Evaluation of the impact of two educational interventions on GP management of familial breast/ovarian cancer cases: a cluster randomised controlled trial

Eila Watson, Alison Clements, Patricia Yudkin, Peter Rose, Colleen Bukach, James Mackay, Anneke Lucassen and Joan Austoker

SUMMARY

Background: *It has been suggested that primary care should become more involved in providing genetic services, such as basic risk assessment, to enable patients with a moderate/high risk to be referred and those with a low risk to receive reassurance and advice from their general practitioner (GP). However, GPs currently lack knowledge and confidence in this area.*

Aim: *To investigate the effect of an in-practice educational session and information pack on GP management of familial breast/ovarian cancer cases.*

Design of study: *Cluster randomised controlled trial.*

Setting: *GP principals in 170 practices in Oxfordshire and Northamptonshire. Of the 688 GPs, 426 (62%) participated.*

Method: *Practices were randomised either to Group A (receiving an in-practice educational session plus information pack), Group B (receiving an information pack alone), or Group C (receiving neither an educational session nor a pack). The main study outcome was the proportion of GPs making the correct referral decision on at least five out of six family history vignettes. A secondary outcome was GPs' reported confidence in managing patients with a family history of breast/ovarian cancer, measured by a score that was generated by combining responses to four questions.*

Results: *There was a 40% (95% CI = 30–50%,* P*<0.001) improvement in the proportion of GPs who made the correct referral decision on at least five out of the six vignettes in Group A (111/140 [79%]) compared with Group C (controls) (63/162 [39%]), and a 42% (95% CI = 31–52%,* P*<0.001) improvement in Group B (100/124 [81%]) compared with the control group. There was a trend in reported confidence in the management of individuals with a family history of breast/ovarian cancer from a mean confidence score of 2.3 in Group A to 2.0 in Group B and 1.5 in Group C (*P*<0.001).*

Conclusion: *Providing GPs with an information pack significantly improved referral decisions regarding patients with a family history of breast/ovarian cancer. Although extremely well received, an in-house educational session produced no additional improvements. There were, however, greater levels of reported confidence in the group who received the educational session in addition to the information pack.*

Keywords: *genetic counselling; risk assessment; patient management; referral.*

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Submitted: 24 October 2000; Editor's response: 23 January 2001; final acceptance: 12 April 2001.

Introduction

OVER the past few years the number of primary care referrals to genetics clinics on account of a family history of cancer has increased dramatically (Lucassen A, Mackay J, personal communication. 2000) Specialist genetic services are limited and it has been suggested that primary care needs to become more involved in providing genetic services.[1-3] National consensus on the management of individuals with a family history of breast/ovarian cancer is that patients should receive a basic risk assessment in primary care to enable patients with a moderate/high risk to be referred and for those with a low risk to receive reassurance and advice from their general practitioner (GP).[4,5]

However, previous studies have shown that GPs currently lack knowledge and confidence in this area[6-9] and that, in practice, many of the patients referred from primary care are actually at low risk of having an inherited predisposition to cancer.[10] Furthermore, GPs have unrealistic expectations of the services offered by the genetics clinic and the options available to their patients.[11] We therefore developed an information package for GPs on the management of patients with a family history of breast/ovarian cancer.

Changing clinical practice and implementing guidelines is the subject of an extensive literature.[12,13] Some studies have shown that the provision of written referral guidelines can be helpful to GPs.[14,15] However, reviews have tended to conclude that the effectiveness of printed materials alone to disseminate new knowledge has little effect on medical practice and that a combination of methods is required to implement guidelines successfully.[16] An educational visit has been reported as one of the more successful strategies for implementing change[17] and so, in addition to the information pack, we developed an accompanying educational session designed to be delivered to GPs within the practice.

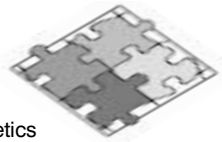
This study set out to evaluate the effectiveness of these two educational interventions. We hypothesised that GPs exposed to both the educational session and the information pack would make better referral decisions and report greater confidence than those GPs who received the pack alone, who in turn would do better than GPs who received neither intervention.

Method

Interventions

Information pack. The content of the pack was informed by previous research with GPs[6,9,10] and patients,[19] as well as input from a multidisciplinary expert panel. The pack con-

HOW THIS FITS IN



What do we know?

