Management of women with a family history of breast cancer in the North West Region of England: training for implementing a vision of the future

M McAllister, K O’Malley, P Hopwood, B Kerr, A Howell, D G R Evans

Breast cancer is common in the general population, affecting one woman in every 12. About 5% of breast cancers are caused by dominantly inherited high risk susceptibility mutations in genes such as BRCA1 and BRCA2. Another, larger proportion may be caused by mutations in (as yet) unidentified lower penetrance genes, because even where such high risk mutations are not implicated, a family history of breast cancer increases a woman’s lifetime risk of developing the disease herself. There are no external markers of risk (no phenotype) to help identify those who carry a faulty gene, except in very rare cases such as Cowden’s disease. In order to assess the likelihood of there being a predisposing mutation in a family, it is necessary to assess the family tree. Inheritance of a germline mutation can cause the disease at a young age and often, if the woman survives, cancer in the contralateral breast. Some gene mutations may give rise to susceptibility to other cancers, such as ovary, colon, and sarcomas. Multiple primary cancers in one woman or early onset cancers in the women or their relatives are, therefore, suggestive of a predisposing gene. Apart from family history, age, gender, and previous cancer, other risk factors include exposure to oestrogen, alcohol, weight gain, and the presence of proliferative breast disease. The management options for a woman with a significantly increased risk are limited. She may choose to do nothing. To reduce her risk, a woman can plan to limit prolonged use of the oral contraceptive pill (OCP) and hormonal replacement therapy (HRT) and prevent weight gain. Clinical management options include screening by mammography, prophylactic mastectomy, artificial early menopause (oophorectomy), and anti-oestrogen therapy (the subject of a current clinical trial (RAZOR)). Assessment of risk factors, calculation of the resulting life time risk of developing breast cancer, appropriate communication of that risk to a client, and discussion of management options is a skilled endeavour, requiring specialist training.

CURRENT SERVICES IN THE NORTH WEST REGION

Media coverage of the discovery of the BRCA1 and BRCA2 genes has resulted in a large number of women with relatives with breast cancer seeking advice from their GPs and breast surgeons about their own risk of developing breast cancer. This has resulted in a large and often inappropriate demand for specialist cancer genetics services and, on average, a quarter of all referrals to specialist services are for people with a population risk level. Recommendations have already been made with regard to the management of hereditary breast cancer. These essentially endorse a management for hereditary breast cancer along the lines of the Calman-Hine report for cancer, a triage system from primary care through breast cancer specialist (Calman) units to a cancer centre. The idea behind these recommendations is that management of high risk families would be undertaken by specialist cancer genetic centres with moderate risk subjects being seen at unit level and those women at average or marginally increased risk being appropriately reassured in primary care. However, while the Harper report makes recommendations, there is still no National Health Service (NHS) policy on service provision for familial breast cancer, and a recent study has shown great diversity in all aspects of care provision in the UK. The study showed that up to 13% of subjects at population risk were being unnecessarily screened, highlighting the importance of accurate risk assessment for risk management advice. Variance in referral rates, waiting time for appointments, and access to screening result in an inequitable service from the national perspective.

In the Manchester area (population 4 million), specialist cancer genetics clinics have been receiving about 1300 referrals per year for a family history of breast cancer. However, when these women are seen in the cancer genetics clinic, only about 35% of them are found to have a family history suggestive of a high risk of developing breast cancer. The delay in appointments because of the large number of referrals means that those who are not at high risk can be left feeling unnecessarily anxious, and those at high risk are not being seen quickly. GP referral guidelines recently produced by the CRC Primary Care Education Research Group will ensure that high risk women are not being missed.

FUTURE SERVICES IN THE NORTH WEST REGION

We propose an approach that involves a close partnership between the specialist cancer genetics clinics and the local Calman Breast Unit. Overall, the proposed approach involves initial referral of all women at suspected increased risk for breast cancer because of their family history to a dedicated Family History Clinic at a local Calman Breast Unit. Risk assessment would be performed by trained specialist nurses and women would be triaged into high risk (risk >1 in 4), moderate risk (1 in 6 < or = risk < or =1 in 4), or low risk (risk <1 in 6). Only high risk women would be referred to a specialist cancer genetics clinic. We have taken this approach because of concerns about the practicality of assessing family history in the primary care setting. Research involving nearly 400 GPs in Scotland showed that GPs are concerned about the role expected of them in cancer genetics services, particularly in view of ever increasing workload. There is also evidence from The Netherlands showing that triaging in primary care is not very effective. Even under the guidance of a cancer geneticist, referral guidelines were often ignored so that inappropriate referrals were still made. Initiatives using computer software to facilitate the assessment of breast cancer risk in primary care are being researched, but the efficacy and acceptability of these methods remain to be proven. Furthermore, the appropriateness of training cancer nurses to assess familial cancer risk is increasingly being recognised.

