Non-Invasive Testing, Non-Invasive Counseling

Rachel Rebouché

Introduction

A regulatory moment for prenatal health care is here. An increasing amount of legislative attention has concentrated on the decisions pregnant women make after prenatal testing. The impetus for this legislation is a new non-invasive prenatal genetic test (NIPT). From the beginning of pregnancy, cell-free fetal DNA travels across the placental lining into the mother's bloodstream, increasing in quantity as the pregnancy progresses. Laboratories can now analyze that DNA for chromosomal abnormalities and for fetal sex at 10 weeks of gestation. NIPT, which relies on a sample of the pregnant woman's blood, is painless, occurs early in pregnancy, and is available for clinical and commercial use. In 2013, major health insurance plans began to cover NIPT for certain populations of women, such as women over 35 years old.[1] And private companies have started marketing prenatal testing kits directly to consumers, who return a blood sample from the prospective mother to a company laboratory.[2]

Traditionally, patients, obstetricians, genetic counselors, and health care insurance companies — not state or federal governments — have played the central role in decisions of when and why to test and how to interpret test results.[3] But current anti-abortion strategies that respond to NIPT threaten the option of terminating a pregnancy after prenatal testing. State legislatures have entered the regulatory field with bills that prohibit abortions if performed for specified reasons and that manage the information a patient may receive. In the former category, states have passed laws that ban abortion if the termination is for reason of the fetus's sex, race, or diagnosis of fetal abnormality. In the latter, laws in Virginia and Nebraska allow genetic counselors to refuse to communicate any information, including testing results or options after testing, if the counseling, in the words of the Virginia law, "conflicts with the counselor's deeply-held moral or religious beliefs."[4]

There is no clear evidence of how decisions to terminate pregnancies will intersect with NIPT. Research in genetic medicine and interviews with health care providers and patients disagree about how and if NIPT will influence the prevalence or occurrence of abortion. Articles on NIPT in medical and science journals presume that abortion rates will increase.[5] With advancements in gene and whole genome sequencing, NIPT will reveal more information about

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fetal characteristics much earlier in pregnancy, when some patients might feel more comfortable terminating a pregnancy. Yet, studies of patient and provider attitudes reveal deep ambivalence about abortion as a post-testing option.[6] Potential parents using NIPT are making decisions about pregnancies they wanted to conceive, and some research suggests that abortion rates will remain constant because parents' post-testing decisions will not change significantly.[7] Legal scholarship has, to date, focused on the constitutional problems of the reason-based abortion bans that respond to NIPT.[8] Constitutional challenges to abortion restrictions may or may not succeed; it is not at all clear how the U.S. Supreme Court, for example, would decide on the laws described in this article.[9]

A place at which conversations across disciplines converge is in describing the early success of NIPT and the need for thoughtful approaches to new informed consent standards and counseling processes. NIPT promises to transform the substance and the timing of genetic counseling. At present, prenatal counseling occurs after serum and ultrasound screenings reveal risk of a genetic or somatic fetal condition, and before traditional, invasive testing methods, such as amniocentesis or chorionic villus sampling (CVS). NIPT could replace current screening and diagnostic tools, which portends genetic counseling that occurs earlier in pregnancy and must communicate complicated information about fetal characteristics.

To grapple with the challenges of evolving prenatal testing and counseling, this article considers the role that termination decisions play in current options counseling. Over the last several decades, scholars and clinicians have been attentive to the concern that some women feel pressure to terminate pregnancies after receiving test results. One response has been to carve out professional standards for non-directive, client-centered counseling that neither discouraged nor encouraged patients' abortion decisions. However, the present legislative attempts to control and to limit abortion decisions after testing strip from options counseling the nuanced considerations that potential parents bring to bear as they consider both whether to test and test results.

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Thinking critically about how abortion animus and NIPT counseling intersect is a vital project for those invested in defending women's reproductive rights. Those supportive of abortion rights might focus not only on resisting their opponents' efforts in receptive state legislatures, but also on standards for genetic counseling and on patient experiences in physicians' offices. Part I of this article explains the use of NIPT and its uptake by patients and providers. Part II describes state (and, to a lesser extent, federal) legislation that restricts abortion as a response to NIPT. Part III explores how abortion politics may co-opt complicated questions about the timing, content, and limitations of the genetic counseling that accompanies NIPT.

