

**Why you should read this article:**

- To improve your understanding of clinical trials in oncology
- To familiarise yourself with the concept of patient and public involvement
- To understand that listening to patients' views is essential to service improvement

# Using patient and public involvement to improve the clinical pathway for participants in clinical trials

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**Abstract**

Clinical trials are commonly conducted to improve the care of patients with cancer, identifying new cancer treatments and methods for detecting and diagnosing the disease. In January 2017, a service evaluation investigated the effectiveness of the clinical pathway for cancer patients who are referred for inclusion in early phase clinical trials. The service evaluation included the views of patients, and a patient and public involvement group. The researchers used various methods such as semi-structured discussions with patients and a questionnaire.

The service evaluation identified essential information that patients and their family members felt would be useful to know before an initial early phase clinical trial appointment; for example, information about what early phase clinical trials involve at the point of referral. The service evaluation also produced a patient information booklet for patients who had been newly referred for early phase clinical trials.

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**Keywords**

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ONE OF the primary methods of improving the care of patients with cancer is by conducting clinical trials. Clinical trials are important for discovering new types of anti-cancer treatments, as well as discovering new methods for detecting and diagnosing cancer. In the development of new medical treatments, clinical trials demonstrate those elements of a treatment that are effective and those which are ineffective in people who are affected by disease, for example, any side effects a medicine may have.

The process of developing new treatments involves many healthcare professionals and pharmaceutical companies; however, active patient involvement in clinical trials is important (Sacristán et al 2016).

**Types of clinical trials**

Clinical trial designs are generally categorised into four phases. Phase one and two trials are regarded as early phase research and are the first steps in treatment development, whereas phase three and four trials are categorised as late-phase research.

**Early phase clinical trials**

In a cancer research setting, the majority of patients who take part in early phase clinical trials will have exhausted all of the available standard treatment options. This is usually because their cancer is at an advanced stage, and because of the lack of evidence of response rates to treatments that might be prescribed (Halpern et al 2019). However, there is an

increasing number of early phase clinical trials that now offer patients with advanced cancer additional treatments at an earlier stage in their clinical pathway (Adashek et al 2019).

Early phase clinical trials aim to find out how much of a new treatment is safe to administer and how it is metabolised, as well as developing an understanding of any side effects (Cook et al 2015). Early phase clinical trials generally recruit low numbers of patients and the treatments administered in this phase of research are often 'first-in-human' trials. It may also be the case that an early phase clinical trial is the first time that a treatment is being used for a particular type of cancer (Vickers 2018). In oncology, early phase clinical trials are primarily delivered through a network of experimental cancer medicine centres across the UK. These centres are staffed by specialist early phase research medical consultants and research nurses who have a vital role in the care of patients undergoing experimental cancer treatments. These centres are a fundamental first step in developing new treatments for cancer patients.

#### Late-phase clinical trials

Experimental treatments that have generated sufficient efficacy data within early phase clinical trials will then progress to late-phase clinical trials (Cook et al 2015). Late-phase clinical trials recruit substantially higher numbers of patients and aim to compare investigative treatments against or in combination with 'gold standard' care treatments, while simultaneously obtaining information on therapeutic effects and long-term side-effects (Mahan 2014). Existing standard of care treatment options are available to patients eligible for phase three trials (Cook et al 2015). For example, phase three clinical trials are generally delivered in standard of care areas such as chemotherapy or outpatient departments within a hospital setting (Cancer Research UK 2020), as opposed to the experimental cancer medicine centres that host early phase clinical trials.

#### Patient safety

Patient safety in any clinical trial is crucial and is governed by Good Clinical Practice, a global set of ethical and scientific quality standards for designing, conducting, recording and reporting clinical trials that involve human participation (Shaw and Townend 2016). Within these quality standards, patients taking part in clinical trials are legally required to participate in an informed consent process (Halpern et al 2019). This process ensures

that patients make an informed decision about their participation in a clinical trial. Patients are made fully aware that their participation is voluntary and that they can withdraw their consent at any time, for any reason (Halpern et al 2019).

It is a moral obligation within clinical research that patients fully understand the research they are consenting to take part in. In early phase clinical trials in oncology, it is also important that patients fully understand the ramifications of the clinical trial they have consented to. Every effort should be made to reduce any unrealistic beliefs that patients may have concerning the potential benefits of early phase clinical trials, particularly because such beliefs are common among patients who are participating in cancer research (Crites and Kodish 2013).