LETTER TO JMG

The management options for a woman with a family history of breast cancer increases a woman’s lifetime risk of developing the disease itself. There are no external markers of risk (no phenotype) to help identify those who carry a faulty gene, except in very rare cases such as Cowden’s disease. In order to assess the likelihood of there being a predisposing mutation in a family, it is necessary to assess the family tree. Inheritance of a germline mutation can cause the disease at a young age and often, if the woman survives, cancer in the contralateral breast. Some gene mutations may give rise to susceptibility to other cancers, such as ovary, colon, and sarcomas. Multiple primary cancers in one woman or early onset cancers in the women or their relatives are, therefore, suggestive of a predisposing gene.

Apart from family history, age, gender, and previous cancer, other risk factors include exposure to oestrogen, alcohol, weight gain, and the presence of proliferative breast disease. The management options for a woman with a significantly increased risk are limited. She may choose to do nothing. To reduce her risk, a woman can plan to limit prolonged use of the oral contraceptive pill (OCP) and hormonal replacement therapy (HRT) and prevent weight gain. Clinical management options include screening by mammography, prophylactic mastectomy, artificial early menopause (oophorectomy), and anti-oestrogen therapy (the subject of a current clinical trial (RAZOR)). Assessment of risk factors, calculation of the resulting life time risk of developing breast cancer, appropriate communication of that risk to a client, and discussion of management options is a skilled endeavour, requiring specialist training.
TRIAGE IN THE CALMAN BREAST UNITS

Our approach rests on the assumption that the breast units are best placed to perform detailed assessment of family history of breast cancer, and the accurate triaging of women into high, moderate, and low risk. Family histories may be difficult to assess and thus triage could best be done in the context of dedicated Family History Clinics within the breast units, where the family history can be documented and women could be (1) given an accurate assessment of their risk based on family history, (2) offered screening, if appropriate (that is, for women at a risk > or = 1 in 6), (3) offered a referral to a specialist cancer genetics clinic if they are assessed as high risk (1 in 4).

The breast unit would then continue to be responsible for ongoing screening for moderate and high risk women. Moderate risk women, who may belong to families with lower penetrance breast cancer predisposing gene mutations, but for whom predictive testing would not be a possibility at present, would have no need for the involvement of specialist cancer genetics services. Data are accumulating on the benefits of mammographic screening for moderate risk women in the 30-50 year age group. Population risk women, if referred to the Breast Unit Family History Clinic, could be reassured that they are not at increased risk for developing breast cancer because of their family history. High risk women would be identified by the Breast Unit Family History Clinic, and offered a referral to specialist cancer genetics services, where high risk women can be offered: (1) mutation testing, where possible, and provision of presymptomatic genetic testing, with attendant clinical, counselling, and laboratory services; (2) discussion of management options only appropriate for those at high risk, such as prophylactic mastectomy, oophorectomy, and chemoprevention trials; (3) inclusion in the genetic family register service, if a proven mutation is found in the family.

Over the past 18 months, proven BRCA1 and BRCA2 families in the North West Region have been approached and invited to join the genetic family register system. Interest in the service has been high and, to date, 93 members of BRCA1/2 families (68% of those approached) have consented to join the register recall system.

THE TRAINING PROGRAMME

The North West Regional Genetics Service has developed a training programme to put this vision into practice in the region. So far, 20 breast care nurses have been trained in breast cancer risk assessment. Two local breast units in the region have been operating pilot dedicated Breast Cancer Family History Clinics for the last nine months, which have been closely supported and monitored. A further five local breast units started dedicated Breast Cancer Family History Clinics in Autumn 2001, using expertise gained through the pilot scheme. The training course consists of the following: (1) Part 1. A structured information day, which at present is run once per year and is open to breast surgeons, GPs, nurses, and other interested parties (table 1). (2) Part 2. A three day teaching workshop on “Communication and counselling skills”. (3) Part 3. A five day training course on “Breast cancer risk assessment and counselling skills” (table 2), which is operated on a day release basis.

