An Exploration of the Involvement of Genetic Counselors in the Delivery of Aneuploidy Screening and Testing

Master’s Thesis

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The Faculty of the Graduate School of Arts and Sciences
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in
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by
Qian (Lorraine) Lei

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ABSTRACT

An Exploration of the Involvement of Genetic Counselors in the Delivery of Aneuploidy Screening and Testing

A thesis presented to the Graduate Program in Genetic Counseling

Graduate School of Arts and Sciences
Brandeis University
Waltham, Massachusetts

By Qian (Lorraine) Lei

There is a current shortage of certified clinical genetic counselors to keep up the publics’ growing demand for genetic counseling services. This is especially a concern for the field of prenatal genetic counseling because of the introduction of non-invasive prenatal testing via cell-free DNA analysis and a recent American College of Obstetricians and Gynecologists (ACOG) practice guideline that suggests that this testing be available to all women. The purpose of this study is to assess prenatal genetic counselors’ involvement in offering aneuploidy screening and testing. An anonymous survey was distributed to the National Society of Genetic Counselors listserv and was completed by 193 prenatal genetic counselors. The demographics of the sample were reflective of the 2016 NSGC Professional Status survey. Only 29.7% of the respondents stated that they do follow the ACOG guideline. Barriers for implementing the ACOG guideline reported by all participants included: busy work schedule, adding additional time to counseling sessions, limited insurance coverage, and poor pre-test counseling by other health care providers. Participants reported seeing an average of 4.4 patients daily and a Quantitative Workload Inventory was an average of 16, indicating a reasonable workload. However, 14.7% participants
mentioned their busy work schedule as a barrier for implementing the ACOG practice guideline. In general, participants indicated that genetic counselors are the most appropriate provider to consent patients for both screening and diagnostic aneuploidy tests regardless of indication. Participants who indicated that the non-genetics providers in their practice received education on aneuploidy screening and testing found it to be more appropriate for non-genetics providers to consent patients for cffDNA in two circumstances: AMA and isolated echogenic intracardiac foci (p<0.05). Although 43.3% of participants distributed educational pamphlets in their practice, other forms of alternative service delivery were much less frequently utilized. The majority of participants did not utilize genetic counselor assistants. This study suggests that prenatal genetic counselors are not yet offering cffDNA to all women and few are utilizing alternative service delivery to increase workplace efficiency. In order to accommodate the demand for prenatal genetic counseling services it is important for prenatal genetic counselors to focus on education for non-genetics providers and incorporate more alternative service delivery.
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**Introduction**

Genetic counseling and prenatal diagnosis share a long and intimate history. The profession of genetic counseling first developed in the 1970’s, which was around the same time amniocentesis was first introduced (Rubin et al., 1983). Therefore, many of the first graduates from genetic counseling programs found employment in centers offering prenatal diagnosis (Resta, 2002). Prenatal genetic counselors at that time mostly counseled women of advanced maternal age about their age-related risk of having a fetus with a chromosomal abnormality and the option of amniocentesis. However, as the testing technologies developed over time, prenatal genetic counselors’ responsibilities also evolved.

With the introduction of first and second trimester maternal serum screening, prenatal genetic counselors began meeting with women younger than 35 who were found to have an increased risk for their fetus to have a chromosomal condition via maternal serum screening. (Huerta-Enochian, et al., 2001, Wald et al., 1988, Malone et al., 2005). In 2011, non-invasive prenatal testing (NIPT) became clinically available for detecting select chromosomal aneuploidies (Bianchi et al., 2012). NIPT is a screening test that uses cell free fetal DNA (cffDNA) from the plasma of pregnant women to detect fetal aneuploidy (Lo et al., 1997). This test is performed as early as 10 weeks gestation and is highly accurate with a low false positive rate for the most common trisomies. After the introduction of aneuploidy serum screening and cffDNA, the uptake of diagnostic testing significantly declined while the uptake of non-invasive testing methods increased (Wray et al., 2005, Nakata et al., 2010, Warsof et al., 2015).
The clinical availability of cffDNA has changed the practice of prenatal medicine. The American Congress of Obstetricians and Gynecologists (ACOG), National Society of Genetic Counselors (NSGC) and American College of Medical Genetics (ACMG) each published position statements and guidelines regarding the utility of cffDNA. NSGC recommends that cffDNA be offered as a testing option to patients with high-risk pregnancies, such as AMA, abnormal screening test/ultrasound, or positive family history (Dever et al., 2013). All three governing bodies agree that cffDNA should be offered with pre-test counseling and that any patient who had an abnormal cffDNA result should be offered diagnostic testing (ACOG, 2012; Gregg et al., 2013; Dever et al., 2013). In 2015, ACOG published guidelines that recommended cffDNA be discussed as an aneuploidy screening option for all women regardless of age (ACOG, 2015). In 2016, an updated statement from ACMG stated that cffDNA can replace the conventional aneuploidy screening tests for trisomy 18, trisomy 13, and Down syndrome. This guideline is well supported by clinical studies that have shown cffDNA is a very accurate and sensitive aneuploidy screening tool even when used in the general obstetric population (Taneja et al., 2016; Zhang et al., 2015). This trend of shifting the use of cffDNA to the general obstetric population has the potential to dramatically increase the number of patients referred to prenatal genetic counselors to discuss the options for aneuploidy screening and testing.

