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Decisional regret in women receiving high risk or inconclusive prenatal cell-free DNA screening results

Betsy L. Gammon[a,b], **Carolina Jaramillo**[a,*], **Kirsten A. Riggan**[a], **Megan Allyse**[a,c]

[a]Mayo Clinic, Biomedical Ethics Program, Rochester, MN, USA

[b]University of Virginia School of Medicine, Charlottesville, VA, USA

[c]Obstetrics and Gynecology, Mayo Clinic, Rochester, MN, USA

Abstract

Objectives: This study examined the experiences of women receiving high-risk cell-free DNA (cfDNA) screening results, with particular focus on decisional satisfaction after receiving high-risk, false, or inconclusive results. It is already known that cell-free DNA screening is rapidly expanding in the clinical practice. A growing number of women are offered cfDNA screening for an increasingly broad range of chromosomal and microdeletion syndromes. However, research shows that the very low false positive rate attributed to cfDNA screening for trisomy 21 does not apply to other conditions.

Methods: As a part of the larger study on patient experiences, 40 semistructured telephone interviews were conducted with women who were, or had recently been, pregnant and received high-risk (n = 15), false positive/negative (n = 20), or inconclusive (n = 5) results from cfDNA screening.

Results: One third of participants would not elect to have cfDNA screening in a future pregnancy, and another third would only have the screen under particular circumstances or if the scope of the panel was limited. Many women reported feeling misled by the information they received prior to accepting cfDNA screening or receiving their results.

Conclusions: Study participants described issues with the clinical dialog when cfDNA screening is offered; when results are returned; and problems with the availability of information about the existence of false positives. These reports suggest that inadequate pretest discussion contributes to women's experience of decisional regret after receiving high-risk, false positive, or inconclusive results. Given the confusion about cfDNA screening accuracy, the prevalence of follow-up invasive tests, and the number of women who reported that they regretted choosing cfDNA screening, the mode of offering cfDNA should be reassessed.

Keywords

High-risk; inconclusive; noninvasive prenatal testing; pretest counseling

CONTACT Megan Allyse Allyse.megan@mayo.edu Mayo Clinic, 200 First St SW, Rochester, Minnesota, USA.
*Carolina is now a student of Harvard Medical School in Boston, MA.

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Introduction

Prenatal screening has changed dramatically over the last decade with the introduction of noninvasive cell-free DNA screening (cfDNA screening) [1–4]. Robust clinical trials of cfDNA screening for common fetal trisomies, including trisomy 21, 18, and 13, have demonstrated higher sensitivity and specificity than the past protocols, yet as a screening test direct sampling of fetal DNA is required for definitive diagnosis of fetal genetic anomaly [5–8]. Professional societies initially amended their professional practice guidelines to support cfDNA screening in high risk pregnancies [9,10] and private and public health insurance plans gradually followed suit [11,12].

Between 2012 and 2015, many laboratories expanded their cfDNA screening to include the detection of sex chromosome aneuploidies which also has the benefit of fetal sex determination [13–17]. In 2015, some laboratories began to add subchromosomal abnormalities, such as microdeletions, to their panels. Although positive predictive values and clinical utility were difficult to establish due to the rarity of these conditions, commercial laboratories claimed that they had demonstrated sufficient analytic validity to make commercial provision reasonable [18–20]. Subsequent research on the specificity, sensitivity, and positive and negative predictive values of these expanded panels, however, shows inconsistent findings of clinical utility [21,22].

Despite its higher fidelity in screening for trisomies 13, 18, and 21, cfDNA is far from infallible. Studies indicate that cfDNA screening is less successful at accurately detecting placental DNA in women who are obese, pregnancies with multiple gestations, and pregnancies that are affected by an aneuploidy, leading to potentially inconclusive results [23–25]. Maternal serum samples taken earlier in the pregnancy also contain lower levels of placental DNA which can confound cfDNA screens [26,27]. A higher rate of false positives on expanded cfDNA panels has been indicated, particularly for monosomy X (Turner syndrome) [13,28]. False positive findings have been associated with an increase in maternal anxiety and reports of more negative pregnancy experiences [29,30].

The ERRORS Study is a qualitative study on the experiences of women receiving high-risk, inconclusive, or false positive results from cfDNA screening. Here, we explore findings of decisional regret as a component of their overall experience and their post-test views of the advisability of cfDNA screening.

