

Accepted refereed manuscript of:

Abhyankar P, Velikova G, Summers BA & Bekker HL (2016)  
Identifying components in consent information needed to  
support informed decision making about trial participation: an  
interview study with women managing cancer, *Social Science  
and Medicine*, 161, pp. 83-91.

DOI: [10.1016/j.socscimed.2016.05.040](https://doi.org/10.1016/j.socscimed.2016.05.040)

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Journal: Social Science and Medicine

Revision Submitted: 29/04/2016

Manuscript ID: SSM-D-15-02401R1

Date accepted: 26/05/2016

**Title:** Identifying components in consent information needed to support informed decision making about trial participation: an interview study with women managing cancer

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**Funding:** The study was funded by an Overseas Research Scholarship, supporting PA's doctoral project.

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**Competing Interests** – PA, BS, GV and HLB declare they have no competing interests.

### **Authors' contributions**

PA made substantial contributions to conception and design, acquisition of data, analysis and interpretation of data, drafting the manuscript and revising it critically for important intellectual content and gave final approval of the version to be published.

GV made substantial contribution as a clinical supervisor to conception and design, interpretation of data, and revising the manuscript critically for important intellectual content and gave final approval of the version to be published.

BS made substantial contribution as an academic supervisor to interpretation of data, and revising the manuscript critically for important intellectual content and gave final approval of the version to be published.

HLB made substantial contribution as lead supervisor to conception and design, analysis and interpretation of data, drafting the manuscript and revising it critically for important intellectual content and gave final approval of the version to be published.

### **Acknowledgements**

We would like to acknowledge the research nurses at the oncology outpatient clinic who helped in patient recruitment and all patients who took part in the study. We would also like to thank Dr Fiona Harris for advice on qualitative aspects of this paper and helpful comments from the anonymous peer reviewers, both of which have significantly improved the manuscript.

**Identifying components in consent information needed to support informed decision making about trial participation: an interview study with women managing cancer**

**Abstract**

*Background:* Research governance requires patients give informed consent to participate in clinical trials. However, there are concerns that consent information may not support patient participation decisions. This study investigates the utility of consent information in supporting women's trial participation decisions when receiving treatment for cancer.

*Design:* An interview study with women receiving cancer treatments at a medical oncology outpatient clinic in Yorkshire (UK). All women over 18 years, not admitted to a hospital ward and who had currently or previously been invited to take part in a trial were invited to take part in the study over a three month period. Interviews were audio-tape recorded, transcribed and analysed using thematic analysis.

*Results:* 21/41 eligible women with breast ( $n=11$ ), ovarian ( $n=8$ ) and endometrial ( $n=2$ ) cancer participated; mean age 57 years. Eighteen had made at least one trial decision and three were considering taking part in a trial. Findings are synthesised under two analytical themes: 1) Influence of the cancer and cancer treatment context on decision making for trial participation and 2) Experiences of the consenting process and their influence on decision making.

*Conclusions:* Designing trial information to represent explicitly the trial participation decision as being between standard care and study-related care options is more likely to effectively support patients in making informed decisions between standard care treatments and taking part in a trial.

**Keywords:** shared decision making, informed consent, trial participation, cancer treatment, decision aids.

## **Introduction**

Obtaining consent from patients to take part in a clinical trial is guided by the principles of good clinical practice, the Declaration of Helsinki (World Medical Association, 2013) and health service research governance (International Conference on Harmonisation, Good Clinical Practice [ICH GCP], 1996). Consent refers to the ethical-legal principle of patients giving their permission to practitioners for a treatment or procedure to be carried out, either by gesture, verbally or in writing. To be valid, this consent must be voluntary and informed, and the person consenting must have the capacity to make the decision (NHS Choices, 2014). Information provided to support patients' trial participation choices is required to include details of the study team, sources of funding, conflicts of interest, aims and methods, procedures, anticipated risks and benefits of procedures, available alternatives, confidentiality, and the right to withdraw from the trial. Its purpose is to ensure patients are informed about the study, and their trial choices are made voluntarily, when they give their consent to participate (World Medical Association, 2013). An outstanding question is whether this information is sufficient to support informed consent.

Patients and professionals have described informed consent for a trial as an empty ritual in which patients are provided with complex information that is difficult to understand and has little impact on their decision making (Armstrong et al., 2012; Lidz et al., 2004). Although the information provided during elicitation of informed consent has improved (Bjorn et al., 1999; Flory & Emanuel, 2004; Synnot et al., 2014), patients' understanding of consent remains suboptimal, leaving unmet patient needs (Bell & Balneaves, 2015; Brehaut et al., 2012a; Gillies et al., 2014; Moynihan et al., 2012). Previous studies show that patients possess poor knowledge and understanding about key aspects of trial processes and treatments (Dixon-Woods et al., 2007; Lidz et al., 2004; Pope et al., 2003) and find it difficult to integrate the

information with their values and goals (Baker et al., 2013). Patients often draw on their prior knowledge or use rule-of-thumb decision strategies when making a choice, rather than evaluate the trial details (Moynihan et al., 2012). These strategies tend to be influenced by contextual and emotional factors that encourage patients to make choices based on cues in the context such as the way the trial was communicated or their relationship with trial recruiters (McCann et al., 2013). Patients report trial consent information is sufficient to raise their awareness of the study and inform them of associated procedures, but not sufficient to help their reasoning about (non) participation (Gillies et al., 2014).

