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Navigating Informed Consent: Practices and Perceptions in Clinical Trials in Ho Chi Minh City, Vietnam

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Abstract

The process of obtaining informed consent in clinical trials is intended to safeguard participants and support their autonomy. Nonetheless, implementing consent in a way that is truly meaningful remains a challenge in many settings, due to both practical difficulties and the influence of sociocultural dynamics. This study examined how informed consent is conducted and perceived in two clinical trials run by the Oxford University Clinical Research Unit in collaboration with the Hospital for Tropical Diseases in Ho Chi Minh City, Vietnam. A combination of qualitative approaches was used, including direct observation, interviews with physicians and participants, review of consent forms from 2009 to 2018, and engagement with patients' family members. Seven physicians and twenty-five trial participants were recruited, with five physicians and thirteen participants completing in-depth interviews. Twenty-two observation sessions were also conducted. The concept of "fragmented understanding" emerged to describe participants' varying comprehension of the consent process and to reveal the factors contributing to these differences. Findings highlight that both the conduct of consent and participants' interpretations are shaped by individual characteristics and the broader sociocultural context in which clinical trials occur.

Keywords: Informed consent, Clinical trials, Comprehension, Sociocultural context, Participant experience, Vietnam

Introduction

For decades, the process of obtaining informed consent in biomedical research involving human participants has been a central concern for both researchers and ethicists. While the core elements of valid consent—providing adequate information, ensuring participants' comprehension, and supporting voluntary decision-making—have been well established [1], ongoing debates continue regarding what constitutes truly valid consent [2, 3]. The delivery of information during the consent process and participants' understanding of that information are widely recognized as critical components [4–6]. A persistent challenge is that participants may not fully grasp certain aspects of a study when they agree to participate in clinical trials [7, 8]. Socioeconomic and demographic factors, such as older age, limited education, and lower socioeconomic status, can further

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complicate the informed consent process and act as barriers to comprehension [7, 9, 10].

Different interests among study sponsors, principal investigators, recruiting physicians, and participants can result in varying interpretations, motivations, and potential conflicts regarding informed consent [11–14]. In Vietnam, for example, the use of the term "nghiên cứu" (research) in consent documents, though legally required, may create confusion or anxiety among participants, as it is sometimes associated with being treated as "lab rats" or "guinea pigs," potentially affecting recruitment [13]. Research on participation in low- and middle-income countries (LMICs) has highlighted a range of motivations, including altruism, personal health benefits, access to care, financial incentives, acquisition of knowledge, social support, and trust [11]. In this context, the concept of "therapeutic misconception" has emerged, describing participants' misunderstanding of research as standard clinical care, particularly when trials are conducted in hospital settings [15–17]. Relatedly, "therapeutic optimism" suggests that participants may understand the research but still hope for the most favorable personal outcome from their involvement [18, 19].

Sociocultural and economic factors play a critical role in shaping perceptions and practices around informed consent [1, 20–22]. In LMIC settings, participants often learn about clinical trials through informal community discussions rather than formal consent sessions [23]. Trust in healthcare providers can lead participants to defer decision-making to research staff, influenced by their relationship with providers and the severity of their condition [24]. In Vietnam, trust has been shown to strongly influence attitudes toward data sharing and participation in research [13, 25]. More broadly, structural challenges such as poverty and limited access to healthcare have been identified as significant barriers to achieving valid consent in low-resource contexts [26, 27].

The informed consent process is thus complex, intertwined with an array of sociocultural, economic, and systemic factors. To better understand these dynamics, we conducted a qualitative study with physicians and trial participants in a hospital setting in Ho Chi Minh City. This paper presents insights from participants and physicians regarding their experiences and perceptions of the consent process, illustrating how fragmented understanding arises from individual characteristics, motivations, and systemic influences. Our findings highlight the need for context-sensitive approaches to implementing universal research ethics guidelines and underscore the importance of improving the quality of informed consent practices.

Study context

Vietnam, located in Southeast Asia, had a population of approximately 99 million in 2022 and is recognized as one of the region's fastest-growing economies. The country has significantly reduced its poverty rate to under 2% of the population. Since establishing social health insurance in 1992, which remains the primary mechanism for public healthcare financing, coverage has expanded to 90.85% of the population by 2020. Nonetheless, out-of-pocket healthcare expenses remain substantial [28]. According to a 2020 human development report, while literacy rates reach 95%, the average years of schooling across the population is only 8.3 years.

