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Privacy practices using genetic data from cell-free DNA aneuploidy screening

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PURPOSE: Cell-free fetal DNA (cfDNA) analyzes maternal and fetoplacental DNA, generating highly personal genetic information for both mother and fetus. This study aimed to determine how laboratories retain, use, and share genetic information from cfDNA. Other outcomes included laboratories' adherence to American Society of Human Genetics (ASHG) privacy principles, and the readability of privacy policies.

METHODS: Laboratories offering cfDNA aneuploidy screening were identified from online searches, curated databases, and a genomics news website. Of 124 laboratories identified, 13 were commercial laboratories offering cfDNA aneuploidy screening in the United States, and were included. Genetic privacy policies from eligible laboratories were identified by reviewing requisition and consent forms, which were obtained online or by direct contact.

RESULTS: Most laboratories use prenatal genetic information for research ($n = 10$, 77%), and more than half ($n = 7$, 54%) shared genetic information with others. Overall, laboratories inadequately disclosed privacy risks. In a readability analysis, 9 of 11 (82%) laboratories' genetic privacy policies were written at or above a 12th grade reading level.

CONCLUSION: Most laboratories allowed for prolonged use and sharing of cfDNA data, demonstrated incomplete adherence to ASHG privacy recommendations, and provided consents written in college-level language. Laboratories should revise their consent forms, and providers should help patients understand these forms.

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INTRODUCTION

Cell-free fetal DNA screening (cfDNA) is endorsed by the American College of Obstetrician and Gynecologists (ACOG) as a screening option for common aneuploidies in all pregnancies.[1] Since its introduction in 2011, cfDNA screening for fetal aneuploidies has expanded rapidly in the United States and internationally, with a projected 15% annualized growth in testing.[2] It is now considered the most rapidly adopted genetic test in medical history,[3,4] and is performed by both commercial and hospital-based laboratories.

While there are different methods for producing cfDNA data, the most common use massively parallel shotgun sequencing (MPSS) or targeted single-nucleotide polymorphism (SNP) analysis to generate detailed genotypic information for both mother and the placenta, which typically reflects fetal genetics. cfDNA data contains genotypes for hundreds or even thousands of SNPs,[5–7] and the allele frequencies at these loci contribute to aneuploidy risk estimation models. Although invasive prenatal genetic testing has for decades collected genetic material for karyotype or microarray, the ubiquity of cfDNA has greatly expanded the number of women who undergo genotyping during pregnancy.

In contrast to serum screening results or ultrasound images, the genetic information generated by cfDNA methods may contain unanticipated insights into the present and future health of mother, fetus, and even extended family. With the falling cost of sequencing, the scope of noninvasive prenatal genetic screening is expanding.[8,9] cfDNA-based prenatal detection for sickle cell anemia,[10] hemophilia,[11] and numerous other monogenic diseases[12] is now commercially available, and cfDNA may someday be used to test for *BRCA* variants.[13] With ever-improving analytical methods, cfDNA data collected today may be reanalyzed later to reveal new insights, enabled by chance sequencing coverage at informative loci or by imputation.

In addition to containing unanticipated information about patients' future health status, genetic data is difficult to de-identify, and patients may be re-identified from their DNA even after it has been stripped of protected health information (such as name, contact information, and demographics). Information at 30 to 80 SNP loci is sufficient to uniquely identify an individual,[14] far fewer than what is produced by cfDNA.[5–7] If prenatal genetic data were to come into the possession of a party already equipped with identified genetic data from the individual in question, these may provide additional (and perhaps compromising) genetic information. Even more concerning, an individual's genetic data may be traced back to them by a party with no prior access to their information using anonymized public genetic databases,[15–17] and such tracing may be possible even if the anonymized genotype data are sparse and of low quality.[18] These scenarios could have long-term implications for both the mother and fetus undergoing cfDNA testing: while protections exist that may safe safeguard individuals from health insurance or employment discrimination (such as the Genetic Information Nondiscrimination Act), there are no similar guidelines for disability, life, and long-term care insurance.

