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Variation in Women's Understanding of Prenatal Testing

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Abstract

Objective—*To* investigate women's understanding of prenatal testing options and of their own experience with screening, diagnostic genetic testing, or both.

Methods—This was a secondary analysis of data from a randomized controlled trial of enhanced information and values clarification regarding prenatal genetic testing in the absence of financial barriers to testing. Women in the third trimester of pregnancy were asked whether they had discussed prenatal genetic testing with their providers, whether they understood this testing was optional, and whether they had undergone testing during their pregnancy. Multivariable logistic regression models were fit to determine independent predictors of these outcomes.

Results—Data were available from 710 study participants. Discussions about screening tests were reported by 654 participants (92%); only 412 (58%) reported discussing diagnostic testing. That screening and diagnostic testing were optional was evident to approximately 2/3 of women (n=470 and 455, respectively). Recall of actual tests undergone was correct for 626 (88%) for screening and for 700 (99%) for diagnostic testing. Racial–ethnic and socioeconomic variation existed in the understanding of whether screening and diagnostic tests were optional and in the correct recall of whether screening had been undertaken in the current pregnancy. In the usual care group, women receiving care in low-income settings were less likely to recall being offered diagnostic testing (aOR 0.23 [0.14, 0.39]).

Conclusions—Disparities exist in women's recall of prenatal genetic testing discussions and their understanding of their own experience. Interventions that explain testing options to women and help clarify their preferences may help to eliminate these differences.

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Introduction

Prenatal testing for fetal aneuploidy has been integral to obstetric care since the introduction of amniocentesis to diagnose Down syndrome in the 1970s and the advent of serum screening to determine risk of Down syndrome in the 1980s[1,2]. While testing choices have become more complex, a central tenet remains that pregnant women should be offered both screening and diagnostic testing with the understanding that these tests are optional, not required[3]. In the context of the busy health care environment, however, sufficient time to ensure informed decision-making, consistent with women's values, may be lacking. Previous studies have demonstrated suboptimal rates of truly informed decision-making among pregnant women contemplating prenatal testing[4-6].

Also, racial, ethnic and socioeconomic disparities in health care are prevalent. In obstetrics, for example, particular groups of women are more likely than others to receive inadequate prenatal care[7], to deliver by primary cesarean[8,9] and to suffer severe maternal morbidity and mortality during pregnancy, labor and delivery[10]. While racial and ethnic and socioeconomic differences in uptake of prenatal screening and diagnostic testing have been reported, some of this variance is explained by differences in attitudes[11]. However, we hypothesize that patient-level variation also exists in the degree to which women are making informed decisions about prenatal testing. We tested this hypothesis by assessing 1) women's recall of whether screening and diagnostic testing were discussed during prenatal care, 2) whether women understood that testing was optional, and 3) whether they correctly recalled whether or not they personally had undergone screening or diagnostic testing during their pregnancy.

Materials and Methods

We conducted a secondary analysis of a randomized controlled trial that explored the effect of providing a prenatal testing decision-support guide that included enhanced information about prenatal testing and its voluntary nature, along with a series of values clarification exercises, and removing financial barriers on use of prenatal screening and diagnostic tests[12]. A diverse group of 710 English and Spanish speaking women of varying literacy levels and sociodemographic backgrounds was recruited for study participation at less than 20 weeks gestation. Participants were enrolled between January 2010 and June 2012; the last deliveries occurred in January 2013. These women were randomized to the intervention group (access to a decision-support guide and prenatal screening and diagnostic testing without financial barriers), or to the control group (usual clinical care). Participants were interviewed at the time of enrollment and again at 24-36 weeks of gestation. During the second interview, they were asked whether or not they had undergone first or second trimester maternal serum screening, nuchal translucency screening, chorionic villus sampling, or amniocentesis. They also were asked several questions about their understanding of these tests, including whether they had discussed first- or second-trimester screening and diagnostic testing with their provider, whether they had undergone any of these tests, and whether it was clear that the choice of whether or not to have any of these tests was up to them. Screening tests included serum analyte measurement in the first or second trimester or both, or nuchal translucency measurement in the first trimester.

Diagnostic tests included chorionic villus sampling and amniocentesis. Medical record review was employed after delivery to assess actual prenatal test use. Institutional review board approval was obtained from all participating sites.

