

Responding to the FDA Warning and ACOG Statement on NIPT: Implications of Prenatal Screening for Down Syndrome

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Non-Invasive Prenatal Testing (NIPT) has become a popular standard of prenatal care as a screening method for Trisomy 21 (Down syndrome). However, there are many shortcomings of the test—both scientific and ethical. This research paper critically examines the implications of NIPT, arguing against its moral permissibility as a standard test for Down syndrome, even though the FDA and American College of Obstetricians and Gynecologists continue to support its use. Scientifically, false positives associated with NIPT raise doubts about the accuracy of results and the subsequent decisions made based on them. Moreover, the responses triggered by NIPT outcomes often lead to actions that are either scientifically impossible or ethically impermissible. Ethically, natural rights and utilitarian theories can be seen as justifications for NIPT. A common thread among these theories and proponents for NIPT is freedom and autonomy. However, liberty based on faulty information is not true freedom nor respect - it is demeaning. Drawing upon natural law theory and Kantianism, I support the argument against NIPT. I demonstrate how NIPT violates the principle of double effect (PDE) within natural law theory and emphasize the importance of human dignity for individuals with Down syndrome from a Kantian perspective. Ultimately, I will call for a more nuanced approach to prenatal care decision-making that respects principles of accuracy, autonomy, and human dignity for all.

I. INTRODUCTION

On April 25, 2023, Barbie doll manufacturer Mattel, Inc. launched a doll with Down syndrome. The doll is part of Mattel's aim to create the "most diverse and inclusive doll line...to inspire even more stories" (1), and it accentuates the ever-present need to promote acceptance and inclusion for those with physical and intellectual disabilities. The president of the National Down Syndrome Society (NDSS) commented on Matell's promotion of progress: "this Barbie serves as a reminder that we should never underestimate the power of representation. It is a huge step forward for inclusion and a moment that we are celebrating" (1). While strides such as this one are being made towards inclusion for individuals with Down syndrome, screening tests for Down syndrome, such as noninvasive prenatal testing (NIPT), may be promoting an adverse effect.

Utilized to assess the probability of a fetus being born with specific genetic abnormalities, NIPT primarily screens for chromosomal disorders resulting from additional or missing copies of a chromosome. Trisomies 13, 18, and 21 are commonly tested, as well as abnormalities of the sex chromosomes. Since trisomies 13 and 18 are incompatible with life (2) and NIPT's ability to study sex chromosome aneuploidies is less established, this paper will largely focus on testing for trisomy 21, which is better known as Down syndrome. The screening test involves analyzing cell-free DNA (cfDNA), which is typically identical to the DNA of the fetus, via a blood test targeting the mother's placenta.

The process is completely safe and does not harm the fetus or the mother in any way. NIPT can occur any time after the tenth week of pregnancy. It is crucial to acknowledge that NIPT cannot provide a conclusive answer regarding the presence of a genetic condition in a fetus; rather, it can only make an estimation of the associated risk. Any preliminary results must be confirmed with invasive diagnostic testing, which is typically via amniocentesis or chorionic villus sampling (CVS) procedures (3).

False positive and false negative results may occur, which incorrectly display an increased or decreased risk for a genetic abnormality, respectively (4). For this reason, in 2022, the US Food and Drug Administration (FDA) issued a warning about the use of NIPT. The FDA stated that NIPT should not be used as a diagnostic test for fetal chromosomal abnormalities unless the positive results are confirmed through invasive diagnostic testing. The FDA also advised healthcare providers regarding the necessity of informed consent for the possibility of false positive results and the need for confirmatory testing (5). Crucially, the FDA makes no mention of the delineation between trisomies 13 and 18, which are fatal, and trisomy 21, which still allows affected individuals to lead fulfilling lives.

