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Informed Consent for Mobile Phone Health Surveys in Colombia: A Qualitative Study

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Abstract

Public health surveys deployed through automated mobile phone calls raise a set of ethical challenges, including succinctly communicating information necessary to obtain respondent informed consent. This study aimed to capture the perspectives of key stakeholders, both experts and community members, on consent processes and preferences for participation in automated mobile phone surveys (MPS) of non-communicable disease risk factors in Colombia. We conducted semi-structured interviews with ethics and digital health experts and focus group discussions with community representatives. There was meaningful disagreement within both groups regarding the necessity of consent, when the purpose of a survey is to contribute to the formulation of public policies. Respondents who favored consent emphasized that consent communications ought to promote understanding and voluntariness, and implicitly suggested that information disclosure conform to a *reasonable person* standard. Given the automated and unsolicited nature of the phone calls and concerns regarding fraud, trust building was emphasized as important, especially for national MPS deployment. Community sensitization campaigns that provide relevant contextual information (such as the name of the administering institution) were thought to support trust-building. Additional ways to achieve the goals of consent while building trust in automated MPS for disease surveillance should be evaluated in order to inform ethical and effective practice.

Keywords

bioethics, informed consent, mobile phone survey, mHealth, non-communicable diseases, Colombia

Introduction

The increasing use of mobile phone technology on a global scale, particularly within low- and middle-income countries (LMICs), constitutes an opportunity to collect and monitor health-related information by interviewing respondents over their mobile phone. Mobile Phone Surveys (MPS) can be used to gather and store self-reported health information in real time, potentially improving the efficiency of data collection, diagnostic capabilities and personalized medical care (Carter et al., 2015). MPS can be conducted through various automated communication modalities, including interactive voice response (IVR) and short message service (SMS). In IVR surveys, respondents listen to pre-recorded audio questions and often respond through pressing numbers on the phone's keypad; in SMS surveys text message questions are sent to the respondent's mobile phone (Gibson et al., 2017a).

Surveys using IVR and SMS may be relatively affordable and provide advantages over traditional face-to-face surveys for frequent and large-scale data collection in support of public health initiatives (Gibson et al., 2017a; Pariyo et al., 2017). These surveys may provide increased access to individuals in physically hard-to-reach areas or across conflict-stricken regions (cf. Firchow & Mac Ginty, 2017). As such, active evidence generation is underway to refine and validate approaches for MPS, including to enhance population-level public health surveillance of non-communicable disease (NCD) risk factors in LMICs (Gibson et al., 2017b). Parallel discussions are occurring with respect to the ethical requirements associated with such surveys and other related uses of mobile phones for

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health data collection to support responsible digital health practice (Ali et al., 2017; Doerr et al., 2017; Parker, 2012).

Those conducting MPS should be aware of several potential ethical and regulatory challenges (Ali et al., 2017), which include appropriate navigation of respondent consent. Internationally recognized ethics standards highlight four core elements of informed consent: capacity to consent, information disclosure, comprehension, and voluntary authorization (Declaration of Helsinki, 2013). Challenges associated with satisfaction of all four elements are well described in "traditional" research contexts and can potentially be magnified for remote mobile and digital health data collection (Moore et al., 2017).

Given inadequate and unclear ethics guidance for MPS practice, and lack of documented preferences for consent at the community and country levels (Ali et al., 2017), there is a need to capture the attitudes and practices of key stakeholders, particularly those conducting and responding to MPS, to inform ongoing and future digital health activities. We report here the findings of a qualitative study that sought to identify the critical elements to consider when consenting potential respondents for participation in a MPS of NCD risk factors. Information was derived from expert key informants and community members (i.e., potential MPS respondents) and focused on informed consent for large-scale IVR- and SMS-based NCD risk factor surveys in Colombia. In this study, we explored: (1) general opinions related to MPS consent, (2) information disclosure, (3) understanding, (4) voluntariness, (5) mode of authorization, (6) data security considerations, and (7) technological illiteracy and other relevant considerations. We hope this research will support future optimization of MPS consent process for health data collection.

