Is untargeted outreach visiting in primary care effective? A pragmatic randomized controlled trial

Lesley Hall, Martin Eccles, Roger Barton, Nick Steen and Mark Campbell

Abstract

Background There is increasing evidence that clinical guidelines can lead to improvements in clinical care. However, they are not self-implementing. Outreach visits may improve prescribing behaviour.

Methods Within a before-and-after pragmatic randomized controlled trial, involving all general practices in one health district, routine methods were used to distribute guidelines for management of Helicobacter pylori eradication. Intervention practices were offered a visit and the conduct of an audit by a pharmacist trained in the techniques of outreach visiting. The intervention was evaluated using level three prescribing Analysis and Cost (PACT) data for metronidazole and omeprazole for the two 12 month periods around the introduction of the guidelines.

Results Of the 38 intervention practices 19 accepted an outreach visit and three accepted the offer of an audit. There was a significant increase in omeprazole use during the study of 0.24 (95 per cent confidence interval (CI) +0.19 to +0.29) dose units per year but no effect from the offer [−0.02 (95 per cent CI −0.12 to +0.08) dose units] or acceptance of a visit [−0.03 (95 per cent CI −0.15 to +0.08) dose units]. The results for metronidazole were similar, with an increase in use of 0.028 (95 per cent CI +0.018 to +0.038) dose units per year. The effect of the intervention was a non-significant change in prescribing of −0.005 (95 per cent CI −0.025 to +0.015) dose units. Accepting a visit had little effect on prescribing; a change of 0.003 (95 per cent CI −0.021 to +0.027) dose units.

Conclusions The routine use of untargeted outreach visiting is probably not a worthwhile strategy.

Keywords: outreach visiting, RCT

Introduction

There is increasing evidence that clinical guidelines can lead to improvements in both the process and outcome of care.1,2 They also figure prominently within the fast-developing UK National Health Service (NHS) clinical effectiveness3,4 and, more recently, clinical governance5 agendas. However, clinical guidelines are not self-implementing and the growing body of implementation research has highlighted the limitations of single strategy approaches,6–10 with some empirical evidence to support the use of multiple or combined strategies.11 The commonly used strategy of postal distribution, as a single strategy, rarely leads to large changes in practice.1 Outreach visits, using a trained person to meet face-to-face with a health care professional to provide information, may improve practice, especially prescribing behaviour.9 However, in the face of calls for evidence-based implementation,12 there is little evidence of the effectiveness of combined implementation strategies within routine NHS settings.

In 1996, Newcastle and North Tyneside Health Authority established a Clinical Effectiveness Unit. The remit of the Unit was to provide support to local health care teams in primary and secondary care, with the aim of promoting clinical effectiveness5 and encouraging the use of best evidence in daily practice through systematic, evidence-based approaches to guideline implementation. The strategy adopted by the Clinical Effectiveness Unit was to concentrate on five clinical areas. These were selected by a multi-disciplinary steering group using explicit criteria (evidence of inappropriate variation in practice; a good evidence base for what should be done; the topic was a source of significant morbidity or mortality; large cost implications in the management of the topic).

Helicobacter pylori eradication was one of the topics chosen as a clinical area in the context of the discovery of the role of the H. pylori bacterium as a major cause of peptic ulcers13 and suggested benefits of improved health outcomes and cost savings.
from its eradication.\textsuperscript{14} Studies also suggested that although there was strong evidence that \textit{H. pylori} infection was the principal cause of peptic ulcer,\textsuperscript{15,16} many patients presenting with dyspepsia in general practice were not being investigated or treated appropriately. Instead, they were being managed with long-term treatment with acid-suppressing drugs, one of the most expensive cost categories in NHS drug expenditure.\textsuperscript{17} At the time of the study presented here, there was local evidence of high expenditure on proton pump inhibitors (PPIs) and H\textsubscript{2}-receptor antagonists (H\textsubscript{2}RAs) with an annual expenditure for these drugs in excess of £3.5 million.

The aim of this study was, for the clinical topic of \textit{H. pylori} eradication, to evaluate, within a pragmatic randomized controlled trial, the effectiveness of outreach visiting in addition to postal distribution of educational materials.

**Methods**

**Study design**

The study was a pragmatic randomized controlled trial based in a single health authority district. When evaluating a behaviour change strategy patient randomized trials may be susceptible to bias. There is a danger that the treatment offered to control patients will be contaminated by doctors' experiences of applying the intervention to patients receiving the experimental management, with the result that the evaluation may underestimate the true effects of strategies. Therefore general practices were the unit of randomization and analysis.\textsuperscript{18}

Randomization was performed by numbering the practices then allocating them to either intervention or control groups according to a computer-generated random number list. Immediately before the study, two health authority districts had been amalgamated to form one. Because of the continuation of a number of organizational structures the practices were stratified by former district. As the study was restricted to a defined geographical area the number of available units was pre-determined. The total number of practices available was 76. With 38 practices randomized to each arm of the trial, we determined that we had 80 per cent power to detect an effect size of 0.65 assuming a type 1 error rate of 0.05.

