approach is likely to have influenced the clinicians in the control arm in some way, and the aim of this study was to see whether use of the intervention could result in changes compared with usual care, not with some other comparator.

Similarly, parents were not blinded to study arm, but this is unlikely to have influenced the study results. Lack of blinding may have influenced self-reported outcomes like satisfaction and enablement, and may even have influenced patient (parent) directed behaviours such as consulting, but is unlikely to have had an influence on a hard outcome like reported antibiotic use.

Finally, and importantly, the interviewers conducting the two-week follow-up telephone interviews were blinded at the start of the interviews. It was not possible to ensure that blinding would be maintained throughout the interview, as parents may mention receipt of a booklet, but this was measured by asking interviewers to record each time they became unblinded. Blinding of interviewers was maintained for 93% of interviews, and therefore is unlikely to have resulted in significant bias.

#### **7.2.3.5 Ascertainment bias**

Most outcomes were measured via a telephone-administered questionnaire administered by two interviewers. The interviewers remained blinded to study arm in 93% of the interviews. One interviewer (NF) administered the majority (85%) of the

interviews. However, there was no association between interviewer, or blinding status, and the main results, and therefore no evidence of interviewer bias.

Another potential source of error is the instruments used to measure the subjective parent-reported outcomes. Enablement was measured using a modification of the Patient Enablement Instrument.(243) This instrument has been subject to validation assessments, however it had to be adapted from its original target use (self complete by adults) for use with a parent consulting with an unwell child, and this adapted version was not subjected to any form of validation. Furthermore, it was developed for use immediately after a consultation, not two weeks later, although it has been used a number of weeks after the consultation in other studies.(244, 245) These changes to its intended use may have had an impact on the validity of the observed enablement scores. This may explain why there was a lack of difference in enablement scores between the two groups when the qualitative data from the process evaluation revealed that the booklet increased self reported parental knowledge about RTIs and confidence in managing these illnesses (which are both components of enablement).

Similarly, satisfaction, reassurance, and usefulness of information were all measured using single item scales, none of which had been subjected to any form of validation. It is possible that these simple scales were not accurately measuring the intended constructs, or were not able to accurately discriminate between small differences in levels of these constructs, leading to a type II error.

#### **7.2.3.6 Intervention fidelity**

Evidence from the process evaluation suggested that the intervention was sometimes not delivered as intended by the researcher. Evidence from quantitative process measures (such as time on the web-based training), and interviews with both clinicians and parents suggest that there were problems at every stage of the intervention delivery. Some clinicians did not complete the intervention training, or spent very little time on the training, the booklet (according to parental report in the qualitative interviews) appears to have been used interactively in the consultation only about half the time, and occasionally was not provided to the parent at all, and parents

were not often able to recall the use of the communication skills that the clinicians were asked to use in these consultations.

However, intervention fidelity cannot be measured with any degree of certainty, and measurement error is likely to have influenced the ascertainment of the degree of intervention fidelity. Nevertheless, two issues are raised by this possible failure to consistently use the intervention as intended. The first is how it impacts on the internal validity of the results. If an intervention is not actually received by participants *as intended*, it is impossible to measure what the effect of receiving it *as intended* would be. In this study, the effect of poor intervention fidelity would be to dilute any treatment effect. Therefore, poor intervention fidelity may have led to a type II error but is unlikely to have led to a type I error (finding a positive effect of the intervention when, in reality, there was none).

The second issue is why the intervention was not delivered as intended, possibly by as many as half the intervention clinicians? Some insights are to be found in the qualitative process evaluation. Parents almost uniformly valued having the booklet discussed with them in the consultation, and most clinicians who used it in this way thought that it was valuable. Barriers to using the booklet interactively were time constraints within the consultation (especially in the context of a trial where registering the patient into the study was time consuming), the challenge of fluidly incorporating use of the booklet into routine consultations, and possibly a perception amongst some clinicians that the message(s) in the booklet (particularly around antibiotic prescribing) were not in accordance with their proposed treatment plan, or their beliefs about what is best for this particular patient. Time constraints are much less likely to be a concern outside of a trial setting, particularly once familiarity with using the booklet has been established. A number of clinicians talked about there being a learning curve for using the booklet in consultations, and that after using it a few times it became much easier to incorporate into the consultation. Effecting change in clinician behaviour is not a simple matter, and it may have been that a number of busy clinicians gave up on using the booklet interactively before they had the opportunity to become fluent in its use in this way. Face-to-face training that incorporated the use of role-play may have led to greater use of the booklet in the consultation. In addition, logistical factors, such as storage and easy access, may have

played a role. The availability of the booklet in an electronic format that can be printed off on demand within consultations may have resulted in greater use for some clinicians. Finally, one clinician in the process evaluation talked about a sense of unease when he was thinking about prescribing antibiotics as his perception was that the message in the booklet was that antibiotics are not helpful. However, this clinician indicated that despite this sense of unease, he still felt the booklet was useful, and used the booklet, in consultations where he had made a decision to prescribe an antibiotic. Therefore, this may not actually be a barrier to use of the intervention, and may actually have been one of the factors that led to its effectiveness in reducing prescribing.

### ***7.3 Interpretation of findings and comparison with other published work***

The findings from the two qualitative components of the study (focus group development work and process evaluation) are in keeping with published evidence suggesting that parents find caring for a child with an RTI challenging and worrying.(7-9) Parents report frustration and confusion as a result of a lack of information, poor communication in consultations,(19) and perceived inconsistencies and ‘mystique’ in the management of these illnesses by clinicians.(19) These findings help reinforce the need for an intervention to try and improve the management of RTIs in children, and provide reassurance that the parents that participated in the focus groups and interviews were representative of parents in the UK.

#### **7.3.1 Intervention development**

The development of the study booklet, and training in its use, involved an iterative, evolving process. Early plans for the booklet development gradually generated into an eight-stage process, including consultation with parents and general practitioners through focus groups. This proved to be a valuable process, with important changes to the size, content, and layout resulting from focus groups with both sets of stakeholders, changes to enhance the safety of its messages resulting from the ‘safety review’, and changes to enhance its readability resulting from review by a ‘basic skills professional’. As recommended by others,(234) consulting with intended users (including clinicians who will be providing the booklet), and having the booklet reviewed by other relevant experts (including an expert in improving the readability

of documents), are essential steps in the development of written materials. The findings from this phase of the research were used to write a scientific paper describing the development process and outlining a framework for good practice in the development of material designed for interactive use within consultations (appendix 6).

Development of the online training in use of the intervention was informed by the study aims, the booklet content, the focus group results, behaviour change theories, evidence on communication strategies, and consultation models. The use of online training was moderately well received. In the intervention practices, 68% clinicians registered to take part in the study accessed the training, and they accessed it for a median of 43 minutes each. Most clinicians participating in the process evaluation were happy with the training being online and would not have wanted it to be face-to-face, and about half were enthusiastic about the training.

### **7.3.2 Reconsulting**

The crude reconsultation rates (12.9% in the intervention arm and 16.2% in the control arm) suggest that use of the intervention may have an effect on reconsulting. However, the difference was not statistically significant (either before or after adjusting for clustering). This could be because use of the intervention does not effect reconsulting, or that its effect size is smaller than we anticipated, and the study was not powered to detect it (type II error). The difference in reconsulting found in this study (3.3%) is considerably less than the 10% reduction that was considered to be clinically meaningful when used in the sample size calculation. However, given the frequency of consulting for these conditions, a reduction in reconsulting of even such a small magnitude, if it were shown to be a real difference, may be considered significant to policy makers.

One possible reason why the difference in reconsulting was small and not statistically significant is that the underlying level of reconsulting was less than expected. Previous studies have found that around 20% of children reconsult for the same illness,(15, 16) and this was the figure used for the sample size calculation. However, only 16.2% of children in the control arm reconsulted over the first two weeks. Demonstrating a similar relative reduction from a lower baseline level would require

a larger sample size, and therefore the study would have been underpowered to detect the same relative effect. Furthermore, a degree of reconsulting will always be necessary, even desirable. Some children will deteriorate, or fail to show signs of recovery, and need re-assessment. If the level of reconsulting has declined over time, it may be that it is now closer to a minimal safe level, and therefore more difficult to safely reduce further.

Another possible explanation for such a small difference is that clinicians in the intervention arm felt compelled to ask parents to reconsult more frequently because they were prescribing antibiotics less frequently. There is some evidence to support this possibility from the process evaluation. One clinician described feeling the need to ask patients to reconsult after a few days just to reassure himself, and a couple of parents reported reconsulting only because they had been told to, not because they had particular concerns. If widespread, this practice could have diluted any beneficial effect of reducing reconsulting behaviour. Indeed, given that not receiving antibiotics may increase the likelihood that a parent will seek a reconsultation, not prescribing may increase the likelihood of a clinician organising a reconsultation, and the size of the reduction in antibiotic prescribing found in this study, the finding that there was no *increase* in reconsulting in the intervention group is an important finding in itself.

### **7.3.2.1 Comparison with other published work**

Previous studies examining the effect of providing leaflets or booklets on reconsultations for RTIs have had mixed results. MacFarlane et al. found that providing adults consulting in primary care with LRTI with a simple leaflet, resulted in a 6.5% absolute reduction in the proportion reconsulting within four weeks.(98) However, Little et al. found that use of an information leaflet was associated with a statistically significant increase in reconsulting over the first month.(181) The reasons for this difference in findings are not entirely clear. In the study by Little et al. clinicians were asked to provide verbal information to all patients (from a standardised prompt sheet), whereas in the study by MacFarlane patients in the control group only received usual care. This may have diluted any beneficial effect from use of the leaflet in the study by Little. Furthermore, given that the patients in both of these studies had LRTI, and were therefore arguably, as a population, more unwell than the patients in the study in this thesis, it may be that reconsulting was



appropriate for a greater proportion of these patients. However, the reconsultation rate in the group that did not receive a leaflet in the study by Little et al. was only 11%, less than the 21% seen in the study by MacFarlane et al., and the 16.2% in the trial in this thesis. Furthermore, in the study by Little et al. the use of three prescribing strategies was also being evaluated, and the overall antibiotic prescribing rate (56%) was lower than in the study by MacFarlane (72%). As such, reconsulting may have been more appropriate for the patients in the MacFarlane study. Nevertheless, the possibility that use of a leaflet increased unnecessary reconsulting in the Little study, can not be excluded. If the booklet had a similar effect for some parents in our study, this would have diluted any positive effect, and may have led to the effect size being small (and not statistically significant).

### **7.3.3 Antibiotic prescribing**

The most important positive finding from the trial was the statistically significant and clinically meaningful reduction in antibiotic prescribing in the intervention arm compared with usual care. Reducing antibiotic prescribing for these infections, which are largely self-limiting and do not meaningfully benefit from antibiotic treatment in most cases, has important implications for individual patients and public health. The main reduction in prescribing was at the index consultation. However, there was also a reduction in prescribing over the initial two-week period, and importantly, a reduction in parent-reported antibiotic consumption. The process evaluation results suggest that the reduction in prescribing was mediated through changes in the beliefs, knowledge, and skills of prescribers. The process of completing the study training, reading through the study booklet, and / or using the booklet in consultations, resulted in increases in clinicians' beliefs about the importance of changing their prescribing behaviour (outcome expectations). In addition, the booklet was used as a prompt to increase awareness of clinical knowledge (benefits and harms of antibiotic treatment, normal duration of illness), to facilitate the use of skills (information-sharing, risk communication), and as a resource that reinforced or supported the message of a non-prescribing approach in consultations where the clinician believed there was an expectation for antibiotics. These uses of the booklet help to increase clinicians' confidence in their ability to change (self-efficacy). It is not entirely clear which of these changes, alone or in combination, had the main impact on prescribing, nor is it clear how important the training was in this process. Data from the process evaluation

suggest that clinicians may not have elicited parental concerns and expectations as frequently as expected, and therefore it is not clear what role these strategies might have played in achieving the observed results.

### **7.3.3.1 Comparison with other published work**

No other study has evaluated the use of an interactive booklet on RTIs in children designed for use in the consultation, or leaflets or booklets that provide parents with information about the likely illness duration, how they can help their child, the signs and symptoms that should prompt further consultation, and evidence based information about antibiotics.

The study results are consistent with the study by MacFarlane and colleagues in adults with LRTI who were judged not to need immediate antibiotics.(180) They found that provision of a simple leaflet, providing reassurance, advice about the normal duration of symptoms, advice about managing symptoms, and advice about when to consider using the antibiotics, resulted in nearly a 25% reduction in use of antibiotics. A more recent study, again in adults with LRTI, did not find a reduction in antibiotic use as a result of providing a leaflet.(181) However, this was a factorial design, evaluating the use of three prescribing strategies (immediate antibiotics, delayed antibiotics, and no antibiotics) as well as provision of the leaflet, and the main outcome measures were symptom duration and severity. The study power calculation was not based on detecting differences in prescribing, and given that it is only those in the delayed prescribing category who are likely to be influenced by a leaflet, it was almost certainly underpowered for this outcome. Furthermore, the leaflet in this study was brief, and was provided in addition to verbal information about the likely illness duration.

A number of other studies have evaluated the use of leaflets designed with the aim of reducing antibiotic prescribing in patients with RTIs. However, most of these have evaluated multi-faceted interventions, of which the leaflet was only one component.(162-170, 172-179) Some of these studies have demonstrated a reduction in prescribing, however it is not possible to distinguish the effect of using the leaflet from the other intervention components.

Two studies in paediatric offices in the United States, that evaluated the passive provision of a leaflet on use of antibiotics along with a brief videotape on judicious antibiotic use, found improvements in parental awareness, but no reductions in antibiotic prescribing.(141, 142, 144) This may reflect the need to provide parents with positive, helpful messages rather than negative messages about the overuse of antibiotics.

#### **7.3.4 Consulting behaviour over one year**

No differences in one-year consultation rates were found, either in just consultations for RTIs or in all consultations. The reasons for this lack of effect are not clear. Parents reported that they found the information in the booklet valuable, and at two weeks parents in the intervention arm were statistically significantly less likely to report that they would consult in the future if their child had a similar illness. Consultation rates in this cohort were higher than in observational data of consultation rates in the general population,(12) which is unsurprising given that this is a population who have recently consulted for an RTI. Possible explanations for the lack of observed effect include: a genuine lack of effect (which may be related to poor implementation or delivery of the intervention, or problems with the underlying assumptions that its construction were based upon), chance, an effect that was too small to detect in this study, errors in the measurement of consultations, or a reduction in consulting in the control arm, as a result of participation in the trial, which was off a similar magnitude to the reduction in consultations in the intervention arm.

Chance is unlikely to have resulted in a type II error, unless the effect was very small, because the point estimates for the one-year consultation outcome odds ratios were all close to one, with confidence intervals that ranged from around 0.7 to 1.25.

Measurement error is also unlikely to have resulted in a type II error in this instance. It is possible that clinicians in the control arm modified their behaviour as a result of participating in the trial, and that this had an impact on consulting. However, given that the decision to consult is largely made by parents, it is unlikely that this would have had much of an effect. Therefore, the most likely conclusion is that the pragmatic use of the intervention, as used in the trial, does not result in the desired changes in consulting behaviour. Whether this is related to the way in which the intervention was used, or other factors, remains to be uncovered.

### **7.3.4.1 Comparison with other published work**

Four studies have examined the effect of educational interventions for parents along with leaflet provision, on consulting behaviour, and a further six studies have examined the effect on consulting of sending booklets on minor illnesses to families through the post.

Of the three studies of educational interventions, two of them found a reduction in consultation rates in the intervention group, and one did not. However, one of the studies that showed an effect had significant methodological problems; allocation was non-random and not concealed, and participants were excluded post allocation; and therefore its findings are not reliable.(85) The other study found an effect from a nurse-run educational session about acute otitis media, backed up by written materials, on consulting.(83) Participating parents attended the session at the time of their child's fifteen-month well child visit, and the sessions focused on measures to try and control ear pain (including the use of prescribed analgesic ear drops), recognising signs of more serious illness, and decreasing the sense of medical urgency for uncomplicated ear pain. Quite dramatic reductions in consulting for ear pain in the emergency department (80% reduction), urgent care clinics (40% reduction), and in primary care (28% reduction) were found. Only the reduction in emergency department visits remained statistically significant after controlling for baseline characteristics and comparing intervention sites with control sites, however the 36% reduction in total consultations for ear pain was statistically significantly different from the control site, even after correcting for baseline characteristics.

It is not easy to draw comparisons between the study described above (by McWilliams et al.) and the study in this thesis. The McWilliams study was only focused on acute otitis media / ear pain. Large reductions in consulting are more feasible for acute otitis media, where the baseline consultation rate is higher than for many other RTIs (only about a quarter of children in our study had ear pain). In addition, consultation rates for AOM are much higher in North America(83) than in Europe,(42) allowing more room for a reduction.

The third study involved exposure to a video and leaflet on antibiotic use or injury prevention, and has already been described in sections 1.4.2.3.2 and 7.3.3.1.(142) The intervention in that study was aimed at promoting rational antibiotic use, but did not provide parents with guidance on normal duration of illness, treating symptoms, or when to reconsult, and therefore it is not surprising that it had no effect on consulting behaviour.

None of the studies evaluating posting booklets had a clinically important effect on consulting (although some found minor reductions in sub-groups), suggesting that the passive distribution of written materials, outside the context of the consultation or another form of educational encounter, is unlikely to have much of an impact. The findings of the process evaluation, in which most parents indicated that they found having the booklet discussed with them in the consultation helpful, add weight to this conclusion.

### **7.3.5 Other outcomes**

#### **7.3.5.1 Satisfaction**

An additional important finding was that parental satisfaction was high in the intervention group. Reported satisfaction was high in both trial arms, a finding that is at odds with the qualitative findings from my development work and from other published qualitative studies,(19) but not dissimilar to reported satisfaction about primary care consultations for RTIs in other trials.(170, 181) This high level of reported satisfaction (over 90% satisfied) may be a true indication of a high degree of satisfaction (with the qualitative findings representing a biased finding), or may have resulted from patients not wanting to be disloyal to their primary care clinician, fear that poor ratings might get back to their clinician, a change in the behaviour of clinicians as a result of being observed (the Hawthorne effect), or poor discrimination of the instrument used to measure satisfaction. One of the concerns that clinicians cite when discussing reducing prescribing, is that it will have an impact on patient (parent) satisfaction. Therefore, the finding that there was no difference in parent reported satisfaction (which was high), despite important reductions in prescribing in the intervention arm, is an important and reassuring finding.

### **7.3.5.2 Enablement, reassurance, and value of information**

The failure of this study to demonstrate quantitative increases in parental empowerment, reassurance, or value of information received, are surprising findings that are not in keeping with the results of the qualitative process evaluation. In the process evaluation, parents talked about feeling more confident and less anxious. They described having a greater knowledge about symptoms that should prompt reconsultation and a greater confidence in RTIs resolving without the need for antibiotics. A few parents described the information in the booklet as, 'pretty obvious' or said that they, 'knew most of the stuff in it', and one described the consultation she had as being mostly taken up with, 'doing this survey for you guys'. However, these were in the minority, with most parents describing the booklet as 'useful' or 'helpful'. Data from the process evaluation did not provide any clues as to why enablement, reassurance, and value of information were not statistically significantly higher in the intervention arm. Clinicians in the control arm might have changed their behaviour toward providing more information or reassurance than usual, as a result of participating in the study. This would have attenuated any effect that might have resulted from use of the intervention by clinicians in the intervention arm. In addition, as discussed in section 7.2.3.5, the instruments used to measure enablement, reassurance, and value of information received, may not have been accurately measuring the intended constructs. Finally, as discussed in the section above about parent satisfaction, parents may have given high ratings because they did not want to be disloyal to their primary care clinician.

### **7.3.5.3 Consultation length**

The length of the index consultation (the consultation in which the booklet was used in intervention practices) was an average of 2.8 minutes longer in the intervention arm compared with the control arm. Clinicians participating in the focus groups in the development stage raised concern that use of the intervention might significantly lengthen consultations. A number of clinicians who participated in the process evaluation also talked about consultations being lengthened, although most felt that it was the process of registering the patient into the study had a greater impact on consultation length than use of the intervention, and some indicated that they considered the increased consultation length to be a good investment in time. Furthermore, many clinicians talked about their being a learning curve to using the

booklet fluidly, and it is likely that after a familiarisation period, use of the booklet would have less of lengthening effect on consultations. It is not yet clear whether most clinicians will consider a lengthened consultation a reasonable trade-off for reduced antibiotic prescribing. High antibiotic prescribing rates in primary care are associated with a low level of satisfaction with the time spent by the GP listening.(246) However, a study from the United States has shown that reduced antibiotic prescribing does not have to come at the cost of increased consultation length.(247) Although the average consultation length in this study was approximately 13 and a half minutes which is more than the average consultation length in the UK.(248)

#### **7.3.5.4 Adverse events**

Although the trial described here was not intended (and therefore not powered) to detect differences in adverse events, the limited number of hospitalisations and the lack of apparent serious adverse events that could have been attributed to use of the intervention are reassuring. One clinician reported an ‘adverse event’ which constituted a consultation which he felt had not gone well as a result of using the booklet. This clinician was uncertain whether the event was a result of using the booklet, was related to a culturally related belief held by the parent, or some other factor. However, he felt that a change in his consulting style that came about through use of the booklet might have played a role. Further analysis and reflection upon this case suggest that, if the clinician’s consultation style had impacted on the perceived dissatisfaction, it is likely that this is a training issue that would be resolved once familiarity with using the booklet had been established.

In contrast to causing adverse event, data from the process evaluation suggest that use of the booklet may have helped contribute to preventing, or lessening the impact of, an adverse event. One parent described using information in the booklet to help her decide that she needed to reconsult with her child, who was subsequently admitted to hospital with serious sounding symptoms.

