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Lost in translation: Informed consent in the medical mission setting ☆

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ABSTRACT

Background: Informed consent is a fundamental tenet of ethical care, but even under favorable conditions, patient comprehension of consent conversations may be limited. Little is known about providing informed consent in more uncertain situations such as medical missions. We sought to examine the informed consent process in the medical mission setting.

Methods: We studied informed consent for adult patients undergoing inguinal herniorrhaphy during a medical mission to Guatemala using a convergent mixed-methods design. We audiotaped informed consents during preoperative visits and immediately conducted separate surveys to elicit comprehension of risks. Informed consent conversations and survey responses were translated and transcribed. We used descriptive statistics to examine informed consent content, including information provided by surgeon, the translation of information, and patient comprehension, and used thematic analysis to examine the consent process.

Results: Thirteen adult patients (median age 53 years, 69% male) participated. Surgeons conveyed 4 standard risks in 10 out of 13 encounters (77%); all 4 risks were translated to patients in 10 out of 13 encounters (77%). No patient could recall all 4 risks. Qualitative themes regarding the informed consent process included limited physician language skills, verbal domination by physicians and interpreters, and mistranslation of risks. Patients relied on faith and prior or vicarious experiences to qualify surgical risks instead of consent conversations. Many patients restated surgical instructions when asked about risks.

Conclusion: Despite physicians' attempts to provide informed consent, medical mission patients did not comprehend surgical risks. Our data reveal a critical need to develop more effective methods for communicating surgical risks during medical missions.

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Introduction

Interest in short-term medical missions (STMs) and global health opportunities is exceedingly high among surgical trainees and licensed practitioners in the United States.[1,2] Many participants cite altruism and a desire to be challenged as reasons for participation.[3] Despite their popularity among participating physicians, STMs have also been criticized for neglecting ethical issues related to their care.[4] Arguably, the most fundamental of these is the practice of obtaining preoperative informed consent—a standard of modern surgical care indicating recognition of risk and respect for patient autonomy.[5]

In fact, practitioners from high-income countries are bound by federal and state regulations to obtain and document written informed consent. However, even in high-income countries like the United States, patients' comprehension and recall of preoperative informed consent conversations are limited.[6] Thus, the Nuffield Council on Bioethics supports the idea of genuine consent, which allows for verbal consent that is properly witnessed and documented, particularly in resource-poor settings. The Council recommends "to obtain genuine consent, health professionals must do their best to communicate information accurately and in an understandable and appropriate way. The information provided to participants must be relevant, accurate and sufficient to enable a genuine choice to be made."[7]

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Regulation or even guidelines supporting informed consent among STMs are not readily available, and the frequency of successful patient comprehension is unknown. Previous editorials have described the difficulties of obtaining informed consent on STMs.[8,9] Furthermore, the concept of patient autonomy may be relatively novel in many low- and middle-income countries, where medical care may retain aspects of paternalism once common in the United States.[10-12] For visiting physicians attempting to practice informed consent during STMs, existing barriers to patient comprehension and autonomy may be further compounded by the need for translation, chaotic clinics, divergent cultural norms, and reduced literacy.

In this study we employed a mixed-methods approach to examine the informed consent process for inguinal herniorrhaphy during an STM. Specifically, we quantitatively measured physician communication of 4 standard operative risks, adequacy of translation, and patient comprehension, and qualitatively analyzed the content and process of communication among physicians, interpreters, and patients during a surgical mission trip in Guatemala.

Methods

Overview

We designed a convergent mixed-methods study to describe the following: (1) clinicians' communication of surgical risks, (2) patient comprehension, and (3) the standard informed consent process during a clinical encounter in the setting of a short-term medical mission trip.

Setting

The study was conducted in July 2017 at a hospital servicing a rural population in western Guatemala. The hospital provides year-round primary care, ophthalmology, and basic emergency services through 4 full-time Guatemalan physicians. Each year, 4–6 short-term medical missions provide specialty care in gynecology, ophthalmology, general surgery, pediatric surgery, and plastic surgery.