Background

In this section we briefly summarize some of the challenges raised in the literature related to informed consent (content and process) in the context of MPS. Traditionally, adequately securing a potential respondent's consent to participate involves: (1) ensuring that the potential participant possesses the capability to give consent; (2) presenting information with adequate detail to enable, among other things, an appreciation of the potential benefits and harms that can be reasonably expected to result; (3) facilitating respondent understanding of this information, and, when necessary, verifying comprehension and correcting important misunderstandings; and (4) ensuring, to the greatest extent possible, that consent is given voluntarily (Kongsholm & Kappel, 2017; Millett et al., 2001).

Information Disclosure

As a matter of respect for individual autonomy, it is an ethical obligation of those conducting MPS that information considered relevant be offered to potential respondents such that an informed decision about whether or not to participate can be made (Balestra et al., 2016). Respondents should not be overwhelmed with information, but rather should be presented with a clear articulation of key information (Bok, 2017). Not doing so could constitute manipulation (Kongsholm & Kappel, 2017).

Though evidence of effectiveness is limited, it has been suggested that mobile phone capabilities may *improve* the consent process through applications (apps) that provide visual, auditory and tactile information to enable multimedia interaction at ones' own pace, by means of repeated self-directed exploration (Doerr et al., 2017). Along these lines, others have encouraged engagement of mobile technology developers in the creation of apps that have the potential to help respondents comprehend relevant information necessary to consent (Carter et al., 2015). This would of course have limited utility for mobile phone surveys, such as those described in this study, which intentionally do not use smart phone capabilities for consent or survey administration, in an effort to reach a wider range of populations in low-resource settings.

Capacity and Understanding

Disclosure of all information considered pertinent is not alone sufficient (Garrett et al. 2017). In order to satisfy informed consent requirements, respondents ought to comprehend the information offered. Often, consent processes do not verify that subjects are truly informed (Fitzgerald et al., 2002). Acknowledging that both capacity and comprehension are practical presumptions of everyday communicative relations, a challenge for achieving informed consent (in its ideal form) for remote, automated MPS often lies in ensuring that respondents sufficiently understand the implications of given information to make an autonomous decision.

Voluntariness

Voluntariness implies that respondents participate freely, without being subjected to undue influence, force, deceit or coercion (Kongsholm & Kappel, 2017). In the MPS context, according to Ferreira and Serpa (2018), respondents should be informed about incentives, which might be cash benefits or other kinds of rewards. Incentives that are appropriate in type and magnitude are unlikely to interfere with the capacity of respondents to consider their full range of interests when approached to participate in MPS (i.e., they are unlikely to compromise voluntariness); though precise characterizations of the boundaries of appropriate use of incentives in MPS have not been articulated.

Process Challenges

Consent information is too often presented using inaccessible terminology (Marshall et al., 2006; Wilbanks, 2018),

and especially in mobile health (mHealth) contexts, is delivered under great time pressure (Parker, 2012; Wilbanks, 2018). In automated IVR and SMS surveys, where there isn't participant-researcher dialog, ensuring comprehension and voluntariness becomes further complicated because the mode of data collection may not readily accommodate the opportunity for researchers to clarify information or address questions (cf. Balestra et al., 2016). Succinct and simple communications are perceived necessary to secure responses and capture representative data, but consent norms have yet to be developed and current practices and preferences are not fully documented (Ali et al., 2019).

Method

Study Design

This was a qualitative study that employed semi-structured key informant (KI) interviews and focus group discussions (FGDs) to collect participants' opinions on ethical requirements of informed consent for mobile phone surveys. The study was conducted as part of a larger project that sought to develop and optimize MPS to capture NCD risk factor data in Colombia and elsewhere under the *Bloomberg Data for Health Initiative* (Bloomberg, 2019).

Study Population and Recruitment

For the KI interviews, we sought to recruit a range of informants, including NCD researchers, ethicists/Institutional review board members, and technical experts in mobile phone surveys in Colombia. Potential respondents were identified by convenience and snowball sampling for face-to-face interview in Spanish. To identify individuals, members of the study team who had expertise in each of these pre-defined areas identified and contacted potential informants within their professional networks, by email or phone, to invite them for interview. Those who were contacted were also invited to recommend others whose insight on the topic would be potentially beneficial to capture. The informants had affiliations with major Universities in Bogotá, and most also had prior experience conducting or reviewing health surveys administered by or on behalf of the Colombian government.

