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Characteristics Associated With Consent and Reasons for Declining in a Randomized Trial in Pregnancy

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Abstract

Objective: To evaluate the maternal characteristics associated with consent to a randomized trial of labor induction in pregnancy.

Methods: This is a secondary analysis of low-risk nulliparous women randomized to induction of labor at 39 weeks or expectant management. During the trial, the Data and Safety Monitoring Committee requested additional fields on the screening log, which already included race and ethnicity: maternal age, type of insurance, and the reason for declining consent if declined.

Results: From August 2016 (start of additional data collection) to August 2017, 1,965 (28%) of the 7,112 eligible women consented to the trial. Consent was more likely for black women (41%, adjusted odds ratio (aOR) 1.47, 95% confidence interval (CI) 1.24–1.74), and less likely for Asian women (15%, aOR 0.64, 95% CI 0.48–0.84), compared with white women (24%). Women without private insurance were more likely to consent (38%, aOR 1.55, 95% CI 1.34–1.79),

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*A list of other members of the NICHD MFMU Network is available in Appendix 1 online at <http://links.lww.com/xxx>.

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compared with those with private insurance (22%). Younger women were also more likely to consent. Among eligible women who declined participation and provided a reason (68%), preference to be expectantly managed (85%) was most common, a response more common in Asian women (aOR 1.75, 95% CI 1.31–2.33) and less common in women without private insurance (aOR 0.60, 95% CI 0.51–0.70). Not wanting to participate in research was more common in Asian women (aOR 2.41, 95% CI 1.44–4.03). Declining consent because family or friends objected was more common in Asian women (aOR 2.51, 95% CI 1.27–4.95) and women without private insurance (aOR 1.68, 95% CI 1.10–2.59).

Conclusion: Frequency of consent and reasons for declining consent were associated with age, type of insurance, and race and ethnicity. These findings should be considered when developing recruitment strategies that promote diverse participant representation.

Précis:

In a randomized trial in pregnancy, frequency of consent and reasons for declining consent were associated with age, type of insurance, and race and ethnicity.

Clinical trials are considered the gold standard for improving clinical care and health outcomes, and correspondingly it is important to have a diverse and representative population take part in these trials. Understanding the reasons why some individuals choose to participate in clinical trials while others do not is therefore important. Similarly, successful consent and enrollment, though challenging, are essential to timely completion of any clinical trial.^{1,2} In fact, there are now entire companies devoted to providing resources to improve recruitment and retention of research study participants. A better understanding of what motivates or deters patient participation in clinical trials is vital for identification and implementation of better recruitment strategies.³

Inclusion of pregnant women in clinical trials is of particular importance, given they are often underrepresented or not studied at all, and treatment options that might provide better outcomes during pregnancy, labor and after delivery are difficult to evaluate.⁴ The National Institutes of Health Office of Research on Women's Health called for the necessity of addressing the "therapeutic needs of pregnant women and to study pregnancy as it may shed light on a pregnant woman's health later in life as well as the health of her child."⁴

Yet, few studies have examined reasons why pregnant women participate in clinical trials, and the studies that have, included selected populations such as pregnant women with cancer, respiratory illnesses, and cardiovascular diseases.¹ The objective of this secondary analysis was to evaluate the characteristics associated with consent and the reasons for declining consent to a randomized trial of induction of labor in pregnancy.

Methods

From 2014 to 2017, we conducted a randomized trial of induction of labor vs. expectant management in low-risk nulliparous women at 41 hospitals in the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Maternal–Fetal Medicine Units Network. Details regarding the ARRIVE trial (A Randomized Trial of Induction Versus Expectant Management) have been described previously.⁵ Briefly, women were screened for

eligibility between 34 weeks 0 days and 38 weeks 6 days of gestation. Consenting women were assessed again between 38 weeks 0 days and 38 weeks 6 days of gestation to confirm eligibility. Consenting women who remained eligible were randomized to either induction of labor at 39 weeks 0 days to 39 weeks 4 days or expectant management (i.e., foregoing elective delivery before 40 weeks 5 days unless a medical indication arose, and to have delivery initiated no later than 42 weeks 2 days). Women eligible for the trial were low-risk nulliparous women with a singleton pregnancy, without contraindications to vaginal delivery or plans for cesarean delivery, and a reliably-dated gestation. The ARRIVE trial evaluated whether labor induction at 39 weeks versus expectant management reduced a composite outcome of perinatal death or severe neonatal morbidity; the principal secondary outcome was cesarean delivery. The trial was approved by the institutional review board (IRB) at each participating center and informed consent was obtained from each woman before randomization. This secondary analysis was conducted using data from participating centers wherein open IRB status is maintained for the ARRIVE study.

