A randomised controlled trial of the effect of educational outreach by community pharmacists on prescribing in UK general practice

Nick Freemantle, Irwin Nazareth, Martin Eccles, John Wood, Andrew Haines and the Evidence-based OutReach (EBOR) trialists

SUMMARY

Background: *Educational outreach visits are commonly used to promote changes in prescribing in family practice. However, the effectiveness of outreach visits has not been evaluated across a range of settings.*

Aim: *To estimate the effectiveness of educational outreach visits on United Kingdom (UK) general practice prescribing and to examine the extent to which practice characteristics influenced outcome.*

Design of study: *Randomised controlled trial.*

Setting: *General practices in 12 health authorities in England.*

Method: *Educational outreach visits were made to practices that received two of four guidelines. Each practice provided data on treatment of patients for all four guidelines for both pre and post-intervention periods. The primary outcome is average effect across all four guidelines. Secondary analyses examined the predictive effect of practice and guideline characteristics.*

Results: *Seventy per cent of practices approached agreed to take part in the intervention. Overall, educational outreach was associated with a significant improvement in prescribing practice (odds ratio [OR] = 1.24 [95% CI = 1.07 to 1.42]), a 5.2% (95% CI = 1.7% to 8.7%) increase in the number of patients treated within the guideline recommendations. Smaller practices (two or fewer full-time equivalent practitioners) responded much more favourably to educational outreach than larger practices. Smaller practices improved their performance in line with the guidelines by 13.5% (95% CI = 6% to 20.9%) attributable to outreach, while larger practices improved by only 1.4% (95% CI = -2.4% to 5.3%,* P*-value for interaction <0.001).*

Conclusion: *In large practices, educational outreach alone is unlikely to achieve worthwhile change. There is good evidence to support the use of educational outreach visits in small practices.*

Keywords: *prescribing; educational outreach; randomised controlled trial.*

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Introduction

EDUCATIONAL outreach visits are commonly used to promote changes in prescribing in family practice. However, the effectiveness of outreach visits has not been evaluated across a range of settings and the potential influence on the effectiveness of outreach, from both the content of the educational message and the practice characteristics, is not known.

The Evidence-based OutReach (EBOR) trial was designed to examine the acceptability and effectiveness of outreach visits, using a range of evidence-based clinical practice guidelines to promote changes in prescribing practice in primary care. We also aimed to examine the importance of several practice level factors with potential influence on the effectiveness of outreach visits that were identified a priori. These factors consisted of the number of practitioners working together in the targeted practice, the level of social deprivation, and the practitioner training status. The influence of specific guideline topics was also examined. The rationale and design of the EBOR trial has been described in detail previously.[1]

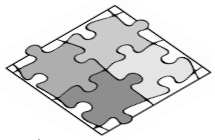
Method

Protocol

The study participants were general practices that were selected at random from lists provided by the 12 participating United Kingdom (UK) National Health Service (NHS) health authorities. Health authorities have an average population of around 250 000 and cover a defined geographical area. Around 95% of the general population are registered with a general practitioner (GP). All practices were potentially eligible for the study as long as they were willing to take part. Practices were offered outreach visits on two of four guidelines topics, according to a predetermined random schedule. Practices were offered Postgraduate Education Allowances (equivalent to Continuing Medical Education credits) for educational outreach visits where these met the local criteria for continuing education accreditation. Ethical committee approval was granted to all relevant health authorities.

The four clinical practice guidelines were developed using established techniques by the North of England Guidelines Development Project.[2] They examined the use of aspirin as antiplatelet therapy,[3] the use of angiotensin-converting enzyme (ACE) inhibitors in heart failure,[4] the use of non-

HOW THIS FITS IN



What do we know?

Educational outreach by clinical pharmacists is a commonly used intervention that aims to influence prescribing practice. It has been evaluated in many health care settings, but not in UK general practice.

What does this paper add?

The Evidence Based OutReach (EBOR) trial examined the effectiveness of outreach in UK general practice. Although effective overall, the benefits of outreach are concentrated in small practices.

steroidal anti-inflammatory drugs (NSAIDs) in the treatment of pain thought to be due to osteoarthritis,[5] and the choice of antidepressants in the treatment of depression.[6]

Community pharmacists were recruited to the study on a locum basis and undertook a three-day training and orientation programme that focused on the content of the guidelines and social marketing techniques. The community pharmacists' intervention involved two visits for each guideline topic. The content of the educational visits was dependent upon the educational needs of the practice, and followed the model for the content of educational outreach visits developed by Soumerai and Avorn[7] (Box 1). The pharmacists were provided with copies of the guidelines, summary sheets describing the main recommendations on a single sheet of paper, and key clinical papers. They were also provided with promotional materials specific to the guidelines. The intervention period commenced on 1 October 1997 and most interventions were completed by June 1998.