This study was conducted at the Oxford University Clinical Research Unit (OUCRU) in collaboration with the Hospital for Tropical Diseases (HTD) in Ho Chi Minh City. HTD serves as the largest referral center for infectious diseases in southern Vietnam. Since 1991, OUCRU and HTD have jointly led clinical and scientific research programs focused on infectious diseases in the region. All OUCRU studies adhere to both national and international ethical guidelines for biomedical research involving human participants.

The qualitative study was embedded within two randomized clinical trials run by OUCRU and HTD. The first trial was an outpatient study evaluating a shortened treatment regimen for a chronic liver condition (Clinical Trial Registry: 17IC4238) [29]. The second was an inpatient study assessing whether dexamethasone improves outcomes in patients with TB meningitis (Clinical Trial Registry: NCT03100786) [30]. Neither trial involved high-risk interventions, although some inpatient participants were severely ill. Participants received study-specific medications and examinations, and travel expenses were reimbursed.

Methods and analysis

Between March and July 2019, potential participants were recruited from the two clinical trials described above. The original recruitment plan aimed to use purposive sampling to enroll up to 40 participants from

diverse backgrounds to capture a wide range of experiences. However, slower-than-anticipated trial recruitment led to convenience sampling, resulting in a total of 25 participants. The study researcher (YHTN) approached potential participants in the trial waiting areas before their informed consent sessions, providing an explanation of the qualitative study and obtaining consent in a private area to protect confidentiality.

Data were also collected from study physicians to understand their experiences and perceptions regarding the informed consent process. Physicians provided informed consent before approaching potential trial participants, who were unaware of whether their physician had joined the study. Participants who declined were not included in the study.

Direct observations of the informed consent process were conducted, with the researcher maintaining sufficient distance to avoid interference. Observations were documented using handwritten notes and a structured observation guide capturing details such as duration, physical setting, atmosphere, discussion content, and interactions between physicians and participants.

The study did not include formal assessments of participants' understanding. Instead, semi-structured interviews were used to explore perceptions and experiences related to consent, comprehension of trial information, and motivations for participation or refusal. Interviews were conducted with 13 patients and 5 physicians, consistent with qualitative literature recommendations for data saturation [31]. Audio recordings were taken when consented to, and notes were used otherwise. Interviews occurred in private settings, with recordings transferred to a secure server within one to two hours. Transcription and analysis were conducted in Vietnamese.

A total of 22 consent sessions were directly observed. Of the 13 patient interviews, 11 were from the outpatient trial, conducted two to four weeks after the consent session during the participants' second or third study visit. Two interviews were conducted with inpatient trial participants after recovery, typically two to three weeks post-consent **(Figure 1)**.

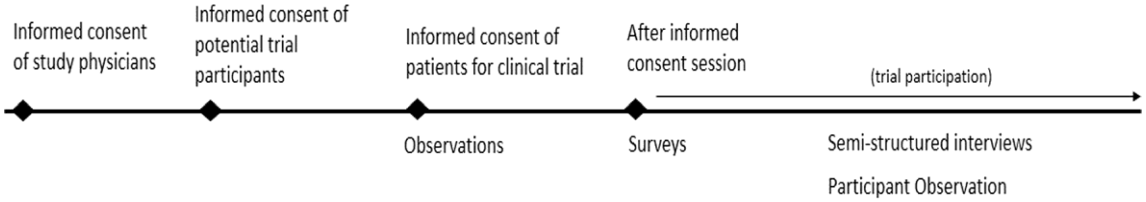

Figure 1. Data collection flowchart

Participant observation and document analysis

Observations were conducted in hospital areas where patients' family members and representatives waited, focusing on the layout, interpersonal interactions, and informal conversations about clinical trials and the informed consent process.

Additionally, we examined 26 informed consent forms and associated guidelines used at OUCRU between 2009 and 2018. This review captured the evolution of form content, length, and language over a decade. A coding framework was developed drawing from Karbwang *et al.* [32], which outlines essential informed consent elements under the Declaration of Helsinki, ICH Good Clinical Practice (GCP), and US federal regulations. Because OUCRU's consent forms combined international and national standards—including ICH GCP [33], Vietnam Ministry of Health guidance [34], and Oxford University Research Ethics Committee rules [35]—the coding template was tailored to reflect these adaptations.

Data from observations, interviews, and field notes were imported into NVivo 12 for thematic analysis. Separate codebooks were used for different participant groups and data sources. Coding included both deductive approaches based on the study guides and inductive coding derived from the data itself. Following initial coding, smaller codes were consolidated into broader categories, relationships among codes were explored, and interpretive processes were applied to identify key themes.