#### Patient and public involvement

Patient and public involvement (PPI) can be defined as an essential element of the research process that ensures that members of the public are involved in the design and delivery of any research (Bagley et al 2016). PPI is a significant element in UK research, and is an essential part of the Research Ethics Service (RES), which protects the rights, safety, dignity and wellbeing of research participants. PPI is essentially a legal requirement of the Integrated Research Application System (IRAS), which is a single system for applying for permission and approval for health and community care research in the UK (IRAS 2019).

To ensure that members of the public are at the forefront of any information provided to future research participants, PPI groups, which comprise volunteer members, often review and provide feedback on research projects at PPI group meetings. Typical meetings involve researchers presenting their research ideas and study documents for review. PPI group members will in turn ask questions and provide feedback to develop and support research projects. In many cases, PPI members become co-applicants in research projects, which can involve aiding the development of a research funding application and having some responsibility for the management and/or delivery of a study (National Institute for Health Research (NIHR) 2020).

PPI enables researchers to identify potential challenges and resolutions within a research design, as well as supporting participant recruitment (McMillan et al 2018). However, little is known about how much PPI exists in research due to limitations around reporting requirements; obtaining study approval

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through the RES only requires researchers to document their plans to use PPI (Price et al 2018). The extent to which researchers use PPI once their study has been approved is unknown and underreported.

### Local early phase clinical trials

In the area of northern England covering Northumberland, Tyne and Wear, Teesside, Cumbria and County Durham, cancer patients who do not have access to proven treatment options are often referred to the Sir Bobby Robson Cancer Trials Research Centre, an experimental cancer medicine centre in Newcastle upon Tyne, for consultation about participating in early phase clinical trials. Weekly outpatient clinics are held for these patients to discuss the possibility of participating in an early phase clinical trial. During their clinic appointment, patients will have a discussion with an oncologist who will provide general information about participating in early phase research. At this appointment, patients may also be given an information leaflet concerning a current clinical trial running at the experimental cancer medicine centre.

The information given during this initial early phase clinic appointment can be daunting and complex, and patients may find it challenging to process in the time available. Mistaken beliefs concerning early phase clinical trials are common among cancer patients (Van der Biessen et al 2013). At this stage, it is crucial that the patient is assisted to understand the primary objectives of a clinical trial and the effect it may have on their life (Sacristán et al 2016, Halpern et al 2019).

### Service evaluation

#### Aim

The aim of the service evaluation was to investigate the early stages of the clinical pathway followed by cancer patients, from referral to the Sir Bobby Robson Cancer Trials Research Centre to enrolment onto an early phase clinical trial. A project incorporating PPI was then used to improve the clinical pathway for patients.

#### Literature review

As part of the service evaluation, a literature review was conducted to improve understanding of the guidelines concerning patient information within a clinical trial setting. Additionally, the review examined the various approaches taken to developing patient educational resources and how PPI could inform the design of these resources.

### Guidelines

International guidelines concerning patient information and participation in clinical trials focus on Good Clinical Practice, which is governed in the UK by the NIHR and adopted by the experimental cancer medicine centre network. It is a legal requirement for members of staff working within clinical research teams to complete the 'introduction to Good Clinical Practice' course and attend a Good Clinical Practice refresher training course every three years. Good Clinical Practice acts as a safety assurance for patients taking part in research, and ensures that their rights, safety and wellbeing are protected, and that research data is reliable (NIHR 2020).

### Informed consent in clinical research

In terms of patient education during clinical research, Good Clinical Practice focuses on the informed consent process, which includes the use of patient information leaflets that provide specific details on clinical trials, as well as face-to-face discussions with medical and nursing staff. Patient information leaflets are produced by the institutions that sponsor clinical research, and in most cases are sponsored either by a pharmaceutical company or an academic institute. These leaflets are specific to individual trials and can be used at any other centre conducting the same study, including in other countries. Nijhawan et al (2013) stated that educational resources dealing with informed consent in a clinical research setting must focus on localised information relevant to the specific country. Bossert et al (2017) suggested that incorporating user feedback into the development of educational leaflets could improve patient decision-making processes in clinical trials.

