

A randomized controlled trial to assess the impact of a printed summary of research findings in general practice

J M PARRY

R C FOY

C B J WOODMAN

J J DEEKS

I WATT

T A SHELDON

SUMMARY

Background. The September 1995 issue of the *Effectiveness Matters* bulletin summarized existing research on the eradication of *Helicobacter pylori* in the treatment of peptic ulcer disease. It described effective diagnostic and eradication strategies, and concluded that individuals with diagnosed peptic ulcer should be considered for eradication therapy.

Aim. To investigate the impact of distribution of a printed summary of research findings on general practitioners' (GPs') self-reported management of peptic ulcer disease and dyspepsia.

Method. Randomized controlled trial incorporating before-and-after measurements in 265 GPs within two health regions in the United Kingdom. Change in self-reported management of peptic ulcer disease, as assessed by baseline and follow-up questionnaire; perceptions of the cost-effectiveness of *H. pylori*-based strategies for upper gastrointestinal disorders; and sources of information used by GPs to gain further advice on the management of dyspepsia were assessed.

Results. Two hundred and six GPs completed both questionnaires. There were no statistically significant differences in the use of *H. pylori* strategies for peptic ulcer (odds ratio [OR] = 0.76; 95% confidence interval [CI] = 0.37 to 1.57), or dyspepsia (OR = 1.36; 95% CI = 0.68 to 2.73). There was also no evidence of a change in perceptions of cost-effectiveness. However, distribution of the bulletin did impact on the information sources, with significant reductions in reliance on pharmaceutical company information (OR = 0.43; 95% CI = 0.22 to 0.83) and academic journals (OR = 0.48; 95% CI = 0.27 to 0.85).

Conclusions. Distribution of a single, printed summary of research findings in isolation from other interventions is unlikely to impact on patient management. However, it may

replace commercial literature and other sources of information for reasons of time efficiency or perceived neutrality.

Keywords: randomized controlled trial; *Helicobacter pylori*; peptic ulcer disease; disease management.

Introduction

EFFECTIVENESS Matters is a bulletin summarizing current evidence on specific health interventions produced by researchers at the NHS Centre for Reviews and Dissemination at the University of York, and is a sibling publication of the *Effective Health Care* bulletins. It is a four-page summary of the results of systematic reviews and other evaluations written in a short semi-journalistic style, and is distributed to over 50 000 practitioners and decision-makers in the NHS, including all general practitioners (GPs). The September 1995 issue summarized existing research on the eradication of *Helicobacter pylori* in the treatment of peptic ulcer disease.¹ The bulletin emphasized the association of *H. pylori* with peptic ulcer, described effective diagnostic and eradication strategies, and concluded that all individuals with diagnosed peptic ulcer should be considered for eradication therapy. The management of uninvestigated dyspepsia was also discussed. *Effectiveness Matters* cited research that had concluded that the use of empirical ulcer-healing drugs was a less cost-effective strategy than referral for endoscopy,² but given the lack of evidence was unable to define precisely the role, if any, for *H. pylori* testing and eradication in the management of patients with uninvestigated dyspepsia.

The aim of this study was to assess the impact of *Effectiveness Matters* on GPs' self-reported management of peptic ulcer disease, using a randomized controlled trial. Secondary objectives were:

- to assess GPs' perception of the cost-effectiveness of *H. pylori*-based strategies compared with empirical ulcer-healing drugs in the management of upper gastrointestinal disorders, and
- to investigate whether receipt of the bulletin influenced the sources of information used by GPs to gain further advice on the management of dyspepsia.

Method

Figure 1 describes the progress of GPs throughout the trial. A pre-existing sample of GPs already participating in a survey of dyspepsia management was utilized opportunistically as the study population. This sample ($n = 396$) had been identified by sampling one in 20 practitioners from the (former) Family Health Service Authorities' (FHSAs') lists in the North West ($n = 177$) and South West ($n = 219$) regions of England.