The community pharmacists aimed to include all members of practices, in-group visits, although the visits went ahead if some practice members were missing. The potential importance of attendance at visits was examined in the analysis, although this factor was not identified prospectively.

For the purposes of the study, specific outcome measures were derived from each guideline on the basis that they reflected important aspects of the recommendations and because it would then be possible to evaluate the degree to which prescribing was in line with the recommendations. All NHS prescriptions are returned to the Prescription Pricing Authority (PPA) once a pharmacist has dispensed them. The pre-intervention period sampling frame of eligible patients was identified from copies of all relevant prescriptions reimbursed by the PPA that were prescribed in September 1997. A similar post-intervention sample for September 1998 was identified from prescriptions selected on the same basis. Therefore, a two-stage process was used, in which the PPA provided photocopies of the prescriptions reimbursed from targeted practices for specific indications and time periods. These data provided the basis of a sampling frame linking target prescriptions with patients' names, which was then used to locate relevant notes within the practice.

Within each practice, patients who met the inclusion crite-

Commentary

I was asked to review this paper in my capacity as an ordinary GP. I recommended against publication because I was unhappy with the design of the study and with the interpretation of the results.

The problem with this paper may be with me because I am no statistician. I cannot get around the small degree of change that was detected and the wide confidence intervals. One of the educated groups showed a decrease in guideline-led prescribing, which instinctively makes me unhappy to accept the small changes in the other areas as significant. I am unhappy with the complicated and unexplained processing of the data. I might not follow the mathematical niceties but I think most data manipulations can be explained in terms understandable to the statistically challenged. This might make me more comfortable with what are bold conclusions.

I have been sent several papers over the past few years that are reports of projects to extend the role of community pharmacists. Most of these papers have followed a pattern of trying to spin the data to show a beneficial result. This may have made me fairly suspicious of this paper, which is wringing every ounce out of the data to show the desired effect. I am concerned that the conclusions are quite far reaching. Once published in a respectable journal, poor data can be come accepted as dogma.

Despite my criticisms of the research I have been sent, I have no difficulty in accepting community pharmacists in an extended role. My experience suggests that the evolution of the National Service Framework guidelines and Primary Care Trusts against a background of limited budgets is increasingly putting pharmacists into positions of education and advice. My own practice has had positive experience of this. Nonetheless, I continue to hold reservations about the conclusions drawn from this paper about this particular educational experiment.

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- Investigating baseline knowledge and motivations for current activity.
- Focusing programmes on specific categories of physicians as well as on their opinion leaders.
- Defining clear educational and behavioural objectives.
- Establishing credibility through a respected organisational identity, referencing authoritative and unbiased sources of information, and presenting both sides of controversial issues.
- Stimulating active participation by physicians in educational interactions.
- Using concise graphic educational materials that highlight and repeat essential messages.
- Providing positive reinforcement of improved practices in follow-up visits.

Box 1. Techniques of educational outreach.

ria for each guideline were identified and random samples of 25 patients for the pre-intervention and post-intervention periods were selected. The proportion of patients treated in line with the recommendations was established from the clinical records (both computerised and paper based) for each guideline for both the pre-intervention and post-intervention periods. Clinical research associates were trained to collect data in a consistent manner according to the trial protocol.

For the aspirin guideline, the outcome evaluated was the proportion of patients receiving low-dose aspirin while also receiving treatment with nitrates for angina. Patients' notes were used to identify any prescriptions of aspirin in the intervention period. As aspirin is available for purchase, we sought to ensure that evidence of appropriate aspirin use was available for audit and outcome evaluation. The outreach visits emphasised the importance of practitioners prescribing at least one dose of aspirin and recording in the notes if aspirin was being purchased over the counter.

For the heart failure topic, similar samples of patients were identified from prescriptions of loop diuretics. Patients with renal failure or other explicit non-heart failure-related diagnoses were excluded. The clinical notes were consulted to identify the proportion of patients who were either treated with ACE inhibitors or for whom heart failure had been investigated and the appropriateness of such treatment explicitly excluded.

The antidepressant guideline recommended the routine first-line use of tricyclic antidepressants, with selective serotonin reuptake inhibitors reserved for second-line use. The pre- and post-intervention patient samples were selected from patients currently treated with an antidepressant who had commenced therapy during the previous 12 months for the treatment of a new episode of depression. Patients' notes and prescribing records were examined to find out whether prescribing was in line with the sequence recommended in the guidelines.