Consent processes may not fully support patients' decisions, in part, because their focus is solely on clinical trial participation. The details they include, and the way information is presented, provide facts key to understanding evidence-based care for an illness, ethically-based research about new and/or different procedures, and engagement with the study (Figure 1 – sections 1, 2, 3). What this approach does not address explicitly is that patients are actively making decisions about their health and/or management of illness in the context of their lives, when offered trial participation opportunities (Figure 1 – section 4). Little is known about how people perceive the clinical trial options in relation to standard care treatment options, how they reason about the trial and standard care options in relation to each other, and what helps or hinders their ability to make a reasoned decision about trial participation or not (Bell & Balneaves, 2015)

An informed or reasoned decision is one based on accurate information about all options and their consequences, people's evaluations of these options in accordance with their values, and a choice made based on trade-offs between these evaluations (Bekker et al., 1999) There is limited evidence on what aspects of information designed to enable informed consent support

patients in making informed decisions about participation, what aspects discourage patients from evaluating the trial facts, and what information is missing which is of relevance to patients' values towards their care and trial participation (Jacobson et al., 2013) This study investigates the role of trial information in enabling women managing cancer to make trial choices and their support needs when making trial and treatment decisions at the same time. This evidence is needed to inform the structure and content of patient information so that it can be designed to support patients' active thinking between healthcare options and trial participation (Cox, 2002a).

<<**Figure 1 about here**>>

## **Methods**

### **Design**

The study used a cross-sectional survey design with face-to-face semi-structured interviews eliciting women's reasoning about, and experiences of making, treatment and trial participation choices. All interviews were audio-recorded and transcribed verbatim.

### **Sampling and participant recruitment**

Potential participants were identified from those attending a medical oncology outpatient clinic at a large University hospital in the north of England, offering non-surgical oncology services and actively engaged in clinical trials. Majority of the trials offered to patients were phase III trials comparing new chemo/hormone therapy with standard treatment. Criteria for potential participants were females 18 years or older, with breast and/or ovarian cancer, who were invited to take part in at least one clinical trial since their cancer diagnosis, attending the clinic between June and December 2005. Those admitted to wards were excluded due to the difficulty of conducting interviews in the busy ward setting and the possibility of their accounts of decisions being influenced by their physical condition at the time.

A purposive sampling strategy with predetermined inclusion criteria was used to ensure a broad range of experiences and views about trial participation choices (Ritchie et al., 2003). Women representing different age groups, cancer stages, times since diagnosis, and trial participation choices were invited to take part in the study. In qualitative research, a-priori estimation of the sample size is not possible, nor advised, and final sample size is guided by findings from preliminary analyses taking place simultaneously with data collection, with data collection ending when interviews no longer give rise to new themes (data saturation). In this case, no new themes seemed to emerge from the data after about 18 interviews; further three interviews were conducted and analysed showing no new themes before concluding data saturation had been reached in relation to the study's objectives. Hence, data collection was ended after 21 interviews.

## **Materials**

The study information sheet, consent form and an interview topic guide were developed in accordance with National Research Ethics guidance (approval granted by Harrogate Local Research Ethics Committee on 19/05/2005). The questions in the topic guide were derived from the literature on decision making about treatment choices (Pierce, 1993; Reynolds & Nelson, 2007) and patients' experiences of trial participation (Cox, 2002b; Snowdon et al., 2006). Three key topics were addressed: experiences of being diagnosed with cancer and being offered trial and treatment choices; process of making decisions about trial participation; experiences of recruitment. Each question was followed by probe questions exploring in more detail their views, reactions, experiences, feelings, reasons and preferences. The interview schedule was piloted by reviewing the responses of the first four participants to assess whether the questions helped address the study's objectives (Figure 2).

<<Figure 2 about here>>

## **Procedure**

A list of women with breast, endometrial, and ovarian cancer who met the study's inclusion criteria was obtained from the clinical team using the clinic's patient records database. Women were identified using demographic information from patient records such as age, type and stage of cancer, date of diagnosis, trials offered and patient's choice about trial participation. Women were approached by the research nurses on the day of their visit to the outpatient clinic and were introduced to the researcher. The researcher briefed the women about the research, handed the study information to them along with a reply slip, and asked if they could be contacted by telephone in case they did not return the reply slip. It was emphasised that agreeing to the phone call did not mean they were agreeing to the study. Those who responded agreeing to participate were contacted to arrange a date, time and venue for the interview. Written informed consent was obtained on the day of the interview. Interviews were conducted by the first author (PA), a female doctoral candidate at the time of the study with training in psychological approaches to health. Interviews were conducted either in a quiet room at the clinic or at the woman's home and lasted an average of 35 to 45 minutes; a patient's partner was present in one of the interviews.

## **Analysis**

Data were analysed using thematic analysis (Ritchie & Spencer, 2002) which allows systematic classification and organisation of the data in terms of key themes and emergent patterns. An initial coding frame was developed based on data from three transcripts selected to ensure a fair representation of experiences and the areas covered in the topic guide. This coding frame was applied systematically by the first author (PA) to all the transcripts using the software package QSR NVivo v8, adding new themes/categories as they emerged from the data. Once all the text had been coded, the categories were refined by revisiting the text in each category. Themes relating to the same theoretical concept were identified and grouped together to form

a more comprehensive and higher-order theme. To ensure reliability and trustworthiness of the analytical process, each stage of the analysis were discussed with the supervisors (HB) and (GV), to ensure interpretation was informed by the clinical context and science explaining people's decision making. Data were categorised under ten themes resulting in a descriptive coding framework (Table 1) (Abhyankar, 2008) Data from the descriptive themes are synthesised under the following analytical themes, using quotes typical of the theme to illustrate the interpretation and synthesis:

- Influence of the cancer and cancer treatment context on decision making for trial participation
- Experiences of the consenting process and their influence on decision making

<<Table 1 about here>>

## **Results**

In total, 21/41 women informed of the study participated; their mean age was 57 years (range 29-81 years). Most were interviewed in the clinic (Table 2). Eighteen had made a trial participation decision in the past, and three were considering one at the time of study. Of those who had made a decision in the past: nine had been offered one trial, and eight agreed to take part in the trial offered; seven were invited to take part in two trials, and three took part in both and four took part in only one trial; two were invited to take part in three trials, and both declined to take part in at least one of them.