Currently, there is a shortage of certified clinical genetic counselors to keep up with the growing demand of genetic counseling services (Hoskovec et al., 2017). Recent studies have looked at the genetic counselor workforce in the United States and demonstrated a movement of many genetic counselors from clinical positions to non-clinical work settings (Cohen et al., 2017; Schulz et al., 2017). This shift in the types of position genetic counselors are accepting could be contributing to the shortage of clinical genetic counselors.
Due to the genetic counseling workforce shortage and increasing number of women who could benefit from cffDNA, more non-genetics providers may find themselves offering this testing. However, it is unclear if non-genetics providers are prepared to serve this patient population. A study surveyed 258 physicians to identify the resources used by physicians to learn about cffDNA and their practice patterns regarding cffDNA. The research revealed that about 28.7% of the physicians acquired information about cffDNA through a commercial laboratory as an initial source. Approximately half of obstetricians reported providing pre-test counseling themselves, and only a few referred patients to a genetics specialist (Farrell et al., 2016). Even if non-genetics providers are adequately prepared to offer cffDNA, the lack of genetic counseling for women having cffDNA testing may result in a failure to identify other genetic risk factors (Bernhardt et al., 2005, Aalfs et al., 2003).

Another approach to possibly alleviate the workforce shortage is to adopt alternative service delivery in an attempt to maximize prenatal genetic counselors’ capabilities to counsel low risk patients for cffDNA. Alternative service delivery options can include: centering, group counseling, pre-visit questionnaires, or use of genetic counselor assistants. Research has shown that these methods can improve the overall efficiency of genetic counseling (Trepanier et al., 2015; Cohen et al., 2013). For example, a randomized trial compared the quality of genetic counseling for AMA patients between individual and group counseling sessions. Patients who received group counseling had a significant increase in knowledge and decrease in decisional conflict whereas patients who received individual counseling had significantly higher levels of satisfaction (Agw et al., 2005). Another study looked at the effect of a web-based multimedia decision aid on informed decision-making for prenatal testing. The results demonstrated that
more women made informed decisions when the decision aid was utilized compared to the standard prenatal care (Beulen et al., 2016).

Genetic counselor assistant is a new role that aims to assist service delivery. Other medical professions have created tiered positions, such as physical therapist assistant, that have proven effective in increasing patient throughput and patient access, and improving patient safety and quality (Moote et al., 2011). When genetic counseling assistants take on simple tasks typically performed by a genetic counselor, genetic counselors are more productive and able to serve larger volumes of patients. For example, a study showed that certified genetic counselors reported a 60% increase in patient volume since the addition of genetic counselor assistants (Pirzadeh-miller et al., 2017). In this study, genetic counselor assistants’ responsibilities included: data entry, administrative tasks, shipping tests, research, and ordering supplies (Pirzadeh-miller et al., 2017).

**Purpose of This Study:**

No study has examined how the recent ACOG guidelines have impacted the work of prenatal genetic counselors. This study was designed to explore prenatal genetic counselors’ involvement in the delivery of aneuploidy screening and testing. We hope to understand how prenatal genetic counselors are incorporating and view the usefulness of alternative service delivery methods.
Methods

Study Design:
Brandeis University Institutional Review Board Committee for Protection of Human Subjects approved this study (IRB Protocol #18062). This was a cross-sectional quantitative study that surveyed prenatal genetic counselors using an anonymous online survey tool, Qualtrics. The survey consisted of 31 questions, which included single and multiple-choice, Likert-scale, and open-ended questions. Demographic questions included: gender, ethnicity, age, location of practice, type of work setting, and year of graduation. Workplace demographics questions asked about: number of full time/part time prenatal genetic counselors, number of patients seen daily, other health care providers in office, types of aneuploidy testing available, indications for visits, use of alternative service delivery, and employment of genetic counseling assistants. To assess participants’ perceived workloads, the quantitative workload inventory (QWI) was utilized (Spector and Jex, 1998). This five-item scale measures the level of quantitative workload with a maximum of 25 points. Participants were asked to rank the importance of genetic counseling for different referral indications: advanced maternal age (AMA), exposure to teratogen, family history of a cousin with Down syndrome, family history of a previous child with Down syndrome, increased risk for aneuploidy on cffDNA or serum screen, increased risk for aneuploidy on cffDNA, low risk patient seeking aneuploidy testing, positive carrier screening, ultrasound finding of cystic hygroma and ultrasound finding of echogenic intracardiac focus. The survey also asked about the appropriateness of non-genetics providers consenting patients for both cffDNA and diagnostic testing for a similar list of indications. Participants were invited to
comment on how the 2015 ACOG guideline recommending cfDNA be offered as a screening test to all women has impacted their current practice.

**Participants and Recruitment:**

Genetic counselors practicing in a prenatal setting in the United States or Canada were eligible to participate in the study. Participants were recruited through the NSGC e-mail listerv, which provided a direct link to the survey. An e-mail reminder was sent through the NSGC listerv two weeks after the initial recruitment notice.

Participation in the study was voluntary. The anonymous online survey allowed participants to opt out any time and skip any question they did not feel comfortable answering. At the end of the survey, participants had the option to enter a raffle for one of three $50 Amazon.com gift cards. Participants interested in entering the raffle were directed to another Qualtrics survey, which asked for their e-mail address. The e-mail address entered did not link to their survey responses and the e-mail addresses were deleted after the raffle winners were selected.

