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Electronic Informed Consent to Facilitate Recruitment of Pregnant Women into Research

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Abstract

Methods to obtain informed consent digitally or electronically may increase participation of racially and geographically diverse pregnant women in prospective research, which is essential to improve the evidence-base for maternity care. We evaluated the feasibility and utility of e-consent in the first year of a multi-year clinical trial involving pregnant women. Of 86 women screened, 71 were eligible, 65 (93% of eligible) agreed to review the e-consent form, and 61 (86% of eligible) completed the e-consent process. Of interested women who were sent the e-consent link, all were able to complete the e-consent process, even those who reported low health literacy. Women of all racial and ethnic groups were equally likely to consent, and the sample of consenting women was consistent with practice demographics. E-consent is feasible and easy-to-use with pregnant women and may expedite enrollment of a representative sample.

Keywords

Informed consent; research ethics; research organization and administration; e-consent; electronic consent; digital consent; research administration

There is an urgent need to engage women in perinatal research to expand the evidence base for clinical care. In the past, legal stipulations designed to protect the woman and fetus stifled prospective research involving pregnant women (Blehar et al., 2013; Welch et al., 2015; White, 2015). Although restrictions have been relaxed to allow research with pregnant women following informed consent, strong evidence is lacking to support much of current maternity care (American College Obstetricians and Gynecologists, 2015; Foulkes, Grady, Spong, Bates, & Clayton, 2011). The National Institutes of Health and the United Nations have called for greater ethical engagement of pregnant women in research to improve knowledge surrounding maternal care (American College Obstetricians and Gynecologists, 2015; Every Woman Every Child & United Nations, 2015; Office of Research on Women's Health & National Institutes of Health, 2010). Rigorous research requires representative sampling from the target population; however, researchers often struggle to recruit diverse

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Disclosure

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samples (Frew et al., 2014). To improve perinatal outcomes, women of diverse backgrounds need the opportunity to consent to research participation with minimal burden (American College Obstetricians and Gynecologists, 2015; Every Woman Every Child & United Nations, 2015).

Women receive maternity care at a wide range of facility types that may see only a few pregnant women per day or week, especially in rural areas. While community-based maternal care increases access to beneficial services, it can complicate researchers' abilities to enroll a diverse cohort representative of a broad population without extensive staff (Hale et al., 2016). Women can be difficult to enroll in prospective research during pregnancy if they must meet with research staff in person (Frew et al., 2014), as they are often busy with work obligations and/or the care of young children (American College Obstetricians and Gynecologists, 2015; Rocheleau et al., 2017).

Informed consent is an essential component of research participation (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978; The Common Rule, Ethical and Regulatory Aspects of Clinical Research, 2003). Before participation, individuals or their legal representatives must receive information about the risks and benefits of the study in understandable, non-exculpatory language and then give their informed consent (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978; U.S. Department of Health and Human Services et al., 2003). Unless exemptions are granted, consent must be documented and archived to remain accessible to researchers and auditors (U.S. Department of Health and Human Services et al., 2003).

Informed decisions for research participation are traditionally documented via handwritten signature; however, paper-based documentation of informed consent has limitations and may hamper women's opportunities to engage in research during pregnancy. When paper forms are used, recruitment and enrollment of individuals in research requires trained staff with access to study documents. Movement of paper forms to and from participants is time consuming and may impede normal clinic flow. The current copy of study forms must be available when the woman is ready to learn about and consent to the study. In addition, a member of the study staff may need to be available to answer the woman's questions as she reads the document, which can be difficult in a busy clinic or hospital where space is scarce. Once hardcopy consent documents are signed, staff must move them to secure storage for archiving and ensure they remain accessible to auditors for years.

Electronic documentation of informed consent, also known as digital or e-consent, can improve researchers' abilities to access and enroll participants and aids in auditing (U.S. Food & Drug Administration, 2015). E-consent permits informed consent and study enrollment without having to meet in-person or move a physical document between participants and study staff. E-consent streamlines archiving, improves oversight, and is favored over paper-based documentation by the National Institutes of Health and the U. S. Food and Drug Administration (U.S. Food & Drug Administration, 2015).

One requirement for e-consent is a secure portal, preferably web-based, for maximum availability. One such portal, Research Electronic Data Capture (REDCap), is a secure research platform used by more than 2430 institutions on six continents. Compliant with protection standards for health care and research (Harris et al., 2009), REDCap allows secure digital completion of consent forms, including participant signature, using a touch screen or mouse. Signed forms can then be downloaded or printed. Using REDCap or a similar portal, study documents can be provided to and obtained from participants then shared among research staff, auditors, monitors, and sponsors.

