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Perspective

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Ethical issues in the use of SMS messaging in HIV care and treatment in low- and middle-income countries: case examples from Mozambique

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ABSTRACT

The introduction of mobile communication technologies in health care in low- and middle-income countries offers an opportunity for increased efficiencies in provision of care, improved utilization of scarce resources, reductions in workload, and increased reach of services to a larger target population. Short message service (SMS) technologies offer promise, with several large-scale SMS-based implementations already under way. Still largely lacking in the research literature are evaluations of specific ethical issues that arise when SMS programs are implemented and studied in resource-limited settings. In this paper, we examine the ethical issues raised by the deployment of SMS messaging to support patient retention in HIV care and treatment and in the research conducted to evaluate that deployment. We use case studies that are based in Mozambique and ground our discussion in the ethical framework for international research proposed by Emanuel et al., highlighting ethical considerations needed to guide the design and implementation of future SMS-based interventions. Such guidance is increasingly needed in countries such as Mozambique, where the local capacity for ethical study design and oversight is still limited and the scale-up and study of mHealth initiatives are still driven predominantly by international collaborators. These issues can be complex and will need ongoing attention on a case-by-case basis to ensure that appropriate protections are in place, while simultaneously maximizing the potential benefit of new mHealth technologies.

Key words: ethics, mHealth, Mozambique, HIV, Africa

INTRODUCTION

The introduction of mobile communication technologies in health care in low- and middle-income countries (LMICs) offers opportunity for increased efficiencies in the provision of care, improved utilization of resources, reductions in workload, and increased reach of services.[1,2] A few decades ago, mainframe computers were the only devices capable of performing tasks now carried out with mobile devices such as smartphones and tablets. "mHealth" is a term applied to any medical or public health practice supported by mobile devices to provide health services and information.[3,4] In LMICs, mHealth is being explored to improve access to health care and the quality of health care delivery. In these settings, the allure of mHealth is heightened by ongoing challenges related to limited infrastructure, human resources, and the burden of communicable and noncommunicable diseases.[2,5–8]

Short message service (SMS) messaging has a maximum length of 160 characters and is an inexpensive means of communication.[9]

It is especially suited for interventions aimed at improving patient adherence to prescribed medication regimens and retention in care through reminders and motivational messaging.[7,10,11] Some studies have found that SMS messaging improves retention in antiretroviral therapy (ART),[5,7,12,13] while others have shown that success is dependent on the way in which it is implemented.[14,15] Despite variable reviews, the World Health Organization has endorsed SMS messaging as a tool to support retention in ART services.[16]

To date, studies of SMS messaging have mainly been pilot studies focused on operationalization rather than outcomes.[17–20] Still largely lacking in the research literature are examinations of specific ethical issues that arise when SMS programs are implemented and studied in limited-resource settings. We examine a number of ethical issues raised by deployment of SMS messaging to support HIV services and research into their deployment. We use Mozambique case examples to ground our discussion, and highlight ethical considerations needed to guide the design and implementation of future SMS-based interventions.

CASE EXAMPLES

Two examples of SMS messaging projects implemented in Mozambique to improve the retention of HIV-positive patients in treatment are presented below to illustrate a number of ethical issues raised by the technology. These cases were drawn from manuscripts in the published literature that are freely accessible online.[21,22] The authors of this paper were not involved with the implementation of either project or otherwise connected to the implementers in any way.

Example 1[21]: The first description is a 2014 pilot study involving volunteer case managers based at clinics that offer HIV care and treatment services in Sofala Province, Mozambique. These community-based volunteers were each provided with a cell phone purchased by the program, and the pilot included sending confidential SMS messages with information about patients who had missed medical appointments. SMS messages sent to the volunteers included the patient's name, gender, presumed location, length of time defaulted, and contact information. This pilot project used a cloud-based server that kept track of this information and allowed volunteers and clinic staff to document whether the patient was located and the date the patient returned to clinic, if applicable.

Data used to generate the lists of missing patients were collected from both clinical and pharmacy records. Electronic pilot data generated during the project were maintained in a parallel database. Stakeholders in the project included the local provincial health directorate and an international donor agency, program implementers from an international nongovernmental organization (NGO) supporting HIV care and treatment in the province, and the technology firm that supplied the SMS messaging service. This pilot was implemented in the context of a research protocol, which was reviewed and approved by both Mozambican and US ethics review boards.

