MEDICAL SCIENCES

OPEN ACCESS

INFORMED CONSENT: CHALLENGES AND PERSPECTIVES OF PATIENTS AND HEALTHCARE PROVIDERS IN GEORGIA

Nino GONGLADZE[1], Nato PITSKHELAURI[1]

[1] Ivane Javakhishvili Tbilisi State University, Tbilisi, Georgia

Corresponding author: Nino Gongladze, e-mail: gongladzeen@gmail.com

https://doi.org/10.38045/ohrm.2026.2.04 CZU: 614.253.83(479.22)

ABSTRACT

Introduction The informed consent process is crucial in ensuring patient autonomy and ethical medical practice. The study aimed to assess understanding, experiences, and perceptions of informed consent among hospital personnel and the general population in Georgia, and to identify key challenges in its implementation.

Materials and methods Two structured questionnaires were developed, one targeting healthcare professionals and the other the general population. The surveys explored respondents' knowledge, experiences, and opinions on informed consent. Data were analyzed to identify key topics and areas for improvement in the process.

Results Among the general population, 68.8% reported receiving the informed consent form before medical services, while only 50.2% were informed of their right to accept or decline it. Nearly half (48.3%) reported misunderstandings of information provided by doctors. For hospital personnel, while there was unanimous agreement on the necessity of obtaining informed consent before procedures, only 59.3% demonstrated full understanding of required consent content, and only 10.2% correctly identified who else can sign the consent form. Notably, only 6.8% comprehended the nuances of verbal consent.

Conclusions Significant gaps persist in the informed consent process in Georgia, including communication barriers, time constraints, and inconsistent understanding among patients and providers. Enhanced training, clear communication strategies, standardized practices, and the integration of technology are recommended to improve the informed consent process.

Keywords Informed consent, patient autonomy, healthcare professionals, patient comprehension, doctor-patient communication, Georgia.

CONSIMȚĂMÂNTUL INFORMAT: PROVOCĂRI ȘI PERSPECTIVE ALE PACIENȚILOR ȘI FURNIZORILOR DE ASISTENȚĂ MEDICALĂ DIN GEORGIA

Introducere Consimțământul informat este esențial pentru asigurarea autonomiei pacientului și a unei practici medicale etice. Acest studiu investighează perspectivele și experiențele personalului spitalicesc și ale populației generale din Georgia, cu privire la procesul de consimțământ informat.

Materiale și metode Au fost aplicate două chestionare structurate, unul destinat personalului medical și altul – populației generale. Studiul a explorat cunoștințele, experiențele și opiniile respondenților despre consimțământul informat. Datele au fost analizate pentru a identifica subiectele-cheie și domeniile care necesită ameliorări în acest proces.

Rezultate 68,8% din populația generală, au raportat că li s-a oferit formularul de consimțământ informat înainte de a primi servicii medicale, și doar 50,2% au fost informați despre dreptul lor de a accepta sau de a refuza acest consimțământ. Aproape jumătate (48,3%) s-au confruntat cu neclarități. În cazul personalului spitalicesc, deși toți au fost de acord cu necesitatea obținerii consimțământului informat înainte de proceduri, doar 59,3% au înțeles complet informațiile necesare ce trebuie incluse în formularul de consimțământ, și doar 10,2% dintre respondenți au identificat corect un alt semnatar al formularului. Este de remarcat că, doar 6,8% au înțeles specificul consimțământului verbal.

Concluzii Studiul evidențiază lacune și provocări semnificative ale consimțământului informat din Georgia, inclusiv bariere de comunicare, constrângeri de timp și niveluri variabile de înțelegere atât în rândul pacienților, cât și al furnizorilor. Se recomandă îmbunătățirea formării, implementarea unor strategii clare de comunicare, standardizarea practicilor, campanii de informare publică și integrarea tehnologiei, pentru a optimiza procesul de consimțământ informat.

Cuvinte-cheie Consimțământ informat, autonomia pacientului, profesioniști din domeniul sănătății, înțelegerea pacientului, comunicarea medic–pacient, Georgia.