While e-consent may require some participant digital literacy, pregnant women are part of a tech-savvy age demographic. Ninety-nine percent of people in the United States between the ages of 18 and 29 and 96% of those between the ages of 30 and 49 are internet users (Pew Research Center, 2018). Globally, approximately 67% of adults have some form of internet access (Pew Research Center, 2016). Of adults in the United States, 79% have completed financial transactions online, which suggests trust of secure websites (Smith & Anderson, 2016). For individuals who are comfortable with online forms and services, the ability to complete consent documents online at a convenient time and location may promote research engagement.

While e-consent documentation satisfies regulations and may extend access to perinatal research, there are no reports detailing the use of e-consent with pregnant women (Shelton, 2011). The purpose of this article is to report on the use of this new method of informed consent. We detail the feasibility and utility of the use of telephone discussion and e-consent documentation of informed consent in the first year of a prospective clinical trial to provide information to assist other researchers.

Methods

Design

We opted for e-consent when designing a multi-year clinical trial of a new format of midwife-physician collaboration for prenatal care of moderate-risk women. During study design, we planned to recruit women from three nurse-midwifery clinics in the greater Nashville area for a period of approximately 3 years. We selected an e-consent instead of the usual paper consent because women who received prenatal care at our recruitment sites had characteristics consistent with participants in previous studies that showed successful use of e-consent (Rothwell et al., 2014). The women frequently used a digital patient portal, were part of an internet-savvy demographic, and often juggled work and/or child care responsibilities. We also needed an approach to consent that facilitated rapid contact since the clinical trial intervention had to occur soon after participants became eligible.

In order to meet the needs of this population and facilitate access to research, we developed a comprehensive informed consent approach that merged telephone discussion with electronic documentation of informed consent. The Vanderbilt Institutional Review Board approved the consent process and all forms before the start of the study. In this article, we report consent outcomes for the first year (July 27, 2016 – July 27, 2017) of this ongoing

study to expedite dissemination of this method of consent as we have found it helpful in efficiently enrolling a representative sample from our target population.

Digital Consent Process

When women who received prenatal care at one of three recruitment clinics met inclusion criteria for the clinical trial, a nurse or midwife described the study. If the woman was interested and gave permission, the nurse or midwife sent a message within the electronic medical record portal to the investigator, who called the woman to explain the study, screen for eligibility, and discuss risks and benefits of participation (Phillippi et al., 2016). After telephone discussion, a link to the e-consent form was emailed via REDCap to eligible, interested women. The link opened a secure web page containing the e-consent document, an online version of a standard consent form. The form was visible and functional on web-enabled computers, tablets, and smartphones, and all response transmissions were encrypted for security. Hardcopy informed consent forms were available and could be mailed to the potential participant if she desired.

After the link to the e-consent form was emailed, the investigator offered to remain on the phone to answer questions while the woman completed the consent process within REDCap. Alternately, she could complete the consent later if she did not want or was not able to complete the process at that time. For example, a woman could read and complete the e-consent while her child napped. If after reading the study details, the woman wanted to participate, she added her name and age in text boxes and signed the consent form using her mouse or finger. Following completion, she could download or print the signed document. If a woman was sent the link and did not complete the consent, the principle investigator contacted her by phone to see if the e-consent form was a problem and offer an alternative consent process.

If a woman did not want to participate in the clinical trial, the principal investigator had IRB approval to note within REDCap the woman's race and ethnicity as stated within her medical record. If a woman consented to participate in the clinical trial, the online platform immediately asked her to complete a demographic questionnaire, including questions about her race and ethnicity, health literacy, socio-economic status, and social support. We used the 3 question brief health literacy survey validated by Chew et al in 2008 to provide context on the woman's ability to read and comprehend medical information. Information about race and ethnicity was compared against practice-level race/ethnicity data to determine if any groups of women were less likely to consent electronically than other groups.