<<Table 2 about here>>

### **Influence of the cancer and cancer treatment context on decision making for trial participation**

Women's accounts suggested that all treatment options raised within the clinic were judged with reference to the goal of receiving care to abate cancer, and to live longer. This goal

seemed to influence the way in which the options were perceived and/or evaluated and women's experience of making the decision. There was a tendency to perceive the active pursuit of treatment as the only option available and there was 'no real choice' to make. Women tended to simplify the choices by dichotomising the options in terms of life versus death. Having some kind of treatment was judged to be obviously superior to 'doing nothing' in light of their goal of fighting cancer. Choosing not to have the offered treatment was rarely considered as a meaningful option or immediately dismissed as irrational.

*'Listen love...when you get to my age and you have a choice of living or dying, you pick to live. Believe me or not..!'* (SN3, ovarian)

*'The treatment? I've got to have the treatment I've got no choice. Well I have, but that would be silly.'* (SN13, ovarian)

This perception of 'no choice' is also reported by other authors studying treatment decision making, particularly among patients with cancer (Charles et al., 1998; Elit et al., 2003; Jansen et al., 2006) and has been attributed to patients' preference for a passive role in decision making, beliefs about the nature of cancer, and the need to maintain a positive attitude through reassurance of having done everything possible.

The perception of 'no choice' prevailed even when one of the options for cancer care was to take part in a clinical trial. The trial participation option was also evaluated against the goal of abating cancer with a tendency to perceive this as the only active option to be involved in making a decision about. Standard care was viewed as a more passive process to be engaged with as adhering to a practitioner-led pathway of care. When offered a clinical trial, the choice often exists between 'taking part in the trial' and 'receiving the standard treatment/s'. To make an informed decision about trial participation, patients must evaluate the pros and cons of having the standard treatment against those of taking part in the trial

where they receive either the standard treatment/s or a newer but less evaluated treatment. However, there was little evidence that participants discriminated between care delivered as part of a trial and, therefore, optional and care offered as part of usual treatment and standard procedure. Women's reports suggested that it was the 'treatment' within the trial that was evaluated more against their goal of cancer care than the other trial aspects such as random allocation to treatments, uncertainty of side effects etc. The 'trial' aspects were not seen as important to consider when making the decision. As the quote below reflects, it did not matter much whether or not the offered treatment was on trial; the decision would not have been any different if the treatment was not on trial.

*'Yeah, well I've got lots of information on it and I know it is a treatment for curing breast cancer, but they think because the two (breast and ovarian cancer) are linked, it could help people like me and erm, I just think that if it is something that you take maybe daily, erm and it will keep it at bay then you know, I think that would be a good thing' (SN14, Ovarian)*

*'No. No, it didn't matter to me whether it was a trial or not, maybe it should have mattered more, but it didn't... It [being offered a trial] didn't make much difference to me really. I would still have gone for it if it wouldn't have been a trial... If it wouldn't have been a trial, the chemotherapy, I don't think I would have made my decision any quicker than with it being a trial, that's all.' (SN17, breast)*

When a treatment or trial was seen as the only option meeting their goal of cancer treatment, the choices were often made quickly and intuitively, with minimal consideration of the trial information. There was little evidence women reasoned explicitly between the advantages and disadvantages of trial participation and standard cancer care options when deciding whether to participate in a trial, or not. Women described 'deciding there and then', 'having

already made their mind up', 'seeing trial as just a natural thing to do', 'going with their gut feelings' and 'putting it to fate'. The following quote reflects participant's quick decision making based on selective consideration of advantages of trial participation.

*'I was offered Herceptin (trial) at the same time as my chemotherapy so that they all started together [...] Well Dr P explained what Herceptin was, that it acts as similar to one of your own antibodies and stops the cancer cells latching on to your own cells and multiplying and growing, and he explained to me that the different people, you know different women who had these trials and you know, well basically they hadn't got a full set of results but you know, things were looking good and I just thought well I may as well try, if it doesn't help me it could help somebody else or something that they find out from me could help somebody else so, I just made the decision there and then, I never discussed it with anybody or, just decided. (SN15, Breast)'*

Others reported feelings of disquiet and conflict around making a decision to consent or not in research, especially when incongruity was sensed between the altruistic and personal goals. Carrying out research to find evidence of better treatments was valued. There was also an appreciation of others' research participation that had benefitted them, and an understanding of their participation benefitting others. Although women were aware of the uncertainty of achieving personal benefit through the trial, they were concerned about making the "right" or "correct" decision.

*'cos you do sometimes think you know you are helping other people by doing this, but then sometimes you think I don't want to help anybody else, I want to look after myself'. (SN16, breast)*

*'I mean you could only.....you can only make one decision at each time. And you can only review it in retrospect whether you think that was the right one, but you never can be quite sure, can you?' (SN2, breast)*

These findings resonate with the concept of 'conditional altruism' reported by McCann et al. (2010) which represents a decision that is motivated by consideration of the collective general good but is conditional upon the prospect of some personal benefit or lack of harm. Women's reports of how they deliberated about pros and cons clearly reflected this tension between seeking personal benefit versus wanting to help others (Locock & Smith, 2011a). However, their reasoning was informed more by their beliefs about the consequences of (not) taking part for them or future patients than a systematic weighing up of all information.

*'like I say my thought process generally is, is it going to do me any harm, no. Is it going to help other people, possibly. So you know that's about it really.'* (SN19, breast)

### **Experiences of the consenting process and their influence on decision making**

All women were invited to take part in trials when attending the service for diagnosis and/or treatment of cancer. There was variation in the way the trial was offered within the clinic appointment, sometimes it was delivered and/or mentioned in consultations when discussing diagnosis and treatments with women's practitioners, and sometimes it was presented on its own 'outside' the consultation by research staff.