INTRODUCTION

Informed consent (IC) is a foundational principle in medical ethics and a cornerstone of patient autonomy. It ensures that patients are provided with sufficient information regarding the risks, benefits, and alternatives of medical procedures, enabling them to make informed decisions about their treatment. The concept of IC is rooted in the Nuremberg Code (1947), which emphasized the importance of voluntary participation in medical treatments and research (1). Since then, the concept has evolved beyond a procedural obligation into a complex ethical, legal and communicative process embedded within modern clinical practice.

From an ethical perspective, informed consent is grounded in the core principles of biomedical ethics – respect for autonomy, but also beneficence and non-maleficence. It serves as the ethical basis that legitimizes medical intervention by ensuring that patients are not treated merely as passive recipients of care but as active decision-makers. In contemporary healthcare, informed consent is not only a legal requirement, but a moral obligation that reflects respect for persons and supports ethically responsible clinical practice (2).

Research on informed consent for medical treatment has developed alongside the broader concept of patient decision-making across three interrelated fields: medicine, law and the social sciences (3). Ethical analyses have further emphasized informed consent as part of a structured model of moral reasoning in medicine, highlighting the patient's right not only to receive information, but also to refuse or withdraw from treatment (2). Within this framework, informed consent is closely linked to respect for autonomy and the promotion of shared decision-making between physicians and patients.

Patient participation in medical decision-making has been shown to influence satisfaction, trust and treatment adherence. Trust in healthcare providers plays a key role in facilitating patient involvement and meaningful engagement in informed consent process (4). However, studies have shown that, despite its critical importance, the process of obtaining informed consent remains inadequate in many healthcare settings. Communication failures, limited time for discussion and insufficient adaptation of information to patients' needs have been identified as significant barriers to obtaining valid informed consent, rather than merely obstacles to building therapeutic relationships (5).

In countries with diverse ethnic and linguistic populations, including Georgia, these challenges may be further exacerbated by social and systemic inequalities. Research has shown that ethnic minorities and socially vulnerable groups are disproportionately affected by barriers to healthcare communication and require adapted policies to ensure equitable access to information and services (6). Such factors may directly influence patients' understanding of informed consent and their ability to engage in informed decision-making.

The legal framework surrounding informed consent also is significant in shaping its practice. Landmark cases like Canterbury v. Spence (1972) have established the reasonable patient standard, which dictates that physicians should disclose information that a reasonable patient would need to make an informed decision (7). Despite these legal standards, studies indicate substantial variation in how informed consent is implemented across healthcare institutions. Research has demonstrated that different formats of consent documentation can influence patient anxiety, satisfaction and understanding (8), while other studies reveal persistent gaps in physicians' legal knowledge regarding patients' rights to informed consent (9).

Importantly, informed consent is a basic concept of autonomy-based medical practice and a key mechanism for facilitating shared decision-making between

physicians and patients. The ethical validity of medical practice therefore depends significantly on patients' ability to comprehend the information presented to them. However, empirical research consistently demonstrates that patients' understanding of the basic components of informed consent is often limited, raising concerns about whether consent obtained in routine clinical settings is truly informed (10).

Despite the central ethical and legal role of IC, there is limited empirical evidence from Georgia on how it is understood and implemented in everyday clinical practice by both patients and healthcare providers. Most existing studies examine only single groups or specific settings. This study addresses that gap by jointly assessing hospital personnel and the general population, providing novel comparative evidence and identifying practical targets for improving informed consent processes.

The aim of this study was to assess the knowledge, understanding, experiences and perceptions of informed consent among hospital personnel and the general population in Tbilisi, Georgia, and to evaluate how informed consent is practiced in relation to patient autonomy and decision-making.

MATERIALS AND METHODS

This study utilized a cross-sectional survey design to assess the understanding and experiences of informed consent among two groups: the general population of Tbilisi and hospital personnel practicing within the same region. Separate structured questionnaires were developed for each group to capture perspectives and insights relevant to each. The questionnaires were disseminated online through Google Forms, allowing for a broad reach and promoting participant anonymity.

