BMC Medical Ethics

RESEARCH Open Access

Compromised informed consent due to functional health literacy challenges in Chinese hospitals

Dangui Zhang[1], Zhilin Hu[2], Zhuojia Wu[2], Ting Huang[2], Tingting Huang[2], Junhao Liu[2], Hongkun Sun[2] and William Ba-Thein[3,4*]

Abstract

Background Medical informed consent stands as an ethical and legal requisite preceding any medical intervention. Hospitalized patients face functional health literacy (FHL) challenges when dealing with informed consent forms (ICFs). The legitimacy of ICFs and informed consent procedures in China remains substantially undisclosed. The study's aim was to investigate if Chinese patients have adequate FHL to be truly informed before providing medical consent.

Methods In this cross-sectional, structured interview-based study, FHL was assessed within the context of the informed consent scenarios in two teaching hospitals (a 1500-bed general tertiary hospital and a 700-bed cancer hospital) affiliated with Shantou University Medical College. Twenty-seven patients admitted across clinical departments, along with their relatives ($n=59$), were enrolled in the study after obtaining informed consent. The participants underwent a three-step assessment with two selected ICFs —teach-back skills, perceived understanding (perception), and informed knowledge (cognizance), with each component carrying a maximum score of 10. Data were analyzed with SPSS (version 22.0) for descriptive and inferential statistics, with consideration of significant *P* values as <0.05.

Results The median age (IQR and range) of participants was 35.5 (28 – 49 and 13 – 74) years. Most participants had only high school education (24.4%, 21/86) or below high school education (47.7%, 41/86). The median score (IQR) of FHL assessments—teach-back, perception, and cognizance—was 4.0 (2.5, 5.8), 8.0 (6.8, 8.8), and 6.5 (5.5, 8.0) out of 10, respectively. A moderate correlation was observed between the scores of cognizance and teach-back ($r=0.359$, $P=0.002$) or perception ($r=0.437$, $P<0.001$). Multivariate linear regression analysis predicted being a patient and having lower education levels as independent risk factors of inadequate FHL ($Ps=0.001$). Lack of patient-centeredness in ICFs, time constraints, and poor clinical communication were identified as barriers impeding informed consent.

Conclusions This study demonstrates inadequacy in personal FHL and impaired organizational HL, resulting in compromised informed consent in Chinese teaching hospitals. As a remedy, we propose improving the quality of ICFs and institutionally mandated outcome-focused training on informed consent for all concerned clinicians to enhance medical ethics, ensure quality health care, address patient values, and mitigate potential medical conflicts.

*Correspondence:
William Ba-Thein
wbathein@stu.edu.cn; williambathein@gmail.com

Full list of author information is available at the end of the article

Keywords Health literacy, Health communication, Medical ethics, Informed consent, Patient values, China

Background

Functional health literacy (FHL), or health literacy (HL), is defined as "the degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others" by the U.S. Department of Health and Human Services in Health Literacy for Healthy People 2030 [1, 2]. FHL is the integrated innate abilities and acquired or learned skills of reading, comprehending, and analyzing information; decoding instructions, symbols, charts, and diagrams; weighing risks and benefits; and ultimately, making informed decisions and taking action [2].

Limited FHL is associated with unawareness of health problems, misunderstanding health information, self-medication, utilizing inappropriate health services, delayed health seeking, higher rates of hospitalization, difficulty following medical instructions, medical errors, medical conflicts, and shorter life expectancy [1, 3]. While personal FHL is the set of skills needed for healthcare consumers to comply with hospital regulations and clinical instructions, organizational HL (the degree to which an organization equitably enables its patients to make informed health decisions) [4, 5] is an indicator of ethical commitment in healthcare provision. Challenges to HL at the personal and organizational levels became apparent during the informed consent process that relies on effective communication between healthcare providers and their patients.

Hospitalized patients face FHL challenges due to a vast amount of hospital documents, notably informed consent forms. Medical informed consent is an ethical and legal process required before any medical intervention. Informed consent can be valid and genuine only when adequate information is provided at the level of FHL the healthcare consumers have. Quality informed consent ensures greater patient satisfaction, an improved professional image, and fewer malpractice claims [6].

Ironically, informed consent documents are nevertheless beyond the understanding level of patients, especially those with limited FHL or language barriers [7–9]. Given the low level of FHL globally [10], patients' rights to autonomy and self-determination in making medical decisions are on the verge of compromise. Particularly, older adults are at health risk (the chance or likelihood of experiencing an unwanted health outcome) from their declining and poor FHL skills [11, 12] and higher hospitalization rates compared with other age groups [13, 14].

In China, legal requirements for informed consent have been stipulated since 1994 and updated sporadically in different laws and regulations [15–18], but informed consent documents and procedures at the institutional level remain unregulated. Considering that only 13% of older Chinese people (50 – 69 years) have adequate FHL as reported in one population-based study [19] and that the hospitalization rate of the elderly (>65 years) had gradually increased from 15% in 2008 to 28% in 2018 [20], FHL has become a public health issue that needs due attention in China. Yet, there is a dearth of evidence specific to FHL and informed consent.

Our research aim was to understand if Chinese patients are truly informed before providing medical consent by investigating their FHL in the context of the informed consent process. Many FHL assessment tools have been developed, such as TOFHLA (The Test Of Functional Health Literacy in Adults) [21] and REALM (Rapid Estimate of Adult Literacy in Medicine) [22], and translated into different languages or adapted for diverse populations [23], including Mainland Chinese [24]. However, these tools are not suitable for FHL assessment under specific situations, viz. informed consent.