The three outcomes for this analysis were defined as follows, and were explored for screening and diagnostic testing separately. First, participants were considered to have recalled discussing screening or diagnostic testing options if they recollected conversations about any of the modes of screening or diagnostic testing. Each type of screening or diagnostic test was described in detail one by one, and women were queried about each separately. Second, they were considered to be clear about the voluntary nature of screening or diagnostic testing if they reported understanding that it was their choice as to whether they underwent any, or none, of the screening or diagnostic tests described. Finally, participants were categorized as having correctly recalled whether or not they had screening or diagnostic testing if their responses to the utilization questions in the interview matched the data obtained from their medical records.

Our primary predictors for these analyses were sociodemographic characteristics, including maternal age, parity, race, ethnicity, preferred language (determined by whether the participant chose the English- or Spanish-language version of the interview), educational attainment, marital status, insurance type, household income, site of prenatal care, literacy, and numeracy. Prenatal care sites were grouped into one of two categories: sites serving primarily low-income women and sites serving women of all income levels. Literacy was assessed using the Rapid Estimate of Adult Literacy in Medicine-Revised measure; a score of less than 7 on an 8 point scale was considered poor literacy[13]. Two or fewer correct responses on a 5-item numeracy scale was considered low numeracy[14].

Univariate and multivariable logistic regression models were fit for each of the three outcomes. The effects of the intervention group indicator were not of primary interest in this secondary analysis. However, it was possible that the study intervention might have modified the effects of any of the predictors on these outcomes. Therefore, all models initially tested interaction effects between group assignment from the randomized study and each predictor on each outcome. Predictors significant at the $p < 0.20$ level (for main effects) and interaction terms significant at the $p<0.05$ level were included in the final multivariable models using backward elimination. After dropping non-significant interaction effects, the effects of the corresponding predictors were estimated pooling across data from the entire sample. For any significant interaction, the effect of the corresponding predictor was estimated and reported separately within each intervention group. Insurance type, site of prenatal care and household income were highly correlated with one another and thus, only site of prenatal care was retained in final models.

All models were fit to 20 multiple-imputed data sets created via a Markov Chain Monte Carlo method using SAS PROC MI version 9.3 (SAS Institute Inc.). Imputation models were stratified by randomization group and included all variables presented in Table 1, as well as participants' median ZIP code income (from 2000 census data). All parameter estimates, standard error estimates, and test statistics were calculated by combining results across the imputed data sets. We used a two-tailed, $\alpha = 0.05$, throughout.

Results

Sociodemographic and other characteristics of the 710 participants are presented in Table 1 and study outcomes in Table 2. While most (92%) of these women reported having discussed some form of screening for aneuploidy with their health care provider, fewer (58.1%) reported any discussion of diagnostic testing. It was clear to approximately two thirds of the participants that screening and diagnostic testing were optional (66.2% and 64.1%, respectively). Most, but not all, participants were able to correctly recall whether they had undergone a screening test or diagnostic procedure (88.3% and 98.6%, respectively) when queried at 24-36 weeks gestation. Those with incorrect recall (13.2%) were approximately evenly split between those who thought screening or testing had been done when the medical record indicated it had not (5.4% incorrectly thought screening was done, 0.8% incorrectly thought diagnostic testing was done), and those who thought they had had no screening or testing but for whom record review showed such testing had been done (6.3% incorrectly thought screening had not been done, 0.6% incorrectly thought diagnostic testing had not been done).

Results of the multivariable analyses are presented in Tables 3 and 4. Compared to women with adequate literacy, women with poor literacy were significantly less likely to recall having had a discussion about aneuploidy screening; (87.3% vs. 93.7%, adjusted odds ratio (aOR) 0.49, 95% CI [0.25-0.94]). Latina women who opted for the English-language version of the interview were less likely to say that they understood that screening was optional (44.5% vs. 74.5% for white women, aOR 0.35 [0.18-0.70]). Women receiving prenatal care in sites serving primarily women of lower income (“low income sites”) were less likely to correctly recall whether screening had actually been done (83.4% for low income sites vs. 93.8% for women in other settings, aOR 0.36 [0.25-0.87]), and, compared to younger women, women aged 35 and older had greater than twice the odds of accurately reporting having been screened (aOR 2.15 [1.11-4.16]). There was no evidence of effect modification by treatment group assignment for any of the screening outcomes.