#### **7.3.6 Economic evaluation**

The economic evaluation demonstrated that the cost of delivering the intervention was small, and would be even smaller if widely implemented. In addition, the overall one-

year costs, from a societal perspective were not statistically significantly different from usual care. This is not surprising given the low cost of the intervention and lack of difference in health service utilisation and parental time off work. Given the apparent effectiveness of this intervention, such a low cost makes this intervention appear attractive. It is hard to imagine an intervention with similar effects being cheaper. However, a one-off web-based training programme would have no ongoing costs, and therefore if effective, would be very competitive from an economic perspective.

## **7.4 Implications and further research**

This section will discuss the implications of these findings for policy and practice, and the implications for future research.

### **7.4.1 Implications for policy and practice**

This work has demonstrated that providing clinicians with an interactive booklet on RTIs in children, and training in its use, can safely reduce antibiotic prescribing while maintaining parental satisfaction. Given the concerns about widespread antibiotic use in primary care (particularly in children), and its relationship with increasing antibiotic resistance, this is an important finding. Furthermore, this approach appears to be safe (although firm conclusions about safety would require a much larger study), can be delivered at a low cost, and does not result in an increase in reconsulting. The latter is important not only because reconsulting for RTIs is often unnecessary, and involves the use of precious healthcare resources, it is also a marker for concerns that remain unresolved after the first consultation.(249)

Questions remain about the effectiveness of such an approach when made available to all relevant primary care clinicians (i.e. to all general practices within a region) and outside of trial conditions, about the sustainability of the effect on antibiotic prescribing, and about how best to deliver it. The latter includes questions about the importance of providing training for clinicians, the most (cost) effective way of delivering the training, if it is important, and the most (cost) effective way of delivering the booklet to parents. These questions will be explored further in the next section (Implications for further research). However, despite these ongoing questions,



the adoption of this intervention into routine clinical practice should be considered at this point.

The magnitude of the reductions in antibiotic prescribing and consumption suggest that use of this intervention could have important implications for patients, and potentially, if beneficial changes in antimicrobial resistance result from reductions in antibiotic prescribing, for public health. The potential risks of implementing use of this resource now are that it would result in a waste of resources if it were ultimately not effective when rolled out, and that it could result in potential adverse effects. However, the cost of using this intervention appears to be negligible (potentially resulting in a cost saving), and there is no evidence that it results in harm. Indeed, one of the aims of the intervention was to help parents recognise signs of serious illness, and there is anecdotal evidence from the process evaluation that this occurred. Furthermore, there are other potential benefits, in terms of greater parental empowerment, satisfaction, and confidence that were not detected through quantitative measurements employed in this trial, but were hinted at in the qualitative evaluation. Weighing these factors in the balance, the immediate use of this intervention, while further evaluation is ongoing, should at least be considered by clinicians and policy makers.

#### **7.4.2 Implications for further research**

Questions relating to the implementation of this intervention, as well as the potential for new developments that emerge from ideas generated in this project, could be explored in further research. The main outstanding questions with regard to the implementation of the intervention are:

- What are the relative importance of the various components of the intervention in achieving its effect, and what is the best way of implementing / delivering it?
- How effective is this intervention when delivered to a population of practices, over time, and outside of trial conditions?

These questions and other potential developments from this study are described below.

### **7.4.2.1 Intervention components**

The process evaluation helped to uncover the relative importance of the various components of the intervention. For example, evidence that few clinicians seemed to ask specifically about concerns and expectations suggests that these elements were unlikely to have been responsible for the observed effect. However, the relative importance of using the booklet within the consultation, and providing training to facilitate its use, are still not clear. This is important because the need for training and the additional time involved in using it within the consultation (average of just under 3 minutes), are potential barriers to its use. Most parents and most clinicians thought that using it as an interactive tool within the consultation was a good idea. However, a further trial would be needed in order to assess the relative importance of these components.

### **7.4.2.2 Effectiveness in a role-out situation**

The trial in this study has provided good evidence that use of the intervention resulted in a reduction in prescribing at the index consultation and in the subsequent two weeks. However, the effects of its use outside of a trial are not known. Long-term prescribing rates were not measured, and therefore it is not clear whether the reduction in antibiotic prescribing will be sustained over time. Use of the intervention may be different outside of the context of participation in a trial. More (or less) clinicians may be willing to use the intervention with more (or less) families. Over time clinicians may find the booklet increasingly useful as they develop expertise in using it, or they may find that they use it less over time.

Participating practices were only asked to recruit ten children each, and given that most practices had more than one participating clinician, most clinicians recruited less than ten children. As such, the time period during which clinicians were participating in the study was often short, and for those in the intervention arm, the patients they recruited were mostly recruited shortly after completing the online training. It is possible that the behaviour of these clinicians was influenced by their awareness that they were participating in a trial and / or the influence of the recent training. There is some evidence from the process evaluation that the training may have influenced the attitudes, knowledge, and behaviour of clinicians, but it is not clear how durable these

changes are likely to be. It may be that clinicians would benefit from a periodic ‘top-up’ in the training. This would need to be examined in further studies.

In addition, the practicalities of using the study booklet may have become more difficult or easier over time. Maintaining a supply of booklets and keeping them in a convenient location so that they are remembered and available when needed may present problems during the implementation of this intervention. Furthermore, if changes in parental pressure to prescribe contributed to the intervention effect, it is not clear how this would be maintained over time. Increasing familiarity with use of the intervention may improve its effectiveness over time.

Further studies are needed in order to address these questions. In order to explore how the intervention is used over the long term an implementation study could be conducted, in which a small number of practices are provided with the training and a supply of booklets over an extended time period. Such a study would need to include quantitative measures, such as training uptake and number of booklets used, as well as a qualitative evaluation that would include interviews with clinicians to explore the perceived benefits and barriers to such an approach. In order to assess the effectiveness of the intervention over the long term, an ecological study could be conducted. This would involve supplying the intervention to a number of practices or all practices within one (or more) region(s), and comparing antibiotic prescribing rates before and after introduction of the intervention, and with control practices or region(s) that do not use the intervention. Prescribing databases in Wales (PACT and PARC) provide an excellent source for such measurements and benefit from measuring dispensed antibiotics as opposed to prescribed antibiotics, and therefore would avoid the problem of including delayed prescriptions that are not collected.

#### **7.4.2.3 Other potential developments**

The work in this thesis could lead to the development and evaluation of a number of related interventions. These include, a similar booklet on RTIs in adults, a web-based tool to help parents manage RTIs in children, a comprehensive approach to helping parents manage minor illnesses that includes educational sessions with a health visitor or nurse, a booklet provided shortly after birth, an educational website, training for

clinicians, an interactive booklet for use in consultations, posters and other 'themed' educational materials all conveying the same messages.

## **7.5 Conclusions**

This thesis has presented work demonstrating that use of a booklet on RTIs in children within primary care consultations can reduce antibiotic prescribing. No effect on reconsulting for the same illness episode or longer term consulting behaviour was found. A small effect on consulting behaviour is possible, but may not be practically meaningful. Qualitative data suggest that the intervention was valued and perceived as useful by parents and clinicians. However, no differences in satisfaction, reassurance, or enablement were found as a result of using the interactive booklet. This may have been due to problems with the instruments used to measure these constructs. The economic evaluation found a minimal difference in overall cost that was not statistically significant. This difference was even smaller when use of the intervention was considered in the context of long-term use. Questions remain about the effectiveness of this intervention in a role-out situation. However, given the importance of the effect seen, no evidence of any harmful effects, high levels of satisfaction amongst parents who received the intervention, and its low cost, use of this intervention should be considered in primary care now.

## 8 Bibliography

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## 9 Appendices

Appendix 1	Search strategy
Appendix 2	Early draft of leaflet
Appendix 3	Parent focus topic group guide
Appendix 4	GP focus group topic guide
Appendix 5	Final booklet
Appendix 6	Publication describing the intervention development
Appendix 7	Publication describing the study protocol
Appendix 8	Case Report Form
Appendix 9	Telephone questionnaire
Appendix 10	Postal questionnaire
Appendix 11	One-year data collection form
Appendix 12	Report of a significant event
Appendix 13	Paper describing main trial results
Appendix 14	Process parent interview guide
Appendix 15	Process parent thematic framework
Appendix 16	Process clinician interview guide
Appendix 17	Process clinician thematic framework

## **Appendix 1 – Search Strategies**

### ***Main search***

1. booklet:.mp.
2. leaflet:.mp.
3. pamphlet:.mp.
4. brochure:.mp.
5. exp Respiratory Tract Infections/
6. respiratory tract infection:.mp.
7. "common cold:".mp.
8. pharyngitis.mp.
9. "sore throat:".mp.
10. otitis media.mp.
11. ear infection:.mp.
12. cough:.mp.
13. bronchitis:.mp.
14. sinusitis.mp.
15. child:.mp.
16. infant:.mp.
17. adolescen:.mp.
18. toddler:.mp.
19. or/1-4
20. or/5-14
21. or/15-18
35. and/19-21

### ***Secondary search***

1. booklet:.mp.
2. leaflet:.mp.
3. pamphlet:.mp.
4. brochure:.mp.
5. inform:.mp.
6. educat:.mp.
7. patient:.mp.
8. 5 or 6
9. 7 and 8
10. exp Respiratory Tract Infections/
11. respiratory tract infection:.mp.
12. "common cold:".mp.
13. pharyngitis.mp.
14. "sore throat:".mp.
15. otitis media.mp.
16. ear infection:.mp.
17. cough:.mp.
18. bronchitis:.mp.
19. sinusitis.mp.
20. primary care.mp.
21. primary health care.mp.
22. family practice:.mp.
23. GP practice:.mp.
24. general pract:.mp.
25. Physicians, Family/
26. family physician:.mp.
27. or/1-4,9
28. or/10-19
29. or/20-26
30. and/27-30

## **Appendix 2 – Early draft of booklet**

### What is a respiratory tract infection?

A respiratory tract infection is an infection of the nose, throat, ears, sinuses, airways or lungs. These infections are common in adults and are very common in children. They include colds, most coughs, throat infections, and 'chest infections'.

### What is this leaflet for?

This leaflet is meant to help you look after your child and decide whether you need to get further help. Having an ill child can be very worrying and it is important that you know what is to be expected and what is a cause for concern. It is impossible for a leaflet to cover every situation though, and **if you are concerned about your child then you should seek help**. This may mean calling NHS Direct or speaking to your GP or practice nurse. Before you call though, have a look at the information here to see if it helps you.

### What can help?

There are many things that can be done to help a child ill with a respiratory infection.

- Pain – sore throat, earache, headache – is best treated with Paracetamol\* (Calpol) or Ibuprofen\* (Nurofen)  
\*See below for information on correct dosages.
- High temperature (fever) can also be treated with Paracetamol\* or Ibuprofen. Also, if your child has a high temperature, it is best to take off outer clothing to try and cool them.
- Give plenty of fluids to drink. Children can often become dehydrated, especially if they have a fever. It does not matter a lot what they drink, as long as it is not too concentrated.
- Lots of rest.
- Coughing is one of the bodies natural defence mechanisms and can not be stopped completely. Some people find things that soothe the throat, like cough mixtures, help a little.
- Congestion in the nose and sinuses can be helped by breathing steamy air. **But be very careful to avoid scalding (never hold a child near a kettle!)**

Medication	Dose
Paracetamol	3 mo. – 1 yr: 60 – 120 mg 1 – 5 yrs: 120 – 250 mg 6 – 12 yrs: 250 – 500 mg Every 4 – 6 hours. Max of 4 doses in 24 hrs.
Ibuprofen	1 – 2 yrs: 50 mg 3 – 7 yrs: 100 mg 8 – 12 yrs: 200 mg Three to four times daily

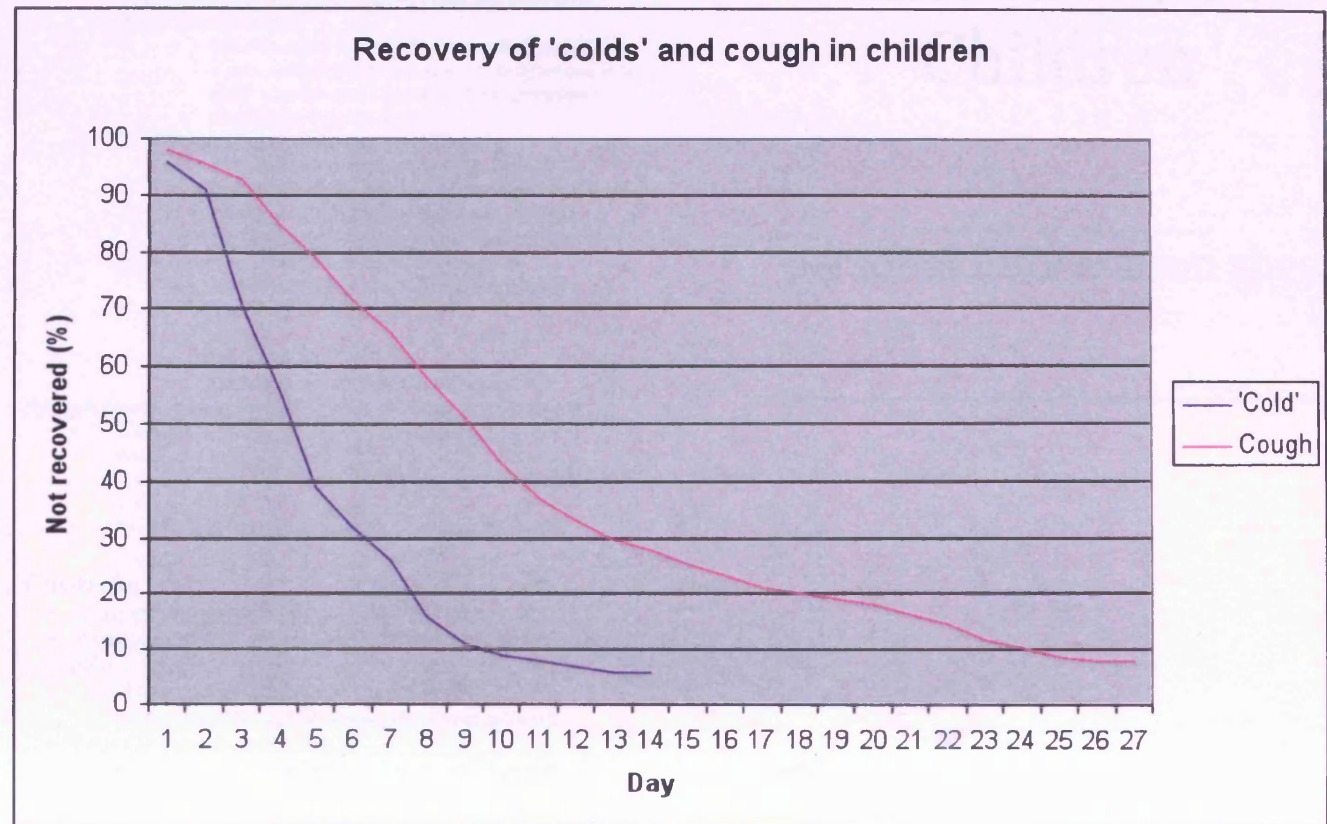
### If antibiotics might help a little, why not take them?

There are several reasons why it is not a good idea to take antibiotics unless they are really needed.

- Most antibiotics have side effects. They commonly cause diarrhoea, rashes and stomach upset, and can cause more serious side effects.
- Antibiotics kill our *natural* bacteria that help to protect us. This can result in infections such as thrush.
- Antibiotics can also cause allergic reactions. These are often just annoying rashes, but can, in some cases cause death.
- Some children develop a rash from a viral respiratory infection and have taken an antibiotic. In these cases it can be difficult to work out if the rash was from the antibiotic or the infection. The child may be labelled as being allergic to an antibiotic when in fact they are not. This may lead to them not being prescribed the best antibiotic when they really need it.
- Antibiotic use leads to the development of bacteria that are resistant to antibiotics. It has been shown that when someone has recently had antibiotics they are more likely to have resistant bacteria found within their nose. Some bacteria have become resistant to virtually all antibiotics. Many fear that if antibiotic resistance continues to increase in the way it has, we will start to see more and more infections that can no longer be treated.

### How long is this likely to last?

The length of time these infections last can vary from a day or two to a number of weeks. They normally last longer than most people expect, and an infection that is lasting longer than expected does not mean that something is going wrong or that it would benefit from treatment with antibiotics. The graph to the right will give you a further idea of how long you can expect your / your child's illness to go on for.





### Will antibiotics help?

Antibiotics help very little in most common respiratory infections. This is partly because most of these infections are caused by viruses, and antibiotics have no effect on viruses, and partly because our own immune systems are very good at fighting most bacterial infections. The table below shows the scientific evidence for the effects of antibiotics for some infections.

Infection	Antibiotic Effect
Common Cold	Antibiotics have no effect on time to get better or preventing complications.
Ear Infections	After 2 days (2-7 days) more than three-quarters of children will be better whether they take antibiotics or not. Of those that take antibiotics 14 out of 15 will have no benefit. One out of 15 will have their ear pain go quicker. Antibiotics have not been shown to prevent complications from ear infections.
Sore Throat (evidence from studies of adults and children)	Some people may be more likely to benefit from antibiotics than others [see section on when you should seek help]. Taken as a whole, more than three-quarters (85%) of people will feel better in 1 week whether or not they take antibiotics. Of those who take antibiotics 13 out of 14 will have no benefit, the other 1 will get better sooner.
Bronchitis (evidence from adults and children)	Antibiotics can shorten the duration of cough in some people. On average cough was shortened by one half of one day (out of one to two weeks).

### When should I seek further help?

It is important that you seek help if you are concerned that your child has a serious infection or complication. If you are worried it is best to seek advice, and you will find information about how to seek advice at the bottom of this page. The following should help to guide you as to what would be the most common reasons for you to need to seek medical attention.

#### Concerns about meningitis / serious illness

There are a number of symptoms that suggest a child is very unwell. This would include meningitis and other serious infections. The things to look for are:

- Drowsiness and irritability
  - children with a temperature are often more sleepy and irritable than usual, but will usually improve after treatment of the fever
  - complete loss of interest in toys and other things shown to a young child is concerning
  - confusion and difficulty waking a child are particularly concerning signs
- High temperature (39C or higher) that does not come down with treatment
  - This does not necessarily mean that a child has a serious infection, but is more concerning if the child also has cold hands or feet, persistent vomiting or above features
- Rapid breathing or difficulty breathing
  - Any child who is experiencing difficulty breathing needs emergency medical treatment
  - Rapid breathing often suggests a serious problem and requires medical assessment
- Symptoms specifically related to meningitis
  - A rash that does not fade with pressure
  - A stiff neck (difficulty putting his / her chin to chest)
  - Does not like the light
  - Unusually severe headache with fever

#### Symptoms that may benefit from further assessment

- A cough persisting more than 2 weeks (especially if worse at night and with family history of asthma)
- A fever without any sign of infection or lasting more than 3 days
- Weight loss that is not re-gained within one week

#### Contacts

- In an emergency dial 999
- If you would like advice, NHS Direct may be able to help.
  - They can be contacted on 0845 46 47
  - or on the internet at [www.nhsdirect.nhs.uk](http://www.nhsdirect.nhs.uk)
- Your GP can be contacted at \_\_\_\_\_
- If your GP has a different number to call for out of hours care they can write it here \_\_\_\_\_



# Respiratory Tract Infections in Children

## personal information sheet

## **Appendix 3 – Parent focus group topic guide**

- Complete Information Sheet and Consent Form
- Introduction
  - Thank group
  - Introduce self and assistant
  - Explain the purpose of the meeting and the structure
  - Explain use of microphone
  - Ground-rules
    - One person speaking at a time
    - If you have something to say and are having difficulty getting a word in then bring yourself to my attention by raising a hand or something similar

### **Questions**

1. Could you please start by telling us your name, how many children you have and how old they are, and something that they enjoy doing at the moment?
2. I am going to start by giving you a sheet of paper describing an ill child which I would like you to read.

Hand out scenario.

3. Can you tell me what you think her parents' main worries or concerns might be?
4. What sort of things do you think might lead her parents to take her to see a doctor?
5. Do you have any thoughts on when antibiotics could or should be used for children with these kinds of infections?
6. If your child were ill with a respiratory tract infection, is there anything that you would like to know, that would make you feel more confident in looking after your child?
7. I am now going to give you some sample leaflets on respiratory tract infections. They are meant to form the basis of a discussion between GPs and parents and be an source of information for parents to take home. Please take some time to have a look through them.

Hand out leaflets.

8. What are your first impressions?
9. Is there information that you would like to have that is not on them?
10. Is there information that you think is unnecessary and could be removed?
11. Considering the graph on the leaflet. I am now going to give you some other sample graphs. Please take a look at them and see if you have a preference for one over the others?

Hand out graphs

12. Do you think that a fridge magnet summarising the important points would be helpful, or is there anything else that would make the information more accessible or useful.
13. If you were going to be designing a leaflet for parents that GPs would use as a focus for discussing these infections, what would you do differently?

Thanks and closing.

## **Appendix 4 – GP focus group topic guide**

- Complete Information Sheet and Consent Form
- Introduction
  - Thank group
  - Introduce self and assistant
  - Explain the purpose of the meeting and the structure
  - Explain use of microphone
  - Ground-rules
    - One person speaking at a time
    - If you have something to say and are having difficulty getting a word in then bring yourself to my attention by raising a hand or something similar

### **Questions**

14. I am going to hand out a piece of paper describing a consultation in which a parent brings her child in with a respiratory tract infection. I would like you to think about consultations like this one and tell me what you see as the challenges to a consultation like this?

Hand out scenario.