All GPs were sent a questionnaire to obtain information on their self-reported management of dyspepsia. Questions were based around brief clinical vignettes with multiple choice therapeutic and investigative options. One vignette described the case of a 42-year-old man with a proven duodenal ulcer and symptoms controlled by maintenance ulcer-healing drugs who was

J M Parry, MChB, lecturer; R C Foy, MRCGP, MFPHM, senior registrar; and C B J Woodman, MFPHM, professor, Centre for Cancer Epidemiology, Withington, Manchester. J J Deeks, PhD, medical statistician, Centre for Statistics in Medicine, Institute of Health Sciences, Headington, Oxford. I Watt, MFPHM, professor, NHS Centre for Reviews and Dissemination; and T A Sheldon, MSc, professor, York Health Policy Centre, University of York.

Submitted: 7 September 1998; final acceptance: 10 March 1999.

© British Journal of General Practice, 1999, 49, 634-638.

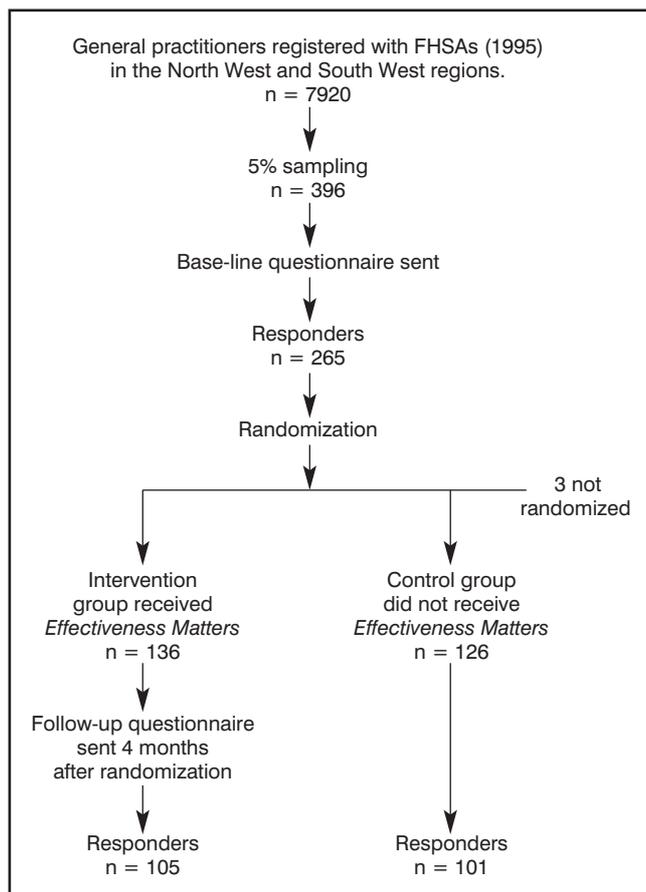


Figure 1. Trial flow chart.

attending for a repeat prescription, and also that of a 32-year-old man presenting with uncomplicated dyspepsia and whose symptoms had not responded to simple antacids or lifestyle advice. Opinions on the cost-effectiveness of *H. pylori* eradication strategies for the management of upper gastrointestinal conditions were sought, as were details of the information sources the GPs had used to guide their management of dyspepsia during the previous six months.

Two hundred and sixty-five (67%) GPs responded to the baseline questionnaire and were randomized to be sent, or not be sent, a copy of *Effectiveness Matters* at the time of its general United Kingdom distribution. Randomization was performed at a separate centre without knowledge of the baseline survey results, using computer-generated random numbers, and was stratified by region. One hundred and thirty-six GPs were randomized to receive *Effectiveness Matters* and 126 were randomized to the control group that received the bulletin after the trial had been completed (three GPs were excluded because of a death, a retirement, and a change of practice). To avoid contamination, the partners of the GPs who were allocated not to receive the bulletin were also temporarily excluded from being sent a copy. While the GPs involved in the trial were aware that we were studying their management of gastrointestinal disorders, they were unaware of the nature of the intervention.

Four months after distribution of *Effectiveness Matters*, the whole sample ($n = 262$) were sent a further questionnaire. This was similar to, but shorter than, the original baseline version, containing just six of the original 12 questions, with no new questions asked. Full copies of the two questionnaires are available from the authors on request.