The potential long-term genetic privacy implications from cfDNA screening have caused the National Council on Disability to call for greater oversight of the use of prenatal genetic information.[19] However, to date, there is no published literature describing whether patients or providers are aware that cfDNA screening may engender long-term consequences for genetic

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privacy. Moreover, the genetic privacy policies of commercial cfDNA laboratories have not been systematically examined to clarify how laboratories handle the many terabases of prenatal genetic information produced each year.

To address this knowledge gap, we performed a review of the genetic privacy policies of commercial laboratories that offer cfDNA screening in the United States. Our primary outcome was to determine how laboratories retain, use and share genetic information generated from cfDNA. Our secondary outcomes included the adherence of commercial laboratories' privacy policies to the American Society of Human Genetics five "core principles" for advancing research and privacy,[20] as well as the readability of relevant portions of privacy policies. This study does not aim to rank or recommend specific laboratories based on their privacy policies, but rather to provide prenatal care providers and genetic counselors with the perspective needed to have an informed discussion with patients.

MATERIALS AND METHODS

Identification of commercial laboratories offering prenatal cfDNA aneuploidy screening

Prior to data collection, we developed and submitted a laboratory-identification and data extraction protocol to PROSPERO (#CRD42020168758). Using four complementary approaches similar to a recent study of cfDNA laboratory methods,[21] we identified companies offering commercially available prenatal cfDNA screening that were available as of 18 February 2020. More specifically, we identified laboratories listed on the https://concertgenetics.com database (searching all results on 18 February 2020 under the "Noninvasive Prenatal Testing [NIPT] Expanded Panel Tests" and "Noninvasive Prenatal Testing [NIPT] for Chromosome 13, 18, 21, X, and Y Aneuploidies" categories), as well as a curated list from the National Society of Genetic Counselors. In addition, we performed an online search using https://google.com, the most-used search engine by search volume, and https://duckduckgo.com, a top five US search engine by volume and the largest that does not profile users, resulting in delivery of uniform search results to all users.[22] Twelve search terms were used in each search engine: *aneuploidy screen*, *cell-free DNA*, *cell-free fetal DNA*, *cfDNA*, *cffDNA*, *NIPS*, *NIPT*, *noninvasive prenatal screen*, *noninvasive prenatal test*, *prenatal screen*, *prenatal test*, and *trisomy screen*. See Supplementary Methods for additional details and rarefaction modeling. In between each search, the browser cache (Chrome v80.0) was cleared. Search results were downloaded and saved in HTML format for future reference. Finally, we reviewed all articles published on the clinical genomics-oriented news website https://genomeweb.com under the "Reproductive Health" heading and pertaining to cfDNA companies, dating from 1 January 2011 (the year in which cfDNA was introduced to prenatal genetics in the United States) to 18 February 2020.

All commercial laboratories offering cfDNA screening in the United States were included, regardless of whether they are independent (e.g., Myriad), owned by a larger laboratory (e.g., Integrated Genetics, a subsidiary of LabCorp), or headquartered outside the United States (e.g., Centogene). Exclusion criteria included the following: tests not offered in the United States, hospital-based laboratories, nongenotyping platforms that do not generate identifiable genetic information about patients (e.g., quantitative polymerase chain reaction [qPCR]-based approaches), cfDNA tests that were not aneuploidy screens and either do not genotype enough loci to risk re-identification or are not routinely ordered as part of prenatal care (e.g., targeting single-gene disorders, paternity tests), tests not commercially available, or tests marketed by an independent company but processed by a third party (e.g., Illumina).

Data collection

Consent and test requisition forms were downloaded from each commercial laboratory's website. Documents not available online were obtained by contacting each company. In addition, data were collected from each company's website regarding other types of testing offered (e.g., carrier screening, nongenetic tests), corporate structure, as well as patient- and physician-oriented promotional information. For each privacy policy, information was collected about the retention and use of genetic data, the retention and use of specimens, alignment with ASHG core principles, readability data, additional online searches for privacy-related policies, and miscellaneous items (e.g., profit from genetic data without compensation to patients, future privacy implications due to use of fetal genetic data). See Table S3 for a complete list of information collected.