Discussions of diagnostic testing were less commonly recalled than screening discussions, particularly for women under the age of 35 (51.4% vs. 82.8%, aOR 0.26 [0.16-0.44]), despite recommendations that diagnostic testing should be offered to women of all ages. We found a significant modification of the effect of site of prenatal care by study group assignment on the likelihood of recall of prenatal test discussion ($p = 0.005$). Therefore, the final multivariable model included that interaction effect and we report the effect of site for each treatment group separately. Among women who had been randomized to the control arm in the main study, being cared for in a low income site was associated with a lower likelihood of recalling a discussion about diagnostic testing (aOR 0.23 [0.14-0.39]); this effect of receiving care in a low income site was not observed in the intervention group (aOR 0.64 [0.39-1.07]). Compared with white women, African American women and women whose race or ethnicity was categorized as “other” (which included Asians, Pacific Islanders, and Native Americans) were less likely to have a clear understanding that diagnostic testing was optional (aOR 0.44 [0.22-0.91] and 0.50 [0.25-0.99], respectively), as were women cared for in low income sites (aOR 0.30 [0.16-0.54]).

Of women who underwent screening, 6.6% had a positive result. Women with a positive result were more likely to recall having discussed diagnostic testing (100% vs. 57.3%, p <0.0001) and to understand that diagnostic testing was optional (90.9% vs. 71.6%, p = 0.049), but were less likely to recall having had screening (83.3% vs. 95.6%, p = 0.008).

Discussion

We found substantial variability in recollection of offers of prenatal screening or diagnostic testing, in understanding that both are optional, and in accurate report of whether either had been performed. On balance, racial and–ethnic minorities and women of lower socioeconomic status were less likely to have a good understanding of prenatal testing options and of their own experience. These data parallel reports documenting disparities in various screening domains[15-19]. While the American College of Obstetricians and Gynecologists recommends that "...screening and invasive diagnostic testing for aneuploidy should be available to all women...regardless of maternal age"[20], it appears that this information is not being effectively provided to all women, and that many do not understand the messages conveyed.

Women were recruited before 20 weeks when universal offer of screening and diagnostic tests would have been appropriate. For women who did not recall being offered such testing, we cannot be certain whether they were explained but not recalled, or whether testing was not offered at all. We suspect both contribute: women of lower literacy might be less likely to understand and recall screening conversations that occurred, and providers may be less inclined to conduct detailed discussions with patients they perceive as less able to engage. Providers may be less likely to offer diagnostic testing to younger women despite recommendations, but younger women, perhaps less interested in such testing, may forget that discussions took place. Neither is optimal.

Also troubling is that correct reports about whether screening had been performed varied by site of care. Women receiving care in facilities primarily serving low-income women were less likely to know whether or not they had had screening. In some cases, this may represent routine ordering of testing without women's knowledge or consent; in others, it may have been assumed that particular women would not want or need screening, resulting in failure to facilitate such services. With increasing utilization of cell free DNA screening, with far higher positive predictive values, routinization of prenatal screening without adequate informed consent becomes even more problematic.

Our study is not without limitations. We chose to rely on women's self-report of offer of testing and were not able not review actual documentation in the record, but believe the patient-centered outcome to be meaningful, particularly in the exploration of disparities. Also, our study population was enriched for diversity of background and does not entirely parallel the underlying U.S. population. However, a substantial number of births in the U.S. are to low-income women and those from racial– and ethnic minorities. Understanding differences in the manner in which we deliver care to these populations is therefore of great relevance.

This study was conducted in California, a state with a formal program for prenatal genetic screening. That we find variability even in this state with significant attempts at standardization (required offer of prenatal screening, brochures provided to all women, access to approved prenatal diagnostic centers) is of concern that these disparities may be wider in states without such a program.

Options for prenatal testing are becoming ever more complex. Recently, cell free DNA screening, use of chromosomal microarray analysis for diagnostic testing, and expanded parental carrier screening have entered the mainstream. Noninvasive means of detecting genetic copy number variants and sequencing of the whole fetal exome or genome are likely not far behind. With this dizzying array of choices, we will need to ensure that all women, no matter their socioeconomic status or literacy, are well informed of their options and have the time and guidance to make decisions concordant with their preferences. Providers are likely discussing screening more commonly than diagnostic tests; this discrepancy may be magnified as more screens become available. That women with positive screens, who would have had specific genetic counseling visits in California, were more likely to understand the optional nature of invasive testing may indicate that dedicated time for these discussions is valuable.

The parent study for the current analysis found that women who were randomized to use an interactive decision-support guide made more informed testing choices than women randomized to usual care[12]. That a disparity by site of care in recall of diagnostic testing discussions was only seen in the usual care group in the current study may suggest that this kind of decision support could prove a useful adjunct to the current paradigm of counseling women and assure provision of consistent information to all women. Further study of the effectiveness and feasibility of such tools in varied settings is critical. In particular, interventions outside of the clinical encounter that empower and educate women and their families to make the informed choices may most benefit those who might otherwise fall through the cracks of a busy, overburdened health care system.