Part 2 is a well evaluated training programme in communication based on a theoretical model requiring three elements, which are reinforced in the five day release sessions. These are cognitive (didactic teaching), experimental, and feedback on performance. These three elements also form the basis for part 3 of the training, which takes the form of five morning teaching sessions and five afternoon experiential sessions with real patients in a breast cancer family history clinic. The morning sessions cover: (1) drawing family pedigrees by hand using completed family history questionnaires; (2) pedigree assessment, including other cancer family histories indicating referral to specialist cancer genetics centres for assessment in relation to other cancer syndromes; (3) risk estimation according to (A) the Claus model and (B) long hand calculation; (4) problem solving; (5) counselling skills; (6) role play; and (7) an introduction to using computer risk packages. Two supervised training clinics (four to five real patients per clinic) are an integral part of the training course. Trainees are observed, ensuring that information is correctly given, and trainees are provided with feedback after each patient. In addition, training clinics can be videotaped as part of the training course (table 3, module 7).

The course has a modular structure, with comprehensive Participant Guides designed (1) to aid with learning and (2) for later use by trainees in the workplace as support materials for the day to day operation of a Breast Cancer Family History Clinic. Comprehensive Instructor Guides are also provided to standardise training, designed for use by genetic counsellors/associates as trainers with minimum preparation time. As well as training in pedigree and risk assessment (table 3, module 2), genetic counselling training on the course involves skills development for four main purposes: (1) to help the counsellor comprehend the medical facts and specifically the way heredity contributes to the disorder; (2) to provide information about the personal risk of cancer, according to how much the counsellor wishes to know; (3) to discuss options for risk and its implications. Nurses are not asked to use a set list of family history questions; rather, they are trained to incorporate both risk assessment and counselling skills into their practice (table 3, module 7). Training also includes coverage of appropriate patient management processes (table 3, module 5).
RESULTS: COURSE ATTENDANCE AND PILOT EVALUATION

Attendance

Four information days have taken place to date. Table 2 summarises attendance at the four days. Two Communication and Counselling Skills courses have been completed, and attended by a total of 27 breast care nurses. The first five day Breast Cancer Risk Assessment and Counselling Course took place in November and December of 1999. Since that time, nine further courses have been completed, and a total of 20 breast care nurses from the North West and the Merseyside and Cheshire regions have now completed the training.

Training evaluation

To date, feedback on the training course is being obtained in three different ways. Firstly, as part of the pilot Breast Unit Family History Clinics, the effectiveness with which trainees have been able to implement what they learned in a clinical setting is being assessed. Secondly, a patient satisfaction survey has been initiated as part of the pilot Breast Unit Family History Clinics. Thirdly, some newly designed training feedback forms were piloted to assess their usefulness. These forms were designed to assess the trainees’ subjective assessment of the training and provided helpful feedback.

Pilot Breast Unit Family History Clinics

Two breast units in the region implemented pilot Breast Cancer Family History Clinics in January 2001, which have been under joint evaluation. The dedicated clinics take place on a weekly or monthly basis, and three to four patients are seen in each clinic. The pilot schemes are operating from local referrals rerouted back to the breast units from the specialist cancer genetics clinics, but it is envisaged that following the end of the pilot, all GP referrals will be routed directly to the breast units in the first instance. This will clearly involve education of the local GP population, and it is envisaged that the GP referral guidelines developed by the CRC Primary Care Education Research Group will be used. The two pilot clinics have now seen 30 women at familial risk for breast cancer, and for each patient seen, they have submitted (1) a clinic summary letter and (2) a three generation family tree for assessment by a consultant clinical geneticist or a cancer genetic counsellor. The outcome criteria for training are (1) accurate assessment of life time breast cancer risk based on assessment of an appropriate three generation family tree and (2) appropriate triaging following risk assessment. All 30 women seen in clinic by trainees were placed into the appropriate risk group. The nine (30%) women found to be at moderate risk were counselled appropriately by the breast care nurse and had screening arranged. Women at average risk (33%) were appropriately reassured and discharged to primary care. Women at high risk (37%) have been offered referral to a genetics centre. Nine of the 10 women assessed as high risk wanted referral to a genetics centre. Nine of the 10 women assessed as high risk wanted referral to a consultation with a genetics counsellor. The outcome criteria for training are (1) accurate assessment of life time breast cancer risk based on assessment of an appropriate three generation family tree and (2) appropriate triaging following risk assessment. All 30 women seen in clinic by trainees were placed into the appropriate risk group. The nine (30%) women found to be at moderate risk were counselled appropriately by the breast care nurse and had screening arranged. Women at average risk (33%) were appropriately reassured and discharged to primary care. Women at high risk (37%) have been offered referral to a specialist cancer genetics centre. Nine of the 10 women assessed as high risk wanted referral to a genetics centre.

