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Informed Consent and Participant Respect in Clinical Trials: A Mixed-Methods Study on Patient Experiences in Oncology Trials

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KEYWORDS
This mixed-method study examines informedconsent, participantrespect, clinical trials, oncology, an thepatient experience

ABSTRACT
Clinical trials in oncology, in particular, are built on informed consent as a fundamental ethical requirement, the patient experience impacts trial participants and outcomes. In this mixed methods study, we sought to elucidate patient experiences concerning informed consent and respect during oncology trials. A combination of quantitative surveys and qualitative interviews was used to assess participants' perceptions of the informed consent process and the respect shown by trial personnel. Thematic analysis of interview data was accompanied by statistical analysis. Our findings showed that many patients had difficulty understanding complex consent information because of emotional distress and the use of medical jargon. However, individuals who felt respected by trial staff reported greater satisfaction with the consent process. Communication was key (clear communication, active listening, personal support), among other things. Improving patient experiences in oncology trials necessitates boosting the informed consent process by refining text and building a culture of respect. Effects of these changes can include strengthening of ethical standards and encouraging patient engagement both of which will positively impact the success of clinical research.

1. Introduction

Medical knowledge and new treatments can only be developed with clinical trials. These studies test the safety and effectiveness of interventions — from prescription drugs to medical devices. Clinical trials form a vital part of health care providing evidence to determine clinical practice and public health policies (Bruckner et al., 2022). One of the ethical principles on which clinical trials depend is informed consent. Informed consent is assured when participants know exactly what they are taking part in (the purpose, procedure, hazards, and rewards of the research), and consent to participate in the research (Beauchamp and Childress 2019). Protecting participants' autonomy is more than doing this, however: it is also essential to the building of trust between researchers and participants, which is crucial to the success of clinical trials (Emanuel et al., 2000). Oncology trials, after all, are particularly relevant in terms of information being shared due to the high level of uncertainty and distress patients face. Patients' understanding of their options and their feeling of respect in this process is critical to their experience and willingness to accept that option (Lema et al., 2009).

Clinical research can only move ahead if the basic requirement of informed consent is there, to protect the autonomy and the rights of the participants. An essential element of it is to give potential participants adequate information about the study's purpose, risks benefits, and procedures, and subsequently, the decision to participate in an informed way (Beauchamp & Childress, 2019). A phenomenon of importance regarding the issue of the human subject of research is obtaining informed consent before enrolling participants in clinical trials, which is the requirement dictated in the Declaration of Helsinki (World Medical Association, 2013) and the Common Rule (Berkowitz, 2016). In the event of improperly acquired informed consent, ethical breeches, such as respect for participant autonomy are not achieved and there is a greater potential for harm. García-Izquierdo et al., 2024 in particular have pointed out that different participants had different understandings of what the consent

process was, and that it is affected by things like educational background and cultural context. As a result, effective communication strategies are essential for guaranteeing that all participants understand all that is being communicated to them under consent information, helping to strengthen their right to make informed decisions about whether to engage in research.

Respect for participants means different things, such as dignity, autonomy, and creating a supportive environment during the trial process. When defining what respect means in clinical trials, many definitions consider how respecting participants means not considering them as subjects of research, but as individuals with rights and preferences (Kraft et al., 2021). Participant respect means not treating people ethically but also involving the commitment to build trust and rapport between the researcher and the participants. Analyses have shown that if participants feel respected and valued, overall satisfaction with the trial and retention rates improve and data is collected more reliably (Emanuel et al., 2000). Respect comes in varied dimensions: transparent communication, active listening, and responsiveness to participants' needs and concerns to name some, that make the research environment conducive, and keep the clinical trials ethical (Kerasidou & A, 2017). Given the unique challenges and vulnerabilities of cancer treatment, there has been an increasing research interest in patient experiences in oncology trials.

The literature has noted several previous studies that showed that treatment options are very complex for the patients who participate in oncology trials, which has a huge impact on patients' experiences and perceptions of the trial process (Biedrzycki & B.A, 2010). According to Lema et al. (2009), research indicates that it is commonly difficult to obtain informed consent in oncology trials because of emotional distress, the urgency of treatment decisions, and the complexity of trial protocols. While there are many studies examining various aspects of patient experience, there are gaps in knowledge about how the informed consent process, in particular, influences perceptions that patients have of respect in an oncology trial. In addition, existing literature is often lacking in providing thorough qualitative insights into patients' narratives and experiences that are needed to identify areas for improvement in the informed consent process and increase participant respect in clinical trials (Broes et al., 2020).