Materials and methods

Study design

We conducted semistructured interviews with 40 women to solicit their perspectives on receiving high-risk or inconclusive results from cfDNA screening. Because high-risk and inconclusive results remain rare and widely distributed, participants were recruited electronically from online pregnancy forums. Participants received an institutionally-sourced gift basket valued at $25 per participant. This study was reviewed by the Institutional Review Board.

Recruitment

Online forums on BabyCenter.com and TheBump.com were analyzed between September 2015 and March 2016 to identify the participants who met inclusion criteria. Search terms included combinations of “NIPT positive”, “NIPT false positive”, “NIPT inconclusive”, “NIPT high risk”, “NIPT microdeletion”, and brand names of common cfDNA screening tests. The inclusion criterion included receiving inconclusive or high-risk results from cfDNA screening within the previous 12 months. Women who posted about receiving high-risk, false positive, or inconclusive results from cfDNA screening were sent a private online message to ask if they were interested in participating. The study contacted 252 women between September 2015 and March 2016. In accordance with standard qualitative methods, recruitment was conducted until thematic saturation was achieved. Respondents were consented and interviewed until the recruitment target of 40 women was reached.

Data collection

Phone interviews ($n = 40$) were conducted between September 2015 to April 2016 using an interview guide created by a team of experts, including representatives from genetic counseling, reproductive medicine, bioethics, and sociology to ensure appropriate readability and content based on preexisting literature. The interview guide consisted of questions regarding participants’ sociodemographic background, prior pregnancy and screening experiences, and prior high-risk results. In addition, the interview guide elicited participants’ experiences with cfDNA screening. Interviews lasted 35 min on average and were audio recorded, transcribed verbatim, and anonymized.

Data analysis

Anonymized interview transcript data were analyzed using a recursive thematic approach. The software package NVivo version 11 was used to facilitate data analysis. Transcripts were analyzed systematically to interpret participant responses and identify salient themes. Thematic analysis was conducted to detect patterns across the data in relation to our research questions. The coding framework and resulting codebook for transcript analysis were developed by BG and MA based on inductively identified themes as well as preexisting literature. Coding was conducted by multiple coders, with discussion between coauthors to resolve any coding discrepancies and achieve consensus.

Results

Participants

The study sample included participants from three countries (US, Canada (1), and England (1)), with 20 US states represented (Table 1). New York and California had the highest representation in the sample. Participant age ranged between 25 and 44 years old. Quotes from participants have been minimally edited for readability.

Participants collectively received high-risk results for seven genetic conditions, as displayed in Table 2. Twenty participants received false results from cfDNA screening as assessed by either follow-up invasive diagnostic testing or testing at birth. The majority were false positives ($n = 19$), with only one participant reporting a false negative result. At the time

of the interview, 11 participants were classified as high-risk, meaning the participant had received a high-risk cfDNA screening result, had not pursued invasive diagnostic testing, and had not yet given birth. Invasive diagnostic testing or testing at birth revealed true positive results from cfDNA screening for four participants. Finally, five participants received inconclusive results from cfDNA screening. Twenty participants had invasive testing following their results.

Positive view of cfDNA screening

Eight participants expressed overall positive opinions of cfDNA screening. Results for microdeletions, T13/18, T21, and Turner syndrome as well as inconclusive results were evenly distributed within this group. Participants discussed early access to information for preparation and noninvasiveness as a particular advantage.

> I like the testing, I wish it could get to the point where it could totally replace the amnio because it doesn't have the risks of that type of testing. It did what I wanted it to do for me, which was to give me the knowledge of the condition before the birth so that I could be prepared
>
> (High-risk, trisomy 21)

Fourteen women reported that they would choose cfDNA screening again in the future. Participants discussed the benefits of having time and opportunity to prepare for a high-risk birth, the low procedure-related risk, and screening option for personal risk factors, specifically advanced maternal age.

> I often think "would I do it again?" I think I really would do it in the same order. I may just go right for the noninvasive testing and then do the amnio. I don't think I'd start with the amnio just because of the risk of miscarriage
>
> (False positive, trisomy 18)

Only seven women stated that they would recommend cfDNA screening to a friend or family without any additional warning or limitation on the screen. Women who reported willingness to recommend the test to others either received inconclusive, high-risk, or true positive results for trisomy 21 only.

Negative view of cfDNA screening

Twelve participants expressed overall negative opinions of cfDNA screening, primarily those who received high-risk results for microdeletions ($n = 4$) or Turner syndrome ($n = 4$). Participants typically discussed their frustrations with the scope of the test, the way in which the accuracy of the screening was marketed, the offer of the screen to women without additional risk factors, and anxiety associated with a false positive.