**Data Analysis:**

Quantitative data was analyzed using SPSS software for the rate of response, frequencies, and means. Paired t-tests and regression analyses were performed. Open-ended responses were coded for common themes.
Results

Demographics:

The survey reached more than 3,062 genetic counselors who are members of NSGC. There were 194 participants, but one response was excluded from analysis because the participant did not answer whether he/she worked as a prenatal genetic counselor. This left a total of 193 responses for analysis (14.7%).

Of the 193 respondents, 143 (74%) participants answered the majority of the demographic questions shown in Table 1. Participant demographics mirrored the 2016 Genetic Counseling Professional Status Survey (PSS).

Table 1: Demographics

<table>
<thead>
<tr>
<th>Region of practice</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Region 1 CT,MA,ME,NH,RI,VT,CN Maritime Provinces</td>
<td>11</td>
<td>7.7</td>
</tr>
<tr>
<td>Region 2 DC,DE,MD,NJ,NY,PA,VA,WV,PR,VI,Quebec</td>
<td>31</td>
<td>21.7</td>
</tr>
<tr>
<td>Region 3 AL,FL,GA,KY,LA,MS,NC,SC,TN</td>
<td>17</td>
<td>11.9</td>
</tr>
<tr>
<td>Region 4 AR,IA,IL,IN,KS,MI,MN,MO,ND,NE,OH,OK,SD,WI,Ontario</td>
<td>41</td>
<td>28.7</td>
</tr>
<tr>
<td>Region 5 AZ,CO,MT,NM,TX,UT,WY,Alberta, Manitoba, Sask.</td>
<td>13</td>
<td>9.0</td>
</tr>
<tr>
<td>Region 6 AK,CA,HI,ID,NV,OR,WA,British Columbia</td>
<td>30</td>
<td>21.0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>143</td>
<td>100</td>
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</table>

<table>
<thead>
<tr>
<th>Work setting</th>
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<tr>
<td>University medical center</td>
<td>54</td>
<td>37.8</td>
</tr>
<tr>
<td>Public hospital/ Medical facility</td>
<td>28</td>
<td>19.6</td>
</tr>
<tr>
<td>Private hospital/ Medical facility</td>
<td>39</td>
<td>27.3</td>
</tr>
<tr>
<td>Diagnostic Laboratory</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Physician's private practice</td>
<td>19</td>
<td>13.3</td>
</tr>
<tr>
<td>Other*</td>
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<td>2.0</td>
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<tr>
<td><strong>Total</strong></td>
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<td>100</td>
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<table>
<thead>
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<td>Male</td>
<td>6</td>
<td>4.2</td>
</tr>
<tr>
<td>Female</td>
<td>135</td>
<td>94.4</td>
</tr>
<tr>
<td>I prefer not to answer</td>
<td>2</td>
<td>1.4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>143</td>
<td>100</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>----</td>
<td>-----</td>
</tr>
<tr>
<td>White</td>
<td>135</td>
<td>90.6</td>
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<tr>
<td>Hispanic/Latino</td>
<td>4</td>
<td>2.7</td>
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<td>American Indian or Alaska Native</td>
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<td>0.0</td>
</tr>
<tr>
<td>Asian</td>
<td>10</td>
<td>6.7</td>
</tr>
<tr>
<td>Native Hawaiian or Pacific Islander</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Other*</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>149</td>
<td>100</td>
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<table>
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<tr>
<th>Graduation year</th>
<th>n</th>
<th>%</th>
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<tr>
<td>2017</td>
<td>26</td>
<td>19.0</td>
</tr>
<tr>
<td>2016-2012</td>
<td>45</td>
<td>32.8</td>
</tr>
<tr>
<td>2011-2007</td>
<td>27</td>
<td>19.7</td>
</tr>
<tr>
<td>2006-2002</td>
<td>8</td>
<td>5.8</td>
</tr>
<tr>
<td>2001-1997</td>
<td>13</td>
<td>9.5</td>
</tr>
<tr>
<td>1996-1992</td>
<td>7</td>
<td>5.1</td>
</tr>
<tr>
<td>1991-1987</td>
<td>8</td>
<td>5.8</td>
</tr>
<tr>
<td>1986-1980</td>
<td>3</td>
<td>2.2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>137</td>
<td>100</td>
</tr>
</tbody>
</table>

**Work Environment:**

Participants (n=173) reported an average of 3.7 full time prenatal genetic counselors and an average of 1.1 part time prenatal genetic counselors in their practice. On average, participants reported seeing 4.4 patients per day (std=2.1, Min=1, Max=20). For each patient, respondents reported spending an average of 13 minutes to prepare, 40 minutes to counsel, and approximately 11 minutes for either telephone or in person follow-up. Reasons for referral are documented in **Figure 1**. The most common reasons for referral were advanced maternal age (33.2%) and abnormal ultrasound (16.4%). The average QWI score reported by participants was 16 out of a maximum of 25 points.
Figure 2 illustrates the tests available at participants’ workplaces. All participants indicated that amniocentesis and cffDNA were available. The majority of participants indicated that first trimester serum screening (92%) and CVS (89.7%) were available. Most participants (89.7%) reported having Maternal Fetal Medicine (MFM) providers at their workplace.
Standard of Practice:

Figure 3 summarizes which providers consent AMA and low risk patients for testing. The majority of participants indicated that in their practice a genetic counselor consents AMA patients for cffDNA (95.5%), serum screening (74.7%), and CVS/amniocentesis (95.2%). MFMs were the second most common providers to consent AMA patients for cffDNA (39%), serum screening (44%) and CVS/amniocentesis (52.7%). Similarly, genetic counselors were the most common provider to consent low risk patients for cffDNA (76.7%), serum screening (62.3%) and CVS/amniocentesis (78.1%). MFMs were also the second most common provider to consent low risk patients for cffDNA (Figure 4).