Obtaining informed consent for a clinical trial involves ensuring that patients understand the objectives, potential benefits and consequences of the trial before signing a consent form (Gupta 2013). In addition, patients should be made aware that research is voluntary and that they have the right not to participate in a clinical trial and may withdraw their consent at any point (Santel et al 2019). However, there is debate concerning the informed consent process, in particular its effectiveness in supporting patients' decision-making ability when they are presented with vast complex volumes of clinical trial information (Halpern et al 2019). Bester et al (2016) stated that in these instances patients can become overwhelmed, adversely affecting the informed consent process. Also, researchers have proposed that the informed consent process in early phase clinical trials has

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limitations, and that disease severity can have an important role in patients' decision-making process. For example, a patient may be eager to gain access to a potentially life-changing medical treatment, which can influence their decision about whether or not to enrol for a clinical trial (Halpern et al 2019).

Patient comprehension is an important component of the informed consent process (Ruske et al 2020). Some studies have indicated that patients remember little of the information that is discussed during the process and their level of understanding around essential information is often overestimated (Hall et al 2012). Systematic reviews into the informed consent process have outlined that the level of patients' knowledge gained from informed consent is frequently inadequate and that further educational interventions need to be developed (Schenker et al 2011, Nishimura et al 2013).

#### **Novel approaches to improving patient comprehension**

A number of studies have identified the need for interventions to improve patient understanding within the informed consent process for clinical trials (Nishimura et al 2013, Bhatt 2015, Lentz et al 2016). These studies demonstrated that providing patients with additional written information and audio-visual programmes could promote further discussion and prepare patients for initial clinical trial discussions as well as improving their comprehension of these discussions (Nishimura et al 2013, Bhatt 2015, Lentz et al 2016).

#### **Patient and public involvement**

Pollard et al (2015) found that a person-centred, co-design methodology approach was increasingly accepted within UK healthcare policy as a means to improve the quality of care delivery. Also Pollard et al's (2015) attempt to involve service users as research partners had positive results.

Wolf et al (2014) advocated the use of PPI in developing healthcare educational resources, considering it vital to move beyond the use of surveys to determine patient satisfaction. By using PPI appropriately, accurate patient experiences can be gathered and employed to modify healthcare services (Wolf et al 2014).

Studies that have explored and examined the effects of educational interventions within a healthcare setting have produced encouraging outcomes. Han et al's (2018) review of an educational intervention which took the form of extra written information provided alongside

nurse-led educational sessions in patients with laryngeal cancer found that this intervention improved patients' negative emotions concerning their health status and clinical pathway. However, the sample size was small.

Capanna et al (2015) featured a larger sample size and found that novel theory-based educational strategies that included PPI within their design positively influenced prostate cancer patients' understanding of their disease and treatment options. The study indicated that measuring patients' disease and clinical pathway knowledge alerted researchers to educational gaps, which could then be targeted with interventions (Capanna et al 2015). Kizza and Muliira (2019) suggested that healthcare educational interventions that are based on patients' and patient family members' educational requirements can significantly improve patients' experience of cancer and clinical pathways.

Roberts et al (2015) collaborated with a chronic obstructive pulmonary disease (COPD) PPI group and a COPD nurse specialist to develop a co-designed healthcare project that reviewed standards of patient care and developed strategies to address gaps in this care. The study identified major gaps in patients' knowledge of pulmonary rehabilitation. Through further co-designed work, educational interventions were developed and subsequently piloted in practice. This approach resulted in significant improvements to patients' understanding of their disease and improved awareness of the additional accessible support available; this was evidenced by an increase in referrals to pulmonary rehabilitation.

#### **Service evaluation: initial stage**

In January 2017, the initial stage of the service evaluation focused on unscripted discussions between members of staff at the Sir Bobby Robson Cancer Trials Research Centre and patients who had been enrolled on an early phase clinical trial and who were receiving treatment at the centre. Family members of these patients were also included in the discussions. These discussions covered subjects such as the effectiveness of the patient pathway, from the point at which patients received standard care to being enrolled on a clinical trial. During these discussions, patients were encouraged to reflect on this clinical pathway and asked to explain what elements they thought had 'gone well' and what could have been improved upon.