> You start looking for all the information you can, and it's a screening test with all of these variables that can affect the accuracy, but they boast this 99% accuracy and sometimes higher. I'm not comfortable with that
>
> (High-risk, trisomy 21)

In light of their experiences, 14 women reported that they would not choose cfDNA screening in the future. More women who received high-risk or false results than women who received inconclusive or true positive results said they would not pursue cfDNA screening in the future.

> I think it's stupid. I would never recommend it to anybody unless it's absolutely needed. I love my doctor and nothing against what she was doing, but looking back I wish she would have said, "You don't need this, you'll be fine. Your age, your background … if you have an ultrasound that's abnormal then let's do the test, but you haven't had that yet" kind of thing.
>
> (High-risk, microdeletion)

Several women felt that the benefits of gaining knowledge about the fetus did not outweigh the emotional costs of receiving high-risk or false positive results.

> If I'm ever to get pregnant again, I would never do it. I would either choose no screening or go straight to a diagnostic test to help me out […] It caused so much undue stress on me and so much sadness and anxiety on everybody who's in this baby's life. (False positive, Trisomy 13)

Overall, 14 women would not recommend cfDNA screening at all and 19 women would recommend the test only with limitations and with caution. No women who received results for microdeletions, T13/18, or Turner said they would recommend cfDNA screening to a friend in its current formulation. No women who received false results reported that they would recommend cfDNA screening to others, and several women ($n = 13$) who received results other than false positives also said that they would not recommend cfDNA screening or would only recommend the screen under limited circumstances. Participants stressed that they would only recommend cfDNA screening for trisomy 21 or if other risk factors were present (e.g. abnormal ultrasound or family history). Women's hypothetical and actual recommendations to family and friends pertained to the accuracy of cfDNA screening and stressed the difference between screening and diagnostic tests.

> I just would have told them that yes, this happened. It comes back highly positive sometimes, and it's just false positives sometimes (…) Maybe, if they['re] high risk, after 35. (False positive, Turner syndrome)

Ambiguous view of cfDNA screening

Half ($n = 20$) of the participants reported mixed feelings about cfDNA screening. The majority of those who reported a nuanced view received results for T13/18 ($n = 6$), T21 ($n = 6$), or Turner syndrome ($n = 5$). These participants generally praised the low risk and the return of results early in pregnancy; however, they recounted concerns about the screen's accuracy and utility, as well as the lack of information provided prior to and following screening. Some participants who received false positive or high-risk results remarked that they would only choose future cfDNA screening after researching the positive predictive value for each component of the screening panel as a means of reducing the anxiety and stress associated with a positive result.

> Ultimately, with any new type of technology, there's going to be problems. I just feel like if I would have been told ahead of time that it is a screening and there is an error rate and this is how it works, I would have done it, and when I got the results I wouldn't have panicked. I just feel like no information was given to me so I was just completely blindsided. If there had been more information going in, it would not have been a problem
>
> (False positive, Turner syndrome)

Discussion

Overall, participants reported that when they made the decision to undergo cfDNA screening, they felt that they understood the potential benefits of cfDNA screening and that these perceived benefits – noninvasiveness, perceived accuracy, the ability to detect fetal sex drew them to accept the screening. After their personal experiences with cfDNA screening, however, many recounted considerable concerns about the screen's performance, how it was offered, the return of results, and how the test was marketed. The significant segment of participants who reported they would only elect to do cfDNA screening again under certain circumstances or not at all argued that there remain significant gaps in the effective clinical integration of expanded cfDNA screening. These results raise important questions about the value of routine use of such panels and may suggest that practices reconsider whether the use of such panels is advisable, absent a specific indication.

Women frequently expressed that they "wished [they] had known" certain information before consenting to the screen. This sentiment frequently surfaced in the context of accuracy and concerns about the scope of the test, i.e. that so many conditions would be screened and that different conditions had different positive predictive values. The pervasiveness of the 99% accuracy statistic led to false expectations of the screen and overestimation of the reliability of the returned high-risk result. Our findings suggest that a significant portion of women regret their decision to have cfDNA screening in light of the distress and additional medical interventions they experienced. Believing they had received a diagnosis, rather than a screen positive, led to considerable stress and anxiety about the health of the fetus. These findings echo previous research that shows members of the public perceive cfDNA screening as highly accurate and trustworthy [31–33]. This level of trust places increasing demands on pretest conversations to manage patient expectations, disclose the high variability in positive predictive values between conditions, and facilitate more informed choices on behalf of women and their families. As seen here, a failure to achieve robust patient comprehension pretest can lead to classic manifestations of decisional regret: frustration, anxiety, and anger, toward medical or test providers [30,34].

