Modifying dyspepsia management in primary care: a cluster randomised controlled trial of educational outreach compared with passive guideline dissemination

Gurvinder Banait, Bonnie Sibbald, David Thompson, Chris Summerton, Mark Hann and Stuart Talbot (on behalf of the Salford and Trafford Ulcer Research Network, SATURN)

SUMMARY

Background: *Quality improvement initiatives in health services rely upon the effective introduction of clinical practice guidelines. However, even well constructed guidelines have little effect unless supported by dissemination and implementation strategies.*

Aim: *To test the effectiveness of 'educational outreach' as a strategy for facilitating the uptake of dyspepsia management guidelines in primary care.*

Design of study: *A pragmatic, cluster-randomised controlled trial of guideline introduction, comparing educational outreach with postal guideline dissemination alone.*

Setting: *One-hundred and fourteen general practices (233 general practitioners) in the Salford and Trafford Health authority catchment area in the northwest of England.*

Method: *All practices received guidelines by post in July 1997. The intervention group practices began to receive educational outreach three months later. This consisted of practice-based seminars with hospital specialists at which guideline recommendations were appraised, and implementation plans formulated. Seminars were followed up with 'reinforcement' visits after a further 12 weeks. Outcome measures were: (a) the appropriateness of referral for; and (b) findings at, open access upper gastrointestinal endoscopy; (c) costs of GP prescriptions for acid-suppressing drugs, and (d) the use of laboratory-based serological tests for* Helicobacter pylori*. Data were collected for seven months before and/or after the intervention and analysed by intention-to-treat.*

Results: *(a) The proportion of appropriate referrals was higher in the intervention group in the six-month post-intervention period (practice medians: control = 50.0%, intervention = 63.9%,* P*<0.05); (b) the proportion of major findings at endoscopy did not alter significantly; (c) there was a greater rise in overall expenditure on acid-suppressing drugs in the intervention as compared with the control group (+8% versus +2%,* P *= 0.005); and (d) the median testing rate per practice for* H pylori *in the post-intervention period was significantly greater in the intervention group (four versus 0,* P*<0.001).*

Conclusion: *This study suggests that educational outreach may be more effective than passive guideline dissemination in changing clinical behaviour. It also demonstrates that unpredictable and unanticipated outcomes may emerge.*

Keywords: *dyspepsia; guidelines; educational outreach.*

G Banait, MB ChB, research fellow; D Thompson MD, professor of gastroenterology, Department of Gastrointestinal Science, Hope Hospital, Salford. B Sibbald, PhD, Professor of Health Services Research; M Hann, PhD, statistician, National Primary Care Research and Development Centre, University of Manchester. C Summerton, MD, consultant gastroenterologist, Trafford General Hospital, Manchester. S Talbot, MB ChB, medical adviser, Salford and Trafford Health Authority, Manchester.

Address for correspondence

Dr Gurvinder S Banait, Blackburn Royal Infirmary, Bolton Road, Blackburn BB2 3LR.

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Introduction

QUALITY initiatives in the NHS rely upon the effective introduction of clinical guidelines. However, even well constructed, evidence-based guidelines appear to have little effect on clinical behaviour unless supported by a combination of development, dissemination and implementation strategies.[1-3] Educational outreach is a dissemination strategy defined as 'personal visits by a trained person to health care providers in their own setting'.[4] A recent Cochrane review concluded that while it appeared to be a 'promising approach to modify professional behaviour [in relation to prescribing]'; there was a need to assess the effectiveness of educational outreach for other aspects of practice.[5]

The management of dyspepsia in accordance with clinical practice guidelines has been advocated as a means of reducing inappropriate practice and improving efficiency. We describe the impact of educational outreach on dyspepsia management guideline introduction. The study was designed as a pragmatic randomised controlled trial. It was hypothesised that, compared with passive guideline dissemination alone, educational outreach would lead to a greater proportion of appropriate referrals for open-access upper gastrointestinal endoscopy (open-access endoscopy), an increase in the proportion of relevant findings at open-access endoscopy, a reduction in expenditure on acid suppressing drugs, and a greater use of laboratory-based serological tests for *Helicobacter pylori* as a precursor to eradication therapy.