The guideline examining the use of NSAIDs described a sequence for analgesia, involving the routine first-line use of paracetamol, followed, if necessary, by low and high doses of ibuprofen, and then diclofenac sodium and naproxen. Ultimately, alternative simple analgesia and alternative NSAIDs were recommended. The guideline also stressed the importance of regular review and the avoidance of long-term exposure to NSAIDs where possible. It was not feasible to make a direct examination of the use of paracetamol. Paracetamol is often not prescribed, as patients are able to purchase it. Consequently, we examined the proportion of prescriptions for NSAIDs that were within the guideline recommendations, i.e. for ibuprofen, or for an alternative drug where this was prescribed in accordance with the sequence indicated in the guideline.

For each guideline, the outcome of interest was represented as the proportion of patients treated in accordance with each guideline's recommendations, using a random sample of 25 patients per practice. Given the costs of providing the outreach visits, the minimum change in treatment that was considered to be significant and attributable to the guidelines was for two patients per practice to move from outside to within the guideline recommendations for each guideline. Applying a conservative range of assumptions, the trial had at least 80% power at conventional (5%) levels of statistical significance to identify this effect.

The effect of educational outreach was examined using generalised linear modelling.[8-9]

The trial Steering Group could find, a priori, no consistent rationale to suspect that any combination of guideline topics would be more or less likely to be associated with a change in practice as a result of outreach visits. Therefore, the primary analysis was the average effect of outreach across the four guideline topics. Secondary analyses included examination of the effect of specific guidelines and the potentially predictive factors identified above. Analyses were conducted by intention to treat.

Assignment

Six health authorities in the north of England and six in north London were allocated in pairs through a central random process to each of the six possible combinations of two of the four available guidelines for active outreach (Box 2). In each case the other two non-targeted guidelines provided control data. Guidelines were allocated at the health author-

Box 2. Allocation of guidelines for active delivery through outreach visits listed by health authority.

Pair of health authorities	Guidelines delivered through outreach
Camden and Islington/ North Yorkshire	NSAID and aspirin
Redbridge and Waltham Forest/ Leeds	Aspirin and ACE inhibitors
Enfield and Haringey/ Bradford	ACE inhibitors and antidepressant
Brent and Harrow/ North Humberside	NSAID and antidepressant
Barnet/ South Humberside	NSAID and ACE inhibitors
Barking and Havering/ Calderdale and Kirklees	Aspirin and antidepressant

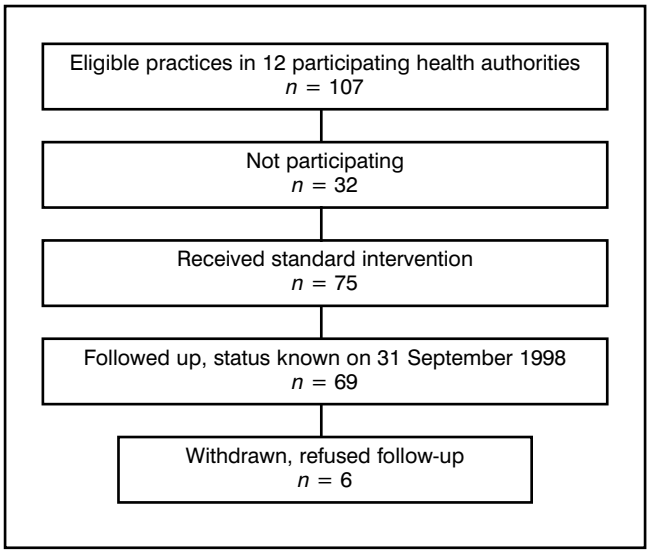

Figure 1. Profile of randomised trial.

ity level rather than the practice level to replicate the real world as far as possible. Block allocation also avoided potential contamination through communication between practices, simplified the training of the outreach workers, and aided the general support of health authority staff in the delivery of the intervention. Lists of practices in each health authority were stratified by size and used to randomly select practices for potential inclusion in the trial. To provide sufficient patient data for stable estimation, smaller practices (those with fewer than three full-time equivalent prescribers) were over-sampled and combined to form 'virtual practices' for the purposes of the analysis.

Masking (blinding)

The data collection staff were initially blinded to treatment allocation. However, on a few occasions practices unmasked themselves either through verbal comments from practice staff (for example; 'are you here with the aspirin project?') or through promotional materials left by the outreach worker. The subjects of the experiment (the practice staff) could not be blinded as to whether they received the intervention, and where possible the study was intended to provide a naturalistic setting in which to evaluate the effects of the intervention.[10] Practices were blind to the alternative guidelines for which they provided control data.