The study objective was to investigate the informed consent process, informed consent forms (ICFs), and the FHL of Chinese healthcare consumers (i.e., patients or their proxies) by using self-designed tools for assessment of teach-back (a health communication technique to ensure patient understanding by asking patients to repeat their physicians' instructions in their own words) [25], perception (subjective interpretation of knowledge or self-perceived understanding), and cognizance (informed knowledge). The teach-back technique was included as it has been shown effective across a wide range of settings, populations, and outcome measures in healthcare, such as patients' FHL and clinical communication [26].

Methods

Study design

This study was a cross-sectional, structured interview-based health literacy assessment for the informed consent procedure.

Study population and study site

Inpatients and their proxies (relatives) in two teaching hospitals (a 1500-bed general tertiary hospital and a 700-bed cancer hospital) affiliated with Shantou University Medical College.

FHL assessment approach

Our assessment approach was based on three FHL-related research questions derived from on-site observation of informed consent scenarios, focus group interviews with clinicians and patients/their proxies,

and evaluation of ICFs in the participating hospitals. The research questions, self-developed assessment tools (teach-back, perception, and cognizance tests), and outcome measures are shown in Table 1. These tools were designed to investigate if the study participants have the ability to make informed decisions.

Development of FHL assessment tools

We first reviewed informed consent documents in two participating hospitals and selected two ICFs—hospitalization and chemotherapy (Supplementary File 1). We chose the hospitalization ICF for its simplicity, generality, and relevance to all inpatients and the chemotherapy ICF for its challenging and specialty nature. Based on the content of these ICFs, we developed three FHL tools: a teach-back test (Supplementary File 2), a perception test (Supplementary File 1), and a cognizance test (Supplementary File 3). The teach-back test included a short paragraph of the excerpts (235 words in Chinese) from the ICFs, whereas two original ICFs were used without modification for the perception test. For the cognizance test, the most pertinent information from the ICFs was extracted and paraphrased in plain language into 20 questions (10 questions per ICF, 0.5 points for each correct answer) with additional text fillers in a conversational tone to reflect real-life situations.

The FHL assessment tools were pretested with a group of volunteers and validated by bilingual clinicians in the focus group for suitability and functionality which included the construct validity (Can these assessment tools measure the FHL of the participants during the informed consent procedure?), content validity (Are the tools adequate to measure the informed-consent FHL?), translational validity (Are these tools originally designed in English accurately translated into Chinese?), and face validity (Are these tools suitable for the study population?).

Table 1 Functional health literacy assessment

Research Question	Assessment tool	Outcome measure	Score (max.)
Q 1. Can patients/proxies understand, memorize, and recall the information after having just heard one time?	Step 1. ***Teach-back***[1] (asking them to explain in their own words the ICF content a healthcare provider has just explained to them)	Understanding, retention, and recollection of the information	10
Q 2. How do they perceive their understanding after reading the information in a short time in a stressful environment?	Step 2. ***Perception*** (self-rated understanding after reading the two ICFs under the healthcare provider's observation)	Self-perceived understanding, or subjective interpretation of knowledge	10
Q 3. How much do they truly understand after being informed?	Step 3. ***Cognizance***[2] (true-false reading comprehension of a 20-item questionnaire derived from two ICFs)	Informed knowledge, or recognition of provided information	10

[1] Supplementary File 2, [2] Supplementary File 3

The procedure of interview and FHL assessment (Table 1)

For our FHL assessment interviews the participants needed to be conscious, mentally stable, not distressed, and fit to follow the verbal and written instructions. Therefore, before the interviews, attending physicians screened suitable patients based on their medical conditions and mental status, and obtained verbal consent from potential participants. For pediatric patients and patients who could not read, understand, or refused to read ICFs, their proxies (family members) were recruited with the same eligibility criteria.

After that, investigators, who had been trained for the interview and teach-back techniques [25], approached the potential participants at their convenience and explained the study objectives, privacy, confidentiality, data utilization, and the procedure of the interview and FHL assessment. Written informed consent was obtained from those who agreed to participate in the study.

The interview and FHL assessment were conducted by six trained investigators in three teams (two investigators per participant; one who speaks the participant's dialect for the interview and the other for recording). The entire assessment process was audiotaped with the participant's permission for further analysis. Each participant took a three-step FHL assessment: (1) teaching back after the investigator explained the teach-back items, (2) reading two ICFs and self-rating their perceived understanding, and (3) answering the true-false questionnaire for their cognizance.

For teach-back, the interviewer first handed in a copy of teach-back test items and then slowly and clearly explained each item only once while allowing the participant to refer to the written material and recite it in their own words without being interrupted or assisted. Teach-back scoring was done in real time during the interview by the interviewer and verified by the recorder after reviewing the audiotape. Inter-rater consistency of scores by two raters was 0.885 (Cronbach's alpha). Only onsite scoring was done for those who refused audio recording ($n=25$).

For the perception test, the participants were asked to read the ICFs at their reading pace until they felt completely understood. A maximum score of 10 was given for each component of the assessment. Each interview lasted up to one hour including the time for the prelude and offering a gift after the interview.