**The guidelines**

The aim of the guidelines was to encourage general practitioners (GPs) to undertake \textit{H. pylori} eradication. The guidelines were developed using consensus methods by local GPs, consultant surgeons and gastroenterologists. They covered the investigation and treatment of ulcer-like dyspepsia (including first choice eradication regime for \textit{H. pylori}) in both new patients and those on long-term PPIs and H\textsubscript{2}RAs. The \textit{H. pylori} eradication regime suggested in the guidelines was 7 days treatment with a combination of three drugs: omeprazole 20 mg twice daily; amoxycillin 500 mg three times daily and metronidazole 400 mg three times daily.

Routine methods were used to distribute the guidelines to all practices. This involved sending the guidelines through the health authority courier or postal system to each individual GP. In the North Tyneside area, this also involved a guideline launch meeting which was held in July 1996. The guidelines were distributed by post to the GPs in North Tyneside during August 1996 and in Newcastle during March 1997. The distribution was staggered to allow for the outreach visits to occur within a reasonable time period of the guidelines appearing.

**Outreach visiting**

A community pharmacist was seconded to act as the outreach visitor. Shortly after the guidelines were distributed she wrote to all intervention practices with the offer of a visit. This was followed up by a telephone call. The purpose of the visit was to encourage implementation of the main messages from the guidelines using the principles of outreach visiting\textsuperscript{19} in which she had received training. Invoking the credibility of the Clinical Effectiveness Unit, within the visit she explored GPs’ knowledge and patterns of current activity, offered clear behavioural objectives (identifying, investigating and treating patients) and acknowledged areas of controversy (such as differing treatment regimes and their cost). She used a prepared set of educational materials based on the content of the guideline. These concisely represented the issues, although key messages were highlighted and repeated at the end of the session. When performing the visits she tried to see, in a single visit, as many of the GPs in a practice as possible. In addition, the practices were also offered the time of the pharmacist to perform an audit of their patients currently receiving ulcer-healing drugs to identify those who might be eligible for \textit{H. pylori} eradication.

**Analysis**

To minimize any Hawthorne Effects we chose to use routinely available prescribing data for the evaluation. The data were level three Prescribing Analysis and Cost (PACT) data. As the unit of analysis was the practice this was aggregated to practice level. Of the three eradication drugs, metronidazole and omeprazole were considered the best potential indicators. Metronidazole is not commonly prescribed in general practice, where it is primarily used to treat vaginal anaerobic infections. Omeprazole, when used for maintenance therapy, is usually prescribed in units corresponding to 28 days treatment and not in the short courses recommended in the guideline. Unfortunately, it was not possible to identify such short courses using PACT data, which provide information only on total quantity and strength. In addition, omeprazole is supplied in packs of 28 tablets and we were unable to obtain information as to how these packs were dispensed and charged if the prescription was only for 7 or 14 days.

Therefore, we conducted a before-and-after analysis of overall usage of omeprazole and metronidazole for the two 12 month periods around the introduction of the guidelines. The primary
analysis was of prescribing of the two drugs within those practices offered a visit compared with control practices. PACT data provide total quantity of dose units (i.e. tablets or capsules) prescribed per practice in each quarter. As we were studying a relatively novel indication for the drugs we chose not to standardize to defined daily dosages. Instead, we used the total number of dose units per practice, per quarter, adjusted for practice size to achieve mean prescribing dose unit per patient. As this was a pragmatic study and we anticipated that some practices would decline a visit, we pre-defined a secondary analysis of prescribing rates of the two drugs within those practices accepting a visit compared with control practices.

Drug use was broken down by practice and by quarter. For each practice we had, therefore, a series of repeated measures: eight quarters in the 2 year study period. Drug use was analysed using multilevel modelling to take into account the repeated measures (quarters nested within practices). Variation between practices and variation between quarters within practices were modelled as random effects. Where a graphical plot indicated the presence of a linear trend in the data this was fitted as fixed effect. In the main analysis the data were analysed on an intention to treat basis. An indicator variable was defined to take a value of one for observations corresponding to practices randomized to receive the intervention in quarters following the intervention and zero for all other observations. The effect of the intervention was thus modelled as a fixed effect. In the secondary analysis, the variable indicating treatment allocation was replaced with a variable that indicated whether the practice had actually accepted and received a visit. In both cases interval estimates of effect size are given.

Confidentiality issues
The use of aggregated practice level data meant that it was possible to maintain anonymity of individual GPs. The health authority supplied the prescribing data, and, to enable us to identify the intervention and control practices for analysis, codes were developed and used by the health authority to mark data accordingly. A letter was sent to every GP in the district outlining the study, informing them that anonymized, aggregated PACT data were being used for analysis and assuring them of confidentiality. A representative from the Clinical Effectiveness Unit and from the local health authority signed this letter. As patients were not directly involved, and no patient identifiable data were to be included in the final analysis, a full application to the Joint Ethics Committee was not required.

Results
The visits took place between August 1996 and April 1997. All 79 practices in Newcastle and North Tyneside were included in the study – 33 in North Tyneside and 46 in Newcastle. However, three single-handed practices were removed as the GP retired during the course of the study. This left 76 eligible practices – 32 in North Tyneside and 44 in Newcastle (Table 1).

