PRIMETIME study: comments from Chief Investigator, Dr Charlotte Coles

What aspects of the research study were changed following recommendations from patient advocates?'

PRIMETIME is a study in early breast cancer investigating whether we can identify a group of women with a very low risk of recurrence who can safely avoid radiotherapy as we anticipate the side effects of radiotherapy outweigh the benefits. The study is funded by Cancer Research UK and sponsored by the Institute of Cancer Research

Lesley Turner and Hilary Stobart are our patient advocates on the study and were introduced to us through Independent Cancer Patients' Voice and the NCRI. Lesley is a member of the NCRI Supportive and Palliative Care Clinical Studies Group and Hilary is a member of the NCRI Breast Clinical Studies Group

We initially planned a simple single cohort design, but this funding application was unsuccessful. Following feedback from the funding committee, we then considered directing patientsto radiotherapy or not based on whether their cancer was in the left or right breast. A previous Danish breast cancer study investigating nodal irradiation had used this design. The basis for this was that patients with left-sided breast cancers were at slightly higher risk of cardiac related radiotherapy side effects, so the risk-benefit profile would be different compared with patients with right-sided breast cancers.

Hilary and Lesley felt that the decision to join a study like this depended on patients' perception of risk, a difficult concept particularly at these low levels of riskand benefit. The left-right design would add complexity to the patient information sheet and therefore affect recruitment, without necessarily answering the primary question better. They suggested reconsideringthe single cohort design but introducing bio-marker direction to give patients a measure of their individual risk of local recurrence. Wethen worked with them to develop the concept of biomarker directed radiotherapy as determined by the IHC4+C biomarker. This is a research calculation which estimates the chance of an individual patient's breast cancer returning.

Did this improve the study?
This received good feedback from independent peer review and was subsequently funded by Cancer Research UK.

Did this improve patient recruitment?
The study has only just opened so it is too premature to comment, but the early signs are that patients are keen to participate and appreciate the pictorial patient decision aid developed with Hilary and Lesley.

Would this study have been a success without Consumer involvement?
The original designs may have been less acceptable to patients and impacted negatively on recruitment.

What overall impact do you feel Consumer involvement has had on the PRIMETIME study?
Consumers, as integral members of the team, have had an impact on PRIMETIME at every stage from study design, protocol development to design of patient decision aids to supplement the patient information sheet and enhance understanding.

We are also developing a study within PRIMETIME that will investigate whether an additional video to supplement the standard patient information and decision aid, will reduce the uncertainty associated with deciding whether or not to participate in a clinical trial. The wording and diagrams used in the video have been developed in conjunction with Hilary and Lesley and have been changed and adapted as a direct result of their comments.

PRIMETIME study: comments from patient advocates, Lesley Turner and Hilary Stobart

How do you feel you had an impact on the design of the study?
We have been included as full members in this study from the start; through the initial working group discussing the grant applications; as members of the protocol working group and now the trial management group; contributing to the ethics applications; working on design of a decision aid. We have made suggestions and possible edits to documents where relevant throughout the study process as part of the team. In particular we strongly advocated against a left breast versus right breast cohort design, in favour of a study which might use bio-markers to clarify the balance between risk and benefit of radiotherapy for an individual woman. We felt that this design would be more acceptable to patients and more likely to change practice.

What difference do you think that made to the study?
The new design was developed, funded and has now opened.

Was your involvement essential? What did you bring to the study that would have been missing otherwise?
Our involvement was essential because only patients can bring the perspective of patients. A decision to enter this study requires patients at low risk of recurrence to understand the benefits and risks of radiotherapy for them. As breast cancer patients ourselves we have an understanding of how we approached the decisions which have to be made. We also explained that not every patient understands the concept of absolute and relative risk and worked with the team to make patient decision aids clearer.

What are your hopes for the outcomes of this study, and its impact on the way that women with breast cancer receive treatment?
We hope that the study will change practice in the UK and internationally by identifying a group of women, who will still have excellent outcomes without the need for radiotherapy. The biomarker-directed test used in this study is inexpensive and could be used widely to help women and their clinicians make a much more fully informed, personalised decision about the benefits and risks of radiotherapy for them so that one size no longer fits all.