Results

Participant flow and follow-up

Overall, 107 practices were approached across the 12 participating health authorities, and 75 (70%) practices initially agreed to take part (Figure 1). Neither the topic of outreach visit nor the size of practice significantly predicted participation in the educational intervention and subsequent data collection. In two health authorities, recruiting practices proved particularly difficult. In one, eight practices out of 15 approached refused to participate. In a second health authority, seven out of 14 refused. There was no systematic difference in the extent to which practitioners in the north of England were prepared to participate than practices in north London ($P = 0.79$).

Altogether, data on 11 328 patients were collected, representing the work of 162 GPs in 69 practices. Although they participated in the intervention, nine (5.6 %) practitioners in six small practices ultimately refused to allow data collection for the evaluation. All six practices that refused follow-up were based in north London. There was a non-significantly larger effect in practices in the north of England than in the south (OR = 1.18, 95% CI = 86 to 1.62).

Practice characteristics

Practices that were included supplied data on both the intervention and control guidelines. The mean practice size was 2.75 partners and 5615 patients. All but three (4%) practices were computerised, at least in part, for prescribing. Only two practices (3%) had completely 'paperless' computerised systems.

Table 1. Baseline adherence to guideline recommendations.

	Percentage	95% CI	
		Lower limit	Upper limit
Overall	41	34	48
Large	42	34	49
Small	40	32	47

Baseline rates of adherence to guidelines recommendations

Overall, the baseline adherence to guidelines recommendations was 41%.

Primary outcome measure

Overall, outreach had a significant effect upon practice (OR = 1.24, 95% CI = 1.07 to 1.42). This is equivalent to a 5.2% (95% CI = 1.7% to 8.7%) improvement in the number of patients treated according to the guideline recommendations with the distribution of baseline values seen in this trial.

Effect of practice characteristics

We examined a predefined range of potentially important practice characteristics that may influence uptake of guideline messages. Neither practice population deprivation scores nor training status significantly predicted outcome. However, practice size did predict outcome significantly to a degree that may be considered of practical importance.

Smaller practices had a similar baseline rate of adherence to guidelines recommendations as larger practices (Table 1). Practices with two or fewer practitioners showed a substantial reaction to the effect of outreach. The odds ratio for the effect of outreach in smaller practices was 1.73 (95% CI = 1.28 to 2.33). In contrast, the effect in larger practices was modest and statistically non-significant (OR = 1.06, 95% CI = 0.90 to 1.24, P-value for interaction <0.001). On average, smaller practices improved their performance in line with the guidelines by 13.5% (95% CI = 6% to 20.9%) attributable to outreach, while larger practices improved by only 1.4% (95% CI = -2.4% to 5.3%).

Effect of specific guidelines

The trial steering committee, including clinicians and health policy makers, could find no consistent rationale to suggest that any specific guideline or combination of guidelines would prove more or less effective. Therefore, the primary outcome measure focused on the average effects across all guidelines, since this represented the best estimate of effect that may be associated with educational outreach on any guideline topic in the future.

The guidelines on aspirin and NSAID prescribing had significantly different effects on practice compared with the other two. The odds ratio associated with the effect of outreach with the aspirin guideline was 2.11 (95% CI = 1.76 to 2.54) and for the NSAID guideline it was 0.73 (95% CI = 0.56 to 0.94). Based upon the raw unadjusted data, the aspirin guideline was associated with a 7% average increase in patients managed in line with the recommendations. Similarly, the antidepressant guideline was associated with a 4% increase and the ACE inhibitor guideline was associated with a 2% increase. In contrast, the NSAID guideline was associated with a 3% reduction in patients managed appar-

ently in line with the guideline.

Discussion

Educational outreach visits had a modest (5.2%) average effect on the number of patients managed within the guideline recommendations compared with those whose management did not coincide with the recommendations. This result suggests a smaller effect than found by Avorn and Soumerai,[7] who reported a 14% change in prescribed drugs as a result of outreach visits that advised against prescription of propoxyphene, cerebral and peripheral vasodilators, and cephalexin, in selected US office-based practitioners who prescribed these drugs. Similarly, Diwan *et al*[11] observed a 10% increase in the use of first-line lipid-lowering drugs attributable to group outreach visits in non-academic practices in Sweden. However, in both previous trials the outcome was described as a change in the use of pharmaceuticals by a practitioner or within a practice, rather than a change in the proportion of patients managed according to specific guideline recommendations.

