Dragon's Den Presentation

ICPV Conference 3rd May 2013 Beatson Institute, Glasgow

Presenter: Patsy Whelehan, does research at University of Dundee, her background is as a diagnostic radiographer specializing in mammography. Mostly works with Professor Andy Evans in the area of taking and interpreting images, her other role is in radiography and interpreting patient experience in breast screening mammography.

Studies

Grants are already in place for two projects MIMIC & PRISM. Now patient information and ethics sheets need to be prepared.

The studies plan to recruit patients to have extra imaging with the purpose of trying to identify underlying tumour features that can presently only be identified by the pathologists. The detailed images, MRI scan, 3D Mammogram and latest kind of ultrasound will need to be sent to collaborating centres e.g computer scientists etc. These are different projects which require the same set of patient scans and data.

There are various criteria for inclusion, so some patients may not be able to be recruited.

Patsy outlined the patient journey through the trial and asked for feedback. ICPV delegate comments are added in italics.

(1) Patients will receive a clinic appointment, usually with a surgeon and a breast care nurse, to receive the results of their needle biopsy. Treatment options which have been discussed at a prior MDT meeting will be offered at this meeting. It is also planned to identify eligible patients for these studies at the MDT, so that written information about the studies can be offered to patients. Thus an info pack could be offered by the surgeon or breast care nurse with a brief explanation and encouragement to read the pack at home later. Sometimes the surgeon and breast care nurse may decide the patient is not in a frame of mind to receive the pack and so the subject is not broached.

Comments: Strong feeling that this is patronizing because it denied those patients the choice to participate. Most patients would like to be offered the information and make their own decision. They can always refuse. One member who sits on an ethics committee said that she would object if eligible patients were denied the opportunity to take part.

Patsy noted that ethics science committees tend to be very conservative, and always want someone directly in control of patient treatment to make the first approach about a research study. ICPV delegates felt it was important to make sure that giving out the information pack to eligible patients is not optional.

Patsy also noted that, with this type of project, researchers sometimes think that they are offering very little to benefit the patient themselves, and equally that the patient will not miss out if they do

not take part. However it was pointed out that the patient group will one day benefit, and patients are pleased that "my opinion matters. my experience matters". They often have an altruistic view, that the project will help someone.

A member noted that as a professional she had been concerned about being over-protective, but had learnt that patients often were keen to be involved, and wished to be asked. In her own personal experience of serious illness and death she had found taking part in research to be very cathartic.

It was suggested that the point of principle of always asking all eligible patients could be taken to the RCN Breast Nurses Forum by researcher and patient together.

A member asked if the risk of the extra radiation from additional scans would be explained to the patients. They are being quantified for ethics committee. Patsy noted that tomosynthesis gives about the same radiation dose again as that for a standard mammogram. Explaining the risks in an understandable manner was felt to be very important. One member said that using the sort of analogy "Risk about same as radiation received from transatlantic flight" went down very well in the Marmot report and citizen's jury work.

(2) Contacting Patients for the Study: Patients will be asked to agree to being contacted by phone and will be able to give their phone number via breast care nurse when they are given the information pack at their results appointment. Ethics committees will not allow researchers to use phone numbers from hospital notes to contact patients without explicit permission from the patient, so asking the breast care nurse to collect this seems the best option. Patsy would be keen to hear any better ideas and is very happy to hear from anyone by email.

Patients who have received the information pack and agreed to further contact will be rung at home. They will be asked if they would like to take part in the study. If they agree an imaging appointment will be made for them. Written consent will be taken at the imaging appointment. It is hoped that all required scans can be done in one visit.

Members thought it was essential to fit everything in in one visit. Patsy said that she hoped this would be possible, although there were some patients who had pre-op chemotherapy who would be asked to be scanned twice. An enquiry was made about the length of time the imaging visit would take, (hopefully not more than half a day). Patsy hoped that funding would allow for a staff member to accompany patients around the hospital as the scan equipment was spread about the hospital. It was thought important that expenses were paid for extra appointments and that suitable refreshments etc were provided during extended visits.

(3) Photography during surgery: The scientists analyzing the scans would also like to take photographs during surgery limited to the surgery site and tumour as it is removed. This would need separate consent and patients might be able to opt out of this. The photographs will be used to facilitate orientating and superimposing the different types of scans (co-registration).

(4) Tissue Samples: Will want to do additional imaging on tissue samples after it has been removed? This will also probably need separate consent.
(5) Information governance will be very important as data shared outside UK.
(6) Two different studies, different funders/same patient intervention: It is hoped that the scans once taken for a patient can be used in both studies. The researchers need to make two ethics applications, one for each study, but they are hoping to make the patient information sheets and consent forms the same for each study, including an opt in section. This would allow opt-in for either/both studies by name, but could also include an opt-in for any other relevant study in the future. Would these scans be useful in the future for studies which have not yet been thought of? If so can we consent patients now to allow researchers to contact them again in the future to collect extra data?
A member suggested that contacting 'me or my relatives' is added. Perhaps this should be in two separate clauses, so that patients can opt for 'contact me' only or 'me and my relatives'.

It was noted that initialing multiple boxes can be a barrier, particularly in pre-op situations, although this seems less of a problem in outpatient settings.

Patsy asked about ICPV involvement in NRES .Maggie Wilcox noted that ICPV is involved in advising the HRA on their PPI, and goes to stake-holder meetings. Jacqui Gath is a member of a Research Ethics Committee in Sheffield.

Patsy asked if it was best to cut to the chase, and have a form that asks for consent for this study, and that study, and any suitable study in the future, and also asks permission to re-contact patients at a later date if more information is needed. There was general agreement that this was the best approach. Someone also added that the contact should be specifically for medical research

A member felt it would be good to inform patients if their scans/data were used in future studies, perhaps with a brief card.

A member thought that there should be sufficient time allowed for the patient to make a decision about joining study. Patsy thought that there would be a minimum of a week in this study between receiving information pack and making decision. It was agreed that this was adequate.

Jacqui Gath who sits on ethics committee said that lay members are always impressed when researchers give plenty of detail about the PPI that has been sort for the application rather than just ticking boxes.

Hilary Stobart (ICPV member present at the Glasgow Dragon's Den)

14th May 2013