![Figure 3: Health Care Providers Who Consent AMA Patients for Different Types of Aneuploidy Testing](image-url)
When asked to indicate how important (1=not important, 5=very important) genetic counseling is for a variety of indications, increased risk for aneuploidy on cffDNA was the most important indication for genetic counseling (mean=4.96), followed by ultrasound finding of cystic hygroma (mean=4.91). History of a previous child with Down syndrome was ranked as the least important indication for genetic counseling (mean=3.11) (Figure 5).
For cfDNA, participants indicated that they felt it was more appropriate for a non-genetics provider to consent low risk patients (mean=2.77) than any other indication. Among all indications, participants felt it was least appropriate for a non-genetics provider to consent patients with an ultrasound finding of cystic hygroma (mean=1.74) (Figure 6). When asked about the appropriateness of having a non-genetics provider to consent patients for CVS/amniocentesis, participants’ responses showed minimal fluctuation between different referral indications (mean=1.86) (Figure 6).
For all indications, participants indicated that it was more appropriate (mean=2.3) for non-genetics provider to consent patients forcffDNA than CVS/amniocentesis (mean =1.9). This reached statistical significance for the following indications: AMA, a cousin with Down syndrome, low risk patient seeking aneuploidy testing, and ultrasound finding of echogenic intracardiac focus (p<0.005).

The availability of education for non-genetics providers did appear to impact how participants felt about non-genetics providers consenting patients. Participants who specified that there was education available for non-genetics providers indicated that it was more appropriate for a non-genetics providers to consent AMA patients and patients with an ultrasound finding of EIF for cffDNA (p<0.05). These participants commented on the type of education received by non-genetics providers (Table 2). The most common form of education was formal presentations.
from genetic counselors. However, less than half of participants indicated that non-genetics providers received any education on aneuploidy screening and testing (47.3%).

Table 2: The Types of Education Received by Non-genetics Providers on Aneuploidy Testing

<table>
<thead>
<tr>
<th>Theme</th>
<th>Sub-Themes</th>
<th>n=70</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formal or informal education</td>
<td>Formal</td>
<td>54</td>
<td>77.1</td>
</tr>
<tr>
<td></td>
<td>Informal</td>
<td>13</td>
<td>18.6</td>
</tr>
<tr>
<td>Source of education</td>
<td>From genetic counselor</td>
<td>38</td>
<td>52.8</td>
</tr>
<tr>
<td></td>
<td>From other providers</td>
<td>5</td>
<td>7.1</td>
</tr>
<tr>
<td></td>
<td>From industry</td>
<td>3</td>
<td>4.3</td>
</tr>
<tr>
<td>Education format</td>
<td>In-service/seminar/talk/presentation</td>
<td>28</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td>Industry presentation</td>
<td>3</td>
<td>4.3</td>
</tr>
<tr>
<td></td>
<td>Online written information</td>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Medical training</td>
<td>15</td>
<td>21.4</td>
</tr>
</tbody>
</table>

Use of Alternative Service Delivery:

Some genetic counselors utilized alternative service delivery (Figure 7). A minority (11.3%) of participants indicated that their practice employed genetic counselor assistants. These participants indicated that genetic counselor assistants were involved in case preparation/chart organization, insurance authorization/billing, and filling out requisitions. Educational pamphlets were utilized by 43.3% of participants and pre-visit questionnaires were utilized by 24.2% of participants. Webinar was the least commonly (1.5%) used resource.
Regardless of whether the practice utilized alternative service delivery, participants were asked to rank the potential effectiveness of various methods of alternative service delivery (Figure 8). Overall, at least half of participants who answered this question found all methods to be at least moderately effective.
Implications of 2015 ACOG Guideline:

All participants were asked to comment on how the 2015 ACOG guideline recommending that cfDNA be discussed as a testing option for all pregnant women impacted their current practice. Of the 136 participants who responded to the question, 34.6% did not clearly indicate if they followed the ACOG recommendation, while 39.7% said that they did and 25.7% said that they did not. There were no regional differences for implementing this ACOG guideline. Participants who do follow the ACOG guideline frequently mentioned increased patient load (14.7%) and additional time added to counseling sessions (4.4%). The same themes were stated as barriers for implementing the ACOG guideline in addition to limited insurance coverage (15.4%) and poor pre-test counseling from other healthcare providers (5.1%). Table 3 lists barriers voiced by all respondents disregarding whether ACOG guideline was followed or not.