Participants and procedures

All patients older than 18 years who presented to the preoperative clinic for consideration of inguinal herniorrhaphy were eligible to participate in the study. Inguinal herniorrhaphy was selected as the procedure of choice because it was the most common general surgery procedure performed on prior site visits. Children were excluded from participation because of a more complex informed consent process, different surgical approach (high ligation of sac versus Lichtenstein repair), and different risk profile. Visiting physicians included 2 general surgery residents, 1 attending general surgeon, and 1 attending pediatric surgeon who aided in the clinic evaluations and consents. All were native English speakers with varying levels of Spanish fluency. Bilingual Guatemalan physicians and other fluent bilingual members of the visiting mission team translated for clinical encounters.

Verbal informed consent for the research study was obtained from all participants after the decision to operate was made to mitigate any sense of patient coercion. After the research study consent was obtained, the surgical informed consent process was audio recorded. During the informed consent process, researchers relied on informal translation practices typical of physician-interpreter interactions. A physician would state the operative risks in either English or Spanish; this was an individual choice depending on comfort with the Spanish language. If the physician stated a risk in English, interpreters translated the risk into Spanish. If a physician stated a risk in Spanish, and the patient indicated that they did not understand or the interpreter felt that additional clarification was needed, the interpreter repeated the risk translation in Spanish. This led to some risks being translated into Spanish by both the physician and interpreter. Within 10 minutes after the preoperative clinical encounter, resident physicians conducted a separate structured face-to-face survey with the assistance of a fluent Spanish interpreter. The survey consisted of 26 multiple choice, short answer, and open-ended questions about sociodemographic characteristics, prior surgical experiences, expectations, and comprehension or recall of the potential risks and benefits of surgery. Face-to-face surveys were audio recorded.

A priori the clinical team identified 4 risks deemed central to the consent process for inguinal herniorrhaphy: bleeding, infection, recurrence of hernia, and chronic pain. Successful informed consent was defined as communication of all 4 risks by the visiting physician, translation of all 4 risks by either the visiting physician or translator, and recall by the patient of all 4 risks. Successful risk communication was defined as communication and translation of a specific individual risk in a clinical encounter followed by recall of that risk during the follow-up survey. Thus, there were 13 opportunities for successful informed consent and 52 opportunities for successful risk communication. To ensure standardization of the described risks and benefits, all physicians attended the first clinical encounter, which included an informed consent process.

Data analysis

A certified bilingual medical transcriptionist in Spanish and English who was familiar with the local vernacular transcribed verbatim audio recordings of the clinical encounters and surveys. We assessed informed consent content using the PARQ (Procedure, viable Alternatives, material Risks, Questions) model, which requires a description of the procedure, alternative treatment, and risks, followed by elicitation of patient questions.[13] In the transcribed clinical encounter, we specifically assessed the visiting physician's statement of the 4 most common risks of herniorrhaphy (infection, bleeding, recurrence, and chronic pain), and Spanish translation of the 4 risks by either the visiting physician or interpreter. In the immediate follow-up survey, we assessed the patient's recall of the 4 most common risks. Frequencies and descriptive statistics were calculated. McNemar's test for paired dichotomous data was used to compare surgeon statement of risks, Spanish translation of risks, and patient recall of risks. Statement of risk by physicians was used as the reference group.

To analyze the process of informed consent, 3 researchers inductively developed preliminary codes pertaining to the content and structure of the clinical encounter and open-ended questions in the follow-up survey. The preliminary coding scheme was iteratively discussed and refined until consensus regarding the codebook and definitions was reached. Three researchers then independently coded all transcripts, and emergent themes were discussed to consensus. Thematic saturation was achieved by the tenth encounter. Themes were validated through triangulation among researchers, confirmation between methods, and a software-assisted search for disconfirming evidence.