15. What are the main challenges to a consultation like this from the GPs perspective?
16. What sort of things do you think parents find most challenging about having a child with a respiratory tract infection?
17. I am now going to give you a draft version of a leaflet that we are creating. The intention of this leaflet is that GPs will be able to use it in consultations with children with RTIs as a prompt to addressing the parents concerns. Please take a few minutes to read it through completely.

Hand out leaflet.

18. What are your first impressions of the leaflet?
19. Are there any parts of it that you disagree with or you think are irrelevant or not helpful?
20. Is there anything that you think should be included on a leaflet like this that we haven't included?

21. I am now going to give you some different graphical representations of the same information that is presented in the leaflet. Can you take a look at them and say which you think would be better?
22. What one thing would you change about the leaflet to make it more useful?
23. Do you see any barriers to the use of a leaflet like this in consultations?
24. Do you think you would use a leaflet like this if one were available to you? (If not, why?)
25. We are planning on using the finished leaflet in a clinical trial to see if its use will affect a number of outcomes like re-consultations and antibiotic use. In the trial we would be providing GPs with some training in use of the leaflet. This would include talking about the use of a patient centred approach. Do you think such training would be acceptable to GPs?
26. Is there anything that we have missed?

Thanks and closing.



**WHEN SHOULD I WORRY?**

- Your guide to Coughs, Colds, Earache & Sore Throats

Information For:-

## Who is this booklet for?

Having an ill child can be a very scary experience for parents. If you understand more about the illness it can help you to feel more in control. This booklet is for parents (and older children) and deals with common infections in children who are normally healthy. It is not meant for children who have ongoing health problems such as asthma, heart, or kidney problems. **You should not rely on the advice in this leaflet for children who are less than 6 months old.** Babies younger than this can respond differently to infections.

*"..She woke in the middle of the night with a fever, vomiting, and a terrible cough. It was really quite scary .."*

### What is it that you are most worried about?

If you are seeing your GP or nurse, it is important to tell them what it is you are most worried about.

### What are you expecting from the consultation?

When you consult with a doctor or nurse, it is a good idea to think about what you are expecting. If you have any ideas about what you would like done, you should tell the doctor or nurse. This will allow them to try and deal with the things that you are expecting.

#### Fever (Raised Body Temperature)

- Fever is a normal response that may even help to fight infections.
- Fever does not harm your child. Bringing temperature down does not seem to prevent fits (see next page).
- Children with a high temperature (40 C or more) are more likely to have a more serious infection (though most will not). Look at page 7 to see other signs of more serious infections.

#### What can you do about it?

To make your child more comfortable, you may want to try and lower their temperature by giving them Paracetamol and / or Ibuprofen (see also page 6). Take off outer clothing (do not wrap your child up if they have a fever). Sponging a child with water can sometimes make matters worse by upsetting a child or making them shiver (which can raise their temperature more). However, as long as it does not upset your child, bathing/sponging with luke warm water may help a little.



## Temperature Fits (Febrile Seizures)

- Young children can sometimes have a fit as a result of having a temperature. It can be very scary if your child has a seizure, but it is usually not serious. Treating fever with paracetamol or ibuprofen does not prevent fits.
- If your child has a fit – try to stay calm. Most of these fits will not cause your child any harm and will last less than 5 minutes.
- Unless your child has had previous febrile seizures and you are familiar with what to do, it is best to dial 999 immediately for an ambulance.
- It is a good idea to make sure a child who is having a fit is away from things they may hurt themselves on, and to roll them on their side (recovery position).

## Cough/Chesty Cough

- When young children catch a cold they often develop a 'noisy chest' or a 'chesty cough'. This can be worrying for parents who believe that a chesty cough is a sign of a 'chest infection'.
- Young children often get noisy chests. This is because they have smaller airways and thinner rib cages than adults.
- A child with a true chest infection will generally be more 'unwell'. See page 7 for signs of a more serious problem.

### How long will it last?

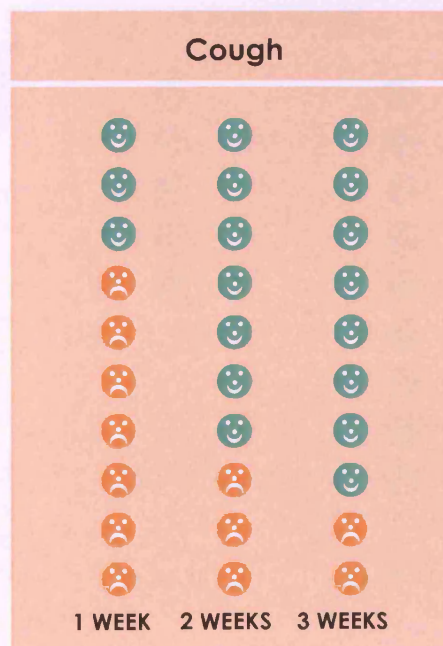
This chart shows you how long cough often lasts in children. The faces represent ten children who have seen their GP with a cough. Green faces are those who have recovered at each time period.

### What can I do about it?

Coughing helps the body fight against infection and can take a while to go. Cough syrups probably do not help. See page 6 for other things that may help.

### Do antibiotics help?

Most people who take antibiotics do not get better any faster than people who do not take them. Looking at adults and children with bronchitis (chesty cough), on average, **people taking antibiotics will have a cough for only half a day less than those who don't.**





## Common Cold

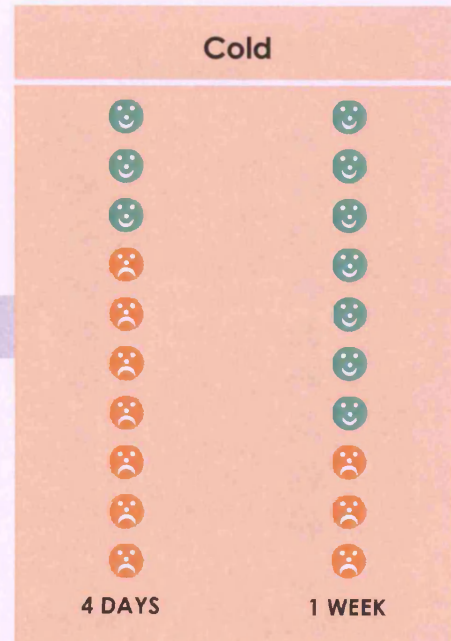
- Colds are very common. Normal, healthy children can sometimes have 8 or more colds in a year!

### How long will it last?

This chart will give you an idea of how long colds often last. The faces represent ten children who have seen their GP with a cold. Green faces are those who have recovered at each time period.

### Do antibiotics help?

There is no evidence that antibiotics help with colds.



## Green Phlegm/Snot

- Some parents and doctors have long believed that the colour of nasal discharge (snot) gave an indication of the type (or seriousness) of an infection.
- Recent research suggests that this is not the case. Green nasal discharge can be caused by many types of infection and does not need to be treated with antibiotics.

## Sore Throat

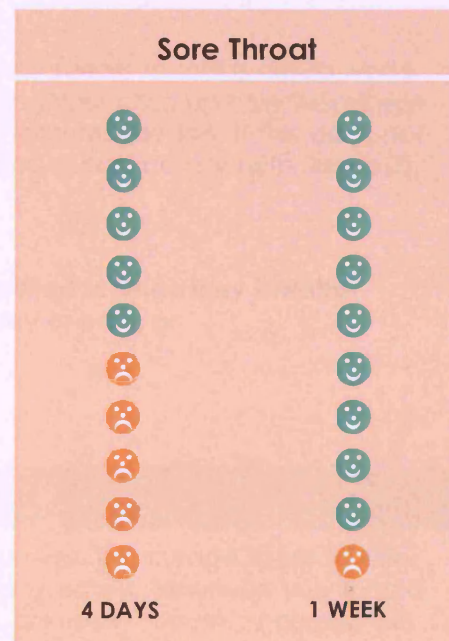
- A sore throat does not need any treatment to make it go away. It will get better by itself
- If your child seems very unwell or has a sore throat and temperature, but no cough, for more than 3 days, he or she should see a doctor or nurse.
- You do not need to look in your child's throat. If you have, and you are worried about large tonsils, this is not, by itself, something to be concerned about. However, if your child is having difficulty breathing, or seems very unwell (see page 7), you should consult your doctor urgently.

### How long will it last?

This chart shows you how long sore throats often lasts in children. The faces represent ten children who have seen their GP with a sore throat. Green faces are those who have recovered at each time period.

### Do antibiotics help?

After one week, more than three-quarters of those with a sore throat will be better whether they take antibiotics or not. **Most (13 out of 14) who take antibiotics will get better just as quickly as if they had not taken them.**



## Earache

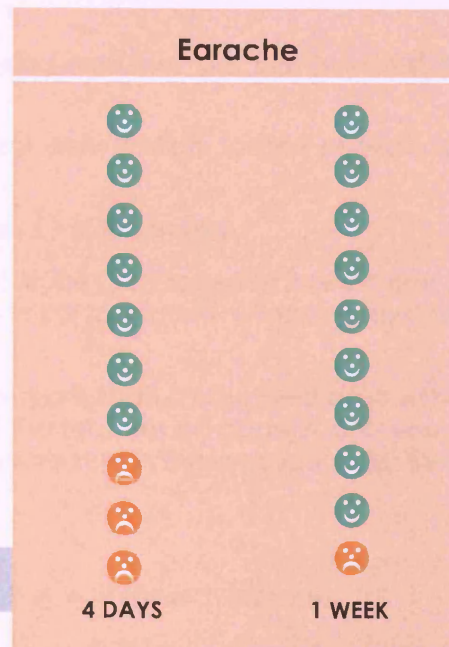
- There is normally no need to treat ear infections with antibiotics. Pain control with Paracetamol and / or Ibuprofen is all that is normally needed.
- If your child is having hearing problems, or the ear is draining, they should see a GP.

### How long will it last?

This chart shows you how long earache often lasts in children. The faces represent ten children who have seen their GP with earache. Green faces are those who have recovered at each time period.

### Do antibiotics help?

After one week, more than three-quarters of children will be better whether they take antibiotics or not. **Most (14 out of 15) children who take antibiotics get better just as quickly as if they had not taken them.**



## Croup

Croup can occur in children from 6 months to 12 years, but is most common in children under 3 years old. It is caused by a virus in the voice box and upper airway and causes a 'barking' cough (like a seal bark). It is usually worse at night.

### What can I do about it?

Comfort and hold your child to keep them calm – anxiety seems to make croup worse. Give your child sips to drink to prevent dehydration. Sitting your child up may help them with the cough. Most croup will improve with simple measures like this. If this does not settle your child or they are having difficulty breathing you should call for help (see p.8).

### Your child should see a doctor urgently if:

- **Their breathing is rapid**
- **The tissues around the neck or below the ribs are pulled in when they breathe**
- **They are becoming agitated, exhausted, bluish-grey or pale, or**
- **They can not swallow, or are drooling**

### Do antibiotics help?

Antibiotics do not help with croup.

## Not Eating/Drinking

- Children often eat and drink less when they are unwell. Encourage them to drink plenty. Most will start to drink before becoming dehydrated. However, you should watch for signs of dehydration, such as drowsiness, dry eyes / mouth, or peeing less. This is especially so for young children (under 1) and those who are vomiting.
- Most children can go a few days without eating much. See page 7 for advice on when you should seek further help.

## What can I do?

- A child's immune system is very powerful, and will clear up most common infections by itself.
- You can help your child fight the infection by making sure they get plenty of rest and offering them healthy food (like fruit).
- Give your child plenty to drink. This will help prevent dehydration, loosen phlegm, and lubricate the throat. Try to avoid very sugary drinks.
- **Pain and fever** are best treated with **Paracetamol** and / or **Ibuprofen**.
- Paracetamol and Ibuprofen work differently. They can be used together if one alone has not worked. Just make sure you do not give more than the maximum recommended dose of either of them.
- These products often tell parents not to use them for more than a couple of days without seeing a doctor. If your child does not have any of the features on page 7, and you are not overly worried about them, you can continue to treat with these products for longer than this.
- Make sure no-one smokes around your child.
- See sections on fever and cough for advice on dealing with these symptoms.

## Why not take antibiotics?

There are several reasons why it is not a good idea to take antibiotics unless they are really needed.

- Using antibiotics can make bacteria **resistant** to antibiotics. In other words, the antibiotics will no longer work against the bacteria. Someone who has recently had antibiotics is more likely to have resistant bacteria in their body. Some bacteria have become resistant to almost all antibiotics!
- Most antibiotics have side effects, e.g. diarrhoea, rashes and stomach upset.
- Antibiotics kill our natural bacteria that help to protect us. This can result in infections such as thrush.
- Antibiotics can also cause allergic reactions. These are often just annoying rashes, but can, in some cases, be severe reactions.



## When should I seek further help?

No guide can be complete. **If you are still worried about your child after reading this leaflet then you should get advice.** This could be telephone advice or a consultation with a doctor or nurse at your surgery. Telephone advice is also available from NHS direct and out-of-hours services (see contact numbers on the back of this leaflet). **If you feel that it is an emergency you should dial 999 for an ambulance.**

### The following are signs of possible serious illness:

- Your child is **drowsy or irritable**. (Although children with a temperature are often more sleepy, irritable and lacking interest than usual, they usually improve after treatment with paracetamol and / or Ibuprofen. If they do not improve, or if they are very drowsy indeed, they should see a doctor urgently).
- Your child has **problems breathing** - including rapid breathing and being short of breath or 'working hard' to breath. (It sometimes looks as though the tissues between the ribs and below the ribs get sucked in each time they breath). Any child who has a lot of difficulty breathing needs to see a doctor urgently.
- **Cold or discoloured hands or feet** with a warm body
- Severe **arm and/or leg pains** (for no obvious reason)
- **Unusual skin colour** (pale, blue or dusky around lips)
- **High temperature** (40 C or higher) (not necessarily a sign of serious infection, but if the temperature does not come down with treatment or your child has other features on this list then you should seek help).
- An **infant who is not feeding** or any child that is showing signs of **dehydration** (see page 5).

#### Symptoms related to meningitis:

- Unusually severe headache
- A stiff neck (difficulty putting chin to chest)
- Dislike of bright lights
- A rash that does not fade with pressure (see page 8)

### Other symptoms that should be assessed by a GP:

- A cough lasting more than 3 weeks (or sooner if becoming breathless more easily or there is a family history of asthma).
- A fever for 24 hours or more with no other sign of infection (cough, runny nose, earache etc.)
- Your child loses weight and does not re-gain it within two weeks in an under 5 year old, or within four weeks in an older child.

## 'Meningitis / Septicaemia Rash'



Images provided by the Meningitis Trust.

### GLASS TEST

*A rash that does not fade under pressure will still be visible when the side of a clear glass is pressed firmly against the skin*

Glass test devised by Dr Petter Brandtzaeg

## Contacts

GP phone number

GP out of hours number

You can get general health advice from NHS Direct on 0845 46 47 or [www.nhsdirect.nhs.uk](http://www.nhsdirect.nhs.uk)

**In an emergency dial 999**

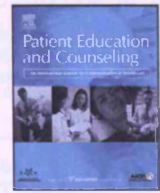
## Summary

- Most common infections do not get better quicker with antibiotics.
- Most children with a cold, cough, sore throat or earache, who see their GP, will still be ill 4 days later. This does not mean that they need treatment or need to be seen again.
- One third of children who have seen their GP with a cough will still be coughing 2 weeks later. This does not mean that they need treatment.
- Only children with signs of more serious illness generally need to be seen by a doctor or nurse. These signs include:
  - Excessive drowsiness
  - Difficulty breathing or rapid breathing
  - Cold or discoloured hands &/or feet with warm body
  - Abnormal pains in arms &/or legs
  - Abnormal colour (pale or blue)
  - Signs of meningitis

This booklet was developed by The Department of General Practice, Cardiff University, May 2006. We would like to thank the parents, GPs, and paediatricians who helped us develop the booklet, and the Medical Research Foundation who funded this project.

## **Appendix 6 – Peer-reviewed publication describing the development process**

Francis N, Wood F, Simpson S, Hood K, Butler CC. Developing an 'interactive' booklet on respiratory tract infections in children for use in primary care consultations. *Patient Education and Counseling*. 2008;73(2):286-93.



## Developing an ‘interactive’ booklet on respiratory tract infections in children for use in primary care consultations

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### ABSTRACT

**Objective:** To construct a systematic process for developing an ‘interactive’ booklet for use in primary care consultations and to use this process to develop a booklet on respiratory tract infections in children.

**Methods:** Booklet development occurred through a number of stages, which included: expert group brainstorming and literature review, professional graphic design, readability assessment, and consultation with users. Consultation was achieved through the use of focus groups and interviews with parents, focus groups and independent booklet review by general practitioners, and booklet review and feedback by paediatricians.

**Results:** All development stages led to meaningful enhancements to the booklet. Consultation with parents demonstrated a desire for more information than anticipated, with a particular emphasis on the interpretation of signs and symptoms, and the recognition of serious illness. General practitioners contributed to the design and clarity of the booklet and helped to ensure that it would be acceptable for use within consultations.

**Conclusion:** Written material needs to be developed in a systematic way and include consultation with the intended users. Focus groups are a valuable tool for consulting with consumers and practitioners in this regard.

**Practice implications:** The process described can be used as a guide for those wishing to develop similar written materials.

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### 1. Introduction

There are a multitude of different patient information leaflets available for use in primary care [1], and many patients report they want, use, and value written information in consultations [2]. The provision of leaflets have been shown to improve information retention by up to 50% [3], and members of the public indicate they would be less likely to consult with their general practitioner (GP) if they had more information about managing minor ailments [4]. Unfortunately, many patient information leaflets in use in primary care are of poor quality [1] because of inadequate attention to design, accuracy and appropriateness of information, and readability. Consulting with intended users helps address many of these issues [2,3,5,6].

The most common reason for patients to consult in primary care is respiratory tract infections, and children consult more than any other age group [7]. Antibiotics have been shown to produce little benefit in the treatment of most of these self-limiting infections [8–12], yet they continue to be widely used [13,14], and their overuse has been linked to the development of antibiotic resistance [15–18]. Parents report that the experience of caring for their acutely ill children often leaves them feeling anxious and disempowered, and they express a need for readily available, accurate, helpful information on these illnesses [19,20]. Furthermore, around one in five children who consult with a respiratory tract infection will re-consult during the same illness episode [21], which may represent a considerable opportunity cost to the health service as such consultations may be unnecessary if parental concerns can be addressed by alternative means.

A key driver for consulting with a respiratory tract infection is a belief that the illness has lasted longer than expected [22]. We have previously shown that GPs rarely provide parents with any information about the likely duration of these illnesses, and when

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they do they frequently predict the duration to be brief [23]. Therefore providing parents with natural history data in an easy-to-understand format, along with information about the effectiveness of antibiotics, home treatment advice, and when they should seek further help, may result in improvements in parental empowerment and satisfaction, more appropriate use of antibiotics, and reduced consulting. Leaflets that describe the normal duration of symptoms and give advice about self-help for lower respiratory tract infections in adults reduce re-consultations and antibiotic use [24,25].

Written information is more likely to be remembered and considered relevant if it has been discussed with the recipient [26], and yet consideration of this 'interactivity' is seldom mentioned in guidance on developing patient information.

With these principles in mind we set out to develop an information booklet on respiratory tract infections in children that could be used as a prompt to enhance communication within the consultation, and also as a take-home resource. Studies which involve sending booklets about minor illnesses to family homes have not shown meaningful reductions in consultation rates [27–31]. However, these studies did not involve using the booklets interactively within consultations, and the booklets used were developed either without, or with only minimal, consultation with parents. The effect of information booklets on respiratory tract infections or minor illnesses in children, used interactively within the consultation, has not been examined.

This paper describes the process of developing a booklet on respiratory tract infections in children, designed specifically for use in primary care consultations, with the aim of facilitating the delivery of information and enhancing communication. The use of this booklet is being evaluated in a randomised controlled trial [32], which will be reported elsewhere.

## 2. Methods

### 2.1. Overview of development process

The booklet was developed in partnership with parents and general practitioners in an eight-stage process (Fig. 1). These stages cover the broad areas of initial generation, testing and revision, and include two cycles of testing and revision with the primary stakeholders (parent and GPs) and one with paediatric consultants to ensure safety issues were adequately dealt with.

### 2.2. Initial generation

The research team decided that early parental input was important, but that this would be most valuable if parents were given a clear remit, based on up-to-date evidence, and a draft booklet on which they could base their comments. In order to achieve this we established a multi-disciplinary group, consisting of GPs, a health psychologist, a medical sociologist, and experts in respiratory tract infections and communication skills (stage 1). The group's remit was to establish the broad aims and content areas for the booklet by reviewing existing information leaflets on respiratory tract infections in children, and the scientific evidence pertaining to the development of patient educational material, respiratory tract infections in children, health behaviour change and shared decision-making. A draft booklet was then prepared and agreed by the group (stage 2).