Statistical methods

Only GPs completing both questionnaires for each outcome measure were included in the analysis. For each outcome a logistic generalized estimating equation model was used to analyse the change in responses while retaining the paired nature of the data.³ Terms were included in the models for time (to test whether there was an overall change in response between the two questionnaires) and for the interaction between time and group (to test whether the change was different in the group that received *Effectiveness Matters*). The results are reported as odds ratios, together with 95% confidence intervals. Confidence intervals and significance tests were computed using robust standard errors. Analysis was undertaken using STATA statistical software.⁴

Sample size estimates used the response to the vignette regarding the management of proven peptic ulcer disease. At baseline, 190 (73%) GPs who responded to the baseline questionnaire used *H. pylori*-based management strategies. Assuming 80% power with 5% two-sided significance, a sample size of 242 (121 in each group) is required to demonstrate a 15% difference in the use of *H. pylori* eradication strategies between the control and intervention groups. The incorporation of baseline data was not considered in this calculation but will have increased statistical power.

Results

General practitioners in the intervention ($n = 136$) and in the control ($n = 126$) groups had similar characteristics (Table 1). Two hundred and six (79%) GPs (105 and 101 in the intervention and control groups respectively) responded to the follow-up questionnaire sent out after distribution of *Effectiveness Matters*. The only factors for which responders and non-responders differed by more than 10% were that they were more likely to be from a general practice involved in training, to consult the GP press, and to have access to urea breath-testing.

Almost all (195/201) GPs reported in the baseline survey (Table 2) that they believed eradication of *H. pylori* infection to be a more cost-effective treatment for proven peptic ulcer than traditional acid suppressing therapy. In contrast, only a minority (23/201) cited eradication of *H. pylori* to be more cost-effective in the management of a hiatus hernia. However, substantial uncertainty was apparent in responders' perceptions of the usefulness of eradication therapy in both the treatment of uninvestigated dyspepsia (76/201) and the prevention of gastric cancer (74/200). Distribution of the bulletin had no impact on these rates, which remained stable during the study period.

General practitioners in the intervention group were significantly less likely to cite pharmaceutical company representatives or literature (OR = 0.43; 95% CI = 0.22 to 0.83) and academic journals (OR = 0.48; 95% CI = 0.27 to 0.85) as sources of information following receipt of *Effectiveness Matters*, and more likely to cite *Effectiveness Matters* as a source of information (OR = 3.99; 95% CI = 1.10 to 14.5). Non-significant reductions in the use of other sources (other than the GP press) were also noted.

The responses to the two vignettes are summarized in Tables 4 and 5. The use of *H. pylori*-based strategies for the management of uninvestigated dyspepsia increased equally in both groups during the study period. There was some evidence that GPs who received *Effectiveness Matters* were less likely to prescribe ulcer-healing drugs alone (OR = 0.54; 95% CI = 0.29 to 1.01) than those in the control group. There were no significant changes in either group regarding the treatment of proven duodenal ulceration.

Table 1. Distribution of characteristics of GPs who returned the base-line questionnaire (n = 262).

Characteristic	Effectiveness Matters distribution group	Effectiveness Matters withheld group
Response rates		
Included in trial	136	126
Responded to second survey	105 (77%)	101 (80%)
Sample characteristics		
In North West region	71 (52%)	66 (52%)
In South West region	65 (48%)	60 (48%)
Fundholding ^a	52 (40%)	51 (42%)
Group practices ^a	110 (91%)	107 (93%)
Training practices ^a	44 (51%)	42 (54%)
Availability of diagnostic services		
Open access endoscopy	98 (72%)	85 (67%)
Local gastroenterologist	130 (96%)	118 (94%)
H. pylori laboratory tests	60 (44%)	57 (45%)
H. pylori desktop tests	23 (17%)	18 (14%)
H. pylori urea breath tests	11 (8%)	7 (6%)
Endoscopy waiting time (weeks)	6	6
[median, interquartile range]	[4,12]	[4, 8]

^aFigures reported are percentages of all those responding to these questions.

Table 2. Opinions on cost-effectiveness of *Helicobacter pylori* eradication.

