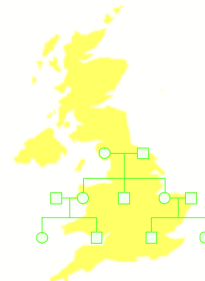


Report from FH01 Collaborator's Meeting  
16th June 2006  
St Bartholomew's Hospital, London



Professor Stephen Duffy welcomed about 60 delegates to the 2<sup>nd</sup> FH01 Collaborators Meeting.

Dr Paul Pharoah from Cambridge gave the first presentation of the day entitled

**'The BOADICEA' gene carrier probability model'**

A family history of breast cancer is one of the strongest risk factors for the disease. Several breast cancer susceptibility genes are known, with the most important being BRCA1 and BRCA2. Risk prediction models can be used to estimate the probability that an individual carries a deleterious mutation in BRCA1 or BRCA2 and to estimate the risk of breast cancer for an individual. This information can be used to inform clinical counselling and enable efficient targeting of genetic testing and interventions aimed at risk reduction. The various risk models that have been developed for the analysis of breast cancer families were described and their applicability, strengths and weaknesses discussed.

Professor Gareth Evans from Manchester, then updated the meeting with a talk entitled

**'Current NICE screening guidelines for women under 50 years'**

Key recommendations in the guideline include:

- Taking a family history in primary care because this allows appropriate classification and care.
- Recognising that access to psychological support and assessment is a key part of the package of care needed for many women covered by the guideline.
- Only carrying out mammograms after giving women information about its potential advantages and disadvantages for the early detection of breast cancer
- Recognising that genetic testing is appropriate only for a small proportion of women who are from high-risk families.
- Recognising that risk-reducing surgery is appropriate only for a small proportion of women and should be managed by a multidisciplinary team.
- Offering women standard written information to provide consistent advice alongside individually tailored information that outlines sources of support (including local and national organisations).
- Giving patients the opportunity to make informed choices and share in decision making.

After the coffee break Dr Sheila Stallard from Glasgow explained to the meeting how FH01 had been implemented very successfully in Scotland

**FHO1 recruitment in Scotland**

Although FHO1 started recruiting in 2002, Scotland did not come on board until about 2 years later. Scotland started recruiting to FHO1 about 14 months ago in February 2005.

The population of Scotland is roughly one tenth of the England and Wales (about 5 million people) and within Scotland half the population is served by the West of Scotland Breast service. The four recruiting centres for Scotland are the West (Glasgow) the East (Edinburgh), Dundee and Aberdeen. This report will present figures for the whole of Scotland but will focus on the West of Scotland who have been particularly successful in recruiting to FHO1.

The West of Scotland Family History Group was formed on May 14<sup>th</sup> 2004 from a Managed clinical Network education day. This group agreed to take part in FHO1 and acted as a local steering group for the study. The group applied for funding for a study co-ordinator part time from FHO1. We were given

£6000 per annum, which funded a co-ordinator post for 12 hours per week. The first step for us was to appoint Karen Duffy to this post.

We went around the 11 breast units in the West of Scotland and enlisted the support of the Consultant Surgeons and the breast teams. Karen then helped each unit to get started and provided back up and support for the centres. She collects forms, inputs data and deals with problems that arise. For example in 2 hospitals, Radiologists were not happy to read FHO1 films. The Radiologists in the FH group solved these issues with Karen so that all units could take part in the study.

Recruitment in Scotland by June 2006 is now 752 women. This is about 18% of the total recruitment to FHO1, and we are well on target to recruiting 1000 women by the time recruitment stops in December 2006. The West have recruited 385 women, the East 237, Aberdeen 81 and Dundee 49 women.

### **Clinical examination Study added onto FHO1**

Surveillance strategies for FH patients vary across the UK. In Scotland all centres carry out Clinical Breast examination (CBE) as well as mammography for FH patients. The value of CBE is not clear. In a recent review of the literature it has been found that only about 8% (35 out of 471) cancers are detected by CBE alone and are mammographically occult. It is likely therefore that CBE has little role to play in the assessment of these patients but further study is needed. We are planning an add on study to FHO1 with the aim of evaluating CBE. This is currently in progress.