<table>
<thead>
<tr>
<th>Themes</th>
<th>n=136</th>
<th>%</th>
<th>Example Quote</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased patient load</td>
<td>20</td>
<td>14.7</td>
<td>“significantly increased patient volume”</td>
</tr>
<tr>
<td>Limited insurance coverage</td>
<td>21</td>
<td>15.4</td>
<td>“Insurance companies do not pay for cfDNA for patients with low risk indications. Sometimes they don't even pay for this testing when there is an appropriate indication. Insurance is the limiting factor at my practice for offering all patients cfDNA.”</td>
</tr>
<tr>
<td>Poor pre-test counsel by other health care providers</td>
<td>7</td>
<td>5.1</td>
<td>“If the OB sent all pregnant patients to us, we couldn't see them all. However, when I see patients who do the NIPT thru their OB, they have usually not been informed of the limitations, PPV, etc. However, most patients are only doing it for gender and will have normal results.... It is the new requirement of insurance demanding preauth that is killing us…”</td>
</tr>
<tr>
<td>Adding time to counseling session</td>
<td>6</td>
<td>4.4</td>
<td>“Lengthens the time spend with each patient”</td>
</tr>
</tbody>
</table>
Discussion

Current Testing Practices:

In 2015, ACOG published a practice guideline that recommended that cffDNA be offered to all pregnant women regardless of age (ACOG, 2015). In light of this new guideline and increased acceptance of offering cffDNA to low risk women by other professional societies this study aimed to assess prenatal genetic counselors’ roles in the delivery of prenatal aneuploidy screening and testing. To our knowledge, this is the first study of its kind. The demographics of our sample are comparable to the 2016 NSGC PSS, suggesting that these results may be generalizable to the field of prenatal genetic counseling (Gregg et al, 2016).

Although aneuploidy screening has evolved significantly since its inception, the most common referral indication for prenatal genetic counseling in this study was advanced maternal age. Despite the most recent ACOG guideline, participants were not regularly offering cffDNA to all women. However, participants indicated that in their practices genetic counselors were the primary provider to consent both AMA and low risk patients for cffDNA. Interestingly, both participants who do and those who do not offer cffDNA to all women noted similar barriers in their practice including increased patient load, additional time added to counseling sessions, limited insurance coverage, and poor pre-test counseling from other health care providers. A recent study also identified lack of time to explain screening and testing options as an issue for integrating cffDNA into current prenatal care (Gammon et al; 2017).
Participants indicated that genetic counselors are the most appropriate provider to consent patients for both screening and diagnostic testing, regardless of indication. Although non-genetics providers were less appropriate to consent patients for testing, participants felt it was more appropriate for non-genetics providers to be involved in screening than diagnostic testing. This finding reached statistical significance for the indications AMA, family history of a cousin affected with Down syndrome, and low risk patient with ultrasound finding of EIF. Overall, these indications are associated with a very low risk for aneuploidy and therefore it is less common for patients to pursue diagnostic testing for these indications. A patient undergoing diagnostic testing despite having a low risk of fetal aneuploidy could be a sign of patient misunderstanding and the need for further counseling, which could explain why a greater disparity was seen for these three indications.

*Patient Volume:*

Given the ongoing shortage of genetic counselors, it is surprising that participants’ patient volume was quite low. It is possible that the busiest prenatal genetic counselors did not have time to complete the survey. Another explanation for this finding is that some participants are part-time prenatal genetic counselors, but this study did not ask participants to disclose whether they work full-time or part-time. All participants did also complete the quantitative workload inventory, but this did not portray the busy schedules we anticipated either. Furthermore, there was no relationship between QWI score and following the ACOG guidelines.

With the relatively low patient volumes and workload inventories reported, it is therefore also somewhat surprising that busy work schedules were reported as both barriers and challenges of implementing the ACOG guidelines. Perhaps this discrepancy could be attributed to a lack of
workflow efficiency, as the majority of participants did not utilize genetic counselor assistants or alternative counseling resources beyond educational pamphlets. This finding could also be attributed to alternative service delivery utilized by genetic counselors in industry. Arjunan et al. (2018) reported on how web education, counseling, and automated notifications were implemented to issue 64,501 cffDNA results over a 39 month period through Counsyl. Many other genetic testing laboratories provide customers the option to access a genetic counselor through this channel. As the current study did not include prenatal genetic counselors working in industry, it is not possible to assess this type of delivery model in clinical setting from this data.

It is interesting to note that no participants commented on the utility of patients accessing genetic counseling through the genetic companies directly. It is unclear whether this represents a lack of awareness of this type of resource. Lastly, it is possible that more low risk patients receive cffDNA from their obstetricians than from prenatal genetic counselors.

**Practice Implications:**

In this study, the majority of participants were not offering cffDNA to all patients, but did believe genetic counselors were the most appropriate providers to consent patients for this testing. Regardless of their practice of offering cffDNA, participants cited their busy schedules as a challenging aspect of this recommendation despite having a fairly low patient volume. This raises the question of whether prenatal genetic counselors are the provider who will see general population patients seeking cffDNA and if so, whether prenatal genetic counselors will be able to meet the increased demand for their services.

Although participants found it most appropriate for genetic counselors to consent all patients for cffDNA regardless of indication, they were more accepting of non-genetics providers
consenting patients forcffDNA in certain scenarios when the non-genetics providers received education. This education was often in the form of a lecture given by a genetic counselor. Studies have shown general healthcare providers are capable of offering prenatal aneuploidy screening when given appropriate education. A recent study implemented a program called DNAFirst, where obstetrical care providers received specific educational training regarding cffDNA screening and had validated patient-friendly information materials available. These obstetrical care providers offered cffDNA screening for aneuploidies to a general pregnancy population and patient surveys showed that most of the patients understood the concept of cffDNA and were satisfied with the care provided (Palomaki et al., 2017). Perhaps more efforts should be placed on educating non-genetics providers about aneuploidy screening to help them develop competency and practice patterns regarding cffDNA. In the future, non-genetics providers may be able to routinely offer cffDNA to patients with common indications and genetic counselors will have more time to counsel patients with complex indications for either screening or diagnostic testing.