In total, 30 patients and their family members were included in this initial stage

## **Key points**

- Patient and public involvement (PPI) in early phase clinical trials can have a positive effect on future patient care
- PPI can outline any gaps in patients' understanding of clinical care
- Ensuring patients' views are central to any service improvements can reduce patients' anxiety concerning early phase clinical trials
- The use of PPI in developing effective patient education tools ensures these are written in patient-friendly language that demystifies complex areas of care

of the service evaluation. At this stage, the findings indicated that the majority of patients and their family members felt that, from the point when they were initially referred for an outpatient appointment at the Sir Bobby Robson Cancer Trials Research Centre, they would have appreciated more information about what the process of enrolling on an early phase clinical trial would involve. At the point where they were initially referred to the centre, patients and their family members had minimal knowledge of what early phase clinical trials were and what they might entail. In addition, at the point of initial referral, a lack of information concerning the clinical pathway was a recurring theme, and this increased feelings of anxiety and stress among patients and their family members.

#### Service evaluation: second stage

As a result of the work undertaken at the initial stage, semi-structured discussions were conducted with a further 20 patients and their family members, which investigated the lack of information in further detail. At the same time, all 18 experimental cancer medicine centres within the UK were contacted to investigate whether they had resources that could be used within the Sir Bobby Robson Cancer Research Trials Centre to address the lack of patient information. The findings indicated that none of the other experimental cancer medicine centres had a resource for patients at the point of initial referral to an experimental cancer medicine centre for the purpose of discussing early phase clinical trials.

These semi-structured discussions with patients participating in research at the Sir Bobby Robson Cancer Research Trials Centre and the Newcastle PPI group for cancer research identified essential information that patients and their families felt would be crucial before an initial research appointment. The following are the themes that were generated from this information:

- » Background information on how a clinical trial works.
- » General information about study visits and their effect on time. Study visits were those that patients would have as part of being in a clinical trial.
- » What would happen if there was not a clinical trial?
- » Information being explained by staff in terms that patients can understand.
- » Information about the patient journey.
- » Study design of early phase clinical trials.
- » Difference between experimental drugs and standard care drugs.

- » Positive and negative aspects of drugs in early phase clinical trials.
- » Previous patient experiences.
- » Support offered to patients while they are on an early phase clinical trial.
- » What happens with the patient's GP when they are included on an early phase clinical trial?
- » Who is the main point of contact and what is their role?
- » What questions should patients ask the doctor at an initial appointment?
- » Travel arrangements and transport links for the Sir Bobby Robson Cancer Research Trials Centre.

These discussions also identified the optimal time to deliver this information, which was at the beginning when patients were first asked if they would like to be referred for an early phase clinical trial, and the preferred format, which was the booklet and website.

Following these discussions, the Newcastle PPI group and the patients enrolled on clinical trials worked together using focus groups to produce resources for patients newly referred to an early phase clinical trial. The focus groups consisted of ten people and were run by the author. They reviewed and evaluated the patient information booklets that were being used in research and in standard care areas. Good design elements from these booklets were incorporated into a new booklet that was created to provide information for patients embarking on early phase clinical trials. The focus groups also discussed the amount and quality of written information used in the current booklets, as well as issues such as graphics and the optimal size of any new booklet.

The outcome of the focus groups was a booklet template that was designed to integrate the information identified as essential by the Newcastle PPI group and patients enrolled on early phase clinical trials. Once integrated, a draft of the booklet was developed and updated on numerous occasions by the focus group until a final version was agreed upon.

The final booklet was titled: Early Phase Oncology Research Trials: Helping Your Journey from the First Appointment. The booklet includes information on what early phase clinical trials are, what will happen at the first appointment and what will happen if the patient decides to take part in a trial. Also included are patients' first-hand experiences of taking part in early phase clinical trials and family members' first-hand experiences of supporting those taking part in an early



phase clinical trial. The booklet also contains details of the local support available to patients should they decide to take part in a clinical trial.

The booklet was approved by the local hospital trust in 2018 and subsequently integrated into practice. Once integrated, all patients who had been newly referred to the Sir Bobby Robson Cancer Research Trials Centre received a copy of the booklet, which was included with their appointment letter. There was also a covering letter explaining the background to the newly developed booklet and a feedback questionnaire about the booklet.