Decisional regret also appears to be a key factor in why so few participants who received high-risk results for microdeletion syndromes, T13/18, or Turner syndrome reported that they would agree to cfDNA screening in a future pregnancy. Similarly, the participants would not recommend cfDNA screening to a friend or family member without changes in the scope of the test or an accompanied warning about the accuracy and predictive value of the test, particularly in reference to the expanded panels of microdeletions and

sex chromosome aneuploidies. Interestingly, some participants suggested that they would feel comfortable doing cfDNA screening in a future pregnancy, even though they may have had a negative experience overall, because they had gained important understanding of the accuracy and predictive value of the test and would be more prepared in a future pregnancy.

Clinical recommendations

Despite the expression of decisional regret in the majority of participant interviews, approximately one third ($n = 14$) of participants said they would choose cfDNA screening for the future pregnancies, in spite of receiving false, inconclusive, or high-risk results, and some ($n = 8$) expressed overall positive feelings about cfDNA screening. This suggests that receiving a high-risk result is not, in and of itself, sufficient to cause enough decisional regret to lead to rejection of future screening. It may be that participants who were willing to undergo cfDNA in the future were inherently less disposed to decisional regret, either because they had higher tolerance for uncertainty, placed higher value on information at all costs, or had higher emotional resilience than other participants. This suggests even when high-risk or inconclusive results must be returned, practices can proactively implement procedures to reduce long-term decisional regret. In particular, our results stress the importance of setting expectations in pretest discussions, which may reduce adverse reactions to results. Additional research in this area should focus on the combination of patient information, counseling, and results delivery that leads to reduced decisional regret, even when a high-risk or inconclusive result is reported.

Limitations

The method of recruitment utilized in this study may have biased the sample toward those who had strong, typically negative views of cfDNA screening. Women who felt positively or neutrally may not have been interested in participating. The recruitment method targeted women willing to talk online about their pregnancy, potentially biasing the sample toward those who were comfortable sharing their experiences and away from those women who had extremely negative or traumatic experiences. As such, it is unclear to what extent the data provided can be generalized to other populations. The low response rate may reflect women's temporary engagement in pregnancy forums or a hesitance to participate in research regarding a highly emotional time. Finally, the majority of our study population was well-educated and white, limiting generalizations to populations of greater diversity or with less education.

Conclusions

Our findings suggest that women who have undergone cfDNA screening and received inconclusive, high-risk or false positive results have important concerns about the way in which this screen is conveyed and has been incorporated into prenatal care, with particular emphasis on the inadequacy of the information they received about cfDNA screening prior to the test. Women suggested that much of their post-test anxiety and regret could have been prevented by improvements in pretest clinical conversations. As the scope and uptake of cfDNA screening grows, it is increasingly important to take ample time for counseling and informed consent, particularly given that awareness of this screen is often

via nonclinical sources. The findings of this study suggest that robust patient comprehension and expectation setting is necessary to mitigate unnecessary stress and regret experienced by expectant women and their families following cfDNA screening.

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Table 1.

Participant demographics.

	***N* (%)**
Mean age in years	35.3 (s.d. = 4.5)
Race	
Latina	4 (10)
White	32 (80)
Asian	4 (10)
Education	
Some college	5 (12.5)
2-year junior or community college	4 (10)
4-year college or university	14 (35)
Graduate or professional school	17 (42.5)
Religion	
None	13 (32.5)
Christian	22 (55.0)
Jewish	2 (5)
Mormon	1 (2.5)
Wiccan	1 (2.5)

Table 2.

cfDNA screening result categories.

Screening Result	***N* (%)**
False Positive (T13/18/21)	10 (25)
False Positive (Sex Chrom. /Microdel.)	9 (22.5)
False Negative (Sex. Chrom. /Microdel.)	1 (2.5)
High-Risk (T13/18/21)	7 (17.5)
High-Risk (Sex. Chrom. /Microdel.)	4 (10)
True Positive (T13/18/21)	2 (5)
True Positive (Sex Chrom. /Microdel.)	2 (5)
Inconclusive	5 (12.5)