Example 2[22]: The second describes a case control study implemented in 2012 in Maputo Province (which includes the national capital). Patients on ART were randomized into either an intervention arm, in which they received automated medication reminders via text message, or a control arm, in which they received standard of care that included contact tracing by lay counselors if they missed medical appointments. Eligibility criteria included being over age 18, being on ART for >15 days, owning a cell phone, and having self-reported literacy in Portuguese.

SMS message content was designed following focus group discussions with ART patients and clinic staff. In order to maintain participants' confidentiality, text messages did not specifically mention HIV or ART. Messages were divided into 4 categories: general messages (welcome and goodbye), appointment reminders, medication reminders, and educational messages. Appointment and medication reminders were timed to be sent 2 and 7 days before the individual's next scheduled visit to the clinic.

Messages were sent using a modem connected to the clinic's cellular network and pulled data from the clinic's electronic health record. Data that were generated through the study were maintained on a secure, dedicated server at the clinic.

Stakeholders in this project included the local provincial health directorate and an international NGO that provided technical support for HIV care and treatment at the clinics, as well as a local cell phone provider that supported this initiative as a public-private partnership. This pilot project was implemented in the context of a research protocol, which was reviewed and approved by the Mozambican National Ethics Committee.

Approach and ethical framework

The Declaration of Helsinki, Belmont Report, and International Ethical Guidelines for Biomedical Research from the Council for International Organizations of Medical Sciences, generally considered the ethical standards for biomedical research involving human subjects around the world, do not address any particular technology or tool that might be used in conducting research.[23–25] Even the most recent guidelines from the World Medical Association and the Council for International Organizations of Medical Sciences are silent on the ethics of using technology to communicate with participants or gather personal health information.[23,25] Nonetheless, their common emphasis on fundamental ethical principles can be extended to mHealth interventions on multiple levels.

To examine the salient ethical issues raised by our examples, we organize our discussion with reference to the ethical framework for international research described by Emanuel et al., which specifically provides guidance for evaluating biomedical research in developing countries.[26] In particular, Emanuel articulated 8 principles and benchmarks that can be readily applied to conduct research on mHealth technologies in LMICs. Four of these principles and their associated benchmarks are of particular relevance to our 2 cases: *collaborative partnerships, scientific validity, fair selection of study populations,* and *favorable risk-benefit ratio*.[26] The other 4, *social value, informed consent, independent review,* and *respect for participants*, while equally important for contextualizing research in developing countries, have more to do with study design and the ethics review process in general, and as such are not discussed here.

Collaborative partnerships

Implementations of mHealth technologies in LMICs usually involve multiple stakeholders and often rely on international donors.[27,28] This is especially true in Mozambique, where 80% of the health sector budget comes from international aid.[2] In both of our examples, SMS implementation and evaluation of its impact depended on collaborations between local and international stakeholders.

In Mozambique, HIV services are largely supported by programs such as the President's Emergency Plan for AIDS Relief and the Global Fund to Fight AIDS, Tuberculosis, and Malaria. Technical support for health information systems, from which SMS messaging systems have evolved, has relied on international NGOs, which initially implemented their chosen systems with few common standards and very little harmonization.[29] This approach often fosters an

environment in which control of the system lies outside of local structures, leading to duplication and fragmentation of efforts, in turn creating interoperability challenges.[2,20,29] Furthermore, donor support is often short-term, making sustainability difficult once the project ends. Dependence on short-term funding may be one of the reasons why many mHealth initiatives do not move beyond the pilot phase into wider adoption.[1,2]

