Sociocultural Considerations for Equitable Non-invasive Prenatal Testing Administration

A Research Paper submitted to the Department of Engineering and Society

Presented to the Faculty of the School of Engineering and Applied Science

University of Virginia • Charlottesville, Virginia

In Partial Fulfillment of the Requirements for the Degree

Bachelor of Science, School of Engineering

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Spring 2023

On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

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Introduction

Non-invasive prenatal testing (NIPT) is often advertised as being over 99% accurate at non-invasively predicting fetal genetic abnormalities early in pregnancy (Samura & Okamoto, 2020). But a sobering analysis by the *New York Times* suggests that some positive NIPT results can be wrong more than 85% of the time (Kliff & Bhatia, 2022). As with all statistics, context is key, and it is this context that appears to be solely missing in the current discussion around the efficacy and benefits of NIPT. Diving deeper into the details reveals that tests for some genetic abnormalities are more likely to result in false positives than others, but patients are only seldom provided this type of nuance when presented with their prenatal screening options. The cases of patients such as Meredith Bannon and Allison Mihalich, who both received positive NIPT results for incredibly rare diseases and began planning abortions before further testing revealed their pregnancies as healthy, hint at the very real possible cost of these false results (Kliff & Bhatia, 2022). This cost was tragically faced by an unnamed patient interviewed by the *New York Times*, who terminated her pregnancy following a positive NIPT result before follow-up testing indicated that her pregnancy had actually been healthy (Kliff & Bhatia, 2022).

NIPT is a method that uses a combination of biological and analytical techniques to screen for possible fetal aneuploidies early in pregnancy. Fetal aneuploidy occurs when a chromosome or a part of a chromosome is present in the growing fetus in an abnormal number, and is estimated to occur in up to 1% of live births (Queremel Milani & Tadi, 2022). An aneuploidy is termed a monosomy if the fetus has only one copy of a chromosome instead of the requisite two, and trisomy if a fetus has three copies (Queremel Milani & Tadi, 2022). Hereafter, a finding of monosomy or trisomy will be referred to as a positive NIPT result, while a finding of no chromosomal aneuploidy will be referred to as a negative result.

Chromosomal abnormalities are typically associated with genetic disorders such as Down syndrome, caused by trisomy 21, Edwards's syndrome, caused by trisomy 18, and Patau's syndrome, caused by trisomy 13 (Queremel Milani & Tadi, 2022). These three trisomies are the most common in live births, and therefore are the most tested across various NIPT offerings (Gadsbøll et al., 2020). Knowing whether their baby is likely to be born with one of these conditions can help expecting parents make more informed decisions about their pregnancy and better prepare to meet the needs of their child. The benefit of NIPT over other fetal aneuploidy tests is that it can be performed non-invasively (Warsof, 2015). In a prenatal care program that includes NIPT, only patients with a positive NIPT are typically recommended for a follow-up invasive procedure, which reduces the number of invasive procedures that need to be done (Warsof, 2015).

In this paper, I argue that the current integration of NIPT into the prenatal care process is inequitable and improper due to a lack of appropriate consideration for patients' sociocultural backgrounds and medical literacy. First, I present an overview of the literature on NIPT, its benefits and drawbacks, as well as some issues with its current implementation. Then I analyze patient, provider, and NIPT company perspectives on the technology to show how their various ways of approaching this tool have contributed to the current implementation challenges. Through this analysis, I highlight the sociocultural considerations that must be taken into account for a more equitable and appropriate integration of NIPT into the field of maternal health, with an emphasis on economic and racial barriers to access, as well as the importance of providing patients sufficient information to make an informed decision about using NIPT. Finally, I end with a discussion of how it is not enough to rely on the technology itself to do all of the talking; social guidelines and systems must be put in place around the application of the technology to

ensure it is used in a way that leads to the greatest benefit. For NIPT, I discuss how this manifests as making NIPT available for all patients who wish to use it, without forcing it on the unwilling or the uninformed.