Even though the majority of participants were not utilizing alternative service delivery beyond educational pamphlets to increase workplace efficiency, the majority of participants did feel that all methods would be at least moderately effective in increasing efficiency. This may illustrate a need for genetic counselors to have further education and training on how to incorporate more innovative methods of delivering their services. Although the participants in this study who had genetic counselor assistants reported similar roles for genetic counselor assistants as previous studies (Pirzadeh-Miller et al., 2017), participants with genetic counselor assistants did not have lower QWI scores. Perhaps this is could reflect the underlying reason for hiring genetic counselor assistant and overall staffing. If a genetic counselor assistant was hired due to an inability to hire another genetic counselor due to the workforce shortage, the presence
of a genetic counselor assistant may not have a significant impact on the genetic counselors’ workload.

**Future Directions:**

Future studies should more closely examine how prenatal genetic counselors utilize their time in an effort to achieve efficient workflow. More in depth research could also be conducted to understand which alternative service delivery models are most impactful in a prenatal setting. Specifically, further research should aim to understand the distribution of patient care between genetic counselors employed by genetic testing companies and genetic counselors working in a hospital setting. Future research could also examine non-genetics providers’ competence in offeringcffDNA after additional education on a broader scale.

**Study Limitations:**

The study was limited by sample size and sample bias. The survey was distributed through the National Society of Genetic Counseling (NSGC) email listserv, but not the prenatal Special Interest Group (SIG) email listserv. Prenatal SIG members may have had different responses. However, it is possible the members of the prenatal SIG did receive the recruitment message through the general listserv. Another possible limitation to this study is that prenatal genetic counselors with busier work schedules may have been less likely to participate. Although all geographic regions are represented in the study, there is no way to rule out overrepresentation of a single institution employing a large number of genetic counselors. This study did not include genetic counselors employed by genetic testing companies who provide counseling to patients having cffDNA through alternative service delivery.
Conclusion:

Overall, this study provides insight into how prenatal genetic counselors are involved in the delivery of aneuploidy screening and testing. For participants in this study, it is not yet routine to offer all patients cfDNA testing. However, participants viewed genetic counselors as the most appropriate provider to consent patients for cfDNA across all indications. Although participants viewed non-genetics providers as less appropriate to consent patients for cfDNA, they were more open to this for more straightforward indications. Furthermore, education for non-genetics providers appeared to increase genetic counselors’ comfort with non-genetics providers’ involvement in aneuploidy screening. The majority of participants did not utilize methods to increase workforce efficiency beyond educational pamphlets. In order to provide appropriate care for all individuals seeking cfDNA testing in the future, prenatal genetic counselors should prioritize education of non-genetics providers and the incorporation of alternative service delivery.
References

25. Resta, R. (2002). Historical Aspects of Genetic Counseling: Why was Maternal Age of 35 Chosen as the Cut-off for Offering Amniocentesis?
Appendix A: Recruitment Materials

Recruitment Notice Email:

Subject: Calling all prenatal genetic counselors!

My name is Qian (Lorraine) Lei and I am a second year genetic counseling student at Brandeis University. You are invited to participate in an online survey to investigate how genetic counselors are involved in offering aneuploidy screening and testing across the United States.

Eligibility:
This study is open to ABGC board-certified or board-eligible prenatal genetic counselors who currently work in the United States.

Participation involves an anonymous online survey that will take an average of 15-20 minutes to complete. Your survey participation is completely voluntary and you may choose to skip any questions you do not feel comfortable answering or exit the survey at any point.

All participants who complete the survey are eligible to enter a draw for one of three $50 Amazon.com gift cards. If you choose to enter the raffle, you will be directed to a separate survey to enter your email address. This is to ensure the anonymity of your survey response.

Please click here to take the survey!
https://brandeis.qualtrics.com/jfe/form/SV_4MXv8tkRfJLz7x3

If you have any questions or concerns please feel free to contact me, Qian (Lorraine) Lei (qianlei@brandeis.edu) or the Principal Investigator Lauren Lichten MS, CGC (laurlic@brandeis.edu) by email.

Thank you in advance for your time and participation.

Sincerely,

Qian (Lorraine) Lei, MS
Master’s Degree Candidate, Class of 2018
Genetic Counseling Program
Brandeis University

Lauren Lichten, MS, CGC
Associate Director, Genetic Counseling Program
Associate Professor of the Practice of Genetic Counseling
Brandeis University
Appendix B: Survey

A National Exploration of the Involvement of Genetic Counselors in the Delivery of Aneuploidy Screening and Testing

Q1 A national exploration of the involvement of genetic counselors in the delivery of aneuploidy screening and testing

Welcome! You are being asked to participate in this anonymous study because you are currently a prenatal genetic counselor who is employed in the United States. The purpose of this study is to investigate how genetic counselors are involved in offering aneuploidy screening and testing.

Your response to this online survey will be anonymous. The survey is estimated to take 15-20 minutes to complete. Participation in the survey is voluntary and you may exit the survey at any time.

Participants who complete this survey may enter a drawing for one of three $50 Amazon.com gift cards by providing their email address on a form that is not linked to their survey response. Please only take this survey once.

By clicking "Next" you acknowledge that you have read the information above and you consent to participate in this survey.

☐ Next

☐ I do not wish to participate

Q2 Do you currently counsel pregnant women for aneuploidy screening/testing?