*'When I was diagnosed with my lung secondaries, I was...I don't know what the alternative was,...any way... various chemos were run past me, like "we could do this or we could do the other.....and by the way, there is a trial on Taxol. Mm and that was broadly what I was told [...]' (SN2, breast)*

In this cancer outpatient service, women were at different points in their identification, adjustment and management of illness. Receiving new information about a diagnosis and/or options about cancer treatment left women to assimilate this information and their reactions to the details, while trying to participate effectively in care planning decisions. They felt baffled with the amount of information and found it difficult to concentrate during the consultation, picking up on only some bits of the information.

*'...to tell you the truth I don't know that day to this what the doctor, consultant I should call him, said to me because the only thing I picked up on was chemotherapy. "What you telling me?" and that was it. So...' (SN8, ovarian)*

Receiving an opportunity to take part in a trial at this point added to the complexity of this process, especially when the new treatments offered in the trial and standard treatments appeared similar, and impacted on how they reasoned about the different options. Women found it difficult to differentiate between treatments offered as standard and within the trial.

*'cos there didn't seem a great deal of difference in a lot of them it's just different drugs. That's another thing with a lot of these trials and things, you don't see a great deal of difference and they, it's just something they want to test with, whether it would be any better'. (SN16, breast)*

Given women's perceived difficulty in assimilating all the information and to make choices, it is not surprising that many made decisions after asking for another's opinion and/or using another's experiences of treatment. Using opinions from health professionals seemed to be a way of tapping into expertise the participant did not have themselves.

*'We talked about it, we went back the following week and agreed to do the trial. But I actually went to my own doctor and asked him what he thought. Because I've more faith in my family doctor' (SN6, breast)*

The experiences of other patients provided an additional viewpoint on particular treatment options, including the experience of side effects. As this participant explains, her decision to take part in the trial was influenced by her beliefs about the ill-effects of chemotherapy, which were informed by other people's experiences.

*'Well, as I say, you know, they were talking about chemotherapy and I said "No, I wouldn't, I'm not having chemotherapy". I was adamant that I wouldn't have it because of what I'd seen and how ill it made people [...] As far as I was concerned it (Herceptin trial) was the only option that I had because I didn't want chemotherapy.'* (SN9, Breast)

Most participants regarded the consent information as easy to understand and the trial well explained, yet lacking in detail about the trial treatment options and their consequences. Information about the options and their consequences was seen as necessary to make an informed decision. For instance, details about the dose of the drug, the nature and likelihood of experiencing side effects and personal relevance of the trial tended not to be described.

*'It is easy to sort of understand what they were trying to achieve but as I said it doesn't give you any information as to whether what they feel would be adequate for you, if it was on a banding system, whether it would actually be higher or lower than the toxins that you are getting now. That we don't know,'* (SN 20, breast).

Sometimes, it was felt that further details about the trial were only provided post consent. As one participant stated, she was told that the details about the trial will be explained if she decides to take part in the trial.

*'They just asked me and when I said no, they didn't bother anymore. Well they didn't tell me anything about the trial, what it would do. They just asked me if I would do it...I said no, I'd rather not [...] In fact I asked to ask the doctor ...so what does that entail, you see.'*

*So....well.. it's a trial that you go through, but if you decide to have it will be explained to you. And as I say I made the decision that I wouldn't have it' (SN 4, ovarian)*

Women knew the choice to participate in a trial was theirs to make. Staff explicitly reinforced this message, although some portrayed trial participation favourably. Some women felt persuaded by this possible framing, whilst others thought it was probably their perception that staff held a positive view rather than an explicit statement.

*"I also, in July last year, on my birthday, which was really bad timing, is mm...I was suddenly offered, not by the doctor, but by somebody else in the team, "wow we have got two new trials and this is the answer...this is the answer for your care"(SN2, breast)*

*'When they talk about one thing more than the other one. I can't think of any example I'm afraid. When they've got two lots of tablets and they are sort of saying something about it, I don't know. It's a state of mind I think at the time, I think could be misinterpreted when you are not feeling great,' (SN 16, breast)*

## **Discussion**

This qualitative study analysed women's decision making about trial participation when they were informed of trial participation being an option during their attendance at a cancer outpatient clinic. It adds to the qualitative evidence on the process and experiences of decision making about clinical trial participation (Bell & Balneaves, 2015; Cox, 2002b; Locock & Smith, 2011a; Locock & Smith, 2011b; Pierce, 1993; Reynolds & Nelson, 2007; Snowdon et al., 2006; Thomas & Menon, 2013), and provides novel insight into the complexities of making trial decisions in the context of active illness management. The findings indicate women made trial participation choices within the context of treating and managing their cancer, rather than the context of an opportunity to participate (or not).

Though aware of the research context and altruistic benefits, there was little evidence they made choices by thinking systematically about the advantages and disadvantages of both participation and non-participation in accordance with their values. While the consent information was perceived to be easy and sufficient to understand the trial, these details were not sufficient to support women's reasoning about trial participation in the context of their illness, and/or make informed trade-offs between the trial participation and standard cancer care treatment options. Within a service delivery context, presenting the trial in a way such that the choice between trial participation and standard care options is not made explicit may hinder women's reasoning by influencing their evaluation of the trial information and/or judgments (Abhyankar et al., 2014).