Group	Before n (% yes)	After n (% yes)	Effect of intervention OR (95% CI)
Is <i>H. pylori</i> eradication cost-effective for dyspepsia?			
Effectiveness Matters distributed (n = 101)	34 (34)	33 (33)	1.30 (0.67–2.50)
Effectiveness Matters withheld (n = 100)	42 (42)	34 (34)	P = 0.4
Is <i>H. pylori</i> eradication cost-effective for peptic ulcer?			
Effectiveness Matters distributed (n = 101)	99 (98)	97 (96)	0.36 (0.05–2.62)
Effectiveness Matters withheld (n = 100)	96 (96)	97 (97)	P = 0.3
Is <i>H. pylori</i> eradication cost-effective for hiatus hernia?			
Effectiveness Matters distributed (n = 101)	8 (8)	6 (6)	1.33 (0.39–4.52)
Effectiveness Matters withheld (n = 100)	15 (15)	9 (9)	P = 0.6
Is <i>H. pylori</i> eradication cost-effective for prevention of gastric cancer?			
Effectiveness Matters distributed (n = 101)	38 (38)	40 (40)	0.81 (0.43–1.53)
Effectiveness Matters withheld (n = 99)	36 (36)	43 (43)	P = 0.5

Discussion

This study reports one of the rare examples of dissemination activities being evaluated experimentally. However, the study has some significant weaknesses. The study did not record any objective measure of clinical practice and instead relied on self-reported responses to questions about vignettes. The use of vignettes to assess practice may produce responses that reflect more what the GP thinks the investigator wants to hear, rather than one that truly reflects practice. Prescribing data were not analysed because drugs used in *H. pylori* eradication regimens are also used for other indications; drug use data would therefore be difficult to interpret.

This study has not been able to demonstrate a significant difference between the control and intervention groups with regard to their reported management of proven duodenal ulcer disease. However, the baseline survey demonstrated a high level of background knowledge with respect to *H. pylori* and duodenal ulcer disease, and there was thus little scope for improvement in response to receipt of the *Effectiveness Matters* bulletin.

The change in the frequency of use of ulcer-healing drugs in the management of uninvestigated dyspepsia was of borderline significance but was consistent with the evidence presented in *Effectiveness Matters*. Owing to the considerable uncertainties in the evidence base, no specific advice was given in the bulletin of the role of *H. pylori* testing or eradication in the management of

uninvestigated dyspepsia. Despite this, the use of *H. pylori*-based strategies increased substantially in both groups of GPs during the study period. There is still no clear evidence to support the use of such strategies in primary care, and the results of ongoing randomized controlled trials are awaited.

Only 16 (15%) GPs who were randomized to receive *Effectiveness Matters* cited it as a source of information. It is possible that this comparatively low overall citation rate may reflect the difficulties of a single item of educational material being noticed among the mass of mail received by GPs.⁵ However, the *H. pylori* issue of the bulletin was only the second in this new series and so may not have reached its maximal 'product recognition'. Of note, analysis of the subgroup of the GPs who were randomized to receive the bulletin and who cited it as a source of information revealed that they were more likely to respond in a manner consistent with the evidence than other responders. For example, all 16 (100%) would use eradication therapy in the management of proven peptic ulcer disease, compared with 147/190 (77%) among those who were not allocated to receive or did not cite the bulletin (Fisher's exact test, $P = 0.03$). This was an increase of 31% for the subgroup following distribution of the bulletin, compared with 4% in the other group. However, it is not clear if this indicates that materials such as the bulletin have more effect on evidence-sensitive doctors and so should be better targeted in future, or whether referring to the

Table 3. Sources used to guide management in the past six months.