### 2.3. Testing and revision

The next few stages involved a series of focus group meetings. After a pilot focus group involving clinicians and staff working in the

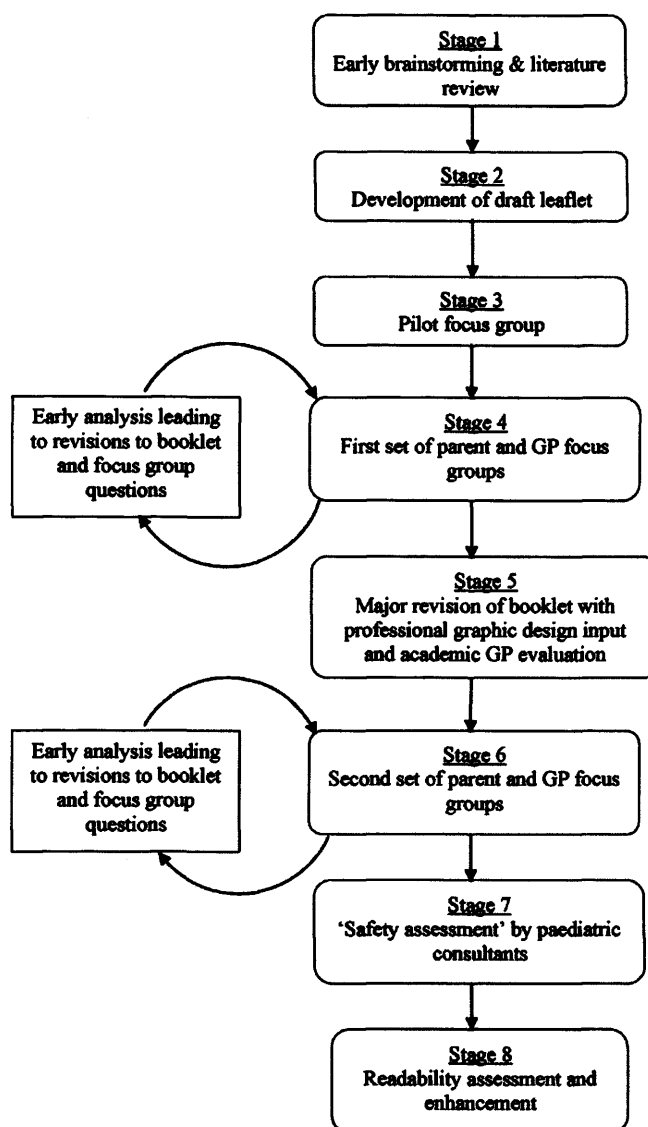


Fig. 1. Overview of development process.

Department of Primary Care and Public Health (stage 3), two sets of focus group meetings were arranged. The first set consisted of four parent focus group meetings (26 participants in total) and one GP focus group meeting (7 participants) (stage 4). In the parent meetings, parents were encouraged to discuss their experiences and concerns about respiratory tract infections in children, and their thoughts about the use of written information on these illnesses, during the first half of the meeting, and to scrutinise and discuss the draft booklet during the second half of the meeting. The GP focus group meeting was conducted in a similar fashion: participating GPs were invited to discuss their experiences and opinions before being shown the draft booklet. Following the first set of focus groups the booklet was reviewed by six practising academic GPs who gave written feedback on content and design issues. The booklet was then revised in accordance with suggestions from the first set of focus groups and the academic GPs, and was re-designed by a professional graphic designer (stage 5).

A second round of focus group meetings, which comprised of two parent interviews, one parent focus group (seven participants), and one GP focus group (five participants), resulted in additional amendments to content and design (stage 6). The



booklet was then reviewed by two practising paediatricians who focused in particular on patient safety issues (stage 7).

Finally, the booklet was assessed for its readability (stage 8).

#### 2.4. Focus groups

An 'in-house' pilot focus group was undertaken to test the facilitation exercises and clarity of interview schedule. Parents and GPs were then approached using purposive sampling with the aim of achieving maximum variation for both groups. Parents were sampled to include those with only pre-school children (less experienced) and those with at least one school age child. Parents were approached from a number of general practices and also through parent-toddler groups. The recruiting centres varied in terms of their levels of deprivation. GPs were sampled to ensure variation in the size of the practice as well as level of deprivation of the community served. The planning, moderating, and analysis of the focus groups followed accepted methods [33].

##### 2.4.1. Focus group meetings

Meetings were conducted at or close to the general practices or parent-toddler groups from which they had been recruited. Participants all provided written informed consent. Meetings were facilitated by a trained moderator (NF). A research assistant was also present at three of the parent meetings and one GP meeting to pay particular attention to group dynamics and non-verbal communication. Focussing exercises were used during both the parent and GP focus groups. These exercises included discussion of a case scenario, review of the draft booklet, and review of natural history data presented in different formats. All focus group meetings were audio-recorded and transcribed. All participant data were anonymised and kept confidential.

##### 2.4.2. Analysis

Development of the booklet was guided iteratively by the experiences and views of the participants. Thus, data collection and analysis occurred in tandem. A preliminary analysis was conducted after each meeting so that the materials and prompts used in subsequent meetings could be modified in order to test the ideas that had been generated. A more complete analysis was subsequently conducted using a thematic approach. The data from GP and parent groups were analysed concurrently, but different coding frameworks were developed for each type of group.

Three qualitative researchers (NF, FW, SS) reviewed one parent focus group transcript and identified themes were used to develop an initial coding framework. All transcripts were then examined and coded on a line-by-line basis using a qualitative software package (QSR NUD\*IST). Three transcripts were double coded by two researchers (NF and FW) to assess reliability, and inconsistencies were discussed and resolved. A process of constant comparison was used to generate new themes, re-classify themes, and incorporate themes within other themes. This was an iterative process which was revisited many times during each analysis. A similar process was undertaken for the GP focus groups, with one of the two GP focus group transcripts dual coded. The end result was a hierarchy of themes for each set of groups (parents and GPs).

### 3. Results

#### 3.1. Initial generation

The early drafts of the booklet were influenced by health behaviour change theory (such as the importance of addressing

'How to change' (outcome expectations) as well as 'Why change?' (efficacy expectations)) [34], the study of clinician communication and the elements of a consultation [35], shared decision making [36,37], and risk communication [38]. Guidance on the development of health educational material also proved valuable in informing the process, content and design of the booklet development [5,6].

The end result of this process was a booklet (or leaflet) on two sides of A4 sized paper folded in thirds. The booklet included a graphical presentation of natural history data on upper respiratory tract infections [39], and coughs [40], and information on: the effectiveness of antibiotic treatment, potential adverse effects from antibiotics, other treatment suggestions, and symptoms that should prompt re-consultation.

#### 3.2. Focus group participants

##### 3.2.1. Parent focus groups

Seven parent focus groups had been planned but two of these meetings were attended by only one participant and therefore were regarded as single interviews. This resulted in a total of five focus groups (with an average of 6.6 participants per group) and two interviews. The total number of participants was 35 with an average age of 30 years. All but 1 of the participants were female, 46% had only one child, 33% had no children over 2 years of age, 29% were single parents. Data were available on the employment status of 24 out of the 35 participants. Of these, eight (32%) were employed and were classified as belonging to the following National Statistics Socio-Economic Classification (NS-SEC) groupings: one in social class V, three in social class III-N, and four in social class II.

##### 3.2.2. GP focus groups

Seven GPs participated in the first focus group and five in the second. There were two female participants, and all of the participants consult with children on a regular basis.

#### 3.3. Parent and GP experiences and beliefs

Although the main aim of the focus groups was to make the booklet more useful and acceptable to parents, both parent and GP participants frequently talked more broadly about their experiences and beliefs. The main themes identified are summarised in Table 1.

#### 3.4. Influence on booklet development

##### 3.4.1. Parent meetings

**3.4.1.1. Thirst for information.** Almost all parents expressed a belief that having a leaflet or booklet on respiratory tract infections in children would be valuable, and most had a very positive overall impression of the draft booklet. The main emerging theme was the desire for more information, and as a result the draft grew (from two sides of A4 paper) into an eight-page A5 size booklet.

A number of parents had questions about the interpretation of symptoms, and found that these were not adequately addressed in the draft booklet that was organised around conditions (common cold, sore throat, ear ache, etc.) As a result, sections were added that dealt with symptoms such as, 'discoloured nasal discharge,' 'large tonsils,' and 'noisy sounding chests.'

The early draft included information on topics identified in previous research as causing parental anxiety, for example: fever, cough, and the signs of meningitis. While most participants commented on the value of this information, others wanted still more.

**Table 1**  
Parent and GP experiences and beliefs with regard to respiratory tract infections in children

Parent themes	
1. <i>Fear.</i>	Parents described high levels of anxiety around caring for their children when they have an RTI. The main fears were of meningitis, breathing problems, and febrile seizures
2. <i>Disempowerment.</i>	A number of parents expressed frustration about a lack of understanding about their child's illness; in particular the interpretation of symptoms. This was often compounded by what they perceived as conflicting advice from healthcare professionals
3. <i>Consulting.</i>	Many parents found it difficult deciding when to consult; without wanting to attend too early and possibly waste the doctors time, or appear over-anxious, but also worrying about missing something serious or attending too late. Other concerns mentioned were problems getting urgent appointments, insufficient consultation lengths, feeling dismissed or 'fobbed off,' problems understanding medical jargon, and a failure to identify their main concerns
4. <i>Antibiotics.</i>	The parents in our groups were divided in their beliefs about antibiotics, with many believing that they were wonder drugs and berating the fact that 'you have to battle with the doctor to get them,' and others concerned about their use and feeling that doctors, 'dish them out too easily'
GP themes	
1. <i>Parental consulting behaviour.</i>	Participants expressed the belief that parents consult mostly for reassurance, but that many had unrealistic expectations about what could and should be done for them. However they also talked about the importance of parental anxiety, both as something that needed to be addressed, and as an indicator of potentially serious illness
2. <i>Challenging consultations.</i>	Although seen as routine, many participants acknowledged that these consultations could be very challenging, especially when dealing with perceived parental pressure
3. <i>Diagnostic uncertainty.</i>	A number of GPs talked about the challenges of trying to accurately diagnose these illnesses, and the anxiety this could provoke. This was seen as particularly challenging in young febrile children
4. <i>Fears.</i>	GPs worried about missing serious illness with its subsequent effects on patient outcome, medico-legal implications, and the doctor-patient relationship. They also worried about the impact of 'antibiotic discussion' on doctor-patient relationships

"Have you got anything in there if they go into fits? For temperature fits I'm on about now. Because some people with a high temperature ... they can experience fits cant they? Cos my niece did. I don't know anything about em ... what to do, what to do with an attack of fits" (Parent focus group 3, high deprivation area)

As a result, sections were added on febrile seizures and croup, information on recognising dehydration in a child, and images of a septicaemia rash. The section on febrile seizures provides an example of the value of conducting a series of focus groups. Following the addition of information about this condition, two subsequent focus groups (one parent and one GP) suggested changing the advice about managing a new seizure in a febrile child (changed from 'call for an ambulance if the fit has not stopped after 5 min to 'call immediately for an ambulance'). Finally, members of a further parent group endorsed inclusion of this section, with one parent saying:

"I have to say though, in this leaflet, that's the best thing is these febrile seizures. That's the first time I've ever seen anything in a leaflet about that" (Parent focus group 5, low deprivation area)

**3.4.1.2. Do not discourage consulting.** A section of the booklet was designed to provide parents with information about signs and symptoms in their children which should prompt them to seek further help. While many parents commented on the value of this section, a number expressed anxiety about possibly deterring a worried parent from consulting.

"It should say something about the parent's discretion or something because if there is something serious and they've read this and you know it could be a bit of a problem. ..." (Parent interview 2, high deprivation area)

"... that every child is different and if you are not happy you still need to come. Because I would hate to think of somebody reading this thinking, well it says this in the book, and then 24 hours later their child is an awful lot worse because they've followed black and white in a book. ..." (Parent focus group 5, low deprivation area)

As a result, a highlighted sentence was added to the booklet which advised parents to re-consult if they are still worried after reading the booklet.

**3.4.1.3. Natural history data.** The focus groups assessed the acceptability of various graphical representations of this data, such as bar graphs, line graphs, pie charts, pictographs (with smiling and sad faces), and textual information. There was no single favourite format. However, the format that seemed to convey the information most clearly, to most people, was the face pictograms (see Fig. 2).

**3.4.1.4. Language, design, and organisation.** Although we had set out to avoid jargon, a few examples were identified by the participants and the wording was subsequently changed. An example of this was a change to the booklet title from, "Respiratory tract infections in children" to "When should I worry? – Your guide to coughs, colds, earache & sore throats."

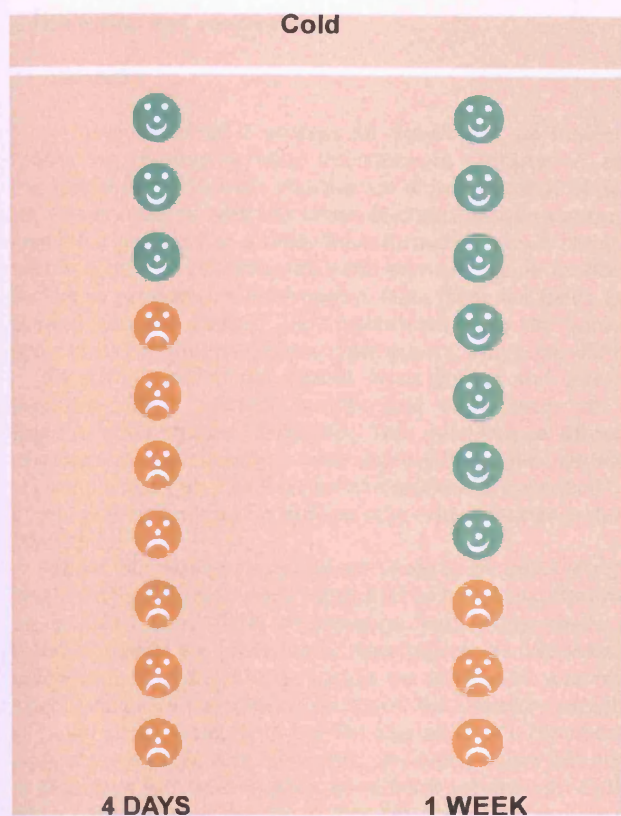
Early drafts of the booklet were divided into sections by topic ('What can be done to help them feel better?' 'How long is it likely to last?' 'Will antibiotics help?' etc.) Some parents commented that this resulted in them having to search through the booklet in order to 'pick out' the pieces of information relevant to a specific illness. As a result, almost half of the information was grouped by illness or symptom. Some 'topic' sections were felt to be applicable to most of these illnesses and so were retained. Examples of this include, 'What can I do?' 'Why not take antibiotics?' and 'When should I seek further help?'

Design improvements suggested by parents included the addition of a fridge magnet with key points written on it that could be used to stick the booklet to the fridge.

### 3.4.2. GP meetings

**3.4.2.1. Endorsement.** Most GPs were positive about the use of a booklet on respiratory tract infections in children. A number talked about the benefits of having something from an 'outside agency' endorsing the messages that they were trying to convey. They felt this would be helpful for those challenging consultations that involved negotiation around the use of antibiotics. A couple of GPs expressed some concern about maintaining a steady supply of booklets, indicating that they were more used to printing patient materials now.

"... that would be my concern is how ... is ensuring regular use ... a regular supply of them. And, I don't know, more and more as we get the computers to print these things, we haven't ... we



This chart will give you an idea of how long colds often last. The faces represent 10 children who have seen their GP with a card. Green faces are those who have recovered at each time period.

Fig. 2. Example of graphical representation of natural history data using pictograms. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of the article.)

seem to have less and less use for ready printed material.” (GP focus group 2)

**3.4.2.2. Safety-netting.** One of the main roles the GPs took on during focus groups was in clarifying the wording to ensure that the messages were clear and were not likely to cause confusion. For example, concern was expressed about a statement giving advice about re-consulting for a child who had lost weight during a respiratory tract infection.

“...it's not very practical, because, do we expect the parents to weigh them ... twice within a week? And also it's age related ... weight loss in younger, infants, you know, is quite significant, you know, older children ... is quite different.” (GP focus group 1)

After some discussion it was suggested that the advice should be made more age specific. Similarly, re-wording was suggested for advice about persistent coughing. Some GPs were concerned that the advice to consult if a cough had persisted for more than 3 weeks may result in some children with asthma not being seen for this length of time. A caution was added indicating that the booklet should not be used for children with asthma, and the advice around persistent cough was amended to suggest that a child becoming breathless more easily, or with a family history of asthma, should be seen earlier. Similar wording modifications were made to sections on febrile seizures, croup, discoloured nasal secretions, and

weight loss. The GPs, like the parents, wanted to ensure that the booklet did not discourage worried parents from consulting.

**3.4.2.3. Use of the booklet.** Unlike the parents who wanted the booklet expanded considerably, some GPs in both focus groups thought the booklet was too long. Some were concerned that parents would not read it, but the main concern was that use of the booklet would lengthen the consultation. However, other GPs believed that having clear sections would enable them to just go through the relevant parts, and that this would be feasible within a normal consultation. Most GPs agreed that having some training on how to use the booklet within the consultation would be acceptable, and were happy for the booklet to include prompts which encourage the exploration of concerns and expectations.

### 3.4.3. Selecting suggestions from the focus groups for final inclusion in the booklet

While most suggestions from both the parent and GP focus groups were incorporated in the final draft of the study booklet, some were not. Certain ideas were rejected because they were considered infeasible or outside the remit of the study. Examples included a suggestion to provide the booklet to all new parents (either handed out by health visitors or included in the current ‘red book’ which is given to all new parents), including information in the booklet about the number and types of viruses that can cause respiratory tract infections, and expanding the booklet to include a wider range of minor illnesses.

Several parents requested information in the booklet about diagnosing and treating asthma. While we felt it was important to provide parents with information about symptoms that should prompt them to consult, we decided that including information about diagnosis and management of asthma would make the booklet too large and lose its focus.

Other ideas were rejected because it was felt they may create confusion or be difficult to interpret. For example, we rejected the suggestion that we incorporate a guide as to what rate of breathing would be considered too rapid. Normal respiratory rates vary considerably with age, and measuring respiratory rate accurately is not always easy. We decided that it would be safer to simply suggest that parents should seek an urgent medical opinion whenever they believe that their child is breathing rapidly.

Finally, we did not incorporate some suggestions because little or no relevant accurate information was available. For example, some parents asked for advice about whether children should be kept indoors when they have an infection and others asked for advice on proven preventions for respiratory infections.

### 3.5. Readability

There are a number of ‘tools’ available for assessing readability. However, a reading age ‘score’ is not in itself a reliable indicator of readability [5]. We therefore employed a ‘basic skills’ professional to assess readability and to make recommendations for enhancing accessibility by those with low literacy levels. The booklet was initially assessed as having an average SMOG (simplified measure of gobbledygook) [41] score of approximately 15, which indicated that a large proportion of the UK adult population would have some difficulties reading it. The basic skills professional provided a four-page report containing detailed advice on word choice, sentence structure, and design features. A large number of the recommended changes were possible without any change to the meaning, and as a result the final booklet had an average SMOG score of approximately 10, which according to the National Literacy Trust suggests readability by most people [42].

## 4. Discussion and conclusion

### 4.1. Discussion

We have described a process for developing an information booklet on respiratory tract infections in children. A central component of this process was the use of focus groups of parents and GPs in order to seek the views of clinicians and parents. We found that parents had a thirst for information about respiratory tract infections in children, and were enthusiastic about having a booklet to provide this information. Data from the focus groups allowed iterative changes and improvements to the booklet in terms of its comprehensiveness, appearance, and accessibility.

The participants of our parent focus groups and interviews described similar worries, beliefs, and experiences to those found in other studies [19,43–47]. This data helped inform the development of our booklet as well as providing some validation of our sample selection. The beliefs and experiences described by our GP groups were also similar to those of previous studies in this area [48–52].

Patient information resources are likely to be more effective if developed through systematic steps that include consultation with the intended users. Early consultation with users needs to be balanced against the provision of clear objectives. We wanted to ensure that the patient information we developed was broadly based upon up-to-date clinical evidence. We therefore established an expert group to clearly define the objectives and broad content areas of the booklet from the outset. We believe that this enabled us to achieve early and ongoing input from parents and clinicians while ensuring that the focus was on the development of an evidence based information resource.

Our finding that focus groups are a valuable way of developing and improving nascent patient information materials is in keeping with others who have used this method [53–56]. A number of other methods for seeking the views of the intended users have been described including questionnaires [56,57], interviews [53], and the Delphi technique [58]. Each of these methods has advantages and disadvantages, but none allows for the exploration of emerging ideas with respondents, which is possible in focus groups. In addition, the views of users were generally sought only at a late stage in the development of previous patient orientated materials. Our experience confirms that it is helpful to seek the views of users at an early stage; and that by conducting a series of meetings, views can be obtained on subsequent changes. Focus groups lend themselves to this iterative type of approach. Furthermore, we feel the development of our booklet benefited from the inclusion of both parents and GPs. It is especially important to consult with the healthcare professionals who will be providing the information when materials are being designed to be used 'interactively' within a consultation.

An important aspect of the development of information resources is rigorous evaluation of effectiveness and acceptability. We will evaluate the impact that use of this booklet has on re-consultation rates, antibiotic use, parental satisfaction and enablement, intention to consult with a similar illness in the future, illness costs, and consultation rates for respiratory tract infections over the following year, in a cluster randomised controlled trial [32]. We will also explore parents' and clinicians' views of the booklet, both as a take-home resource and as an 'interactive' tool within consultations, using qualitative research methods. This process evaluation will provide a perspective from those who have actually used the booklet, and will be invaluable in exploring its acceptability and perceived value. For example, we will explore whether an eight-page booklet provides the depth and breadth of information desired by parents, or whether it is too long and therefore off-putting.

#### 4.1.1. Study limitations

We were only able to recruit one father into our parent focus groups. Although childcare is often provided by mothers, fathers frequently play a key role in decision-making about medical consulting. The timing of the meetings (during working hours) and our recruitment methods (through general practices and parent-toddler groups) reduced our success in recruiting fathers.

Although we sought the views of GPs, we did not consult with practice nurses. Practice nurses are increasingly managing minor illnesses and have frequently taken a lead in patient education. Consultation with practice nurses should be included in future, related work. We did not include clinician gender in our sampling frame, and subsequently only recruited two female GPs (one in each group). We were able to supplement this GP focus group data by having the booklet evaluated by six academic GPs, two of who were women.

### 4.2. Conclusion

When developing written patient information, it is important to follow a systematic approach that includes an assessment of the key aims of the material being developed, a review of the relevant literature, and seeking the views of key stakeholders. Focus groups are a valuable method for seeking the views of both the intended recipients of the information, and the clinicians who will be providing it.