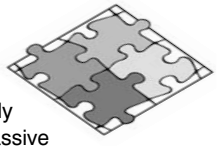
Method

Practice allocation

The study was carried out in the Salford and Trafford Health Authority catchment area in Greater Manchester, which has a population of approximately 465 000 served by 236 general practitioners (GPs) in 115 general practices. The area is served by two hospitals, Trafford General (TGH) and Hope Hospital.

One-hundred and fourteen general practices were allocated to intervention and control groups using a process of minimisation.[6,7] This number fell to 113 as one control practice amalgamated with one from the intervention group and was randomly reallocated to the latter (Figure 1). The criteria used for minimisation were practice size, fundholding status, previous expenditure on acid-suppressing drugs, and previous involvement in a local guideline initiative. These characteristics were ascertained from local health authority

HOW THIS FITS IN



What do we know?

Quality improvements in the NHS will rely upon effective guideline introduction. Passive guideline dissemination alone is an ineffective strategy for clinical behaviour change. The effect of guidelines on referral appropriateness is unclear.

What does this paper add?

Educational outreach is an effective means of modifying clinical practice and referral appropriateness using clinical guidelines, but is a time-consuming and expensive intervention. The outcome of guideline introduction may be unexpected.

records and Prescribing Analyses and Cost (PACT) data.

Guideline development and the intervention

Preliminary work was conducted adapt pre-existing British Society of Gastroenterology dyspepsia management guidelines[8] for local use. This process included a questionnaire-based survey of local GPs to establish whether they agreed with the national guideline recommendations. A copy of the guidelines was posted to all GPs in July 1997, three months prior to the intervention. Practices in the intervention group were invited to receive educational outreach. Educational visits were only arranged with practices that agreed to receive the intervention. The practices that did not respond to the invitation were regarded as having refused it, and along with the control group received no further contact.

The educational outreach programme comprised post-graduate education allowance-approved practice-based interactive educational workshops, to which GPs and practice personnel were invited. Seminars were held over a period of six weeks, with each seminar involving four to eight GPs from two to three practices. Local hospital specialists chaired the seminars. Each seminar consisted of a standard 15-minute presentation that described the guidelines and the development process, followed by an hour-long discussion. The seminars also provided information about the available endoscopy and *H. pylori*-testing services, together with summaries of local prescribing data for acid-suppressing drugs. All attending GPs received a copy of the text used during the discussion as well as contact details for enquiries. A reinforcement visit was made by one of the research team (GB) after three months.

The cost-effectiveness of the intervention was not formally assessed in this study. However, approximately 200 hours of doctors' time was spent providing or receiving the intervention. In addition to this there were costs relating to the time taken to arrange meetings, telephone charges, travelling expenses, and the production of presentation materials.

Outcome measures and the collection of data

The following outcome measures were selected:

The appropriateness of referrals for open access endoscopy. Referrals for open access endoscopy were included if the GP had requested the procedure without a prior hospital consultation. The characteristics of each referral made in the seven months following the initial outreach visit were appraised using predefined medical review criteria based on the guidelines.[9] The identities and trial status of referring practices were masked before the appropriateness of referrals was ascertained. Inter-rater reliability of ratings of appropriateness were carried out in 35 randomly selected referrals, and assessed by a κ statistic.

Findings at open access endoscopy. Findings at open-access endoscopy carried out in the seven months before and after the intervention were recorded. The identities and trial status of referring practices were masked before categorising endoscopic findings according to whether they constituted a major abnormality (neoplasia, peptic ulcer disease, erosive gastritis/duodenitis, or complicated/uncomplicated oesophagitis), a minor abnormality (uncomplicated hiatus hernia, non-specific gastritis/duodenitis), or were normal. All referrals for endoscopy in the departments that receive these requests were checked, as well as all completed endoscopy reports, to ensure completeness of data collection.

Prescribing costs for acid-suppressing drugs. These data were extracted from electronic PACT data provided by the local health authority. These recorded prescriptions for H_2 receptor antagonists (H_2RAs) and proton pump inhibitors (PPIs) by each practice in the six months before and after the intervention. Expenditure was expressed as the net ingredient cost per prescribing unit (NIC/PU) in sterling.

