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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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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: Of those eligible ($n = 41$), 21 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.

1. 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 and Emanuel, 2004; Synnot et al., 2014), patients' understanding of consent remains suboptimal, leaving unmet patient needs (Bell and Balneaves, 2015; Brehaut et al., 2012a; Gillies et al., 2014; Moynihan

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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 (Fig. 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 (Fig. 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 and 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).

2. Methods

2.1. 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.

2.2. 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. In the majority, 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

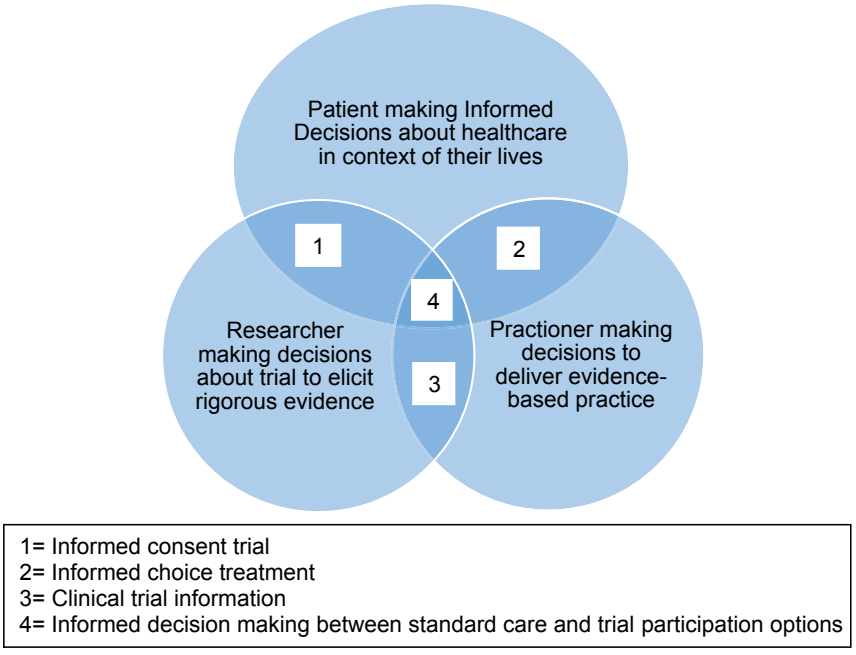

Fig. 1. Representation of informational needs by people involved in trial participation.