Parents are enthusiastic about having a booklet of information to support them when their children are suffering from a respiratory tract infection. They report that they would consult with primary care clinicians less often if they had this information. However, they do not want the booklet to discourage parents from consulting when they were worried or to replace face-to-face consultations altogether.

Focus groups with both parents and GPs resulted in significant changes to the content and design of the booklet. As a result of the parent focus groups, the booklet grew to include content on a wide range of topics which would not otherwise have been covered. The inclusion of information on the interpretation of various symptoms, and on potentially serious conditions such as febrile seizures and croup, were two of the main additions. The GP focus groups also played a key role in the development of the booklet. GPs helped to ensure that the wording of the booklet was clear and in-line with current practice, and that it was a tool which could feasibly be used in primary care consultations.

### 4.3. Practice implications

Parents of children consulting with respiratory tract infections should be provided with information on the interpretation of symptoms and signs, potential serious complications and how to recognise them, how long the illness is likely to last, and the likely benefits and risks of various treatments (including antibiotics). Providing this information in a written format is likely to be highly acceptable and valued by parents, and lead to improved information retention.

Those developing written patient materials should consult with both the intended recipients of the information, and the clinicians who are likely to provide it. Focus groups are a valuable way of achieving such consultation.

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### Conflict of interest

The authors declare no conflict of interest.

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## **Appendix 7 – Peer-reviewed publication of the trial protocol**

Francis NA, Hood K, Simpson S, Wood F, Nuttall J, Butler CC. The effect of using an interactive booklet on childhood respiratory tract infections in consultations: Study protocol for a cluster randomised controlled trial in primary care. *BMC Family Practice*. 2008;9.

Study protocol

Open Access

## The effect of using an interactive booklet on childhood respiratory tract infections in consultations: Study protocol for a cluster randomised controlled trial in primary care

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### Abstract

**Background:** Respiratory tract infections in children result in more primary care consultations than any other acute condition, and are the most common reason for prescribing antibiotics (which are largely unnecessary). About a fifth of children consult again for the same illness episode. Providing parents with written information on respiratory tract infections may result in a reduction in re-consultation rates and antibiotic prescribing for these illnesses. Asking clinicians to provide and discuss the information during the consultation may enhance effectiveness. This paper outlines the protocol for a study designed to evaluate the use of a booklet on respiratory tract infections in children within primary care consultations.

**Methods/Design:** This will be a cluster randomised controlled trial. General practices will be randomised to provide parents consulting because their child has an acute respiratory tract infection with either an interactive booklet, or usual care. The booklet provides information on the expected duration of their child's illness, the likely benefits of various treatment options, signs and symptoms that should prompt re-consultation, and symptomatic treatment advice. It has been designed for use within the consultation and aims to enhance communication through the use of specific prompts. Clinicians randomised to using the interactive booklet will receive online training in its use. Outcomes will be assessed via a telephone interview with the parent two weeks after first consulting. The primary outcome will be the proportion of children who re-consult for the same illness episode. Secondary outcomes include: antibiotic use, parental satisfaction and enablement, and illness costs. Consultation rates for respiratory tract infections for the subsequent year will be assessed by a review of practice notes.

**Discussion:** Previous studies in adults and children have shown that educational interventions can result in reductions in re-consultation rates and use of antibiotics for respiratory tract infections. This will be the first study to determine whether providing parents with a booklet on respiratory tract infections in children, and discussing it with them during the consultation, reduces re-consultations and antibiotic use for the same illness without reducing satisfaction with care.

**Trial registration:** Current Controlled Trials ISRCTN46104365



## Background

Acute respiratory tract infections (RTIs) are the most common illnesses experienced by individuals of all ages worldwide [1]. Children, who experience more illness episodes than any other age group, will on average have between five and six respiratory infections per year [1]. In the United Kingdom, 97% of pre-school age children will consult with a doctor at some point, mostly for symptoms related to respiratory tract infections [2]. These illnesses are the most common reason for patients to consult in primary care, and children consult more than any other age group [3]. In addition, around one in five children consulting because of a RTI will re-consult for the same illness episode [4], a proportion that has changed little over the past thirty years [5]. Parents frequently describe anxiety and disempowerment when coping with respiratory tract infections in their children [6,7]. These problems may be addressed by the provision of clear, reliable information [7,8].

Furthermore, most respiratory tract infections benefit very little from treatment with antibiotics [9-13], yet their use continues to be widespread [14,15] with children receiving more antibiotics than any other age group [16]. Approximately 25% of consultations with children with a RTI result in an antibiotic prescription [16], and approximately half of all children aged 0 – 4 will receive an antibiotic prescription in any one year period [17]. Unnecessary antibiotic prescribing results in wasted healthcare resources, leads to a cycle that encourages further consulting in the future for similar illnesses [18] and contributes to the problem of antibiotic resistance [19].

Parental factors influencing the decision to consult include concerns, knowledge, beliefs, and expectations. Parents often fear serious illness, and worry that they will not be able to recognise symptoms of serious illness [6]. Despite their concerns, a number of parents worry about 'bothering' their general practitioner with these illnesses [20,21]. They also lack knowledge about the likely risks and benefits from antibiotic treatment, and the normal duration of illness [22]. Patients may hold beliefs about the causes of respiratory tract infections [22-24], the meaning of symptoms [25,26], and the effectiveness of medications [22,23,25,27], that are at odds with biomedicine.

Providing parents with written information about respiratory tract infections in children may help alleviate anxiety and improve parental feelings of satisfaction and enablement. In adults, the use of leaflets describing the expected duration of symptoms and giving advice about self-help for lower respiratory tract infections, has resulted in reductions in re-consultations [28] and antibiotic prescribing [29].

Expectations that patients (and parents) bring to consultations can have an impact on outcomes. There is an increased likelihood that antibiotics will be prescribed when parents consult with expectations for an antibiotic prescription [30]. However, clinicians seldom explicitly enquire about expectations [31], and often over-estimate the expectation for antibiotics [21]. A clinician's perception of an expectation for antibiotics is associated with an even greater likelihood of prescribing than actual patient expectations [30,32]. Parents value a thorough examination, explanation, reassurance and advice or guidance more than a prescription for antibiotics [21,33].

Other studies have evaluated the use of printed patient information on respiratory tract infections. Sending booklets on a range of minor illnesses (including respiratory tract infections) to patients' homes has been shown to have little impact on consultation rates in a number of studies [34-38]. However, an editorial accompanying the two most recent of these studies suggested that the use of written material to support the management of minor illnesses was more likely to be of value if it was used within the consultation and was context-specific [39].

A study conducted in the 1980's in one health centre in the United States showed a reduction in consultation rates for patients provided with a pack containing a pamphlet, sticker and thermometer [40]. However, this study was limited by non-random allocation, and post-allocation exclusion of subjects with chronic illnesses. In another US study, parents were randomised to receive educational materials on either the use of antibiotics or injury prevention [41]. There were no differences in consultation rates or antibiotic prescribing between these two groups, which may reflect the need to provide parents with positive information about managing an illness rather than a negative message about a treatment option (antibiotics). A more recent non-randomised US study examined the role of patient educational materials and providing clinicians with prescribing profiles and practice guidelines [42]. This led to reductions in antibiotic prescribing for bronchitis in adults, but not for paediatric pharyngitis.

Printed educational materials have frequently been used as part of larger multi-faceted interventions [43-48]. A number of these interventions have been associated with either a reduction in prescribing or improvements in parental knowledge and awareness about antibiotics. However, it is not possible to determine the role of the educational materials within these complex interventions, and in none of these studies were the materials designed for use specifically within the consultation.

We set out to address high levels of consulting and antibiotic prescribing, and parental disempowerment and dissatisfaction, by developing a booklet on respiratory tract infections in children, designed to be used within primary care consultations and then provided to parents as a take-home resource. The booklet and clinician training have theoretical roots in Social Cognitive Theory [49,50] and the Theory of Planned Behaviour [51,52]. The key aspects of these theories incorporated in the intervention are outcome and efficacy expectations. Behaviour change is more likely if the individual believes in the importance or value of change (outcome expectations) and feels that they have the confidence or skills to change (efficacy expectations). To enhance the likelihood that the intervention will result in reductions in health service utilisation and antibiotic prescribing it has been aimed at both clinicians and parents. Clinicians are provided with information about the implications of high levels of consulting and antibiotic use, in order to increase outcome expectations. They are also provided with specific tools to facilitate change (efficacy expectations). These tools include communications strategies provided within the training programme, and the study booklet, which acts as an aide memoir and a prompt to enhance communication within the consultation. Similarly, we aim to influence the behaviour of parents by providing them with information about the importance of change (benefits of self-management and implications of overuse of antibiotics), and by attempting to enhance their confidence and skills. We aim to achieve the latter through use of the study booklet which encourages them to have their concerns addressed within the consultation, and provides them with clear, relevant information about their child's illness.

#### **Main research questions**

Our main aim is to determine whether the pragmatic use of this intervention can result in a reduction in the proportion of children who re-consult during the same illness episode. We will also examine the impact that use of this intervention has on: antibiotic prescribing and use, parental satisfaction, parental enablement, intention to consult with a similar illness in the future, illness costs, and consultation rates for RTIs over the following year. In this paper we describe the study protocol.

#### **Methods**

This will be a cluster randomised controlled trial with randomisation at the level of the general practice. Recruited general medical practices will be randomised to one of two arms; use of an interactive booklet or usual care (see Figure 1).

#### **The intervention**

The study booklet was developed through a multi-stage process, which is outlined below and will be reported in full elsewhere.

The aims and broad content areas were decided through a number of 'brainstorming' sessions held by a multidisciplinary development group. Systematic searches were undertaken to identify existing patient information leaflets and literature on development of patient educational materials, management of respiratory tract infections in children, healthcare communication and shared decision-making. These materials were reviewed and synthesised, and a draft booklet (2 sides of A4 paper) was developed. This was presented to a number of parent focus groups, individual parents through an interview process, and two general practitioner focus groups. In addition, six practising academic GPs, two practising paediatricians, and a 'basic skills professional', who focused on improving readability, reviewed the emerging booklet. This process led to important changes to content and design. The design was also enhanced through input from a professional graphic designer. The end result was an eight-page A5 booklet, the content of which is summarised in Table 1.

The aims of the interactive booklet are to act as an evidence-based information resource for parents, an aide memoir for clinicians, a tool to help set realistic expectations, and a prompt to enhance communication within the consultation. The booklet is described as 'interactive' because it has been designed for use within consultations to facilitate interaction between the clinician and the parent. It aims to achieve this by providing specific prompts which encourage discussion of the parent's main worries, and their expectations for the consultation. In addition, the booklet includes boxes and spaces, which allow for personalisation.

#### **Clinician training**

All participating clinicians will be provided with training in study processes. This includes the background and aims of the study, how to recruit patients, inclusion and exclusion criteria, obtaining informed consent (including determining when a child should be asked to provide consent), and how to complete the patient encounter sheet (including the importance of accurate data collection). This training will be provided through a dedicated website, accessed by means of a username and password provided to all participating clinicians [53].

In addition to the training in study processes, clinicians in practices randomised to the intervention arm will complete a training module on use of the study intervention (booklet) within their consultations. Unique log-in details provided to these practitioners will automatically ensure that they are provided access to the additional training module. This training describes the contents of the booklet, encourages its use within the consultation, and encourages clinicians to use the booklet to facilitate

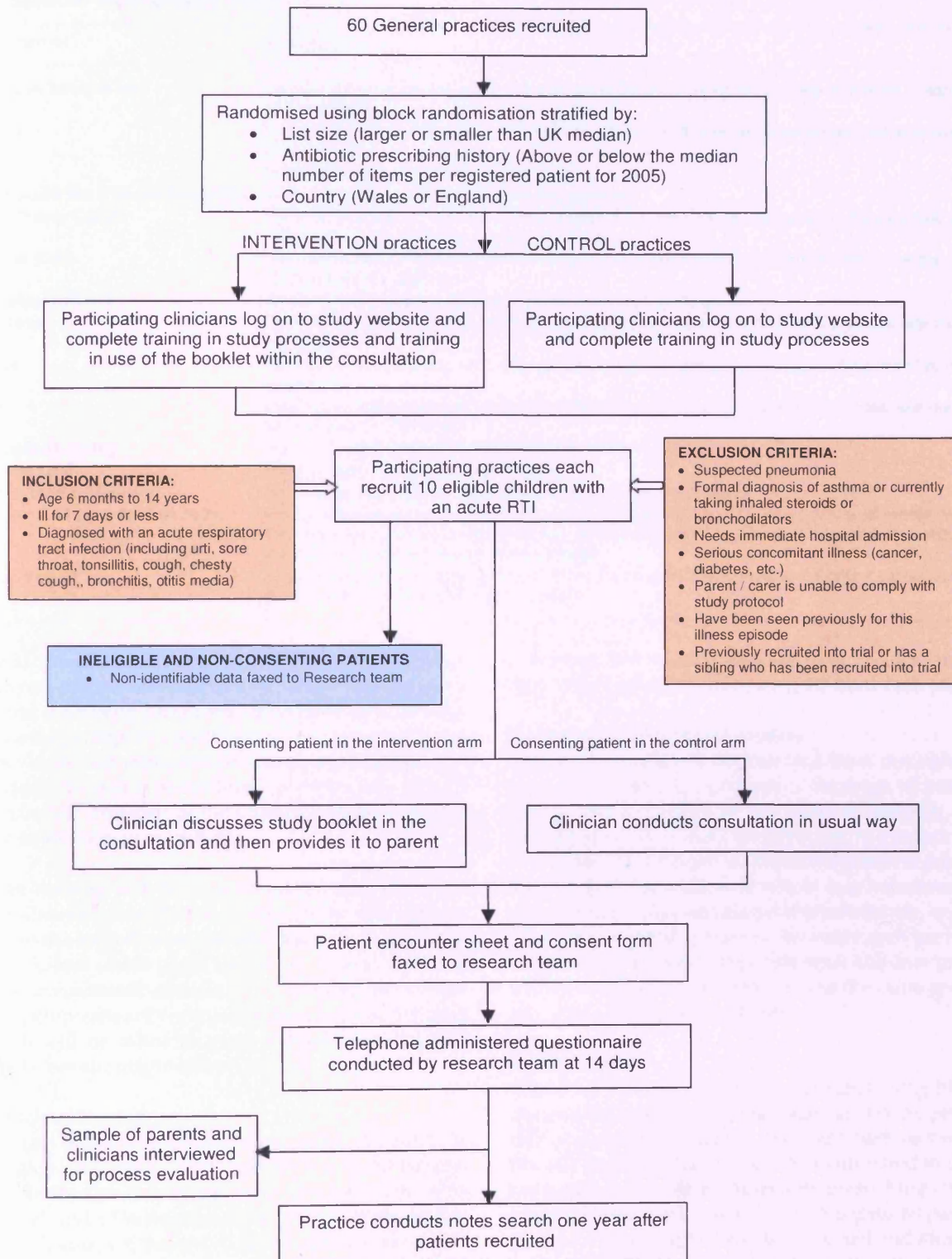


Figure 1  
Study flow chart.

Table 1: Summary of study booklet content

Section name	Contents
<b>Who is this booklet for?</b>	General introduction and advice on who the leaflet does not apply to (under 6 months, children with chronic illnesses)
<b>Prompts</b>	Prompts to remind the practitioner (and the parent) to discuss the parent's main concerns and their expectations.
<b>Fever</b>	Facts about fever and advice on managing it.
<b>Temperature fits (Febrile Seizures)</b>	General information and advice on management.
<b>Cough/Chesty Cough</b>	General information, graphical representation of normal duration, advice about management, and information about the effectiveness of antibiotics.
<b>Common Cold</b>	Information about frequency and graphical representation of normal duration. Advice on the effectiveness of antibiotics.
<b>Green phlegm/Snot</b>	Advice about the interpretation of discoloured nasal discharge.
<b>Sore Throat</b>	General advice, graphical representation of the normal duration, information about the effectiveness of antibiotics.
<b>Earache</b>	General advice, graphical representation of the normal duration, information about the effectiveness of antibiotics.
<b>Croup</b>	Information about symptoms and management (including signs of respiratory distress) and the effectiveness of antibiotics.
<b>Not Eating/Drinking</b>	Advice on these symptoms including signs of dehydration.
<b>What can I do?</b>	General section on management advice.
<b>Why not take antibiotics?</b>	Information about the potential disadvantages to use of antibiotics.
<b>When should I seek further help?</b>	Comprehensive section providing a description of symptoms and signs suggestive of serious illness, including pictures of a meningitis/septicaemia rash (and the 'tumbler test'). Also advice on other situations that should prompt re-consultation.
<b>Contact details</b>	Space for clinicians to write 'in-hours' and 'out-of-hours' contact numbers. Contact details for NHS direct (national health information service).

the use of certain communication skills; namely exploring the parents' main concerns, asking about their expectations, and discussing prognosis, treatment options, and what should prompt re-consultation. The training incorporates videos that demonstrate use of the booklet in a consultation, as well as audio feeds, pictures, and links to study materials. This part of the training will take approximately 40 minutes to complete.

Clinician training will be monitored through the study website. This will allow the study team to identify whether a clinician has logged on to the site, how much time they spent on it, and which pages they have viewed. This will allow for a reasonable assessment of whether or not participating clinicians are completing the required training. Clinicians will be asked to complete all their required training before starting to recruit patients.

#### **Sample size estimation**

The primary outcome is re-consultation for the same illness episode. In order to show a reduction in the proportion of children re-consulting from 20% to 10%, with 80% power, and a 5% significance level, we would require 438 participants for an individually randomised trial. From a previous study of upper respiratory tract infections in children [4], we calculated an intra-cluster coefficient of 0.04 for re-consultation rates. Using 60 clusters (practices) we would need 524 participants to have the same power as an individually randomised trial. To allow for loss to

follow-up and missing data we have decided on a target recruitment of 600 participants, 10 from each practice.

#### **Recruitment of general practices**

General practices will be recruited from throughout England and Wales. We will use a database of practices in Wales, and a number of UK Clinical Research Network primary care local research networks to contact practices in a wide range of regions. Recruited practices are asked to sign a Study Agreement. Practices can have one or more participating clinicians (general practitioners, nurse practitioners, or practice nurses), however each participating clinician must consult regularly with children presenting with acute illnesses. All clinicians in the same practice are allocated to the same trial arm.

#### **Randomisation**

Recruited practices will be randomised using block randomisation stratified by list size, antibiotic prescribing rate, and country (Wales or England). Each recruited practice will provide a list size which is compared to the mean for England and Wales. Antibiotic prescribing rates (antibacterial items prescribed per 1000 registered patients for 2005) for each practice will be obtained and these will be compared with the mean rate for each country. For each of the eight strata the study statistician will create a randomisation table using random permuted block sizes. These tables will be kept securely and allocation for each practice will be provided only after the practice has agreed

to participate and the practice ID and stratification variables are provided to the statistician.

#### **Patient recruitment**

Participating clinicians are asked to invite sequential eligible patients (see Figure 1) consulting with a respiratory tract infection (including common cold, cough, bronchitis or chesty cough, sore throat, tonsillitis, and ear ache). Exclusions (see Figure 1) include children with asthma, pneumonia, and those with ongoing serious disease (cancer, kidney disease, heart disease, etc.) Parents will be asked to provide informed consent, and where a child is deemed capable of consenting, they will be asked to provide consent in addition to the parental consent.

#### **Data collection**

In order to assess possible selection bias we will collect non-identifiable data on all 'potentially eligible patients'. This includes recruited patients as well as those approached but then deemed to be ineligible, those who decline participation, and those not recruited for other reasons (clinician was too busy, etc.) For these patients we will collect: date of consultation, duration of illness, age in years, gender, and presence or absence of the following symptoms: cough, earache, sore throat, runny nose, fever, looks unwell (subjective assessment by clinician). For eligible, consenting patients, we will also collect the patient's and parent's names, contact details (address and phone numbers), and the child's date of birth.

#### **Follow up data collection two weeks after the initial consultation**

Most outcomes will be measured by a telephone-administered questionnaire two weeks after the initial consultation. A member of the study team will telephone the parent or guardian of each participant fourteen days after they were enrolled into the study. If the researcher is unable to make contact with the parent on this day they will continue attempting to make telephone contact daily for at least three days. If the researcher is unable to make contact after three days of calling, or if the number given has been found to be incorrect or unavailable, the telephone number will be confirmed with the practice which recruited the patient, and checked with directory enquiries. Parents for whom we are still unable to make contact will be sent a brief questionnaire by post. In order to increase the likelihood of response this questionnaire will deal with only the main outcomes – namely re-consultations and use of antibiotics.

The telephone administered questionnaire will ask about consultations with primary, secondary, and out of hours care providers in the two weeks since enrolment, prescriptions for and use of antibiotics, either at the index consultation or subsequently, use of other medications, satisfaction, usefulness of information provided to them

in the initial consultation, level of reassurance, intention to consult with similar illnesses in the future, and questions related to the costs of the illness for the family (time off school/work, etc.) An adaptation of the Patient Enablement Instrument [54] will also be completed over the telephone.

#### **Follow up data one year after the consultation**

Additional measurements will be made one year following the recruitment of the final patient for each practice. Each practice will be sent a list of all recruited patients and asked to provide details of the length of each index consultation, and information on the total number of consultations and the number of consultations for RTI, for the one-year period following each patient's recruitment. To facilitate the collection of data from the practice records the study team will provide practices with support on obtaining consultation length data from their computer system, and beginning and end dates for each one-year follow-up period. General practices will be asked to include information about consultations occurring in other locations (out-of-hours, hospital, out-of-area, etc.) as well as consultations within the general practice.