Analyses

To assess consent and requisition forms systematically, we developed a genetic privacy data abstraction and scoring system (see Supplementary Materials). Consent and requisition forms were reviewed independently by two reviewers (C.M.P. and A.K.L.); in cases of unresolved disagreement, a third reviewer (M.L.R.) adjudicated. In addition, each privacy policy was assessed against the American Society of Human Genetics Core Principles of genetic privacy,[20] using a newly developed scoring instrument (see Supplementary Materials). Each privacy policy earned 1 point on a scale from 0 to 5, with 5 representing adherence to all five ASHG principles. Finally, the readability of each privacy policy's genetic data storage, use, and sharing policy was assessed using the Flesch-Kincaid Reading Ease[23] and SMOG Indices,[24] which were selected given their widespread use and particular utility for health care.[25,26] The principal measures for the primary and secondary outcomes were summary statistics. Because this study does not aim to rank or recommend specific laboratories, aggregate and anonymized results are presented in the main text. Laboratory-specific findings are available in the Supplementary Materials.

RESULTS

Of the 124 companies identified and screened, 14 met the original inclusion criteria (Fig. 1, Table S1). As one company offered prenatal cfDNA aneuploidy screening to laboratories, but not directly to patients, there were no patient- or provider-facing requisition or consent forms to analyze, and this company was excluded (Fig. 1, Table 1). Rarefaction modeling projected that expanded online searches would be unlikely to identify laboratories beyond those identified by our multimodal approach (Figure S1). Search engine performance is compared in Table S2.

Requisition forms were obtained for all 13 laboratories. In addition, 10 of 13 (77%) laboratories had distinct consent forms that addressed genetic testing, which were also obtained and reviewed for our analysis. For 7 laboratories, the requisition and/or consent forms were not accessible online and the company was contacted directly to obtain these resources. For the primary outcome, the majority of laboratories allowed for genetic data retention (8/13, 62%), research (10/13, 77%), and sharing (7/13, 54%). Moreover, 4/8 (50%), 3/10 (30%), and 2/7 (29%) did not allow patients to opt out of these activities, respectively. One laboratory (7.7%) explicitly stated that genetic data would not be shared. Consents and requisitions were more likely to address specimen retention and research than genetic data retention and research. Three laboratories (23%) addressed specimen research but did not address genetic data research, and four laboratories (31%) addressed specimen retention but did not address retention of genetic data (Table 2, Table S3). Similarly, eight laboratories (62%) addressed state-specific laws for specimen handling (e.g., New York), but did not address any state-specific requirements for genetic data handling. Notably, two laboratories offered no language in their consents or requisitions pertaining to genetic data storage, use, or sharing (Table S3).

Each laboratory's adherence to the American Society of Human Genetics' 2019 core principles for genetic privacy[20] was rated on a scale from 0 to 5, with 5 representing adherence to all five ASHG principles. Individual laboratories' scores ranged from from 0 to 4 (Table S3), with a mean score of 2.19 and median score of 2.00. Specifically, most commercial laboratories offering cfDNA aneuploidy screening adhered to ASHG genetic privacy recommendations 1 ("Individuals should have a right to maintain the confidentiality of their own genetic information and should not be compelled to disclose it") (9/13, 69%), 2 ("Entities holding human genomic data must take robust measures to protect the confidentiality of individuals' medical and genetic information") (11/13, 85%), and 5 ("Research policies should both facilitate data