GP referrals of individuals with a family history of breast/ovarian cancer to genetics and breast clinics have been rising steadily. Many referrals are of individuals at low genetic risk, and studies show that GPs currently lack the knowledge and skills to perform their traditional 'gatekeeper' role effectively in relation to cancer genetic services.

What does this paper add?

Providing GPs with a tailored information pack, which includes clear referral guidelines, led to considerable improvements in GP referral decisions and increased GP confidence. While no additional improvement in referrals were seen in GPs who were provided with an educational session to complement the information pack, levels of confidence increased further.

tained a laminated summary card with simple referral guidelines, a booklet with more detailed background information, and two patient leaflets.[19]

Educational session. The educational session lasted one hour and was structured around a series of overheads covering the information presented in the pack. Interaction was encouraged. Sessions were conducted by one of two researchers, both experienced in the field of cancer genetics and teaching. Each participant was asked to complete a short questionnaire which asked for a rating of the session and assessed levels of knowledge and confidence before and after the session, using a four-point Likert scale. Session participants were told that they would be sent a follow-up questionnaire, but no details regarding the content of this questionnaire were provided. The interventions were conducted between March and November 1999.

Practice randomisation and contact

All 170 practices in Oxfordshire and Northamptonshire were randomly assigned to one of three groups. Prior to randomisation, practices were stratified by county (two strata) and by the number of partners in the practice (three strata). Randomisation within each stratum was in blocks of three, using computer-generated random numbers. Practices randomised to Group A were offered an educational session within the practice and were given a pack at this session; GPs who did not attend were sent a copy of the pack. GP principals in Group B were sent a copy of the pack. The group was split into three further groups: the first group were sent the pack at the beginning of the period during which we were conducting the educational sessions, the second group in the middle of the period, and the third group at the end. Group C received neither the in-house education nor the copies of the pack, but would receive the pack on completion of the study.

Study outcomes

The main study outcome was the appropriateness of GPs' referral decisions. As most GPs will make relatively few referrals per year, we had to adopt a proxy measure for this outcome. GPs were sent a questionnaire which asked for a risk assessment (low/higher risk) and referral decision (referred/not referred) on a series of six family history vignettes (Box 1). The vignettes were based on actual clinic referrals and were chosen to represent a range of different risks (three lower risk and three higher risk). The questionnaires were sent to all GPs in Groups A and B three to four weeks post-intervention. GPs in Group C were split into three groups and questionnaires were mailed at times corresponding to the times that Group B were sent the questionnaire. The primary outcome was the proportion of GPs who made the correct referral decision on at least five out of the six vignettes.

The questionnaire also asked for views on the session and information pack and asked GPs to say how confident they currently felt in relation to different aspects of managing a patient with a family history of breast/ovarian cancer (a four-point Likert scale was used with possible responses ranging from 'very confident' to 'not at all confident'). A confidence score was constructed, with one point for each question where the response was 'very confident' or 'confident'. Non-

1. The patient is a healthy 35-year-old woman. She has one sister who is well, aged 37 years. The patient's mother developed breast cancer aged 49 years and is still alive. The patient has two maternal aunts. One developed breast cancer aged 47 years, the other is now aged 50 years with no history of cancer. The patient's maternal grandmother is alive and well, aged 82 years.
2. The patient is a healthy 34-year-old woman. She has one sister, aged 36 years who is well. The patient's mother developed breast cancer at the age of 37 years, and ovarian cancer at the age of 50 years. She died aged 52 years. The patient has one maternal aunt, aged 57 years, who is well. The patient's maternal grandmother died of ischaemic heart disease aged 82 years.
3. The patient is a healthy 44-year-old woman. Her maternal aunt developed breast cancer aged 66 years. She is still alive and well. The patient's maternal grandmother developed breast cancer aged 62 years and died aged 64 years. The patient's paternal cousin developed breast cancer aged 55 years. The patient's paternal grandmother died of lung cancer aged 71 years.
4. The patient is a woman, aged 37 years, who is well. The patient's mother developed breast cancer aged 60 years and recently died of the disease when she was 63 years old. The patient's grandmother died aged 84 years from a stroke. The patient's paternal aunt is 64 years old and is well. The patient's paternal grandmother developed breast cancer aged 62 years and died from the disease.
5. The patient is a healthy 31-year-old woman. She has a mother aged 54 years and a maternal aunt aged 49 years who are both well. Her maternal grandmother died aged 68 years from congestive cardiac failure. The patient has two paternal aunts who both developed breast cancer, one was diagnosed aged 46 years and the other was diagnosed aged 48 years. The patient's paternal grandmother also had breast cancer, diagnosed at age 51 years.
6. The patient is a 43-year-old woman with no relevant medical history. She has two sisters. One is aged 45 years and is well. The other recently developed breast cancer aged 55 years. Her mother developed breast cancer aged 69 years. She is now aged 79 years. Her maternal grandmother died of a heart attack, aged 82 years.