Group	Before n (% yes)	After n (% yes)	Effect of intervention OR (95% CI)
Dyspepsia management guided in the past six months by postgraduate education meetings			
Effectiveness Matters distributed (n = 104)	75 (72)	67 (64)	0.68 (0.35–1.31) P = 0.2
Effectiveness Matters withheld (n = 101)	67 (66)	68 (67)	
Dyspepsia management guided in the past six months by local guidelines			
Effectiveness Matters distributed (n = 104)	56 (54)	50 (48)	0.64 (0.35–1.19) P = 0.16
Effectiveness Matters withheld (n = 101)	49 (49)	54 (53)	
Dyspepsia management guided in the past six months by pharmaceutical company representatives and information			
Effectiveness Matters distributed (n = 104)	56 (54)	39 (38)	0.43 (0.22–0.83) P = 0.01
Effectiveness Matters withheld (n = 101)	36 (36)	40 (40)	
Dyspepsia management guided in the past six months by Drugs and Therapeutics Bulletin			
Effectiveness Matters distributed (n = 104)	60 (58)	42 (40)	0.53 (0.27–1.02) P = 0.06
Effectiveness Matters withheld (n = 101)	50 (50)	49 (49)	
Dyspepsia management guided in the past six months by Effectiveness Matters newsletter			
Effectiveness Matters distributed (n = 104)	6 (6)	16 (15)	3.99 (1.10–14.5) P = 0.04
Effectiveness Matters withheld (n = 101)	4 (4)	3 (3)	
Dyspepsia management guided in the past six months by GP press			
Effectiveness Matters distributed (n = 104)	58 (56)	59 (57)	1.07 (0.57–1.99) P = 0.8
Effectiveness Matters withheld (n = 101)	57 (56)	56 (55)	
Dyspepsia management guided in the past six months by academic journals			
Effectiveness Matters distributed (n = 104)	42 (40)	35 (34)	0.48 (0.27–0.85) P = 0.01
Effectiveness Matters withheld (n = 101)	35 (35)	46 (46)	

Table 4. Management of a dyspeptic patient.

Group	Before n (% yes)	After n (% yes)	Effect of intervention OR (95% CI)
Would use <i>Helicobacter pylori</i> serology and/or eradication ^a			
Effectiveness Matters distributed (n = 104)	19 (18)	36 (35)	1.36 (0.68–2.73) P = 0.4
Effectiveness Matters withheld (n = 101)	19 (19)	29 (29)	
Would use ulcer-healing drugs and monitor symptoms			
Effectiveness Matters distributed (n = 104)	71 (68)	48 (46)	0.54 (0.29–1.01) P = 0.05
Effectiveness Matters withheld (n = 101)	61 (60)	54 (53)	
Would refer for endoscopy alone			
Effectiveness Matters distributed (n = 104)	6 (6)	9 (9)	1.73 (0.63–4.72) P = 0.3
Effectiveness Matters withheld (n = 101)	11 (11)	10 (10)	
Would do serology test for <i>H. pylori</i> alone			
Effectiveness Matters distributed (n = 104)	5 (5)	9 (9)	1.40 (0.25–7.76) P = 0.7
Effectiveness Matters withheld (n = 101)	3 (3)	4 (4)	
Would use ulcer healing drugs and refer for endoscopy			
Effectiveness Matters distributed (n = 104)	7 (7)	11 (11)	1.91 (0.65–5.59) P = 0.2
Effectiveness Matters withheld (n = 101)	10 (10)	8 (8)	
Would use ulcer healing drugs and do serology test for <i>H. pylori</i> ^a			
Effectiveness Matters distributed (n = 104)	12 (12)	24 (23)	1.10 (0.46–2.64) P = 0.8
Effectiveness Matters withheld (n = 101)	13 (13)	24 (24)	
Would prescribe course of <i>H. pylori</i> eradication therapy without further testing			
Effectiveness Matters distributed (n = 104)	2 (2)	3 (3)	4.67 (0.37–58.7) P = 0.2
Effectiveness Matters withheld (n = 101)	3 (3)	1 (1)	

^aSignificant time effects were detected for these two outcomes.

bulletin is a marker of those GPs who would have changed practice anyway. This should be tested prospectively in further experiments.

The significant reduction among the intervention group in reliance upon commercially-sponsored advice from pharmaceutical representatives or associated literature is interesting, and may indicate the worth attributed by clinicians to printed evidence originating from nationally recognized, 'neutral' organizations. The non-significant trends away from other sources of information suggest a substitution of information sources among GPs in

the intervention group. The provision of credible summaries of evidence may allow GPs to make more efficient use of limited reading and educational time. It is possible that we have identified such a substitution effect.