Non-invasive Prenatal Genetic Testing

In 1997, researchers discovered that fetal DNA exists in the maternal bloodstream.[10] Cell-free DNA travels across the placental lining and comprises three to six percent of the DNA in maternal circulation.[11] After birth, almost all fetal DNA leaves the mother's bloodstream, although a very small quantity of fetal DNA can linger for years.[12] This discovery facilitated a new genetic test that, relying on DNA sequencing technologies, analyzes fetal DNA from a maternal blood sample.[13]

Until this discovery, prospective parents had two options in diagnosing fetal conditions before birth

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— CVS or, the more frequently-used method, amniocentesis.[14] Both CVS and amniocentesis rely on a fetal sample extracted *in utero* and both have notable drawbacks. The tests are not commonly administered until late in the first trimester or early in the second trimester. CVS is available a few weeks earlier than amniocentesis, but it is a more complicated procedure than amniocentesis. Both tests can be painful and expensive, and have up to a one-percent risk of miscarriage.[15]

Most pregnant women screen for a range of genetic conditions with ultrasound, which can assess the likelihood of physical abnormalities, and maternal blood tests, which measure chemical levels that correspond with fetal aneuploidies (that is, missing or extra chromosomes).[16] Serum and ultrasound screenings are "as commonplace and widely accepted as some of the more routine aspects of prenatal care"[17] for women of all ages and family or personal medical histories. These screening tests predict risk and do not have near the accuracy of CVS or amniocentesis; rather, screening identifies at-risk patients for additional testing.

Screenings with maternal blood samples and ultrasounds occur at around 13 weeks of pregnancy and again between 16 to 18 weeks of pregnancy.[18] By the point of amniocentesis or CVS, most patients have assessed the risk of certain genetic and physical conditions with two ultrasounds and two serum screenings.[19] The two-step nature of screening means that results are not useful until close to or in the second trimester of pregnancy. Thus, as a practical matter, many patients will not decide to have an invasive test until well into the second trimester or in the third trimester of pregnancy.[20] Moreover, obstetricians do not discuss invasive testing options (and possible test results) during an early prenatal visit. Typically, only pregnant women who screen positive for genetic conditions receive some form of genetic counseling.[21]

NIPT could alter the timing and process of prenatal diagnosis. The accuracy of NIPT increases with gestational age. Tests for sex and aneuploidies are reliable and accurate after ten weeks of gestation.[22] Thus, providers could order tests on blood drawn during an initial prenatal visit, which occurs between 8 and 12 weeks of gestation.[23] Although not a present reality, NIPT has the potential to either supplement prenatal screenings and testing or displace screening and invasive testing altogether.[24] If NIPT replaces ultrasound and serum screening early in pregnancy, invasive testing could still serve to confirm a diagnosis. But the "most likely scenario" is NIPT will become "a substitution for the present combination of risk assessment and invasive diagnostic testing."[25] This will necessitate different counseling arrangements, particularly because NIPT is administered much earlier in pregnancy than invasive tests. And, as the last part contemplates, the ease and the safety of NIPT might increase test usage, but not necessarily with an adequate infrastructure to support patients' decision making.

Providers and patients have started to use NIPT because a market that is ready to expand supports NIPT. Companies such as Verinata, Sequenom, and Panorama sell NIPT for sex and aneuploidies to health care providers and health care organizations. These companies currently offer NIPT through physicians and advertise NIPT as "screening tests" that may require follow-up procedures.[26] Companies have branded tests as appropriate for women over 35 — an age group considered at higher risk of carrying a pregnancy with a genetic disorder.[27] Researchers have warned previously that companies selling NIPT products are pushing tests ahead of the present recommendations of professional organizations.[28] The American College of Obstetricians and Gynecologists advises that providers should only offer NIPT to pregnant women with serum and ultrasound screenings that indicate high risk of fetal genetic anomalies.[29] A study released in March 2014, however, found that NIPT has the accuracy of invasive methods for a diverse population of women, including women at low risk of an aneuploidy fetus.[30] The earliest studies of NIPT's accuracy tested patients who carried fetuses with known genetic abnormalities.[31] The 2014 study tested pregnant women with varying risk — from low risk, as most of the population, to high risk, as the previous studies — and found the same level of accuracy.

These findings have not yet been incorporated into clinical practice or changed insurance coverage.[32] But with new research suggesting that NIPT is accurate for all women, companies have started to revise their marketing strategies.[33] At some point, new research will influence the opinions of professional societies and the coverage determinations of insurance companies. Private health care insurers such as United Health Group, WellPoint, Blue Cross/Blue Shield, Primary Health, and Aetna cover NIPT for pregnant women with personal or family histories of genetic conditions, prior affected pregnancies, of advanced maternal age, or who screen positive (serum or ultrasound) for moderate to high risk of fetal abnormality.[34] Coupled with NIPT, most health care insurance plans cover genetic counseling before and after testing, and some plans *require* genetic counseling before testing.[35] Moreover, health insurance plans can deny coverage based on the purpose of the test. Primary Health, for example, will not cover the costs of genetic tests for sex determination, in establishing paternity, or as part of using assisted reproductive technologies.[36]