The FGDs were formed as homogeneous groups with members of the Colombian public. It can be methodologically desirable to have homogeneous groups in FGDs because participants tend to more easily share their experiences and opinions with those they consider similar to themselves (Hennink et al., 2010). Demographic homogeneity within groups was considered relevant due to the characteristics of the problem studied in relation to conceptions about consent and use of mobile phones, as well as to possible differences in technological literacy associated with group characteristics.

FGD participants were identified through convenience sampling and by employing a "snowball" sampling technique. To identify potential participants, the study team contacted community and University leaders with whom we had previous relationships. These leaders helped to identify individuals who met the pre-established inclusion criteria for each group. As individuals were identified they were invited to also refer others. Potential participants were guided to contact a study team member who was then able to provide additional information about the study and inquire further about their interest.

Tools

Separate semi-structured KI interview and FGD guides were originally drafted by researchers from Johns Hopkins University (JHU) with experience in bioethics and digital health and were refined through discussions between the JHU and Pontificia Universidad Javeriana (PUJ) study teams. The two guides covered similar domains (described below) with questions prompts and probes worded differently within each guide to ensure appropriateness to the type of respondent. Both instruments were translated into Spanish and standardized to the specific context where they were applied (Colombia) by PUJ researchers (A.T. and M.R.) before their use. Consent forms were also developed in English and translated into Spanish.

Data Collection

Data were collected from May to November 2018. All KI interviewees were presented with two hypothetical cases that simulated research and surveillance-like MPS, respectively, on NCD risk factors to help contextualize the discussion on consent practices. Interviews lasted approximately 1 hr; KI interviewees were asked about regulatory policies, experiences, opinions and preferences related to MPS focusing on consent processes, disclosures, and modes of authorization.

Following common practices for administering FGDs (Cyr, 2016; Fuller et al., 1993; Wolff et al., 1993), each discussion lasted approximately 2 hr and was led by an interview facilitator experienced in qualitative research and attended by at least one note-taker, who registered central aspects of the discussion and relevant elements of participants' verbal and non-verbal expressions in field notes.

Each FGD included 7–10 individuals and was stratified based on age range (18–25 years and 26–65 years), area of residence (rural and urban areas of Bogotá/from nearby rural towns) and gender.

The participants used their personal mobile phones to complete a standardized MPS on NCD risk factors (demonstration), administered either through IVR and SMS. After completing the sample MPS, FGD participants were asked

Table 1. Demographic Characteristics of Focus Group Participants.

MPS modality	Gender	Age range	Area of residence	*n*
IVR	Female	Young: 18–25 years old	Urban	9
	Female	Adult: 26–65 years old	Rural	8
	Male	Adult: 26–65 years old	Rural	8
SMS	Female	Adult: 26–65 years old	Urban	9
	Male	Young: 18–25 years old	Urban	10
	Male	Young: 18–25 years old	Rural	9

to share their general impressions of MPS, the purpose of the survey they had just taken, the consent section, its disclosure language and specific elements they considered important. The various consent disclosure elements discussed included aims and procedures, potential risks, potential benefits, confidentiality, compensation, further contact authorization, and perceived voluntariness of participation. Participants also provided feedback about their preferences regarding available modes of authorization (i.e., signaling agreement through active vs. passive forms of authorization; and opting in vs opting out of participation).

All KI interviews and FGDs were audio recorded after participants gave their consent. FGD participants were instructed to choose and use fictitious names during the discussion to protect their identities while permitting association of recorded information to individuals.

Data Management and Analysis

After completing all KI interviews and FGDs, all audio recordings were transcribed into Spanish (A.C).

Transcripts for KI interviews and FGDs were thematically coded. The interview and focus group data were analyzed independently by two team members (M.R. and N.F.) according to categories of analysis established largely *a priori* by the study team (King and Horrocks, 2010). Themes from both participant groups were then compared. Specifically, six domains were used to organize findings during analysis: experience with MPS, impressions of consent for MPS, disclosure of information during consent, modes of authorization, modes of disclosure (e.g., pre-recorded audio or text), and remote consent capabilities. These domains tracked the topics around which the interview and focus group guides were structured, and were further specified in a codebook to include several themes that emerged through the process of analysis (e.g., voluntariness, understanding, data security, technological literacy). The themes were applied to help organize and characterize recurrent, consensus or dissenting views among participants.