Data management and analysis

Collected data were manually entered into an Excel database and cross-checked for accuracy. SPSS (version 22.0) was used for data analysis. Differences in the median (IQR) of FHL scores were analyzed by the Mann-Whitney U test for two groups, the Kruskal-Wallis test for more than two groups, and the Friedman test for three dependent/paired data (3 scores). Pearson's correlation was used to analyze the correlations between FHL scores. Multivariate linear regression analysis was used to identify relationships between FHL scores and demographic factors. Two-tailed *P*-value < 0.05 was considered statistically significant.

Results

Participant characteristics (Table 2)

Participants ($n=86$) included 27 patients (31.4%) and 59 patients' relatives (68.6%) in the respiratory medicine, thyroid and breast surgery, pediatrics, otolaryngology and head-neck surgery, gynecology, and dentistry departments. Male to female ratio was 0.86. The median age of participants was 35.5 years (IQR: 28 – 49, range: 13 – 74). Most participants had education below the high school level (47.7%, 41/86), at the high school level (24.4%, 21/86), or at the college and above level (27.9%, 24/86).

FHL scores (Table 2)

The median score (IQR) for teach-back, perception, and cognizance was 4.0 (2.5, 5.8), 8.0 (6.8, 8.8), and 6.5 (5.5, 8.0) out of 10, respectively. FHL scores differed significantly by participant type, education, or admitted ward (*P*s < 0.001 ~ 0.015), but no difference was observed by sex and prior experience with ICFs (*P*s = 0.127 ~ 0.96).

Correlation of FHL scores (Fig. 1)

A significant but moderate correlation was observed between cognizant score and teach-back ($r=0.359$, $P=0.002$) or perception score ($r=0.437$, $P<0.001$).

Multivariate linear regression analysis of FHL-associated factors (Fig. 2)

Being a patient was an independent risk factor of poor teach-back and cognizance (beta, 95%CI: -1.18, -2.21 ~ -0.16, $P=0.024$; -1.38, -2.16 ~ -0.60, $P=0.001$, respectively). A lower level of education was also an independent risk factor of poor teach-back, perception, and cognizance (beta, 95%CI: -0.55, -1.00 ~ -0.09, $P=0.019$; -0.93, -1.39 ~ -0.47, $P<0.001$; -0.63, -0.98 ~ -0.28, $P=0.001$, respectively).

Discussion

Despite its long-standing practice and omnipresence, clinical informed consent receives less attention than research informed consent, and thus it is less researched,

Table 2 Characteristics of study participants and their functional health literacy (FHL) scores on informed consent documents

	Total (*N* = 86) *n* (%)	Teach-back score (10) *n* = 83	Perception score (10) *n* = 83	Cognizant score (10) *n* = 84	*P*-value[1]
Participant		***P* = 0.005**[2]	*P* = 0.264[2]	***P* < 0.001**[2]	
Total	86 (100)	4.0 (2.5, 5.8)	8.0 (6.8, 8.8)	6.5 (5.5, 8.0)	**< 0.001**
Patient	27 (31.4)	3.1 (1.9, 5.0)	7.9 (6.6, 8.8)	5.8 (4.5, 6.5)	**< 0.001**
Patient's relative	59 (68.6)	4.3 (3.0, 6.1)	8.0 (7.0, 9.0)	7.5 (6.0, 8.5)	**< 0.001**
Sex		*P* = 0.960	*P* = 0.181	*P* = 0.417	
Male	40 (46.5)	4.0 (2.9, 5.1)	8.0 (7.0, 9.6)	6.3 (5.5, 8.0)	**< 0.001**
Female	46 (53.5)	4.3 (2.1, 6.1)	7.9 (6.5, 8.8)	7.0 (5.6, 8.0)	**< 0.001**
Age (Mdn 35.5; IQR: 28, 49; Range: 13–74)		*P* = 0.168	*P* = 0.07	*P* = 0.138	
< 35.5 years	41 (47.7)	4.3 (3.2, 5.6)	7.8 (6.5, 8.5)	7.5 (5.5, 8.3)	**< 0.001**
> 35.5 years	45 (52.3)	3.5 (2.3, 5.8)	8.3 (7.3, 9.3)	6.5 (5.5, 7.5)	**< 0.001**
Education		***P* = 0.015**	***P* = 0.006**	***P* = 0.003**	
Primary school and below	12 (14.0)	2.3 (1.0, 3.9)	7.3 (1.7, 7.8)	6.0 (2.9, 6.8)	0.089
Junior high school	29 (33.7)	3.5 (2.0, 6.0)	7.5 (6.5, 8.6)	6.0 (5.0, 7.5)	**< 0.001**
High school	21 (24.4)	5.0 (4.1, 6.3)	8.3 (6.6, 10.0)	7.3 (6.1, 8.4)	**< 0.001**
College and above	24 (27.9)	4.8 (3.3, 6.0)	8.5 (7.8, 9.0)	7.5 (6.5, 8.5)	**< 0.001**
Admitted clinical department		***P* = 0.012**	*P* = 0.683	*P* = 0.280	
Respiratory medicine	31 (36.0)	3.6 (2.3, 4.8)	8.0 (7.3, 8.8)	6.5 (5.0, 7.0)	**< 0.001**
Thyroid and breast surgery	21 (24.4)	5.0 (3.1, 6.4)	7.8 (6.2, 9.4)	7.0 (5.1, 7.9)	**0.001**
Pediatrics	19 (22.1)	4.3 (1.6, 5.9)	7.5 (6.5, 8.5)	7.5 (6.0, 8.5)	**0.001**
Otolaryngology and head surgery	10 (11.6)	3.4 (2.7, 4.6)	9.0 (5.6, 10.0)	7.5 (4.8, 7.8)	**0.017**
Others[3]	5 (5.8)	7.0 (5.8, 7.6)	8.0 (8.0, 8.5)	7.5 (6.3, 8.3)	**0.044**
Prior experience with the ICFs[4]		*P* = 0.619	*P* = 0.836	*P* = 0.127	