☐ Yes

☐ No

End of Block: General Information

Start of Block: Referral structure

Q3 How many prenatal genetic counselors (including yourself) work at your institution?

Full-time : _______
Part time : _______
Total : _______

End of Block: Referral structure
Q4 Which other professional(s) work in your clinic?

Maternal-fetal Medicine physician

Midwife

Nurse

Nurse practitioner

Obstetrician

Other ________________________________

Q5 Does your department employ genetic counselor assistants?

☐ Yes

☐ No
Q6 Which of the following tasks is part of a genetic counselor assistant's job responsibility at your workplace? (Please select all that apply)

- Calling patients with normal results
- Calling patients with abnormal results
- Case prep/ chart organization
- Documenting patient encounter
- Entering pedigree into electronic medical record
- Filling out requisitions
- Insurance authorization/ billing
- Other

Q7 How many genetic counselor assistants work at your department?
Full-time: _______
Part-time: _______
Total: _______

Q8 Approximately how many patients do you see per day?
__________________________________________
Q9 Please indicate the approximate percentage of the following prenatal referral indications at your practice (all should add up to 100%).
Abnormal ultrasound : _______
Advanced maternal age : _______
Positive family history : _______
Increased risk of aneuploidy on serum screening : _______
Increased risk of aneuploidy on NIPT/ cfDiNA : _______
Exposure to teratogen : _______
Positive carrier screening : _______
Low risk patient seeking aneuploidy screening/testing : _______
other : _______
Total : _______

Q10 Please indicate the average number of minutes spent per patient on each of the following tasks.

<table>
<thead>
<tr>
<th>Task</th>
<th>0</th>
<th>10</th>
<th>20</th>
<th>30</th>
<th>40</th>
<th>50</th>
<th>60</th>
<th>70</th>
<th>80</th>
<th>90</th>
<th>100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient prep</td>
<td></td>
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<tr>
<td>In-person counseling</td>
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<tr>
<td>Telephone follow-up</td>
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<tr>
<td>In-person follow-up</td>
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</tr>
</tbody>
</table>
Q11 Please fill in the following table to comment on your work environment

<table>
<thead>
<tr>
<th>How often does your job require you to work very fast?</th>
<th>less than once per month</th>
<th>once or twice per month</th>
<th>once or twice per week</th>
<th>once or twice per day</th>
<th>several times per day</th>
</tr>
</thead>
<tbody>
<tr>
<td>How often does your job require you to work very hard?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How often does your job leave you with little time to get things done?</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>How often is there a great deal to be done?</td>
<td></td>
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</tr>
<tr>
<td>How often do you have to do more work than you can do well?</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
Q12 Which types of aneuploidy screening/testing are available to patients at your practice? (Please select all that apply)

Amniocentesis

cffDNA/ NIPT

Chorionic Villus Sampling

First trimester screen

Integrated screen

Level II ultrasound

Nuchal Translucency scan

Quad screen

Sequential screen

Other, please specify __________________________________________

Q13 In your clinic, which health care provider consents advance maternal age (AMA) patients for the following tests? (Please select all that apply)

<table>
<thead>
<tr>
<th>NIPT/ cffDNA</th>
<th>Serum screening</th>
<th>CVS/ Amniocentesis</th>
</tr>
</thead>
</table>
Genetic Counselor
Genetic Counselor Assistant
Maternal-fetal Medicine physician
Midwife
Nurse
Nurse practitioner
Obstetrician
Other, please specify

Q14 Do you know if the non-genetics providers at your current workplace received any education on aneuploidy screening/testing?

- Yes
- No
- I don't know

Q15 What type of education did non-genetics providers receive on aneuploidy screening/testing?

__________________________________________________________________________
Q16 In your clinic, which health care provider consents *low risk* patients younger than 35 who have no other risk factors for fetal aneuploidy for the following tests? (Please select all that apply)

<table>
<thead>
<tr>
<th>Click to write Column 1</th>
<th>NIPT/ cfDNA</th>
<th>serum screening</th>
<th>CVS/ Amniocentesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genetic Counselor</td>
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<tr>
<td>Genetic Counselor</td>
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<tr>
<td>Assistant</td>
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<tr>
<td>Maternal-fetal</td>
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<tr>
<td>Medicine physician</td>
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<tr>
<td>Midwife</td>
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<tr>
<td>Nurse</td>
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<tr>
<td>Nurse Practitioner</td>
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<tr>
<td>Obstetrician</td>
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<td></td>
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<tr>
<td>Other, please specify</td>
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<td></td>
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</tr>
</tbody>
</table>
Q17 How important is it for a patient to receive genetic counseling for the following indications?

<table>
<thead>
<tr>
<th>Indication</th>
<th>Very important</th>
<th>Important</th>
<th>So-so</th>
<th>Somewhat important</th>
<th>Not important</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced maternal age</td>
<td></td>
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<tr>
<td>Exposure to teratogen</td>
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<tr>
<td>Family history of a cousin with Down syndrome</td>
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<tr>
<td>Family history of a previous child with Down syndrome</td>
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<tr>
<td>Increased risk for aneuploidy on serum screen</td>
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<tr>
<td>Increased risk for aneuploidy on NIPT/cffDNA</td>
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<tr>
<td>Low risk patient seeking aneuploidy screening/testing</td>
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<tr>
<td>Positive carrier screening</td>
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<tr>
<td>Ultrasound finding of cystic hygroma</td>
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<tr>
<td>Ultrasound finding of echogenic intracardiac focus</td>
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<tr>
<td>other</td>
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</tbody>
</table>
Q18 How appropriate is it for a non-genetics provider to consent the following patients for NIPT /cffDNA?