Representative quotations were identified to illustrate commonly raised and other noteworthy views (e.g., dissenting opinions) within each area, with source-identifiers retained to permit independent and comparative review of perspectives provided across FGDs or between FGDs and KI interviews.

Ethics Statement

This research was approved by the Research and Ethics Committee of the Public Health Institute of Pontificia Universidad Javeriana (Act No. IC-0012) and the Johns Hopkins Bloomberg School of Public Health Institutional Review Board. All KI and FGD participants provided their informed consent to participate and granted permission to have the discussions audio recorded.

Results

A total of 62 individuals participated in this study: nine interviewees and 53 participants across six focus group discussions. KI interviewees represented a range of stakeholder profiles, including four mHealth researchers, two ethics experts and three technical experts in data collection pertaining to NCD risk factors.

Three FGDs focused on IVR-administered MPS of NCD risk factors, and three others on SMS-administered MPS. The FGDs were grouped according to demographic characteristics including gender, age range and area of residence (Table 1).

In the following, we present findings according to FGDs and KI interviews. Results are organized into the following domains, responding to the emerging categories: (1) general opinions related to MPS consent, (2) information disclosure requirements, (3) understanding, (4) voluntariness, (5) mode of authorization, (6) data security considerations, and (7) technological illiteracy and other considerations.

Table 2 organizes key themes from FGDs we considered particularly relevant when designing and applying an MPS. These issues are classified by group according to mode of delivery discussed (IVR or SMS), age range (Adult or Youth), area of residence (Rural or Urban), and gender (Women or Men). An "x" signifies that the concept listed was mentioned by the majority of participants in the corresponding FGD.

Table 2. Focus Group Discussion Key Themes by Mode of Delivery, Gender, Age Range, and Area of Residence.

	IVR			SMS		
Theme	ARW	YUW	ARM	YRM	YUM	AUW
MPS is potentially insecure	x	x	x	x	x	x
It is important to provide the contact information of those conducting the survey to respondents	x	x	x	x	x	x
The concept of "consent" is understood as an autonomous decision	x	x		x	x	x
It is clear, without stating, that participation in the survey is not compulsory		x	x	x	x	
Informed consent is required in a mobile phone health survey	x	x		x		x
Informed consent is required when a mobile phone survey on health is performed by the government	x	x		x		
Belief that incentive negatively affects reliability of survey responses	x					
Preference for SMS mode of delivery		x		x	x	x
Preference for face-to-face survey	x		x			

ARW = Adult Rural Woman; ARM = Adult Rural Man; AUW = Adult Urban Woman; YUW: Young Urban Woman; YRM = Young Rural Man; YUM = Young Urban Man.

General Opinions related to MPS Consent

Some FGD participants defined the concept of *consent* as the ability to "judge their own doings" or to follow their conscience. However, most participants more specifically felt that giving consent encompassed autonomous authorization – having sufficient knowledge about an MPS to make a decision about whether or not to complete the survey and allow those implementing it to use the information provided. There was controversy among FGD participants around the need to secure consent when the purpose of the survey was to contribute to the formulation of public policies. For one young urban woman, consent was required because *"one is talking about certain private life* [matters], *about what one does with one's body on a daily basis, with one's life. Then I think that if those data are going to be used, I have to authorize for them to be utilized"* (IVR - YUW - 02). For one young rural man, use of information without consent *"would be a crime"* (SMS - ARM- 01). On the contrary, other FGD participants from both rural and urban areas pointed out that if the government was administering the survey to inform public policy decisions, it was not necessary to obtain consent. Along these lines, an adult rural man said: *"For me*, [consent] *isn't needed because it's for one's own good, for the own community, for the very people"* (IVR - ARM - 02). Similarly, another rural man said, *"it is not needed* [obtain the consent], *because we have the duty to give it"* (IVR-ARM-05).