Study participants

The study recruited seven physicians involved in informed consent procedures: two from the outpatient trial and five from the inpatient trial. One physician did not participate due to scheduling conflicts. A total of 25

patients were included, consisting of 22 from the outpatient trial and three from the inpatient trial. Among these, one patient declined enrollment after the consent session, and two were deemed ineligible for the trial; nevertheless, their consent sessions were observed and included in the analysis.

Participant ages ranged from 24 to 67 years, with a median age of 50. Educational levels were generally low: eight participants (36.4%) had no more than five years of schooling, seven (31.8%) had up to nine years, five (22.7%) had completed high school, and two (9.1%) had higher education. Only five participants were from Ho Chi Minh City; the remaining participants came from other southern and central provinces in Vietnam **(Tables 1 and 2)**.

Table 1. Demographic of study participants—trial participants and potential participants

Trial participants and potential participants	n (%)
Gender	
Male	9 (36)
Female	16 (64)
Age	
Up to 30	3 (12)
31–50	8 (32)
51–60	7 (28)
Above 60	7 (28)
Educational level	
No schooling	0/22 (0)
Grade 1—5	8/22 (36.4)
Grade 6—9	7/22 (31.8)
Grade 10—12	5/22 (22.7)
University or above	2/22 (9.1)
Location	
Ho Chi Minh City	5 (20)
Other provinces	20 (80)

Table 2. Demographic of study participants—study physicians

Study physicians	n (%)
Gender	
Male	3 (42.9)
Female	4 (57.1)
Age	
Up to 30	2 (28.6)
31–45	5 (71.4)
Years of experiences in research	
Under 1 year	1 (14.3)
1–5 years	5 (71.4)
6–10 years	0 (0)
Above 10 years	1 (14.3)
Ward category	
Out-patient ward	2 (28.6)
In-patient ward	5 (71.4)

Results

This section presents our findings on participants' understanding of the informed consent process, introducing the concept of "fragmented understanding." We then examine the factors contributing to this variability, including participant characteristics, the motivations of both participants and physicians, and broader contextual influences.

Fragmented understanding

We define "fragmented understanding" as the uneven and selective comprehension participants had of clinical trial information. Although all participants were aware that they were enrolled in a research study, their grasp of the trial's objectives, procedures, risks, and benefits varied considerably. Interviews were conducted several weeks after the consent sessions, which made precise recollection challenging. Participants often could not distinguish between routine consultations and those dedicated to the consent process.

Despite these limitations, participants demonstrated understanding of specific aspects of the trials, particularly those emphasized by physicians or frequently discussed during the sessions. For example, one physician repeatedly clarified study procedures and potential side effects to ensure the participant understood their responsibilities before enrolling.

In the outpatient trial, participants often focused on instructions related to adherence to study procedures:

"The physician told me I had to follow the treatment schedule carefully. If I could not comply, someone else should have the chance to join. I considered it seriously and decided to participate." (Participant 11)

This example shows that participants' comprehension of trial requirements was influenced by what physicians highlighted as essential. Across both trials, participants tended to remember study benefits most clearly, even when other details were vague. Knowledge of benefits and minor risks increased participants' confidence in continuing their participation:

"I felt fine, except for some mild sleep problems. I didn't experience vomiting or dizziness, so I felt okay to continue in the study." (Participant 07)

Among inpatient participants, some struggled to recall details accurately or misremembered possible side effects, despite these being covered during the consent discussion:

"I think one of the two medicines could cause diabetes. I am not sure if I remember correctly." (Participant 15)

Conversely, aspects such as study procedures and overall trial goals were the most difficult for participants to recall. Many outpatient participants insisted they understood the consent information at the time, but they were unable to remember it later:

"The physician explained everything carefully, but now I don't remember much. I only understood it at the moment." (Participant 10)

Inpatient participants showed similar challenges. When asked about randomized assignment or the use of placebos, many appeared confused or unsure, highlighting gaps in understanding core trial elements.

"I think the physician mentioned that, but I don't remember the details." (Participant 22) "I've never heard of randomization or double-blind procedures." (Participant 15)

Limited understanding of these trial components was also acknowledged by the physicians conducting the consent sessions.