Literature Review

Reports suggest that 25-50% of pregnant people currently use NIPT as part of their prenatal care experience, but NIPT is not yet equally accessible to all pregnant people who want it (Ravitsky et al., 2021). NIPT uptake is lower in socioeconomically disadvantaged communities compared to other neighborhoods (Ellison et al., 2022; Meij et al., 2021). Insurance is a large part of this, as there is no standardization in the US on insurance coverage for NIPT, and most private companies only cover NIPT for high-risk pregnancies (Gadsbøll et al., 2020). Medicaid provides no coverage for NIPT at all in nine states, and covers patients defined as average-risk in only six states (Gadsbøll et al., 2020). There also exists evidence of a racial disparity in NIPT uptake. Just after NIPT became available, Caucasian women were more likely than Hispanic women to use NIPT over an invasive procedure at the studied testing center (Chetty et al., 2013). Numerous studies have also shown that Black and Hispanic women are less likely to receive NIPT compared with White women (Ellison et al., 2022; Smith-Lin et al., 2018; Yarrington et al., 2021). These racial disparities are compounded by the fact that people of color are disproportionately likely to also be of lower socioeconomic status and face the economic barrier as well (Williams et al., 2016).

Blindly attempting to increase NIPT access can lead to routinization, which has the potential for emotional and mental harm. Routinization is the process of NIPT becoming so ubiquitous that it is offered to all women as a standard of prenatal care, without providing them appropriate information, taking into account their cultural values, or offering them the option to

decline (van der Meij et al., 2022). NIPT's role as a non-invasive, non-harmful procedure conducted entirely from a blood draw makes it uniquely vulnerable to this way of thinking, as there is real risk of pregnant patients viewing it as "just another blood test" without giving sufficient consideration to its significance and the potential implication of its findings (Cernat et al., 2019). A study in 2017 on NIPT failures found that many patients felt deceived by the advertisement of NIPT being 99% accurate, and stated they would have felt less post-text anxiety had they received adequate pre-test counseling (Allyse, 2017). Echoing some of the themes from the patients interviewed by the *New York Times* mentioned in the introduction, these patients reported lasting effects on their views toward NIPT and even their willingness to have more children as a result of false positive NIPT results, highlighting the real consequences of routinization (Allyse, 2017). Routinization is especially concerning for already-vulnerable populations, who are less likely to receive adequate genetic counseling during their first prenatal care visit (Christopher et al., 2022).

In my analysis, I use the Social Construction of Technology framework proposed by Pinch and Bijker in 1984. A central tenet of this framework is that technology is not created or used in a vacuum, but is the product of the values and motivations of the relevant social groups involved. A relevant social group is defined as a group of people who assign the same meaning to a piece of technology, in this case NIPT. Other important terms include interpretative flexibility, which is the idea that the same technology can mean different things to different groups, and therefore be used differently by each of them; and closure, which is when the meaning and subsequently the use of a technology converges between different groups. Power imbalances between different social groups, such between a provider and a patient, are important and highlighted by this framework, which is why I chose it for my analysis.

I use SCOT to analyze the social groups involved in the NIPT process, including patients, providers, and NIPT companies. I want to see how their motivations and power dynamics resulted in the current NIPT administration process and the interpretive flexibility around this technology. I will also discuss the sociocultural factors that will be important to consider to ensure a more fair, equitable, and beneficial NIPT experience for patients of all backgrounds.

Methods

I will gather secondary sources, primarily research articles in reputable journals that discuss the application of NIPT in the prenatal care process, statistics regarding NIPT use, and patient and provider perspectives on NIPT. I will be focusing on research published in the last ten years, prior to which NIPT was not widely in use, and will primarily be looking at journals in the fields of Prenatal Care and Obstetrics & Gynecology. In my review of this literature, I will examine various perspectives and attitudes toward NIPT, with a focus on how the values and motivations of each social group shaped their perspective.