Table 2 (continued)

	Total (*N* = 86) *n* (%)	Teach-back score (10) *n* = 83	Perception score (10) *n* = 83	Cognizant score (10) *n* = 84	*P*-value[1]
Yes	47 (54.7)	4.0 (2.5, 5.7)	8.0 (7.0, 9.0)	7.0 (6.0, 8.0)	**< 0.001**
No	39 (45.3)	5.0 (2.9, 5.9)	8.0 (6.6, 8.6)	6.5 (5.3, 7.8)	**< 0.001**

Scores shown as median (IQR); *P* values analyzed by the Mann-Whitney U test for 2 groups, or the Kruskal-Wallis test for more than 2 groups. [1] Three dependent/paired data (3 scores) analyzed by the Friedman test; [2] Patient vs. patient`s relative; [3] Including gynecology and dentistry departments; [4] Prior experience of providing consent to the ICFs used in the study.

discussed, regulated, or standardized. This is the first study from China addressing the legitimacy of informed consent in routine clinical care due to apparent compromises in patient autonomy and self-determination, attributable partly to inadequacy in personal FHL and mainly to deficiencies in organizational HL.

Inadequate personal FHL

Our three-step (teach-back, perception, cognizance) assessment captured the challenges the participants had in the multidimensional nature of informed consent.

Teach-back: We modified the original approach of the teach-back technique (which involves restating the information until the patient displays clear comprehension) and explained only one time to simulate the informed consent scenario within our hospital setting. Poor teach-back performance underscores the participants' inability to understand, retain, and recollect recently received information. This serves as a compelling reminder to clinicians regarding the importance of adhering to the teach-back technique as recommended.

Cognizance: The purpose of the cognizance test was to assess the participants' genuine comprehension upon completion of the "informed" part of the informed consent procedure. Despite nearly half of the participants having prior experiences with the same ICFs, their moderate level of cognizance signals the lack of full understanding, essentially undermining the legitimacy of informed consent. It should be acknowledged though that the cognizant test included numerous commonsense inquiries, therefore, potentially leading the participants to make educated guesses for correct responses.

Perception: Despite the low teach-back and modest cognizant scores, the participants' perceived understanding was significantly high. Given the correlation between perception and cognizance being only moderate, this overrated perception suggests their miscomprehension (i.e., lacking the capacity to know their ignorance) during clinical communication.

Participants' FHL performance can be affected by memory encoding (i.e., learning of new information), which is subject to distortion in high-stress situations [27] like the informed consent procedure, where they are under the healthcare provider's observation. As has been discussed before [28], the emotions associated with poor FHL, such as shame or embarrassment, can also affect the participants' self-perceived understanding. A high perception, therefore, could also be a display of social desirability bias (the tendency to respond in a socially acceptable manner) due to the audience effect (alteration of behavior when being observed) [29] or it is just a result of the skimming or hurried reading of the documents, which occurred with some participants who completed our assessment in just 10 min.

The outcomes of the three assessments affirm that clinicians should anticipate the impact of inadequate FHL in clinical communication, regardless of the characteristics of patients or their proxies. As our multivariate regression model predicted, the participants with lower education levels, in particular, face a heightened risk of these FHL challenges.

Impaired organizational HL

Informed consent is a ubiquitous and critical procedure in the continuum of healthcare. The quality of informed consent in an organization thus reflects its HL. High-quality informed consent entails that informed consent documents be clearly and logically written in plain language that patients can understand and that healthcare providers help patients understand [30], but both aspects fell short in the study hospitals.

The quality of informed consent forms ICFs used in our investigation are lengthy and loaded with medical terms (i.e., 9 words in the hospitalization ICF and 39 words in the chemotherapy ICF); poor, confusing, and wordy expression; and demanding or intimidating tone; and in a clinician-centered mode, thereby illustrating the lack of patient-centeredness. While the participants were aware of the characteristics of these documents, only three criticized them. This shows the tolerance Chinese healthcare consumers have for formalities.

Clinicians' perspectives A focus group interview with 10 senior attending physicians (data not shown) revealed provider-level deficiencies in information disclosure and interaction with patients. While they all acknowledged that ICFs are generally difficult for patients, most usually failed to ensure the patient's understanding and at times, entirely bypassed the "informed" part of the procedure due to reasons such as the considerable time consumption (up to 30 min) out of their demanding schedules, their own challenges in articulating the content clearly, and the patient's inability to understand their explanations—a challenge exacerbated by dialect barriers as reported pre-