"I don't believe patients fully grasp what we're doing with the study procedures. For example, they may want to know when we started the study drug, but the overall concept seems unclear to them." (Study physician 05)

Misunderstandings about the nature of research were also common among participants. Many perceived participation as receiving guaranteed treatment or a cure. In the outpatient trial, despite repeated explanations from physicians about the research purpose, some participants believed they were receiving specialized care and expected to be cured, expressing gratitude for being selected.

"The physician examined me thoroughly to treat my condition. I'm very happy to be in this study—I hope it will cure me." (Participant 12)

This participant also misunderstood aspects of confidentiality, assuming that it was her personal responsibility to maintain privacy rather than a shared responsibility with the research team. She asked whether she could discuss the study with friends or relatives, a confusion echoed by other participants.

"If someone asks about my participation, should I tell them? Can I share this with friends or family? Does the physician expect me to keep it secret?" (Participant 12)

We use the term "fragmented understanding" to describe this mixture of partial understanding, selective attention to certain aspects, and misinterpretations. While participants often retained information deemed important by themselves or emphasized by the researchers, other fundamental details of the study remained unclear or misunderstood.

Factors contributing to fragmented understanding

Fragmented understanding arises from a complex interplay of individual characteristics, participant and physician motivations, and structural or systemic factors within the clinical trial environment.

Participant characteristics

Participants' age, literacy level, and health status at the time of consent significantly influenced their comprehension and recall of study information. Older participants frequently reported difficulties remembering details.

"I don't recall the study information. I'm older now and tend to forget things." (Participant 10)

Physicians noted that older participants often needed information repeated and presented in multiple ways, which could slow the consent process.

"Explaining study details to older patients usually takes extra effort. I often repeat the information or use different ways to explain. Sometimes I invite a family member to attend. They can interpret or rephrase the information in a way the patient understands better than we can." (Study physician 05)

Involving family members helped address challenges linked to low literacy or advanced age, and the emotional impact of receiving a serious diagnosis also affected participants' ability to process information accurately.

"They weren't in the right mental state to grasp everything I explained." (Study physician 03)

For some participants, comprehension was challenging not just due to age or literacy, but because the study information itself was complex. In several cases, participants decided to join the trials despite not fully understanding certain details.

"Even if you explained more, I probably wouldn't understand it. I only know the medicines can help cure me. I can't grasp it at your level because this is your expertise, not mine." (Participant 06)

Some participants admitted that the information was overwhelming, making it difficult to focus during the

consent session, even when researchers tried to simplify it. Both participants and physicians highlighted that factors like age, education, and current health condition significantly influenced participants' ability to absorb and interpret study details.

Motivations of participants and study physicians

The differing motivations of both physicians and participants during the consent process also played a role in fragmented understanding. Some physicians prioritized recruitment over comprehension. One physician from the in-patient trial viewed a successful consent session as one where patients agreed to participate, even if they did not fully grasp the study.

"My consent process went as I intended because patients agreed to join the study. Their level of understanding didn't necessarily align with what is formally defined as informed consent." (Study physician 03)

Focusing on enrollment sometimes led physicians to unintentionally neglect ensuring that participants truly understood the study. Fragmented understanding was further influenced by participants' own motivations. Many hoped for access to treatment they could not otherwise afford, trusted the hospital and healthcare providers, or wished to help future patients.

For instance, several out-patient trial participants had lived with chronic liver disease for many years and lacked resources for effective treatment. Completing the standard treatment could cost 10–30 times the average monthly income, not including travel or testing expenses. Clinical trial participation offered a potential cure without financial burden, making the trial appear as the only viable option.

"I thought I would receive treatment and get cured without paying. I couldn't afford the usual treatment, so I just hoped for a cure." (Participant 06)

In the in-patient trial, participants similarly reported hope for recovery as their primary motivation. Despite physicians explaining the research nature, the desire for a cure often overshadowed doubts or concerns.

"I was worried about joining, but the virus was already in me. I decided to try the trial. Maybe the medicine will work and I will be cured. I thought about it a lot, but I joined anyway." (Participant 17)

While many participants considered understanding the study important, others prioritized access to treatment above all else.

"How well I understood the trial didn't affect my decision. I told my wife: 'I'll accept whatever they do.'" (Participant 06)

Trust in the healthcare providers and the hospital also influenced participation decisions.

"I signed because I trusted the physicians. I told my husband, they've always been right, so we shouldn't doubt them." (Participant 22)

This deep trust sometimes meant participants consented with minimal attention to study details, creating a dual challenge for physicians. On one hand, patients' reliance on physicians made ensuring comprehension difficult; on the other, building trust was recognized as essential for improving the quality of informed consent.