#### **Potentially discardable pilot**

We conducted a pilot study using two practices in South-East Wales. Both are group practices in areas of high socio-economic deprivation. These practices were randomly assigned by the study statistician, one to intervention and one to control. Recruitment and data collection processes were piloted and participating clinicians provided feedback on these processes and the on-line training. In addition, those clinicians who were in the intervention practice provided feedback on use of the intervention. Minor amendments were made to the on-line training as a result of this experience. As there were no major changes required, data from the pilot practices will be included in the main trial.

#### **Analysis**

Statistical analyses will be conducted using SPSS, STATA, and MLwiN. The primary analysis will be intention to treat and will compare the proportion of patients who re-consulted for the same illness during the fourteen days following recruitment, in the intervention and control arms of the study. A two-level logistic model will be fitted to account for individual and practice-level factors.

Secondary outcomes include: proportion reporting having received a prescription for an antibiotic, proportion reporting having used antibiotics, parental enablement, parental satisfaction, parental assessment of the usefulness of any information received in the consultation, perceived reassurance, and the number of consultations for respiratory tract infections over the following year. These

will be analysed using either two-level logistic or linear regression models as appropriate.

We will explore whether a three-level model to control for practitioner factors improves the fit of the model for each analysis.

No formal sub-group analyses are planned. However, exploratory analyses will be conducted of the impact of child's age, presenting symptom complex, and socio-economic background (using postcode of residence) on the effectiveness of the intervention.

#### **Process evaluation**

We will conduct a qualitative process evaluation which will be reported in detail elsewhere. The purpose will be to gain a greater understanding of the clinicians' and parents' perceptions of the intervention (booklet and training) and the elements of it that were perceived to be helpful, and those which were unhelpful. A purposive sample of parents and clinicians in the intervention arm will be invited to participate in semi-structured interviews. These will be conducted between one and four months after enrolling in the study for the parents, and after completion of recruitment for the clinicians.

#### **Discussion**

This will be the first study to explore the impact of using an interactive booklet on respiratory tract infections in children, designed for use within consultations, on re-consultations and antibiotic prescribing. Our intervention has been designed primarily for use with parents, although it could easily be understood by many older children, and acts as an aide-memoir for primary care clinicians. It is applicable to a wide range of childhood respiratory tract infections. The interactive booklet is more likely to be used, understood, and believed, if it is seen to be endorsed by the parent's primary care clinician. Clinicians using the intervention will be provided with training in its use that encourages them to endorse the booklet, to identify and highlight relevant sections of the booklet, and to use it as a prompt to improve communication within the consultation.

The Medical Research Council and others have recommended that complex interventions are based on a theoretical framework [55]. Our intervention is grounded in Social Cognitive Theory and the Theory of Planned Behaviour. Understanding the theoretical underpinnings of the intervention will help us explore which components of the intervention contributed to the effectiveness or lack of effectiveness of the intervention, and will aid in the implementation of the intervention if it is found to be effective [56].

#### **Outcome measures**

Re-consultation for the same illness during the fourteen days following enrolment was chosen as the main study outcome for a number of reasons. Our previous studies have shown nearly one in five children re-consult for the same illness episode [4] Worried parents should not be discouraged from consulting. However, when a significant proportion of parents who have consulted feel the need to re-consult for the same illness, it suggests that they are not being empowered to self-manage these illnesses. Small reductions in resource use in common conditions could result in large savings on a national level. Finally, clinicians are likely to perceive greater pressure to prescribe antibiotics for children who seen for a second or third consultation for the same illness episode.

In addition to other 'clinical' or 'process' outcomes such as antibiotic prescribing and consultations for similar illness over the following year, we will also examine patient-related outcomes including parent reported satisfaction, reassurance, value of information received, and enablement. Enablement is a concept developed by Howie and colleagues which is related to, but different from satisfaction [54] The concept draws on the themes of patient centeredness and empowerment, and on the patient's perceived changes in understanding, coping, and confidence. We adapted the Patient Enablement Instrument for use with parents about care of their children. This involved mainly minor changes to the wording, but did require the item examining impact of the consultation on "ability to cope with life" to be dropped, as this seemed inappropriate when talking about a consultation regarding a third party (the child). No formal validation of this adaptation was conducted. However, its use was found to be acceptable in the pilot.

We will also measure potential adverse effects from the intervention. One UK study randomised 120 parents of infants in a single practice to receive a booklet on child-care followed by a visit from a health visitor, or usual care [57] There was no impact on use of healthcare services, and parents in the intervention arm reported lower levels of feeling confident and knowledgeable than in the control arm. We will measure parental enablement, satisfaction and reassurance, as well as serious adverse outcomes such as complications and hospitalisations.

#### **Design issues**

One central issue relevant to the selection of study design was whether to conduct an efficacy or an effectiveness evaluation. A narrowly defined, closely controlled trial may have allowed us to show an effect that would not be shown in a pragmatic trial. However, such a trial would need to be followed by a further pragmatic trial to show whether the intervention is effective 'in real life general

practice'. We have therefore decided to use a pragmatic trial design with broad inclusion criteria. We excluded children under six months of age because symptoms can be more difficult to interpret in very young children, and younger children have higher rates of complications [58]. Children over fourteen years of age were excluded because older children are less likely to consult [3] and be prescribed antibiotics [16]. A disadvantage of a pragmatic approach is an inability to control fidelity of intervention delivery, and this may result in an underestimation of any effect. We will however attempt to gain an understanding of how and whether the intervention was used through the process evaluation.

A further key decision regarding the design of the trial was whether to use an individually or cluster randomised design. Individually randomised trials are generally preferred because cluster trials suffer from a loss of power due to clustering effects. However, since the intervention in this case involves not just the booklet, but a change in the process of the consultation, an individually randomised trial would result in a risk of contamination of intervention delivery. It is not feasible for a clinician who has received training in using the booklet and communicating within the consultation, and has discussed the booklet with some parents, to switch between using this approach and 'usual care' at random.

The use of a cluster design can lead to selection bias at either the level of cluster or the individual. Practices who agree to take part in the study may find that they no longer wish to participate, leading to attrition bias. This would be of greater concern if there is differential drop-out of practices; for example if practices randomised to the control arm are less likely to recruit (resentful demoralisation). We aim to minimise attrition by maintaining regular contact and providing encouragement to all randomised practices, and will monitor and report on the attrition of clusters. Selection bias can also occur in cluster randomised trials where those who are recruiting participants are aware of the allocation given to their cluster [59]. We are not able to blind practices to their allocation as their use of the booklet within the consultation forms part of the intervention. We have attempted to minimise the risk of selection bias by asking practices to recruit sequential eligible patients, and we are trying to measure any selection bias by asking practices to record non-identifiable data on all 'potentially eligible' patients (i.e. all patients who have been given an information sheet about the study, including those who are deemed ineligible, do not consent, or are not recruited for other reasons).

#### **Other potential sources of bias**

Outcomes will be measured primarily through a telephone-administered questionnaire at two weeks. It will

not be possible to ensure that the interviewer remains completely blinded to study arm due to the possibility of participants discussing receipt of a booklet during their consultation. However, in order to minimise the risk of information bias, interviewers will not have any information about allocation, and questions will be devised to minimise the chance of participants disclosing which group they are assigned. If a participant discloses their allocation, the interviewer will record this so that these participants can be compared to those in which the interviewer remains blinded to allocation.

Similarly, it was not possible to blind participants to grouping. A 'placebo' booklet was considered. However, use of any booklet is likely to change a consultation, and we wish to assess effectiveness. In order to minimise reporting bias, participants will not be provided with specific information about the intervention or the outcomes being measured. Instead, information sheets state that the study team is interested in determining whether, "the type of information, and the way in which a primary care clinician (GP or practice nurse) communicates this information, can have an effect on your child's illness and the ways in which you deal with it."

#### **Use of web-based training**

A novel aspect of our study will be the use of the Internet to provide training for practices. A clear advantage of this approach is that it precludes the need for a practice visit by the study team, and therefore makes recruitment of practices over a large geographical area possible. In addition, providing training on-line allows clinicians to complete the training at a time and place of their choosing, and at their own pace. Disadvantages of this approach include the time and cost of developing the training; we produced videos, recorded audio-clips, and developed shockwave animated objects for inclusion on the site. Other problems include the loss of face-to-face contact with clinicians, which is likely to have an impact on recruitment, and challenges in measuring training process and outcomes. With regard to the latter, because each clinician is provided with a unique log-in password, we will be able to monitor which pages they access and the amount of time spent accessing the site. This, in addition to written feedback which is requested from all users, will provide us with a measure of amount of training accessed, and their opinions of it.

#### **Conclusion**

This study aims to evaluate the effect of a booklet developed specifically for use within consultations involving children with RTIs, on re-consulting for the same illness episode and antibiotic prescribing. We will determine whether changes in antibiotic use and re-consultation are achieved at the expense of patient satisfaction, and will

determine whether the interactive booklet enhances patient enablement. We will evaluate the effect on medicalisation over the subsequent year. If this intervention is found to be effective, even small changes for the commonest acute consultation could have major effects on help seeking behaviour and free up consultations in primary care for other conditions. If not effective, resources spent on developing, printing, and distributing leaflets and booklets on respiratory tract infections in children can be re-directed, and the research agenda can be re-focused. We believe that this is the first evaluation of the use of written material on respiratory tract infection in children during the consultation.

### Competing interests

The authors declare that they have no competing interests.

### Authors' contributions

NF is the principal investigator and wrote the first draft of the paper. KH helped design the study and is the study statistician. SS helped design the study and manage the trial, FW contributed to the development of the intervention and helped manage the trial, JN helped with data collection and contributed to the trial management, CB conceived of the study, helped design the study, and provided overall leadership to the project. All authors contributed to drafting the manuscript and approved the final manuscript.

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## **Appendix 8 – Case report form**

## Patient Encounter Sheet

Clinician name: <input type="text" value=" &lt;automatic&gt;"/>	Site number: <input type="text" value=" &lt;automatic&gt;"/>
---	--

### BOX A: Complete for ALL POTENTIAL PARTICIPANTS

Date of consultation:	<input type="text" value=" / /"/> dd / mm / yyyy												
<b>Symptoms</b>	<table border="0"> <tr> <td><input type="checkbox"/> Cough</td> <td><input type="checkbox"/> Runny nose</td> <td>Duration of illness</td> <td><input type="text" value=""/> days</td> </tr> <tr> <td><input type="checkbox"/> Earache</td> <td><input type="checkbox"/> Fever</td> <td>Age</td> <td><input type="text" value=""/> years</td> </tr> <tr> <td><input type="checkbox"/> Sore throat</td> <td><input type="checkbox"/> Looks unwell</td> <td>Gender</td> <td><input type="text" value=""/> M / F</td> </tr> </table>	<input type="checkbox"/> Cough	<input type="checkbox"/> Runny nose	Duration of illness	<input type="text" value=""/> days	<input type="checkbox"/> Earache	<input type="checkbox"/> Fever	Age	<input type="text" value=""/> years	<input type="checkbox"/> Sore throat	<input type="checkbox"/> Looks unwell	Gender	<input type="text" value=""/> M / F
<input type="checkbox"/> Cough	<input type="checkbox"/> Runny nose	Duration of illness	<input type="text" value=""/> days										
<input type="checkbox"/> Earache	<input type="checkbox"/> Fever	Age	<input type="text" value=""/> years										
<input type="checkbox"/> Sore throat	<input type="checkbox"/> Looks unwell	Gender	<input type="text" value=""/> M / F										
<b>Eligible for inclusion?</b>													
Age	Between 6 mo. & 14 yrs												
Diagnosis	Acute respiratory tract infection (including URTI, sore throat, otitis media, sinusitis, acute cough, LRTI, bronchitis, croup)												
No exclusion criteria	<p>If none of the exclusions below apply tick here: <input type="checkbox"/></p> <ul style="list-style-type: none"> <li>▪ Diagnosed with <b>asthma</b> or currently <b>using inhalers</b></li> <li>▪ Current illness <b>severe</b> (pneumonia, Quinsy, etc.)</li> <li>▪ Needs immediate <b>hospital admission</b></li> <li>▪ Serious <b>concomitant illness</b> (malignancy, cystic fibrosis, etc.)</li> <li>▪ <b>Already seen</b> for this illness episode</li> <li>▪ Patient or other member of family <b>previously recruited</b></li> <li>▪ <b>Unable to follow</b> study protocol</li> </ul>												

Only complete Box B if all three of the above are ticked

**BOX B:**

Patient recruited (complete Box C)	<input type="checkbox"/>	Consent declined	<input type="checkbox"/>	Not recruited for other reasons (no time, etc.)	<input type="checkbox"/>
------------------------------------	--------------------------	------------------	--------------------------	---	--------------------------

Only complete Box C if consent obtained

**BOX C:**

Child's name:	<input type="text"/>	Child's date of birth:	<input type="text" value=" / /"/> dd / mm / yyyy
Name of primary carer / parent:	<input type="text"/>	Mobile number:	<input type="text"/>
Home number:	<input type="text"/>	Alternative contact number:	<input type="text"/>
Address:	<input type="text"/>		
		Postcode:	<input type="text"/>

Please **FAX** this form and signed consent forms **today** to: **029 2068 7219**  
If you have any questions, please call Sue Evans on 029 2068 7168.

**Thank you!**

## Appendix 9 – Telephone administered questionnaire

Patient Name & ID:	
Date:	
In the two weeks following the first time your child was seen for this illness (the time when they enrolled in the study):	
1. Has your child recovered from their illness yet?	Y / N
2. If yes, roughly how many days, from the time they were first seen by the doctor or nurse, did it take for them to recover?	
Since they were entered into the study two weeks ago, have they had to go back to the GP, or have you received telephone advice, seen any other healthcare provider or taken them to the hospital?  If yes, how many times have they:	<i>If no, skip to question 15</i>
3. Been seen by a GP in the surgery?	
4. Been seen by a nurse or nurse practitioner in the surgery?	
5. Received telephone advice from a GP or nurse in your surgery, regarding this illness?	
6. Been seen by an out of hours doctor for this illness?	
7. Received telephone advice about this illness from an out of hours doctor?	
8. Been seen any other healthcare professionals regarding this illness (i.e. Health Visitor or Alternative practitioner)?	
9. If other healthcare professionals were consulted, please provide details (i.e. type of practitioner)	
10. Been seen at A and E for this illness?	
11. Was your child admitted to hospital for any reason during the first two weeks after they were seen?	
12. If yes, do you feel it was something to do with the initial illness?	
13. How many nights did they spend in hospital?	
14. Notes on hospitalisation:	
15. When you first saw the GP or nurse, were antibiotics prescribed? If so, were you advised to start using them straight away or to 'delay' the use of them? (Indicate 'delayed' if a prescription was issued but the parent was told not to use it straight away.)	Yes No Delayed
16. Have antibiotics been prescribed at any time in the two weeks since the first time you were seen?	Y / N
17. If antibiotics have been prescribed at any point, have they been taken?	Y / N
Has your child taken any of the following for this illness? Were they prescribed?	
18. Paracetamol / Calpol	Taken Prescr.
19. Ibuprofen / Nurofen:	
20. Cough mixture:	
21. Other medication (describe):	
22. Thinking about the first time you saw the doctor or nurse for this illness, how satisfied were you with the visit?	Very satisfied Satisfied Neutral Dissatisfied Very dissatisfied

23. How useful was any information you received from this first visit?	Very useful Useful Neutral Unhelpful Very unhelpful
24. How reassured did you feel after seeing the GP or nurse?	Very reassured A little reassured Not reassured
As a result of seeing the doctor or nurse (the time when you agreed to join the study), do you feel you are able to:	
25. Understand your child's illness?	Much better Better Same Less
26. Cope with your child's illness?	Much better Better Same Less
27. Keep your child healthy?	Much better Better Same Less
As a result of seeing the doctor or nurse, do you feel you are:	
28. Confident about your child's health?	Much more More Same Less
29. Able to help your child?	Much more More Same Less
30. If your child were to have a similar illness again, do you think you would consult with a GP or nurse the next time?	Y / N
31. How many days, if any, has your child had to take off school as a result of this illness?	
32. How many days, if any, have you or anyone else had to take of work during this illness?	
33. What is the occupation of the person who has had to take most time off work? (describe)	
34. Did you have to arrange additional childcare as a result of this illness? If so, how much did it cost?	
If there have been no follow-up visits then skip questions 35 - 37. Not including the first time your child was seen for this illness:	
35. Have any trips to see a healthcare professional for this illness involved driving? If so, what is the total amount of time you have spent driving for these visits? (In minutes)	
36. Did you have to pay for parking? If so, how much?	
37. Did you have to pay other transportation costs? If so, how much?	
After the study has been completed we would be happy to send you a summary of the study results. Would you like us to do this?	Y / N
Interviewer: Indicate whether you were aware, at any point in the interview, which group the patient was randomised to.	Y / N

## **Appendix 10 – Postal questionnaire**

# Study Questionnaire

Child's name:

Name of person who took child:

ID: 1

Name of parent or legal guardian,  
if different from above:

We would like to know if your child needed to be seen again during the two weeks following the time when you agreed to take part in the study. For your child, the two week period that we are interested in is from when they were first seen on 05/03/2007 up until 19/03/2007.

1. During this two week period, did you have to take your child back to the surgery to be seen again about the same illness?

Please circle your answer.

YES / NO → If no, go to question 3.

2. Please tell us how many times during this two week period you had to go back and see each of the following about this illness:

Please write the number of times seen in each box.

GP

Practice nurse

Health visitor


3. During this two week period, did your child have to be seen at an "Out of hours" or "Emergency" Clinic for this illness?

YES / NO

4. During this period, did your child have to be seen in an "Accident and Emergency" or "Casualty" Department for this illness?

YES / NO

5. Did your child have to be admitted to hospital as a result of this illness?

YES / NO

If Yes, please tell us about this, including what the diagnosis was, and how many nights they had to spend in hospital?

.....  
.....

We are also interested in whether your child was prescribed antibiotics for this illness.

6. When your child was seen at the surgery on 05/03/2007 (when you agreed for them to be in the study), were antibiotics prescribed?

YES / NO

7. Were antibiotics prescribed at any other time in the two weeks following this consultation?

YES / NO

Thank you very much for your time. Please return the questionnaire in the enclosed envelope or post to:

## Appendix 11 – One-year follow-up data collection form

Address

«Address2»

10 March 2010

Dear Name:

It has now been just over a year since you and your practice kindly recruited patients into the EQUIP study. Two key questions the study hopes to answer are whether the intervention has any impact on longer term consulting rates, and what the impact on consultation length was. To answer these questions we need your help.

For each of the children you recruited into the study we need information about the number of consultations they have had in the year following their enrolment. We need to know how many surgery consultations, telephone consultations, home visits, and out-of-hours consultations they have had in the year, and we need to know how many of these consultations were for respiratory tract infections (RTIs). The consultation information we need for each patient is summarised in the table below.

	Surgery consultations	Telephone consultations	Home visits	Out-of-hours consultations
All conditions (including RTIs)				
Consultations for RTIs				

If you prefer, you can send us printouts of all the consultations that each patient had in the one year period from the date they were enrolled, and we will summarise the information for you. If you decide to do this, please ensure that you send us information about out-of-hours consultations as well as those that were conducted by clinicians from the surgery.

We also need information about the length of the consultation in which each of the children was recruited into the study. The best way of providing us with this data is to let us know the start and end times of the consultation. As far as I know all GP computer systems record consultation start and end times, and it should be fairly straight forward to extract this information. Any records sent will be kept confidential and destroyed once the data has been extracted.

We have enclosed a list of all the patients recruited by your practice and the dates that they were recruited, and space for entering the number of consultations in each category and the consultation start and end times (or length).



Please send all data by fax or post using the contact details at the top of this letter. If you have any questions or need advice about extracting the data from your computer system please get in contact with us.

The EQUIP study has been a highly successful primary care randomised controlled trial thanks to your help. Please help us collect this final, but important, set of data.

Many thanks,

Dr Nick Francis  
Principal Investigator  
The EQUIP Study

# EQUIP Study *One year follow-up data*

For each patient we need to know the total number of surgery consultations telephone consultations, home visits, and out-of-hours consultations, for each patient's follow up year. We would also like to know how many of these consultations were for respiratory tract infections (URTI, common cold, cough, LRTI, bronchitis, pneumonia, chest infection, sore throat, otitis media, sinusitis).

**Example** *For a child that was seen twice in the surgery, once for a sore throat and once for a rash, and once in an out-of-hours centre for a cold, you would complete the grid as follows:*

	<i>Surgery consultations</i>	<i>Telephone consultations</i>	<i>Home visits</i>	<i>Primary care out of hours consultations</i>
<i>Any condition including RTI</i>	<i>2</i>	<i>0</i>	<i>0</i>	<i>1</i>
<i>RTI</i>	<i>1</i>	<i>0</i>	<i>0</i>	<i>1</i>

In addition, we need to know the length of the consultation in which the patient was entered into the study - this is the consultation that occurred on the 'Consultation date' listed below. Most GP computer systems will record the start and end times for consultations; please provide us with these times or a length for the consultation.

<i>Practitioner</i>		<i>Consultation date</i>	<i>End date for follow-up period</i>	<i>Consultation</i>	
<i>Patient's name</i>	<i>Date of birth</i>			<i>start time OR length</i>	<i>End time</i>

	<i>Surgery consultations</i>	<i>Telephone consultations</i>	<i>Home visits</i>	<i>Out of hours consultations</i>
<i>Any condition (including RTI)</i>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<i>RTI</i>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

*Thank you for your help!*

*Form completed by:* \_\_\_\_\_

Please fax this report to:

*Date:* \_\_\_\_\_

**Department of Primary Care and Public Health 029 2068 7612**

## Appendix 12 – Email from a participating GP about a possible adverse event

I have participated with interest in the Equip study, trialling the use of a booklet of information for parents of children with upper respiratory tract illness.