The study population comprised individuals aged 18 and older who had previously accessed healthcare services in Tbilisi and could provide informed consent to participate in the survey. The second group targeted licensed hospital personnel working in clinical settings within Tbilisi.

To establish a statistically representative sample size, a sample size calculation was conducted based on Tbilisi's population, estimated at approximately 3.5 million. A confidence level of 95% and a margin of error of 5% were applied, resulting in a target of 385 respondents for the general population sample. This calculation was performed using a standard sample size formula for population-based surveys. For hospital personnel, a non-probability convenience sampling approach was applied. Participants were recruited voluntarily through professional networks and online dissemination, and the sample size was determined based on feasibility and response availability rather than formal population-based calculation. A total of 59 hospital personnel completed the questionnaire, exceeding the initially targeted minimum of 50 respondents. Given the exploratory nature of this component, the hospital personnel sample was intended to provide insight into professional perspectives rather than statistical representativeness of all healthcare workers in Tbilisi.

Data collection occurred over a 1.5-month period. The questionnaire links were distributed through social media networks, leveraging online platforms to maximize the participation rate and accessibility for diverse population segments. Of the responses collected, three were excluded due to insufficient completion, resulting in a total sample of 450 responses: 391 from the general

population and 59 from hospital personnel. To maintain confidentiality, no personally identifiable information or signatures were collected from respondents.

The general population questionnaire contained 27 items, which included socio-demographic characteristics (such as age, gender and education), general awareness, and understanding of informed consent, and experienced-based questions for individuals, who had visited hospitals in Tbilisi since 2020. Several questions specifically assessed how respondents understood informed consent, including whether it was perceived primarily as a formal legal requirement or as part of a shared decision-making process with healthcare providers.

The hospital personnel questionnaire comprised 20 items, focusing initially on general informed consent knowledge, with additional items presented only to respondents who reported direct involvement in obtaining informed consent from patients. These items explored practical aspects of consent delivery, perceived challenges and understanding of legal and ethical requirements.

Both questionnaires included multiple-choice, yes/no, and open-ended questions, as well as Likert scale items (ranging from 1 to 5, with 5 representing complete agreement or understanding, and 1 indicating strong disagreement or lack of understanding). Likert scale questions were specifically designed to assess respondents' understating of informed consent, clarity of information provided and perceived involvement in decision-making. Each questionnaire was written in clear, accessible language to facilitate accurate comprehension.

Data were analyzed using IBM SPSS Statistics version 27. Descriptive statistics, including frequencies, percentages, means, and standard deviations, were calculated to summarize participant demographics and response patterns. Inferential statistical tests, including chi-square and one-sample t-tests, were applied to examine associations between respondents' socio-demographic characteristics (gender, age, education) and their knowledge, perceptions and experiences related to informed consent. A p-value of <0.05 was considered statistically significant. Responses to open-ended questions were categorized based on thematic relevance to enable qualitative insights.

RESULTS

The study investigated respondents' experiences, understanding, and perceptions of the informed consent process, with a focus on both patients and medical providers in Tbilisi.

Questionnaire for Tbilisi population

The study included a diverse sample of individuals from Tbilisi, Georgia, ranging across different demographic categories. Table 1 summarizes the demographic characteristics of the participants, highlighting key aspects such as age distribution, gender representation, educational backgrounds, employment status, and their affiliation with the medical field where applicable.

Table 1. Social and demographic characteristics of the population.

Categories and Indicators	n	%
Age		
18-30	256	65.5
31-40	91	23.3
41-50	19	4.8
51-60	13	3.3
61 and more	12	3.1
Gender		
Female	287	73.4
Male	104	26.6
Education Level		
University complete	106	27.1
University Incomplete	248	63.4
Basic Education Complete	34	8.7
Basic Education Incomplete	3	0.8
Employment Status		
Employed	287	73.3
Unemployed	23	5.9
Student	62	15.9
Housewife	9	2.3
Pensioner/Retired	10	2.6
Connection to Field of Medicine		
Yes	183	46.8
No	208	53.2

Respondents' perceptions and experiences regarding informed consent are summarized in Table 2.