"You need to earn patients' trust first. Then you can clearly explain the study and answer their questions so they understand." (Study physician 07)

In addition to trust in individual physicians, participants frequently cited confidence in the hospital and its partnership with an international institution as a motivating factor for joining the trials. Several participants mentioned that the foreign collaboration enhanced the perceived reliability of the study.

"I felt more confident about receiving quality medicine. Knowing that this study involved an American university gave me extra reassurance." (Participant 15)

Although this participant misunderstood the exact origin of OUCRU, the association with a high-income country provided additional comfort, especially given concerns about the quality of medicines available locally.

Participants also highlighted altruistic motivations, expressing empathy for others and the desire to contribute to the broader community.

"I hope I get cured, and that others do too. This study might help treat more people because I've seen so many patients struggling." (Participant 11)

Beyond individual factors

Fragmented understanding was also influenced by systemic factors extending beyond individual characteristics. Key contributors included complex consent forms, the perception of consent as a legal safeguard, and cultural norms surrounding hierarchical physician–patient relationships.

Both physicians and participants criticized the informed consent forms as overly long and difficult for those with limited literacy. Review of OUCRU consent documents from 2009 to 2018 revealed information sheets

containing over twenty-five items. These forms were drafted in English by the research team and translated into Vietnamese for participant use, without direct involvement from the physicians conducting consent sessions. Translating complex English terminology into simple, clear Vietnamese proved particularly challenging. A literal translation often created confusion, making some concepts, such as "confidentiality" (bảo mật), difficult to understand and resulting in misunderstandings about who was responsible for maintaining participants' privacy.

The complexity of the forms was further compounded by the perception of informed consent as primarily a legal tool. Many physicians described their approach as ensuring the forms contained every possible detail to protect both parties. In a context where most participants had not completed elementary education, expecting full comprehension of these extensive forms was unrealistic.

Cultural norms around hierarchical relationships between physicians and patients also contributed to fragmented understanding. Some participants were reluctant to admit gaps in their comprehension, while others hesitated to ask questions out of fear of inconveniencing the physician. Consequently, participants often signed consent forms to secure access to treatment without fully understanding the study details. Many relied on reviewing the consent documents themselves over time to gradually make sense of the information, even though verbal explanations were available.

"Over time, I started to understand more. For parts I didn't get at first, I read the text slowly, word by word. Eventually I understood it, but later I didn't remember everything." (Participant 10)

Overall, the combination of complex language, legal framing of consent, and cultural deference to physicians limited participants' ability to fully access and understand key study information.

Our findings indicate that the challenges in informed consent practices and participants' fragmented understanding arise from a combination of individual, sociocultural, and systemic factors.

Participant characteristics such as older age, limited literacy, and poor health at the time of consent posed considerable obstacles to comprehending study information. Similar observations have been reported by Nguyen and colleagues, who found that participants with lower education levels often struggled to understand core study elements, including randomization, placebo use, and their right to withdraw, and frequently could not identify even a single study risk [7]. In our study, participants generally grasped some aspects of the research but not all, with risks and side effects being the most salient and memorable components. Although we did not formally assess understanding at the moment of consent, due to the interviews occurring weeks later, difficulties in recalling information highlight the importance of ongoing communication. While recall and understanding are distinct, ensuring that key information is revisited throughout the trial is critical. Repeating essential details at each visit and providing participants opportunities to reconsider their participation could enhance the quality of consent. Further research on assessing understanding during and after the consent process would be valuable in this context.

There is broad consensus that valid informed consent requires participants to acquire general knowledge about the purpose of research, procedures, responsibilities, the option to withdraw, and potential risks [38–40]. The information disclosed should also be tailored to local context and focus on participants' priorities and interests [21, 22, 38].

Cultural context plays a pivotal role in shaping informed consent practices. Research has highlighted differences in conceptualizing autonomy between Western and East Asian settings, with Western bioethics emphasizing individual self-determination, while East Asian approaches highlight family involvement and harmonious interdependence [45]. In many Asian and African contexts, family members are integral to shared decision-making, making their involvement in consent processes culturally appropriate [42]. Our findings align with this perspective: including family members in the consent process enhanced participants' understanding and was logistically feasible.