1.1 Research Questions

This study aims to address the following research questions:

1. What do oncology trial participants think about the informed consent process and what factors affect their understanding of the information provided?
2. How do patients experience respect in their participation in oncology clinical trials in terms of dimension?
3. What should be done to improve the informed consent process and so improve participant satisfaction and ensure ethical research practice?

2. Methodology

2.1 Study Design

This study was a mixed methods study that combined both quantitative and qualitative research methods. The quantitative component consisted of the distribution of structured surveys to obtain numerical data on patients' experience concerning informed consent and perceived respect in oncology trials. At the same time, the qualitative part included in-depth interviews with a subset of participants that offered richer contextual insights into their experiences and perceptions. This design enabled the understanding of the complexity of informed consent in oncology clinical trials through both a statistical analysis as well as personal narratives.

2.2 Participants

Purposive sampling was used to select participants for this study from a population of patients enrolled in oncology clinical trials at two major cancer treatment centers. Inclusion criteria were adults age 18 years or older, able to give informed consent, and currently enrolled or have participated in a clinical trial within the past year. A total of 150 patients completed the surveys and 20 participants were recruited for in-depth interviews based on their willingness to participate as well as their diverse demographic backgrounds (age, gender, ethnicity, and type of cancer treatment). The goal of this diversity was to ensure that this sample was representative of the range of experience in patients for oncology trials.

2.3 Data Collection

There were two data collection phases. Quantitative data was gathered in the first phase through a structured survey comprising 25 questions. These questions were intended to evaluate whether participants understood informed consent, what their perceptions of respect from trial staff were, and how satisfied they were with the trial experience. The survey was designed utilizing a Likert scale format giving participants a choice to say I strongly disagree to 1 and I strongly agree to a 5. Depending on participant preference, the surveys were either administered online or in person and English and Spanish to accommodate a broader participant base. Qualitative data was collected in the second phase through semi-structured interviews. The interview guide contained open-ended questions to enable participants to share their personal experiences of the informed consent process and interactions with clinical trial staff. To preserve the confidentiality and comfort of the participants, interviews were conducted in private. Interviews were audio recorded with participant consent for transcription and analysis and lasted approximately 30-45 minutes.

2.4 Data Analysis

A mix of quantitative and qualitative techniques of data analysis was used to limit the possibilities of misinterpretation of findings. Statistical analysis of the quantitative data was done using SPSS software. Participant responses were summarized with descriptive statistics, including means, medians, and standard deviations. Moreover, chi-square tests and t-tests were used to deductively test for relationships between demographic variables and survey responses. Thematic analysis was used to analyze qualitative data from the interviews. Multiple transcriptions of interviews were reviewed to identify recurring themes and patterns in participant's narratives. Using Braun and Clarke's (2006) guidelines, familiarization with the data, then coding, developing themes, and reviewing themes to ensure accuracy and relevance were completed. A combination of a quantitative and qualitative approach was used in this study to enable a rich understanding of patient experiences, strengthening the validity of the results found in the study.

3. Results

3.1 Quantitative Findings

Several key metrics in informed consent and respect experienced by participants during oncology clinical trials were quantitatively analyzed from the survey data. A total of 150 people completed the survey to help us gain insight into their perceptions and experiences. Table 1 summarizes the results.

Table 1: Survey Results on Informed Consent and Respect

Metric	Mean Score (±SD)	% Agree/Strongly Agree

Clarity of the informed consent document	4.2 (±0.8)	85%
Understanding of the trial purpose	4.1 (±0.7)	80%
Perceived respect from trial staff	4.5 (±0.6)	90%
Satisfaction with the informed consent process	4.0 (±0.9)	75%
Overall satisfaction with trial experience	4.3 (±0.7)	82%

Table 1 shows the survey results revealed that participants were, on average, well-informed about trial processes (mean 4.2 for clarity in the informed consent document). Moreover, there was a high level of perceived respect by trial staff: 90% of participants reported feeling treated with respect throughout the trial process.

