

Reducing antibiotic use for acute bronchitis in primary care: blinded, randomised controlled trial of patient information leaflet

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Abstract

Objective To assess whether sharing the uncertainty of the value of antibiotics for acute bronchitis in the form of written and verbal advice affects the likelihood of patients taking antibiotics.

Design Nested, single blind, randomised controlled trial.

Setting Three suburban general practices in Nottingham

Participants 259 previously well adults presenting with acute bronchitis.

Intervention In group A, 212 patients were judged by their general practitioner not to need antibiotics that day but were given a prescription to use if they got worse and standard verbal reassurance. Half of them (106) were also given an information leaflet. All patients in group B (47) were judged to need antibiotics and were given a prescription and encouraged to use it.

Main outcome measures Antibiotic use in the next two weeks. Reconsultation for the same symptoms in the next month.

Results In group A fewer patients who received the information leaflet took antibiotics compared with those who did not receive the leaflet (49 *v* 63, risk ratio 0.76, 95% confidence interval 0.59 to 0.97, *P* = 0.04). Numbers reconsulting were similar (11 *v* 14). In group B, 44 patients took the antibiotics.

Conclusion Most previously well adults with acute bronchitis were judged not to need antibiotics. Reassuring these patients and sharing the uncertainty about prescribing in a information leaflet supported by verbal advice is a safe strategy and reduces antibiotic use.

Introduction

Acute bronchitis is a common condition that results in nearly 2 million consultations in England and Wales each year.^{1,2} General practitioners prescribe antibiotics in three quarters of such consultations, even though there is little evidence to justify it.^{2,3} The widespread belief among patients with acute bronchitis that infection is the problem and antibiotics the solution has considerable influence on prescribing of antibiotics by

general practitioners, even when their clinical judgment is that antibiotics are not definitely indicated.³⁻⁵ This is a factor in the overuse of antibiotics and the increasing prevalence of drug resistance, adverse effects, and cost.⁶

As a major reason for the use of antibiotics in acute bronchitis seems to be the expectations of patients, we conducted a randomised, controlled, clinical trial to determine the impact of a patient information leaflet on the use of antibiotics in patients with this condition.

Methods

Recruitment and initial assessment of participants

Participants for the trial were recruited from three general practices in Nottingham familiar with research in this topic.^{3,4,7-9} Between September 1999 and August 2000 (excluding a month over Christmas and the millennium period), we recruited consecutive adults presenting with “acute bronchitis,” defined as a “new, acute lower respiratory tract illness in a previously well adult,” using previously reported definitions (box 1).^{4,8-11} The study was approved by the Nottingham City Hospital ethics committee, and all participants provided written consent.

Each general practitioner managed the patients according to their usual clinical practice and based on their clinical judgment divided them into two groups: group A, in which antibiotics were not definitely indicated that day, and group B, in which antibiotics

Box 1: Definitions for recruitment

- Patients aged ≥ 16 years who were previously well and not under supervision or management for an underlying disease (for example, no pre-existing asthma, chronic obstructive pulmonary disease, heart disease, and diabetes)
- Lower respiratory tract illness required all of:
 - Acute illness present for 21 days or less
 - Cough as the main symptom
 - At least one other lower respiratory tract symptom (sputum production, dyspnoea, wheeze, chest discomfort or pain)
 - No alternative explanation (for example, not sinusitis, pharyngitis, a new presentation of asthma)

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were definitely indicated that day. This decision was made without additional guidance or investigations.

Antibiotic prescriptions and randomisation

All patients were given a prescription for an antibiotic, the choice of which was left to the general practitioner, and a sealed envelope containing a two week diary card with instructions, pen, and a stamped, addressed return envelope. Patients in group B were advised to take the antibiotics.

For all patients in group A the general practitioner provided verbal information based on a prompt card (box 2). These patients were then randomised by using permuted blocks of four to receive or not receive a patient information leaflet about the natural course of lower respiratory tract symptoms and the advantages and disadvantages of antibiotic use (fig 1). The patient information leaflet was in the sealed envelope, blinded from the general practitioner by means of a blank leaflet, together with the diary card and return envelope.

I'VE GOT A TROUBLESOME COUGH: WILL AN ANTIBIOTIC MAKE ME BETTER?