Box 1. Family history vignettes.

responders were sent two reminders.

Sample size

Pilot work suggested that 10% to 20% of GPs in the control group would make correct referral decisions on at least five out of the six vignettes. If randomisation were by individual then a sample of 83 GPs in each group would be required to detect an increase from 15% in the control group to 35% in Group B (two-sided $\alpha = 0.05$, $\beta = 0.20$) and a sample of 106 per group to detect an increase from 35% (Group B) to 55% (Group A). To allow for cluster randomisation, we assumed an intra-cluster correlation coefficient of 0.05[20] and a mean of four GPs per practice, giving an inflation factor of 1.15[21] and a maximum required sample size of 106 x 1.15 = 122 GPs in each group.

Data analysis

All analyses were carried out on an 'intention to educate' basis. Comparisons between proportions were made using the χ^2 test and between means using one-way ANOVA, including tests for trend. No allowance was made for multiple comparisons. Adjustment for clustering[22] made no material difference to the results and we have therefore presented the results without adjustment.

Results

Response rates and participant characteristics

The involvement of practices and individual GPs in the trial is summarised in Figure 1. The overall response to the questionnaire was 62% (426/688). Response rates differed between the three groups ($P<0.001$). Non-responding GPs were more likely to be male (75% versus 63%, $P = 0.001$) and had been qualified for slightly longer (mean = 20.6 years versus mean = 18.9 years, $P = 0.009$), but included a similar proportion from a training or teaching practice (64% versus 69%, $P = 0.13$).

Risk assessment and referral decisions

There was a 40% (95% CI = 30–50%, $P<0.001$) improvement in the proportion of GPs who made the correct referral decision on at least five out of the six vignettes in Group A (79%) compared with the control group (39%) and a 42% (95% CI = 31–52%, $P<0.001$) improvement in Group B (81%) compared with the control group (39%). There was no significant difference between Groups A and B (Table 1). Groups A and B performed better than Group C for each of the six vignettes. Group C had most difficulty with vignette 5 (a family history on the father's side). Exclusion of this vignette from the analysis did not change our overall finding.

There was almost complete agreement between risk assessment and referral decisions across all three groups; i.e. where risk was assessed as low, GPs indicated they would not refer and where risk was assessed as higher, GPs indicated they would make a referral.

Sixty-seven per cent (95% CI = 60–75%) of GPs in Group A, 75% (95% CI = 68–83%) of GPs in Group B, and 16% (95% CI = 10–21%) of GPs in Group C reported using guidelines when answering all/some of the vignettes. Group C were not provided with the study guidelines but must have had access to other versions. The difference in proportions using guidelines between Groups A and B was not statistically significant ($P = 0.11$).