With insurance coverage, NIPT now is increasingly affordable, costing between $200 and $235. Laboratories offering NIPT have begun to sign test-specific contracts with insurance plans, which will result in even lower out-of-pocket costs for patients.[37] The cost of NIPT, without insurance coverage, is between $1,200 to $2,800.[38] But Verniata and Sequenom have attracted customers by offering caps on out-of-pocket costs and introductory pricing specials.[39]

As NIPT enters clinical use, it raises concerns about the ethics of parents selecting the genetic traits of their future children.[40] In this way, it is similar to preimplantation genetic diagnosis (PGD). PGD is a process by which patients can test an embryo cultivated by in vitro fertilization before implanting it; patients then can discard an embryo for any number of reasons.[41] Both NIPT and PGD screen for genetic characteristics, but NIPT takes place when a woman is pregnant and PGD occurs in a lab outside the womb. Providers who offer PGD for medical as well as nonmedical traits argue that it helps "prevent multiple pregnancies and abortions" and is "the most humane, scientifically sound option for women."[42] Even though PGD differs in significant ways from NIPT (in practice and under law),[43] both processes raise questions about the appropriate regulation of fetal diagnosis.[44] Indeed, the legislation discussed in the next part urges that the temptation of parents to design their future children is a compelling reason to restrict abortion.[45] If NIPT makes prenatal testing easy, safe, and accurate, one fear is that it "may contribute to trivializing abortion and abortion decisions."[46] Without a better understanding about what actually happens in prenatal testing and counseling, concerns about "neo-eugenics" and fears that termination after testing will become "a public health measure" threaten to fill the current regulatory void.[47]

Current and Emerging Regulation

The legal and ethical questions raised by NIPT echo through the history of advances in prenatal testing technologies, beginning with the emergence of amniocentesis in the 1950s and the application of ultrasound to pregnancy in the 1960s.[48] But recent anti-abortion strategies, particularly at the state level, have enjoyed unprecedented success. From 2011 to 2013, 205 state abortion restrictions were enacted, more than the number of restrictions passed in the entire previous decade.[49] Growing in popularity, a movement to restrict pregnant women's options after prenatal testing now influences the proposals of legislators across the country. In the first half of 2014, 12 state legislatures introduced new bills addressing abortion based on sex, race, or genetic selection.[50] This part first describes the legal landscape for prenatal testing as it currently exists and then explains the content of new laws and proposed bills.

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A. The Regulation of Prenatal Testing

A patchwork of state and federal policies incentivize prenatal testing and screening, but do not directly regulate how, why, and when prenatal testing occurs.[51] The Food and Drug Administration (FDA) has indicated a need to monitor genetic testing, but it only has issued fact sheets and reports and not guidelines or rules.[52] Gail Javitt highlights recurring discussions about the need to regulate genetic testing: "Although government advisory committees have been urging the government to strengthen genetic testing oversight for more than a decade, none of their myriad recommendations has resulted in regulatory change."[53]

The call for oversight extends to all types of genetic testing — for adults seeking health-related or ancestry information as well as new prenatal testing. The Advisory Committee on Genetic Testing to the Secretary of Health and Human Services concluded that "the current oversight of genetic tests [is] insufficient to ensure their safety, accuracy, and clinical valid-

ity," but the Committee's recommendations have not been implemented. Congress also has unsuccessfully tried to strengthen oversight over prenatal genetic tests.[54] And the FDA, Federal Trade Commission, and National Institutes of Health have considered legal action against at-home, prenatal genetic testing kits, like the Baby Gender Mentor test, but has yet to act.[55]

Moreover, the clinical and commercial introductions of NIPT have attracted controversy.[56] Companies that market NIPT differ in how they analyze and report sequencing data and are not required by law to test clinical utility.[57] The FDA has classified NIPT as a laboratory-developed test, governed by the Clinical Laboratory Improvement Amendments (CLIA).[58] CLIA requires labs to demonstrate a test's accuracy, precision, specificity, and sensitivity in the lab, but not necessarily its clinical validity or use.[59] As compared to amniocentesis and CVS, which were developed in academic settings with independent clinical trials and federal financial support,[60] NIPT was licensed quickly and funded by venture capital that moved new tests to the market as soon as possible.[61]

As a consequence of this fragmented regulatory landscape, health care professionals remain the managers of prenatal testing, and they have been the focus of recent state legislation.