Some information to help you in the next week or so

We don't always know when antibiotics help a chesty cough.
For patients who are normally fit and well, we do know:

- Most chesty illnesses get better on their own
- Antibiotics don't help most coughs get better quicker
- Antibiotics can have unpleasant side effects (for example, thrush, rashes, tummy upsets and diarrhoea)
- Taking antibiotics when you don't need them isn't sensible
- Overusing antibiotics produces resistant germs, which means the medicines may not work when they are really needed.

So you will see that deciding when to use antibiotics isn't always easy!!

Your doctor has examined you during your visit to the surgery today, and even though you feel unwell, he or she hasn't found any serious illness that definitely needs antibiotics today. However, you have a prescription for antibiotics in case you do need them in the next period of time.

What does a "chesty cough" mean?
A cough is not a "bad" thing: it is there for a reason. It helps defend your lungs by making sure that any secretions your tubes produce are coughed UP, rather than settling in the lower lungs where they would cause trouble. "Phlegm" or "sputum" is there to act as a barrier to catch the dust and germs that we breathe in.

Your cough is part of your body's defence mechanisms, and is likely to be the last symptom of your current illness to go back to normal. It may take a long time to go completely.

The process of recovery, even with any prescribed treatment, is likely to take up to two or three weeks to complete. Assuming you are not getting worse, you need not worry if your cough and phlegm take this time to settle, especially if you are getting gradually better each day.

So, your chesty cough will quite likely get better by itself, and you won't need any antibiotics. However, your doctor has given you a prescription to have available in case you **do** need antibiotics in the next period of time. Use your judgement whether to get them; the prescription is valid for a month.

When should I use my prescription?
If **you** feel your illness is getting worse.
If **you** feel your cough is getting worse.

If you do decide to use antibiotics, do take the FULL course.

Is there anything I should look out for?
Should you find that you develop any new or worrying symptoms, or if you start to cough up blood, it would be sensible to telephone the surgery and make an appointment for a further check.

Four ways to help your chesty cough

1. **Make sure you're drinking plenty of fluids so you don't get dehydrated.**
2. **Take some regular paracetamol if you have fever or aches and pains.**
The proper dose for an adult is two tablets taken four times a day.
3. **Some patients find cough linctus or sucking a lozenge or sweet is soothing.**
4. **The "old fashioned" remedy was to take a basin of warm water, add some menthol crystals or Friar's Balsam to it and inhale the fumes. The vapour is soothing, and helps make your secretions less sticky and so easier to cough up. Although it is rather inconvenient, it can be helpful, especially last thing at night.**

Fig 1 Information leaflet given to patients

Box 2: Prompt card for verbal information given to patient by general practitioners

"I have examined you and I am happy there is no sign of serious disease which definitely needs antibiotics today. Most chesty illnesses get better on their own, although the cough may take a long time to go completely.

Antibiotics don't seem to make much difference to how quickly most people recover. However, if you feel you are getting worse after a while, considering taking antibiotics then would be reasonable.

So, here is a prescription for an antibiotic for you to keep at home. You are quite likely not to need it, but use your judgment whether to get them in due course."

Patients were asked to open and read the contents of the envelope after the consultation.

End points and follow up

The primary end point was whether the patient took the antibiotics they had been prescribed. This information was obtained from the symptom diary, which included a space to record daily antibiotic use, and by telephone contact. Patients were contacted by telephone at around one week and two weeks after the consultation by research assistants blinded to the grouping of the patients. Answers to structured questions regarding antibiotic use were recorded.

The secondary outcome was whether patients initiated a further consultation for the same symptoms within the next month. Patients were not asked to return routinely by the general practitioner. We have previously reported that reconsultation is an easily measured and consistent end point for acute bronchitis and relates to persistent cough and patient dissatisfaction with their progress.^{8 9 11 12}

We carried out a pilot study of 33 consecutive patients with acute bronchitis to develop consistency of data collection by the general practitioners and telephone follow up by the research assistants.

Statistical analysis

Our primary hypothesis was that the proportion of patients in group A who would take antibiotics during the two week follow up period would be lower in those who received the leaflet than in those in the control group. We calculated the risk ratio and 95% confidence interval using EpiInfo and used a χ^2 test with Yates's correction for the hypothesis test. Using these data we calculated the number need to treat as the reciprocal of the absolute difference in antibiotic uptake between the two groups.