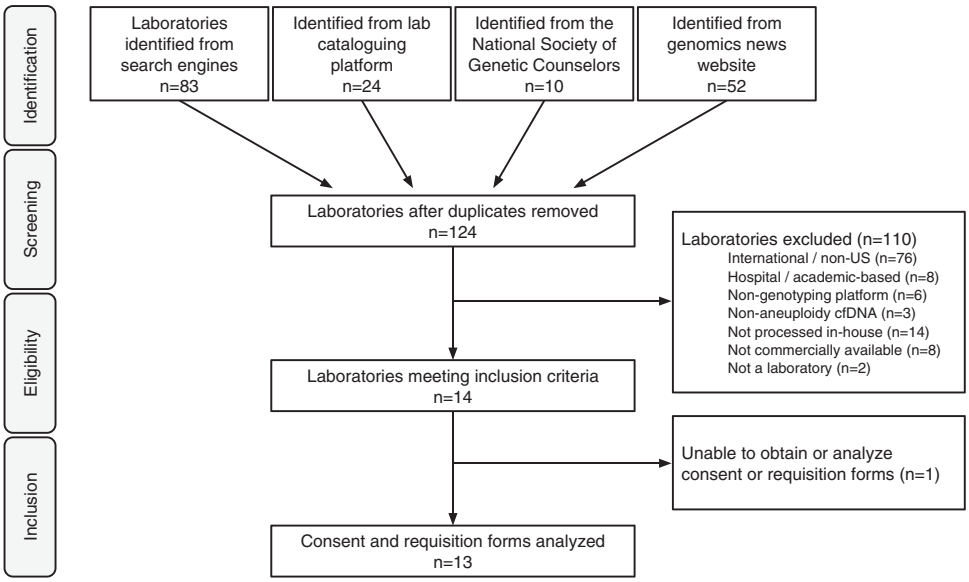

Fig. 1 Flow diagram of search and screening strategies for laboratories offering commercially available cell-free DNA (cfDNA) aneuploidy screening. A multimodal identification approach was used to identify 124 laboratories potentially offering prenatal cfDNA screening. Of these, 13 were commercial laboratories that offered a genotyping cfDNA-based aneuploidy screening test within the United States for direct clinical use, and were eligible for inclusion.

Table 1. Characteristics of laboratories and commercially available cfDNA screening tests included in review (listed alphabetically by company name).

Company name[a]	cfDNA test name	Technology[b]	Nongenetic laboratory services[c]	Documents reviewed for genetic privacy content	Privacy of genetic data addressed by
Avero	NIPT	MPSS	Yes	Requisition	Requisition
Centogene	CentoNIPT	MPSS	No	Requisition, consent[d]	Requisition, consent
Genpath	ClariTest	SNP-based	Yes	Requisition, consent[d]	None
Invitae	NIPS	MPSS	No	Requisition, consent	Consent
LabCorp (Integrated Genetics)	MateriT21	MPSS	Yes	Requisition, consent	None
Lab Genomics	Determine10	MPSS	No	Requisition, consent	Consent
Myriad Women's Health	Prequel	MPSS	No	Requisition, consent[d,e]	Consent[e]
Natera	Panorama	SNP-based	No	Requisition	Requisition
NxGen MDx	Informed Prenatal Test	MPSS	No	Requisition	Requisition
Progenity	Innatal	MPSS	No	Requisition, consent	Requisition, consent
Quest	QNatal	MPSS	Yes	Requisition, consent[f]	Consent
Roche (Ariosa)	Harmony	SNP-based	Yes	Requisition, consent[d]	Requisition, consent
Sema4	Noninvasive Prenatal Select	MPSS	Yes	Requisition, consent	Requisition, consent

cfDNA cell-free DNA, *MPSS* massively parallel shotgun sequencing, *SNP* single-nucleotide polymorphism.
[a]Laboratories are listed alphabetically by company name.
[b]SNP-based includes microarray or amplicon deep-sequencing technology.
[c]Does the company or parent company offer nongenetic testing services?
[d]Distinct requisition and consent were contained into a single document.
[e]An additional document titled "Notice of Privacy Practices" was reviewed because the associated consent form specifically referenced this as a source for additional information.
[f]This company provided a patient and a provider consent, which were both reviewed.

sharing and protect the confidentiality of research participants' medical and genetic data in a way that both advances research and respects participants' preferences") (8/13, 62%), while fewer laboratories adhered to recommendations 3 ("The users of research participants' genetic and genomic information should assess the risks and benefits for both the participants and for society; the nature of those analyses should determine which privacy protections and data-sharing practices are appropriate") (4/13, 31%) and 4 ("When establishing privacy policies and practices, it is important to consider context—when it is desirable and appropriate for genetic information to be treated the same way as other biological, health, or personal information and when

there are factors that require genetic information to be treated differently from other forms of health data") (4/13, 31%) (Table 3).