We integrated quantitative and qualitative methods during convergent data collection, content analysis, and thematic analysis of open-ended responses, and finally in a joint display of findings focused on clarity of information provided by surgeon, accuracy of translation, and patient understanding. The study was approved by the Institutional Review Board of Stanford University (IRB #33456). All personal health information was deidentified to maintain participant privacy. NVivo Version 11.4 (QSR International, Melbourne, Australia) and Stata Version 14.2 (Stata Corporation, College Station, TX) software were used for analysis.

Table 1
Patient sociodemographic characteristics.

	Patients (N = 13)
Age in years, median (IQR)	53 (39–59)
Sex	
Male	9
Female	4
Education level	
None	3
Primary school	8
Secondary school	2
Occupation	
Agriculture or farming	6
Personal business	2
Construction	1
Transportation	1
Unemployed	3
Consistent income	
Yes	4
No	9
Time from last health care encounter	
≤1 mo	6
≤1 y	4
>1 y	2
Never	1

IQR, interquartile range.

Results

During the 10-day STM, 13 patients with inguinal hernias were eligible for the study and all consented to participate. After providing consent for the study, we audio recorded the clinical informed consent process and the face-to-face survey administration. Median patient age was 53 years (interquartile range, 39–59). The majority of patients were men (69%), had no education beyond primary school (85%), and did not earn a consistent income (69%). Demographic characteristics are summarized in Table 1.

Informed consent content

Visiting physicians clearly conveyed all 4 relevant risks in 10 out of 13 clinical encounters (77%) and attempted to state all 4 risks in Spanish in 6 out of 13 encounters (46%). Interpreters translated all 4 risks to patients in Spanish in 2 out of 13 encounters (15%). Physicians and interpreters worked in combination to translate all 4 risks in 2 out of 13 additional encounters (15%), resulting in all 4 risks being presented in Spanish in 10 out of 13 encounters (77%). Among the 3 encounters in which all 4 risks were not stated, 3 out of 4 risks were delivered by physicians and translated into Spanish by physicians or interpreters. In the face-to-face survey immediately after the preoperative clinical encounter, no patient was able to recall all 4 risks. Eight patients could not recall any risks, 3 patients recalled only 1 risk, 1 patient recalled 2 risks, and 1 patient recalled 3 risks. Therefore, we identified no cases of completely successful informed consent among 13 encounters.

Visiting physicians clearly conveyed individual risks in 49 out of 52 of all possible opportunities (94%; 4 risks communicated to 13 patients) (Table 2). Visiting physicians delivered 40 out of 52 risks in Spanish (77%). Interpreters translated 22 out of 52 of all risks in Spanish (42%). Every risk that had been mentioned in English was presented to patients in Spanish either by visiting physicians, interpreters, or both. During the face-to-face survey, patients were able to name or repeat only 8 out of 52 individual risks (15%).

The following exchange was typical of patient recall in the face-to-face survey (italics indicate translation from Spanish):

Interpreter: *"Do you remember if there are complications that can occur after the surgery?"*
Patient: *"No."*

Table 2
Frequency of successful risk communication.

	Statement of risk by physician (reference group) N (%)	*Translation of risk by physician N (%)*	*Translation of risk by interpreter N (%)*	*Recall of risk by patient N (%)*
Risk				
Bleeding	13	12	5*	2*
Infection	13	12	5*	2*
Recurrence	12	9	6*	3*
Chronic pain	11	7*	6*	1*
Total	49 (94)	40 (77)	22 (42)	8 (15)

Total risks are reported as a percentage out of 4 risks delivered in 13 encounters (52 total).
*$P < .05$.

Interpreter: *"They told you downstairs, do you not remember of any?"*
Patient: *"No, they didn't tell me."*
Interpreter: *"Do you understand it, or do you not remember?"*
Patient: *"I didn't understand."*

Informed consent process

Salient qualitative themes were categorized as relating to the physician, interpreter, or patient (Table 3) as follows.

Language limitations

Major limitations in physician Spanish language skills became apparent as all participating physicians attempted to speak Spanish during the informed consent process, despite the presence of an interpreter in all encounters. Communication limitations were revealed by interruption of the consent process to request assistance in translation, the use of broken or "pidgin" Spanish, and misuse of Spanish terms.

