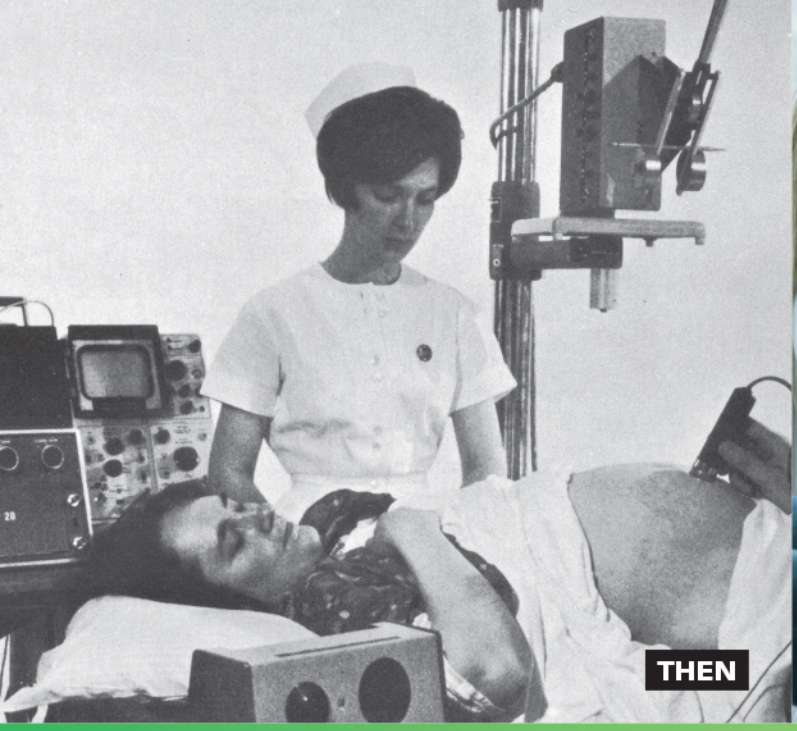

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Reasons Why Pregnant Women Participate in Ultrasound Research Involving Transvaginal Scans

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Objectives—The aim of this study was to explore the motivations of pregnant women in participating in an ultrasound study and the acceptability of vaginal ultrasound examinations.

Methods—A prospective sample of 270 women were asked one question: "Can you tell me what motivated you to participate in the study?" The data were then analyzed through a qualitative thematic analysis with an inductive approach. In addition to the thematic analysis, quantification of the data was performed to enhance the qualitative result.

Results—Through the thematic analysis, 5 themes emerged from the responses of the participants: altruism, research, personal experience, personal benefit, and finding out. All responses were relatively short, and some responses included more than one theme.

Conclusions—Vaginal ultrasound examinations were acceptable to the participants, and pregnant women had many motivations to participate. Regardless of race, ethnicity, or insurance status, the women in our study were altruistic and curious about our research.

Key Words—pregnant women in research; preterm birth; recruitment; research participation; ultrasound research

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Ensuring pregnant women's participation in research is essential to provide evidence-based obstetric care.[1–3] Underlying reasons not to pursue research with pregnant women can be fear of harm to the fetus, legal liability, or uncertainty of the pregnant woman's wish to participate.[4,5] Often there is uncertainty regarding the risk-benefit relationship that hinders inclusion in research, leading to a better-safe-than-sorry approach.[6]

As clinicians, we knew that vaginal ultrasound examinations were acceptable to women. During our years of applying for grant funding, grant reviewers frequently had concerns that pregnant women would not participate in research involving vaginal ultrasound examinations, making recruitment challenging. Our experience has proven that not to be the case. Undergoing a vaginal ultrasound examination has not been a primary reason given by women for declining participation and has never been given as a reason for not returning for a second research visit, which includes another vaginal ultrasound examination. Vaginal ultrasound examinations are a routine part of prenatal care and, as such, are

acceptable to women and usually not painful or distressing.[7–9] To date, we have been successful at meeting our overall recruitment goals.

In this study, the goal was to recruit at least 800 pregnant women over 5 years to evaluate the use of a new ultrasound technology to assess the risk of preterm birth. At the time of this analysis, 270 participants had been recruited out of the 800. The study required recruitment from the following 3 groups of pregnant women: low risk for spontaneous preterm birth (normal); a previous spontaneous preterm birth; and a short cervix during the current pregnancy. Women were considered to have a short cervix if the transvaginal cervical length was 25 mm or less by 18 weeks' gestation. Unless refused, it is the standard of care in our institution that women have a transvaginal ultrasound cervical length measurement performed at the time of their 18-week anatomy scan. Pregnant women with chronic medical illnesses, receiving steroid therapy, who had a fetus with a congenital anomaly, or who received a cerclage were not eligible to participate in the study. Women recruited for the study needed to have 2 transvaginal ultrasound examinations of the cervix at 20 and 24 weeks of pregnancy and to give permission for the research team to access their medical records. Recruitment staff included a physician, certified nurse midwives, and research specialists who were sexually, racially, and ethnically diverse. The sonographers were 2 registered diagnostic medical Sonographers/certified nurse midwives and another sonographer, all of whom were experienced women's health care providers. The aim of this study was to explore the motivations of pregnant women in participating in an ultrasound study and the acceptability of vaginal ultrasound examinations.