To calculate sample size we set a minimum difference of 20% in primary outcome between the two intervention arms in group A and a discriminatory power of 80%. The required number in group A was 206.

To look for possible confounding by age, sex, surgery, smoking status, description of cough, duration of cough, and the presence of chest signs we used a series of bivariate logistic regression models within Stata (version 5). We also examined whether the impact of the leaflet on antibiotic uptake was modified by any of these variables by fitting a series of multiplicative

interaction terms and comparing the nested models using the likelihood ratio test.

We constructed a Kaplan-Meier plot from the days between consultation and the day antibiotics were started and calculated the rate ratio using a Cox regression model within Stata. We tested the proportional hazard assumption of this model using the diagnostic section within Stata (ph1test).

Results**Participants**

During the study, the general practitioners saw 280 patients with acute bronchitis, 259 of whom agreed to participate in the study (table, fig 2). Of the 212 patients in group A, 106 received the patient information leaflet and 106 did not. Among patients who were given the leaflet, two were lost to follow up, and 49 (47%) took their antibiotics. For patients in the control group five were lost to follow up, and 63 (62%) took their antibiotics (risk ratio 0.76, 95% confidence interval 0.59 to 0.97, $P=0.04$; number needed to treat 6.7).

Within the logistic regression model we found no evidence of confounding by age, sex, smoking status, whether patients paid for their prescriptions, description of cough or sputum, duration of cough, presence of chest signs, or general practice. In addition there was no evidence of significant effect modification by any of these variables.

Figure 3 shows the Kaplan-Meier plot. The rate ratio for the intervention group compared with the control group was 0.66 (0.46 to 0.96). The reconsultation rates were similar for all patients in group A (table). For the 47 patients in group B (20% of all patients), all of whom were told by their doctor that

Details of patients with acute bronchitis for whom general practitioners thought that antibiotics were not definitely indicated on day of consultation, according to whether patient received written information. Figures are numbers of patients unless stated otherwise with denominators shown when data were incomplete

| | Patients received leaflet (n=106) | Patients did not receive leaflet (n=106) |
|---|-----------------------------------|--|
| Median (range) age (years) | 45 (16-84) | 44 (17-84) |
| Women | 60 | 64 |
| Smokers: | | |
| Current | 26 | 29 |
| Former | 28 | 31 |
| Never | 52 | 46 |
| Sputum: | | |
| None | 13 | 19 |
| Clear | 22 | 28 |
| Discoloured | 71 | 59 |
| Median (range) duration of cough (days) | 7 (1-21) | 7 (1-21)* |
| Results of chest examination: | | |
| Clear | 85 | 84 |
| General signs | 19 | 18 |
| Focal signs | 2 | 4 |
| Taking antibiotics | 49/104 | 63/101 |
| Reconsulted within four weeks | 11/104 | 14/105 |
| Received antibiotics at reconsultation | 4 | 6 |
| Antibiotic prescribed: | | |
| Amoxicillin | 102 | 101 |
| Macrolide | 8 | 4 |
| Cephalosporin | 0 | 1 |

*Not known for one patient.

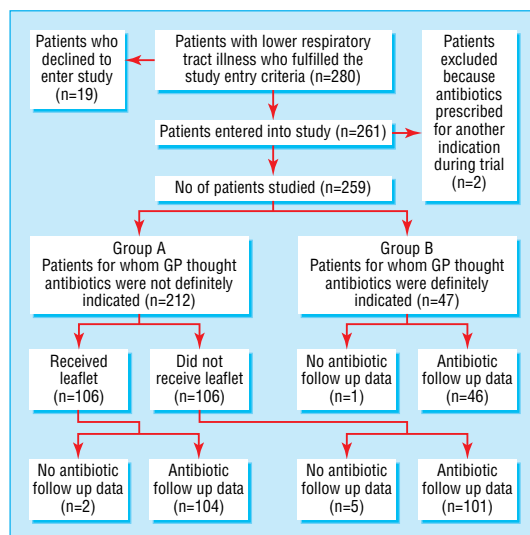


Fig 2 Flow of patients through whole study and nested trial of information leaflet

antibiotics were definitely indicated, 44 (94%) took their antibiotics.