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Précis

Variation exists in women's understanding of the voluntary nature of prenatal genetic testing and in recall of whether or not they underwent testing themselves.

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Table 1

Characteristics of study population

Characteristic	N (% [95% CI])
Maternal age	
<35 years	558 (79% [75-82%])
≥ 35 years	152 (21% [18-25%])
Multiparity	405 (57% [53-61%])
Race, ethnicity and language	
African American or Black	112 (16% [13-19%])
Caucasian or White	182 (26% [22-29%])
Latina (English-speaking)	72 (10%) [8-13%])
Latina (Spanish-speaking)	250 (35% [32-39%])
Other (Asian, Pacific Islander ,Native American, mixed or other)	94 (13% [11-16%])
Highest level of education	
Some high school or less	200 (28% [25-32%])
High school graduate	126 (18% [15-21%])
Some college	153 (22% [19-25%])
College graduate	114 (16% [13-19%])
Professional or graduate degree	117 (17% [14-19%])
Neither married nor living with partner	191 (27% [24-30%])
Public insurance	438 (62% [58-65%])
Household annual income < $25,000	336 (47% [44-51%])
Prenatal care site serving primarily low income women	418 (59% [55-63%])
Poor literacy	180 (25% [22-29%])
Low numeracy	316 (45% [41-48%])
Group assignment	
Intervention (enhanced information, values clarification, and removal of financial barriers to testing)	357 (50% [47-54%])
Control (usual care)	353 (50% [46-53%])

Table 2

Outcomes for analysis

Outcome	N (% [95% CI])
Recall discussing screening test with any health care providers	654 (92% [90-94%])
Recall discussing diagnostic test with any health care providers	412 (58% [54-62%])
Clear that screening test was optional	470 (66% [63-70%])
Clear that diagnostic test was optional	455 (64% 60-68%])
Recall of whether screening test was performed	
Correctly recalled that screening was done	514 (72% [69-76%])
Correctly recalled that screening was not done	112 (16% [13-19%])
Incorrectly recalled that screening was done	39 (5% [4-7%])
Incorrectly recalled that screening was not done	45 (6% [5-8%])
Recall of whether diagnostic testing was performed	
Correctly recalled that diagnostic testing was done	60 (8% [7-11%])
Correctly recalled that diagnostic testing was not done	640 (90% [88-92%])
Incorrectly recalled that diagnostic testing was done	6 (0.8% [0.2-1.5%])
Incorrectly recalled that diagnostic testing was not done	4 (0.6% [0.3-1.7%])

Table 3

Predictors of adequate understanding of screening

	Recall of screening discussion		Clear understanding that screening was optional		Correct recall of whether screening was done	
	OR (95%CI)	**aOR† (95%CI)**	**OR (95%CI)**	**aOR† (95%CI)**	**OR (95%CI)**	**aOR† (95%CI)**
Maternal age < 35 years	0.51 (0.21-1.23)	0.54 (0.22-1.30)	0.78 (0.51-1.20)		1.39 (0.77-2.51)	**2.15 (1.11-4.16)**
Multiparity	0.65 (0.35-1.20)	0.63 (0.34-1.19)	0.90 (0.64-1.27)		0.62 (0.35-1.09)	
Race, ethnicity and language						
African American or Black	0.74 (0.30-1.84)		**0.50 (0.28-0.90)**	0.75 (0.38-1.46)	**0.29 (0.12-0.68)**	0.66 (0.23-1.89)
Latina (English-speaking)	0.96 (0.5-2.06)‡		**0.27 (0.14-0.52)**	**0.35 (0.18-0.70)**	0.49 (0.18-1.33)	0.93 (0.30-2.94)
Latina (Spanish-speaking)	‡		0.80 (0.51-1.27)	1.17 (0.64-2.15)	0.58 (0.27-1.23)	1.74 (0.62-4.93)
Other (Asian, Pacific Islander, Native American, mixed, other)	0.77 (0.30-1.99)		0.63 (0.36-1.10)	0.75 (0.41-1.35)	0.86 (0.28-2.64)	1.36 (0.42-4.45)
Caucasian or White	Reference		Reference	Reference	Reference	Reference
Highest level of education						
Some high school or less	0.67 (0.34-1.30)		0.92 (0.61-1.39)		**0.48 (0.26-0.90)**	0.53 (0.24-1.19)
High school graduate	0.74 (0.32-1.72)		**0.60 (0.38-0.95)**		**0.34 (0.18-0.66)**	0.45 (0.20-1.04)
Some college or higher	Reference		Reference		Reference	Reference
Single marital status	0.64 (0.34-1.21)		**0.57 (0.38-0.85)**	0.74 (0.48-1.15)	0.77 (0.41-1.45)	
Low literacy	**0.46 (0.24 - 0.90)**	**0.49 (0.25-0.94)**	**0.66 (0.45-0.98)**		0.54 (0.30-1.00)	
Low numeracy	0.55 (0.30-1.02)		0.93 (0.66-1.31)		0.61 (0.36-1.04)	
Prenatal care site serving primarily low income women	0.55 (0.29-1.03)		**0.66(0.46-0.95)**	0.65 (0.40-1.07)	**0.36 (0.20-0.65)**	**0.36 (0.15-0.87)**
Assignment to intervention group	1.35 (0.70-2.61)		1.27 (0.91-1.79)	1.26 (0.89-1.80)	1.13 (0.61-2.11)	