B. The Content of New Legislation

A few states have already legislated to limit testing and counseling options of pregnant women. Missouri forbids state-sponsored genetic counseling programs from making a referral for an abortion unless the mother's life is in danger,[62] and an Oklahoma law states that genetic counselors need not mention abortion as an option.[63] Tennessee forbids prenatal testing offered by state programs for a condition that cannot be cured.[64] Arizona and Oklahoma protect physicians from lawsuits if they fail to disclose fetal abnormalities to patients. Providers may omit information about a potential fetal abnormality if they believe the patient would seek an abortion.[65]

In the last few years, however, legislators have addressed prenatal testing in three types of bills. First, states have considered legislation that bans abortion on the basis of fetal diagnosis. North Dakota, for example, enacted a ban on abortion for genetic abnormalities detected by prenatal genetic tests. Specifically, the law prohibits physicians from performing abortions solely because "the unborn child has been diagnosed with either a genetic abnormality or a potential for a genetic abnormality."[66] Legislators in Missouri introduced a bill in 2013 that would punish physicians for performing abortions because of fetal genetic abnormality or the potential for a fetal genetic abnormality.[67] These new bills move in the opposite direction of laws that have explicitly permitted abortion *because of* fetal diagnosis.[68] Georgia, Louisiana, Texas, Utah, and Maryland, for instance, allow abortions at any point of pregnancy for lethal or serious (the severity depends on the state) genetic anomalies.[69] As recently as 2014, Mississippi enacted a ban on abortions at and after 20 weeks that contains an exception for pregnancies with "severe fetal abnormalities."[70]

Second, over half the country's statehouses have debated sex-selective abortion bans and, to a lesser extent, bans on race-based abortions. Pennsylvania and Illinois prohibited sex selective abortion decades ago; Arizona,[71] Oklahoma,[72] North Carolina,[73] Kansas,[74] North Dakota,[75] and South Dakota[76] passed laws restricting abortion because of fetal sex in the last four years.[77] The South Dakota law, enacted in March 2014, prohibits sex-selective abortions that are "either solely or partly due to the unborn child's sex."[78] Moreover, South Dakota now requires that abortion providers report to a state agency: "(a) Whether the pregnant mother used a sex-determining test; (b) What type of sex-determining test the pregnant mother used; and (c) The approximate gestational age of the unborn child, in weeks, when the test was taken."[79]

On the federal level, a bill titled the Prenatal Non-Discrimination Act (PRENDA) begins by citing advances in testing technologies, like NIPT, as the reason to regulate.[80] The bill states that there is "a growing sex determination niche industry" that "market[s] low-cost commercial products, widely advertised and available, that aid in sex determination of an unborn child."[81] Under PRENDA, any person who knowingly performs or facilitates "an abortion undertaken for purposes of eliminating an unborn child of an undesired sex…or race"[82] may be fined; sentenced to up to five years in prison; enjoined from further medical practice; and face civil action by the patient, by the father of the fetus, and by the parents of the patient.[83]

In support of reason-based abortion bans like PRENDA, a few states require physicians to keep a record of (or report to a governmental agency) the reasons patients give for seeking an abortion.[84] Laws require patient-completed questionnaires,[85] open-ended questions for a physician's short answer,[86] or patient affidavits.[87] These reporting requirements attempt to respond to the problems of enforcing a reason-based abortion ban. Even if providers ask patients to disclose their motives for abortion, clinics neither employ mechanisms to vet truthfulness nor can they stop a patient from seeing another provider and then misrepresenting her reason.[88] But these laws demonstrate states' attempts to police abortion decisions in potentially ineffectual but nonetheless intrusive ways.

Third, new laws oversee and manage the practices of genetic counselors through licensing standards. As of May 2014, 15 states have passed licensing laws for genetic counselors.[89] These licensing laws are an important step toward uniformity in genetic counselors' professional standards. The National Society of Genetic Counselors (NSGC), for example, in advocating for licensing legislation, stated: "The NSGC's goal in developing the principles and language is to ensure as much uniformity among the nation's genetic counselors so that laws regulating the practice of genetic counseling are widely applied…and, most importantly, ensure the highest quality services."[90]

Two states, Virginia and Nebraska, recently incorporated refusal clauses for genetic counselors in their licensing laws, which allow genetic counselors to omit discussion of abortion in options counseling. The Nebraska Genetic Counseling Practice Act mentions abortion explicitly: no "genetic counselor [is required] to counsel or refer for abortion, and licensing of a genetic counselor shall not be contingent upon his or her participation in counseling or referral with respect to abortion."[91] The Virginia bill states, "Nothing in this chapter shall be construed to require any genetic counselor to participate in counseling that conflicts with their deeply held moral or religious beliefs, nor shall licensing of any genetic counselor be contingent upon participation in such counseling."[92] Both laws shield the refusing counselor from any "disciplinary or recriminatory action" if the counselor informs patients of his or her refusal and directs patients to the state-maintained, online directory of licensed genetic counselors. Neither law offers guidance as to the timing of referral or what information the referral must include (professional qualifications or locations of other counselors, for instance).