Discussion

Use of antibiotics by patients with acute bronchitis can be reduced by providing patients with a simple information leaflet about the use of antibiotics and the natural course of acute bronchitis and giving reassurance after a consultation and examination that their condition is not serious. The use of the patient information leaflet reduced the use of antibiotics by nearly a quarter. If these results are extrapolated to national figures, about 750 000 fewer courses of antibiotics could be prescribed each year.

This may underestimate the true efficacy of the leaflet as all patients were also reassured verbally by their general practitioner that antibiotics were not definitely indicated at the time of the consultation. The effect of the leaflet was seen not only at the time of the consultation but continued over the following two weeks of observation. By contrast, when the general practitioner recommended that antibiotics were definitely indicated, nearly all patients said they did take them, emphasising the strong influence of doctors' advice on patient compliance.

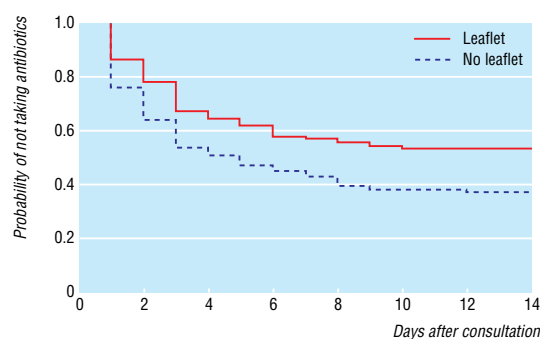


Fig 3 Kaplan-Meier plot of number of days between consultation and day of taking antibiotics for those who did and did not receive information leaflet

Prescribing and management strategies for acute bronchitis

Most episodes of acute bronchitis resolve on their own, and how to identify those few patients who may benefit from antibiotics is not clear.^{2,13} Prescribing antibiotics for patients with such self limiting conditions can be counterproductive as it reinforces the belief that antibiotics are beneficial and encourages future consultations.^{10,13}

Providing patients with information and using a delayed prescription have been advanced by the National Prescribing Centre of the NHS¹³ and the Standing Medical Advisory Committee of the Departments of Health¹⁴ as strategies for reducing antibiotic use in the community. Open studies of managing uncomplicated respiratory infection in adults¹⁵ and sore throat and otitis media in children in primary care¹⁶⁻¹⁸ have shown that such strategies result in fewer people taking antibiotics. Our study supports this approach for adults with acute bronchitis. There are nearly three million consultations for acute bronchitis annually in England and Wales¹ and an incidence of up to 70 per 1000 for a practice population of previously well adults.⁸ Reducing antibiotic use by a quarter would substantially influence antibiotic use in the community, as currently up to three quarters of UK adults who consult with acute bronchitis receive antibiotics, and the figures are even higher in some other European countries.¹⁰⁻¹³

Further studies could assess whether reassurance and sharing information and prescribing decisions would lead to longer term benefits for individuals and the community in terms of less dependence on antibiotics.^{10,13,19} Little et al showed that prescribing antibiotics for sore throat and otitis media increased the likelihood of consultations during future episodes.^{18,20} For acute bronchitis, we have shown that pressures at home and work and concerns about the seriousness of the problem are also associated with the likelihood of seeking medical attention.²¹

The strategy of verbal and written information seems practical and safe. The leaflet was cheap and simple to produce, and the study was conducted during normal consultations by general practitioners. Most patients seemed happy with the approach. Few declined to take part in the study or expressed concern about sharing the prescribing decision with their doctor. Rates of reconsultation were no higher in the leaflet group, and no patients required referral to hospital for respiratory illness during follow up. A similar study on management of acute cough also showed that an information leaflet led to fewer future consultations for minor coughs and no delays in consultations for more serious respiratory symptoms.¹⁹ We developed our leaflet from one we used successfully to reduce reconsultation rates in a previous study of acute bronchitis (that is, acute lower respiratory tract illness in a previously well adult).⁹ Our results support the development of a more robust study in which no prescription would be offered.