Another issue raised frequently by FGD participants was the need to obtain the consent of community leaders. In this regard, participants recognized that there are certain organized groups in which it is necessary to first request the permission of the leader prior to surveying the wider community. An urban woman noted: *"For example, the case of indigenous people, you can't enter, go talk to all indigenous immediately. You must have a previous conversation with the leaders"* (SMS - AUW- 07). Although, if only the leader were to give consent, "*the principle of autonomy would be violated, one of the principles of the freedom, in which each person is free to decide if he wants to be surveyed or not (. . .) not only the leader* [gives his consent], *but also the person who is going to be interviewed*" (SMS - YUM- 07)

Similarly, some KIs expressed that consent requirements may vary depending on whether the MPS was conducted for *research* or for *public health surveillance*.

> [T]*he prospective participant of a research study is subjected to a higher risk than someone who is being observed. (. . .) To a certain extent, there are certain things that could simply be taken automatically to databases because they are identified, and there's record of them (. . .) they should be less strict when monitoring public health problems than for research, totally, if not, there will never be quality data on vigilance and I think that at the population level it gets worse* (KI 6-06).

Information disclosure requirements

When asked what information needs to be presented to potential MPS respondents prior to completion of a NCD risk factor survey, at least 4 of the 6 FGDs agreed in considering that the consent disclosure should include information about the purpose of the survey, confidentiality protections, a contact person for asking questions, and a description of any compensation and/or anticipated social value.

On this last point, in the sample MPS presented to FGD participants, the survey introduction indicated provision of an incentive of COP $5,000 (around USD $2) in phone airtime or data when the respondent completed all responses. However, several FGD participants suggested that the MPS

should only mention the incentive at the end of the survey, not the beginning. The concern being that individuals would proceed quickly through the survey without paying close attention in order to obtain the incentive. As articulate by one respondent from a rural area, incentives may *"keep the results from being transparent, because many people can answer simply to get the job over with, so they will get the reward"* (IVR - ARW - 02).

In terms of social value, a KI said that in many cases, such surveys make reference to the fact that the results obtained will serve as an input for the generation of public policies. But, ethically, it is necessary to actually plan for how research results will be used to inform policy and practice, and conveying this in more concrete and realistic terms to survey participants: "[Saying that the survey results will directly impact public policy decisions] *isn't truthful. There's* [often] *a big gap between the results of the investigation and decision making.* [Researchers or survey sponsors should] *clearly state how results will become policies* (. . .) *for example, we used a strategy that consisted in incorporating the decision makers into the planning process of the research, its development, and its publication"* (KI 6-03).

Understanding

When the MPS about NCD risk factors was demonstrated using IVR and SMS modalities, FGDs participants declared having certain gaps in their understanding of the purpose, the risks and the institution that carried out the survey. For IVR, participants suggested that respondents be given the opportunity to replay the introduction in order to enhance understanding.

Participants went on to discuss whether MPS respondents are likely to comprehend key information disclosures when consent is conducted through brief pre-recorded IVR and SMS messages, and what implications, if any, there may be for satisfaction of the goals of consent. Participants focused primarily on challenges related to not having any way of knowing if consent information was adequately understood. They debated the importance of this for a MPS designed to support NCD risk factor surveillance, and whether it was important to communicate specifically and directly about the voluntary nature of participation.

One informant who conducted research commented that *"it can happen that people don't understand what is being asked of them and, this being a pre-recorded survey, would have them answer without really understanding or, simply, in an offhand way"* (KI 6-04). Another KI mentioned the importance of a clear consent process, noting that *"when consent is formalized, the respondent may know and understand what is being said"* (KI 6-06). Yet another asserted that consent obtained through a pre-recorded MPS *"is not really an informed consent, especially when it cannot be guaranteed that* (. . .) [the respondent] *understood the information"* (KI 6-01). The informant went on to clarify that this did not mean that consent given for all MPS surveys is invalid, just that there may be better ways of conducting consent if the goal is *informed* consent in its ideal form; the type of consent expected traditionally of research.

Voluntariness

Regarding voluntariness, in the FGDs focusing on SMS-administered surveys, it was asked whether the survey introduction needed to include the language: "While we hope you can answer the entire survey you are not obligated to do so." FGD participants largely rejected this proposal and indicated it was clear the survey was not compulsory; it was thought unnecessary to state the obvious. One of the participants went further to indicate: "*Telling me that I am not obliged* [to answer the survey] *discourages me to respond*" (SMS - YUM- 09).