<table>
<thead>
<tr>
<th></th>
<th>Very appropriate</th>
<th>Appropriate</th>
<th>Indeterminate</th>
<th>Somewhat appropriate</th>
<th>Not appropriate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced maternal age</td>
<td></td>
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<tr>
<td>Family history of a cousin</td>
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<tr>
<td>with Down syndrome</td>
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<tr>
<td>Family history of a previous</td>
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<tr>
<td>child with Down syndrome</td>
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<tr>
<td>Increased risk for aneuploidy</td>
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<tr>
<td>on serum screen</td>
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<tr>
<td>Low risk patient seeking</td>
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<tr>
<td>aneuploidy testing</td>
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<td>Ultrasound finding of</td>
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<tr>
<td>cystic hygroma</td>
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<tr>
<td>Ultrasound finding of</td>
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<tr>
<td>echogenic intracardiac</td>
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<tr>
<td>focus</td>
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<tr>
<td>Other</td>
<td></td>
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</tbody>
</table>
Q19 How appropriate is it for a non-genetics provider to consent the following patients for diagnostic procedures (CVS/Amniocentesis)?

<table>
<thead>
<tr>
<th></th>
<th>Very appropriate</th>
<th>Appropriate</th>
<th>Indeterminate</th>
<th>Somewhat appropriate</th>
<th>Not appropriate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced maternal age</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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</tr>
<tr>
<td>Family history of a cousin with Down syndrome</td>
<td>☐</td>
<td>☐</td>
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<td>☐</td>
</tr>
<tr>
<td>Family history of a previous child with Down syndrome</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Increased risk for aneuploidy on serum screen</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Increased risk for aneuploidy on NIPT/cffDNA</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Low risk patient seeking aneuploidy</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Ultrasound finding of cystic hygroma</td>
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<tr>
<td>Ultrasound finding of echogenic intracardic focus</td>
<td>☐</td>
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<tr>
<td>Other</td>
<td>☐</td>
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<td>☐</td>
</tr>
</tbody>
</table>
Q20 For which of the following patients would you take a full family pedigree?

Abnormal ultrasound

Advanced maternal age

Positive family history

Increased risk of aneuploidy on serum screening

Increased risk of aneuploidy on NIPT/cffDNA

Exposure to teratogen

Positive carrier screening

Low risk patient seeking aneuploidy screening/testing

other ____________________________

End of Block: Referral structure

Start of Block: Genetic Counseling Assistance
Q21 Does your current workplace utilize any of the following strategies in patient care? (Please select all that apply)

- Centering
- Group counseling
- Educational videos
- Webinar
- Educational pamphlet
- Informational website
- Pre-visit questionnaires
- Other ________________________________________________
- None of above
Q22 Please indicate the effectiveness of the following strategies when incorporated in your current workplace.

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Extremely effective</th>
<th>Very effective</th>
<th>Moderately effective</th>
<th>Slightly effective</th>
<th>Not effective at all</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centering</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
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<tr>
<td>Group counseling</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
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<tr>
<td>Educational videos</td>
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<tr>
<td>Webinar</td>
<td>○</td>
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<tr>
<td>Educational pamphlet</td>
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<tr>
<td>Informational website</td>
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<tr>
<td>Pre-visit questionnaires</td>
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<tr>
<td>Other</td>
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</tbody>
</table>

Q23 Current ACOG guidelines recommend that all pregnant women be offered NIPT/cffDNA. Please comment on how this recommendation impacts your current job.

End of Block: Genetic Counseling Assistance

Start of Block: Demographic questions
Q24 In which region do you practice genetic counseling?

- Region 1 CT, MA, ME, NH, RI, VT, CN Maritime Provinces
- Region 2 DC, DE, MD, NJ, NY, PA, VA, WV, PR, VI, Quebec
- Region 3 AL, FL, GA, KY, LA, MS, NC, SC, TN
- Region 4 AR, IA, IL, IN, KS, MI, MN, MO, ND, NE, OH, OK, SD, WI, Ontario
- Region 5 AZ, CO, MT, NM, TX, UT, WY, Alberta, Manitoba, Sask.
- Region 6 AK, CA, HI, ID, NV, OR, WA, British Columbia

Q25 Which of the following best describes the setting where you practice genetic counseling?

- University Medical Center
- Public Hospital/ Medical Facility
- Private Hospital/ Medical Facility
- Diagnostic Laboratory
- Physician's Private Practice
- Other, please specify ____________________________

Q26 What year did you graduate from your Genetic Counseling Program?

__________________________________________________________

Q27 How many years of experience do you have providing prenatal genetic counseling?

__________________________________________________________

40
Q28 Which of the following gender do you identify with?

- Male
- Female
- Other ________________________________
- I prefer not to answer

Q29 What is your ethnicity?

- White
- Hispanic/ Latino
- American Indian or Alaska Native
- Asian
- Native Hawaiian or Pacific Islander
- Other ________________________________

Q30 How old are you?

__________________________________________
Q31 Thank you for completing this survey! If you would like to be entered for a chance to win a $50 Amazon gift card, please select "yes," and you will be directed to another survey to fill out the your email address. The information that you provided in this survey will not be linked to the draw.

☐ Yes

☐ No, thank you

End of Block: Demographic questions