GP confidence

Table 2 presents GPs' reported confidence in several

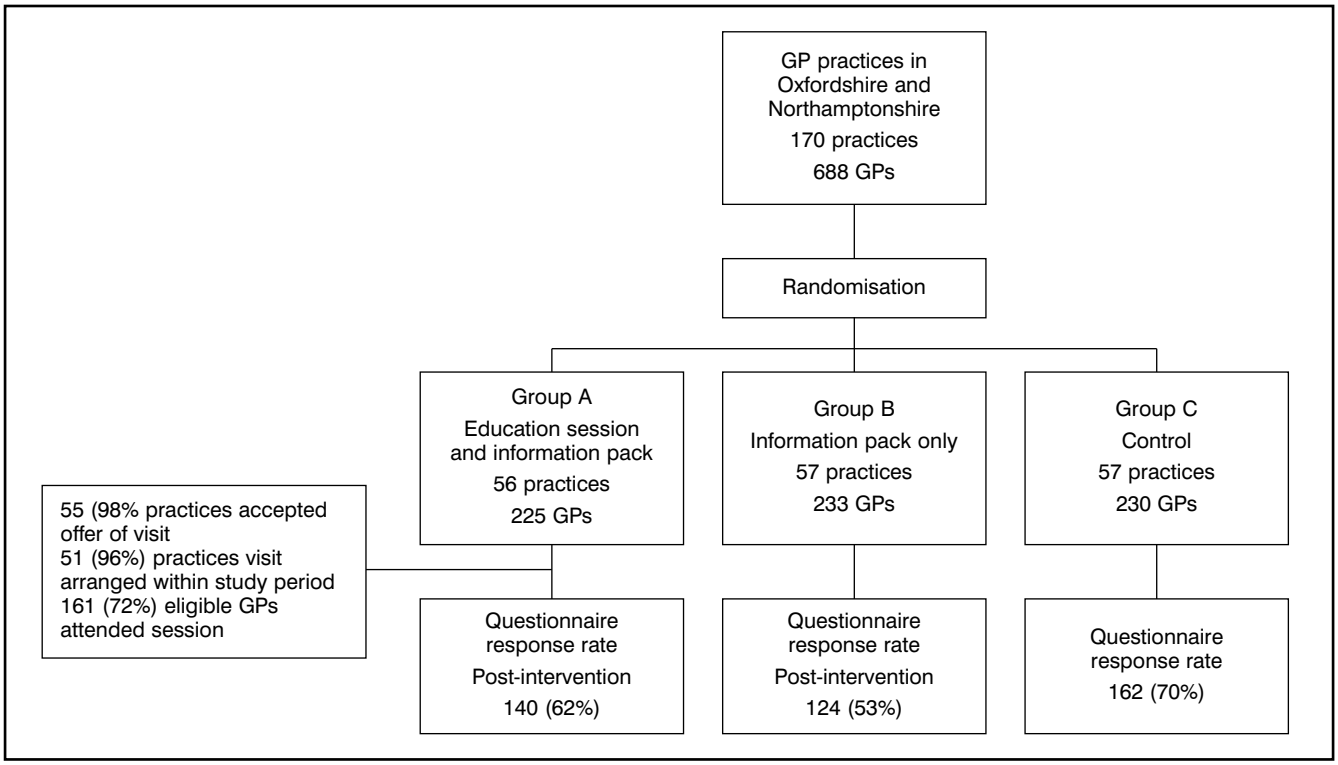


Figure 1. Flow chart summarising involvement of GPs in trial.

Table 1. Percentage of GPs making correct referral decisions on six family history vignettes, and percentage making at least five correct decisions.

Family history vignette	Group A (n = 140) Educational session and information pack [% (n)]	Group B (n = 124) Information pack [% (n)]	Group C (n = 162) Control [% (n)]
1. Moderate/high risk	85.0 (119)	87.1 (108)	66.7 (108)
2. Moderate/high risk	92.9 (130)	93.5 (116)	84.0 (136)
3. Low risk	90.0 (126)	89.5 (111)	84.6 (137)
4. Low risk	95.7 (134)	91.9 (114)	89.5 (145)
5. Moderate/high risk	78.6 (110)	82.3 (102)	37.6 (61)
6. Low risk	82.9 (116)	80.6 (100)	54.3 (88)
At least 5 referral decisions correct	79.3 (111)	80.6 (100)	38.9 (63)[a]

[a]Comparisons between groups: overall — $P<0.001$; Group A versus C — $P<0.001$; Group B versus C — $P<0.001$; Group A versus B — $P = 0.45$.

*Table 2. Proportion of GPs who expressed confidence (very confident/confident) in four aspects of managing patients with a family history of cancer [% (*n*)], and mean (SD) overall confidence score.*

Management	Group A (n = 140) Educational session and information pack	Group B (n = 124) Information pack	Group C (n = 162) Control
Taking a brief family history and making a referral decision[a] [% (n)]	92.0 (126)	87.5 (105)	76.4 (123)
Counselling patients regarding inherited risk[a] [% (n)]	32.1 (44)	26.0 (32)	9.9 (16)
Discussing other risk factors for breast cancer[a] [% (n)]	77.0 (107)	65.9 (81)	50.9 (82)
Discussing possible management options, according to level of risk[b] [% (n)]	27.7 (38)	26.8 (33)	15.5 (25)
Mean (SD) overall confidence score for questions above[c] (possible score 0–4)	2.3 (1.0)	2.0 (1.1)	1.5 (1.0)

Percentages based on number of valid responses to each question; minimum numbers are 137, 120, and 161 in Groups A, B, and C respectively. [a]χ^2 test for trend, $P<0.001$; [b]χ^2 test for trend, $P = 0.011$; [c]ANOVA linear trend, $P<0.001$.

aspects of the management of patients with a family history of cancer which had been addressed in our educational interventions. There was a significant trend in levels of confidence, with GPs in Group A (mean confidence score = 2.3) reporting greater confidence than those in Group B (mean confidence score = 2.0), who in turn reported greater confidence than those in Group C (mean confidence score = 1.5, $P<0.001$). In all groups, less than one-third of GPs expressed confidence in counselling patients regarding risk and discussing possible management options.