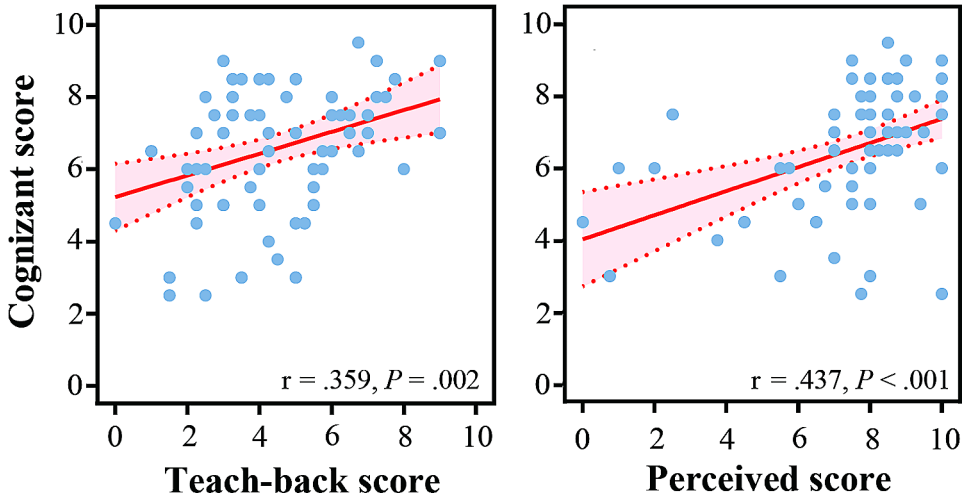

Fig. 1 Correlation between participants' teach-back or perception (perceived understanding of ICFs) and their cognizance (informed knowledge), analyzed by Pearson's correlation

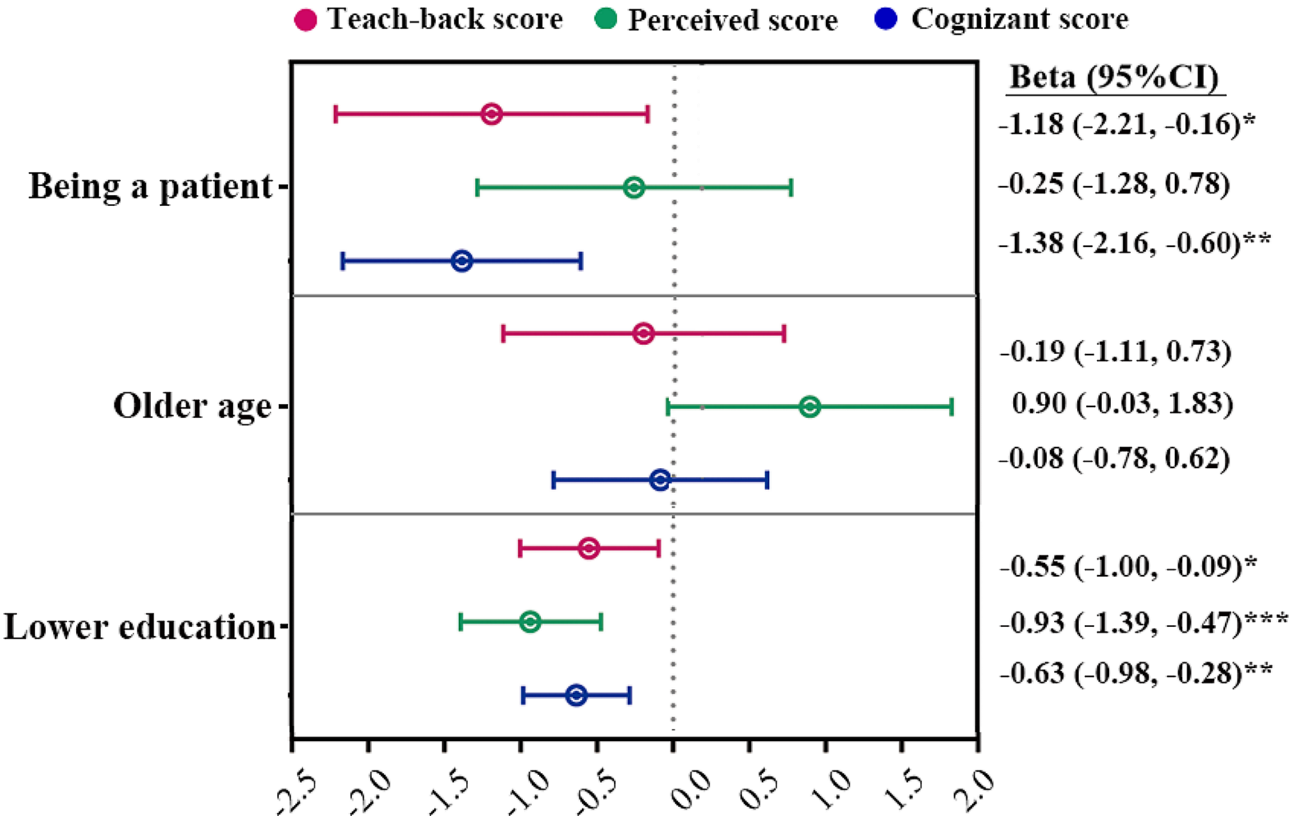

Fig. 2 Multivariate linear regression analysis of FHL-associated factors

viously [31]. They also attested that unless there are concerns about the risks or costs of suggested interventions, generally, no patient disagreed to provide consent, apparently in an effort to comply with hospital regulations. Their feedback exposed the complexities behind informed consent from the doctors' perspectives.