Materials and Methods

A qualitative descriptive design[10,11] for this research was used to better understand why pregnant women participated in a study requiring 2 vaginal ultrasound examinations. The combined total time needed for the 2 visits was 45 minutes. Participants were reimbursed $35 for their time per visit. Only women who consented and were enrolled in the study were asked the following question at their initial intake: "Can you tell me what motivated you to participate in this study?" Their responses were compiled by research personnel and entered into a REDCap electronic data capture tool hosted at the University of Illinois at Chicago.[12,13] Six research team members met in person to review all responses. A thematic analysis was conducted, and themes were identified and included once a consensus was reached by the team.

Women were recruited from a large urban teaching antenatal clinic. The study was approved by the University of Illinois at Chicago Institutional Review Board with a Health Insurance Portability and Accountability Act waiver that allowed us to access electronic medical records to identify eligible participants. Pregnant women aged 15 years or older who had a singleton pregnancy and could speak, read, and write English were invited to participate in the study. All research personal were trained on how to approach, recruit, and consent participants. Researchers were aware that this was a vulnerable population and that many of the participants had earlier pregnancy losses and therefore needed to be treated with kindness and respect. As suggested by another study, we found that devoting extra time with the participants, being kind and respectful of both their situation and their time was integral to enrollment and retention.[14] Other research has shown that logistic factors such as childcare and transportation needed to be considered when scheduling participants.[15,16] All research personnel were trained in respectful recruiting practices.[14] After informed consent was obtained, their demographics, contact information, and obstetric history were recorded directly into the REDCap database.[12,13]

Results

In the first 17 months of the study, 270 pregnant women participated. Of the total number of participants, 15 did not respond to the question of why they choose to participate. The mean age $\pm$ SD of the 270 participants was 28 $\pm$ 6.3 years. Self-identified race and ethnicity was as follows: 135 (50%) as non-Hispanic black, 67 (24.8%) as Hispanic, 49 (18.1%) as non-Hispanic white, 9 (3.3%) more than 1 race, 5 as Asian (1.9%), 1 as a Native American, 1 as a Native Hawaiian/Pacific Islander, and 3 as "other or declined to respond." Sixty-two (23%) women reported that they had never been pregnant before.

Concerning their last pregnancy outcome, 78 (28.8 %) women had a prior full-term birth; 33 (12.2 %) had a prior spontaneous preterm birth; 9 (3.3%) had an induced prior preterm birth; and the remaining 88 (32.6%) had a miscarriage, abortion, or stillbirth. Public insurance paid for prenatal care for 178 (65.9%), whereas 88 (32.6%) women had private insurance, and 4 (1.5%) women were self-pay.

Through the thematic analysis, 5 themes emerged from the responses of the participants: altruism, research, personal experience, personal benefit, and finding out. The results are reported as themes by group Risk (Table 1), themes by last pregnancy outcome (Table 2), and themes by parity (Table 3). All responses were relatively short. Since some responses included more than 1 theme, a total of 300 responses were analyzed. Of the 270 participants, 15 women had no response, and 29 women had responses that did not fit into any of the 5 themes. A description of each theme follows.

Altruism

Altruism is a quality in which people focus on someone or something other than themselves. Its root in French means "other people."[17] Altruistic people are often viewed as unselfish and wanting to help. More than one-third (n = 103 [38%]) of the women in this study responded with altruistic reasons for choosing to participate. Many women described "wanting to help," "wanting to help other women," and wanting to "benefit babies in the future." Some women who had a previous preterm neonate reflected that participating in this study was a "way to help other women," and 1 participant related that she "didn't want anyone to go through what she did." She hoped that her participation might benefit not only her but other women as well. Another woman who had experienced a loss due to prematurity also remarked that she "didn't want others to experience a loss like hers." Wanting to help other women, even if they experienced no benefit, was a common theme of women enrolled in this study. In each risk group, altruism was the most prevalent theme. This was also true for both groups in themes by parity. When looking at themes by last pregnancy outcome (Table 3), the only woman in the stillbirth category did not have altruism as a theme.