Emanuel's benchmarks call for stakeholders from both the beneficiary and the donor country to become full and equal partners in the research enterprise. A fundamental concern in this regard is the power differentials that arise from differences in financial resources and/or technical expertise. One area where power differentials may be evident is in how different stakeholders interpret the evaluation of a new technology or its implementation. Analysis of SMS messaging projects intended to improve retention in HIV treatment can frequently fall within a gray zone between "research," "program evaluation," and "quality improvement," depending on stakeholder interests. For local caregivers interested in improving patients' access to treatment, questions may arise as to whether the pilot intervention and its evaluation even constitutes research, especially given the additional time and administrative work required for ethics review. Local authorities may seek a community-oriented assessment with broadly disseminated, practical outcomes targeted at generating future funding, whereas academic partners typically prefer outcomes research that can be published in the peer-reviewed literature. Funders want to know whether their investment is well spent, whereas private companies like cellular service providers may seek primarily to increase market share.[30]

Establishing a framework for international partnership from the outset helps to overcome differences in partners' perceptions of their joint work and the effects of power differentials on their efforts to carry out the project.[31] This framework will require data-sharing agreements and assignment of intellectual property rights, as well as a means to determine appropriate authorship and other credits for contributions to the research.[26] The framework that is ultimately established will play a fundamental role in whether programs like SMS messaging systems for HIV retention will be sustainable over time.

Scientific validity

Research on SMS messaging for retention in HIV care and treatment must be conducted so that it ensures the study is feasible within the social, cultural, and political setting in which the intervention is operationalized, and produces scientifically valid results that are suitable for the given setting. As highlighted in the first example, SMS messaging can be implemented in such a way that the data collected related to patient retention in care cannot be readily integrated into other HIV-related health information or medical record systems. Moreover, meeting the dual benchmarks of ensuring that the study design achieves stakeholders' scientific objectives and that participants receive the desired intervention requires program implementers to recognize and assess the additional burdens that a new SMS messaging program may create when monitoring data across multiple systems.

Geographic and related sociodemographic factors must also be taken into account in study design, in light of the different types of infrastructure available to support SMS messaging in developing countries like Mozambique.[32] Rural areas often lack electricity or cellular networks to support 24/7 text message services through which reminders and information can be delivered accurately and on time.[33] In limited-resource settings, acquiring a mobile phone and purchasing cellular credit may be a significant financial challenge, causing some people to share a single device among relatives, friends, and neighbors. This practice not only raises the familiar issue of protecting privacy and confidentiality, it may also compromise the practical assumption that an SMS message will be received by the intended individual. Providing phones to participants using project funds may appear to resolve some of these problems for pilot testing, but in the long term it is an unsustainable strategy for achieving improvements in the local health care infrastructure.

Additional care must be taken when considering disparities in technical savvy between the mHealth designers and the end users. For example, in our first case, one of the pilot's recommendations was to move away from smartphones to a simpler model in order to shorten the time needed to become familiar with the device, as well as to mitigate interruptions caused by electricity outages (the battery life of non-smartphones is longer). Although smartphones are increasingly pervasive in LMICs, some people's limited experience with a given technology may threaten the validity of the data collected and diminish the overall uptake of the given intervention.[6]

Fair subject selection

Emanuel's benchmark for the fair selection of research participants starts with the need to select a study population that ensures the scientific validity and social value of the research to be undertaken. LMIC populations that are least likely to be able to use cellular phones in a manner consistent with the design of many SMS programs are typically less privileged, more vulnerable, and more likely to face significant barriers to HIV treatment generally. Rather than automatically excluding such groups on logistical grounds, this tension requires researchers to design studies that ensure their inclusion and protocols that yield meaningful data on the technology's use in the context of social, political, or economic deprivation.[26]

Justice requires that everyone who meets eligibility requirements be accorded the right to participate in research, free from discrimination based on race, gender, religion, ethnicity, or socioeconomic status.[34] In studies of SMS messaging, it is essential to conduct pre-study assessments that identify vulnerable groups; their barriers to HIV care and treatment; and their strengths, limitations, and needs as study participants. If pre-study assessments are insufficient, vulnerable groups who could benefit from the technology could inadvertently be excluded.[35] In a developing country like Mozambique, which has a disproportionately rural population with little formal education, literacy must be considered in study design to ensure that the large number of illiterate persons within the broader population are not automatically excluded from the study. This issue is illustrated in our second example, where inclusion was limited to those with self-reported literacy in Portuguese. While this criterion was presumably intended to facilitate the study itself, it both limited the findings' generalizability and further marginalized individuals on the basis of a factor that already excluded them from many services.