What we found in this study is much in common with a qualitative study of surgical informed consent in Guangdong province which identified three barriers to informed consent in Chinese patients' perspectives: insufficient information to make decisions, overuse of medical jargon, and insufficient patient-doctor interaction, with the highlights on poor attitudes of doctors towards the entire

informed consent procedure [32]. Similarly, in Singapore, inadequate clinical communication has led to medical disputes with patients undergoing elective surgeries [33]. Part of these problems could be explained by misconception of informed consent and ignorance of its original ethical principles among healthcare providers, as meticulously discussed in the study from Japan [34].

Since hospitalized patients are typically required to provide multiple informed consents, they could face exponential challenges with an increased risk of erroneous decision-making in the observed literacy-poor environment. This malformed consent problem could be a common phenomenon in any healthcare environment, irrespective of country, wherein informed consent lacks regulation and formalized training.

Suggestions for improvement

Health literacy The observed shortcomings in the personal FHL and organizational HL in this study perhaps reflect the widespread nature of informed consent in China and elsewhere where the HL rate is considerably low. Informed consent can become a hotbed for medical conflicts if and when healthcare consumers feel they are not real decision-makers, particularly when there are unwanted outcomes. Intervention for inadequate personal FHL is practically unachievable without nationwide HL promotional efforts and long-term commitment by the government. To improve organizational HL, healthcare institutions must conduct fact-finding surveys, like this study, with the stakeholders (i.e., patients, their relatives, and clinicians) to understand root causes and limitations at the institutional level and thus formulate evidence-based interventions as discussed below.

Informed consent documents There are recommendations, guidelines, and tools as interventions to improve patient comprehension via enhanced ICFs [33–38]. Most of these interventions are for research participation in clinical settings, not directly relevant to routine clinical care because the scientific terms/concepts in research ICFs significantly differ from the medical terms incorporated in clinical ICFs. Therefore, Chinese hospitals should, at least, consider revising their existing ICFs to improve font, size, length, and logicality, and adding visual aids as recommended elsewhere [35–37, 39, 40].

Formal training Like in the West where the concept originated, informed consent is legally mandated in China. However, in the absence of penalties for noncompliance, it is merely considered a bureaucratic formality by administrators, educators, and healthcare providers. Consequently, there is no formal training or oversight of informed consent procedures in hospitals. While the time constraint due to strained clinician-to-patient ratios, particularly in overcrowded tertiary hospitals, still could be an unbreakable barrier within China's current healthcare system, providing mandatory institutionally endorsed training on informed consent for all concerned clinicians as recommended by the Agency for Healthcare Research and Quality (AHRQ) [41] should be a realizable option for improvement across various healthcare facilities. In support of this, formalized training has demonstrated effectiveness in improving the confidence and comfort of American clinical residents in obtaining informed consent and disclosing complications [42].

Study limitations

Our findings were derived from participants who were physically and mentally stable, and thus, are not generalizable to individuals experiencing physical or mental discomfort, who could find informed consent more challenging. Having more family members than patients in the study will not accurately represent patients' FHL. But consent by proxy is a common phenomenon and acceptable in clinical practice, particularly for pediatric cases and also with adult patients, who are illiterate or mentally incapacitated, like in this study. It is also an acceptable social norm in some cultures. For example, in Japan, it is not uncommon to have consent from the families of elderly patients [34]. The FHL assessment tools in this study were developed for ICF-specific situational FHL, not intended as universal assessment tools. However, our approach should be applicable for FHL assessments across various patient populations in any country, provided customized and validated documents are used. Given the multidimensional nature of informed consent, our investigation can only provide evidence of a compromised patient's autonomous decision-making. Further mixed-method studies should focus on the legitimacy of informed consent procedure from the perspectives of all stakeholders, exploring associated clinical and social burdens, and examining medicolegal consequences.

Conclusions

This study demonstrates the shortcomings surrounding the informed consent procedure with compromised medical ethics in Chinese teaching hospitals due to inadequacy in personal FHL and impaired organizational HL. Time constraints and poor clinical communication were identified as barriers impeding informed consent. We propose improving the quality of ICFs and institutionally mandated outcome-focused training on informed consent for all concerned clinicians to enhance medical ethics, ensure quality health care, address patient values, and mitigate potential medical conflicts.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12910-024-01089-x.

Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

Acknowledgements

The authors like to thank the study participants, Drs. Chuangxing Lin, Jiehua Zheng, and Shaowei Xu for assistance with patient recruitment, and physicians in the focus group for their insightful discussion. The authors report there are no competing interests to declare.

Author contributions

DGZ supervised the interviews, statistically analyzed the data, and prepared final tables and figures; ZLH, JHL, TH, TTH, HKS, and ZJW interviewed the patients, analyzed the data; WB-T conceived, designed, and supervised the study, analyzed and interpreted the data, and wrote the manuscript; all authors approved the final manuscript.

Funding

This work was supported by the Undergraduate Research Training Program (UGRTP), grant number: LE0003, Guangdong Medical Education Reform Program in 2020, and the Undergraduate Innovation and Entrepreneurship Training Program in Shantou University Medical College, grant number: 2021-43.