The high participation rate in the study (70% of practices consenting to participate) may be surprising, given recent questioning of the use of guidelines as standards of care on which practitioners may be judged, rather than as advice to be considered but not slavishly followed.[12]

The use of promotional items was optional, and most outreach workers used them only rarely.

In our trial the change in patient management attributable to outreach visits in larger practices was only 1%, while that achieved in solo practice and two-partner practices was 13.5%. How, then, might we account for the substantial differences observed? First, in small practices, staff may be more amenable to the decision to adopt different working practices, while in larger ones working practices may have greater organisational complexity and be much harder to influence. This suggestion is in line with the trend in the pharmaceutical industry away from relying solely upon visits from representatives to influence practice, and also in line with industry practice favouring individual rather than group visits.

Secondly, the intervention may be more intensive in smaller practices because of the nature of group educational interventions. Not all practitioners were present at every meeting or available for follow-up visits in larger practices, while in single-handed practices the visit could only proceed if the doctor was present. It is not possible to identify fully the extent to which these competing explanations account for the observed effect of practice size, but explanatory analyses undertaken *post hoc* identify a consistent linear decrease in effect with each additional partner (OR = 0.92, 95% CI = 0.86 to 0.99).

In single-handed or two-partner practices (mean = 1.4 partners, SD = 0.5) included in the trial, 96% of doctors attended outreach visits, while in larger practices (mean = 4.4 partners, SD = 1.5), 48% attended. The extent to which participation in meetings affected uptake of guidelines messages was examined directly in the generalised linear model. In two separate analyses, those practices in which 75% or more practitioners were present at meetings did not differ in response from those who had a lower level of attendance ($P = 0.45$). Similarly, in those practices in which 60% or more of doctors attended meetings no difference was found ($P = 0.57$). Thus, the differences in observed effect may not be explained simply through a dilution effect from reduced attendance in larger practices.

The influence of the size of practice is consistent with inconclusive suggestions from previous small studies that examined educational outreach for a single clinical area. Fender *et al*[13] examined the management of menorrhagia in East Anglia (UK). Poorer prescribing was associated with larger practice size, although the trial was limited by the inclusion of only a single health authority and clinical condition and the use of self-reported outcome measures, which were open to considerable reporting bias. Also, it was not possible to differentiate between different potentially confounding factors, for example; size, training status, and urban location. Similarly, Modell *et al*[14] observed a substantial change in single-handed practices, but little effect in larger practices in a general practice randomised trial of an outreach approach to promote screening for haemoglobin disorders.

We may speculate that practitioners in larger practices share implicitly or explicitly an approach to prescribing that is more deeply embedded in culture than in smaller practices, and that it may therefore be harder to influence them. Where there is a perceived need to assist larger practices to change their practice, on the basis of the evidence presented here, educational outreach visits do not appear to be an effective intervention.

The results for the NSAID guideline merit further explanation. The significant effect in the opposite direction to that expected for this outcome measure emphasises the uncertainty of family practice reaction to the educational outreach visits for a specific guideline. It seems unlikely that, for NSAIDs, practitioners elected to act in a manner at odds with the recommendations. In a *post hoc* explanatory analysis we counted all scripts prescribed for NSAIDs in practices that received the guideline through outreach or who acted as controls; a total of over 20 000 scripts. Over this total sample a 3% increase in reimbursed prescriptions for ibuprofen against all NSAIDs was identified, a proportion completely in line with the average overall effect identified across all four guideline topics.

Analyses that are based upon individual guidelines, or that examine the influence of practice characteristics, have less statistical power than the overall analysis defined as the primary outcome. The standard error for the change score for an individual guideline topic is about 4%, taking into account extra binomial variability owing to clustering of the data. This contrasts with a standard error of about 1.7% for the average effect of outreach across all four guidelines. In other words, a robust explanation for the apparently contradictory effect for NSAIDs is that it is simply the play of chance through measurement error in the sample of patients considered. This finding mediates against overinterpretation of the specific findings for individual guideline topics.

How can prescribing in larger practices be influenced in line with evidence-based guideline recommendations? There remains considerable uncertainty on the effectiveness of different interventions that aim to influence prescribing

practice.[15] A large trial of computerised decision support in prescribing, which will describe the effects of another commonly used intervention to influence prescribing, is currently underway.[16]

In conclusion, our results quite strongly support the use of educational outreach visits in small practices with the aim of implementing recommendations based upon evidence-based clinical practice guidelines. Educational outreach presented in a group manner is unlikely to be worthwhile in larger practices and further research is required to identify effective means for influencing prescribing in large practices.

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