On the other hand, KIs noted that respondents should always be told that they are free to end the survey at any point and discussed the importance of participants feeling that they retain their personal interest in the information they share. One KI who was a mobile phone researcher explained that: *"it is key to make people feel they own that information, I mean, that the results* [of the survey] *are also owned by them and that they're entitled to make use of those results"* (KI 6-03).

Mode of Authorization

When we asked about preferred models for MPS respondents to indicate their willingness to participate (modes of authorization), there was a clear preference for active consent, "Press 1 if you wish to participate. Press 3 if you do not want to participate" over passive consent, "by completing this survey you agree to participate." Active approaches where considered to be laid out in a simpler, more approachable language. As a young urban man said: ". . .*it gives me the option to continue or to say NOT, that is, I have the freedom to choose*" (SMS - YUM- 08). Other participants indicated that a simple active, opt-in such as: "press 1 if you wish to participate" could be even better. A young urban man noted: "*If I don't want to do it* [answer the survey], *I leave. It is not necessary to press a key to say NO, that seems to me irrelevant*." (SMS - YUM- 06).

On the other hand, a KI who was an ethics committee member considered that more passive forms of authorization may be well suited to particular populations, noting:

> [T]*he person who is responding can have some visual impairment, be a senior or have the keypad* [of the mobile phone] *faded away. . . There are plenty of phones that are exclusively used for receiving calls. Then, I think that either by*

> *omission, or by voicing YES or NO*, [a person can grant authorization] (IC 6-02).

An informant further elaborated that it may be useful to differentiate between two aspects when reference is made to the authorization: (1) accepting to take the survey and (2) authorizing particular uses of the information gathered. They suggested posing two different and distinct questions addressing these aspects that could each be answered by a YES or NO within the survey.

However, similar to concerns raised above, it remains a concern among some that regardless of mode of authorization, individuals may not pay close attention to consent modules in MPS.

> *What worries me is that people may not be willing to listen to the consent section, but that they get lazy and then say YES* [I wish to participate and give my authorization], *without listening to it. The purpose of the consent section is that the person genuinely says: YES, I want to take part, because I understand, am informed; and not: look, don't give me all that, I don't really care! That's what happens with information technologies, I mean, you scroll all the way to the bottom where it says: 'To Accept', even though you didn't read any of it* (KI 6-09).

Data security considerations

Trust-related concerns were also commonly raised and believed to be important. KI's discussed the possibility of not being able to reach a representative sample of Colombians given entrenched distrust about phone surveys. In Colombia, there are frequent cases of victims of extortion and fraud through mobile phones.

A young, urban woman expressed that she would not answer an MPS about NCD risk factors even if she was told that her phone number was chosen randomly. She felt that her privacy was not guaranteed: "*if they already have my* [phone] *number, and I get to answer, I would hesitate to take* [the survey]. *I'd feel that it might affect me in the future, or I'd be sent advertisement about something I don't want*" (IVR - YUW - 07). Similarly, a KI with expertise in surveys opined, "*the main challenge* [in MPS] *is a security challenge, of encrypting the information*" (KI 6-09).

Two potential solutions were brought up by the participants that could minimize distrust with MPS. First, to communicate with potential respondents about how confidentiality will be maintained and data management. Second, to have adequate community sensitization campaigns. One KI who was a health researcher suggests that information about the survey should be communicated prior to the phone call, that is "*people should be contacted by a different means* [other than a phone call; e.g., public awareness campaigns that take different forms] *or be offered, once they are reached on the phone, to verify that the interview is secure and real before taking the survey*" (IC 6-08). In the same vein, a young rural man emphasized that, "*if* [the information about the survey] *shows up on radio and TV, on the different means of communication, that renders it much more trustworthy. It gives a greater sense of confidence than an anonymous message. . .* [for example] *it may come from a well-known local university*" (SMS - YRM - 03).

Technological Illiteracy and Other Considerations

While indirectly related to consent, both KI and FGD participants identified several technological considerations believed relevant to the conduct of MPS in Colombia. KIs identified technological illiteracy in certain areas of the country as a challenge, especially among rural populations. In addition, the culture of mobile phone use was thought to potentially influence response rates. For example, one urban woman stated: "*normally people who are in rural areas do not pay much attention to the cellular phone. They have it like to receive important calls. They do not check if they get messages, if they get a strange call, they hang up"* (SMS - ARM - 06).