I find that the promotion of a screening test, supported by the FDA, with strong ethical implications and scientific ineptitude is incredibly problematic. Hence, I will argue that NIPT cannot be morally permissible as a standard of prenatal care testing for trisomy 21, also known as Down syndrome. NIPT

represents a problematic shift in the way genetic screens are performed for Down syndrome since the testing is plagued by false positives and the results activate a set of responses which are scientifically impossible and/or ethically impermissible. After further explication of the scientific and ethical bases of NIPT, I will assess natural rights and utilitarian justifications for the provision of NIPT. Then, I will support the argument against NIPT under the lenses of natural law theory, demonstrating how NIPT violates the principle of double effect (PDE), and Kantianism, highlighting the importance of dignity for individuals with Down syndrome.

II. PRESENTATION OF NIPT AND ITS ETHICAL ISSUES

A. NIPT's Screening Capabilities

As mentioned previously, NIPT assesses aneuploidies in both autosomes and sex chromosomes.^{1,2} Detectable by NIPT, trisomy 13, 18, and 21 are chromosomal disorders caused by the presence of an extra copy of chromosome 13, 18, or 21, respectively. These conditions can result in a wide range of physical and intellectual disabilities, and some affected individuals may have life-threatening complications.

Trisomy 13, also known as Patau syndrome, is a rare condition that affects about 1 in 10,000 births. The presence of an additional chromosome 13 is associated with physical abnormalities, including cleft lip, microcephaly, polydactyly, and debilitating cardiac defects. Infants with trisomy 13 often have severe intellectual disabilities and experience seizures (2). Trisomy 18, also known as Edwards syndrome, is another rare chromosomal disorder that affects about 1 in 6,000 births. It is associated with many similar symptoms to Patau syndrome, including physical abnormalities, heart defects, and severe intellectual disabilities. Most affected infants do not survive past the first year of life for either trisomy 13 or trisomy 18 (6). Hence, trisomies 13 and 18 are similar in symptomatology and prognosis.

Trisomy 21, on the other hand, also known as Down syndrome, is a common chromosomal disorder that affects about 1 in 700 births. Down syndrome is associated with a wide range of intellectual and physical disabilities, including developmental delay, intellectual disability, and distinct facial features such as upward-slanting eyes and a flat nasal bridge.

1. Autosomes: non-sex chromosomes

2. NIPT can detect various sex chromosome aneuploidies, including Turner syndrome (monosomy X), Klinefelter syndrome (XXY), Triple X syndrome (XXX), XYY syndrome (XYY), and XXY mosaic syndrome (XXY/XY). Symptoms of sex chromosome aneuploidies may include developmental delays, learning difficulties, behavioral and social difficulties, physical abnormalities, and hormonal imbalances with cascading primary and secondary sex characteristic changes (7). Overall, there is a variety of symptomatology both within and between the sex chromosome aneuploidies. For the purpose of this paper, they will not be addressed.

Individuals with Down syndrome may also have heart defects, gastrointestinal problems, and other health issues (6). However, many individuals with Down syndrome live into adulthood and can lead fulfilling lives. Within the umbrella category of Down syndrome, there is a subcategory of mosaic Down syndrome. While individuals with the more common form of Down syndrome exhibit an extra copy of chromosome 21 in every cell, individuals with mosaic Down syndrome have extra chromosomes in only some cells. For this reason, individuals with mosaic Down syndrome typically exhibit fewer physical and intellectual impairments (8). Mosaic Down syndrome can still be detected by NIPT (3).

B. Timeline of NIPT's Advent

Since its advent in 2011, NIPT has had a storied history. Direct-to-consumer advertising (DTCA) initially promised relief from concern and freedom from risks for the unborn child, which has some truth to it. That is, compared to previous invasive options of amniocentesis or CVS for Down syndrome testing, NIPT is undoubtedly much safer. In an amniocentesis, amniotic fluid is withdrawn via a needle and tested, whereas, in CVS, tissue is taken from the placenta. Both of these procedures are associated with modest risks of miscarriage (9). Additionally, the FDA considered regulating NIPT as early as 2012 due to its "aggressive marketing" and lack of "comprehensive validation" (4). \$788 million in sales (4) and ten years later, the path was laid for an ultimate FDA warning on NIPT.