Patient satisfaction survey

In total, 24 of the 30 women seen in clinic have returned completed patient satisfaction survey forms; 96% of respondents (23/24) felt that the Breast Care Nurse had clearly explained to them the relevance of their family history, and were satisfied with the information provided, regardless of the risk given.

Table 3 Breast cancer risk assessment and counselling skills course: course timetable

<table>
<thead>
<tr>
<th>Day</th>
<th>Morning</th>
<th>Afternoon</th>
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<tbody>
<tr>
<td>Day 1</td>
<td>9:00-10:00 Module 1: Basics of genetics</td>
<td>Breast Cancer Family History Clinic</td>
</tr>
<tr>
<td></td>
<td>All day: Teaching, Q&amp;A</td>
<td>Referred women being counselled by training staff</td>
</tr>
<tr>
<td></td>
<td>10:00-12:30 Module 2: Drawing and assessing pedigrees. Calculating risks 1. Teaching, problem solving</td>
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</tr>
<tr>
<td>Day 2</td>
<td>9:00-11:00 Module 2: contd</td>
<td>Breast Cancer Family History Clinic</td>
</tr>
<tr>
<td></td>
<td>11:00-11:30 Module 3: Calculating risks 2.</td>
<td>Referred women being counselled by training staff</td>
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<tr>
<td></td>
<td>11:30-12:30 Module 4: Management options:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Recap, teaching, Q&amp;A.</td>
<td></td>
</tr>
<tr>
<td>Day 3</td>
<td>9:00-10:00 Module 5: Risk assessment</td>
<td>Breast Cancer Family History Clinic</td>
</tr>
<tr>
<td></td>
<td>Process Flow, Teaching, Q&amp;A</td>
<td>Referred women being counselled by training staff</td>
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<tr>
<td></td>
<td>10:00-12:30 Module 6: Skills transfer to clinic</td>
<td>1. Structuring the session</td>
</tr>
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<td></td>
<td>Teaching/discussion, role play</td>
<td></td>
</tr>
<tr>
<td>Day 4</td>
<td>9:00-12:30 Module 7: Skills transfer to clinic. 2. Putting it all together</td>
<td>Breast Cancer Family History Clinic</td>
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<tr>
<td></td>
<td>Role play examples/discussion</td>
<td>Referred women counselled by trainees under supervision</td>
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<td></td>
<td>Video &amp; audiotape</td>
<td>(Video &amp; audiotape)</td>
</tr>
<tr>
<td>Day 5</td>
<td>9:00-12:30 Module 7: Skills transfer to clinic. 2. Putting it all together</td>
<td>Breast Cancer Family History Clinic</td>
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<tr>
<td></td>
<td>Debrief</td>
<td>Referred women counselled by trainees under supervision</td>
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<td></td>
<td>Role play examples/discussion</td>
<td>(Video &amp; audiotape)</td>
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<td>Video &amp; audiotape</td>
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<tr>
<td>Day 6</td>
<td>Follow up</td>
<td>ASSESSMENT</td>
</tr>
<tr>
<td>Day 7</td>
<td>Follow up</td>
<td>ASSESSMENT</td>
</tr>
</tbody>
</table>
One woman was not satisfied because she had been given a risk lower than she had expected. Women who are dissatisfied with the risk provided in the Breast Unit Family History Clinic can be given a second opinion, or a review if they so prefer, at the specialist cancer genetics centre. A total of 62% of respondents (15/24) replied that there was no change in their anxiety or stress related to cancer risk following her appointment, 17% (8/42) felt a decrease, and one woman reported an increase in anxiety/stress, although she commented “… (the service) was quick and very reassuring - (the nurse) is easy to talk to, understanding and helpful …”. No correlation emerged in this small sample between post-clinic anxiety/stress and level of risk given. For 15 of those 24 respondents (62%), it was possible to assess the accuracy with which they were able to recall the risk provided in clinic. All 15 women were able accurately to recall the risk given.