Requests for laboratory-based tests for H. pylori*.* These data were extracted from the logs of the microbiology departments of each hospital. Requests for this test had to be recorded in these logs as a prerequisite for the test to be performed. The tests were introduced at TGH immediately prior to the circulation of the guidelines, but had already been available at Hope Hospital for 18 months.

Sample size estimation

It was estimated that, given 25 practices in each arm each referring 20 patients, and an intraclass correlation coefficient of 0.07 (based on referrals for open-access endoscopy made by 35 practices in the study area over a six-month period), the study would have a power of 80% to detect a difference of 10% in the proportion of significant open access endoscopy findings at the 5% level of statistical significance. With a similar intraclass correlation coefficient, the study would have a power of 77% to detect a difference of one-third in the proportion of inappropriate referrals (assuming an inappropriate referral rate of 20%) and a power of 82% to detect a difference of 25% in prescribing cost changes for acid-suppressing drugs.

Data analysis

All analyses were performed on an intention-to-treat basis, i.e. all practices in the intervention group were included regardless of whether they accepted the intervention or not. The unit of analysis was the practice. Analysis of covariance was used where appropriate, to assess differences in the

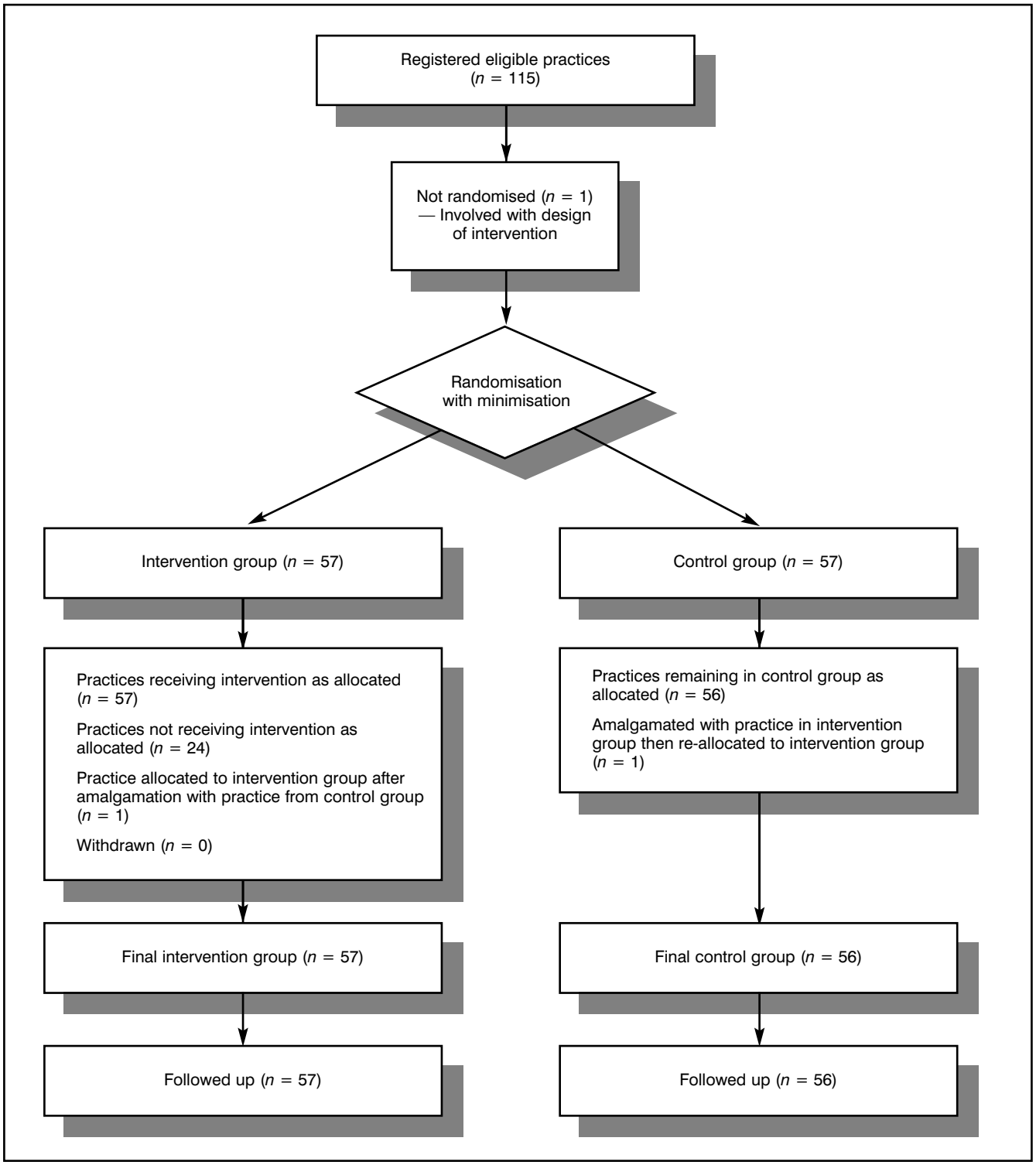


Figure 1. Flow chart describing progress of general practices through the trial.

change from baseline between intervention and control practices. Otherwise, non-parametric tests were used.

Results

Results of recruitment and characteristics of practices accepting the intervention

The characteristics of the intervention and control practices are shown in Table 1. Thirty-three out of 57 practices (58%) allocated to the intervention group accepted the invitation to participate. The remainder did not reply to the invitation and were therefore deemed to have 'refused' it. There were no significant differences between practices accepting or refusing the intervention with respect to practice location, partnership size, fundholding status, level of expenditure on

Table 1. Characteristics of final intervention and control groups. Figures indicate the number of practices unless stated otherwise.

	Control group	Intervention group	Intervention-accepting group
Total number of practices	56	57	33
Total number of GPs	104	129	75
Total population served	213 706	250 805	143 068
Partnership size			
Single-handed	27	25	13
Multi-partner	29	32	20
Fundholding status			
Fundholders	21	22	13
Non-fundholders	35	35	20
Dyspepsia drug usage			
Below average	29	29	16
Above average	27	28	17
Previous involvement in local guideline initiatives			