On April 19, 2022, the FDA issued a warning about the use of NIPT and its frequency of generating false positives. The FDA stated that NIPT should not be used as a diagnostic test for fetal chromosomal abnormalities unless the positive results are confirmed through invasive diagnostic testing. The FDA also advised healthcare providers to inform patients about the possibility of false positive results and the need for confirmatory testing (5):

While genetic non-invasive prenatal screening tests are widely used today, these tests have not been reviewed by the FDA and may be making claims about their performance and use that are not based on sound science. Without proper understanding of how these tests should be used, people may make inappropriate health care decisions regarding their pregnancy. We strongly urge patients to discuss the benefits and risks of these tests with a genetic counselor or other health care provider prior to making decisions based on the results of these tests"(5).

The FDA warning alludes to the potential limitations and drawbacks of NIPT as a screening tool for genetic conditions. While NIPT has become increasingly popular due to its non-invasive nature and fair accuracy rates, its potential to generate incorrect results may cause unnecessary anxiety and distress for expectant parents. In some cases, false positives may even lead to decisions to terminate a pregnancy that may not have been otherwise pursued. The FDA warning emphasizes the importance of confirmatory testing to verify NIPT results before making any decisions about pregnancy management or treatment. This recommendation aligns with ethical principles such as autonomy and informed consent, which require healthcare providers to provide patients with accurate and reliable information to make informed decisions about their healthcare. However, diagnostic testing is invasive and carries the possibility of harming the fetus. These diagnostic options are the same ones which were previously the first-line tests for Down syndrome (amniocentesis and CVS).³

In response to the FDA warning on the use of NIPT and its potential to generate false positives, the American College of Obstetricians and Gynecologists (ACOG) released a statement outlining best practices for the use of NIPT in clinical practice:

All patients, regardless of maternal age or baseline risk, should be offered both screening and diagnostic tests and all testing for chromosomal abnormalities should be an informed patient choice based on provision of adequate and accurate information, the patient's clinical context, accessible health care resources, values, interests, and goals" (10).

This selection from a lengthy ACOG statement emphasizes the importance of informed consent and patient counseling about the benefits and limitations of NIPT. ACOG recommends that NIPT should only be used as a screening tool and not as a diagnostic test, which concurs with the FDA warning. The ACOG statement also highlights the importance of ensuring that NIPT is used appropriately and responsibly, i.e., only used for medical purposes and not for non-medical purposes, such as sex selection or predicting non-medical traits (11). Overall, the ACOG response to the FDA warning on NIPT is ambivalent and emphasizes the importance of informed consent, patient counseling, and responsible use of the test in clinical practice. While the FDA and ACOG recognize NIPT's scientific shortcomings and ethical issues, both organizations continue to support its use.

3. Interestingly, although NIPT was promised as a non-invasive test, it may actually foster a paradox effect in that more invasive, diagnostic procedures are performed now as they are needed to confirm the results of NIPT (4).

C. Ethical Controversy Surrounding NIPT

There are three main considerations when accounting for the ethical issues surrounding NIPT: i) respect for autonomy of women, ii) respect for autonomy of the fetus, iii) equity and impact on society. I will take each into account in the following ethical analysis.

i. *Respect for Autonomy of Women*

NIPT provides information to mothers regarding the risk of Down syndrome for their fetus. This information can have significant emotional, psychological, and practical implications for the mother and her family, as it may influence decisions about continuing the pregnancy and preparing for a child with physical and intellectual disabilities.

On one hand, respecting the mother's autonomy means recognizing her right to make informed decisions about her own reproductive health and respecting her choices. It also means providing her with accurate and unbiased information about the risks and benefits of NIPT, as well as the limitations and potential implications of the test results, so that she can make a well-informed decision based on her own values and beliefs. From a teleological perspective, respecting the mother's autonomy can be viewed in the lens of overall well-being. Being informed allows her to make decisions that are more fully aligned with her desires and circumstances. It can also foster trust between the mother and her healthcare provider, which can lead to better communication, shared decision-making, and ultimately better patient outcomes.