The readability of consent and requisition language pertaining to retention, use, and sharing of patients' genetic data was assessed. Two laboratories offered no language in their consents or requisitions pertaining to genetic data storage, use, or sharing, and were not included in this analysis. For the remaining laboratories, the SMOG Index for individual laboratories ranged from 9th to 17th grade (mean 13.7), with 9 of 11 (82%) laboratories' materials at or above a 12th grade reading level. Flesch-Kincaid scores ranged from 9th to 23rd grade (mean 15.7), with 10 of 11 (91%) laboratories' materials above a 12th grade reading level (Fig. 2, Table S3).

Table 2. Retention, use, and sharing of genetic data and specimens among commercial laboratories offering cell-free DNA (cfDNA) aneuploidy screening.

	Genetic data	Specimens
Retention		
Number of labs that may retain genetic data (or specimens)	8/13 (62%)	11/13 (85%)
Do not provide option for opt out	4/8 (50%)	5/11 (45%)
Number of labs that do not address retention	5/13 (38%)	1/13 (7.7%)
Use/research		
Number of labs that may use genetic data (or specimens) for research	10/13 (77%)	10/13 (77%)
Do not provide option for opt out	3/10 (30%)	2/10 (20%)
Number of labs that do not address research	3/13 (23%)	0/13 (0%)
Sharing		
Number of labs that may share genetic data (or specimens) for research	7/13 (54%)	5/13 (38%)
Do not provide option for opt out	2/7 (29%)	2/5 (40%)
Number of labs that do not address sharing	5/13 (38%)	5/13 (38%)
Number of labs that explicitly do not share	1 (7.7%)	3 (23%)

DISCUSSION

This report describes how commercial laboratories may retain and use the inherently identifiable genetic information generated during cfDNA screening for nonclinical purposes. The majority of laboratories offering cfDNA in the United States provide consent forms containing provisions that allow them to retain the genetic data of women and their offspring for nonclinical uses (i.e., research) and even to share these data with other entities (e.g., academic, federally funded, or commercial). Some laboratories do not allow patients to opt out of these uses. We identified a concerning trend that while policies regarding specimen retention, use, and sharing are typically explained in detail, policies regarding genetic data (arguably a far more sensitive resource) are often left vague (Table 2, Table S3). Given that little attention has been given to the privacy implications of prenatal cfDNA screening—despite the National Council on Disability's recent call to action—our findings highlight the urgent need for providers and patients to understand the genetic privacy implications of prenatal screening.

While privacy issues surrounding genetic data generated from cfDNA screening have not previously been studied, the privacy of genetic testing in general is an area of growing concern. The American Society of Human Genetics recently outlined five core principles for laboratories as they attend to genetic privacy. As a secondary outcome, we assessed laboratory adherence to these principles. From a review of consent and requisition forms, we found marked variability in laboratory adherence to these principles, with one laboratory demonstrating no adherence (0 of 5 principles), two laboratories demonstrating improved adherence (4 of 5 principles), and the remainder falling in between (Table S3). We also found that on a per-principle basis, the two principles that pertain to a consideration of the risks and benefits of research or the unique privacy concerns inherent to genetic data had much lower adherence rates than others. As stewards of sensitive genetic information, laboratories bear responsibility for patients' understanding about these tests. Some laboratories substantially outperform in this area, and these should be emulated.

A patient's ability to understand the testing process is a key condition for informed consent.[27] Readability of consent forms is a

Table 3. Adherence to American Society of Human Genetics (ASHG) privacy recommendations among commercial laboratories offering cell-free DNA (cfDNA) aneuploidy screening.

ASHG genetic privacy recommendation	Number of laboratories demonstrating partial or complete adherence (%)
1: Individuals should have a right to maintain the confidentiality of their own genetic information and should not be compelled to disclose it.	9/13 (69%)
2: Entities holding human genomic data must take robust measures to protect the confidentiality of individuals' medical and genetic information.	11/13 (85%)
3: The users of research participants' genetic and genomic information should assess the risks and benefits for both the participants and for society. The nature of those analyses should determine which privacy protections and data-sharing practices are appropriate.	4/13 (31%)
4: When establishing privacy policies and practices, it is important to consider context—when it is desirable and appropriate for genetic information to be treated the same way as other biological, health, or personal information and when there are factors that require genetic information to be treated differently from other forms of health data.	4/13 (31%)
5: Research policies should both facilitate data sharing and protect the confidentiality of research participants' medical and genetic data in a way that both advances research and respects participants' preferences.	8/13 (62%)