Until recently, patient participation in clinical trials has been conceptualised and studied either as a type of behaviour (Mills et al., 2006) or as an act or process of consent (Lidz et al., 2004), with a focus on increasing recruitment rates and/or improving consent information. The trial is usually presented as an 'opportunity' to participate or not and any written information provided to patients focuses mainly on the trial. This study conceptualises trial participation as a 'decision' in the wider context of disease management/treatment. The current findings highlight that when a trial is integrated within a patient's care pathway, patients are evaluating trial options at the same time as managing their illness and making treatment decisions. This suggests that trials need to be framed as an active decision between healthcare options, i.e. between standard care and trial participation. This conceptualisation as a deliberate decision between healthcare options helps place the decision in the context of patients' illness management and lifestyle. Our findings add to others' evidence for trial information to be framed in the context of patients'

illness management (Abhyankar et al., 2014; Brown et al., 2004; Entwistle, 2008; Gillies et al., 2014; Juraskova et al., 2008; Juraskova et al., 2014).

Trial participation represents a complex decision problem, with nested options and uncertain consequences. For instance, compared to standard treatment, the treatments offered in the trial may be novel or familiar, possess similar or different attributes, involve unknown and/or serious risks, and, in the end, may not be received by the patient on consenting to participate if they are allocated to the control group. While vital for the benefit of future patients, taking part in a trial may or may not be personally beneficial to the patient, but it should not be worse than standard care. Patients thus have to evaluate treatments offered within their standard care pathway and those in the trial, and make consent judgements about standard and study procedures. However, women in this study found it difficult to separate the trial decision from the treatment decision and evaluated the treatment, rather than trial, consequences. Despite meeting the ethical and legal requirements of informed consent, our data show that the consent information may not be sufficient to support explicit reasoning between trial participation and standard care options. The insufficiency of the consent information may be explained by the complexity of competing patient, professional and trial staff goals at play, when a trial is located in clinical practice. Staff delivering the trial are focussed on eliciting rigorous evidence while meeting the clinical and research governance best practice requirements and thus provide information explaining the trial, its benefits and risks. Patients are making informed decisions about their care, not just the trial, in the context of their lives and need explicit and balanced information on all available options and their consequences. Practitioners involved in patient care are focussed on delivering best possible, evidence-based and patient centred care across the management of illness, therefore must present appropriate options

and information to enable effective healthcare practice. Practitioners often find it challenging to balance their 'clinical' and 'recruiter' roles which inadvertently affects their recruitment practices (Brown et al., 2004; Donovan et al., 2014). The extent to which patients are enabled to make informed decisions between trial participation and standard care options depends on the goal with which the information is delivered. Consent documents, which are primarily designed to provide accurate and factual information about trial/research, are unlikely to enable deliberation and comparison of different options in light of personal values and illness behaviours (Brehaut et al., 2012b).

The context of trial information delivery such as how and when options and information are presented, by whom and with what purpose has a significant influence on patients' evaluation of information, decision making strategies and ultimately their decisions (McCann et al., 2013; Moynihan et al., 2012). From the science behind people's decision making, we know that context affects the extent to which patients are enabled to use cues from the context (use heuristic strategies) or be reasoned (use systematic strategies) in their decision making (Chaiken, 1980; Tversky & Kahneman, 1981). Our data show that women used mainly heuristic rather than systematic strategies to make decisions such as making intuitive judgements about options, referring to other people's choices, and outcomes, immediately accepting doctor's advice, dichotomising choices as life versus death, feeling that there was only one option and selectively focussing on options/attributes. It is likely that the consent information was impoverished (Gillies et al., 2014) as it does not present all alternatives explicitly and does not allow comparative evaluation of other options in relation to the trial. The impoverished nature of consent information may have encouraged women to use contextual cues to guide their decisions, such as: a) attributes of staff and/or timing of the offer may impact on patients' judgements about the trial and decision making

strategy (e.g. trial offered by a patient's treating doctor in the consultation may be evaluated differently to when offered by a research nurse before or after the consultation) (McCann et al., 2013) b) framing of the trial offer and information (e.g. depending on who is providing information, it may be framed positively or negatively, which then impacts on patients' evaluation of that information and choices)(Moynihan et al., 2012). Evidence suggests personal views of health professionals about clinical equipoise, need for trial, patient's eligibility etc. have a significant impact on trial recruitment and create systematic variations in the way patients are consented and how options are presented (Donovan et al., 2014) c) the trial participation option, and consent information, is presented as an opportunity or choice rather than a decision between options, which affects people's representation of the decision problem and judgements about the options (Abhyankar et al., 2014).

### **Strengths And Limitations**

The study's strengths include use of thorough and rigorous methods to collect, analyse and interpret data. The purposive sample meant experiences of women with different characteristics, cancer type, stage and treatment, and trial participation experience were captured. The study methods and results are informed by the understanding of purpose of informed consent and research governance, the evidence on how people make sense of illness and reason about treatment options, and the goal of delivering evidence-based and good quality information to support people's decision making. The study helps people think differently about the needs of the patients, health practitioners and research community to ensure clinical trials are more effectively integrated in the clinical context. Nevertheless, there are some limitations. First, our findings draw from experiences of women deciding about breast and ovarian cancer trials; it remains unclear if they are representative of people

making trial choices in other cancers and clinical contexts as well as in men. Future research would benefit from exploring differences by gender and clinical contexts. Second, all trials in this study were phase III comparisons of new vs standard chemo/hormone therapy. Decision making about participation in such trials may be different to decision making about trials comparing two or more standardly available treatments and/or surgical options. Third, women's experiences of decision making were elicited in semi-structured interviews with no observational data on how choices were presented and discussed with health professionals. Studies of patient-professional interactions about trial participation in real time would provide further evidence of the associations between trial presentation and patients' reasoning about participation.

