

INVOLVING PEOPLE AFFECTED BY CANCER IN CLINICAL TRIAL DESIGN & AMENDMENTS

This research looked at pre-surgery systemic therapy trials for kidney cancer, which require intensive bio-sample collection from patients during the study. This novel clinical trial aims to personalise treatment for patients with drugs before surgery to try and prevent recurrence. Patient and Public Involvement (PPI) was used when developing the research idea/trial design and when carrying out research.

How was PPI established in the project?

The researcher attended a [face-to-face workshop](#) with the NCRI Clinical Study Group to discuss the general idea of providing patients with novel drugs, prior to undergoing surgery to remove kidney cancer. This idea was [presented](#), discussed and altered by the 10 attendees.

PPI evolved to the creation of a [dedicated PPI group](#), with the help of the Cancer Research UK (CRUK) Cambridge Centre PPI team. Those from the focus group who were interested in developing the trials design further were invited to join a PPI Trial Development Group. This panel:

- Developed the trial protocol
- Shaped patient facing documentation

This group queried things that had been suggested in the larger group discussion.

[Patient representatives](#) on the Trial Management Group, have since informed on the conduct of the trial and have addressed issues around how best to amend the trial as it proceeds.

“PPI with both kidney cancer patients and other cancer patients provided reassurance about some of the more novel and challenging angles of our study which was hugely reassuring to us” Dr. Stewart, Researcher



What training and support was offered to the PPI groups?

- [Briefing Materials](#) – these were sent out to the focus group members before the meeting, detailing the research project, why they were being consulted and specific questions to think about. This ensured everyone was clear on the research, helped focus discussions and allowed members to prepare questions and thoughts in advance.
- Key Contact - the patient representatives were given a key contact, in case they had any questions regarding the trial and the subject matter between meetings

What was the impact of involving people affected by cancer?

Ethical & acceptability reassurance

People affected by cancer ensured relevance to the research, which is impossible for clinicians to be sure they are achieving. Aspects of the trial that the chief investigator was most concerned about, in terms of acceptability to patients, were of minimal concern to the PPI team. For example, the team were concerned that they could not be sure that the short duration of the drug would alter survival for patients and worried that they would not want to participate in the trial. PPI discussions reassured that this was not an issue as the research measured effectiveness of the treatment in other ways, such as the size of the tumours. They also reassured that patients would be happy to wait for 3 weeks on a drug before a scan was performed. This comforted the team and ethics committee!

Greatly improved the quality & accessibility of the research

PPI discussions greatly altered the trials design, helping to focus the research on the needs of patients. For example, initially tumour size change was not included as an endpoint in the trial, but the PPI group wanted to see this included as it is a measurement that patients understand and would comfort them. They also changed the language and phraseology in patient facing information to make sure it was clear. Changes like this have also made the research more accessible and inviting to potential participants.

What challenges were faced?

1. Recruitment – kidney cancer is a relatively uncommon disease, so it was not easy to identify the best people, with the time and physical health, to get involved.

Working with different PPI groups helped manage this barrier, as did involving people who had previously been less involved to provide new insight to issues.

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

Advice for researchers considering PPI

1. Plan carefully – Don't always approach individual affectional PPI representatives from your own practice. Those you do not know bring a new spin to discussions.

2. Ask for help - organisations like CRUK can generate higher quality PPI by offering guidance and resources, for planning and facilitating PPI. They can also enable robust PPI through workshops and e-consultations.

3. PPI is essential –in the planning stages of research and in the broader sense of research prioritisation work (i.e. gap analyses or Delphi exercises). It also aids funding success!