Involved	11	11	7
Not involved	45	46	26

acid-suppressing drugs, or previous involvement in a local guideline initiative.

Seminar attendance

Thirteen seminars were held over a period of six weeks beginning in September 1997. Fifty-nine GPs (79%) from the 33 intervention-accepting practices attended them. Reasons for non-attendance included annual leave, pregnancy, and unexpected clinical or personal problems.

Twenty-three reinforcement visits were made after three months and all but one of the practices, which declined further input, were revisited. Fifty-five GPs (73%) attended these meetings, comprising 49 who had attended the initial seminars and a further six who had not been able to attend. Therefore, overall, contact was made with 65 of the 75 GPs (87%) who accepted the intervention. Although ten GPs did not attend the initial or reinforcement visits, all of the accepting practices were represented at one or other of them.

Appropriateness of referral

Inter-rater reliability for ratings of the appropriateness of referral was high ($\kappa = 0.824$). Overall, practices in the intervention group made a significantly greater proportion of appropriate referrals than control practices (Table 2). Practices accepting the intervention made a higher proportion of appropriate referrals than those refusing the intervention although this difference was not statistically significant. The reasons for referral are shown in Table 3.

Findings at open access endoscopy

There was no change in the relative proportions of major, minor, and normal endoscopic findings pre- and post-intervention for either group of practices (Table 4).

Prescription costs for acid-suppressing drugs

Overall expenditure. A *t*-test of the differences in expenditure (six months post-intervention – six months pre-intervention) on the combined NIC/PU for H_2RAs and PPIs revealed a significantly greater increase in the treatment group than in the control group ($t = -2.360$, $P = 0.020$; Table 5). This increase was more apparent in the intervention-accepting practices than in the intervention-refusing practices, although not statistically significant.

Expenditure on individual drug classes. The changes in expenditure on H_2RAs for intervention and control practices were in opposite directions, declining in control practices, but increasing in intervention practices. This difference was statistically significant ($t = -2.843$, $P = 0.005$). Expenditure on PPIs increased for both groups, although the rise in the intervention group was greater than that in the control group. This difference was not statistically significant ($t = -1.340$, $P = 0.183$). Although not significant, the increase in overall expenditure in the intervention practices was attributable primarily to the increase in expenditure on PPIs (Table 6).