Evaluation of session and information pack

The session was considered to be relevant and useful by the 161 GPs who attended: 93% (95% CI = 88–97%) reported the session as 'relevant' or 'very relevant' and 94% reported the session as a 'good' or 'very good' use of their time. Self-reported knowledge and confidence also increased following the session with 84% (95% CI = 79–90%) GPs reporting an increase in knowledge, and 67% (95% CI = 59–74%) reporting an increase in confidence.

GPs in both Group A and B also responded very favourably towards the information pack. Most (93%, 95% CI = 90–96%) said it was useful, 99% felt the materials were presented in a clear way, and 96% felt the detail was pitched at the right level.

Discussion

This randomised controlled study involving 170 practices has investigated the impact of two educational interventions on GPs' referral decisions for familial breast/ovarian cancer. Using a vignette methodology, we have shown that provision of a tailored information pack led to major improvements in GP referral decisions. However, no additional improvements in referral decisions were seen in GPs who received an educational session as well as an information pack.

Study limitations

We acknowledge the limitations inherent in the use of a vignette study methodology and the benefits we have reported may not necessarily be translated to 'real-life' referrals. The vignettes we used provided no information regarding the patients' perceived risk or anxiety levels. These are factors that may, in practice, influence a GP's referral decision irrespective of their knowledge of referral guidelines. Furthermore, it is possible that by asking GPs to complete a post-intervention questionnaire we prompted them to refer to the pack, which they may not have done during a real-life consultation. Although the overall response rate to the questionnaire was reasonably high for a GP survey (62%),[23] there was a differential response across the three groups. If non-responders were less knowledgeable in this area than responders then this differential non-response may have overestimated the improvements in Groups A and B. However, sensitivity analysis showed that this would not have affected our conclusion. Finally, we acknowledge that the apparent benefit we have achieved in this study is short

term and that further studies would be required to demonstrate that this benefit persists with time.

As previous studies have shown practice visits to be a more effective method of education than passive methods of information transfer, we have considered possible reasons for the lack of effect between Groups A and B in this study. One possibility is that the outcome measure was not sensitive enough and because both intervention groups scored highly on the referral decisions, there was relatively little scope for additional improvement in Group A. It is also possible the educational session had some shortcomings. Although they were well attended and very well received the focus was on improving knowledge, which meant that less time was devoted to practical skills training. Providing GPs with the opportunity to practice risk assessments within the session, for example, may have been useful.

Although improved referrals is clearly an important outcome, which can be relatively easily measured, we have evidence suggesting other important, but less tangible, benefits for Group A. We hoped that our educational session would increase GPs' confidence in dealing with patients with a family history of breast/ovarian cancer, thereby potentially increasing patient satisfaction with the GP consultation. Although measuring patient satisfaction is beyond the scope of the present study, and measuring GP confidence is not straightforward, the findings from our post-session and post-intervention questionnaires suggest increased confidence in the group of GPs who had the educational session. Nonetheless, even in this group less than one-third of GPs feel confident in counselling about risk and the management options available. This may, in part, be because genetic risk counselling would be a new role for the GP and because time prevented the chance to practice risk counselling skills during the session. It seems that provision of written materials is sufficient to improve referral decisions whereas if, in the future, GPs are expected to provide genetic risk counselling, then a more intensive educational approach may be required.

In summary, we have shown that there can be benefits from the provision of written materials, with an almost twofold improvement in referral decisions in GPs provided with an information pack. This study included all GP practices from two counties. We did not rely on practices who expressed an interest in the study topic or who were part of a research network, thereby increasing the generalisability of the findings. If the study outcome is translated into clinical practice there will be real benefits to overstretched genetics and breast clinics.

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Acknowledgements

We would like to thank all of the GPs who took part in the study. We would also like to acknowledge the Cancer Research Campaign who funded this study.