I would like to let you know about a seriously dysfunctional consultation that occurred with one of my patient whom I had enrolled into the trial.

The presentation was of a child who had been unwell with a fever for six days. She was eligible for the trial and her mother agreed to participate and signed the consent form.

I elicited that nature of the problem and enquired about the expectations for the consultation. (Fever and off food, and something to make the child better.) I examined the child carefully and obtained excellent cooperation from the infant. I then proceeded to consider the history and examination findings with the mother, using the relevant sections in the booklet, in accordance with the training I had undertaken on the trial web site. There was no identifiable focus of infection and the child was not in need of additional investigation or referral and I indicated my expectation that the child would recover spontaneously and could continue to be treated with paracetamol and ibuprofen in combination.

Abruptly during my explanation, the mother revealed negative and hostile feelings and declared that if I was going to do nothing to help her child, she would waste no more of my time, got up and left the room.

I had a colleague, a dermatologist, sitting in with me for that session. The dermatologist was eastern European and so was the patient. The dermatologist suggested that there may have been a gap between the cultural expectations of the patient and me as the doctor, which I had not identified.

A few days later, the child was still unwell and her mother contacted the surgery for an "on the day" appointment and received a triage call from a colleague who agreed that she needed to be seen again. I saw the child and her mother and again elicited a history and examined the child carefully. The mother rejected my opinion that an antibiotic was not indicated and again appeared hostile. I commented gently on my observation that she did not appear to trust my judgement and she stated bluntly that she did not. I asked her what she thought a doctor from her own country might have done (she is of eastern European extraction) and she said "at least he would have offered me a light antibiotic". I offered her a second opinion with my colleague and she accepted this offer.

I explained to my colleague (who had dealt with the earlier triage call) and she saw the infant and mother immediately. She could not find any focus of infection but agreed to prescribe an antibiotic on the grounds that one tympanic membrane could not be seen as it was obscured by wax which might be hiding otitis media and that the child had now had a fever for eight or nine days and had clearly lost weight.

Such a profound breakdown in communication and dissatisfaction is exceptionally rare in my consultations. I have a particular interest in consultation skills and have developed sophisticated strategies for eliciting ideas concerns and expectations. I am used to winning the trust and confidence of my patients and I have a large following of patients who see me as their preferred doctor, especially for paediatric problems. I was left feeling distressed and shocked by my experiences and the mother was very unhappy with the service that she had received.

I have reflected at length on the episode and discussed it with colleagues.

All this may of course have happened even if I had not involved the patient in the study, but there is clearly a coincidence between the events and my participation. Cause and effect cannot be established. However, I have noticed that the use of the booklet changes my consultation style because I am aware that I am following some externally imposed rules and protocols. I suspect that my "antennae" in the consultation were being interfered with by the tasks that I knew that I had to complete for the study. The consultation had at times become more focussed on the doctor's agenda and I may have missed an opportunity to elicit more thoroughly the patient's perceptions. Furthermore, I notice that one prescribing strategy that I employ: the issue of a "delayed prescription" (in which I hand over a prescription for an antibiotic but suggest that the parent takes responsibility for monitoring the child during an anticipated interval during which recovery could reasonably be expected without using the medication) has not been the outcome of any of the five consultations that I have so far undertaken in the study. I suspect that the presumption of non-prescription of an antibiotic grows in the minds of both the doctor and the patient (parent) and may dominate the consultation, leading to the perception of an intransigent doctor and a patient (parent) thwarted in their expectation.

I suggest therefore, that I may have been involved in a "side effect" of the intervention and offer this report in the spirit of a "yellow card".

I suggest that for experienced doctors with established routines and strategies, learning to accommodate a potent intervention seamlessly and without disturbing effective consultation may take rather more than an on-line training session.

I have found the information in the booklet of interest for myself and for my patients and I will go on using the information and diagrams in the future. I believe it can help to reduce inappropriate prescribing and improve parents' knowledge and understanding of the natural history and management of respiratory illness. As an intervention, the study may not be entirely without adverse effects. Perhaps informed consent for participation by both doctors and patients (parents) needs to take this into consideration.

## **Appendix 13 – Publication of the main trial results**

Francis NA, Butler CC, Hood K, Simpson S, Wood F, Nuttall J. Effect of using an interactive booklet about childhood respiratory tract infections in primary care consultations on reconsulting and antibiotic prescribing: a cluster randomised controlled trial. *BMJ*. 2009;339:b2885.

## Effect of using an interactive booklet about childhood respiratory tract infections in primary care consultations on reconsulting and antibiotic prescribing: a cluster randomised controlled trial

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### ABSTRACT

**Objective** To establish whether an interactive booklet on respiratory tract infections in children reduces reconsultation for the same illness episode, reduces antibiotic use, and affects future consulting intentions, while maintaining parental satisfaction with care.

**Design** Pragmatic cluster randomised controlled trial.

**Setting** 61 general practices in Wales and England.

**Participants** 558 children (6 months to 14 years) presenting to primary care with an acute respiratory tract infection (7 days or less). Children with suspected pneumonia, asthma or a serious concomitant illness, or needing immediate hospital admission were excluded. Three withdrew and 27 were lost to follow-up, leaving 528 (94.6%) with main outcome data.

**Interventions** Clinicians in the intervention group were trained in the use of an interactive booklet on respiratory tract infections and asked to use the booklet during consultations with recruited patients (and provide it as a take home resource). Clinicians in the control group conducted their consultations as usual.

**Main outcome measures** The proportion of children who attended a face-to-face consultation about the same illness during the two week follow-up period. Secondary outcomes included antibiotic prescribing, antibiotic consumption, future consulting intentions, and parental satisfaction, reassurance, and enablement.

**Results** Reconsultation occurred in 12.9% of children in the intervention group and 16.2% in the control group (absolute risk reduction 3.3%, 95% confidence interval -2.7% to 9.3%,  $P=0.29$ ). Using multilevel modelling (at the practice and individual level) to account for clustering, no significant difference in reconsulting was noted (odds ratio 0.75; 0.41 to 1.38). Antibiotics were prescribed at the index consultation to 19.5% of children in the intervention group and 40.8% of children in the control group (absolute risk reduction 21.3%, 95% confidence interval 13.7 to 28.9),  $P<0.001$ ). A significant difference was still present after adjusting for clustering (odds ratio

0.29; 0.14 to 0.60). There was also a significant difference in the proportion of parents who said they would consult in the future if their child developed a similar illness (odds ratio 0.34; 0.20 to 0.57). Satisfaction, reassurance, and parental enablement scores were not significantly different between the two groups.

**Conclusions** Use of a booklet on respiratory tract infections in children within primary care consultations led to important reductions in antibiotic prescribing and reduced intention to consult without reducing satisfaction with care.

**Trial registration** Current Controlled Trials  
ISRCTN46104365

### INTRODUCTION

Respiratory tract infections are the most common reason for patients to consult in primary care, with children consulting more than any other age group.<sup>1</sup> One in five children who consult for a respiratory tract infection returns during the same illness episode, and many of these visits are unnecessary.<sup>2,3</sup> Unnecessary re-consulting represents an opportunity cost and can increase the pressure on clinicians to prescribe antibiotics. Acute cough in children alone is estimated to cost the NHS at least £31.5m (€36.8m; \$51.4m), with most of this cost arising from consultations with general practitioners.<sup>4</sup>

Complications of respiratory tract infections are rare, and there is little or no benefit from treatment with antibiotics.<sup>5-9</sup> Guidelines of the National Institute for Health and Clinical Excellence (NICE) recommend against the immediate use of antibiotics for most children who have respiratory tract infections, and promote effective communication and information provision including an indication of the likely duration of illness.<sup>10</sup> Nevertheless, antibiotics continue to be overprescribed for these illnesses,<sup>11,12</sup> with children receiving more antibiotics than any other age group.<sup>13</sup> Prescribing for non-specific upper respiratory tract infections, which declined in the late 1990s, is

once again increasing.<sup>14</sup> Unnecessary antibiotic use wastes healthcare resources, encourages further consulting in the future for similar illnesses,<sup>15</sup> contributes to the problem of antibiotic resistance, and unnecessarily exposes patients to risk of adverse effects.<sup>16</sup>

Parental beliefs, fears, and expectations play an important part in both consulting behaviour and determining whether an antibiotic is prescribed.<sup>17</sup> Parents fear serious illness, and worry that they will not be able to recognise the symptoms.<sup>18</sup> Few are aware of the likely risks and benefits from antibiotic treatment and the normal duration of illness.<sup>19</sup> Providing information on recognising the signs of serious illness and the likely duration of illness can reduce anxiety, increase confidence, and empower parents to manage their child's illness without needing to consult a healthcare professional. A nurse administered educational intervention aimed at helping parents cope with ear pain in the United States resulted in a reduction in consultations for ear pain over the following year.<sup>20</sup> Patient information leaflets for adults with lower respiratory tract infections that describe expected duration of illness and suggest simple self-help measures reduce reconsultations<sup>21</sup> and antibiotic prescribing.<sup>22</sup>

Communication within the consultation is central to addressing parental concerns and expectations, and helps parents to manage their child's illness effectively and safely. Clinicians seldom explicitly ask parents about their expectations about antibiotic treatment,<sup>23</sup> and overestimate the expectation for antibiotics.<sup>24</sup> When clinicians believe that patients (and parents) expect antibiotics, they are more likely to prescribe them.<sup>17</sup> Clinicians often tell parents that their child should recover in a few days, although children usually have symptoms for substantially longer than this.<sup>25</sup> Setting realistic expectations about the likely duration of illness could reduce parental anxiety and rates of visits. Furthermore, parents value a thorough examination, explanation, reassurance, and advice or guidance more than a prescription for antibiotics.<sup>24,26</sup>

We therefore set out to establish whether training clinicians in the use of an interactive booklet, designed to enhance communication within the consultation, and act as a take home resource for parents, would have an effect on rates of reconsultation and antibiotic prescribing. A cluster design was needed, since the intervention was partly directed at the clinicians in the practice. Clinicians who had received training in use of the booklet, and through its use had learnt from its content, would therefore have been unable to not use this knowledge in each consultation where a patient was recruited.

## METHODS

The methods for this cluster randomised controlled trial have been described in detail elsewhere,<sup>27</sup> and are summarised below.

Half of all general practices from nine local health boards in Wales (n=147) were randomly selected to be sent information about the study (our research group was conducting another randomised controlled

trial assessing a related intervention and the other practices were sent information about that study). This procedure was followed by attempts to contact a general practitioner or practice manager in each practice. Telephone contact with a general practitioner or practice manager was successful for 81 practices. Sixty two practices in Wales agreed to take part, although only 49 of these returned a practice agreement and were subsequently randomised. Of the 49 randomised practices, 36 recruited study participants. In England, four primary care research networks agreed to help recruit practices. The total number of practices approached in these networks is not available. However, 38 practices in England verbally agreed to take part, 34 of these returned a practice agreement and were randomised, and 25 of the randomised practices recruited participants. Practices were randomised by a statistician using block randomisation with random block sizes and stratification by practice list size, antibiotic prescribing rate for 2005, and country.

Participating clinicians were asked to recruit sequential eligible children (6 months to 14 years) consulting with a respiratory tract infection (cough, cold, sore throat, earache for seven days or less) and their parents. Exclusions included children with asthma and those with serious ongoing medical conditions such as malignancy or cystic fibrosis.

## Sample size calculation

We calculated that we would need 524 participants recruited from 60 clusters (practices) in order to show a reduction in the proportion of children who reconsult from 20% to 10%, with 80% power, at a 5% significance level, and with an intracluster coefficient of 0.04. Our aim was to ask 60 practices to recruit ten children each (total of 600 participants) which would allow for loss to follow-up and missing data.

## The intervention

The intervention consisted of an eight page booklet on respiratory tract infections in children, designed to be used within the consultation and then provided to parents as a take home resource (see [www.equipstudy.com](http://www.equipstudy.com)). Online training on the use of the booklet was also provided for clinicians. The study booklet was developed through a multistage process which has been described elsewhere.<sup>28</sup> The online training described the content and aims of the booklet, and encouraged its use within the consultation to facilitate the use of certain communication skills, mainly exploring the parent's main concerns, asking about their expectations, and discussing prognosis, treatment options, and any reasons that should prompt reconsultation [http://?/?](http://?). Clinicians in practices randomised to the control group were asked to conduct the consultation in their usual manner.

## Measures

Baseline data, including age, duration of illness, and symptoms, were collected by participating clinicians

at the time of recruitment. We asked clinicians to collect non-identifiable data for all potentially eligible patients (including those who were not approached, those who were approached but were ineligible, and those who declined participation) to assess for possible selection bias. Follow-up was via a telephone administered questionnaire with the child's parent or guardian, 14 days after recruitment. Where a participant's parent could not be contacted on day 14, further attempts were made for at least three days. If still unsuccessful, the telephone number was checked with the relevant general practice and with directory inquiries, and if this approach was unsuccessful then a self completion questionnaire was sent to the parents. Follow-up measurements included reported consultations in primary and secondary care in the two weeks after recruitment, prescriptions for and use of antibiotics, intention to consult with a similar illness in the future, parental enablement (using a modification of the patient enablement instrument<sup>29</sup>), satisfaction with the index consultation, reassurance, and value of any information given to them during the index consultation. Telephone interviewers were blinded to treatment group and were asked to record any subsequent unblinding of allocation (such as a parent talking about receiving a booklet).

Primary outcome was a reconsultation during the two weeks after the index consultation. Antibiotic prescribing, antibiotic consumption, future consulting intentions, parental satisfaction, perception of the usefulness of information received, reassurance, and enablement were secondary outcomes.

#### Analysis

Data were analysed using Stata version 9 and MLwiN version 2.10. After checks for missing data and ranges, and double entry of a 10% sample of the case report

forms, Stata was used to obtain summary statistics and undertake univariate analyses. "Satisfaction" and "usefulness of information received" were measured using five point items, but their response distributions were highly skewed. For this reason, these items were transformed into binary outcomes, split into "very satisfied" or "satisfied" versus "neutral", "dissatisfied" or "very dissatisfied" and "very useful" or "useful" versus "neutral", "unhelpful" or "very unhelpful". Similarly, the outcome "reassured" was transformed from a three response item into a binary outcome, split into "very reassured" versus "a little reassured" or "not reassured". The enablement score was calculated in the standard way, but since one item had been excluded, possible scores ranged from 0 to 10. Enablement scores had a skewed distribution and were therefore converted into a binary outcome using a mid-range cutpoint of 5.

The primary analysis was intention to treat, conducted by fitting two level (practice and patient) random intercept logistic regression models using MLwiN. Similar models were fitted for the secondary outcomes.

After the initial analyses, sensitivity analyses were done by adding the stratifying variables (practice size, practice prescribing status, and country), age, duration of illness, and any symptoms found to be significantly associated in univariate analyses at the 10% level into each model as covariates. Exploratory analyses were conducted by including factors likely to affect reconsulting and antibiotic prescribing into these two models. The interaction factors were then examined to look for subgroup effects.

#### RESULTS

Eighty-three practices were randomised, and 61 of these recruited a total of 558 eligible patients between October 2006 and April 2008 (fig 1).

Intervention and control practices, and randomised practices that did and did not recruit participants, were similar in terms of list size, antibiotic prescribing history, and location (Wales or England) (table 1). Patients recruited by intervention and control practices were similar in terms of age, sex, duration of illness, and symptoms (table 1). Patients were recruited by intervention and control practices at a similar rate (fig 2). We achieved a follow-up rate of 94.6% (93.4% intervention, 95.8% control) for the primary outcome data. Telephone interviewers reported becoming aware of the participant's treatment group in 34 of 509 interviews (6.7%).

The number and proportion of patients experiencing each outcome, and odds ratios (with 95% confidence intervals) for the primary and secondary outcomes are shown in table 2. There was no significant difference between the intervention and control groups in the odds of reconsulting in primary care during the two weeks after registration. Children in the intervention group were significantly less likely to receive a prescription for antibiotics at the index consultation, less likely to take antibiotics during the first

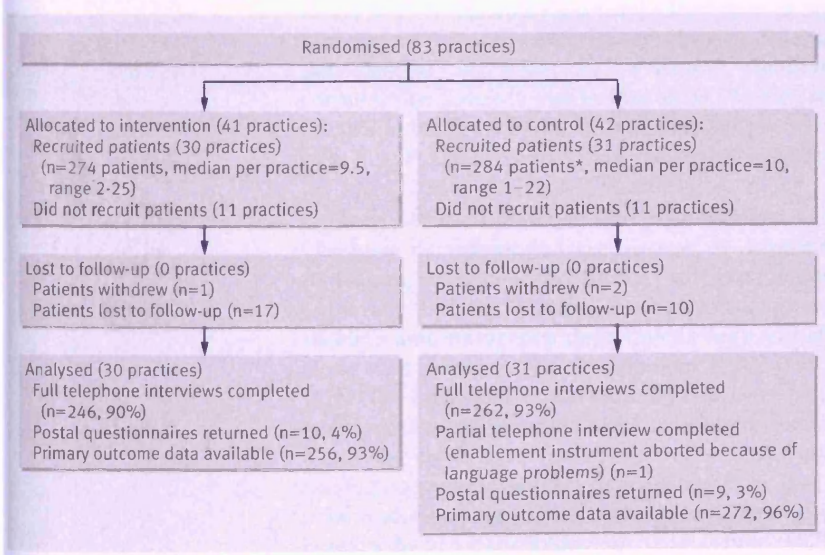


Fig 1 Study profile. \*One patient from the control group was subsequently found to have longstanding asthma and was therefore determined (after consultation with the trial steering committee) to have been "recruited in error" and has not been included as a recruited patient



**Table 1** | Baseline characteristics of randomised recruiting and non-recruiting practices, participating clinicians, and patients, by treatment group

	Intervention	Control
<b>Randomised, non-recruiting practices</b>	<b>11</b>	<b>11</b>
Median (IQR) list size	7000 (3680 to 12 000)	8300 (4300 to 9200)
No (%) above average prescribing practice	5 (45.5)	3 (27.3)
No (%) of practices in England	3 (27.3)	6 (54.6)
<b>Recruiting practices</b>	<b>30</b>	<b>31</b>
Median (IQR) list size	6750 (4400 to 9000)	6800 (3700 to 8700)
No (%) above average prescribing	9 (30.0)	10 (32.3)
No (%) of practices in England	14 (46.7)	11 (35.5)
Median (IQR) cluster size	9.5 (5 to 10)	10 (7 to 10)
<b>Participating clinicians</b>	<b>55</b>	<b>53</b>
No (%) of nurses	5 (9.1)	11 (20.8)
Proportion of patients recruited by a nurse	11.4%	19.4%
<b>Patients</b>	<b>274</b>	<b>284</b>
Mean (SD) age (years)	5.1 (3.9)	5.3 (3.8)
Male	45.3%	53.5%
Duration of illness, days (SD)	3.2 (1.7)	3.3 (1.8)
No (%) with symptom:		
Cough	173 (63.4)	167 (58.8)
Earache	74 (27.1)	69 (24.3)
Runny nose	85 (31.1)	97 (34.2)
Sore throat	89 (32.6)	112 (39.4)
Fever	103 (37.7)	109 (38.4)
Looks unwell	36 (13.2)	48 (16.9)

IQR=interquartile range. No=number.

two weeks, and their parents were less likely to report that they would consult in the future if their child had a similar illness. There were no significant differences in terms of satisfaction, level of reassurance, parental enablement, or the parent's rating of the "usefulness of any information received in the consultation." Similar results were found at the univariate level, with a non-significant difference in reconsulting (absolute risk reduction 3.3%, 95% confidence interval -2.7% to 9.3%,  $P=0.29$ ), and significant differences in antibiotic prescribing (absolute risk reduction 21.3%, number needed to treat 4.7,  $P<0.001$ ), antibiotic consumption (absolute risk reduction 20.6%, 95% confidence interval 12.7% to 28.5%, number needed to treat 4.9,  $P<0.001$ ), and future consulting intentions (21.1%, 13.1% to 29.2%, 4.7,  $P<0.001$ ).

There was no significant intervention effect when telephone consultations were counted as reconsultations along with face to face primary care consultations (odds ratio 0.81; 0.47 to 1.42), or when consultations at accident and emergency departments were included along with primary care consultations (0.85; 0.48 to 1.51). The intervention had a similar effect size on the antibiotic outcomes of receiving a prescription for antibiotics for immediate use at the index consultation (excluding prescriptions for delayed use; 0.26; 0.11 to 0.62) and receiving an antibiotic prescription at any point in the two week follow-up (0.31; 0.16 to 0.62).

The sensitivity analyses for the main reconsultation outcome and the antibiotic prescribing outcome did not result in any meaningful changes to the results

(that is, there were no significant intervention effects in the sensitivity analyses for the reconsultation outcome and similar significant effects for all analyses with the antibiotic prescribing outcome).

#### Subgroup analyses

No significant interaction effects were seen in the reconsultation models. In the antibiotic prescribing model, the intervention was more effective in above-average prescribing practices (table 3). There were no other significant interaction effects.

#### Adverse events

Seven patients (three in the intervention group and four in the control group) were subsequently admitted to hospital or observed in a paediatric assessment unit. One patient in the control group had a longstanding diagnosis of asthma, and as such was excluded (after discussion in the trial steering committee). The longest hospital admission (two nights) was a patient in the intervention group who had febrile convulsions. The remaining admissions were one night or less.

#### Comparing recruited and non-recruited patients

Ninety three patients were not recruited into the study (50 were ineligible, 27 declined participation, and 16 were not recruited because of a lack of time in the consultation or for other unspecified reasons). There were no significant differences between recruited and non-recruited patients in terms of age or presenting symptoms; however, cough was more common in non-recruited patients (71.9% v 61.0%). Of the non-recruited patients, there was no significant difference in cough between the intervention and control groups. Previous duration of illness was higher in non-recruited patients than in recruited patients, although this finding was not surprising, since a duration of illness of more than seven days was a common reason for exclusion from the study.