Of the 16 intervention practices in North Tyneside, 11 (69 per cent) took up the offer of the visit and three (19 per cent) took up the offer of an audit. The visits were carried out between October and November 1996 and the audits were completed by December 1996. In Newcastle, of the 22 intervention practices eight (36 per cent) took up the offer of a visit and no audits were carried out. The visits took place during April 1997.

Prescribing data for omeprazole and metronidazole from February 1996 (three quarters before the first visits in October 1996) up to and including January 1998 (three quarters after the final visits in April 1997) were used for the analysis. The level of prescribing of omeprazole and metronidazole broken down by quarter, by location and by treatment allocation are given in Tables 2 and 3, respectively.

The analysis of omeprazole prescribing shows a significant linear trend in use during the study of 0.24 [95 per cent confidence interval (CI) 0.19 to +0.29] dose units per year. In the main analysis the effect of the intervention was a non-significant change in the use of omeprazole by −0.02 [95 per cent CI −0.12 to +0.08]. Similarly, there was no evidence that accepting a visit to the practice had any effect on the use of omeprazole. In the secondary analysis the change as a result of the visit was −0.03 (95 per cent CI −0.15 to +0.08) dose units.

The results for metronidazole were similar, with a general increase in the use of 0.028 (95 per cent CI +0.018 to +0.038) dose units per year. The effect of the intervention was a non-significant change in prescribing of −0.005 (95 per cent CI −0.025 to +0.015) dose units. Accepting a visit had little effect on prescribing: a change of 0.003 (95 per cent CI −0.021 to +0.027) dose units.

Table 1 Description of GP practices (values are numbers, with percentages given in parentheses)

<table>
<thead>
<tr>
<th></th>
<th>North Tyneside</th>
<th>Newcastle</th>
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<tr>
<td></td>
<td>Control (n = 16)</td>
<td>Intervention (n = 16)</td>
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<tr>
<td>Average partners per practice</td>
<td>3.75</td>
<td>3.13</td>
</tr>
<tr>
<td>Female GPs</td>
<td>27 (45)</td>
<td>21 (42)</td>
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<tr>
<td>Training practices</td>
<td>2 (13)</td>
<td>3 (19)</td>
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<tr>
<td>Single-handed</td>
<td>1 (6)</td>
<td>4 (25)</td>
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Discussion

This study showed no effect within a pragmatic evaluation of outreach visiting in a service setting. Even allowing for the uptake of a visit there was still no effect of the visit. This is at variance with the results of previously reported studies.9

It is possible that the drug markers may not have been sensitive, although drug markers have been previously used.20 Omeprazole may not have been a particularly sensitive indicator of change as there was a high background level of prescribing. However, metronidazole has relatively few indications in primary care and its commonest indication, anaerobic vaginitis, has a low incidence. It is much less susceptible to secondary care influence and should therefore be a sensitive marker. There was a general increase in prescribing of both drugs during the study. Although for omeprazole this could represent the effect of marketing activities of the pharmaceutical industry, or increasing prescribing initiated in secondary care, neither of these explanations should apply to metronidazole, which is a long-established drug with clear clinical indications. The most likely explanation of the overall increase in metronidazole use is an increase in *H. pylori* eradication that was occurring anyway and on top of which the intervention produced no effect.

It is relevant to compare the intervention we used with those used in previous studies. There are both similarities and differences that may have contributed to our negative result. However, given the relative paucity of experience in the technique these are largely conjectural. First, our visitor was a pharmacist. Previous studies have suggested that the visitor needs to be credible and, in particular, studies of influencing prescribing behaviour have found positive effects with pharmacist visitors.21 We conducted only a single visit, whereas previous studies have used a wide range of number of visits from one to weekly for several months. There does not seem to be a clear relationship between number of visits and effect, with positive effects coming from studies at either end of the range.

In a recent review of outreach visiting,9 in 13 of the 18 trials included the targeted behaviour was prescribing; in at least nine of the 13 the aim was to reduce inappropriate prescribing. In this study we were aiming to increase activity and were addressing a more complex behaviour that involved the investigation of patients and then their subsequent treatment. This, and two other features, may have contributed to the lack of impact of the intervention. First, the intervention was not targeted at specific barriers to change, although the offer to conduct an audit was designed to remove the barrier of a practice not being able to identify the relevant patient group. Previous studies have used social marketing methods that have allowed clinicians to identify individual barriers to change and their potential solutions.22,23 Such studies tended to have larger effects. Second, the intervention was offered to all practices in the intervention group rather than being focused on those that had specific

### Table 2 Mean prescribing dose units of omeprazole per quarter, per patient

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<td>1.53</td>
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<td>1.63</td>
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### Table 3 Mean prescribing dose units of metronidazole per quarter, per patient

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<tr>
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difficulties. It is therefore likely that some practices in each group were already dealing with the clinical and organizational issues posed by *H. pylori* eradication.

The routine use of untargeted outreach visiting is probably not a worthwhile strategy. Future evaluations could usefully focus on pragmatic evaluations of targeted visits and consider greater use of social marketing strategies.

**References**


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