### **Implications For Practice**

The findings have pragmatic implications for ensuring informed consent and/or informed choice as well as for supporting women to make informed decisions between trial and treatment options. To enable informed consent, efforts must be made to reduce framing and bias in the presentation of trial participation options in service delivery context (Abhyankar et al., 2013; Winterbottom et al., 2015). This could be achieved by 1) improving information in consent to help patients' active decision making between consequences of other treatment options and consequences of taking part in trial (Abhyankar et al., 2011). A decision aid (DA) developed by Juraskova et al. (2008; 2014) to assist women's decision making about participation in a cancer prevention trial has shown promising results in improving understanding, reducing decisional regret and enhancing decision quality over and above the usual consent information. The DA presents an explicit choice between the trial participation and standard care options, which is a more balanced and complete presentation than the choice between 'trial' and 'no trial' (Abhyankar et al., 2013;

Abhyankar et al., 2014) 2) collaborative working between care staff and trial staff to ensure trial is embedded appropriately in care pathway and 3) training to non-trial staff in how to provide information about the trial in the context of delivering care (Mills et al., 2014). To enable individuals to make informed decisions between trial participation and standard care treatment options, the clinical trial needs to be presented as a decision with all available options made explicit, detailed information provided on all their attributes and consequences, and patients' preferences elicited and addressed (Abhyankar et al., 2013; Abhyankar et al., 2014; Mills et al., 2014).

### **Conclusion**

This study reports on the experiences of using trial information and making decisions about trial participation among women with breast, endometrial or ovarian cancer. Findings highlight that information used in eliciting informed consent may not be sufficient for helping people make informed decisions between the trial and other available treatment options. Clinical trial information must be presented in a way that enables unbiased evaluation of all available options, not just the trial.

## References

- Abhyankar, P. (2008). Decision making about cancer treatment and clinical trial participation (Unpublished doctoral thesis). University of Leeds, UK.
- Abhyankar, P., Bekker, H. L., Summers, B. A., & Velikova, G. (2011). Why values elicitation techniques enable people to make informed decisions about cancer trial participation. *Health Expectations, 14*, 20-32.
- Abhyankar, P., Volk, R. J., Blumenthal-Barby, J., Bravo, P., Buchholz, A., Ozanne, E. et al. (2013). Balancing the presentation of information and options in patient decision aids: an updated review. *BMC Medical Informatics and Decision Making, 13*, S6.
- Abhyankar, P., Summers, B. A., Velikova, G., & Bekker, H. L. (2014). Framing Options as Choice or Opportunity: Does the Frame Influence Decisions? *Medical Decision Making, 34*, 567-582.
- Armstrong, N., von-Woods, M., Thomas, A., Rusk, G., & Tarrant, C. (2012). Do informed consent documents for cancer trials do what they should? A study of manifest and latent functions. *Sociology of Health & Illness, 34*, 1230-1245.
- Baker, J. N., Leek, A. C., Salas, H. S., Drotar, D., Noll, R., Rheingold, S. R. et al. (2013). Suggestions from adolescents, young adults, and parents for improving informed consent in phase 1 pediatric oncology trials. *Cancer, 119*, 4154-4161.
- Bekker, H. L., Thornton, J., Airey, C., Connelly, J., Hewison, J., Robinson, M. et al. (1999). Informed decision making: an annotated bibliography and systematic review. *Health Technology Assessment, 3*, 1-159.

Bell, J. & Balneaves, L. (2015). Cancer patient decision making related to clinical trial participation: an integrative review with implications for patients' relational autonomy. *Support Care Cancer, 23*, 1169-1196.

Bjorn, E., Rossel, P., & Holm, S. (1999). Can the written information to research subjects be improved?--an empirical study. *Journal of Medical Ethics, 25*, 263-267.

Brehaut, J. C., Carroll, K., Elwyn, G., Saginur, R., Kimmelman, J., Shojanian, K. et al. (2012a). Informed consent documents do not encourage good-quality decision making. *Journal of Clinical Epidemiology, 65*, 708-724.

Brehaut, J. C., Carroll, K., Elwyn, G., Saginur, R., Kimmelman, J., Shojanian, K. et al. (2012b). Informed consent documents do not encourage good-quality decision making. *Journal of Clinical Epidemiology, 65*, 708-724.

Brown, R. F., Butow, P. N., Butt, D. G., Moore, A. R., & Tattersall, M. H. N. (2004). Developing ethical strategies to assist oncologists in seeking informed consent to cancer clinical trials. *Social Science & Medicine, 58*, 379-390.

Chaiken, S. (1980). Heuristic versus systematic information processing and the use of source versus message cues in persuasion. *Journal of Personality and Social Psychology, 39*, 752-766.

Charles, C., Whelan, T., Gafni, A., Reyno, L., & Redko, C. (1998). Doing Nothing is No Choice: Lay Constructions of Treatment Decision-making Among Women with Early-stage Breast Cancer. *Sociology of Health & Illness, 20*, 71-95.

Cox, K. (2002a). Informed consent and decision-making: patients' experiences of the process of recruitment to phases I and II anti-cancer drug trials. *Patient Education and Counseling, 46*, 31-38.

Cox, K. (2002b). Informed consent and decision-making: patients' experiences of the process of recruitment to phases I and II anti-cancer drug trials. *Patient Education and Counseling, 46*, 31-38.

Dixon-Woods, M., Ashcroft, R. E., Jackson, C. J., Tobin, M. D., Kivits, J., Burton, P. R. et al. (2007). Beyond misunderstanding: Written information and decisions about taking part in a genetic epidemiology study. *Social Science & Medicine, 65*, 2212-2222.

Donovan, J. L., Paramasivan, S., de Salis, I., & Toerien, M. (2014). Clear obstacles and hidden challenges: understanding recruiter perspectives in six pragmatic randomised controlled trials. *Trials, 15*, 1-12.

Elit, L., Charles, C., Gold, I., Gafni, A., Farrell, S., Tedford, S. et al. (2003). Women's perceptions about treatment decision making for ovarian cancer. *Gynecologic Oncology, 88*, 89-95.

Entwistle, V. (2008). Supporting participation in clinical research: decision aids for trial recruitment? *Health Expectations, 11*, 205-207.