These laws may contradict the NSGC's *Code of Ethics* (the Code) — standards to which the Virginia and Nebraska laws refer in defining their states' licensing processes. Both laws draw on the language of the Code in setting out the duties of genetic counselors; for example, the Code requires counselors to give nondirective advice, tailored to the individual. And the Code does not include a refusal clause.

The laws also repeat the NSGC's model *Genetic Counselor Scope of Practice*, which describes a counselor's responsibility to "evaluat[e] the patient's and family's responses to the medical condition or risk of recurrence and provid[e] client-centered counseling and anticipatory guidance."[93] Although the statutory duty to refer patients to another counselor mitigates the burdens of refusals, rights to a referral remain ill defined and seemingly difficult to enforce. Given these problems, refusal provisions appear inconsistent with the duties of counselors as interpreters and evaluators of genetic information as provided by licensing legislation.

More fundamentally, a client-centered approach, which the next part argues is fundamental to modern genetic counseling, sits uncomfortably with genetic counselors' refusals to explain test results. Compare Virginia and Nebraska's refusal laws to a Michigan statute on genetic counseling enacted in 1978. The Michigan law focuses entirely on the provider's duties to convey meaningful information about a genetic test so that a patient can make an informed decision upon learning test results. The statute requires providers to describe the medical risks and benefits, as well as the meaning and future uses of results.[94] This is an approach to informed consent accepted broadly by health care professionals, and recent anti-abortion legislation is a departure from this standard. This is not to denigrate health care professionals' religious and moral beliefs as unworthy of respect and protection. But without clearer statutory guidance, more rigorous safeguards, or the promise of a referral system that works, refusal clauses may cut against core professional responsibilities of genetic counselors.

These refusal clauses do not depend on understanding the patient's motives or reasons; a refusal can limit the patient's access to information based on the counselor's personal beliefs. As abortion has long been part of the choice (and dilemma) to test, omitting explanation of a termination option from counseling eviscerates the purpose of delivering nuanced and tailored information.

The next part considers the practices of physicians and genetic counselors that will influence testing decisions. One current problem with anti-abortion laws is that none of them actually responds to the challenges of counseling for NIPT. The next part explores those challenges by reviewing the role and history of genetic counseling, the possible trajectory of genetic counseling's evolution, and the problems of ensuring meaningful access to counseling services. Developing new approaches to pre- and post-testing counseling can help patients realize the promise of NIPT and understand NIPT's limitations.

NIPT and Genetic Counseling

Evolving standards for genetic counseling and informed consent will shape how patients make decisions after testing.[95] There are new opportunities to evaluate how providers and genetic counselors will interpret and communicate the results of NIPT. Those who oppose the laws described in the previous part might direct their efforts to influencing the uptake of NIPT in physicians' and counselors' offices.

A. The History and Role of Genetic Counseling

The history of genetic counseling demonstrates a careful, yet often fraught, approach to abortion. Termination of pregnancy is a crucial option for women who discover any number of fetal conditions through testing.[96] However, the role of discussing abortion after testing has been and is a complicated one. Since the 1970s, genetic counselors have worked to change the perception that they encourage patients to terminate pregnancies diagnosed with certain conditions. Alexandra Stern describes these shifting perceptions against the backdrop of eugenics, which informed the counseling profession as it initially developed in the 1950s. Even before the legalization of abortion, some women carrying "diseased fetuses" could terminate pregnancies in a number of states on health grounds.[97] Early proponents of prenatal testing stressed finding and eliminating disease in the population. As such, counseling was heavy handed and directive. Moreover, physicians and counselors (and state law) encouraged women and men carrying certain genetic (and non-genetic) traits to seek sterilization; in some cases, health professionals sterilized patients without their knowledge.[98]

The revelation of non-consensual and forced sterilizations was an impetus for change in prenatal counseling in the 1970s.[99] By 1979, genetic counselors had formed professional societies and issued new professional standards.[100] They called for counseling that shed its prescriptive past and adopted an approach that was client-centered and non-directive.[101] The introduction of legal abortion was also a cause for change in professional standards, which began to emphasize patients' rights to make "autonomous decisions about screening, diagnostic testing, possible preparation for the birth of a child or pregnancy termination."[102]

As testing technology evolved, counselors had to understand new research on what testing could reveal as well as develop the interpersonal skills to describe what results mean and what options patients have after learning results. Describing the contemporary professional duties of counselors, Stern writes:

> Most genetic counselors devote their time to obtaining and presenting test and screening results and then calculating and conveying genetic risk information to a wide range of clients, ideally in an empathetic and empowering manner. Genetic counselors are trained to present complex technical and scientific information in accessible language and to work with their clients to determine the most appropriate next step.[103]