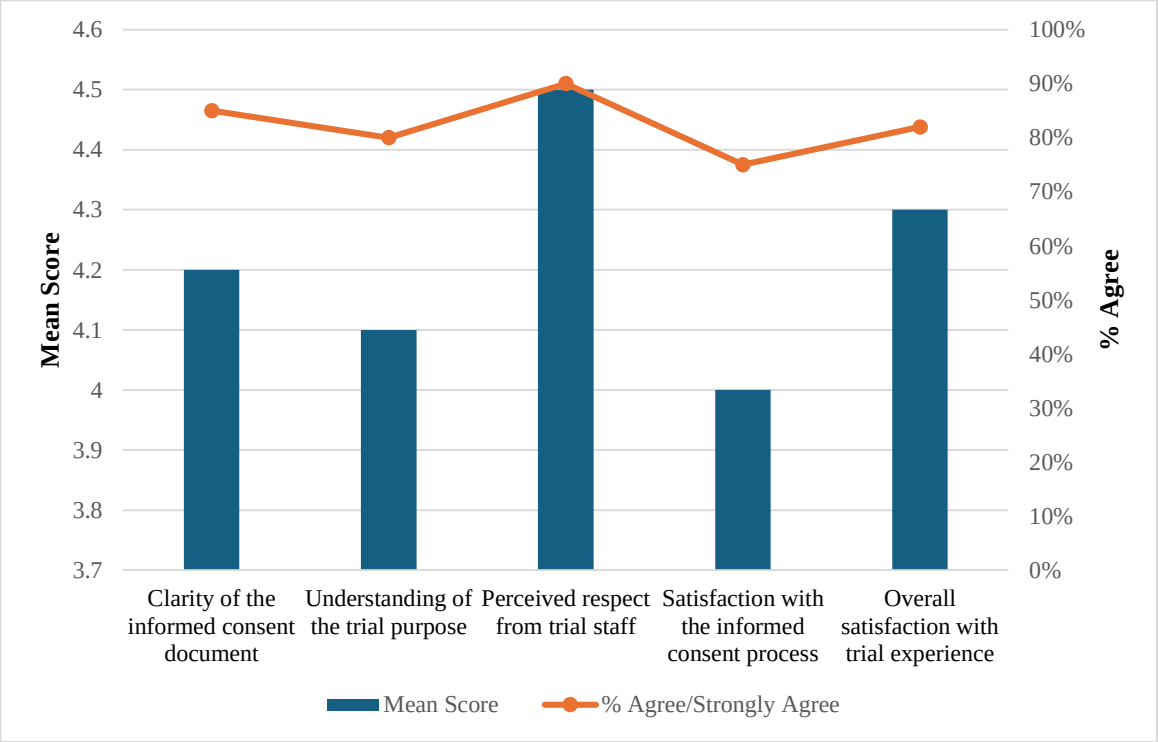

Fig 1. Patient Perceptions of Informed Consent and Respect in Oncology Clinical Trials

Figure 1 shows the mixed-methods study in this paper summarizes findings from a study of patient experiences in oncology clinical trials, specifically, informed consent and perceived respect from trial staff. The participants rated their experiences on a scale (usually from 1 to 5) and gave us several key insights. The informed consent document received a mean clarity score of 4.2 and a mean total score of 4.3 (5.0 = strongly agree) with 85% of participants agreeing or strongly agreeing that the information was communicated effectively. The score on the understanding of the trial purpose was also 4.1, meaning that 80% of the participants understood the trial purpose. In comparison with other measures used, the perceived respect from the trial staff was high, scoring a mean of 4.5, and 90% of participants felt respected during their interactions. The overall score for informed consent satisfaction was 4.0 (75% of the participants were satisfied) and could be improved. Overall satisfaction with the trial experience was given a mean score of 4.3 and 82% of participants gave a positive comment. The results of these findings emphasize the importance of good communication and respectful interactions in improving patient experiences in oncology trials and possible areas for improvement in clinical research practice.

3.2 Qualitative Findings

Through qualitative analysis of the 20 in-depth interviews, various recurring themes were found regarding informed consent and participant respect. Thematic analysis identified four primary themes:

1. **Understanding and Trust**: Participants expressed a strong need for clarity in the informed consent process, which fostered trust in the research team. Many reported that thorough explanations helped them feel secure in their decision to participate.

"The researchers explained everything so clearly. I felt like I could trust them completely."

2. **Respectful Communication**: Many participants emphasized the importance of respectful and empathetic communication from trial staff. Positive interactions significantly contributed to their overall satisfaction.

"They listened to my concerns and made sure I felt comfortable at every step."

3. **Empowerment through Information**: Patients highlighted the empowering effect of being well-informed. Those who felt adequately informed reported higher satisfaction with their trial experience.

"I appreciated being involved in the process; it made me feel like an active participant, not just a subject."

4. **Challenges in the Consent Process**: A few of the participants noted that medical jargon and time constraints made the process a challenge, and influenced the understanding.