#### DISCUSSION

Clinicians' use of an interactive booklet on respiratory tract infections in children within primary care consultations resulted in a significant reduction in antibiotic prescribing and consumption and high levels of parental satisfaction. Use of the intervention did not result in a

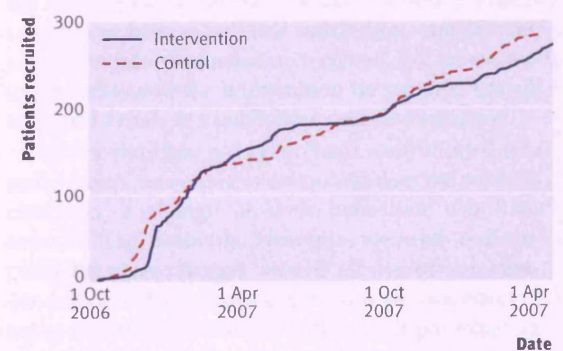
**Fig 2** | Recruitment rates in the two groups

Table 2 | Effect of the intervention on patient outcomes

	No (%) experiencing the outcome		Odds ratio from multilevel modelling (95% CI)
	Intervention	Control	
<b>Outcomes with data collected from telephone administered and postal questionnaires</b>			
No of patients	256	272	
Primary outcome: primary care reconsultation within first two weeks* (intracluster correlation coefficient=0.06)	33 (12.9)	44 (16.2)	0.75 (0.41 to 1.38)
Antibiotic prescribed at index consultation (intracluster correlation coefficient=0.24)	50 (19.5)	111 (40.8)	0.29 (0.14 to 0.60)
<b>Outcomes with data collected from telephone administered questionnaire only</b>			
No of patients	246	263	
Antibiotics taken within first two weeks (including antibiotics prescribed after index consultation)	55 (22.4)	111 (43.0)	0.35 (0.18 to 0.66)
Parent intends to consult if their child has similar illness in future	136 (55.3)	201 (76.4)	0.34 (0.20 to 0.57)
Parental enablement score (≥5)	99 (40.2)	94† (35.9)	1.20 (0.84 to 1.73)
Satisfaction‡	222 (90.2)	246 (93.5)	0.64 (0.33 to 1.22)
Reassurance§	177 (72.0)	198 (75.3)	0.84 (0.57 to 1.25)
Usefulness of information received¶	210 (85.4)	224 (85.2)	1.01 (0.60 to 1.68)

\*Parental report that child attended a face to face consultation with a primary care clinician in their general practice, or with an out-of-hours provider, in the two weeks after registration.  
†No=262 for this group as one parent was unable to complete enablement questions because of language problems.  
‡Proportion of parents who reported being very satisfied or satisfied with the consultation.  
§ Proportion of parents who reported feeling very reassured after their consultation.  
¶Proportion of parents who reported that information they received in the consultation was very useful or useful.

significant reduction in the proportion of children who reconsulted in the two weeks after the index consultation. However, fewer parents in the intervention group said that they would consult in the future should their child develop a similar illness. No significant differences were seen in terms of parental satisfaction, reassurance, enablement, or perception of the usefulness of any information received about their child's illness.

#### Strengths and limitations of the study

This was an adequately powered randomised controlled trial. Practices were recruited from throughout Wales and England and were broadly representative of UK general practice. The results of this study are therefore likely to be highly generalisable to UK general practice. The stratified randomisation procedure helped ensure practices in both groups were similar in terms of size, location, and historical antibiotic prescribing rate. We achieved the target sample for both clusters (general practices) and patients, with a high follow-up rate.

Cluster randomised designs can increase risk of selection bias. Our intervention was aimed not only at individual patients, but also at the primary care clinicians (through the online training). For this reason, an individually randomised trial was not possible: once trained in new consulting skills, clinicians cannot switch back to their untrained state. Selection bias can occur at the level of the cluster (that is, through differential dropout) or the individual. There were 11 practices in each arm of the trial that did not recruit any participants. Of these 22 practices, there were no significant differences in terms of list size, historical prescribing rate, or proportion located in Wales or England. We asked all participating clinicians to identify sequential eligible patients, and to record non-

identifiable data for all those who were not recruited, in order to look for evidence of selection bias at the individual level. We found no important differences in the patients who were and were not recruited or between the patients who were not recruited by clinicians in the intervention and control groups. Similar recruitment rates in the two groups also suggest minimal selection bias.

The non-significant difference in scores of parental enablement and usefulness of information received are surprising and seem inconsistent with the significant reduction in the proportion of parents stating that they would consult with a future similar illness. The patient enablement instrument was designed for first person use in routine general practice consultations and might not have been sensitive enough for measuring changes in parental enablement two weeks after the consultation.

Clinicians in the control group might have altered their behaviour (towards providing more information than usual) as a result of their participation in the study, which could have attenuated any effect that changes in the behaviour of doctors in intervention practices might have had on parental satisfaction, enablement, and usefulness of information received. We are exploring the effects of the intervention on parental knowledge and beliefs in a qualitative process evaluation.

Neither clinicians nor participants were blinded as to study group. As our intervention was directed partly at clinicians, a change in their behaviour was both expected and desirable. However, we need to distinguish between changes related to use of the intervention and changes associated with an awareness of being observed (Hawthorne effect). All participating clinicians were provided with information about the aims of the study. However, antibiotic use was listed

fourth in a long list of outcome measures and is therefore unlikely to have resulted in meaningful changes in prescribing behaviour. The effect of the intervention on antibiotic prescribing was not modified by practice location, which, given that many practices in Wales would be aware of the research group's interest in antibiotic prescribing, suggests that the Hawthorne effect was unlikely to be playing a significant part. Clinicians did not have any involvement in measuring outcomes, and are therefore unlikely to have contributed to ascertainment bias. Children (and their parents) were not blinded to treatment group. However, practices were instructed not to inform participants of the group to which they had been assigned before obtaining consent. Telephone interviewers were blinded to trial group in 93% of all interviews.

Although we recognise that interventions are not always delivered as planned in pragmatic trials, we did not measure treatment fidelity because we wanted the assessors to remain blinded to study group where possible. However, suboptimum fidelity of intervention delivery is likely to dilute the treatment effect and therefore could have led to a type II error regarding reconsultations, but is unlikely to have led to a type I error regarding the positive findings.

There were unequal numbers of nurses in the study groups (and thus patients recruited by nurses). We believe that this discrepancy was due to chance. We found no association between clinician's profession (doctor or nurse) and either reconsultations or antibiotic prescribing, either at a univariate level or using multilevel modelling, and therefore believe that this did not have an important effect on our results.

#### Comparison with other published work

Our findings are consistent with those of Macfarlane and colleagues who found that the use of a leaflet on lower respiratory tract infection in adults resulted in a reduction in antibiotic use by nearly 25%.<sup>22</sup> However, Macfarlane and colleagues have also shown a reduction in reconsultations from use of a leaflet,<sup>21</sup> whereas our results did not show a significant reduction. This finding might be because the underlying reconsultation rate in our study was lower than that found by Macfarlane and lower than that used in our sample size calculation. This lower rate could indicate societal changes in knowledge or beliefs over time and might be much closer to a desirable level of reconsulting, and therefore more difficult to reduce. Certainly the 3.3% absolute difference found in our study was

substantially smaller than the 10% reduction we had considered to be clinically important. Although we did not identify any studies that used a booklet designed specifically for use in consultations on respiratory tract infections in children, studies that have evaluated sending information booklets on minor illnesses to patients' homes have generally found little effect on consultation rates.<sup>30-34</sup> A recent study in the United States found that a sustained, multi-faceted intervention, conducted over three years and aimed at reducing antibiotic prescribing in young children, resulted in minimal reduction in antibiotic use beyond underlying trends.<sup>35</sup> The intervention in this study included several printed and web-based educational materials but did not encourage interactive use of the material within the consultation. Use of a leaflet for patients with lower respiratory tract infections resulted in an increase in reconsultations in the first month, and no significant difference in use of antibiotics or satisfaction.<sup>36</sup> However, the leaflet in this study was brief, was not designed for interactive use in the consultation, and was provided in addition to verbal information about the natural history. A further United States study found that providing patients with a pack containing a pamphlet, a sticker, and a thermometer was associated with reduced consultation rates. However, this study was limited by non-random allocation and post allocation exclusion of patients.<sup>37</sup> Another study where parents were randomised to receive written materials on either antibiotic use or injury prevention found no reduction in antibiotic use in the families who received the intervention.<sup>38</sup> This finding could indicate the need to provide parents with positive messages (how best to manage the illness) rather than negative ones (don't use antibiotics).

#### Interpretation of the results

We found a statistically non-significant reduction in the proportion of children who reconsulted in the intervention group, which was considerably smaller than the 10% difference that was specified as clinically meaningful.

We did demonstrate statistically and clinically significant reductions in antibiotic prescribing and consumption, which have important implications for policy makers, practitioners, and ultimately patients. How the reduction in prescribing was mediated is not yet clear, but it was possibly through a combined effect on clinician and parental behaviour. Clinicians probably recognised the importance of changing their prescribing behaviour and felt that they had the resources to effectively achieve this.

A significant reduction in the proportion of parents who said that they would consult if their child had a similar illness in the future is encouraging and suggests that use of the intervention could have an effect on future consulting.

No differences were recorded in terms of satisfaction, reassurance, value of information received, or parental enablement. Reassuringly, a high level of satisfaction

**Table 3** | Effect of practice prescribing history and study intervention on probability of being prescribed an antibiotic

	Practice antibiotic prescribing history	
	Higher (above national average for 2005)	Lower (below national average for 2005)
Intervention	16.3%	15.4%
Control	64.1%	27.3%

Values show probability of being prescribed an antibiotic, calculated from coefficients derived from multilevel modelling.

**WHAT IS ALREADY KNOWN ON THIS TOPIC**

Respiratory tract infections in children are largely self limiting and benefit very little from antibiotic treatment. However, consultation rates continue to be high and antibiotics are still frequently prescribed.

**WHAT THIS STUDY ADDS**

Providing primary care clinicians with a carefully developed booklet on respiratory tract infections in children, and training in its use within the consultation, reduces antibiotic prescribing by around two thirds. Satisfaction among parents receiving this intervention was high, and no significant difference was found between those receiving the intervention and those receiving usual care.

Use of this intervention seems to have little effect on reconsulting for the same illness episode, but does reduce future consulting intentions.

Clinicians should consider the use of this intervention in routine consultations with children with respiratory tract infections.

was reported in the intervention group despite the significant reduction in antibiotic prescribing.

The routine use of this intervention in primary care should now be considered along with other effective interventions such as delayed prescribing.<sup>39</sup> The magnitude of the reduction in antibiotic prescribing achieved suggests that its use could have important implications for patients, and, as a result of the threat posed by increasing antimicrobial resistance, for public health. Furthermore, the booklet and online training could be produced and distributed fairly cheaply. Its use also seems to be safe and result in high levels of parental satisfaction. However, like any complex intervention, the precise elements that contributed to its effectiveness are unclear. The intervention not only provided parents with a take-home resource, it also aimed to modify the consultation process (especially communication within the consultation), which could have had an effect on consultation length. We are currently exploring which aspects of the intervention led to its effectiveness, the impact of its use on consultation length, its effects on long term consulting rates, and its economic impact. For example, we do not know if another booklet or leaflet on the same subject would result in a similar effect, or whether the training programme or the interactive use of the booklet was important. In the meantime, higher prescribing clinicians, or those who would like to reduce their prescribing but feel that they lack the tools to achieve this, might wish to consider use of this intervention.

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## **Appendix 14 – Process evaluation parent interview guide**

*Thank you for agreeing to take part in this part of the study. The purpose of the EQUIP study is to try and improve consultations in general practice for parents whose children have a cough, cold, or other respiratory tract infection. The purpose of this interview is to find out more about the consultation that you had when you signed up for the study, and about your thoughts and feelings since then. Everything you tell me will be kept confidential. We will not tell your surgery or anyone else what you have told us, and if anything you tell us is published in a medical journal or used in any other way, it will not have your name or anything else that might identify you on it.*

*Do you have any questions before we get started?*

1. Can you start by telling me about the illness your child had and what made you decide to go to the surgery?
  - a. How long had your child been ill?
  - b. Was it a routine or emergency appointment?
  - c. Did you have any problems getting an appointment?
2. Can you now tell me about the consultation with the GP or nurse that you had on the day when you signed up to take part in this study? I'm interested in hearing about your general impressions of the consultation, whether it was what you expected, and what you liked and / or didn't like about it?
  - a. Was it what you expected?
  - b. What did you like about it?
  - c. What did you not like about it?
  - d. Did they ask you what your worries or concerns were?
  - e. Did they ask you what you were expecting from the consultation?
3. Do you remember being given an orange booklet about infections in children?

**IF NO, SKIP TO QUESTION 7.**

4. Was the booklet used or discussed in the consultation? If it was, please tell me about this?
  - a. Did you find this useful?
5. I'm interested in knowing more about what you thought of the booklet.
  - a. Did you think it was useful? If you thought it was useful, what bits of it did you like or find useful?
  - b. If you didn't think it was useful, can you tell us why?



## **Appendix 15 – Process evaluation – parent thematic framework**



**Parent process evaluation - coding framework**

**Notes**

Parent process evaluation - coding framework			Notes
1.0 The Illness	1.1 Duration of illness		
	1.2 Main worries		Parents main concerns / worries
	1.3 Parental expectations		Discussion of expectations for consultation
	1.4 Reason for consulting		Main reasons for consulting
	1.5 Symptoms		Description of main symptoms / problem
2.0 The consultation	2.1 Concerns explored		Discussion of whether parental concerns were identified and addressed - either explicitly or in a more subtle way
	2.2 Consultation as expected?		How did the consultation compare to what the parent expected?
	2.3 Liked about the consultation		Any aspects of the consultation that were liked
	2.4 Disliked about the consultation		
	2.5 Examination		Any mention of clinical examination (not conducted, conducted poorly / well, importance of examination)
	2.6 Expectations explored		Discussion of whether parental expectations were identified and addressed - either explicitly or in a more subtle way
	2.7 Impressions of clinician		Mention of the characteristics of skills of the clinician - either positive or negative
	2.8 Satisfaction with consultation		General overall satisfaction with consultation
3.0 Booklet	3.1 Booklet delivery	3.11 How delivered	Description of how booklet was delivered, responses to questions about whether delivered as intended (i.e. discussed with parent)
		3.12 Thoughts on delivery	Thoughts / feelings about the value of using it as a tool in the consultation versus handing out at the end
	3.2 General impressions of booklet		
	3.3 Liked / found useful		Any mention of aspects of the booklet that were liked or valued
	3.4 Disliked		Aspects of booklet that were considered wrong, confusing, irrelevant, etc.
	3.5 Use after consultation		Any mention of use of the booklet after the consultation (i.e. reading it after getting home, or referring back to it at a later stage)
	3.6 Fridge magnet		Thoughts or comments on use / value of the fridge magnet (including responses indicating non-use of magnet)
3.7 General thoughts on use of leaflets / booklets			
4.0 Antibiotics	4.1 Prescribing decisions		Any discussion about the reasons why antibiotics were or were not prescribed
	4.2 Changes in beliefs		Any mention of change in beliefs or knowledge about antibiotics as a result of the consultation or use of the booklet
	4.3 Feelings about receiving / not receiving AB		Parental feelings about the AB prescribing decision
	4.4 Past experience		Mention of past experiences which have influenced beliefs or feelings about antibiotics
5.0 Reconsulting	5.1 Effect of intervention		Any discussion about ways in which either the initial consultation, or subsequent use of the booklet, may have influenced the decision to reconsult or not reconsult
	5.2 Other discussion		Any other discussion about factors influencing the decision to reconsult or not
6.0 Parental changes from intervention			Any discussion about ways in which the intervention (initial consultation or subsequent use of the booklet) may have influenced the parent
7.0 Other sources of information			Discussion about other sources of information about RTIs in children
8.0 Lack of / poor information leading to consulting			Any examples of lack of information or incorrect information contributing the the decision to consult
9.0 Parent feeling brushed off			Any mention of feeling brushed-off or dismissed in the consultation
10.0 Suggestions for improving consultations			Parental thoughts about how these consultations (or home care) could be improved

## **Appendix 16 – Process evaluation clinician interview guide**

*Thank you very much for taking the time to participate in this part of the study. The aim of this interview is find out what it was actually like taking part in the study, and what your views are on a number of issues relating to the management of respiratory tract infections in children, and the use of printed information for patients. I will be recording the interview so that I do not forget what was said. I would like to reassure you that everything you say will be kept confidential. The recording, and any transcripts made of it, will be kept secure, and if anything you have said is used in a publication or presentation, it will be anonymised so that no one will be able to identify you.*

*Do you have any questions before we get started?*

1. Could you start by giving me your general impressions of taking part in the study?
  - a. Were there any aspects of the study that you thought were problematic or did not work well?
  - b. Were there any aspects of the study that you particularly liked?

I'd now like to ask you a bit more about the study intervention.

2. Did you give the study booklet to patients?
  - a. If not, why not?
3. What are your overall impressions of the booklet?
  - a. What do you think parents thought of it?
    - i. Can you remember any of the parent's reactions to receiving it?
  - b. Were there any specific things about it that you did not like or sections you would have liked removed?
  - c. Were there any sections that you found particularly helpful or well received?
4. Did you complete the on-line training?
  - a. Did you find it helpful?
  - b. Did the training help you to use the booklet?
  - c. Were there any barriers to doing what we asked you to do, or to using the booklet?
  - d. Did the training help you to communicate with parents about RTIs at all?
5. Did you use the booklet as a tool within consultations or give it to parents at the end of the consultation?

- a. If no, can you tell me why you decided not to?
  - b. If yes, can you tell me what it was like using it in the consultation?
    - i. Did you talk through sections with the parent?
    - ii. Did you write on it at all?
    - iii. What worked well?
    - iv. What did not work well?
  - c. Some parents have told us that they did not think the booklet was an 'official' booklet and therefore did not regard it with as much importance as they might have. What do you think would have made parents feel that the booklet was 'official'? Do you think that you really endorsed use of the booklet?
6. Has participating in the study changed your knowledge or beliefs or the way you manage RTIs at all?

*I'd now like to ask some more general questions about the management of respiratory tract infections in children, and the use of printed information.*

7. Do you think that there are ways in which we can improve the management of RTIs in children in primary care?
  - a. How can this best be achieved?
8. Do you think that parents generally have enough information about these infections?
  - a. Do you think that you generally provide them with enough information?
  - b. Do you think it is your role?
  - c. What are your general thoughts on using booklets or leaflets for this?
  - d. Do you think that discussing printed material **within the consultation**, as was encouraged in this study, increases the effectiveness?
9. Do you have any other comments or points you would like to make about managing respiratory tract infections in children, using the study booklet, or taking part in the trial?

*Thank you very much for your time. I will send you a summary of the process evaluation once it is complete.*

## **Appendix 17 – Process evaluation clinician thematic framework**

### Clinician process evaluation - coding framework

Clinician process evaluation - coding framework		Notes	
1.0 Ways in which the intervention may have had its effects	1.1 Antibiotic prescribing / use	Any description of changes that may have had an impact on antibiotic prescribing or use	
	1.2 Consulting (intentions)	Any description of changes from use of the intervention that may have impacted on consulting	
2.0 Intervention fidelity	2.1 Completion of training	Description of the extent to which training was accessed	
	2.2 Booklet delivery	Indications about whether the booklet was delivered interactively in the consultation or not	
	2.3 Communication	Description of whether the communication prompts (eliciting concerns and expectations) were followed.	
3.0 Clinicians views on intervention	3.1 General impressions	Clinician's overall impression of the intervention (booklet and training)	
	3.2 Use of training	Clinician's impressions of training in use of the booklet.	
	3.3 Impressions of booklet	Clinician's impressions of the study booklet.	
	3.4 Use within consultation	3.4.1 How used	Description of how the booklet was used
		3.4.2 Views on use in consultation	Clinician's views on using the booklet interactively in the consultation
		3.4.3 Consultation length	Description of ways in which use of the intervention (and participation in the trial) affected consultation length
3.4.3 Other challenges		Any other challenges to use within the consultation	
3.5 Other potential barriers	Any other potential barriers to use of the intervention		
4.0 Impact of intervention	4.1 Changes in clinicians beliefs / knowledge / practice	Description of changes in the clinician's beliefs, knowledge, or behaviour as a result of using the intervention (training or booklet)	
	4.2 Benefits described by parents	Any recounting of parent-reported benefits	
	4.3 Negative impacts	Any negative impacts from use of the booklet	
	4.4 Ongoing use	Discussion about ongoing use of the booklet - ie would they use in after the trial if they had access	
5.0 Perception of parents views	5.1 General impressions of intervention	5.1.1 Booklet official / endorsed? Parent-reported impressions of the booklet and /or changes in consultations as a result of completing the training (including whether they perceived it as official or endorsed).	
	5.2 Participation in study	Any perceptions of parents views of taking part in the study	
	5.3 Antibiotics	Perceptions of parents general views about antibiotics	
	5.4 Consulting	Perceptions of parents views about consulting and reconsulting for these infections	
6.0 Clinicians views on participating in study		General views about taking part in the study	
7.0 Clinicians wider views on managing RTIs		Wider views on the management of RTIs in children in primary care (i.e. ideas for how to improve management etc).	
8.0 Clinician views on providing information	8.1 Written information	Views on the use of leaflets / booklets etc in primary care	
	8.2 Internet	Views on the use of the internet - both as a resource for clinicians to print off patient leaflets, and as a resource to direct patients to for information	
	8.3 Other	Thoughts about other ways of providing information to patients.	