Verbal domination

Physicians were noted to verbally dominate consent conversations by delivering large volumes of information regarding risks, sometimes combined with instructions, without pausing to allow time for translation or patient questions. In 85% of encounters, physicians delivered "risk boluses," defined as statement of 2 or more risks without pausing to allow time for translation or patient questions.

Mistranslation

Mistranslated or incompletely translated risks were a common phenomenon and occurred to some extent in most clinical encounters. Interpreters mistranslated or incompletely translated risks 45% of the time a risk bolus was delivered.

Teach-back technique

Some interpreters used a teach-back technique as an effective method of risk communication. This was characterized by asking patients to repeat the risks immediately after they were conveyed during the clinical encounter.

Restricting communication

Some interpreters limited or restricted patients' opportunities to communicate with physicians by interrupting, asking leading questions, and responding to physicians' questions for the patient.

Limited patient speech

During the clinical encounter, patients spoke very little throughout the informed consent process to ask questions or clarify risks, uttering only 5.1% of words spoken. Rather than inquiring about risks, patients more typically asked questions about the practicalities and instructions related to proceeding with surgery.

Table 3
A joint display of thematic processes and limitations of informed consent during the clinical encounter (italics indicate translation from Spanish).

Theme	*No. of encounters*	*Subthemes*	*Example quote*
Language limitations	11/13	Requesting assistance	(From clinical encounter)
		Use of broken/pigeon Spanish	Physician*: "Is one more risk—because there are intestines in your scrotum, that after surgery is very possible that there is liquid in your scrotum, that liquid is like your intestine now, is very*...how do you say 'similar'? *Is more, very similar to the liquid in the intestine after surgery, but with weeks, liquid outside and scrotum small"*
		Misuse of Spanish terms	(From survey)
			Interpreter*: "She says downstairs they explained the problems that you could have after the surgery, can you describe some of them? What did they say to you downstairs? Can you repeat some of those problems? Do you remember?"*
			Patient*: "They said that I was leaking from my intestine."*
Verbal domination	12/13	Risk bolus	(From clinical encounter)
		Mixing instructions and consent	Physician: *"With surgery, we expect that surgery is to remove the pain and the hernias, it's a very safe surgery, it is very common. Few risks of surgery, okay. One risk is a little bleeding, usually very very little. Another risk is a possibility of infection to the skin or the mesh. Use mesh to repair, is stronger. Little risk of mesh infection, okay. We give you antibiotics* before...how do you say before...*before the surgery. Another risk is the possibility of the hernia returning, 2% risk in the future, in one or two years*, ok. *Another more risk, usually after surgery you have pain for a week, two weeks. It is possible that some people have pain for one month, two months, one year, but only a percent."*
			Interpreter: *"One percent."*
			Physician: *"One percent, ok. Questions?"*
			Interpreter: *"Did you understand the doctor?"*
			Patient: *"Yes, a little."*
Mistranslation	10/13		(From clinical encounter)
			Physician: "Surgery is possible, tell her I think it'll help some of the pain, but I…it's hard to say whether it will take away all the pain. Sometimes there are other things that can cause pain." Interpreter: *"The doctor says they will do the surgery and you will have some pain after the surgery, is normal."*
Teach-back technique	1/13		(From survey)
			Interpreter: *"There are two that can happen to you, is a minimum chance but can happen, we have to tell you. You may bleed, the other one is that you can get an infection, understand? So, what are the complications that can happen?"*
			Patient: *"I can bleed, and I can get an infection."*
			Interpreter: *"That's right, that's what we want you to know, that you understand, one always has to know when you are having surgery, what are the complications, what are they doing to you"*
Restricting communication	10/13	-Interruption	(From clinical encounter)
		-Leading questions,	Interpreter: "I guess because it came back, he needs another surgery on the same side." Physician: "Could you ask them?"
		-Responding to physician questions for the patient	Interpreter: "*The reason why you are here is because the hernia came back and you want us to do another surgery."*
			Patient: "*Um, yes, another surgery."*
			Interpreter to Physician: "It came back and they want another surgery done."
Limited patient speech	9/13		
Limited patient recall	13/13	Faith in physician and god	(From survey)
		Sense of concern or of being overwhelmed	Interpreter: *"She told me that when you were downstairs they talked about the risks, can you tell us one of those risks for which you were talking about downstairs?"*
		Confusion of risk and postoperative care instructions	Patient: *"I have faith in God that it doesn't get complicated."*
		Reliance on past/vicarious experiences	Interpreter: "*Were you told or are you aware of any risks that can happen to you afterwards*?"
			Patient: "*Fine, of some danger that he asks about maybe."* Interpreter: "*But do you know?"*
			Patient: *"At least once you get the surgery, no lifting"*
Coping with risk information	7/13		(From clinical encounter)
			Physician: "*The third risk is your hernia comes back, is a problem of 1 out of 100, to do this surgery if is come back, is a problem that is possible to need surgery in the future, but is a small risk.* Ok?"
			Patient: "*So, what I understand is that the hernia can repeat itself."*