KIs mentioned additional issues to consider when fielding an MPS of NCD risk factors, several relating to communication and consent. For example, they considered important that potential respondents understand they should respond only if able to do so safely and effectively. For example, if a respondent were driving, they should pull over or decline the survey, or if they are not in an apt state of mind, it would be better to resume at a later point.

Discussion

While the use of mobile phone surveys to support large-scale disease risk-factor surveillance is relatively new to many communities around the world, many have encountered automated and interactive voice and text response systems in other contexts (e.g., bank and mobile network operator hotlines). As such, while IVR and SMS surveys are being optimized for cross application in health research and disease surveillance, there is a meaningful opportunity to engage the public in optimization of consent processes for such surveys. Here we discuss and contextualize the implications of core findings from our interviews and discussions with key informants and members of the public (potential MPS respondents) in Colombia.

Our findings coincide with what is generally reported in the literature in terms of information, understanding and voluntariness as critical elements to consider when consenting potential respondents (Balestra et al., 2016; Bok, 2017; Ferreira & Serpa, 2018; Fitzgerald et al., 2002; Kongsholm & Kappel, 2017; Willbanks, 2018). The belief that respondents tend not to read or listen carefully to consent statements was also evident and amplified by beliefs that

informed consent is characterized by being long and complex (Corneli et al., 2017, Garrett et al. 2017); designed to accommodate legal requirements rather than information meant to promote lay understanding. Additionally, Corneli et al. (2017) found that informed consent documents are extensive because they are full of foreseeable risks and complex study procedures, especially in research related to health.

During the FGDs, we probed about survey information considered important for respondents to comprehend, namely: (i) purpose and procedures, (ii) potential risks, (iii) potential benefits, (iv) confidentiality, (v) compensation, (vi) contact person for asking questions and, (vii) voluntary nature of participation. Consistent with a global survey on ethics and MPS (Ali et al., 2019), while respondents acknowledged the time and format constraints on MPS consent, there was no dominant opinion on what, if any, information should be emphasized during survey deployment. Nonetheless, we found that most respondents hoped that information would be presented in terms that a reasonable person would understand – explanations in simple language and sentences using simple structure. In this sense, it is not necessary to include all possible information in the informed consent to achieve desired results, as has been shown by Garrett et al. (2017) and Corneli et al. (2017).

At the same time, there was clear concern about the consent process in IVR and SMS surveys given the relative ease to consent by simply pressing a button on a mobile phone keypad. As suggested by the KIs and FGDs, this ease may signal a lower priority given to participant comprehension. Indeed, Hunter et al. (2018) warns that mobile device surveys may bear a risk simply because of the ease with which a respondent simply presses a key to agree to provide information that the respondent may not even understand.

Although it is unclear how circumstances affect preferences with respect to the consent process (Simon et al., 2018), we assume the argument of ecological rationality, where choices made often depend on the context in which they are made. Put another way, the decisional context of potential MPS respondents is framed by internal participant characteristics and external factors. These conditions are out of the control of researchers and sponsors, but the consent process should be adapted to these circumstances (Perrault & Keating, 2018).

An important contextual element is trust (Slegers et al., 2015). In our study, the decision whether to respond to an MPS is permeated by trust-related considerations. The apprehension KIs and FGD participants described when receiving a call or text message asking them to participate in a survey was widespread, in light of the fear of data misuse. This is a constant risk that derives from the use of mobile devices (Parker, 2012; Petrini & Ricciardi, 2015). For example, He et al. (2014) presented the deficiencies in the security and privacy of data contained in mHealth applications (cf. Moore et al., 2017). Firchow and MacGinty (2017) have acknowledged that surveys conducted through text messages might leave respondents even more exposed due to the fact that their responses remain in their mobile phones. Therefore, Ali et al. (2019) suggest prior, explicit agreement between relevant primary, intermediate and secondary parties regarding who can access data and for what purpose. This could help improve public trust in the survey methodology.

It is worth noting that, both KI and FGD participants identified that in order to grant authorization in an MPS it is important to know that a well-recognized institution has taken part in the project, such as a reputable University. In Colombia, and perhaps other countries, such Universities are likely to be trusted even over and above government ministries. Kongsholm and Kappel (2017) similarly argue that consent is supported simultaneously, to a greater or a lesser extent, both by the information the person receives and the trust the person has in the researchers or institutions involved.