Rich scholarship has explored the complex emotions with which pregnant women approach questions of termination after prenatal testing. Barbara Bernhardt and her co-authors studied the decision to test using chromosomal microarray analysis (CMA), and their results provide an analogy for NIPT.[104] Because CMA is painless (performed, like NIPT, based on a blood sample), many women reported taking the test because it seemed "risk free."[105] This speaks to a general pressure to test in pregnancy — what Kimberly Mutcherson has dubbed "soft constraints" or the "the subtle societal, social, or legal pressures that lead women to acquiesce to healthcare or testing which they would prefer to avoid."[106]

But just because a prenatal test is easy to administer does not mean that patients approach decisions about termination lightly. In a study of patients' testing decisions, Robert Klitzman demonstrates that potential parents are very sensitive to abortion decisions and prove to be conservative as to what conditions should result in termination.[107] When confronted with evidence of chromosomal deletions, and the attendant consequences that could follow, pregnant women (and their partners) were "tortured" as to the next decision.[108] They experienced a range of emotions in considering termination — stress, relief, and confusion.[109] On the one hand, screening and testing are often framed as to the duty of a responsible mother.[110] On the other hand, women's abortion decisions are met with stigmatization and unnecessary hurdles to proper care.[111] Caught in the middle is often the patient — the pregnant woman — who experiences dueling expectations.

There have been concerted efforts to mange this tension, in part based on the activism and influence of the disability rights community. Abortion after testing is an inextricable aspect of options counseling, but it is not the only option discussed by counselors who are committed to realizing patients' informed choices. In 2008, Congress passed the Prenatally Diagnosed Condition Awareness Act.[112] The Act responds to the concern that parents having children with disabilities (specifically Down syndrome) need more information about how to raise and care for their children. The Act is a targeted federal effort to promote post-testing options beyond abortion. As recent writing on NIPT makes clear, learning testing results can open up a number of options to patients: Early diagnostic testing can reassure potential parents, provide a longer window for decision making, and enable a potential parent to prepare for the birth of a child.[113] Moreover, an increasing number of conditions can be treated *in utero*, making testing information all the more important to potential parents.[114] The laws described in the last part ignore these considerations by focusing only

on the decision to abort and do not engage thoughtfully with how options counseling is delivered.

B. Challenges for NIPT Counseling

Informed and value-reflective decision-making has been hard to realize, both in decisions to test and then in decisions after testing.[115] As Ruth Farrell notes, "Many of the same barriers to women's education and decision-making continue to persist even with ongoing advancement in prenatal applications of genetics."[116] There is a consistent lack of trained providers, lag time between medical education and information about new technologies, and concern about the eugenic overtones of prenatal genetic testing and genetic technologies.[117]

NIPT poses the same challenges as amniocentesis and CVS, but raises new concerns about what information patients should have before and after testing.[118] This section focuses on three concerns: NIPT may change the process of informed consent; introduce patients to more information about a fetus, which affects the content of counseling and raises questions of what patients should learn; and place stress on the already insufficient infrastructure for counseling given the short supply of trained professionals.[119] State legislation focused on restricting abortion promises to exacerbate these challenges.

First, the traditional model of informed consent requires a patient to be well informed about each condition tested and allows the patient to select which outcomes she does not want to know.[120] This has been the standard for invasive tests and it is now urged for NIPT. A joint opinion of the American College of Obstetricians and Gynecologists Committee on Genetics and the Society for Maternal-Fetal Medicine states, "[t]o offer [NIPT] pretest counseling regarding these [described] limitations is recommended. The use of a cell free fetal DNA test should be an active, informed choice and not part of routine prenatal laboratory testing."[121] Peter Benn and Audrey Chapman argue that, for NIPT, "At a minimum, informed consent requires that patients have sufficient relevant information and that their decisions are voluntary and uninfluenced by external pressures whether they be medical insurance, societal, or political."[122] Presently only women offered amniocentesis or CVS receive genetic counseling and women having serum and ultrasound-based screening receive limited pre-test information.[123] A counseling regime lacking depth or substance, with informed consent processes that are "pro-forma," would be inappropriate for NIPT if it takes the place of current screening and testing.[124]

Second, and related to the importance of informed consent, the substance of counseling will change as NIPT yields more information about fetal characteristics. Some of that information can affect a child later in life, will be pertinent to a parent's genetic health, will be of unknown significance, or expressed as probabilities. Prenatal testing has traditionally relied on karyotyping (or visual assessment of chromosomal abnormalities in collected DNA). Because gene sequencing (the molecular processes of mapping genetic information) has only recently begun to replace karyotyping, NIPT has been limited to the detection of aneuploidies and sex. As gene and whole genome sequencing develop,[125] parents will not only be able to learn the sex or existence of chromosomal abnormality, but will soon be able to test for propensities for diseases such as breast cancer and single gene disorders, including late onset conditions like Huntington's disease.[126]

