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PERSONAL VIEW

Informed consent: who are we informing?

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ABSTRACT:

Communication is the foundation of informed consent in research. This article relays the reflections of an American urogynecology fellow and researcher in Kenya on the topic of informed consent. After learning of how a previous foreign researcher's presence in the community had violated the trust that women placed in women's health research, she reflects on how the standard eurocentric approach to obtaining written informed consent in research may sow breakdowns in communication and also perpetuate distrust in research. Particularly for settings in which the language is primarily spoken, or where there are varying literacy levels, the standard research consent should be reimagined to make the informed consent process more equitable and less of an exercise in documentation. Communication of research study information to patients must take into account the diverse and evolving ways in which patients best consume information, and in such a way that it ultimately enhances their autonomy.

Keywords:

global health, health literacy, informed consent, Kenya, women's health.

FULL ARTICLE:

Since April this year I have been conducting research in western Kenya. The project is aimed at evaluating a new set of illustrations to assess for symptomatic pelvic organ prolapse and urinary incontinence. It is an early step in the process of understanding the burden of pelvic floor disorders in Kenya, and informing strategies to better diagnose and treat patients with these conditions. As part

of the study, we are asking patients presenting for outpatient care to tell us whether they have the symptoms represented in different illustrations of prolapse, urgency urinary incontinence and stress urinary incontinence. Then, to determine whether the patient clinically has symptomatic prolapse or urinary incontinence, we speak with the patient about her symptoms and perform a brief pelvic exam. Study participation takes about 15 minutes and patients are compensated the equivalent of US$5 for their time, which is the accepted norm for the region.

I myself am a third-year urogynecology fellow from the USA. While this is my first time in Kenya, it is not my first time in East Africa, as I previously spent 9 months in Malawi as a research fellow during medical school. I am phenotypically a *mzungu* (a Swahili word used to refer to white people). As I make my way through a crowded outpatient patient waiting area on my first day of field work I am reminded of a familiar, disquieting awareness that I had as a medical student. As a *mzungu,* I am an outsider, and a walking symbol of privilege.

From the study's start, we have been plagued by exceedingly slow recruitment, primarily related to patients declining to undergo a pelvic exam, particularly at one of the sub-county hospitals we are recruiting from. My Kenyan co-investigators and I have been perplexed by the slow recruitment rate. However, recently the local research assistant relayed to me that she was explaining the study to a patient, who was initially agreeable to all components including the exam, until she asked whether the *mzungu* would be the one performing the exam. When the research assistant confirmed that I, a *mzungu* gynecologist, would be performing the exam, the patient declined participation. When asked why, the patient recounted a story that happened 2 years ago, when she participated in another research study conducted by a different *mzungu*. When it came to the pelvic exam, she was surprised when the *mzungu* began to take pictures of her genitalia. After feeling violated by that unexpected portion of her study exam, she was not interested in participating in further studies with *mzungu*s. Another woman in clinic that day, in agreement, recalled a similar story.

This justified distrust in research is something that I, a *mzungu*, would not be able to repair during my brief presence in Kenya. Why would the previous researcher have taken pictures of the patient's genitalia? Was the genital picture used to report pathology? Or were the pictures a component of the study itself – like testing a smartphone-based diagnostic application? If either case were to have been true, I could imagine somewhere deep in the institution review board consent form the fact that a camera was to be used may have been mentioned. However, even if the impending presence of a camera *had* been buried somewhere in the consent document that the patient signed, did that ultimately matter if it wasn't communicated to the patient in a way that was crystal clear to her? Surely the patient had signed the requisite consent form document prior to participating in the *mzungu*'s research study. But what did 'informed consent' actually mean in this scenario if she did not understand even the most basic components of study participation?

The official languages of Kenya are English and Kiswahili. However, Kisumu, a port city in the western region of the country, is in a region inhabited primarily by the Luo ethnic group, and where the dominant first language of many inhabitants is Dholuo. Dholuo is a Nilotic language spoken by about 4 million Luo people of Kenya and Tanzania, and is not related to the Bantu language of Kiswahili. And, unlike Kiswahili, Dholuo is principally a spoken language. Therefore, while a primary Dholuo speaker may technically be able to read and write in Kiswahili, they may not easily be able to do the same for their own primary language. This begs the question: What value does a five-page written Dholuo consent document hold for a primarily Dholuo-speaking patient? And even if that patient *could* technically read and write in Kiswahili, is it reasonable to expect that the cognitive burden required to sift through a long document in a second language would lead to equitable access to informed study participation?

The quintessential research study consent document contains pages upon pages of 'patient-friendly' pseudo-legalese that seems designed more to please a gatekeeping review committee and protect the participating institutions than to actually make the study's aims, procedures and risk/benefits clear to the participant. Many times in the USA, after explaining to a study participant, in their native language, the study aims, risks and benefits, and giving her 'as much time as she needs to review the official consent form', I have seen her quickly scroll through an excruciatingly long consent form, only to immediately sign her name at the bottom, trusting *me*, the physician, to have given her all the information she needed.