Limited patient recall of risks

During the follow-up survey, we found that patients had limited recall or comprehension of the risks conveyed during the clinical encounter, as evidenced by 3 common subthemes. First, when queried regarding risks, patients commonly could not answer and instead expressed faith in physicians and in God. Second, some patients expressed concern or a sense of being overwhelmed after the detailed iteration of surgical risks and later sought reassurance that their surgery "would not be too dangerous." Third, many patients seemed to confuse or conflate discussion of potential risks with the instructions for postoperative care.

Coping with risk information

Some patients coped with risk information using a method analogous to the teach-back technique, where they restated a risk immediately after it was conveyed to them. Some also used past or vicarious experiences to place the risks and benefits of their surgery into context.

Discussion

To our knowledge, ours is the first study to critically evaluate the limitations of obtaining informed consent in the setting of an STM. Our results indicate that shortly after the informed consent conversation, physician communication of risks did not consistently result in patients' being able to restate these risks, and in fact completely successful informed consent was never achieved. Qualitative content analysis yielded potential physician, interpreter, and patient-level reasons for this failure.

Physicians displayed meaningful limitations in language abilities but often opted to use their own language skills to deliver consent information instead of relying on available interpreters. This practice resulted in frequent interruptions to ask for assistance, the use of broken Spanish, and occasional misuse of terms. Although physicians plausibly believed that they were acting in the best interests of patients, their inadequate language skills limited the amount of information that was actually conveyed to patients. Although our data do not provide an explanation for this phenomenon, a previous study of resident physicians reported that trainees found it easier to "get by" without calling a professional interpreter, partly because of convenience and partly because of a desire to practice second language skills.[14] Based on our findings, we recommend that physicians who use interpreters in their home country should plan to use an interpreter during an STM. A common ethical criticism of STMs is that medicine is practiced in a manner that would not be acceptable in a physician's home country.[15,16] We maintain that this phenomenon is related to the broader issue of physician-patient communication, which can be compromised by any combination of language mismatch, use of jargon, cultural sensitivity, and patient or family health literacy.

Physician delivery of risks in bolus form occurred in the vast majority of interviews and was often followed by incomplete translations, in which the interpreter only repeated the first of several named risks. Only occasionally did interpreters stop to clarify additional risks mentioned by the physician. Rather than reciting a list of risks, we therefore recommend that informed consent practice include a pause after each risk statement to allow for translation and to answer potential questions that may arise.

We speculate that another barrier to informed consent may be the historical experiences of physicians participating in medical missions. If surgeons who have served on previous STMs perceive that patients tend to speak little and ask few questions about their procedure, it is plausible that some physicians may conclude that a full informed consent will be lost on STM patients. Based on our findings in the present study, we encourage physicians to take the opposite approach—to slow down and spend additional time explaining the consent to ensure adequate understanding.