Research

Research is "the investigation or experimentation aimed at the discovery and interpretation of facts …"[17] When we recruited women for our research, we stated that we

Table 1. Themes by Group

Group	Responses	Altruism	Research	Personal Experience	Personal Benefit	Finding Out	Other Reason	No Response
Normal	203	68	46	19	26	15	19	10
Previous spontaneous preterm birth	86	31	9	18	4	11	9	4
Short cervix	11	4	2	3	0	0	1	1
Total	300	103	57	40	30	26	29	15

Table 2. Themes by Last Pregnancy Outcome

Outcome	Responses	Altruism	Research	Personal Experience	Personal Benefit	Finding Out	Other Reason	No Response
Abortion	42	15	7	4	4	4	4	4
Full-term birth	88	31	17	12	10	4	10	4
Miscarriage	50	15	10	8	5	8	3	1
No prior birth	69	26	20	7	7	3	4	2
Induced preterm	10	2	1	1	1	1	2	2
Spontaneous preterm	39	14	2	7	2	6	6	2
Stillbirth	2	0	0	1	1	0	0	0
Total	300	103	57	40	30	26	29	15

intended to determine whether our new technology would help identify women at risk for preterm birth in the future. Fifty-seven (21%) women stated that they wanted to participate in our study because they were interested in research. Many women stated that they had "an interest in research" and "knew the value of research." Some women had personal experience with research or were researchers themselves. Other women expressed research as a means to the greater good. Women also expressed wanting to generate knowledge and contribute to science in this specific area of research. A respect for research to address the continued problem of preterm birth was commonly stated by the women in our study. Research was the second most common theme overall, except in the participants with a previous spontaneous preterm birth (Tables 1 and 2).

Personal Experience

The importance of having their own experience of premature birth became apparent. Forty (15%) women cited personal experience as the reason they wanted to participate. More commonly, personal experience was their own; however, some cited a family member's or a friend's premature birth as the motivating factor. Some women who experienced a preterm birth did not want to experience it again. One woman stated, "I had 2 preterm baby losses," and other women "knew someone that had a preterm baby that did not survive." Some women stated they did not want others to have losses like they did. Most women who lost a child due to prematurity described their loss but not their treatment. Some women participated in the study because their family member had a preterm infant: "My mom had her babies early," and "Both sisters had babies early." Personal experience with prematurity and loss were strong motivators for participation. For participants who had a previous preterm birth or who were multiparous, personal experience emerged as an important reason for participating (Tables 1–3).

Personal Benefit

Thirty participants responded that motivations included some expectation of personal benefit. Despite careful counseling that no medical benefit was available from study participation, some women nonetheless cited personal benefit as their motivation. Examples of perceived personal benefit included the following: "to support my own and my baby's health"; "does not want preterm baby"; "Mom had her babies early, and I want to help science and concerned about own pregnancy"; "Think I may have baby early"; and "Research wasn't too harmful." Some benefits were not specifically health related but nonetheless tied to the pregnancy: "curious about cervical exam," "like to experience ultrasound," and "see extra pictures of baby." Other personal benefits were not medical in nature but met broader identity needs: "something new for me," and "wants to help, planning on becoming a doctor herself." Three women said the reason they chose to participate was because a partner wanted them to. Some women specifically mentioned money, although often in conjunction with other motives: "wants to help others, a little money helps" and "see ultrasound, diaper money." Although there was no medical benefit to the participant, perceived personal benefit was a motivator to participate in the study. Women who cited personal benefit as their reason for participating were generally in the normal-risk group (Table 1).

Finding Out

Another theme that emerged in the analysis was finding out. Twenty-six women (10%) stated they wanted to find out information from participating in the study. Curiosity or the desire to find out is a behavior that can be considered the basis or driving force in

Table 3. Themes by Parity

Parity (Range)	Responses	Altruism	Research	Personal Experience	Personal Benefit	Finding Out	Other Reason	No Response
Nulliparous (0)	69	26	20	7	7	3	4	2
Multiparous (1–13)	231	77	37	33	23	23	25	13
Total	300	103	57	40	30	26	29	15

human development, and some of the women expressed this curiosity as a motivation. Analysis of the short answers revealed that finding out can relate to wanting the information for oneself, medical science, or the community at large. Some women verbalized a desire for personal knowledge such as those who responded "wants to know results" or "would love to see results in the future." Some of the women had a desire to find out answers for the community at large: "important to find out why women have preterm birth" and "get better information for the future." The drive to find out was a clear motivator for some of the women in this study. Women who cited finding out as their reason for participating were generally in the multiparous group (Table 3).

Discussion

The results of this study provide insights into the many motivations for pregnant women to participate in research requiring vaginal ultrasound examinations. These insights are valuable for the health care team in planning its approach to recruiting pregnant women for research. Themes that were manifested included 3 that appear in the literature, such as altruism, research, and personal experience.[5,18,19] Other themes that were manifested but unexpected were perceived self-benefit and finding out. Knowledge of and about these 5 themes could be beneficial in planning recruitment strategies for future studies.