**Questionnaire**

The questionnaire included with the booklet aimed to capture feedback in the following areas:

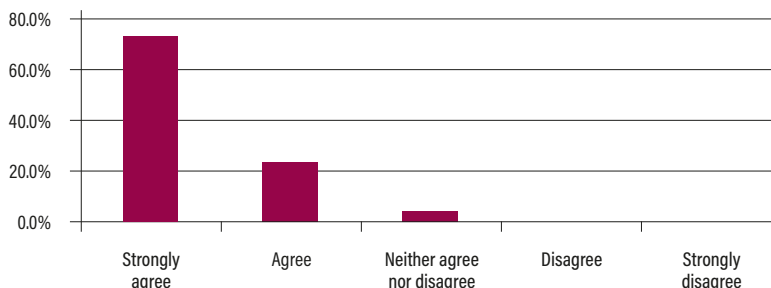
- » Whether the booklet was easy to read.
- » Whether the booklet made patients aware of what might happen at their first clinic appointment and what questions to ask their doctor.
- » Whether the booklet allowed patients to understand what constituted an early phase clinical trial.
- » Whether the booklet allowed patients to understand what might happen to them if they were to take part in an early phase clinical trial.
- » Whether the booklet informed patients of the support available if they were to take part in an early phase clinical trial.
- » Whether the booklet helped to reduce any stress and anxiety patients might have about taking part in an early phase clinical trial.

Over a period of four months, in addition to a covering letter, all patients who had been newly referred to the Sir Bobby Robson Cancer Trials Research Centre were given a copy of the booklet and a feedback questionnaire before their early phase clinical trial appointment. During this period data was collected from 100 patients. Figures 1-6 show the results of the questionnaire relating to the six feedback areas. All 100 patients responded to each of the six statements.

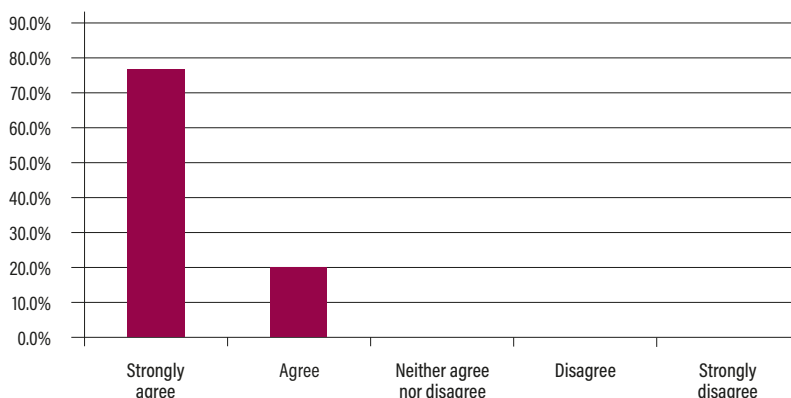
**Ethics**

The service evaluation took place within a hospital trust and was undertaken by a trust member of staff. Before the service evaluation began, a review of the proposal was conducted by the hospital trust’s service improvement team, which deemed that the project was a service evaluation and improvement project rather than a research study. Therefore, no research ethical approval was required. No

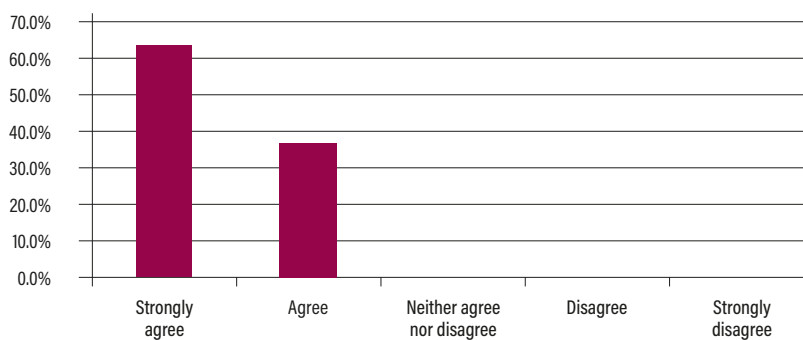
**Figure 1. Booklet was easy to read**



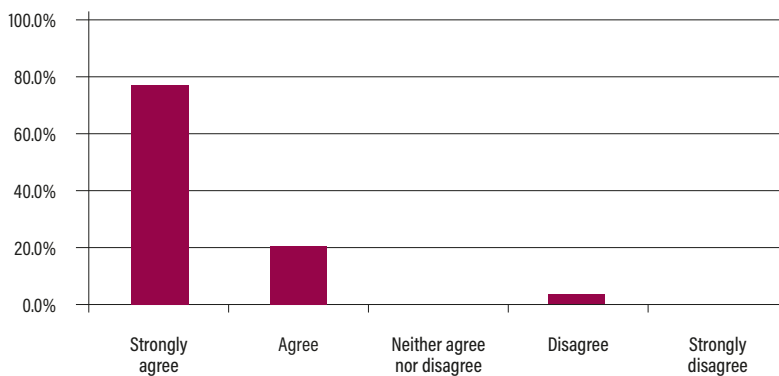
**Figure 2. Booklet made me aware of what might happen at the first clinic appointment and what questions to ask the doctor**