Bold typeface indicates p< 0.05

† Adjusted for other items in the model. Items were retained in multivariable models when p<0.20. No interaction terms retained in final models.

‡ In this model, English- and Spanish-speaking Latinas were combined into one category due to small cell sizes.

Table 4

Predictors of adequate understanding of diagnostic testing

	Recall of diagnostic testing discussion		Clear understanding that diagnostic testing was optional		Correct recall of whether diagnostic testing was done
	OR (95%CI)	aOR† (95%CI)	OR (95%CI)	aOR† (95%CI)	OR (95%CI)#
Maternal age < 35 years	**0.22 (0.13-0.36)**	**0.26 (0.16-0.44)**	**0.49 (0.31-0.79)**	0.65 (0.38-1.10)	1.12 (0.14-9.00)
Multiparity	**0.69 (0.50-0.96)**		**0.76 (0.54-1.09)**		0.56 (0.07-4.33)
Race, ethnicity and language					
African American or Black	0.62 (0.37-1.05)		**0.20 (0.11-0.36)**	**0.44 (0.22-0.91)**	0.27 (0.03-2.92)
Latina (English-speaking)	0.65 (0.34-1.25)		**0.28 (0.13-0.61)**	0.53 (0.23-1.22)	n/a
Latina (Spanish-speaking)	**0.44 (0.29-0.67)**		**0.42 (0.24-0.72)**	1.16 (0.58-2.34)	0.86 (0.07-10.17)
Other (Asian, Pacific Islander, Native American, mixed, other)	0.58 (0.33-1.02)		**0.35 (0.19-0.66)**	**0.50 (0.25-0.99)**	0.37 (0.02-6.26)
White	Reference		Reference	Reference	Reference
Highest level of education					
Some high school or less	**0.43 (0.30-0.62)**		**0.60 (0.39-0.91)**		0.59 (0.12-2.86)
High school graduate	**0.46 (0.30-0.71)**		**0.42 (0.25-0.68)**		n/a
Some college or higher	Reference		Reference		Reference
Single marital status	0.73 (0.49-1.07)		**0.41 (0.27-0.61)**	0.73 (0.46-1.15)	1.16 (0.18-7.66)
Low literacy	0.83 (0.58-1.20)		**0.51 (0.35-0.76)**		0.82 (0.14-4.79)
Low numeracy	0.55 (0.40-0.76)		**0.60 (0.42-0.84)**		0.56 (0.11-2.85)
Prenatal care site serving primarily low income women	**0.33 (0.23-0.47)**	‡	**0.29 (0.19-0.45)**	**0.30 (0.16-0.54)**	0.58 (0.11-3.09)
Interaction with group assignment Within intervention group		0.64 (0.39-1.07)			
Within control group		**0.23 (0.14-0.39)**			
Assignment to intervention group	1.31 (0.94-1.83)	1.15* (0.80-1.67)	**1.49 (1.03-2.17)**	1.46 (0.97-2.18)	0.71 (0.14-3.46)

Bold typeface indicates p< 0.05

† Adjusted for other items in the model. Items were retained in multivariable models when p<0.20.

‡ Main effect not reported because of significant interaction with intervention group assignment (p=0.005). Effects reported separately within each intervention group. No other interaction terms were significant.

* Effect of group, averaged over prenatal care facility type.

#Results of multivariable model not presented due to small cell sizes.