Study weaknesses

We did not measure antibiotic use directly, a problem shared with other studies.¹⁵⁻¹⁸ We have previously reported on a simple technique using a bioassay on urine to check whether patients in the community are

What is already known on this topic

Most adults with acute bronchitis who consult their general practitioner will receive antibiotics

For most patients antibiotics do not modify the natural course of the symptoms

The widespread belief among patients that infection is the problem and antibiotics the solution has considerable influence on prescribing by general practitioners, even when they judge that antibiotics are not definitely indicated

What this study adds

General practitioners judged that about four in five adults with acute bronchitis did not definitely need antibiotics on the day they consulted

Antibiotic use was reduced by a quarter in such patients, who received verbal and written information and reassurance in addition to a prescription for antibiotics

Sharing with the patient the uncertainty about the decision to prescribe seems safe and effective

using their prescriptions for antibiotics.²² However, in the current study we could not devise a method of collecting urine from the patients in an informed manner without compromising our objectives. We considered leaving the filled out prescription with the practice receptionist and recording the number collected, a method used in previous studies.^{15 16 18} However, this does not record antibiotic consumption and is more inconvenient for both the patient and the practice than our approach. Arguably, it is also less representative of typical practice and can lead to patients with acute cough feeling dissatisfied and less empowered.¹⁵

Our practices were used to doing research in this topic, which may make the doctors and patients unrepresentative. This may have encouraged the general practitioners to include more patients in the group thought not to need antibiotics and hence provide a sterner test of the information strategy we used.

How this study helps general practitioners

Of course some patients with an acute lower respiratory tract illness do benefit from antibiotics.²³ In our study nearly one in five patients were thought to need antibiotics, a figure consistent with that found in previous studies.¹⁰ Further research would identify those patients most likely to benefit from antibiotics.² We have shown that investigating patients for infection either at first presentation or when they consult is not a useful strategy for better targeting of antibiotic treatment.^{7 8} For the many patients (around 80%) for whom the general practitioner thinks that antibiotics are not definitely indicated, we have shown that sharing uncertainty about prescribing openly and honestly with the patient is safe and effective and also reduces antibiotic use.

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Contributors: JM had the original idea for the study and all authors were involved in the design and planning. RM coordinated the study logistics throughout and WH, PG, and DT liaised with their colleagues and staff in the three practices and monitored consultations. RM and RH performed the data analysis. The paper was written by JM, who acts as guarantor (with RH as guarantor for data analysis), with input from all authors.

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Commentary: More self reliance in patients and fewer antibiotics: still room for improvement

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The study of Macfarlane et al examines the old problem of overprescribing of antibiotics, but it approaches the problem in a highly original way. To what extent can their findings be applied to routine care in general practice.

Firstly the reduction of antibiotic use. The empirical findings of acute bronchitis in general practice can in all probability be generalised: many prescriptions for antibiotics are given for episodes of illness that usually are self limiting. Use of antibiotics under these circumstances is often spurious and does not contribute to patients' wellbeing. Undue use of antibiotics may at the same time contribute to the growing concerns about resistance. These are sound professional arguments for the restriction of prescribing.

But patients influence prescribing, and there is a strong perception among practitioners—whether true or not—that patients in general value a prescription for antibiotics. Macfarlane et al focused their intervention on the interaction between professional opinion and patients' values. The intervention of inviting patients not to use the prescribed antibiotics is something most general practitioners do most days. They offer reassurance and encouragement to the patient to await the natural, benign course of an infection, without removing the possibility of antibiotic treatment. The advantages are obvious. The procedure takes away the power struggle between the patient and the general practitioner, who is in charge of prescribing, and focuses the patient's decision on the content of the advice. This paper shows that general practitioners can

distinguish between those in need of antibiotic treatment and those who can do without it and can substantially reduce the reliance on antibiotics. But it is important to note that about half of the patients still used the antibiotics that their general practitioner thought they could do without. So there is substantial room for improvement.

One problem with the authors' intervention is the message it gives to the patients, and here the approach used may not be as easy to transfer to routine care. The explicit message ("antibiotics are not required") was accompanied by the handing out of a prescription that implied a totally different message. This inconsistency may trigger doubt and lack of confidence in the proposed self reliance, particularly in patients who value medical as opposed to self treatment and prefer external powers to deal with their problems. This group is particularly at risk of medicalisation, including repeated prescriptions of for unnecessary antibiotics for self limiting infections.

The medical setting is not a harmless placebo and can have positive and negative effects. Macfarlane et al should be complimented on their way of bringing this setting into the test of effectiveness. An obvious alternative way to test their current intervention would be to examine the patient and give advice to come back in a couple of days if the predicted wearing off of their symptoms did not occur. Continuity of care is not a panacea, but I would not be surprised if it were able to reduce such unnecessary use of antibiotics by more than half.