**Figure 3. Booklet gave me an understanding of early phase clinical trials**



**Figure 4. Booklet gave me an understanding of what might happen if I took part in an early phase clinical trial**



patient identifiable information was used at part of this project.

**Discussion**

The findings from the questionnaire data collected from patients who had been newly referred to an early phase clinical trial indicate that the educational booklet had a positive effect on each patient’s clinical pathway from initial referral to the centre. This project also demonstrated, albeit on a small scale, the positive effect of engaging and involving patients and a PPI group to develop a clinical pathway into early phase clinical trials. Applying PPI in this scenario identified a gap in patient understanding of an often complex and highly emotional patient pathway into early phase clinical trials. Furthermore, it allowed the development of an effective educational resource that was developed by patients for future patients.

The methodology used in this project had limitations and refining the approach would have possibly produced more scientifically

quantifiable data. For example, employing a research approach, as opposed to a service evaluation method, would have enabled an evidence-based approach to this project’s design and evaluation. This approach would have yielded a hypothesis, which would have allowed the researchers to assess the booklet’s integration into standard of care through pre and post-interventional validated assessments. This would have demonstrated the effect of this project in greater depth.

**Limitations**

There were several limitations with this service evaluation. The methodological approach was novel with limited academic theoretical consideration given to its initial development, delivery and evaluation.

In addition, no details of patient demographics were recorded from the 20 patients and family members involved in the semi-structured discussions, which meant there was no information on the involvement of people from black, Asian and minority ethnic (BAME) groups. Representation from BAME groups within in this project would have ensured that the booklet was inclusive.

**Future developments**

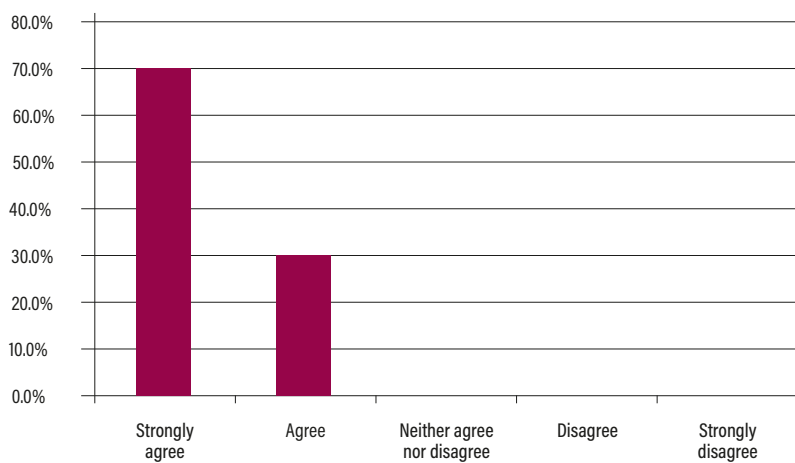
Work to integrate the booklet into hospital trusts that refer patients to the Sir Bobby Robson Cancer Trials Research Centre is ongoing. Also, the booklet is being translated into a video and audio resource that will be embedded within a website. It is hoped that this will allow patients earlier access to essential information that will support a life changing decision-making process.

Through Cancer Research UK’s Senior Nurses Network, this project will be piloted at other experimental cancer medicine centres to support future cancer patients enrolled on early phase clinical trials and their family members.