However, the principle of respect for autonomy is not absolute and may be subject to limitations, such as when it conflicts with other ethical principles or when there are concerns about potential harm to others. For example, since the mother's decision based on the NIPT results could potentially harm the fetus, either physically or via encroachment of autonomy, these ethical considerations warrant further discussion.

ii. *Respect for Autonomy of the Fetus*

The concept of fetal autonomy, or the autonomy of the unborn fetus, is a complex and debated ethical issue and its importance has risen greatly due to the recent overturning of *Roe v. Wade*⁴, giving individual states the ability to regulate or ban abortion (12). A fetus could be considered to have its own autonomy and rights which should be respected. Some ethical theories and perspectives hold that a fetus has inherent moral worth and must be considered as an autonomous being

4. *Roe v. Wade*, 410 U.S. 113 (1973). Overturned on June 24, 2022.

with the right to life and the right to bodily integrity. In this view, NIPT could be seen as impacting the fetus' well-being. On the other hand, other theories do not acknowledge a fetus as human and thus without a right to autonomy.

Since the fetus cannot exercise its own autonomy, there could be questions about who has the authority to make decisions on behalf of the fetus and what criteria should be used to determine what is in the fetus' best interests. Balancing these competing interests can be complex and requires careful ethical consideration.

iii. Equity and Impact on Society

The ethical consideration of equity in the context of NIPT involves examining potential bias and stigmatizing issues that may arise. The cost of NIPT can vary, and it may not be covered by insurance or accessible to all pregnant individuals, especially those with limited financial resources (3). This inconsistency could result in differential access to NIPT based on socioeconomic status, potentially leading to health disparities and exacerbating existing inequalities in healthcare. There are also ethical considerations related to culture in the context of NIPT, as the potential for disparities in access to and social acceptance of NIPT for Down syndrome among different racial and ethnic groups raises important questions. Likewise, NIPT results may also carry unfavorable labels as Down syndrome has been shown to be socially stigmatized (13). Hence, there may be ethical implications in terms of how the information is conveyed and the potential social consequences.

On the same token as social stigmatization, there is a concern that NIPT results could contribute to discrimination against individuals with Down syndrome. That is, a mother could be stigmatized for having a child with Down syndrome if she could have had a chance at having a "normal" child, and/or the child with Down syndrome could face stigma for their intellectual disability. Of course, a ripple effect on individuals living with Down syndrome may be possible if selective abortion against Down syndrome becomes prominent. Ethical concerns related to fairness, justice, and the potential for discrimination against individuals based on their genetic information are brought into question.

III. ARGUMENTS SUPPORTING THE PROVISION OF NIPT

According to many, NIPT may have the potential to revolutionize prenatal care and improve the health outcomes of both mothers and babies. There are several reasons why individuals believe NIPT should become a

standard of prenatal care, based on both deontological and teleological ethical theories, as well as the guidance from the FDA and ACOG.

A. Natural Rights Theory

Developed by John Locke, this deontological ethical theory states that individuals have natural rights to life, liberty, and property, and these rights are protected by the government. In his *Second Treatise on Civil Government*, Locke writes, "The state of Nature has a law of Nature to govern it, which obliges...no one ought to harm another in his life, health, liberty, or possessions" (14). To assess the application of NIPT to natural rights, it may be helpful to analyze them separately. To begin, NIPT can be consistent with the right to life. That is, NIPT helps ensure that expectant parents have the information they need to protect and preserve the life of their child. Secondly, the use of NIPT can be seen as consistent with the right to health. Down syndrome's earmark symptoms include physical and intellectual disabilities and thus a decreased baseline of health. If NIPT can identify a fetus with Down syndrome and allow the parents to instead pursue having a child born with greater health, then natural rights theory suggests that course of action.