What researchers have called an "information overload," testing in the near future could also produce findings that are of unclear genetic significance and that reveal unexpected findings about the parents — knowledge that patients may not want to have.[127] Tests that indicate late-onset disorders and the propensity to develop disease, for example, pose a variety of ethical issues for parents and the children they have.[128] Moreover, as gene sequencing advances, NIPT results will indicate varying risks or probabilities of developing genetic conditions or expressing genetic characteristics, which can be difficult to interpret.[129] Physicians and counselors express concern that the inconclusiveness of NIPT results will have adverse psychological consequences for their patients.[130]

The approach at the moment, in which patients receive only minimal information prior to screening, might prove insufficient given NIPT's expanding informational offerings. Informing a patient that a fetus may have a genetic condition, without adequate pretest counseling, could undermine patients' ability to indicate what conditions or characteristics they prefer not to test and to understand their options once they have test results.[131] One proposal is to deliver "generic" informed consent — "presenting pre-test information in general categories of types of outcomes."[132] Although generic consent is not practiced at present, it is one way to let patients opt out of hearing certain test results. Other researchers have called for a more therapeutic approach, in which counselors start by assessing the patient's needs and then tailor communication about tests and test results to those needs.[133] Likewise, some propose that informed consent should be "filtered" or "narrowed," which would encourage counselors and providers to recommend testing only for conditions that would impair one's health or only for conditions that a patient indicates would lead her to terminate the pregnancy.[134]

At the core of debates about the substance of informed consent is agreement that the nature of genetic counseling is to explain results and help patients understand their options — to "disclos[e] information material to patients' choices" and "not to impose information but to offer it."[135] Counselors are often the gatekeepers of information, and yet new refusal laws chip away at the ethics of disclosing information in a client-centered way.[136] Thus, at a time in which results will be increasingly difficult to understand, states are legislating to vet that information based on abortion politics. Moreover, laws and proposed bills that ban abortion because of fetal diagnosis or limit post-testing information are out of touch with the complexities of genetic diagnosis. Both types of laws presume that interpreting genetic diagnoses is a straightforward task when it is increasingly complex.

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Finally, anti-abortion legislation is blind to the problems with prenatal testing's current infrastructure. Health care professionals' offices may be unable to support broader counseling, in no small part because there is a shortage of genetic counselors.[137] Nationwide, there are approximately two-thousand trained counselors.[138] If NIPT becomes more common — or, as some predict, routine in prenatal care — the demand for trained counselors could be dramatic. Bernard Dickens reflected on the problem that the shortage of counseling professionals creates:

> Access to competent genetic counseling will be difficult in many cases, not just in resource-poor settings. It may be supposed that centers capable of conducting [NIPT] will be equipped with counselors for pre-test and post-test services. If and where testing becomes routine, however, counseling by specially trained genetic counselors may become the exception rather than the rule, and responsibility for counseling on test potentials and results may be shared by general providers of reproductive healthcare.[139]

NIPT, the use of which correlates with higher income and education levels, could magnify the healthcare inequalities that already exist in the United States. Inequality among NIPT users may have the consequence of deepening problems of transparency and access. A consequence of these inequalities, as happens with PGD in part because of its cost, is that only the affluent, educated, or other privileged groups will have the ability to learn the genetic characteristics of their children.[140]

One potential solution to problems of equal access is the coverage of NIPT by states' Medicaid programs and by subsidized insurance plans in state exchanges established by the Patient Protection and Affordable Care Act (ACA). State Medicaid programs cover the costs of prenatal genetic screenings in 36 states and the District of Columbia and of invasive testing in 47 states for certain categories of women. Medicaid programs in 24 states cover the costs of genetic counseling,[141] and Medicaid programs in Iowa, Mississippi, and Virginia pay for terminations in cases of fetal impairment.[142] At present, a brief survey of state websites suggests that NIPT is not covered as testing or screening under Medicaid. But if the extension of private insurance coverage is any indication, NIPT could become part of a Medicaid program if it becomes a common part of prenatal care.