Pilot of training feedback forms
Ten of the trainees were asked to complete training feedback forms to assess the usefulness of these newly designed forms. As part of this piloting exercise, some helpful feedback was obtained from the trainees surveyed. When asked about the information day, nine of the 10 respondents found the day very useful and felt the topics had been well covered. However, six felt that they needed more time to assimilate the information, “… in depth information left me stunned as my own knowledge was very limited …”. Another commented that some of the information on the first day was difficult to understand at the time and only made sense when it was covered in the Risk Assessment and Counselling course. The three day Communication Skills Course run by Professor Peter Maguire of the Psychological Medicine Group based at the Christie Hospital was a resounding success and nearly all students felt positively about every aspect of this course. The five day Risk Assessment and Counselling course was also viewed very positively. All 10 respondents found it useful and felt that the topics had been well covered. However, three students felt there was too much information for the allocated time, “it felt like a crash course in genetics”. Overall, the feedback indicated that too much information was covered too quickly, and that more time was needed to assimilate all that was being taught. This was especially true of both modules 1 and 2, and because of this, a decision has been made to send the participant information pack for module 1 to students in advance of starting the course, along with a recommended reading list. Despite initial reservations, respondents found videotaping of their sessions very worthwhile and “much less intrusive than anticipated”. The training feedback forms will be used on an ongoing basis and may contribute to further training development.

THE FUTURE
Training is continuing, with two to four nurses in training for every five day risk assessment course. Numbers are limited by the requirement for supervised afternoon training clinics and the need for trainees to obtain experience with real patients. Telephone support, by genetic counsellors and clinical cancer geneticists, is available to all breast care nurses running Family History Clinics to help with any clinical, psychosocial, or management difficulties encountered, and annual update training days are planned. Access to a psychiatrist with family history clinics to help with any clinical, psychosocial, or geneticists, is available to all breast care nurses running Family History Clinics. The specialist cancer genetics services in the region will continue to offer support, for example (1) supplying appropriate documentation such as Family History Clinic questionnaires, (2) further training as required, and (3) checking 10% of family trees and clinic summary letters in each clinic.

CAREER DEVELOPMENT
Efforts are under way to obtain university status for the Breast Cancer Risk Assessment and Counselling course. The most appropriate way to include the training in Breast Care Nurse education would be as a module within the cancer nursing degree pathway. Experienced breast care nurses would be able to choose this specialist module on their way to obtaining a degree in cancer nursing. The skills taught on this course may have a valuable contribution to make to the planned new cancer network workforce strategies, contributing to the effectiveness of the specialist multidisciplinary teams providing cancer care in accordance with the NHS Cancer Plan.15

IS THIS AN APPROPRIATE MODEL FOR THE REST OF THE UK?
Discussions regarding management of familial cancer have been taking place at a national level for some years now. The model proposed here is as appropriate one for management of familial breast cancer, as it is in line with previous recommendations.14,15 The model involves: (1) management of women at low risk (< 1 in 6) in primary care, (2) management of women at moderate risk (1 in 6 < or = risk < or = 1 in 4) in cancer units, (3) referral to specialist cancer genetics units for women at high risk (risk > 1 in 4), (4) cancer units to work closely with specialist genetics units, so that as cancer services become integrated to form cancer units, genetic aspects of cancer care can be built into the range of services provided.

The only difference from the recommendations is the importance given to breast units rather than primary care in risk determination. While primary care may be able operate from a set of appropriate referral guidelines and information technology developments, the breast units are best placed to perform the detailed assessment of familial risk of breast cancer, and hence accurate triaging of women into high, moderate, and population risk. Moreover, the attendant genetic counselling needs of patients requires investment of clinic time as well as highly specialised familial risk assessment skills. It is hoped that research comparisons of different methods of service provision for at risk families will be undertaken in the future, to tease out the advantages and disadvantages of different approaches. However, a carefully planned service structure with integral staff training and support is an essential prerequisite to any model of service provision and assessment.

The NHS Cancer Plan15 committed the NHS to providing new opportunities for individual development and extended
roles that will open up new career opportunities for staff. The educational initiative described in this paper will enable breast care nurses to take on a wider range of clinical tasks, thus promoting autonomy and increasing job satisfaction. It is recognised, however, that the staff pool will need to be increased to accommodate this new role, since specialist nurses are already overloaded in their task loads for the physical and psychological care of cancer patients.

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MCALLISTER ET AL.

Key points
• Specialist genetics centres in the North West Region, as elsewhere, have experienced an exponential growth in demand for genetic counselling services for women with a family history of breast cancer.
• We report a strategy to devolve moderate risk breast cancer genetic counselling to the cancer unit level through an integrated education programme for specialist nurses.
• The training programme is described and the pilot evaluation of both the training programme and the breast unit Family History Clinics is reported. Application of this model across the UK is discussed.

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