As an aside, Julian Savulescu underlines this point of health in the realm of procreative beneficence. He argues, "couples should select the child, of the possible children they could have, who is expected to have the best life, or at least as good a life as the others, based on the relevant, available information" (15). From this statement and Savulescu's application to both disease and non-disease genes, it is clear that health should be prioritized when procreating. He provides an example of two fetuses, one with asthma and one without any abnormalities; while the two fetuses could develop into equally successful human beings, one has a higher likelihood of developing asthma and thus having poorer health (15). The same logic can be applied to NIPT and Down syndrome: if a fetus is more likely to have Down syndrome, another fetus should be prioritized in order to maximize health.

The ability to make informed decisions about one's health and the care of one's child is an essential component of individual liberty. By providing information about the risk of Down syndrome, NIPT allows expectant mothers to exercise their right to make free, informed decisions about their pregnancy and the care of their child. Finally, the use of NIPT can be seen as consistent with the right to property. In the context of NIPT, property can refer to not only the fetus as the mother's possession, but also the genetic information that is obtained through the test. Under both lenses,

natural rights argues that the mother owns the fetus and the genetic information and can thus do as she pleases, i.e., so long as it does not harm other individuals.

i. Critique of Natural Rights Theory

The above explanation of natural rights theory for NIPT is a misconstruction of the ethical theory's basis for three reasons. First, a significant aspect of this reasoning is due to the fact that natural rights is a thin ethical theory and only explains what an individual *should not* do, rather than what they should do. It posits negative rights, meaning it may attempt to offer an explanation as to why NIPT is ethical on the basis of lack of interference on others' rights, but it does not address furthering society or a common good.

Second, the natural rights explanation places too much emphasis on the right to health and not enough on other natural rights. While the right to health is an important aspect of natural rights theory, it is not the only one. For example, the right to liberty may be compromised if NIPT results are used to pressure women into terminating pregnancies that are deemed "undesirable" due to the presence of Down syndrome. In this case, the mother's freedom to make her own decisions about her pregnancy and the care of her child may be infringed. This practice may also be the result of a concept called "the nudge." The nudge is a subtle change in the way choices are presented to patients by providers that can influence decision-making without directly taking away their freedom of choice (16). Nudging can be seen as a way to undermine the principle of informed consent as healthcare providers subtly voice their opinion, either in favor or disapproval of NIPT. While not a universal practice, providers who utilize the nudge may limit liberty by delicately persuading the patient to conform to the providers' opinion on NIPT.

Finally, if the use of NIPT leads to discrimination against individuals with Down syndrome, then the right to equality may be violated. Natural rights theory asserts that all individuals have equal rights and should be treated with dignity and respect, regardless of any perceived differences (14). The right to equality is also closely linked to the right to dignity and respect. Discrimination based on genetic information may lead to the stigmatization of individuals with Down syndrome and may infringe upon their right to dignity and respect. This stigmatization could create a harmful societal message that some individuals are inherently less valuable or deserving of equal rights and opportunities than others, simply because of their genetic makeup. Lastly, the argument relies heavily on the assumption that the fetus is the mother's property, but this view is not universally accepted. Some argue

that the fetus has its own inherent rights, including the right to life. If this is the case, then NIPT may be viewed as an infringement upon the fetus' rights rather than a tool to protect the mother's rights.

While the use of NIPT may be consistent with certain aspects of natural rights theory, it is important to consider the broader implications of its use and potential impacts on other natural rights. The right to health should not be prioritized above other natural rights, and discrimination against individuals with Down syndrome or any other disability should be avoided. Ultimately, natural rights theory is not a strong ethical basis for the continuity of NIPT for Down syndrome.

B. Utilitarianism

Utilitarianism is a consequentialist ethical theory, which means that it evaluates the morality of an action based on its consequences or outcomes. This theory was first developed by Jeremy Bentham in the late 18th century and later expanded upon by John Stuart Mill in the mid-19th century (17). According to utilitarianism, the morality of an action is determined by its ability to produce the greatest amount of happiness or pleasure for the greatest number of people. Known as the "Greatest Happiness Principle," Mill explains his central tenet of utilitarianism: "Actions are right in proportion as they tend to promote happiness, wrong as they tend to produce the reverse of happiness" (17). Granted, by "happiness," Mill is referring to pleasure and the absence of pain. In other words, utilitarianism is concerned with promoting overall well-being. The theory suggests that an action is morally permissible if it leads to the greatest amount of happiness for the greatest number of people, regardless of individual interests or preferences.