In addition to potential Medicaid inclusion, the ACA suggests two ways in which the government can subsidize prenatal diagnosis. First, the ACA requires that non-grandfathered health insurance plans sold in state insurance exchanges cover "essential benefits" without cost sharing. The ACA lists maternity and newborn care as an essential benefit. States have the responsibility of defining what "essential benefits"

include based on benchmark plans and, at this point, states appear to include coverage for screening and CVS or amniocentesis (if screening indicated risk). This is because major health plans, which serve as benchmarks, include genetic screening, testing, and counseling, for certain groups of women.[143]

Second, the ACA requires most health insurance plans to pay for preventive services, which could include prenatal genetic testing and screening. Guidelines issued by the Health Resources and Services Administration (HRSA) set out the scope of preventative services. Preventative services include a well-woman visit, which includes prenatal care. Neither the guidelines nor the recommendations spell out what prenatal care involves, but an Institute of Medicine (IOM) report, on which the HRSA relied, suggests that screening and testing are part of prenatal care.[144] Because the IOM Committee on Preventative Services for Women is tasked with "regularly updating the preventative screenings and services to be considered," new technology like NIPT will likely influence policy in the future.

Thus, the question may not be if state-related programs will cover NIPT, but when and how they will cover NIPT. State funding will ease some problems of inequality of access, making NIPT affordable to a broader population of pregnant women. But it also invites state regulation of the informed consent process and the genetic counseling that precedes and follows NIPT. At a time in which testing is becoming more widely available, anti-abortion efforts could co-opt regulatory discussions by managing or restricting testing information and choices. Given the anti-abortion furor and enthusiasm that has gripped so many state legislatures, it is not difficult to imagine laws that place funding restrictions on NIPT for certain conditions, that make post-test results hard to obtain, or laws that ban NIPT for some conditions. State laws could seek to ban NIPT for late onset disorders or non-medical traits, particularly in state-funded programs.[145] State laws would then reproduce the uneven effects for women who cannot afford services unsubsidized by the state, creating a sadly-familiar asymmetry between women who can afford services and women who cannot.

NIPT presents complex questions about the role of legal intervention, and there is a risk that abortion politics will monopolize conversations about regulating genetic testing for any fetal characteristic. Reason-based bans on abortion ignore the values that potential parents have as they make post-testing decisions. Genetic counseling and informed consent standards can help make sense of the purpose of testing and add needed nuance to regulatory choices.[146] Laws and policies that support adequate, non-biased genetic counseling can help shift the focus from one-size-fits-all regulation to policies that meet the divergent needs of pregnant women.[147]

Conclusion

Reproductive rights advocates need to be in conversation with the medical professionals that shape testing ethics because the wider introduction of NIPT suggests that these two groups have common ground — the health care needs of pregnant women. Antina de Jong and her colleagues write, "It is striking that the normative framework for prenatal screening, with its emphasis on reproductive choice, does not provide much guidance when it comes to [what] a responsible screening offer would be."[148] One can too readily imagine a future in which informed consent standards overly restrict termination options, an environment in which pro-choice counselors work in climates of fear, or calls for consent standards that are biased and directive. If this future is realized, pregnant women may have more testing, but fewer choices about how to act on the information testing reveals.

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133. *Id.*, at 52.
134. *Id.*, at 52-53.
135. See Dickens, *supra* note 138, at 182.
136. The International Federation of Gynecology and Obstetrics (FIGO) Ethical Guidelines on Conscientious Objection require that, "Practitioners provide [their] patients with timely access to medical services, including giving information about the medically indicated options of procedures for their care and of any such procedures in which their practitioners object to participate on grounds of conscience."
137. C. J. Chachkin, "What Potent Blood: Non-Invasive Prenatal Genetic Diagnosis and the Transformation of Modern Prenatal Care," *American Journal of Law & Medicine* 33, no. 1 (2007): 9-53, at 23-24.
138. See Stern, *supra* note 95, at 10.
139. See Dickens, *supra* note 125, at 183.
140. See Benn and Chapman, *supra* note 56, at 132.
141. U. Ranji and A. Salginicoff, *Focus on Health Reform: Access to Abortion Coverage and Health Reform* (Washington, D.C.: The Henry J. Kaiser Family Foundation, 2010): at 1, 6.
142. Guttmacher Institute, *State funding of Abortion under Medicaid*, 2014.
143. Take for example the Priority Health coverage policy. The coverage policy requires counseling and informed consent *before* testing. See Priority Health, *supra* note 6, at 1.
144. In describing the routine coverage of private plans and public programs, the IOM report stated: "Pregnant women should receive…prenatal screening and testing for neural tube defects (for all women at elevated risk) and chromosomal abnormalities (for all women at "elevated risk"), including, but not limited to amniocentesis, chorionic villus sampling, and ultrasound." Commission on Preventive Services for Women, *Clinical Preventive Services For Women: Closing the Gaps* (Washington, D.C.: Institute of Medicine, 2011): at 61.
145. See Priority Health, *supra* note 6, at 7.
146. See Stern, *supra* note 95, at 122, 136.
147. See Farrell, *supra* note 116, at 9-11 (problematizing the "voluntariness" of NIPT, based on women's experiences with amniocentesis and CVS).
148. See de Jong, Maya and van Litht, *supra* note 22, at 8.