Table 2. Respondents' perceptions and experiences regarding informed consent.

Statement	Respondents (%)
Identified risks associated with the procedure as essential information	78.3
Identified possible complications as essential information	73.9
Identified information about the recovery process as essential	52.4
Believed patients should thoroughly read all sections of the IC form before signing	85.4
Agreed that doctors should actively ensure patient understanding before signing	90.8
Reported misunderstanding information provided by a doctor at least once	47.6
Were aware of their right to receive detailed information (risks, benefits, alternatives) before signing	80.3
Felt that public education on the informed consent process is necessary	96.7

Most participants identified risks (78.3%) and possible complications (73.9%) as critical elements of informed consent, while fewer emphasized information on recovery (52.4%). A large majority believed that patients should read all sections of the consent form before signing (85.4%) and that physicians should actively ensure patient understanding prior to consent (90.8%). Nearly half of respondents (47.6%) reported having misunderstood information provided by a doctor at least once.

Respondents perceived understanding and experiences related to the informed consent process, as measured by Likert-scale items, are presented in Table 3.

Table 3. Mean Likert-scale scores for perceived understanding and experiences of the informed consent.

Item assessed	Mean	p-value
Ability to ask questions during the consent process	3.78	<0.001
Explanation of unfamiliar medical terms	3.18	0.072
Explanation of benefits and risks	3.5	<0.001
Information provided on alternative treatment options	3.18	0.095
Explanation of possible complications	3.52	<0.001
Information provided on rehabilitation or recovery	3.89	<0.001
Sufficiency of time given to read the consent form	3.29	0.006
Clarity and understandability of the consent form	3.6	<0.001
Satisfaction with information received before signing	3.72	<0.001

Note: Likert-scale responses ranged from 1 (strong disagreement/lack of understanding) to 5 (complete agreement/full understanding). One-sample t-tests were conducted using the neutral midpoint value of 3 as the reference. Statistically significant results ($p < 0.05$) indicate mean scores differing significantly from the neutral midpoint.

Overall, respondents reported a moderate to high perceived understanding of the informed consent process (Table 3). Mean scores for most items exceeded the neutral midpoint, particularly for the ability to ask questions, explanation of risks and complications, clarity of the consent form, and satisfaction with the information received. Lower mean scores were observed for the explanation of alternative treatment options and unfamiliar medical terms, indicating potential gaps in patient involvement and comprehension.

Associations between selected socio-demographic characteristics and familiarity with informed consent are presented in Table 4.

Table 4. Association between selected socio-demographic characteristics and familiarity with informed consent.

Variable	χ^2	df	p-value	Interpretation
Age × familiarity with informed consent	3.896	4	0.420	Not statistically significant
Education level × familiarity with informed consent	7.691	3	0.034	Statistically significant
Gender × familiarity with informed consent	6.686	1	0.010	Statistically significant

Inferential analysis demonstrated a statistically significant association between education level and familiarity with informed consent, as well as between gender and familiarity. No significant association was observed for age. Respondents with higher educational attainment reported greater familiarity with informed consent concepts.

More than half of the respondents (53.2%) had received medical services at hospitals in Tbilisi since 2020, and 68.8% reported being shown and asked to sign a consent form before receiving care. About half (50.2%) were informed that they had the option to accept or decline the consent form, whereas the other half were not.

Qualitative analysis of open-ended responses identified recurring themes, including insufficient explanation by healthcare providers, limited opportunity to ask questions, and the perception that informed consent is primarily a formal document to be signed rather than a collaborative decision-making process. These qualitative findings were consistent with quantitative results.

Questionnaire for Hospital Personnel

The study included hospital personnel representing different professional tasks. Table 5 presents the social and demographic characteristics of the respondents.

Table 5. Social and demographic characteristics of hospital personnel.