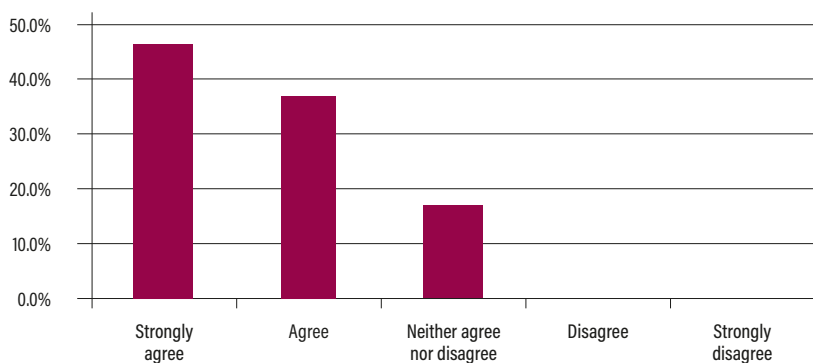
**Conclusion**

This service evaluation has provided an insight into the effect PPI can have on a patient pathway. In this service evaluation, the involvement of PPI identified a lack of information and knowledge for patients who were referred onto early phase clinical trials. The involvement of PPI supported the development of an educational booklet that was able to improve patients’ knowledge and experience. Implementing the use of an educational booklet in other experimental cancer medicine centres will support patients undergoing similar journeys across the country.