Trust emerged as a key factor influencing decision-making. Participants often joined studies because they trusted the physicians, the hospital, and the collaboration with foreign institutions, sometimes making decisions without fully understanding study details. This finding resonates with prior research in Vietnam, which indicated that high levels of trust often guided participation decisions rather than comprehension of information [13, 25]. Other studies in different settings similarly identify trust as central to research participation [11, 46, 47], and highlight that reliance on trusted healthcare providers can render participants vulnerable [48, 49]. In our context, participants' trust reflected both their hope for appropriate medical care and their reliance on healthcare

workers to safeguard their well-being, even when understanding of the research was incomplete.

Access to healthcare was also a major motivation for participation. A review of 94 studies in LMICs identified improved access as the top reason participants joined research [11]. In Vietnam, although social health insurance aims to improve healthcare access, informal workers face multiple barriers, including limited quality of primary care, bureaucratic procedures, and uneven support from social security [28, 50]. Consequently, participation in clinical trials may become the most viable option for receiving treatment. While this does not inherently compromise voluntariness, it can influence participants' ability to make fully autonomous choices [1].

The hierarchical relationship between patients and physicians, rooted in traditional social structures, further complicates meaningful communication during consent. Vietnamese patients often avoid asking questions or requesting clarifications [51], which can lead to limited understanding and decisions that reflect social norms rather than informed choice. In some low-resource settings, participants have been reported to decide on trial participation before receiving study information, reflecting broader structural inequalities rather than deficiencies in the consent process itself [23]. Standard practice guidelines emphasizing disclosure may overlook the quality of decision-making, reducing consent to a legal formality rather than a process of understanding [38, 52].

In our context, while established procedures were in place to protect participants, a standardized approach did not fully accommodate local circumstances. Prior to this study, few investigations had examined informed consent practices at OUCRU and HTD [13], and no large-scale interventions had been implemented to improve understanding. Physicians often devised context-specific strategies, such as involving family members, but systemic support for enhancing informed consent remained limited. Improving consent quality requires coordinated effort from the entire research team and institutional commitment, rather than relying solely on individual physicians.

Recommendations

Based on our findings that participants faced challenges in reading and comprehending information sheets and informed consent forms, we conducted an engagement project to redesign these documents. The revised forms incorporated larger font sizes and illustrative graphics, and were tested with the community advisory board. Board members reported that the changes improved readability and enhanced their understanding of the study materials.

Beyond document design, multiple strategies have been proposed in the literature to strengthen informed consent and decision-making. For instance, Schenker and colleagues [54] found that additional written materials, audiovisual tools, extended discussions, and interactive feedback techniques improved participants' comprehension, particularly regarding study procedures and risks. Similarly, using informed consent forms tailored to participants' self-reported information needs and developed with input from expert groups has been shown to enhance understanding [53, 55]. Moulton *et al.* [56] proposed shared decision-making approaches that emphasize transparency about stakeholders' competing interests and alignment of participants' goals with research participation decisions. Public engagement and open discussions about clinical research have also been suggested as effective ways to improve consent quality [57].

We recommend further studies at OUCRU to identify context-specific and effective strategies to engage participants, enhance communication, and improve comprehension of clinical trial participation.

Limitations

This study had several limitations. First, recruiting participants was occasionally confusing because potential participants were approached before the trial's own consent process. Many had little prior knowledge of clinical trials, making the concept of informed consent abstract. Some individuals interested in joining the study were excluded because they did not fully understand the purpose after explanation.

Second, we were unable to recruit the intended number of participants from the in-patient trial, as many hospitalized patients were too unwell to participate. This limited our insight into the experiences of more severely ill participants.

Third, although informed consent is ideally an ongoing process, our study only observed the initial consent session. As a result, we could not capture the information provided in subsequent interactions during the trials. Additionally, participants' limited recall of the consent

process constrained our analysis of their understanding. Nonetheless, our primary aim was not to formally assess comprehension but to explore perceptions and practices of the consent process using qualitative methods. This approach allowed us to gain in-depth insights into how information was understood, misunderstood, and acted upon despite fragmented understanding.

Conclusion

This study examined the experiences and perceptions of study physicians and trial participants regarding the informed consent process in clinical trials, highlighting how individual and sociocultural factors shape consent practices and fragmented understanding. Participant characteristics, motivations of both participants and physicians, and structural factors-including complex consent documents, barriers to healthcare access, and hierarchical patient–physician relationships-contributed to varied levels of understanding.

Efforts to improve consent practices should extend beyond providing resources to research teams. Structural factors affecting participants' ability to understand research must be addressed, including enhancing healthcare quality, strengthening social health insurance, and reducing inequalities in healthcare access. Addressing these broader determinants can support more meaningful informed consent and foster participant autonomy within the clinical research context.

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