Analysis

A SCOT approach would suggest that the interpretive flexibility of NIPT is a large part of the reason behind its implementation challenges. The most relevant social groups can broadly be split into providers, patients, and NIPT companies, wherein each group shares a common but unique definition of the NIPT technology. Patients, though a diverse group encompassing many different demographics, largely appear to view NIPT as a black-box test providing accurate information about their pregnancy (Allyse, 2017; Cernat et al., 2019; Grafft et al., 2022; Kliff & Bhatia, 2022). Some may have done their own research separate from what they are told by their providers, but many preferred to hear about NIPT directly from their clinicians or did not have

further education about the topic beyond what they were told in their prenatal care visit (Cernat et al., 2019; Grafft et al., 2022). The patients most likely to be part of an underserved community are also most likely to have a low to moderate degree of medical literacy about the test, its benefits, its drawbacks, and the next steps after receiving a positive result (Williams et al., 2016). Hence, to them, NIPT is as much an informative black box as any other type of medical tool. Not magic, but the scientific equivalent.

Providers and NIPT companies differ in their views on NIPT, further illustrating the application of interpretive flexibility in this case. While the provider perspective is most difficult to generalize, a 2016 survey found that a majority of providers felt NIPT improved patient care and was a superior option to other screening methods (Brewer et al., 2016). The same study further found that over 80% of providers would use NIPT as their first screening option if cost was not a barrier, and up to 15% of providers incorrectly described it as diagnostic for fetal aneuploidy rather than merely a screening (Brewer et al., 2016). This indicates that the provider perspective on NIPT is overwhelmingly as a positive, highly informative tool in their prenatal care arsenal. Finally, it can be reasonably argued that NIPT companies see the test as merely a consumer product that can be marketed and sold to providers, who then recommend it to their patients. Therefore, there are three separate, conflicting views of NIPT presented: a magic 8-ball, a positive tool, and a consumer product. With these perspectives in mind, we can use SCOT to further analyze the context in which they were created and refined.

Current NIPT administration is inequitable toward historically underserved populations, including those of lower SES and racial minorities, in part due to the same systemic barriers of discrimination and cost that plague the rest of the medical system. Patients of lower SES are more likely to use Medicaid as their primary insurance, or have no insurance coverage at all

(Williams et al., 2016). As discussed in the literature review, Medicaid coverage for NIPT varies by state, and private insurance coverage varies by company (Gadsbøll et al., 2020). With NIPT companies primarily treating NIPT as a consumer product instead of a critical healthcare tool, out-of-pocket costs can range from hundreds to thousands of dollars depending on the specific test, presenting a clear financial barrier to NIPT access for lower SES patients (Bunnik et al., 2020). Similarly, a plethora of research is available indicating that racial minorities, including Black and Hispanic patients, on average face greater disparities and worse health outcomes across all areas of medicine (Williams et al., 2016). This is compounded by the fact that people of color are disproportionately likely to also be of lower SES, but a racial disparity in NIPT exists even when income and insurance are controlled for (Yarrington et al., 2021). The studies all call for further work to be done to determine the exact reasons behind these socioeconomic and racial disparities, but certainly a large part of both can be explained by known, institutional issues with the American healthcare system.

However, these general disparities present in specific ways in the prenatal care field, indicating issues with the current implementation systems in place around NIPT. This is most easily seen in relation to the socioeconomic disparity. For states and companies where insurance coverage is not universal for all pregnancies, the level of coverage typically depends on a patient's risk category, defined based on factors such as age, history of prior pregnancies with chromosomal abnormalities, or suspected abnormality with the current pregnancy ("Coverage Scorecards," 2023). But how risk is determined is itself biased; those with less access to resources are less likely to have received an initial ultrasound or other such primitive screening measure that would then qualify them for NIPT coverage. Therefore, those of lower SES, already at a global insurance disadvantage, are additionally less likely to qualify for NIPT coverage

based on how NIPT companies and insurance companies have constructed the system. Further, as NIPT is still a relatively new technology that has only been increasing in prevalence over the last decade, not all prenatal care clinics have contracts with NIPT companies (Ellison et al., 2022). While further research is required, it would track with general trends of healthcare disparity that clinics serving low SES communities would be less likely to have established NIPT contracts in place (Williams et al., 2016).