**Figure 5.** Booklet showed me what support is available to patients when they take part in early phase clinical trials



**Figure 6.** Booklet reduced any stress and anxiety I had about taking part in early phase clinical trials



## References

- Adashek J, LoRusso P, Hong D et al (2019) Phase I trials as valid therapeutic options for patients with cancer. *Nature Reviews Clinical Oncology*, 16, 12, 773-778.
- Bagley HJ, Short H, Harman NL et al (2016) A patient and public involvement (PPI) toolkit for meaningful and flexible involvement in clinical trials – a work in progress. *Research Involvement and Engagement*, 2, 15. doi: 10.1186/s40900-016-0029-8
- Bestler J, Cole C, Kodish E (2016) The limits of informed consent for an overwhelmed patient: clinicians' role in protecting patients and preventing overwhelm. *AMA Journal of Ethics*, 18, 9, 869-886. doi: 10.1001/journalofethics.2016.18.9.peer2-1609
- Bhatt A (2015) Improving quality of informed consent in clinical research. *Journal of Postgraduate Medicine*, 61, 4, 221-222. doi: 10.4103/0022-3859.166508
- Bossert S, Kahrass H, Heinemeyer U et al (2017) Participatory improvement of a template for informed consent documents in biobank research – study results and methodological reflections. *BMC Medical Ethics*, 18, 1, 78. doi: 10.1186/s12910-017-0232-7
- Cancer Research UK (2020) What is Cancer? [cancerresearchuk.org/about-cancer/what-is-cancer?gclid=CLHL6YSs9uUCFQhGwodvs4PCw&gclid=c=ds](http://cancerresearchuk.org/about-cancer/what-is-cancer?gclid=CLHL6YSs9uUCFQhGwodvs4PCw&gclid=c=ds) (Last accessed: 16 June 2020.)
- Capanna C, Chujiatalli R, Murray S et al (2015) Prostate cancer educational intervention among men in Western Jamaica. *Preventive Medicine Reports*, 2, 788-793. doi: 10.1016/j.pmedr.2015.09.008
- Cook N, Hansen A, Siu L et al (2015) Early phase clinical trials to identify optimal dosing and safety. *Molecular Oncology*, 9, 5, 997-1007. doi: 10.1016/j.molonc.2014.07.025
- Crites J, Kodish E (2013) Unrealistic optimism and the ethics of phase I cancer research. *Journal of Medical Ethics*, 39, 6, 403-406. doi: 10.1136/medethics-2012-100752
- Gupta UC (2013) Informed consent in clinical research: Revisiting few concepts and areas. *Perspectives in Clinical Research*, 4, 1, 26-32. doi: 10.4103/2229-3485.106373
- Hall DE, Prochazka AV, Fink AS (2012) Informed consent for clinical treatment. *Canadian Medical Association Journal*, 184, 5, 533-540. doi: 10.1503/cmaj.112120
- Halpern J, Paolo D, Huang A (2019) Informed consent for early-phase clinical trials: therapeutic misestimation, unrealistic optimism and appreciation. *Journal of Medical Ethics*, 45, 6, 384-387. doi: 10.1136/medethics-2018-105226
- Han J, Nian H, Zheng Z et al (2018) Effects of health education intervention on negative emotion and quality of life of patients with laryngeal cancer after postoperative radiotherapy. *Cancer Radiothérapie*, 22, 1, 1-8. doi: 10.1016/j.canrad.2017.04.012
- Integrated Research Application System (2019) Integrated Research Application System. [myresearchproject.org.uk/help/hlpcollatedqsg-iras.aspx](http://myresearchproject.org.uk/help/hlpcollatedqsg-iras.aspx) (Last accessed: 16 June 2020.)
- Kizza IB, Muliira JK (2019) The influence of a home-based education intervention on family caregivers' knowledge and self-efficacy for cancer pain management in adult patients within a resource-limited setting. *Journal of Cancer Education*, 34, 6, 1150-1159. doi: 10.1007/s13187-018-1421-x
- Lentz J, Kennett M, Perlmutter J et al (2016) Paving the way to a more effective informed consent process: recommendations from the Clinical Trials Transformation Initiative. *Contemporary Clinical Trials*, 49, 65-69. doi: 10.1016/j.cct.2016.06.005
- Mahan VL (2014) Clinical trial phases. *International Journal of Clinical Medicine*, 5, 21, 1374-1383. doi: 10.4236/ijcm.2014.521175
- McMillan B, Fox S, Lyons M et al (2018) Using patient and public involvement to improve the research design and funding application for a project aimed at fostering a more collaborative approach to the NHS health check: the CaVIAR project (better Care Via Improved Access to Records). *Research Involvement and Engagement*, 4, 18. doi: 10.1186/s40900-018-0101-7
- National Institute for Health Research (2020) Good Clinical Practice (GCP). [www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm](http://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm) (Last accessed: 16 June 2020.)
- Nijhawan LP, Janodia MD, Muddukrishna BS et al (2013) Informed consent: issues and challenges. *Journal of Advanced Pharmaceutical Technology and Research*, 4, 3, 134-140. doi: 10.4103/2231-4040.116779
- Nishimura A, Carey J, Erwin PJ et al (2013) Improving understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials. *BMC Medical Ethics*, 14, 1, 28. doi: 10.1186/1472-6939-14-28
- Pollard K, Donskoy AL, Moule P et al (2015) Developing and evaluating guidelines for patient and public involvement (PPI) in research. *International Journal of Health Care Quality Assurance*, 28, 2, 141-155. doi: 10.1108/IJHCQA-01-2014-0001
- Price A, Schroter S, Snow R et al (2018) Frequency of reporting on patient and public involvement (PPI) in research studies published in a general medical journal: a descriptive study. *BMJ Open*, 8, 3, e020452. doi: 10.1136/bmjopen-2017-020452
- Roberts CM, Gungor G, Parker M et al (2015) Impact of a patient-specific co-designed COPD care scorecard on COPD care quality: a quasi-experimental study. *Primary Care Respiratory Medicine*, 25, 15017. doi: 10.1038/npjpcrm.2015.17
- Ruske J, Sharma G, Makie K et al (2020) Patient comprehension necessary for informed consent for vascular procedures is poor and related to frailty. *Journal of Vascular Surgery*, 71, 1, e23-e24. doi: 10.1016/j.jvs.2019.10.042
- Sacristán J, Aguaron A, Avendano-Sola C et al (2016) Patient involvement in clinical research: why, when, and how. *Patient Preference and Adherence*, 10, 631-640. doi: 10.2147/PPA.S104259
- Santel F, Bah I, Kim K et al (2019) Assessing readability and comprehension of informed consent materials for medical device research: a survey of informed consents from FDA's Center for Devices and Radiological Health. *Contemporary Clinical Trials*, 85, 105831. doi: 10.1016/j.cct.2019.105831
- Schenker Y, Fernandez A, Sudore R et al (2011) Interventions to improve patient comprehension in informed consent for medical and surgical procedures: a systematic review. *Medical Decision Making*, 31, 1, 151-173. doi: 10.1177/0272989X10364247
- Shaw D, Townend D (2016) Division and discord in the Clinical Trials Regulation. *Journal of Medical Ethics*, 42, 11, 729-732. doi: 10.1136/medethics-2016-103422
- Van der Biessen DA, Cranendonk MA, Schiavon G et al (2013) Evaluation of patient enrollment in oncology phase I clinical trials. *The Oncologist*, 18, 3, 323-329. doi: 10.1634/theoncologist.2012-0334
- Vickers E (2018) *A Beginner's Guide to Targeted Cancer Treatments*. Wiley Blackwell, Oxford.
- Wolf JA, Niederhauser V, Marshburn D et al (2014) Defining patient experience. *Patient Experience Journal*, 1, 1, 7-19. doi: 10.35680/2372-0247.1004