Categories and Indicators	n	%
Age		
18-30	24	40.7
31-40	28	47.5
41-50	6	10.1
51-60	0	0.0
61 and more	1	1.7
Gender		
Female	45	76.3
Male	14	23.7
Position		
Doctor	38	64.4
Nurse	8	13.6
Clinic management/administration	13	22.0

Perceptions and practices related to the informed consent process among hospital personnel are summarized in Table 6.

Table 6. Perceptions and practices regarding informed consent.

Statement	Respondents (%)
Importance of detailed information before consent	
Consider detailed information essential	83.1
Believe informed consent enhances patient trust	76.3
Understanding of informed consent content	
Demonstrated comprehensive understanding of essential consent elements	59.3
Information considered essential in informed consent forms	
Risks associated with the procedure	89.8
Possible complications	81.4
Benefits of the procedure	79.7
Rehabilitation or recovery process	71.2
Expected outcomes or results	67.8
Alternatives to the proposed procedure	61.0
Who can sign informed consent (besides the patient)	
Legal representative or guardian	84.7
Family member	59.9
Only the patient	15.3
Person designated by the patient	6.8
Situations where verbal consent is considered acceptable	
Emergency situations	54.2
Routine follow-up visits	37.3
Procedures with minimal risk	23.7
When a legal representative is present	15.3
Strategies used to improve patient understanding	
Simplifying language	80.6
Repeating information	58.3
Seeking help from multilingual staff	47.2
Providing translated written materials	30.6
Training	
No formal training in informed consent	69.4

The majority of respondents, regardless of professional position, considered the provision of detailed information to patients prior to obtaining informed consent to be essential. Although no statistically significant association was observed between professional role and the perceived importance of detailed information (χ^2=2.655, df=4, p=0.617), high levels of agreement were reported across all groups. Perceptions regarding the need for improvement in the informed consent process varied slightly by role, with a higher proportion of nurses and physicians indicating that improvements were needed compared to clinic management.

Hospital personnel were also asked about who, in addition to the patient, may legally sign an informed consent form. Most respondents identified a legal representative or guardian as an acceptable alternative, while family members were also frequently considered appropriate signatories. Only a minority believed that informed consent should be signed exclusively by the patient unless the patient is unable to do so.

Although there was unanimous agreement on the necessity of obtaining informed consent prior to medical procedures, only a proportion of respondents demonstrated a comprehensive understanding of the essential elements that should be included in a consent form. The most frequently identified components included risks associated with the procedure, possible complications, benefits, expected outcomes, alternatives to the proposed procedure, and details regarding rehabilitation or recovery. Differences between professional groups in opinions regarding verbal consent and consent content were examined using chi-square analysis; no statistically significant associations were identified (χ^2=12.47, df=6, p=0.052), although the result approached statistical significance and some variability across professional roles was observed (Table 6).

Despite the perceived importance of informed consent, a majority of hospital personnel (69.4%) reported having received no formal training on the informed consent process, indicating a potential gap in professional preparation and standardization of practice.

Communication challenges were commonly addressed through adaptive strategies. Nearly half of respondents reported seeking assistance from multilingual staff when language barriers arose, while others provided translated written materials. Additional approaches included simplifying medical language, repeating information using different wording or examples, and using visual aids to support patient understanding.

Some respondents reported situations in which family members requested that certain medical information be withheld from patients. Nevertheless, most providers indicated that information should not be concealed, emphasizing respect for patient autonomy even when faced with family pressure.

The results suggest that while patients generally feel satisfied with the information and time provided during the consent process, a notable proportion have experienced misunderstandings, indicating areas for improvement in patient education. Hospital personnel, particularly doctors, view detailed information as essential but may require additional training to enhance their role in ensuring patient comprehension. Both patients and providers agree on the need for more public education on the informed consent process, reflecting a shared recognition of its significance in patient care and autonomy.

DISCUSSION

The survey results reveal several critical insights into patient and provider perspectives on the informed consent process, highlighting both strengths and areas for potential improvement in medical settings.