Testing rates for H pylori. The number of serological tests for *H. pylori* requested by the intervention practices was greater than that for control practices (median = 4 versus 0, respectively; Mann–Whitney $z = -3.31$, $P<0.001$). The practices that accepted the intervention tested more frequently than those that declined it, and more frequently than the controls (median = 8 versus 1 and 0, respectively; Kruskal–Wallis $\chi^2 = 19.59$, $P<0.001$).

Discussion

This study is important because it shows that quality improvement initiatives utilising referral guidelines will be dependent for their success upon an effective dissemination and implementation strategy. Few publications exist of United Kingdom-based studies of educational outreach as a means of facilitating guideline uptake. None in fact have examined how this strategy affects the appropriateness of referral from primary to secondary care.

In this study, the dissemination of clinical practice guidelines using educational outreach proved to be a more effective means of changing practice than passive guideline dissemination alone, supporting the concept that active educational interventions are an effective means of changing clinical behaviour when applied to guideline introduction.[10] Importantly, this study utilised guidelines that were developed with local GPs and congruent with other guidelines

Table 2. Percentage of appropriate referrals from control, intervention-accepting, and intervention-refusing practices, showing the median percentage of appropriate endoscopy referrals from practices that made at least one referral. Significance of difference between control and intervention practices: Mann–Whitney z = –2.235, 1 df, P = *0.025.*

	Median percentage of appropriate referrals per practice (interquartile range)
Control (36 practices)	50.0 (22.1–72.4)
Intervention (44 practices)	63.9 (50.0–100.0)
Intervention-accepting (27 practices)	72.7 (50.0–100.0)
Intervention-refusing (17 practices)	62.5 (41.4–100.0)

Table 3. Reasons for referral. Table shows the number (percentage) of referrals.

Referral reason	Control group referrals (%) (*n* = 197)	Intervention group referrals (%) (*n* = 357)	All referrals (%) (*n* = 554)
Appropriate reasons			
The presence of sinister features	49 (24.9)	92 (25.8)	141 (25.4)
Patient greater than 45 years of age at onset	23 (11.7)	68 (19.1)	91 (16.4)
A continuing need for/unsatisfactory response to therapy	17 (8.6)	45 (12.6)	62 (11.2)
NSAID-related dyspepsia	7 (3.6)	14 (3.9)	21 (3.8)
Other criteria for appropriate referral	4 (2.0)	3 (0.8)	7 (1.3)
Inappropriate reasons			
Under-treatment prior to referral	15 (7.6)	18 (5.0)	33 (6.0)
A paucity of information in the referral	54 (27.4)	72 (20.2)	126 (22.7)
Over-treatment prior to referral	22 (11.2)	29 (8.1)	51 (9.2)
Other criteria for inappropriate referral	6 (3.0)	16 (4.5)	22 (4.0)

Table 4. Findings at open access endoscopy in the pre- and post-intervention periods, showing the number (percentage) of endoscopies performed.

	Control group (56 practices) (%)		Intervention group (57 practices) (%)	
	Pre-intervention	Post-intervention	Pre-intervention	Post-intervention
Endoscopic findings				
Major	83 (37.4)	70 (35.5)	92 (31.1)	113 (31.7)
Minor	55 (24.8)	50 (25.4)	87 (29.4)	89 (24.9)
Normal	84 (37.8)	77 (39.1)	117 (39.5)	155 (43.4)
Totals	222	197	296	357

Table 5. Mean NIC/PU for combined expenditure on H_2RAs and PPIs in the pre- and post-intervention periods (£ sterling).

Practice status (number of practices)	Six months pre-intervention	Six months post-intervention	Difference (post-intervention – pre-intervention)	Percentage increase	Difference (95% CI)
Control (56)	4.0741	4.1754	0.1012	2.48	–0.21[a] (–0.39 to –0.03)
Intervention (57)	4.1102	4.4223	0.3121	7.59	
Intervention-accepting (33)	4.1179	4.4915	0.3736	9.07	
Intervention-refusing (24)	4.0996	4.3271	0.2275	5.55	

[a]t = –2.360, P = 0.020

Table 6. Mean NIC/PU for H_2RAs and PPIs (£ sterling). Figures in parentheses indicate standard deviations.