Altruism

The fact that altruism was the most stated motivation for participating in our study was consistent with the literature.[18,20] During our recruitment we emphasized that 1 in 10 infants were born prematurely,[21] and their participation could help future mothers and infants. Telling mothers about the importance of our study may have tapped into their desire to be altruistic.

Research

Recruiters also discussed the value of our research and research in general. The health care team showed enthusiasm for research in general and the study in particular to encourage those interested in the research process, a motivation stated by 21% of participants. Previous studies[14,16,20] reported that it can be a challenge to recruit vulnerable groups. In this study, 50% of the participants were African Americans and thereby the group with the highest representation and the highest rate of preterm birth. This is consistent with other research[22] showing that this group more than any other ethnic group or race is interested in participating in medical research. African American women have a higher rate of preterm birth than any other race.[21] This could be one reason that these women participated, but it was not confirmed in the thematic analysis. Since this study involved the recording of a short answer to a single question and not an in-depth interview, there may have been many reasons for participation in the study that were not shared with the researchers. With more knowledge, future pregnancies, including the participants' own future pregnancies, may have a better chance of going to term. Having an emotional attachment to the research aim was also described, as was a commitment to the field of research.[20]

Personal Experience

The findings in our study suggest that participants' own relation or experience of preterm birth motivated them to participate, even though most of the participants were considered to have low-risk pregnancies and had no family history of preterm birth. Personal experience could indicate an emotional or empathic aspect of participation. The reason for participation did not seem to depend on their own risk of having a preterm birth, as one other study suggested.[18] During recruitment, women were asked if they had any personal experience with preterm birth or if they knew anyone who had a preterm neonate. In this way, we acknowledged their experiences, which strengthened the relationship with study personnel.

Personal Benefit

It is interesting that despite emphasizing that there was no direct benefit to the mother or fetus during the current pregnancy, many women perceived an immediate personal benefit from participation. Other researchers[5,19] reported personal benefit as a reason for pregnant women to participate in research. Perceived acceptable risk has been cited in the literature as a motivation for pregnant women to participate.[5] The recruiters' perception of a lack of risk may have

affected their willingness to participate. Financial reimbursement for participants' time was a minor motivator, which may have been related to the fact that most of our participants were low income and dependent on public insurance for their care. Other investigators[15,23] also reported that financial incentives were important for recruitment. Investigators, however, do need to be concerned about incentives that may be coercive.[24]

Finding Out

A substantial number of participants were very curious about the results from the study and expressed a desire to read the future publications. Although many studies have shown altruistic reasons for consenting to a research study,[18,23] finding out has not been named as a theme. Finding out could be considered a subtheme of altruism when it involves contributing to medical science, as in the participant statement "help technology and science develop" or "contribute to knowledge in the field."[16,25] Since finding out results as a motivation to participate in research has not been specified as a theme in other studies, it would require more research to see if finding out is a strong motivator for pregnant women to consent to be in a research study.

Other Insights

The relationship between the research team and the participants cannot be overstated. It is important to be considerate, caring, and respectful of the woman's privacy and comfort both during the recruiting process and during the ultrasound examinations. Although not enough to be considered a theme, several participants stated that part of their motivation for saying yes to the study related to the personalities of the recruiters themselves.

As true in other studies,[20,26] our participants often consulted with family members before consenting regardless of their motivations. Whatever the final decision was, many women did not feel comfortable consenting until they had input from family members, including the father of the fetus. There were also women who made the decision alone at the time of recruitment without consulting anyone and instead just informed their family that they were participating. Several women wanted to confer with their health care providers before they decided to consent to the study. Fortunately, there was a great deal of support from the physicians, midwives, sonographers, and nurses in our institution.

Strengths and Limitations

Strengths of our study included the number and diversity of participants. Another strength was that a minimal time commitment was needed by the participants. The research team consisted of staff that were sexually, racially, and ethnically diverse and had excellent support and collaboration from the medical center. Only the answers of women who had already been enrolled in the ultrasound research study were collected. Understanding the women who had declined participation could have led to greater understanding of the phenomenon. Limitations of this study were that all participants came from a single health center, and the motivation for participating in research came from a short answer rather than an in-depth interview. The study was limited to English speakers.

Conclusions

The aim of this study was to explore the motivations of pregnant women to participate in an ultrasound study and the acceptability of vaginal ultrasound examinations. Vaginal ultrasound examinations were acceptable to the participants, and pregnant women had many motivations to participate. Five themes that emerged for motivations to participate were altruism, research, personal experience, personal benefit, and finding out. Regardless of race, ethnicity, or insurance status, the women in our study were altruistic and curious about our research. The women in our study clearly recognized that preterm birth was a serious health care concern. Our results provide a description and insight into the complexities of why pregnant women consent to participate in ultrasound research. Researchers' awareness of motivations can contribute to the development of better recruiting methods and achievement of recruitment goals.

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