In the context of Down syndrome, utilitarianism can be thought to argue that NIPT is permissible because it can lead to overall greater happiness and well-being for individuals and society. One way that NIPT can do so is by providing expectant parents with information about the risk of Down syndrome. This information can allow them to make informed decisions about their pregnancy and the care of their child, which may lead to improved health outcomes. In turn, this preparation can lead to a decrease in suffering and an increase in happiness and well-being for the affected individuals and their families (18).

Additionally, the use of NIPT may lead to a more efficient allocation of healthcare resources according to utilitarian theory. By identifying fetuses at risk for Down syndrome, healthcare providers can advocate for further diagnostic testing and ultimately decision-making over the course of a pregnancy based on maximizing happiness. Since a fetus with Down syndrome will

Possible Outcomes

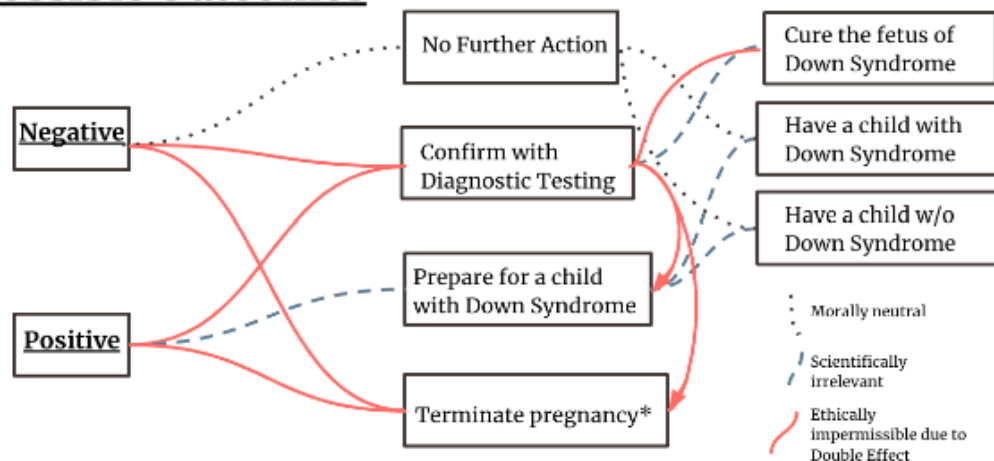


Figure 1. Possible Outcomes of NIPT Screening for Down Syndrome. The key can be utilized to understand which outcomes are morally neutral, which are scientifically irrelevant*, and which are ethically impermissible due to PDE. Following any action besides disregarding the screening tests' results, there are ethical and/or scientific repercussions.

* There are three examples of scientifically irrelevant cases shown here: a) the idea of preparing for a child with or without Down syndrome is not substantive, b) due to the limitations of the screening test, it is useless to predict the condition of the child, and c) there is currently no cure for Down syndrome.

suffer intellectual disabilities, utilitarians may argue that an affected fetus should be terminated and another effort should be made at conceiving a “normal” child. Selection of fetuses with the most potential could lead to a more efficient use of healthcare resources as well as a reduction in overall healthcare costs and a decreased sum of parental pain due to raising a child with disabilities.

Renowned contemporary bioethicist Peter Singer underlines this point. He asserts that “the knowledge that my child would not be likely to develop into a person whom I could treat as an equal, in every sense of the word...would greatly reduce my joy in raising my child and watching him or her develop” (19). Singer argues, from a utilitarian perspective, that his overall happiness would be reduced by having an intellectually disabled child. He continues on to broaden his argument and questions why society values the lives of severely intellectually disabled human beings more than those of animals such as dogs or pigs (19). He identifies this differential treatment as speciesism, a concept that implies unfair privileging of one species over another. By raising this point, Singer aims to challenge societal norms about the inconsistency in valuing human lives with disabilities differently from non-human animal lives. Evaluating quality of life, then, is a more relevant criteria to base worth of life compared to species categorization.