Flory, J. & Emanuel, E. (2004). Interventions to improve research participants' understanding in informed consent for research: A systematic review. *JAMA, 292*, 1593-1601.

Gillies, K., Huang, W. F., Skea, Z. F., Brehaut, J. F., & Cotton, S. (2014). Patient information leaflets (PILs) for UK randomised controlled trials: a feasibility study exploring

whether they contain information to support decision making about trial participation. *Trials*, 15, 62.

ICH GCP (1996). International Conference on Harmonisation, Guideline for Good Clinical Practice. Retrieved from [http://www.ich.org/fileadmin/Public\\_Web\\_Site/ICH\\_Products/Guidelines/Efficacy/E6/E6\\_R1\\_Guideline.pdf](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf) [On-line].

Jacobson, M., O'Connor, A., & Stacey, D. (2013). Decisional Needs Assessment in Populations. Retrieved from [www.ohri.ca/decisionaid](http://www.ohri.ca/decisionaid). [On-line].

Jansen, S. J. T., Otten, W., & Stiggelbout, A. M. (2006). Factors affecting patients' perceptions of choice regarding adjuvant chemotherapy for breast cancer. *Breast Cancer Research and Treatment*, 99, 35-45.

Juraskova, I., Butow, P., Bonner, C., Bell, M. L., Smith, A. B., Seccombe, M. et al. (2014). Improving decision making about clinical trial participation - a randomised controlled trial of a decision aid for women considering participation in the IBIS-II breast cancer prevention trial. *British Journal of Cancer*, 111, 1-7.

Juraskova, I., Butow, P., Lopez, A., Seccombe, M., Coates, A., Boyle, F. et al. (2008). Improving informed consent: pilot of a decision aid for women invited to participate in a breast cancer prevention trial (IBIS-II DCIS). *Health Expectations*, 11, 252-262.

Lidz, C. W., Appelbaum, P. S., Grisso, T., & Renaud, M. (2004). Therapeutic misconception and the appreciation of risks in clinical trials. *Social Science & Medicine*, 58, 1689-1697.

Locock, L. & Smith, L. (2011a). Personal benefit, or benefiting others? Deciding whether to take part in clinical trials. *Clinical Trials*, 8, 85-93.

Locock, L. & Smith, L. (2011b). Personal experiences of taking part in clinical trials ΓÇô A qualitative study. *Patient Education and Counseling*, 84, 303-309.

McCann, S., Campbell, M., & Entwistle, V. (2013). Recruitment to clinical trials: a meta-ethnographic synthesis of studies of reasons for participation. *Journal of Health Services Research & Policy*, 18, 233-241.

McCann, S. K., Campbell, M. K., & Entwistle, V. A. (2010). Reasons for participating in randomised controlled trials: conditional altruism and considerations for self. *Trials*, 11, 31.

Mills, E. J., Seely, D., Rachlis, B., Griffith, L., Wu, P., Wilson, K. et al. (2006). Barriers to participation in clinical trials of cancer: a meta-analysis and systematic review of patient-reported factors. *The Lancet Oncology*, 7, 141-148.

Mills, N., Blazeby, J. M., Hamdy, F. C., Neal, D. E., Campbell, B., Wilson, C. et al. (2014). Training recruiters to randomized trials to facilitate recruitment and informed consent by exploring patients' treatment preferences. *Trials*, 15, 1-13.

Moynihan, C., Lewis, R., Hall, E., Jones, E., Birtle, A., & Huddart, R. (2012). The Patient Deficit Model Overturned: a qualitative study of patients' perceptions of invitation to participate in a randomized controlled trial comparing selective bladder preservation against surgery in muscle invasive bladder cancer (SPARE, CRUK/07/011). *Trials*, 13, 1-13.

NHS Choices (2014). Consent to treatment. Retrieved from <http://www.nhs.uk/Conditions/Consent-to-treatment/Pages/Introduction.aspx> [On-line].

Pierce, P. F. (1993). Deciding on breast cancer treatment: a description of decision behavior. *Nursing research*, 42, 22-28.

Pope, J. E., Tingey, D. P., Arnold, J. M., Hong, P., Ouimet, J. M., & Krizova, A. (2003). Are subjects satisfied with the informed consent process? A survey of research participants. *The Journal of Rheumatology*, 30, 815-824.

Reynolds, W. W. & Nelson, R. M. (2007). Risk perception and decision processes underlying informed consent to research participation. *Social Science & Medicine*, 65, 2105-2115.

Ritchie, J., Lewis, J., & Elam, G. (2003). Designing and selecting samples. *Qualitative research practice: A guide for social science students and researchers*, 2, 111-145.

Ritchie, J. & Spencer, L. (2002). Qualitative data analysis for applied policy research. *The qualitative researcher's companion*, 305-329.

Snowdon, C., Elbourne, D., & Garcia, J. (2006). It was a snap decision: parental and professional perspectives on the speed of decisions about participation in perinatal randomised controlled trials. *Social Science & Medicine*, 62, 2279-2290.