While eliminating these barriers to NIPT access is important, increasing NIPT access should not be misconstrued as an attempt to directly increase the percentage of NIPT use, as there are many cultural reasons that would lead a patient to reject NIPT. Such reasons have been best studied in the United States among patients identifying as Hispanic or Latinx. Reasons include Western views of pregnancy as a medicalized condition clashing with a more traditional view of pregnancy as a natural part of life; the fact that Latina women are more likely to claim they will "accept what is given" and may not actually desire to know whether their baby has a chromosomal aneuploidy; and a view that genetics, the behavior of the mother while pregnant, and the will of god contribute equally to outcome of the pregnancy, so it is better to focus on the controllable factors as opposed to the uncontrollable genetics (Grafft et al., 2022). It can be extrapolated with some confidence that patients from other diverse backgrounds are also likely to have their attitudes toward NIPT shaped by their cultural framework, as childbirth is often a hugely significant and well-discussed phenomenon in cultures around the world (Grafft et al., 2022). Whether those attitudes towards NIPT are ultimately positive or negative, they should not be analyzed, never mind altered, without a deep understanding of the cultural context in which they were formed. Most existing studies appear to suggest that uptake percentage is the best statistic to understand NIPT use among minority communities, with higher percentage correlated

with greater NIPT access, but this research indicates otherwise. The goal should be to ensure that all patients have *access* to NIPT, not that all patients *use* NIPT. Therefore, statistics looking at NIPT availability, rather than NIPT use, are better suited to capturing the desired metric of whether patients have an equal opportunity to receive NIPT if they want to. Similarly, any efforts on the part of providers or NIPT companies to improve NIPT administration should focus on the same goals.

Cultural factors aside, blindly increasing the percentage of NIPT use can actually cause more harm than good, by leading to routinization and eventually even decisional regret. NIPT cannot be treated like an EKG or a COVID test or even a standard blood draw, a kind of routine checkup administered with minimal education and little to no option to decline. The cultural values surrounding pregnancy, motherhood, and childbirth mean that a blood draw for NIPT is inherently different from a blood draw checking for potassium or hemoglobin levels, and should be treated with the appropriate level of gravity and cultural relativism by providers. Some studies suggest that routinization does not appear to be a major problem with NIPT, and that patients appear to be adequately educated (van der Meij et al., 2022). But these studies were largely conducted in the Dutch context. Other research in North America suggests that many women who receive NIPT do initially view it as "just another blood test", which indicates that routinization has already begun to creep in (Allyse, 2017; Cernat et al., 2019).

Informed consent for the test is crucial to a successful NIPT administration and outcome, as shown by the numerous documented cases of decisional regret. This is clearly seen in the cases discussed in the introduction of this paper, regarding patients who received false positive results and subsequently experienced a great deal of anxiety and emotional turmoil (Kliff & Bhatia, 2022). Much of that pain could have been avoided with better systems in place to educate

those patients about the limitations of NIPT, the possibility for false positive results, and the clinical practice guidelines which "recommend that all positive NIPT results should be confirmed with invasive fetal diagnostic testing, as well as that no irrevocable decisions about a pregnancy should be made on the basis of NIPT alone" (Cernat et al., 2019). The need for education is further highlighted by the troubling statistic that up to 6% of women receiving a positive NIPT result terminate their pregnancy without any further confirmatory diagnostic testing (Dar et al., 2014). This clearly highlights the gap between patients and providers in their approach to NIPT, as providers tend to focus on the positive use cases of the technology, while patients are largely reliant on those same providers to educate them on possible downsides and limitations.

NIPT companies, predictably, take a profit-driven approach to creating, advertising, and administering their tests, aiming to provide the largest number of testing options to persuade consumers to choose their product. They are primarily interested in expanding the use of NIPT in order to drive up their economic share, which inevitably leads to advertising statistics such as the greater than 99% accuracy discussed previously. There are a myriad of NIPT options available, which further increases the pressure and competition among companies, leading to a race to try and stand out. To do so, many companies have turned to offering a greater variety of tests beyond the three trisomies already mentioned, even though those are the most accurate, best studied, and most likely to lead to real phenotypes in the baby (Gadsbøll et al., 2020; Kliff & Bhatia, 2022). It is these expanded tests that are most likely to return the false positive results that can lead to so much harm for patients, who often do not understand those intricacies (Kliff & Bhatia, 2022). But companies cannot be relied upon to sacrifice their bottom line in favor of

appropriately educating patients about the pros and cons of their tests, nor should that be the role of a business enterprise.