A recent systematic review⁶ has concluded that printed educational materials have, at best, only a small direct impact on practice. However, the distribution of printed educational materials might still be cost-effective because the small effects seen are at relatively low cost. It may also be unrealistic to judge such educational materials on their direct impact in practice. With respect to

Table 5. Management of a patient with proven duodenal ulcer controlled by ulcer healing drugs.

Group	Before n (% yes)	After n (% yes)	Effect of intervention OR (95% CI)
Would use <i>Helicobacter pylori</i> serology and/or eradication			
Effectiveness Matters distributed (n = 105)	73 (70)	78 (74)	0.76 (0.37–1.57)
Effectiveness Matters withheld (n = 101)	77 (76)	85 (84)	P = 0.5
Would continue H ₂ antagonists			
Effectiveness Matters distributed (n = 105)	8 (8)	7 (7)	1.79 (0.42–7.67)
Effectiveness Matters withheld (n = 101)	6 (6)	3 (3)	P = 0.4
Would check <i>H. pylori</i> status and prescribe eradication therapy if positive			
Effectiveness Matters distributed (n = 105)	53 (51)	50 (48)	0.62 (0.34–1.13)
Effectiveness Matters withheld (n = 101)	54 (53)	63 (62)	P = 0.12
Would prescribe eradication therapy without checking <i>H. pylori</i> status			
Effectiveness Matters distributed (n = 105)	20 (19)	28 (27)	1.64 (0.84–3.17)
Effectiveness Matters withheld (n = 101)	23 (23)	22 (22)	P = 0.15
Would stop H ₂ antagonists and see if symptoms recur			
Effectiveness Matters distributed (n = 105)	20 (19)	18 (17)	1.14 (0.46–2.83)
Effectiveness Matters withheld (n = 101)	15 (15)	12 (12)	P = 0.8

changing behaviour, the research on marketing makes a distinction between strategies to raise awareness of a message and those that lead to implementation.⁷ Both are said to be necessary, although they have different roles. In this respect, materials such as *Effectiveness Matters* (and possibly the *Effective Health Care* bulletins) might be better judged in relation to the extent to which they raise awareness among their target audiences and can be used by others to promote implementation, rather than their direct impact on behaviour. Even in situations such as this study, where there are apparently high pre-existing levels of awareness, printed educational materials may still have a role in helping maintain desired knowledge and practice. Given the frequent use of printed materials to disseminate research findings and the current emphasis in health policy in promoting clinical effectiveness, further research on their impact, which combines quantitative with more exploratory qualitative data collection, is necessary.

References

1. NHS Centre for Review and Dissemination, University of York. *Helicobacter pylori* and peptic ulcer. *Effectiveness Matters* 1995; **1**(2).
2. Sonnenberg A, Townsend WF. Costs of duodenal ulcer therapy with antibiotics. *Arch Int Med* 1995; **155**: 922-928.
3. Diggle PJ, Liang KY, Zeger SL. *Analysis of longitudinal data*. Oxford: Oxford University Press, 1994.
4. StataCorp. *Stata Statistical Software: Release 5.0*. College Station, TX: Stata Corporation, 1997.
5. Kenny D. Analysis of the bureaucratic unsolicited mountainous paper heap (BUMPH) that general practitioners received in 1994. *BMJ* 1995; **311**: 1705-1706.
6. Freemantle N, Harvey E, Grimshaw J, *et al*. The effectiveness of printed educational materials in changing behaviour of healthcare professionals. In: *The Cochrane Database of Systematic Reviews*. Oxford: The Cochrane Collaboration, Update Software, 1997.
7. Lomas J. *Teaching old (and not so old) dogs new tricks: Effective ways to implement research findings*. [Paper 93-4.] Hamilton: Centre for Health Economics and Policy Analysis, McMaster University, 1993.

Acknowledgement

We would like to thank Dr Liam Murray for his assistance in coordinating the distribution of questionnaires in the South West region.

Address for correspondence

Dr J M Parry, NHS Executive West Midlands, Bartholomew House, 142 Hagley Road, Birmingham B16 9PA. E-mail: jparrz@doh.gov.uk