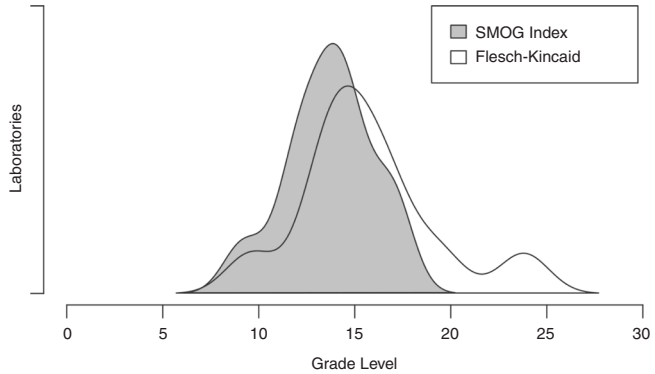

Fig. 2 Genetic privacy language within consents has poor average readability. Two common indices of readability (SMOG Index and Flesch-Kincaid Grade Level) were used to assess the readability of language pertaining to genetic privacy within consents from individual laboratories. Density plots were produced where the relative frequency of laboratories (*y*-axis) is plotted against particular grade-level scores (*x*-axis).

critical component of understanding. Unfortunately, the majority of laboratories discuss potential uses of genetic data in language at or above a 12th grade level (Fig. 2, Table S3). The average US adult reads at the 8th grade level and 20% of US adults read at or below the 5th grade level;[28–30] as such, the American Medical Association recommends that consent forms be written below a 6th grade reading level.[31] Our findings suggest that all cfDNA aneuploidy screening consents should be rewritten to follow AMA guidelines.

Our study highlights specific areas in which laboratories offering prenatal cfDNA screening can improve their communication pertaining to genetic privacy. First, laboratories should ensure that patients have access to information about how their genetic data will be retained, used and shared for nonclinical purposes. Second, laboratories should explain to patients the risks and benefits of research using their genetic data, and describe the unique privacy concerns inherent to genetic data. Finally, laboratories should make their consent forms understandable at a middle-school reading level. Though these are recommendations and not mandates, laboratories should recognize that it is in their long-term interest to proactively engage a well-informed patient population.

Obstetric providers and genetic counselors also hold responsibility for their patients' understanding of genetic testing. Though providers cannot control how commercial laboratories handle genetic data, they should ensure that patients have an opportunity to read and comprehend cfDNA consent forms (including the genetic privacy policy). It is known that up to 20% of nonpregnant patients would not feel comfortable sharing their genetic information for research, and that this rate is higher among minorities,[27,32] making it crucial that patients understand how their data will be used. During counseling, prenatal care providers should be cognizant that patients may be uncomfortable with data sharing, should understand the consent forms for the genetic tests they offer, and should be prepared to discuss patient concerns. While counseling patients, risks to privacy should be weighed against the benefits of the test, and the benefits of ancillary uses like sharing for research. Table S3 provides findings for specific laboratories that prenatal care providers may reference. However, this is a rapidly evolving field, and policies of individual laboratories may change quickly. Because of this, our findings should not be used as a guide for choosing a cfDNA test. Rather, the framework presented here should equip prenatal providers to critically assess the privacy policies of prenatal genetic testing companies and enable them to have informed conversations with patients, if patients request more information.

To our knowledge, the topic of fetal genetic privacy has not been considered in the published literature. In contrast, the genetic privacy of minors has received thorough treatment in the last two decades. There are both similarities and differences between the genetic privacy of fetuses and minors. Neither can give consent, though both may be alive for decades to endure the consequences of a possible privacy breach. However, a fetus has less potential agency than a minor, as a fetus can neither assent nor dissent to testing. Many questions remain unanswered: should individuals who had genetic data collected as a fetus be recontacted to give their autonomous consent for genetic research once they reach the age of majority, as has been suggested for minors?[33] Given the low fraction of fetal DNA (compared to maternal DNA), does genetic research with prenatal samples pose minimal risk to the fetus? Parents are more protective of their children's DNA than of their own,[34] but what are their attitudes toward fetal DNA? Until these and other questions are addressed, the urgency of fetal genetic privacy cannot be adequately gauged against maternal or minors' genetic privacy.