The demographic composition of respondents, largely young, female, and well-educated, likely influenced responses regarding informed consent. The online survey format may have impacted older adults' participation, as some may be less familiar or comfortable with digital platforms, potentially affecting the representativeness of the sample.

A majority (85.4%) emphasized the importance of thoroughly reading informed consent forms, aligning with ethical principles of patient autonomy. Participants valued information about procedure risks, complications, and rehabilitation, but only 39.4% rated information on alternative options as essential, suggesting that this aspect is sometimes overlooked. Lower mean scores on Likert-scale items related to alternative options and shared decision-making further support this finding, indicating that informed consent is often perceived more as an informational or administrative requirement than as a collaborative process. Educating patients on alternatives supports shared decision-making and further empowers patient autonomy.

Results also shed light on experiences with informed consent during hospital visits. While 68.8% reported seeing a consent form prior to medical services, some respondents indicated that they may not have fully understood its purpose. Qualitative responses reinforced this observation, revealing that informed consent was frequently interpreted as a formality requiring a signature rather than an interactive discussion. Confusion surrounding the document's significance may stem from unclear communication by providers, stress associated with hospital visits, or assumptions that patients are familiar with the consent process. Addressing this issue could involve reinforcing the importance of informed consent through clearer explanations of the form's content and purpose, as mandated by Georgian law (14).

Notably, only 50.2% of respondents felt adequately informed of their right to accept or decline the consent form, suggesting a possible lack of explicit communication regarding patient rights. This gap may be influenced by the complexity of medical language, time pressures in clinical settings, or provider assumptions about patient knowledge. Research indicates that factors such as education level, medical background significantly affect patients' comprehension of informed consent, highlighting the need for tailored communication strategies (10, 15). Ensuring that all patients fully understand their options, regardless of background, may help mitigate this issue.

The medical providers' responses also reveal their perspectives on the informed consent process and its application. All providers agreed on the importance of obtaining informed consent before procedures, reflecting a commitment to ethical standards in patient care. Moreover, 83.1% emphasized that patients should receive comprehensive information about procedures before consenting, showing dedication to both legal compliance and patient-centered care.

The low rate of provider understanding (6.8%) regarding when verbal consent is appropriate suggests a potential gap in comprehension and application of verbal consent policies (16). Enhanced training on verbal consent guidelines could promote a more consistent approach and reinforce best practices in obtaining informed consent.

These findings align with international research, which has also identified gaps in healthcare providers' knowledge and application of informed consent. Surprisingly, studies from institutions in Western countries such as Europe, the Netherlands, Croatia, report that many doctors lack adequate understanding of the informed consent process, affecting the quality of patient-provider communication (17, 18). Research further suggests that inadequate working knowledge and attitudes toward informed consent persist among medical professionals, reinforcing the need for targeted education and standardized training protocols (19). Strengthening educational programs and institutional guidelines on informed consent could bridge these gaps and enhance ethical, patient-centered care worldwide (20).

Language and cultural barriers also emerged as significant challenges. Providers often addressed language differences by seeking assistance from bilingual staff (47.2%) and providing translated materials (30.6%), reflecting efforts to enhance communication. However, Georgia's linguistically diverse population may still encounter challenges in understanding informed consent, especially among patients from varying linguistic backgrounds. This may contribute to disparities in patient comprehension, particularly in complex or high-stress settings. Studies have shown that miscommunication due to language barriers can lead to inadequate informed consent, potentially resulting in legal and ethical issues (21, 22). To mitigate these challenges, healthcare providers should utilize professional interpreters and culturally appropriate materials to ensure patients fully understand the information being conveyed (23).

Responses to open-ended questions further highlighted barriers to informed consent, such as time constraints, language difficulties, and cultural tendencies to limit information shared with patients. Addressing these challenges could involve standardized training, resources for patient education, and the use of simplified language or visual aids to facilitate understanding.

The important contribution of this study is the parallel assessment of both hospital personnel and the general population within the same healthcare context. Most previous research has examined informed consent either from the patient perspective or the provider perspective separately. By combining these viewpoints, the present study makes it possible to identify mismatches between perceived practice, knowledge gaps and communication barriers across both sides of the consent process. In addition, locally generated evidence from Georgia remains limited in this field, and these findings provide context-specific data, that can support targeted educational and institutional improvements.

