IN Volving people affected by cancer in biomarker research design

PRIMETIME is a study investigating biomarker-directed treatment for patients deemed to be at a very low risk of their breast cancer returning. It aims to identify a group of women who can safely avoid radiotherapy because their recurrence risk is so low, that the potential benefits associated with radiotherapy are unlikely to outweigh the known risks. Patient and Public Involvement (PPI) has been used when developing the trial’s design, developing the research application and carrying out research.

How was PPI established in the project?

PPI was crucial to inform key decisions as the study involves avoidance of treatment that would normally be given as standard of care. The team went to the NCRI Breast Clinical Studies Group (CSG) and consulted the focus group on 5 occasions, over 2 years. The patients:

- Shaped the early stages of the trial’s design
- Debated the scientific and ethical basis of the research
- Justified their support for the proposal

The CSG linked the researchers to the Independent Cancer Patients’ Voice (ICPV) organisation, where 2 patient representatives were recruited onto the research team’s Protocol Development Group. As integral members of the team and present at all meetings, they have helped to:

- Develop the trial concept and final design
- Prepare the Cancer Research UK (CRUK) funding application
- Develop all patient-facing materials (written, pictorial and video)
- Overcome challenges in the set-up of hospital sites
- Oversee how the trial is managed

“Patient representatives are essential and highly valued members of the PRIMETIME team. This partnership has really improved the quality of the study and ensured that it is patient-centred.”
Charlotte Coles, Chief Investigator

What training and support was offered to those involved?

- Expenses – the CRUK grant provides funding for PPI to cover meeting attendance and the costs of travel for the 2 patient representatives
- Scientific support – this was provided to ensure that any unfamiliar terminology and clinical trial processes were explained. The patient representatives were encouraged to ask for clarification at any time.
- Mentorship – on-going support, enabling the patient representatives to have one-to-one discussions on any issues/feelings they experience and wish to discuss as part of the research partnership

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What was the impact of involving people affected by cancer?

PPI heavily influenced the direction of the research and improved its quality and efficacy, ensuring it is focused on the needs of patients. For example, in one trial design being considered, radiotherapy was to be allocated dependent on whether the cancer was in the left or right breast. The patient representatives thought this was too complex and not appropriate, arguing that a patient’s decision to join the trial depends on their perceptions of risk. They suggested the team develop the revised trial concept and agreed that patients would prefer a biomarker directed approach. They also wanted patients to come to a shared decision with their breast cancer team on whether to have radiotherapy or not, independently of the bio-marker directed treatment allocation.

Although the study is hugely cost saving to the NHS, it incurs small excess treatment costs for Ki67 testing at sites. This has been a barrier for opening sites. PPI has provided vital input to resolve this, by contributing to the development of a study funding guidance document provided to sites, which explains the value of the study for patients to prospective sites.

PPI has informed the design and information of patient facing documents, decision aids and videos. This has increased the transparency of the research by clarifying the benefits and risks of radiotherapy, making the research question clearer. PRIMETIME recruitment is currently exceeding planned projections and the team believe this has been made possible by PPI, which has supported patients to make informed decisions on their participation.

What challenges were faced?

“Our experiences with PPI have only been positive” The study has benefitted from the input of highly experienced patient representatives and PPI infrastructure.

Advice for researchers considering PPI

Seek PPI involvement as early as possible, in the development of new research and maintain that involvement through the lifetime of the project.

“We have been delighted to be involved as full members of the study team in all stages of the trial, from concept to delivery. Our voices have always been listened to and we have ensured that patients remain at the centre of research” Lesley Turner & Hilary Stobart, Patient Advocates

For more help, contact involvment@cancer.org.uk

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