Sheila Stallard

Dr Eila Watson and Dr Alison Clements both from Oxford and lead investigators on the PIMMS study gave us a sneak preview of their findings

### **The PIMMS Study: the story so far.**

A psycho-social evaluation of the impact of mammographic surveillance on women under 50 at increased risk of inherited breast cancer.

PIMMS is a 5 years study, designed to complement FH01, but funded separately by Cancer Research UK. The main aims of the study are to describe the psychological impact of screening, according to screening outcome, and to determine the roles of different appraising and coping styles and personality types in predicting emotional responses to screening. The study is using both quantitative and qualitative research methods.

18 centres throughout the UK are taking part in the study. Recruitment closed in November 2005, with 2,321 women recruited to the study. Follow up is ongoing and final data is expected by September, 2006. Preliminary data from the pre-screening questionnaire indicates that overall this group of women experience generally quite positive appraisals of their family history, and more frequently report positive emotions compared to negative emotions. Participants also expressed positive views about breast screening. The mean Cancer Worries Scale score for the sample is 11.3, with approximately 20% of women scoring 18 or more which indicates quite high levels of cancer worry. Psychological variables show stronger associations with cancer worry than screening and family history variables.

Once all of the follow up data is in, we will be assessing whether or not women who receive an initial clear screening result experience a significant reduction in distress, and whether or not distress is significantly increased in women who are recalled for further tests prior to receiving an all clear result.

### The Qualitative Component

Alison Clements gave an update of the qualitative component to the PIMMS study. The broad aim of this phase is to understand the value to women of participating in an early screening programme, and the degree of protection participation may give to their fears of developing or dying from breast cancer. Women from the four screening outcome groups (initial all clear/all clear after recall/cancer diagnosis on screening/interval cancer diagnosis) have been invited to participate in the study. Interviews with women ultimately receiving an all clear diagnosis have been completed (58 interviews); interviews with women diagnosed with cancer while on an early screening programme are ongoing. Preliminary findings using data from both the qualitative and quantitative parts of the study

were presented. The work is looking at women's understanding of what an 'all clear' result means, and the implications this has for the reassurance women feel after receiving their result.

Alison made an appeal for help with the recruitment of women diagnosed with a screen detected or interval cancer. Ethical approval has been given for recruitment from breast screening and genetics clinics of women who may not be in the FH01 or PIMMS study, but who have been diagnosed with breast cancer in the last 5 years while on an early screening programme. If any one would be able to help, Alison would be delighted to be contacted.

[alison.clements@dphpc.ox.ac.uk](mailto:alison.clements@dphpc.ox.ac.uk) 01865 226926.

Jenny Ramm from the Parapet Breast Screening Unit gave a very interesting and thought provoking presentation that formed much discussion

### **Implementing the NICE Familial Breast Cancer Guidance in a DGH**

The Parapet, diagnostic and screening unit, in Windsor, serves the population of East Berkshire. The NHSBSP screening population is about 373,978 (with 75% uptake) and the unit diagnosed about 300 new breast cancers last year.

In 1999, the family history patients were seen within the symptomatic breast clinic. There was no formal assessment of their risk, no clinical guidelines, and no database to track the patients. At this time, the symptomatic clinics were struggling to meet the 2-week wait for urgent cancer referrals. When they reviewed the case notes from a selection of clinics, they found large numbers of "family history" patients. A collaborative working partnership with Oxford Regional Genetics Unit was sought. In September 2000, all key stakeholders met to agree the service format, and adopt the Oxford referral guidelines. Patient representation was sought informally throughout this period.

All GP's, practice managers and all staff at the Parapet were informed of the service change. Existing "family history" patients were given a family history questionnaire to complete, and were discharged from clinic, with an explanation of the service change. All new referrals to the family history clinic, were given a questionnaire to complete, and were not offered a routine clinic appointment. The risk assessments were performed either by the BCN or triage nurses at Oxford, and then jointly reviewed.