In conclusion, the findings from this study underscore the importance of effective communication, patient education, and respect for patient autonomy in the informed consent process. While most respondents expressed positive perceptions and experiences, there remain clear opportunities for improvement. The results indicate that informed consent in practice is still frequently experienced as a formal requirement rather than a shared decision-making process. By implementing enhanced communication strategies, providing comprehensive information, and addressing knowledge disparities, healthcare providers can strengthen the informed consent process and support patient-centered, ethical care practices.

CONCLUSIONS

1. This study on informed consent in healthcare, based on surveys of the general population and medical providers in Tbilisi, Georgia, provides new comparative evidence on perceptions, practices, and challenges by examining both patient and provider perspectives within the same study framework. The findings confirm that informed consent is widely recognized as an essential ethical and legal requirement, underscoring its role in protecting patient autonomy, fostering transparent communication, and promoting ethical standards in healthcare decision-making.
2. From the patient perspective, most respondents showed a basic understanding of informed consent; however, a significant portion had limited familiarity with its specifics, emphasizing the need for broader public education initiatives. Enhancing patient awareness of their rights and responsibilities in healthcare is essential to supporting informed decision-making and patient empowerment.
3. Hospital personnel demonstrated a shared commitment to informed consent, underscoring the importance of detailed information provision. However, variation in knowledge regarding the essential elements of informed consent and appropriate consent procedures, as well as challenges such as communication gaps, time constraints, and language barriers were highlighted as areas for improvement. These findings suggest that standardized institutional protocols and targeted professional training could help address inconsistencies and improve communication strategies across diverse healthcare settings.
4. The study emphasizes the dynamic nature of the informed consent process, shaped by evolving healthcare practices, cultural norms, and legal requirements. By addressing identified challenges and leveraging best practices, healthcare institutions can strengthen patient trust and satisfaction, leading to improved patient outcomes and alignment with ethical principles.

CONFLICT OF INTEREST There is no conflict of interest to declare.

ACKNOWLEDGMENTS Sincere thanks to all the participants who took part in this study.

ETHICAL APPROVAL The study received ethical approval from the NCDC regional ethics committee. Informed consent was obtained via the questionnaire's introduction, highlighting confidentiality and voluntary participation. Only de-identified, aggregated data were collected.