Data availability

Data sharing statement: The datasets generated and analyzed during the current study are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate

The study protocol was approved by the Ethics Committees of Shantou University Medical College (approval no. SUMC-2021-33) and the hospitals (2021-67 for the general hospital and 2022122 for the cancer hospital). This study was carried out in accordance with the Declaration of Helsinki. Participation in the study was voluntary. Written informed consent was obtained from all the participants and the parents or legal guardians of any participant under the age of 16.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Author details

[1]Research Center of Translational Medicine, Second Affiliated Hospital of Shantou University Medical College, Shantou, P.R. China
[2]Undergraduate Research Training Program (UGRTP), Shantou University Medical College, Shantou, P.R. China
[3]Clinical Research Unit, Shantou University Medical College, Shantou, P.R. China
[4]Department of Microbiology and Immunology, Shantou University Medical College, Shantou, P.R. China

Received: 20 August 2023 / Accepted: 5 August 2024
Published online: 23 August 2024

References

1. Santana S, Brach C, Harris L, Ochiai E, Blakey C, Bevington F, Kleinman D, Pronk N. Updating health literacy for healthy people 2030: defining its importance for a New Decade in Public Health. J Public Health Manag Pract. 2021;27(Suppl 6):S258–64.
2. Brega AGBJ, Mabachi NM, Weiss BD, DeWalt DA, Brach C, Cifuentes M, Albright K, West DR. Health Literacy Universal Precautions Toolkit, Second Edition. https://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/clear-communication/health-literacy. Accessed 27 Jul 2024.
3. Wynia MK, Osborn CY. Health literacy and communication quality in health care organizations. J Health Commun. 2010;15(Suppl 2):102–15.
4. Health Literacy. A Prescription to End Confusion. In: Health Literacy: A Prescription to End Confusion edn. Edited by Nielsen-Bohlman L, Panzer AM, Kindig DA. Washington (DC); 2004.
5. U.S. Centers for Disease Control and Prevention (CDC). What Is Health Literacy? https://www.cdc.gov/healthliteracy/learn/index.html. Accessed 27 Jul 2024.
6. Pape T. Legal and ethical considerations of informed consent. AORN J. 1997;65(6):1122–7. https://doi.org/10.1016/s0001-2092(06)62955-4.
7. Pietrzykowski T, Smilowska K. The reality of informed consent: empirical studies on patient comprehension-systematic review. Trials. 2021;22(1):57. https://doi.org/10.1186/s13063-020-04969-w.
8. Glaser J, Nouri S, Fernandez A, Sudore RL, Schillinger D, Klein-Fedyshin M, Schenker Y. Interventions to improve patient comprehension in informed consent for Medical and Surgical procedures: an updated systematic review. Med Decis Mak. 2020;40(2):119–43. https://doi.org/10.1177/0272989X19896348.
9. Manta CJ, Ortiz J, Moulton BW, Sonnad SS. From the patient perspective, consent forms fall short of providing information to guide decision making. J Patient Saf. 2021;17(3):e149–54. https://doi.org/10.1097/PTS.0000000000000310.
10. Zhang D, Zhan W, Zheng C, Zhang J, Huang A, Hu S, Ba-Thein W. Online health information-seeking behaviors and skills of Chinese college students. BMC Public Health. 2021;21(1):736. https://doi.org/10.1186/s12889-021-10801-0.
11. U.S. Centers for Disease Control and Prevention (CDC). Older Adults. https://www.cdc.gov/healthliteracy/developmaterials/audiences/olderadults/index.html. Accessed 27 Jul 2024.
12. Kobayashi LC, Wardle J, Wolf MS, von Wagner C. Cognitive function and Health Literacy Decline in a cohort of Aging English adults. J Gen Intern Med. 2015;30(7):958–64. https://doi.org/10.1007/s11606-015-3206-9.
13. Kobayashi LC, Wardle J, Wolf MS, von Wagner C. Aging and Functional Health Literacy: a systematic review and Meta-analysis. J Gerontol B Psychol Sci Soc Sci. 2016;71(3):445–57. https://doi.org/10.1093/geronb/gbu161.
14. Department of Statista. U.S. population with a hospitalization 2000–2018 by age. https://www.statista.com/statistics/184447/us-population-with-a-hospitalization-by-age/. Accessed 27 Jul 2024.
15. The National Peole's Congress of the People's Republic of China. Practitioner Law of the People's Republic of China. http://www.npc.gov.cn/npc/c30834/202108/d954d9fa0af7458aa862182dc50a0d63.shtml. Accessed 27 Jul 2024.
16. The National Peole's Congress of the People's Republic of China. Implementation details of medical institutions Management Ordinance. http://www.nhc.gov.cn/fzs/s3576/201808/7a922e4803fa452f99d43a25ec0a3d77.shtml. Accessed 27 Jul 2024.
17. The National Peole's Congress of the People's Republic of China. Administrative Regulations on Medical Institutions. http://www.gov.cn/zhengce/2020-12/25/content_5575075.htm. Accessed 15 Aug 2022.
18. The State Council. T The People's Republic of China. The Regulation on the Handling of Medical Accidents. http://www.gov.cn/zhengce/content/2018-08/31/content_5318057.htm. Accessed 27 Jul 2024.
19. Li Z, Tian Y, Gong Z, Qian L. Health Literacy and Regional Heterogeneities in China: a Population-based study. Front Public Health. 2021;9:603325. https://doi.org/10.3389/fpubh.2021.603325.
20. National Bureau of Statistics. China Health Statistics Yearbook. https://www.yearbookchina.com/navipage-n3022013080000229.html. Accessed 27 Jul 2024.
21. Parker RM, Baker DW, Williams MV, Nurss JR. The test of functional health literacy in adults: a new instrument for measuring patients' literacy skills. J Gen Intern Med. 1995;10(10):537–41. https://doi.org/10.1007/BF02640361.
22. Davis TC, Crouch MA, Long SW, Jackson RH, Bates P, George RB, Bairnsfather LE. Rapid assessment of literacy levels of adult primary care patients. Fam Med. 1991;23(6):433–5.