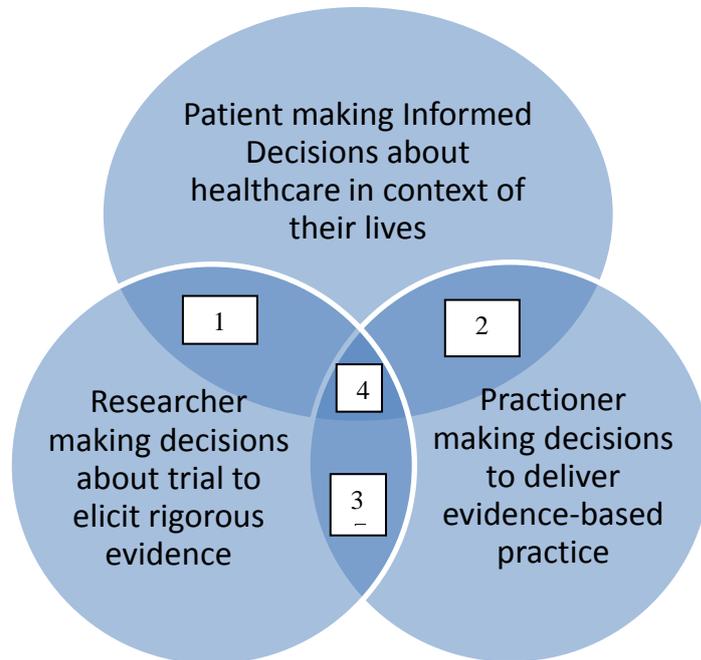
Synnot, A., Ryan, R., Prictor, M., Fetherstonhaugh, D., & Parker, B. (2014). Audio-visual presentation of information for informed consent for participation in clinical trials. *Cochrane.Database.of.Systematic.Reviews.*

Thomas, M. & Menon, K. (2013). Consenting to pediatric critical care research: understanding the perspective of parents. *Dynamics (Pembroke, Ont.)*, 24, 18-24.

Tversky, A. & Kahneman, D. (1981). The framing of decisions and the psychology of choice. *Science*, *211*, 453-458.

Winterbottom, A., Gavaruzzi, T., Mooney, A., Wilkie, M., Davies, S., Crane, D. et al. (2015). Patient acceptability of the Yorkshire Dialysis Decision Aid (YoDDA) Booklet: a prospective non-randomised comparison study. *Peritoneal Dialysis International*.

World Medical Association (2013). World medical association declaration of helsinki: Ethical principles for medical research involving human subjects. *JAMA*, *310*, 2191-2194.



**Figure 1**  
**Representation of informational needs by people involved in trial participation.**

- |  |
|--|
| <p>1= informed consent trial<br/> 2= informed choice treatment<br/> 3= clinical trial information<br/> 4= informed decision making between standard care and trial participation options</p> |
|--|

**1. How did you find out you had cancer?**

**Prompt questions:**

- What symptoms did you have?
- Who did you ask for advice (friends, family, internet)?
- What did you think, and feel, when you had the symptoms?
- What did you think, and feel, when you were diagnosed with cancer?
- What happened next?

**2. What treatments were you told about once you were diagnosed with cancer?**

**Prompt questions:**

- What kind of treatment choices were you told about?
- Were you asked to make the choice for yourself?
- Did the doctors or nurses help you to make the decision – how?
- How did you feel about being asked to be involved in making these decisions?
- What reasons did you have for choosing 'x'?
- What reasons did you have for not choosing 'y'?
- What has been your experience of the treatment you chose?

**3. Have you thought about having a different type of treatment from the one you are on?**

**4. Most of the patients at this hospital are asked to take part in clinical trials, can you tell me a little about the trials you were asked to take part in?**

**Prompt questions:**

- Who asked you to take part?
- Can you recall what the trial involved?
- How easy was it to understand the information given about the trial?
- How did you feel when you were told about the trial?
- Did you find it difficult to be faced with this decision - why?
- How did you come to reach a decision about whether or not to take part in the trial?
- Is there anything that would encourage / discourage you from taking part in a trial?

**5. What did you know about clinical trials before you were asked to take part in this trial?**

**Prompt.**

- Why do you think they are needed?
- Do you think there are other ways of finding out the same information?

**6. How involved do you feel you have been in making choices about your treatment options?**

**Prompt questions:**

- How much time was spent discussing the treatment options/ choice during your consultation?
- Do you feel the doctor wanted you to have one treatment option over another?
- Were your views different or the same as the doctor's?
- Did you feel having different views resulted in a better or worse discussion/ choice?
- Did you have a chance to talk about the different options with other people - who?
- What did other people say about the treatment options?

**7. In the future, do you think you will want to be more involved/ less involved or have the same level of involvement in making choices about your treatment?**

**Prompt.**

- Why?
- Make different choices?
- Different level of involvement for different conditions?

**Figure 2**  
**Topic guide for semi-structured interviews**

**Table 1**  
**Descriptive coding frame developed to classify women's utterances.**

<b>Theme</b>	<b>Sub-theme</b>
Diagnosis of cancer	Diagnosis, Affect surrounding diagnosis, Coping with cancer,
Reasons for treatment	Cancer beliefs, Treatment beliefs, Pros and cons, Trade- offs, Anticipation of regret
Treatment experience	Positive experience, Negative experience Managing treatment effects, Post decisional affect
Decision process	Self-reports of decision process, Seeking information, Use of heuristics, Treatment preferences, Decisional affect
Clinical trial participation	Timing of offer, Offering personnel, Recall of participation, Decision about trial, Time for decision, Prior trial knowledge, Quality of written information,
Trial beliefs, experience and reasons	Positive and negative beliefs about trial, Positive and negative experience of trial, Reasons for trial participation and non-participation
Experience of health service	Diagnostic and referral pathway, Routine treatment delivery, Trial treatment delivery, practitioner communication, Expectation from practitioner
Directiveness in practitioner communication	Perceived directiveness in practitioner communication, practitioner/medical reasons for treatments
Decisional role	Perceived decisional role, Desired decisional role Affect about perceived role, Trust
Perceived role of others	Perceived role of practitioner, Perceived role of family and friends

**Table 2**  
**Demographic and clinical characteristics of participants**

Age	Mean ( <i>SD</i> )	57 years (13.6)
Cancer type	Breast cancer	11
	Ovarian cancer	8
	Endometrial cancer	2
Cancer stage	Primary	15
	Secondary	9
Time since diagnosis	Mean ( <i>SD</i> )	4 years (5.6)
	Range	1 month to 20 years
Place of interview	Clinic	15
	Patients' home	6