Practice status (number of practices)	Six months pre-intervention (H_2RAs)	Six months post-intervention (H_2RAs)	Difference[a]	% change	Six months pre-intervention (PPIs)	Six months post-intervention (PPIs)	Difference[b]	% change
Control (56)	1.3495 (0.49)	1.2843 (0.45)	–0.0652	– 4.83	2.7250 (0.84)	2.8907 (0.88)	+0.1657	+ 6.08
Intervention (57)	1.3442 (0.58)	1.3874 (0.60)	+0.0432	+ 3.21	2.7653 (0.94)	3.0344 (1.17)	+0.2691	+ 9.73
All practices (113)	1.3468 (0.53)	1.3363 (0.53)	–0.0105	– 0.78	2.7453 (0.88)	2.9632 (1.03)	+0.2179	+ 7.94

[a]Control – intervention difference = –0.11, 95% CI = –0.18 to –0.03); t = –2.843, P = 0.005. [b]Control – intervention difference = –0.10, 95% CI = –0.26 to 0.05; t = –1.340, P = 0.183

available in the UK at the time. The superior effect of educational outreach may have been owing to the fact that it encouraged physician involvement in an educational interaction and included clear descriptions of appropriate management supported by reinforcement visits.[4]

The intervention successfully enhanced the appropriateness of referral for open access endoscopy. The main differences between the intervention and control groups lay in the proportions of referrals deemed appropriate because patients were over 45 years of age at the onset of dyspepsia or deemed inappropriate because of a paucity of information in the referral letter. As in previous studies,[11-13] a key reason for inappropriate referral was insufficient empirical therapy prior to referral. The observed difference with respect to age at referral may indicate either an improved appreciation of age as a potential indicator of neoplasia, or its use to legitimise referral in the absence of other criteria for appropriate referral. The overall number of referrals by intervention practices also increased relative to controls, raising the possibility that control practices may have previously underreferred. The study was unable to test this hypothesis. A second limitation is that the appropriateness of referral in this study was based on GP referral letters. Review of patients' medical records would have provided insight into the extent to which doctors failed to refer patients who warranted referral, or selectively used guideline criteria to legitimise inappropriate referrals.[14] Unfortunately this was beyond our resources.

Contrary to expectation, the intervention did not influence diagnostic yield. Other studies[15] have similarly failed to demonstrate a relationship between referral appropriateness and endoscopic findings. This may be because dyspeptic symptoms are poor predictors of underlying pathology, and the use of potent pre-endoscopy therapy may mask any increase in the proportions of non-malignant disorders, such as peptic ulceration or oesophagitis.[16]

Another unexpected finding was the significant increase in drug expenditure following guideline uptake. Previous studies have suggested that prescribing costs for acid-suppressing drugs may be modified through the use of educational outreach.[17-19] The reasons why expenditure on acid-suppressing drugs increased in our study are unclear. The guidelines advocated greater use of acid-suppressing drugs in patients with complicated oesophageal disease and as gastric cytoprotection for at-risk patients using aspirin or NSAIDs. Testing for *H pylori* increased and presumably therefore the use of eradication therapies also increased. We will also have heightened awareness of the need for appropriate prescribing generally. We do not however have any direct evidence that these changes in prescribing were appropriate, as prescribing data from PACT are not linked to clinical data for individual patients. Medical record audit would have provided better information about appropriateness but was beyond our resources.

Although some GPs may have been attracted by the availability of the relatively new technology of *H. pylori* serology as a means of facilitating the management of dyspepsia, the rate of uptake of new technologies is not always matched by the rate at which other types of behaviour are abandoned or altered,[21,22] One explanation for the overall change in behaviour of intervention group practices is that they increased acid-suppressing drug use and testing for *H. pylori* in younger patients while referring older patients for open access endoscopy. All GPs may have felt that the guidelines legitimised a greater use of therapy.

Conclusion

This study supports other research in suggesting that educational outreach is more effective than passive guideline dissemination in promoting changes in clinical behaviour. However, the intervention also produced unintended outcomes, notably an increase in prescribing expenditure. Before it is more widely used, the strategy used here requires further investigation to confirm that changes in GP behaviour improved patient outcomes, and to assess the overall cost-effectiveness of this expensive intervention.

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