All interpreters engaged in instances of mistranslation, incomplete translation, and side conversations not translated to physicians. Standards of practice for physicians working in partnership with interpreters include speaking in short sentences followed by pauses and insisting on sentence-by-sentence translation to limit side conversations.[17] Because few formally trained interpreters may be available in the resource-poor setting of STMs, participating physicians and interpreters should establish baseline expectations regarding translation practices. Cultural sensitivity and tact are particularly critical when bilingual local health care providers are serving as designated interpreters. Although such interpreters are fully trained providers capable of obtaining their own informed consents, they may lack understanding of aspects of procedures performed by the visiting team.

In addition, although interpreters were present for all encounters, they were sometimes covering multiple clinics and were needed to translate elsewhere immediately after the research encounter. They may have felt rushed to complete the informed consent process and postoperative survey to move on to their next assignment. Thus, interpreters may have intentionally or unintentionally hurried the informed consent process or survey assessing understanding, limiting the amount of information conveyed or recognized, to provide services for more encounters. Such a problem could be exacerbated on medical missions with fewer available interpreters. We maintain that interpreters should be considered a vital part of every STM and every effort made to ensure that they are available as needed.

Although patients' ability to recall or rename risks delineated throughout the consent process was surprisingly low, 85% of respondents had a primary school education or less. Prior studies have found that low education correlates with low health literacy levels and that health literacy predicts patient understanding of informed consent information.[18,19] The low level of patient education found in this study is likely representative of STMs in general, underscoring the importance of delivering information in a fashion that is easily comprehensible. One particularly effective technique noted in this study and others[20,21] was a teach-back or restatement technique, in which interpreters asked patients to repeat a risk back during the informed consent process to confirm understanding. We recommend that physicians participating in STMs use this and other well-documented strategies, including pictorial representation of risks, to improve risk comprehension in patients.

Our study has several limitations inherent to qualitative and mixed-methods research. First, the small number of encounters and single location at an isolated medical mission in Guatemala limits the generalizability of our findings. Our goal, however, was to obtain and analyze primary, real-time data regarding informed consent in this well-established STM setting, and we achieved thematic saturation in fewer than 10 encounters. Future work could potentially validate the generalizability of our findings with a broadly representative survey. Second, patients may have actually comprehended and even recalled the risk information but felt uncomfortable speaking it. Although it is impossible to completely know their thoughts, we attempted to limit this possibility by asking about risks and potential complications during open-ended survey responses in a variety of ways. Third, physicians, interpreters, and patients may have been influenced by the presence of the audio recorder during clinical encounters. Our extremely low frequency of successful informed consent, however, supports little to no influence of audio recording on this study's outcomes. Fourth, as in any research study, it is possible that our data interpretation were biased. To mitigate this, we used several accepted techniques to establish validity in qualitative research.[22] Finally, it is possible that despite using an official bilingual medical tran-

scriptionist from the region to translate and transcribe the data, there may have been errors in the transcription. To limit this possibility, we listened to all audio recordings while reading the written transcriptions and found no errors.

In conclusion, in this novel study we directly assessed the process and limitations of obtaining informed surgical consent in the STM setting. We found that significant deficiencies exist in the STM informed consent process, leaving patients with limited understanding of the risks of surgery. Through qualitative analysis, we identified multiple themes related to the quantitatively identified poor patient recall and comprehension of surgical risks. Most themes centered on different types of communication lapses on the part of physicians and interpreters. Based on these findings, we have offered several potential strategies for physicians to adopt when delivering informed consent during STMs, including the following: (1) use of interpreters for physicians not fully fluent in Spanish, (2) statement of risks in a 1-by-1 fashion followed by pauses; (3) establishing ground rules for physician-interpreter partnerships before the clinical encounter; and (4) use of well-established techniques to enhance patient understanding in populations with low health literacy, including teach-back methods or restatement. Taken together, our data indicate a critical need to investigate methods that improve the process and content of informed consent practiced in the STM setting.

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