This study has several strengths. First, it is timely and novel: although prenatal cfDNA aneuploidy screening is the fastest growing genetic test in history,[3,4] little critical attention has been given to its privacy implications for patients and their children. While there is increasing public scrutiny of the privacy practices of direct-to-consumer genetic testing companies (e.g., ancestry tests), prenatal care providers have been understandably absent from this discourse, and there has been little to no public scrutiny regarding the privacy practices of laboratories offering cfDNA screening. Second, we used a rigorous, multimodal identification strategy, making it unlikely that we missed commercial laboratories with meaningful US market share. Third, our abstraction tool provides a resource for systematically characterizing laboratory policies about retention, use, and sharing of prenatal genetic data. Fourth, we provide a framework for appraising laboratory privacy policies in light of ASHG genetic privacy principles. Finally, our readability analysis offers a clear roadmap by which laboratories may better educate and engage with patients.

Some limitations should be considered. First, companies may have additional (e.g., online) resources that were not included in analyses, as our data extraction methods were limited to the consent and requisition forms. However, limiting our analyses to the documents most likely to be read by the patient and physician while ordering cfDNA standardized the amount of data analyzed per company, decreasing the risk of analyzing differing number of documents per company. Second, the authors are physicians, not attorneys specializing in contract or privacy law. Thus, our reading of laboratories' policies does not constitute a legal interpretation of their contractual obligations under a prenatal testing agreement, but rather a common sense interpretation of these consent and requisition forms, and how we would explain them to our patients. Third, the permissions reserved in these documents may not reflect what companies actually do with patients' genetic information—for example, companies may be more conservative in their respect of patient privacy than stated in their consent and requisition forms. Fourth, our study does not address hospital-based laboratories. It is unclear what percentage of tests are performed by hospital-based laboratories, though several large healthcare systems do offer in-house cfDNA aneuploidy testing. This should be an area of future investigation. Fifth, our study design could not assess Illumina's policies around the storage, use, and sharing of genetic data. Illumina (through its subsidiary Sequenom) currently licenses prenatal cfDNA technology to at least 50 companies.[35] However, Illumina does not offer testing directly to prenatal care providers and their patients and therefore does not have provider- or patient-facing consent or requisition forms—a criterion for inclusion in this study. Given the ubiquity of

Illumina's technology, and the fact that some laboratories send samples directly to Illumina for processing, its prenatal genetic data use policies should be carefully evaluated. Sixth, the consent process is a dialogue between provider and patient, and the details of these conversations cannot be captured by our methods. Finally, signed patient consent for cfDNA aneuploidy screening is not required in all states. This will limit the generalizability and efficacy of interventions designed to improve consent- or requisition-based patient education about genetic privacy issues.

While there is no doubt that cfDNA has revolutionized prenatal aneuploidy screening, privacy concerns related to this ubiquitous test must be considered. Laboratories and prenatal care providers should ensure that patients are well informed prior to testing. Laboratories should provide requisition and/or consent forms that are understandable, and that give patients the opportunity to decline nonclinical uses of their sample and data. Prenatal care providers should advocate for transparent and flexible genetic privacy policies on behalf of patients, and be able to discuss prenatal genetic privacy with patients if they inquire. Our field must examine whether prenatal care providers and patients are aware of the privacy issues surrounding prenatal genetic testing, and whether they are aware of the genetic data handling practices commonly employed by commercial laboratories. More specifically, studies are urgently needed to examine patient and provider knowledge of and attitudes toward genetic privacy laws related to cfDNA testing, and to determine whether education on this topic changes patients' attitudes toward undergoing cfDNA screening. Through advocacy efforts and patient education, we as prenatal care providers can equip our patients to confidently participate in genetics research and can establish a relationship of trust that will last throughout pregnancy and beyond.

DATA AVAILABILITY

Abstracted data are included in Table S3. Additional materials and details will be made available upon request.

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ETHICS DECLARATION

This work was not subject to the review of an institutional review board or research ethics committee.

COMPETING INTERESTS

The authors declare no competing interests.

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