Implementers of SMS programs must also consider the different languages used by the populations they plan to serve. In Mozambique, much of the population uses one or more of 40 local languages, most of which are not written. Many terms related to mHealth have no translation in these local languages. For Mozambicans who may have only a cursory understanding of Portuguese, plans for a more ethically and practically appropriate study of SMS messaging in HIV care and treatment would assess the languages used by the target population and then devise and test strategies for implementation across language groups. In most cases, barriers can

be overcome by teaching participants how to identify the message of interest, or by using pictorial menus, icon-driven interactions, voice recordings, or other auditory alerts.

Favorable risk-benefit ratio

The benchmark of achieving an acceptable balance between the risks and benefits presented by a study may appear to be straightforward for SMS messaging in HIV care and treatment, given the increasingly common use of mobile phones in developing countries and the significant harms posed by barriers to HIV care and poor adherence to treatment. Potential benefits include convenient and direct communication between participants and clinic personnel, especially for persons living in rural areas or difficult places to reach.[36] In contrast, assessment of the potential risks of any mHealth intervention in which personal health information is transmitted must focus on whether the program safeguards participants' privacy and confidentiality, and whether the risk of exposing personal information is justified.

Collecting, processing, and disseminating information among stakeholders is a major challenge in LMICs, especially when communications deal with sensitive and stigmatized conditions such as HIV/AIDS. As illustrated in both of our case examples, stakeholders involved in SMS messaging projects may include a wide array of individuals and organizations in multiple locations. The use of unsecured phones and new technologies such as cloud servers for data storage, as seen in example 1, often raises concerns about whether appropriate data security measures are in place.[37,38] Additionally, with a cloud server it can be difficult to know the physical location of online data storage. It is not uncommon for mHealth initiatives in sub-Saharan Africa to use proprietary technologies hosted outside a particular country, with study data neither stored nor accessed within the country where the initiative is implemented.[39,40] When local stakeholders do not have full control of the data transmission or storage system, they lack the means to assume accountability in case that information is accidentally disclosed or intentionally leaked.

To minimize the risk of private health information transmitted through SMS being accidentally or intentionally disclosed without participants' consent, studies must incorporate structural and procedural safeguards. It is essential to disclose to potential participants the nature and extent of the information to be collected, whether intentionally as part of the study or unintentionally as a byproduct of the technology. This disclosure should include the fact that cell phones collect and transmit large amounts of hidden information in the form of metadata, which could include location or information about other texts and calls.[41]

While much of the literature focuses the discussion of the risks of SMS messaging on privacy, other risks must be considered as well. For example, a growing reliance on SMS reminders for HIV retention, in a context in which cellular numbers change frequently, documentation of appropriate numbers is frequently poor, or fear of stigma and discrimination are pronounced, may divert valuable resources away from other retention strategies, leading to suboptimal care and an unintended motivation of patients to abandon care.[42]

CONCLUSION

mHealth tools, such as SMS messaging, which are increasingly being deployed in LMICs to improve patient adherence to medication and retention in treatment, hold promise to overcome many barriers to care that make HIV/AIDS such a devastating public health problem. The lack of formal guidance on the ethics of mHealth practices, the sometimes limited role and capacity of ethics review committees in LMICs to evaluate new technologies, and the variable interpretation of whether and when assessment of SMS messaging projects constitutes research make it vital for stakeholders to incorporate ethical considerations into study design. Using the ethical framework for international research described by Emanuel as a guide,[26] it is possible to identify an assortment of ethical challenges in the use of SMS messaging to improve patient retention in HIV treatment and to outline strategies by which collaborative research can enhance ethical practice. These issues can be complex, but the challenges are not insurmountable. Looking to the future, ongoing case-by-case analysis of current practices should contribute to the articulation of best practices and ethical standards for the field of mHealth.

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COMPETING INTEREST

The authors have no competing issues to declare.

CONTRIBUTORS

All authors contributed equally to the design and analysis of the work. EO and TM were responsible for initial drafting of the work. All authors contributed equally to critical revision related to content. All authors agree equally to be responsible for the final content of this manuscript and give final approval of this version for publication.

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