i. Critique of Utilitarianism

While utilitarianism may seem appealing in promoting overall well-being and happiness, there are several critiques to this theory when applied to NIPT. First, utilitarianism fails to consider individual rights and preferences. It focuses on outcomes rather than the means to achieve them. For this reason, utilitarianism can justify actions that violate the rights of individuals or minority groups, as long as the majority benefits from it. In the case of NIPT, this could mean justifying the termination of pregnancies for fetuses with Down syndrome and disregarding the rights of individuals with disabilities.

Furthermore, the utilitarian approach to healthcare resources can lead to discrimination against individuals with disabilities. It assumes that individuals with Down syndrome have less potential for happiness and well-being than others and therefore do not deserve the same access to resources. This attitude perpetuates ableism and goes against the principle of equal treatment for all individuals. As was mentioned earlier, it is known that intellectual disabilities exist as a spectrum for Down syndrome. For those with mosaic Down syndrome, which is still detectable by NIPT, intellectual disabilities may be incredibly subtle. Many families of children with Down syndrome, likewise, would not change anything if they could, as they feel as though their love for and bond with their child with Down syndrome is

unbreakably strong (20).⁵

In addition, utilitarianism is criticized for being too subjective and difficult to measure. It is not clear how to quantify happiness or pleasure and different individuals may have different ideas of what constitutes happiness. This discrepancy can lead to conflicting opinions on what actions are morally right and potentially lead to harm to individuals and society. One may question if focusing on rule utilitarianism, which argues that actions are right so long as they conform to rules which promote the greatest good, circumvents this issue of differing opinions (17). While this distinction is valid, it does not solve the aforementioned issues with utilitarianism more broadly, i.e., it still burdens an unjust value judgment on individuals with Down syndrome.

Therefore, in light of these critiques, utilitarianism is a weak argument in favor of continuing prenatal testing for Down syndrome. Its focus on outcomes and promotion of overall well-being can justify actions that violate individual rights and perpetuate discrimination against individuals with disabilities. Utilitarianism fails to consider the inherent value and dignity of every human life, regardless of their potential for happiness or productivity.

IV. ARGUMENTS SUPPORTING THE ETHICAL IMPERMISSIBILITY OF NIPT

I will now offer my argument against the continuation of screening tests for Down syndrome. I provide both a natural law argument against the set of options that NIPT reveals, as well as a Kantian argument against the discrimination that NIPT perpetuates.

A. Natural Law

Natural law ethical theory, which delineates NIPT as ethically impermissible, is grounded in the principle of double effect (PDE). This moral principle was first introduced by theologian Thomas Aquinas. It is a framework used to assess the morality of actions that have both good and bad effects. According to PDE, an action can be morally permissible if it meets four conditions: 1) the evil may be foreseen but not intended, 2) the evil may not be the means to the good effect, 3) the action to be done must itself be good or at least morally neutral, and 4) the evil to be risked must be proportionate to the good to be achieved (21). Commonly, PDE is invoked to ascertain the morality of actions such as pain relief in palliative care, where the use of medications may have both beneficial and harmful effects.

In the context of NIPT, there are no ethically

permissible paths resulting from either result (positive or negative) of a screening test for Down syndrome (see Figure 1). While genetic screening activates a set of theoretical options, none are ethically defensible or scientifically relevant. Following up with diagnostic testing, which is a requisite to confirm the results of the NIPT screen, is invasive and carries the risk of harm to the fetus. That is, estimates of miscarriage due to amniocentesis hover around 500-1000 every year, and complications from CVS include pregnancy loss, limb defects, bleeding, and infection (22). For this reason, invasive testing violates the fourth PDE, also known as the proportionality principle. The risk of harm to the fetus and pregnant individual is not proportionate to the good to be achieved.⁶