23. Altin SV, Finke I, Kautz-Freimuth S, Stock S. The evolution of health literacy assessment tools: a systematic review. BMC Public Health. 2014;14:1207. https://doi.org/10.1186/1471-2458-14-1207.
24. Mantwill S, Schulz PJ. Health literacy in Mainland China: validation of a functional health literacy test in simplified Chinese. Health Promot Int. 2016;31(4):742–8. https://doi.org/10.1093/heapro/dav043.
25. Agency for Healthcare Research and Quality. Teach-Back: Intervention. https://www.ahrq.gov/patient-safety/reports/engage/interventions/teach-back.html. Accessed 27 Jul 2024.
26. Talevski J, Wong Shee A, Rasmussen B, Kemp G, Beauchamp A. Teach-back: a systematic review of implementation and impacts. PLoS ONE. 2020;15(4):e0231350. https://doi.org/10.1371/journal.pone.0231350.
27. Shields GS, Hunter CL, Yonelinas AP. Stress and memory encoding: what are the roles of the stress-encoding delay and stress relevance? Learn Mem. 2022;29(2):48–54. https://doi.org/10.1101/lm.053469.121.
28. Lyons B, Dolezal L. Shame, health literacy and consent. Clin Ethics. 2024;19(2):150–6. https://doi.org/10.1177/14777509231218203.
29. Hamilton AFC, Lind F. Audience effects: what can they tell us about social neuroscience, theory of mind and autism? Cult Brain. 2016;4(2):159–77. https://doi.org/10.1007/s40167-016-0044-5.
30. Shah P, Thornton I, Turrin D, Hipskind JE. Informed consent. StatPearls. edn. Treasure Island (FL); 2023.
31. Zhang D, Jiang Z, Xie Y, Wu W, Zhao Y, Huang A, Li T, Ba-Thein W. Linguistic barriers and healthcare in China: Chaoshan vs. Mandarin. BMC Health Serv Res. 2022;22(1):376. https://doi.org/10.1186/s12913-022-07744-6.
32. Gong N, Zhou Y, Cheng Y, Chen X, Li X, Wang X, Chen G, Chen J, Meng H, Zhang M. Practice of informed consent in Guangdong, China: a qualitative study from the perspective of in-hospital patients. BMJ Open. 2018;8(10):e020658. https://doi.org/10.1136/bmjopen-2017-020658.
33. The Medical Protection Society (MPS). Informed consent – a time of change in Singapore. https://www.medicalprotection.org/singapore/casebook-resources/medicolegal-articles/articles/informed-consent-a-time-of-change-in-singapore. Accessed 27 Jul 2024.
34. Masaki S, Ishimoto H, Asai A. Contemporary issues concerning informed consent in Japan based on a review of court decisions and characteristics of Japanese culture. BMC Med Ethics. 2014;15:8. https://doi.org/10.1186/1472-6939-15-8.
35. Cohen E, Byrom B, Becher A, Jornten-Karlsson M, Mackenzie AK. Comparative effectiveness of eConsent: systematic review. J Med Internet Res. 2023;25:e43883. https://doi.org/10.2196/43883.
36. Gesualdo F, Daverio M, Palazzani L, Dimitriou D, Diez-Domingo J, Fons-Martinez J, Jackson S, Vignally P, Rizzo C, Tozzi AE. Digital tools in the informed consent process: a systematic review. BMC Med Ethics. 2021;22(1):18. https://doi.org/10.1186/s12910-021-00585-8.
37. Chimonas S, Lipitz-Snyderman A, Matsoukas K, Kuperman G. Electronic consent in clinical care: an international scoping review. BMJ Health Care Inf. 2023;30(1). https://doi.org/10.1136/bmjhci-2022-100726.
38. Schenker Y, Fernandez A, Sudore R, Schillinger D. Interventions to improve patient comprehension in informed consent for medical and surgical procedures: a systematic review. Med Decis Mak. 2011;31(1):151–73. https://doi.org/10.1177/0272989X10364247.
39. Federation EC. Electronic Informed Consent Implementation Guide Practical Considerations. https://www.eucrof.eu/images/Electronic_Informed_Consent_Implementation_Guide_Practical_Considerations_Version_1.0___March_2021_2.pdf. Accessed 12 Jun 2024.
40. Grady C, Cummings SR, Rowbotham MC, McConnell MV, Ashley EA, Kang G. Informed consent. N Engl J Med. 2017;376(9):856–67. https://doi.org/10.1056/NEJMra1603773.
41. Agency for Healthcare Research and Quality. Ten Attributes of Health Literate Health Care Organizations. https://www.ahrq.gov/health-literacy/publications/ten-attributes.html. Accessed 12 Jun 2024.
42. Yong V, Zhao H, Gilmore K, Cripe J, Conklin C, Dauer E. Procedural-based Specialties Benefit from a formal informed consent and disclosures Educational Program. J Surg Educ. 2022;79(3):725–31. https://doi.org/10.1016/j.jsurg.2021.12.008.

Publisher's Note