JOGNN

METHODS

Electronic Informed Consent to Facilitate Recruitment of Pregnant Women Into Research

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Keywords
digital consent
e-consent
electronic consent
informed consent
research administration
research ethics
research organization and administration

ABSTRACT

Methods to obtain informed consent digitally or electronically may increase the 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 multiyear clinical trial involving pregnant women. Of the 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 the 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 women who consented was consistent with practice demographics. E-consent is feasible and easy to use with pregnant women and may expedite enrollment of a representative sample.

JOGNN, 47, 529–534; 2018. https://doi.org/10.1016/j.jogn.2018.04.134

Accepted April 2018

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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 after informed consent, strong evidence to support much of current maternity care is lacking (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; U.S. Department of Health and Human Services, National Institutes of Health, & Office for Human Research Protections, 2003). For rigorous research, representative sampling from the target population is required; however, researchers often struggle to recruit diverse 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. Although the use of 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) because 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. Before participation, individuals or their legal representatives must receive information about the risks and benefits of the study in understandable, nonexculpatory

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The authors report no conflict of interest or relevant financial relationships.

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language and then give their informed consent. Unless exemptions are granted, consent must be documented and archived to remain accessible to researchers and auditors (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978; Protection of Human Subjects, 2009; U.S. Department of Health and Human Services et al., 2003).

Informed decisions for research participation are traditionally documented via handwritten signatures; 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 require trained staff with access to study documents. Movement of paper forms to and from participants is time-consuming and may impede normal clinic flow. Current copies of study forms must be available when a 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 documents, which can be difficult in a busy clinic or hospital where space is scarce. After hard copy consent documents are signed, staff must move them to secure storage to be archived and ensure they remain accessible to auditors for years.

The use of 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 and Drug Administration, 2015). E-consent permits informed consent and study enrollment without the need to meet in person or move a physical document between participants and study staff. The use of 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 (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 2,430 institutions on six continents. REDCap is compliant with protection standards for health care and research (Harris et al., 2009), and its use allows for secure digital completion of consent forms, including participant signature, using a touch screen or mouse. Signed forms can then be downloaded or printed. With the use of REDCap or a similar portal, study documents can be provided to and obtained from participants and then shared among research staff, auditors, monitors, and sponsors.

Although e-consent may require that a participant have some 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 Web sites (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.

Although e-consent documentation satisfies regulations and may extend access to perinatal research, there are no reports in which the use of e-consent with pregnant women is detailed (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 multiyear clinical trial of a new format of midwife–physician collaboration for prenatal care of moderate-risk women. During the 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 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

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