The women at near population risk were informed by letter, with a copy to the GP. They were also sent a breast awareness leaflet and given the contact number for the BCN. The women at moderate risk, were again informed by letter, and offered an appointment to see the BCN. The high-risk women were given an appointment with the Genetics Team. All women aged 35-65, at increased risk were enrolled in 18-monthly mammography, and an excel spreadsheet was created to track all the patients. In May 2004, the familial breast cancer guidelines were published by NICE. Key stakeholders from Oxford Genetics Unit and Parapet staff met to review existing service. They recommended changes to the service, and sought approval from management, PCT cancer leads, commissioners, MDT and Clinical Effectiveness Team.

There were five main changes to be implemented:

1. *Women with 1 first-degree relative diagnosed with breast cancer under 40 were to be offered screening.* By December 2005, 141 women were identified from the spreadsheet, with half of them eligible for breast screening. One screen-detected cancer was found.

2. *The threshold for genetic testing was lowered.* By September 2005, 9 women identified in the over 50 age group who can be considered for genetic testing. Work on the under 50 age group will be completed by April 2007.

3. *Annual mammography recommended for women at increased risk between the ages of 40-50.* In April 2005, a locally agreed protocol was implemented, where no routine screening would be offered under 35. From 35, high-risk families with young onset breast cancers would be offered yearly mammography. All women at increased risk would be offered yearly mammography from 40-50, and high-risk women over 50 would be offered 18-monthly mammography, performed alternatively by NHSBSP and the family history clinic. The results would be sent directly to the women, with a copy to the GP. If they were recalled, they would be seen within 2 weeks.

4. *There should be psychological support available.* Fortunately the psychological team, who already see the cancer patients, were keen to get involved with the family history patients. Four patients seen to date, with a 3-4 month waiting time.

5. *Develop a pathway for prophylactic mastectomy.* A protocol for prophylactic mastectomy was devised, to ensure a multidisciplinary approach to the care and management of these women.

With any implementation programme, there are always lessons to be learnt. Certainly, key personnel should have been in post before the project began. An appropriate database is essential to track all patients, and to collect data for audit purposes. A web-based database has been developed in house and we are currently adding and modifying the database for audit purposes. Many of the moderate risk women declined their appointment to see the BCN, and were just asking for their screening. So routine appointments are no longer offered. It was anticipated that many of the existing "family history" patients would be anxious about being discharged from the clinic. This was not found to be the case, and was probably due to the fact that they were given an exit interview with the doctor who explained the rationale to them, and all advice from the staff was consistent. To ensure high uptake rates for the high-risk clinics with the Oxford Genetics team, the patients are asked to confirm the appointment. Otherwise the FH coordinator will ring the patients.

For the future, we would review the service with any new guidance. We need to consider performing a patient satisfaction survey, and reviewing patient information. The database needs to be developed further for audit purposes. FH01 recruitment finishes December 2006, and data needs to be entered for the trial. Succession planning needs to be considered. There is no doubt this project would not have been successfully implemented without the collaborative teamwork and commitment by all key stakeholders

If anyone would like to know more about the database that has been developed please contact:  
[Jennifer.Ramm@hwph-tr.nhs.uk](mailto:Jennifer.Ramm@hwph-tr.nhs.uk)

After lunch Sue Thomas, demonstrated the database to those users who wanted to ask questions or gain further understanding of the database

The afternoon session was opened by Dr James Mackay who again welcomed everybody to the meeting and thanked them for their hard work

Professor Stephen Duffy then updated the meeting

#### **'FH01 – where are we now and where we go from here'**

The session was then opened up for discussion from the floor.

The main topics discussed:

- How to ensure follow up with annual mammography continues
- How to identify interval cancers in the FH01 cohort
- NHS numbers are very important and need to be entered onto the database.
- Funding issues

The meeting closed with the following reminders

Recruitment is on track **BUT NO COMPLACENCY**

Cancers need to be identified and entered onto the database

**THANK YOU** everyone

For more information, please contact:-Sue Thomas, Study Co-ordinator.  
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