That responsibility is most naturally placed on the shoulders of providers, but even they, especially those who are not prenatal care experts, are often themselves ill-equipped for this task. Hectic schedules mean that time constraints, rather than a patient's level of medical literacy or degree of understanding, can determine how long a provider spends educating a given patient, if education is provided at all (Cernat et al., 2019). Even if education is given, providers tend to deliver information to patients based on a standard counseling repertoire, without taking into account the unique background and demographics of each patient (Grafft et al., 2022). Further, patients who experienced decisional regret report feeling pressured by their providers to choose NIPT, in direct contrast with the ideas of informed consent and reproductive autonomy (Allyse, 2017). Some studies reported that patients felt providers were themselves not adequately educated regarding the technology of NIPT, nor the experience of raising a child with the conditions that can result from chromosomal aneuploidies detected by NIPT, such as trisomy 13 or 18 (Cernat et al., 2019). One study suggested that only 11% of surveyed obstetricians felt "very comfortable" explaining certain aspects of NIPT to patients, which supports this view (Mayes et al., 2016). It stands to reason that providers cannot provide adequate counseling about topics they are themselves unfamiliar with, which helps explain some of the gaps in prenatal genetic counseling. New research also suggests that already underserved populations are less likely to receive adequate genetic counseling during their first prenatal care visit, further exacerbating the issue as another instance of NIPT inequity (Christopher et al., 2022).

Despite being the most impacted social group, it is clear that patients have the least power in the triangle between NIPT companies, providers, and patients. NIPT companies set the cost of

the product, and determine which specific tests are included. In most cases, it is the provider who then determines which NIPT company's test to use, often due to factors unrelated to its actual efficacy (Cernat et al., 2019). Patients, as the least medically literate of the three, and least familiar with the technology, are largely reliant on the provider to accurately give them the necessary information to make an informed decision. But providers are coming from their own perspective, largely with a positive view of NIPT as a medical tool, and can fail to sufficiently educate patients about downsides, consequences, and the possibility of incorrect results, areas with which they themselves may not be as familiar. With the current NIPT administration process driven entirely by NIPT companies and providers, it becomes clear how the needs, values, and literacy levels of patients are not sufficiently taken into account. That, in turn, leads to situations like those of Meredith Bannon, Allison Mihalich, and others, whose experience with the NIPT process brought more harm than good (Kliff & Bhatia, 2022).

Conclusion

We have now seen that there are issues with the current implementation of NIPT, both in terms of barriers to equal access and challenges with appropriate use, due to an overreliance on the technology working without appropriate social systems in place around it. Any possible solution must balance the need for patients of all backgrounds to be able to use NIPT if so desired, while also respecting that those same backgrounds may require considerations be taken into account for cultural values, religious beliefs, and level of medical literacy.

My hope is that through highlighting factors to consider, this research has illuminated several paths forward for a more equitable, successful administration of NIPT. Steps such as standardization of NIPT insurance coverage across state lines, universal availability of NIPT regardless of location or calculated pregnancy risk, and increased education about screening

benefits can reduce barriers to equal NIPT access. Similarly, steps such as mandated genetic counseling pre and post test, increased education regarding limitations and consequences of NIPT for providers and patients alike, and providing patients greater power over various parts of the testing workflow can improve the NIPT administration process in those patients who do choose to use it. Bridging the interpretive flexibility around this technology, so that patients, providers, and NIPT companies begin to view it through the same lens, will be a key first step to embarking on any of these changes.

NIPT is a useful technology that allows expecting parents to gain important insights about their baby in a faster, safer manner than more invasive alternatives (van der Meij et al., 2022). The current challenges with NIPT lay not in the technology itself, but in the way it is promoted and administered. Putting in place social structures that prioritize informed consent, patient autonomy, and cultural relativism at every stage of the process can help ensure a positive prenatal care experience for all patients, with or without NIPT.

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