During the trial, the Data and Safety Monitoring Committee requested the collection of additional demographic screening data in order to compare women who did and did not consent to participate in the ARRIVE trial. Three fields were added to the screening log, which already collected information about race and ethnicity as reported by the patient (white, black, Asian, Hispanic, other, or unknown): 1) maternal age, 2) type of insurance, and 3) the reason for declining consent if consent had not been provided. The collection of race and ethnicity, maternal age, and type of insurance on the screening log was approved by each center's IRB under a waiver of informed consent. The approval of collecting the reason for declining consent on the screening log under a waiver of informed consent varied by IRB; some IRBs allowed this collection only if the patient volunteered a reason without a direct query and the remaining IRBs allowed the patient to be queried. No other data were collected for women who did not consent. For this secondary analysis, we included women who were eligible for the trial and were screened between August 2016 (when collection of these additional data began) and August 2017 (when screening and recruitment for the trial concluded).

The Wilcoxon rank sum test or Kruskal-Wallis test was used for continuous variables and the chi-square test was used for categorical variables to compare maternal characteristics between 1) those included in and excluded from this secondary analysis, 2) those who agreed to consent and who declined consent for this clinical trial. Characteristics of women who declined consent were also compared between those who did and did not cite reasons for declining consent, and, for women who did cite reasons, the characteristics associated with the different reasons. Multivariable binomial (i.e., for consent status) and multinomial (i.e., for reason cited for declining consent) logistic regression were used to estimate adjusted odds ratios (aOR) and 95% confidence intervals (CI), adjusted for each of the demographic variables on the screening log as well as the geographic region (Northeast, Central, South, Southwest, West) where the hospital was located. A P-value of less than 0.05 was considered to indicate statistical significance for descriptive and unadjusted analyses. For multivariable analysis, the level of significance was adjusted post hoc for multiple comparisons with the false discovery rate method.⁶ Because a few sites' IRBs only allowed collection of reason for refusal if the patient volunteered a reason without a direct query, we

conducted a sensitivity analysis of the multinomial multivariable analysis for reason cited for declining consent excluding these sites. No imputation for missing data was performed. All analyses used SAS Version 9.4 software (SAS Institute, Cary NC).

Results

The trial was conducted between March 2014 and August 2017. A total of 50,581 women underwent screening, of whom 22,533 met the trial's eligibility criteria. Of eligible women, 7,112 (31.6%) were screened between August 2016 and August 2017 at 33 of the 41 participating hospitals and were included in this secondary analysis (Figure 1). Eligible women screened beginning in August 2016 were more likely to be black (16.2% vs. 13.6%) and less likely to be Hispanic (19.8% vs. 25.3%) compared with eligible women screened before August 2016 (Table 1). No other maternal characteristics were available on the screening log before August 2016 for comparison.

Among eligible women included in this analysis, 1,965 (28%) consented for participation in this trial. Overall, 9% were age 35 years or older, 38% had government-assisted insurance or were self-pay, 16% were black, 20% were Hispanic, and 6% were Asian. Consent was more likely for black women (41%, aOR 1.47, 95% CI 1.24–1.74), and less likely for Asian women (15%, aOR 0.64, 95% CI 0.48–0.84), compared with white women (24%) (Table 2). Women without private insurance were more likely to consent (38%, aOR 1.55, 95% CI 1.34–1.79), compared with those with private insurance (22%). Younger women were also more likely to consent.