Results

Of 86 women screened for study participation, 71 were eligible, 65 (93% of eligible) agreed to review the e-consent document, and 61 (86% of eligible) consented electronically (Table 1). Demographic characteristics of eligible women, separated into declined and consented groups, are displayed in Table 1. Our consented sample was consistent with the racial/ethnic distribution of women who received prenatal care at this practice (Phillippi et al., 2016). Of eligible women, all racial/ethnic groups were equally likely to consent to participation after screening. All women who entered the study were able to complete the e-consent process

(N=61, 100%). Of women sent the e-consent link, only one had difficulty with the online system and reported signature problems that were ultimately resolved. Even the 5% of participants who reported only *somewhat* confident in filling out medical forms and the 10% who reported problems learning because of difficulty understanding written material *some or most of the time* on the demographic form were able to complete the online consent document. No one requested a hardcopy form or alternative consent process.

Discussion

Results from the first year of our trial demonstrate that telephone contact and digital documentation of informed consent is a feasible method to generate a representative sample from a target population of pregnant women. We successfully recruited women from 3 clinic sites without on-site research staff. While this demonstrates feasibility at our site, further research is needed at other locations and with other populations.

Digital informed consent meets federal documentation requirements (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978; The Common Rule, Ethical and Regulatory Aspects of Clinical Research, 2003), streamlines study enrollment, and may expedite research involvement for pregnant women. E-consent can facilitate research in which in-person, paper-based informed consent would be impractical, prohibitively expensive, or excessively time-consuming. Digital enrollment processes may increase access to research participation for hard to reach and/or under-recruited individuals. The ease of e-consent process may also make it easier for front-line maternity care workers to assist women in joining research studies. Traditional consent methods often involved an in-person meeting between the women and trained research staff. Having research personnel on-site can be cumbersome in busy, small clinical spaces. Greater use of e-consent techniques could expedite enrollment of women from previously hard to reach sites such as rural areas or clinics with a low volume of maternity care, allowing more nurses and providers to offer research options to the women they serve.

Equitable access to research participation and use of informed consent strategies that meet women's needs are consistent with principles of ethical research (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978) and may be one means to study and address health disparities related to race and geographic location (Blehar et al., 2013; MacDorman, Declercq, Cabral, & Morton, 2016). Equitable enrollment of women from diverse backgrounds across wider geographic locations improves research rigor and increases the likelihood that findings are generalizable (Blehar et al., 2013). E-consent has the potential to extend the reach of prospective research involving pregnant women.

E-consent may also assist individuals with low literacy as the electronic document can be programmed to include optional informational videos or have definitions appear when the mouse hovers over a medical term (Allison, 2017). E-consent can also permit display of different videos based on the race, ethnicity, culture, or educational level of the participant, and customization of information can facilitate understanding and trust, essential components of research participation (Allison, 2017).

While our work demonstrates feasibility and acceptability, rigorous testing could determine if e-consent processes are significantly better than paper-based consents for recruitment of diverse populations and expansion of recruitment in rural or low-volume healthcare environments. One such trial, known as Strengthening Translational Research In Diverse Enrollment (STRIDE), is underway at 3 major US research institutions and will systematically assess differences in equitable recruitment of racial and ethnic minorities between research studies using and not using e-consent processes (Allison, 2017). Until this testing is complete, we recommend that perinatal researchers use consent methods that resonate with the target population.

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Callouts

Callout 1

E-consent permits informed consent and study enrollment without the need to meet in-person.

Callout 2

Telephone contact and digital documentation of informed consent are feasible methods to obtain a representative sample of pregnant women.

Callout 3

E-consent has the potential to extend the reach of prospective research involving pregnant women from diverse backgrounds to increase generalizability of results.

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Figure 1.
Flow diagram of the screening and consent process.

Table 1Demographic characteristics of eligible women who declined and consented to study participation ($N=71$).

Characteristics	Declined (<i>n</i> =10)	Consented (<i>n</i> =61)
		Mean (SD) (N)
Age	---	31.3 (5.1) (61)
	<i>n</i> (%)	<i>n</i> (%)
Number with data	9 (90)	61 (100)
Race		
Multiracial	0 (0)	1 (2)
Black	1 (11)	6 (10)
White	8 (89)	54 (88)
Latina/Hispanic Ethnicity	0 (0)	5 (8)
Number of children in home		
0	---	12 (20)
1 or more	---	49 (80)
Confidence filling out forms independently		
Extremely	---	43 (70)
Quite a bit	---	15 (25)
Somewhat	---	3 (5)
Frequency of problems learning due to difficulty understanding written material		
None of the time	---	44 (72)
A little of the time	---	11 (18)
Some or most of the time	---	6 (10)