REFERENCES

1. The Nuremberg Code (1947). BMJ. 1996; 313(7070):1448-1448. https://doi.org/10.1136/bmj.313.7070.1448.
2. Veatch RM. *Case Studies in Biomedical Ethics: Decision-Making, Principles, and Cases*. New York, NY: Oxford University Press; 2010:366-368.
3. Kaufmann CL. Informed consent and patient decision making: two decades of research. *Soc Sci Med*. 1983;17(21):1657-1664. https://doi.org/10.1016/0277-9536(83)90311-8
4. Pokhilenko I, van Esch TEM, Brabers AEM, de Jong JD. Relationship between trust and patient involvement in medical decision-making: a cross-sectional study. *PLoS One*. 2021;16(8):e0256698. https://doi.org/10.1371/journal.pone.0256698
5. Ha JF, Longnecker N. Doctor-patient communication: a review. *Ochsner J*. 2010;10(1):38-43. Accessed July 1, 2024. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3096184/
6. Kevkhishvili N. Ethnic minorities and COVID-19. Health Policy Econ Sociol. 2022;6. Accessed July 11, 2024. https://heconomic.cu.edu.ge/index.php/healthecosoc/article/download/6465/6494/10751
7. Canterbury v Spence, 464 F2d 772 (DC Cir 1972). Accessed July 1, 2024. https://biotech.law.lsu.edu/cases/consent/canterbury_v_spence.htm
8. Goldberger JJ, Kruse J, Kadish AH, Passman R, Bergner DW. Effect of informed consent format on patient anxiety, knowledge, and satisfaction. *Am Heart J*. 2011;162(4):780-785.e1. https://doi.org/10.1016/j.ahj.2011.07.006
9. Plaiasu MC, Alexandru DO, Nanu CA. Physicians' legal knowledge of informed consent and confidentiality: a cross-sectional study. *BMC Med Ethics*. 2022;23(1):93. doi:10.1186/s12910-022-00835-3
10. Pietrzykowski T, Smilowska K. The reality of informed consent: empirical studies on patient comprehension – a systematic review. *Trials*. 2021;22(1):57. https://doi.org/10.1186/s13063-020-04969-w
11. Riordan F, Papoutsi C, Reed JE, Marston C, Bell D, Majeed A. Patient and public attitudes towards informed consent models and levels of awareness of electronic health records in the UK. *Int J Med Inform*. 2015;84(4):237-247. https://doi.org/10.1016/j.ijmedinf.2015.01.008
12. Kwame A, Petrucka PM. A literature-based study of patient-centered care and communication in nurse-patient interactions: barriers, facilitators, and the way forward. *BMC Nurs*. 2021;20(1):158. https://doi.org/10.1186/s12912-021-00684-2
13. Patak L, Wilson-Stronks A, Costello J, et al. Improving patient-provider communication: a call to action. *J Nurs Adm*. 2009;39(9):372-376. https://doi.org/10.1097/NNA.0b013e3181b414ca
14. Georgian Legislative Herald. *On the Rights of the Patient*. 1997. Accessed July 3, 2024. https://matsne.gov.ge/ka/document/view/16978
15. Ghorbanhoseini M, Kang K, Yang A, Abbasian M, Vaynberg E. Assessment of the factors influencing the patient's comprehension of informed consent to interventional pain procedures. *Pain Res Manag*. 2023;2023:7054089. https://doi.org/10.1155/2023/7054089
16. Kakar H, Gambhir R, Singh S, Kaur A, Nanda T. Informed consent: cornerstone in ethical medical and dental practice. *J Fam Med Prim Care*. 2014;3(1):68. https://doi.org/10.4103/2249-4863.130284
17. Leclercq WKG, Keulers BJ, Scheltinga MRM, Spauwen PHM, van der Wilt GJ. A review of surgical informed consent: past, present, and future. *World J Surg*. 2010;34(7):1406-1415. https://doi.org/10.1007/s00268-010-0542-0
18. Leclercq WK, Keulers BJ, Houterman S, Veerman M, Legemaate J, Scheltinga MR. A survey of the current practice of the informed consent process in general surgery in the Netherlands. *Patient Saf Surg*. 2013;7(1):4. https://doi.org/10.1186/1754-9493-7-4
19. Jukić M, Kvolik S, Kardum G, Kozina S, Tomić A, Juraga D. Knowledge and practices of obtaining informed consent for medical procedures among specialist physicians: questionnaire study in six Croatian hospitals. *Croat Med J*. 2009;50(6):567-574. https://doi.org/10.3325/cmj.2009.50.567
20. Porta CR. Training surgeons and the informed consent process: routine disclosure of trainee participation and its effect on patient willingness and consent rates. *Arch Surg*. 2012;147(1):57. https://doi.org/10.1001/archsurg.2011.235
21. Forrow L, Kontrimas JC. Language barriers, informed consent, and effective caregiving. *J Gen Intern Med*. 2017;32(8):855-857. https://doi.org/10.1007/s11606-017-4068-0
22. Schenker Y, Wang F, Selig SJ, Ng R, Fernandez A. The impact of language barriers on documentation of informed consent at a hospital with on-site interpreter services. *J Gen Intern Med*. 2007;22(Suppl 2):294-299. https://doi.org/10.1007/s11606-007-0359-1
23. Espinoza J, Derrington S. How should clinicians respond to language barriers that exacerbate health inequity? *AMA J Ethics*. 2021;23(2):E109-E116. doi:10.1001/amajethics.2021.109

Date of receipt of the manuscript: 21.03.2025
Date of acceptance for publication: 18.02.2026