Among eligible women who declined participation, 68% provided a reason for declining. White women and women with private insurance were more likely not to cite a reason for declining consent (Table 3). When reasons were cited, they included preferring expectant management (85%), not wanting to participate in research (6%), objections from family and friends (5%), preferring induction (3%), or reasons not in other categories (e.g., concerns regarding insurance, compensation, scheduling, or cervical status) (1%). Table 4 and Appendix 2 (Appendix 2 is available online at <http://links.lww.com/xxx>) show the unadjusted results for the reasons for declining consent by maternal characteristics. Cited reasons differed by maternal age, type of insurance and race and ethnicity ($p < 0.001$). In the adjusted analysis, preferring expectant management was more common in Asian women (aOR 1.75, 95% CI 1.31–2.33) and less common in women with government-assisted insurance or who were self-pay (aOR 0.60, 95% CI 0.51–0.70) (Table 5). Not wanting to participate in research was more common in Asian women (aOR 2.41, 95% CI 1.44–4.03). Declining consent because family or friends objected was more common in Asian women (aOR 2.51, 95% CI 1.27–4.95) and women with government-assisted insurance or who were self-pay (aOR 1.68, 95% CI 1.10–2.59). All these reasons for declining consent, as well as preferring an induction, became more frequent with increasing maternal age (Table 5). In the sensitivity analysis, the results were generally consistent although a few differences were observed. Declining consent because family or friends objected was no longer significantly more common in Asian women (aOR 2.07, 95% CI 0.98–4.38) or in women with government-assisted insurance or who were self-pay (aOR 1.44, 95% CI 0.92–2.26) and

black women were significantly less likely to prefer expectant management (aOR 0.74, 95% CI 0.61–0.90) (Appendix 3, available online at <http://links.lww.com/xxx>).

Discussion

In this secondary analysis of low-risk nulliparous women eligible for a randomized trial of induction of labor in pregnancy, consent was more likely among women who were younger and who had government insurance or were self-pay. Black women also were more likely to consent, whereas Asian women were less likely to consent. The most common reason for not consenting was a preference for one of the treatment arms, in particular wanting to be expectantly managed. The reasons provided by women for declining consent varied by several maternal characteristics, including race and ethnicity, age, and insurance status.

Our findings are similar to those of Strömmer et al., who also demonstrated that treatment preference may lead a subject to decline randomization.¹ Lopienski cited fear of the unknown as a reason why some patients may decline.³ Earlier identification of eligible patients, additional time to discuss the trial design and rationale for randomized group assignment, as well as endorsement from a reliable source, such as family or close friends, might heighten personal sense of control and lessen anxiety associated with random group assignment.^{1,3} Lopienski also suggests that declining consent may be related to concerns that participation may be too lengthy and financially burdensome, due to factors such as money for travel to and from study visits, whereas receipt of compensation may be a reason for consent.³

Recognition that women of different self-reported race and ethnicity, which may be a surrogate for different cultural attitudes, cite different reasons for declining consent speaks to the need for more consideration when designing trials. Communication during recruitment may vary by site and the approach may influence consent. It is important to have a consent process that promotes inclusion as well as to develop recruitment strategies that include involvement of important family members in the consent process. This seems particularly important for Asians, as they were more likely to decline consent due to family and friends' objections. Asians were also more likely to decline because they did not want to do research, so greater attention to developing a sense of trust during the recruitment process might help to lessen wariness associated with research participation for some ethnic groups. Our results also demonstrate the importance of developing an approach that could enhance inclusion of older women. This might include greater discussion with a trusted source, such as a medical provider, and access to published papers or on-line sources.

While insurance concerns were not the most common reason for declining to participate in this trial, the fact that this concern was cited emphasized the consideration that should be given to the association of payer and economic status with consent. The concerns about insurance coverage also have been cited by others as a reason for declining consent.³ The majority of people who choose to participate in clinical trials do so for altruistic reasons, such as improving health outcomes for others.³ Furthermore, a reason to participate may include access to care that would not be available otherwise.³ Anecdotally, some research staff found that several black women or women of lower socioeconomic status wanted to

participate because they did not feel their provider would offer them induction of labor; being in a trial gave them some control over their care. Data from Michael Kogan et al (1994) suggesting that black women are not given the same level of care and advice as part of their routine prenatal care, putting them at greater risk for adverse pregnancy outcomes, further supports the lack of options and control felt by this group.⁷ Likewise, the Institute of Medicine's 2003 report "Unequal Treatment – Confronting Racial and Ethnic Disparities in Healthcare" recognizes the negative impact of disparities in quality of health care based on race and ethnicity.⁸

Limitations to this secondary analysis should be noted. Collection of additional maternal characteristics began in the last year of the trial, which reduced the number of participants available for this secondary analysis. We were also unable to collect other important demographic information, such as maternal education, because collection of additional data would have required signed consent from women who declined participation. In addition, a relatively high percentage of participants who declined consent did not provide a reason. Although regional hospital variation in consent was adjusted for in the analysis, regional data were not reported in order to protect the identity of participating institutions. Lastly, this trial is unique because it required decisions regarding the birth process, and women may have strong personal preferences that are emotionally and culturally driven. This is not necessarily the case in other trials with interventions such as different medication regimens. Still, we provide data on over 7,000 ethnically and racially diverse pregnant women representing both university and community hospitals throughout the United States.