Of course, we are all taught that informed consent in research is not merely a 'document' but a *process*. But, at the end of the day, it's a patient's signature at the end of a 2000-word document that is required to proceed, and it is one that may not be fully read. Even as a professional, I can easily empathize with this experience given my own scrolling of countless 'terms and conditions' in which I have at the end surely agreed to share my personal data without so much as reading a word.

The irony of our particular study in Kenya is that we aim to replace written survey questions with illustrations depicting urinary incontinence and pelvic organ prolapse to assess pelvic floor symptomatology. However, prior to study participation, we must present to each potential participant a lengthy written consent form explaining the risks and benefits of participation in a research study that is precisely designed to challenge the utility of long-winded written language documents. The overwhelming emphasis placed on informed consent relative to any other part of the research process speaks to a question recently raised by Couper and Worley: What does research participation actually mean, beyond merely the act of providing informed consent?[1].

Since the creation of the Nuremberg Code in 1945 and the Declaration of Helsinki in 1964, the assurance of voluntary 'informed consent' has become the ethical cornerstone of any study protocol. Indeed, inclusion of a thoroughly descriptive, multi-page patient consent document has become an

unquestionable component of the institutional review board submission process. Do we, with our zeal to aspire to the ideals laid out in these historic policies, overlook the diverse ways in which patients best consume the information they require to fully exercise their autonomy?

Unless the answer to this question is a resounding 'no', it may be time to reimagine the traditional approach to obtaining voluntary consent to participate in research. To start, the eurocentric approach to the standard written consent form must be reimagined. Participants with low literacy skills should not be asked to muddle through a written document that is not immediately comprehensible to them. If the patient's primary language is principally a spoken one, forcibly translating the consent form into an 'acceptable' written version of the local language may satisfy the institutional review board, but likely not the participant's comprehension needs. In both scenarios, we should be challenging the notion that a potentially vulnerable individual has ever been adequately informed.

Some progress is being made at some institutions with the introduction of concise summaries at the beginning of consent forms, efforts to use plain language, and use of the teach-back method to ensure patient comprehension. However, the pace of progress remains slow and far from transformative, and vulnerable adults with diverse literacy skills remain responsible for the content of a verbose document that has remained unchallenged for decades. The relatively scant recent literature in enhancing the research-informed consent process describe the use of multimedia aids for informed consent, such as tablets, videos and websites, for which facile access to internet and electricity are prerequisites[2-4]. A more likely practical adjunct would be that of graphic aids, which have been studied for use with medical and surgical procedural consent forms[5,6]. A graphic procedural consent adjunct depicting the steps of a bronchoscopy in comic-book form was found in a randomized trial to improve patient satisfaction[6]. This is a potentially fruitful avenue for research consent purposes that merits investigation, as the brain can more easily process and remember pictures than words, likely owing to more elaborate neural encoding mechanisms[7].

Until the current consent process is transformed, a consent document should, at minimum, consist of concise, easily digestible bullet points of the study's aims, risks, benefits, and procedures – rather than directly forcing all informed consent to be conveyed in a descriptively written version of the spoken language. A version of this, the Short Form consent form, which aims to present the major points of the research study and rely on verbal explanations from the research personnel, does currently exist. However, its use is limited to rare cases in which a full consent document translated in the language of the potential participant is not available. Rather than being an exception for when a lengthy consent form is not available, these should become the standard and could be further augmented with the inclusion of graphic aids, such as illustrations of what study procedures would entail.

During review of the consent form, research personnel should verbally convey the details of all the important points related to the research study in the patient's primary language prior to obtaining documented consent (be it by signature, fingerprint, or any other culturally accepted forms of documentation). Short Form consent forms that are primarily communicated verbally may even prove useful in settings in which the language *is* both spoken and written, but where the patient's educational background may preclude easily digesting cognitively burdensome consent language – such as in the USA, where 54% of adults lack proficiency in literacy, reading at below a sixth-grade level[8]. With such an approach, one might observe that the research study consent has finally become a true *process*, rather than a documentation exercise.

As for the previous *mzungu* researcher in this case, I do not assume that the patient's horrible experience was the result of a mere miscommunication related to a faulty consent process. However, damaging miscommunication (or more nefarious misconduct) can potentially be prevented by meaningfully engaging members of the very groups we are researching as co-researchers who are able to not only help safeguard their community, but also improve the science being conducted. Journals can also help to institutionalize this practice by committing to reject articles that do not include local author representation, as has recently been declared in a joint statement by *Rural and Remote Health*, *Canadian Journal of Rural Medicine* and *Australian Journal of Rural Health*[9]. Key to the success of such policies will be *meaningful* engagement and acknowledgement, rather than token authorship.

It is ultimately not my place to attempt to justify or explain the prior *mzungu* researcher's actions. But the patient's story underscores our responsibility to consider how, even with the most enlightened of intentions, we can unknowingly perpetuate a well-founded distrust in *mzungus* and in research, wherever it takes place. To keep from perpetuating this distrust, we *mzungus* must be willing to introspect and ask ourselves uncomfortable questions when engaging in global health research. Most importantly, we must continuously examine our approach to our conduct of research, and contemplate *how*, not *if,* we can do better.

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