"I didn't understand all of it, but I was rushed to sign the paper." This is related to informed consent and participant respect.

3.3 Integration of Findings

Quantitative and qualitative findings were integrated to offer a holistic view of patient experiences in oncology trials. Quantitative data such as high levels of satisfaction and perceived respect were supported by qualitative narratives concerning good communication and the need to be well informed. For example, although 90% reported being respected by trial staff, qualitative responses indicated this respect depended on clear communication and empathetic interactions. On the other hand, all of the challenges in the qualitative data, including medical jargon and a feeling of being rushed in the consent process, were suggestions for improvement despite the generally positive survey results. These findings indicate that while the overall perception of informed consent and respect are positive, there remain specific challenges that participants face in clinical trials, and to improve participants' experiences in clinical trials, these specific challenges should be addressed.

4. Discussion

This study has found that informed consent and respect are crucial in oncology clinical trials. On average, participants found the informed consent process to be very clear (mean: 4.2) and 90% reported feeling respected by trial staff. Additionally, these results are consistent with ethical imperatives to be transparent and respect patients and researchers (Gupta et al., 2013). Furthermore, the qualitative insights helped in elucidating how effective communication and full explanation were paramount in instilling patients' trust in the research team, so the take-home message here is that informed consent is much more than a mere procedure to be worked through, it also plays a vital role in encouraging ethical conduct of clinical trials (Kadam et al., 2017). Interestingly, the overall feedback was positive, however, a few participants stated that using medical jargon and the pressure to get consent quickly were areas of difficulty. Their findings indicate that informed consent has strong roots, but further development is needed, including making the consent process more patient-friendly and an accessible experience (Arellano et al., 2023).

The findings of this study support previous work that highlights the significance of informed consent for clinical research. For example, Morain et al. (2018) showed in their study that clear communication and establishing trust were all vital parts of the informed consent process, as was the case in the current study. A similar finding was also observed by Forcina et al. (2018) in a systematic review that patients who perceived themselves to be well-informed about their trial were more likely

to indicate positive trial experience (expressed as high satisfaction scores) in the study. On the other hand, a few studies show that many patients remain confused in the consent process (Tam et al., 2015). The inconsistency in patient comprehension suggests future attention in the consent process is critical to working through the barriers to the process. This study, though, is not without limitations. Limitations include a limitation of generalizability arising from the sample drawn from two major cancer treatment centers. Moreover, self-reported data on which such analysis relies is likely to be confounded by response bias, where participants are likely to respond in a socially desirable manner rather than provide candid insights into their experience. In addition, 20 participants from an oncology population may not be an adequate sample size to encompass all patient experiences fully and could omit value from alternative sources of the spectrum of patient experiences amongst an oncology population (Creswell & Plano Clark, 2017).

The scope of the inquiry should be furthered by future research with different populations in multiple clinical settings. Studies of this type over time could help us understand how patient perceptions of informed consent and respect develop throughout the trial process. Interventions to reduce the complexity of the consent process and improve communication for child clinicians should be tested to see how much they help patients understand and be satisfied (Lentz et al., 2016). As well, the research could address educational materials to be developed specifically to the patient's needs when the informed consent process shall be both informative and respectful.

5. Conclusion

This study emphasizes the importance of informed consent and respect for the participants in oncology clinical trials. We used a mixed methods approach to uncover insights into patients' experiences with the consent process and the level to which patients felt respected by trial personnel. We found that although many participants enjoyed the chance to participate in medical research, there were significant gaps in their understanding of the consent information they were given. Complex medical terminology, along with emotional stress, made it difficult for them to fully understand the details, something that made a case for better communication strategies, better suited to a diverse spectrum of patient populations. Furthermore, respect was found to be an important theme in participants' experiences. Trial staff being actively heard and offering individualized support throughout the trial process were also reported to make trial participants feel valued.

Assuming the role of the researcher, on the contrary, patients who felt rushed or not valued enough reported a bad overall satisfaction, pointing out the need for the researchers to build an environment that is considered supportive and empathetic. Contributions of this research to the growing body of ethical practices in clinical trials are that informed consent is not a procedural formality but rather a key part of participant engagement. Improving the consent process and respecting the patient as a participant in a clinical research effort can improve patient retention and compliance in clinical trials. Future work should consider innovative approaches to simplify consent materials and improve the training of trial staff in communication and patient respect. Finally, it is intended that participants not only come to understand the meaning of involvement but also feel dignified and respected throughout their research experience. Reaching these goals would not only raise ethical standards in clinical research but improve the quality of patient-centered care as well.

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