In conclusion, awareness of the reasons for declining consent and their associations with maternal characteristics presented here provides greater insight into why pregnant women refuse participation in randomized trials. Future research studies should consider the routine collection of reasons for declining to participation, and perhaps also reasons for consent, in randomized trials. This may allow for adaptation in recruitment strategies, more efficient use of research dollars allocated for recruitment, and enhance heterogeneity and generalizability.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1:
Flow chart of eligibility determination for inclusion in this secondary analysis

Table 1.**Maternal Characteristics by Inclusion Status ^{*}**

Characteristic	Included in the Analysis (n=7112)	Excluded from the Analysis [†] (n=15421)	P
Race and ethnicity, n (%)			<0.001
White	3764 (52.9)	7621 (49.4)	
Black	1154 (16.2)	2093 (13.6)	
Asian	454 (6.4)	932 (6.0)	
Hispanic	1405 (19.8)	3894 (25.3)	
Other, unknown, or more than one race	335 (4.7)	881 (5.7)	

^{*} Among eligible women

[†] These participants were enrolled in the trial prior to the start of additional data collection.

Table 2.Maternal Characteristics Associated with Consent Status ^{*}

Characteristic	Consented (n=1965)	Did not consent (n=5147)	Unadjusted OR (95% CI)	Adjusted OR (95% CI) [†]
Age, y, n (%) [‡]				
< 20	304 (15.5)	339 (6.6)	2.75 (2.29–3.32)	2.03 (1.65–2.49)
20–24	732 (37.3)	1174 (22.8)	1.92 (1.67–2.20)	1.56 (1.35–1.82)
25–29	490 (24.9)	1505 (29.3)	1.00 (referent)	1.00 (referent)
30–34	350 (17.8)	1587 (30.8)	0.68 (0.58–0.79)	0.83 (0.71–0.98)
≥ 35	89 (4.5)	539 (10.5)	0.51 (0.40–0.65)	0.64 (0.50–0.83)
Type of insurance, n (%) [‡]				
Private	955 (48.6)	3463 (67.4)	1.00 (referent)	1.00 (referent)
Government-assisted or self pay	1010 (51.4)	1676 (32.6)	2.19 (1.97–2.43)	1.55 (1.34–1.79)
Race and ethnicity, n (%)				
White	906 (46.1)	2858 (55.5)	1.00 (referent)	1.00 (referent)
Black	474 (24.1)	680 (13.2)	2.20 (1.91–2.53)	1.47 (1.24–1.74)
Asian	70 (3.6)	384 (7.5)	0.58 (0.44–0.75)	0.64 (0.48–0.84)
Hispanic	456 (23.2)	949 (18.4)	1.52 (1.33–1.73)	0.99 (0.84–1.17)
Other, unknown, or more than one race	59 (3.0)	276 (5.4)	0.67 (0.50–0.90)	0.62 (0.46–0.84)

Bold indicates significance in the multivariable (adjusted) analysis after controlling for multiple comparisons with the false discovery rate method.

OR, Odds ratio; CI, confidence interval

^{*} Among eligible women

[†] Adjusted for the other variables in the table as well as hospital region.

[‡] Age missing in 3 women and type of insurance missing in 8 women.

Table 3.

Maternal Characteristics of Women who Declined Participation by Whether a Reason was Provided

Characteristic	Provided reason (n=3490)	Missing reason (n=1657)	P
Age, y, n (%) [*]			0.11
< 20	217 (6.2)	122 (7.4)	
20–24	803 (23.0)	371 (22.4)	
25–29	997 (28.6)	508 (30.7)	
30–34	1089 (31.2)	498 (30.1)	
≥ 35	384 (11.0)	155 (9.4)	
Type of insurance, n (%) [*]			0.04
Private	2316 (66.4)	1147 (69.4)	
Government-assisted or self pay	1170 (33.6)	506 (30.6)	
Race and ethnicity, n (%)			<0.001
White	1875 (53.7)	983 (59.3)	
Black	545 (15.6)	135 (8.2)	
Asian	278 (8.0)	106 (6.4)	
Hispanic	646 (18.5)	303 (18.3)	
Other, unknown, or more than one race	146 (4.2)	130 (7.8)	

^{*} Age missing in 3 women and type of insurance missing in 8 women.