Therefore, to improve trust in MPS, a core challenge is to establish both consent language and survey procedures that support principles of privacy and confidentiality, even in the absence of legal provisions that may regulate this matter (Ferreira & Serpa, 2018; Simon et al., 2018), while avoiding raising false expectations.

Each community has its particularities. The challenge for consent in large-scale pre-recorded MPS is in balancing an understanding of the informational needs of subpopulations with the practical need to deploy a survey efficiently. Where possible, perhaps information disclosures could be tailored according to respondent age range, area of residence, or other relevant demographic factors. This would of course require prior engagement with relevant communities to better understand consent preferences and additional resources to develop variations on consent modules for MPS that communicate similar core information in locally tailored ways.

This study has limitations. First, it is unknown to what extent the findings from this study can be generalized to other populations outside Colombia.

Second, when the IVR and SMS survey *demonstration* were shared at the beginning of the rural FGDs, mobile network coverage issues became apparent. Some FGD participants were not able to access the survey at all due to poor network coverage, and others were not able to review it in its entirety due to technical issues. This did not have a significant impact as the technology demonstrations were meant simply to ensure participants had a general sense for what an automated mobile phone survey was, the survey content was also made available in paper form, and the discussion facilitator was able to refer to other familiar examples of automated phone surveys to help ensure a uniform frame of reference.

Best Practices

Best practices in regard to informed consent on MPS include giving the respondents simple, clear and relevant information about risk factors related to specific public health problems and potential benefits of participant responses for health surveillance and public policy. Information must be given using clear, simple vocabulary and organized in a way that permits respondent comprehension. While our study identified that some believed it to be less important (or implicit) when MPS is deployed to support disease risk-factor surveillance, the non-mandatory character of the survey ought to be communicated as a matter of respect, if nothing else. Making clear the institutions that will be responsible of analyzing and keeping safe the information collected is also crucial. Incentives ought to be linked to the survey burden, such as providing airtime credit equivalent to the amount of time spent responding to the survey, while being mindful that incentives may contribute to distortion of data quality.

Research Agenda

Further research into the efficacy and understandability of different communicative approaches for consent in MPS among specific communities would be beneficial. Moreover, since the acceptability of MPS significantly depends on respondents' positive perception regarding the trustworthiness of the survey and those involved, procedures that support respondent verification of those administering surveys could be better protocolized. Conducting consent for MPS in a way that facilitates potential participant engagement under circumstances where it is possible to have complete understanding of relevant facts and considerations continues to be an important area for potential software and process innovation.

Educational Implications

Educational frameworks to address the ways in which, in the scenario provided by mobile technologies, confidentiality, autonomy, free will and public trust are particularly challenged, become an urgent demand to ensure ethical and skilled uses of these tools in the field of public health. As this research has suggested, issues such as understanding and intelligibility of information, consent, institutional confidence, community engagement and adequate practices of collecting, storing and using information provided by recipients through mobile devices in particular contexts should be considered in the education of health practitioners and community leaders. In doing this task, combining social sciences, cognitive psychology and bioethics will be particularly valuable.

Conclusion

In practice, consent may be conceived merely as a formal requisite of authorization; however, as is commonly noted, it should be treated as a process (Henderson, 2011; Wilbanks, 2018). For mobile phone surveys of the type described in the study, this implies engagement during and afterwards to develop locally appropriate consent disclosures and facilitate selection of the best method for MPS respondents to signal their authorization. Importantly, our respondents emphasized the need to address inherent distrust – given the automated and unsolicited nature of calls – and believed that relevant contextual information (such as the administering institution being locally respected and explicitly named early in the consent module) may support trust-building. Additional ways to build trust in MPS when deployed for public health purposes should be evaluated.

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Ethics Statement

This research was approved by the Research and Ethics Committee of the Public Health Institute of Pontificia Universidad Javeriana (Act No. IC-0012) and the Johns Hopkins Bloomberg School of Public Health Institutional Review Board. All KI and FGD participants provided their informed consent to participate and granted permission to have the discussions audio recorded.

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