Table 4.

Maternal Characteristics by Reason for Declining Participation*

Characteristic	Reason for Declining Participation					Other or missing reason [‡] (n=1685)
	Consented (n=1965)	Does not want to do research (n=210)	Family or friends object (n=169)	Prefers to be expectantly managed (n=2980)	Prefers to be induced (n=103)	
Age, y, median (interquartile range) [‡]	24 (21–29)	27 (23–30)	25 (21–30)	29 (24–32)	27 (22–31)	28 (24–31)
Type of insurance, n (%) [‡]						
Private	955 (48.6)	115 (55.0)	60 (35.5)	2055 (69.0)	62 (60.2)	1171 (69.7)
Government-assisted or self pay	1010 (51.4)	94 (45.0)	109 (64.5)	922 (31.0)	41 (39.8)	510 (30.3)
Race and ethnicity, n (%)						
White	906 (46.1)	97 (46.2)	57 (33.7)	1648 (55.3)	51 (49.5)	1005 (59.6)
Black	474 (24.1)	37 (17.6)	33 (19.5)	455 (15.3)	18 (17.5)	137 (8.1)
Asian	70 (3.6)	25 (11.9)	12 (7.1)	232 (7.8)	6 (5.8)	109 (6.5)
Hispanic	456 (23.2)	42 (20.0)	55 (32.6)	521 (17.5)	27 (26.2)	304 (18.0)
Other, unknown, or more than one race	59 (3.0)	9 (4.3)	12 (7.1)	124 (4.2)	1 (1.0)	130 (7.7)

Percentages may not total 100 because of rounding.

* Among eligible women

[‡] Age missing in 3 women and type of insurance missing in 8 women.[‡] Other reasons (n=28) include concern regarding insurance, compensation, scheduling, or medical while missing (n=1657) include those who did not provide a reason

Table 5. Maternal Characteristics Associated with Reason for Declining Participation (Adjusted) *

Characteristic	Does not want to do research (n=210)	Family or friends object (n=169)	Adjusted [†] OR (95%CI) Reason for Declining Participation		
			Prefers to be expectantly managed (n=2980)	Prefers to be induced (n=103)	Other or missing reason [§] (n=1685)
Per unit increase in age, y [‡]	1.04 (1.01–1.07)	1.05 (1.02–1.09)	1.09 (1.08–1.11)	1.08 (1.03–1.12)	1.04 (1.02–1.05)
Government-assisted insurance or self pay (vs. private) [‡]	0.88 (0.61–1.28)	1.68 (1.10–2.59)	0.60 (0.51–0.70)	0.70 (0.41–1.18)	0.66 (0.55–0.79)
Race and ethnicity (vs. white)					
Black	0.80 (0.52–1.25)	0.73 (0.44–1.19)	0.90 (0.75–1.09)	0.92 (0.50–1.71)	0.35 (0.28–0.45)
Asian	2.41 (1.44–4.03)	2.51 (1.27–4.95)	1.75 (1.31–2.33)	1.02 (0.42–2.49)	1.21 (0.88–1.67)
Hispanic	0.62 (0.40–0.97)	1.54 (0.98–2.42)	1.12 (0.93–1.34)	0.95 (0.53–1.70)	0.90 (0.73–1.11)
Other, unknown, or more than one race	1.39 (0.63–3.03)	2.97 (1.49–5.93)	1.37 (0.98–1.91)	0.36 (0.05–2.69)	1.84 (1.32–2.57)

Bold indicates significance after controlling for multiple comparisons with the false discovery rate method.

All analyses are compared with those that consented, n=1965

* Among eligible women

[‡] Adjusted for the other variables in the table as well as hospital region.

[‡] Age missing in 3 women and type of insurance missing in 8 women.

[§] Other reasons (n=28) include concern regarding insurance, compensation, scheduling, or medical while missing (n=1657) include those who did not provide a reason