Besides engaging in confirmatory testing, some pregnant individuals may choose to selectively abort their child based on the results of testing. If this decision is made immediately after a NIPT screening test, it is based on scientifically inaccurate information. NIPT has a false positive rate of 9.79% (23), which means that for every 100 fetuses that show a positive result for Down syndrome, only 90 are accurate results. This discrepancy is staggering when the consequences are incredibly high; causing emotions to skyrocket, whether they be excited, nervous, or scared over a test result that is wrong 10% of the time; this is an incredibly unneeded burden. Even if the decision to selectively abort a fetus with Down syndrome is made after diagnostic testing, it still violates PDE. The action to devalue the fetus' life is still reprehensible and thus violates the third PDE. Not to mention, diagnostic testing cannot typically occur until the week of pregnancy (22).⁷

i. Counterargument to Natural Law

On the other hand, natural law theory may be used to support the use of NIPT as ethically permissible. Proponents of this view might argue that NIPT is morally neutral as it is merely a screening test that does not directly cause harm to the fetus or the pregnant individual. Additionally, NIPT may allow for earlier diagnosis of potential health issues, leading to better care for the fetus and potentially a better outcome for the pregnancy. Thus, PDE would not be violated, as the good achieved outweighs any potential harm caused by the screening test.

Furthermore, those who oppose the application of PDE to NIPT may argue that the principle of proportionality is not violated because the risks of harm

⁵ (20) An interesting read where a mother outlines five blessings of her child with Down syndrome.

⁶ Frankly, there is no good to be achieved from testing, which is the central thesis of this article.

⁷ Again, I bracket the question of the morality of abortion; I am simply stating that diagnostic testing may disturb any possible timelines and limit possible courses of action.

associated with invasive testing can be outweighed by the benefits of having accurate information about the health of the fetus. They may argue that pregnant individuals have the right to make informed decisions about their own health and that of their fetus, and that NIPT provides them with the information they need to make those decisions. In addition, proponents of NIPT may argue that it is not unethical to selectively abort a fetus with Down syndrome because it is a personal decision made by the pregnant individual and their family. They may contend that it is a matter of reproductive autonomy and that individuals should be allowed to make decisions about their own bodies and the health of their fetuses.

There are two main issues with this argument. Firstly, NIPT is simply not scientifically powerful enough to provide accurate results. Informed choice on the basis of screening test results is not violated because the results are not to be taken solely. Both the FDA and ACOG recognize this point, as NIPT cannot provide definite results. To confirm with diagnostic testing is to violate PDE, as explained above. Secondly, while many argue that preparing for a child with Down syndrome would be beneficial, it is unclear as to what this preparation may entail. Like any natural birth, the parents cannot possibly be fully prepared for their child. In an empirical article, Michie explains many of the shortcomings associated with theoretical preparation for Down syndrome: “[M]any families still report dissatisfaction...with the information and support they received afterward, much of which they reported was outdated and overtly negative...after diagnosis, many parents are not guided toward available clinical and family-centered information sources and/or support groups” (18). Education about Down syndrome and other genetic anomalies, much like education regarding different parenting styles, would be beneficial to all expectant parents in general.

B. Kantianism

Kantianism is a moral philosophy based on the teachings of philosopher Immanuel Kant. One of the key principles of Kantianism is the idea that human beings have intrinsic worth and dignity. Kant delineates this point throughout his *Foundations of the Metaphysics of Morals*. Specifically, he writes, “Act so that you treat humanity, whether in your own person or in that of another, always as an end and never as a means” (24). In this imperative, Kant emphasizes the importance of valuing human beings and the inhumanity of disrespecting natural worth. By emphasizing the concept of treating humanity as an end and not merely as a means, Kant highlights the importance of individuality

and autonomy. This perspective rejects any form of dehumanization, objectification, or exploitation of human beings. It underscores the moral duty to treat others with respect, acknowledging their intrinsic value and protecting their rights.

NIPT treating the fetus as a means to an end. Screening for genetic anomalies reduces the fetus to a set of genetic characteristics, rather than valuing it as a future individual with inherent worth and dignity. From a Kantian perspective, individuals with Down syndrome are still deserving of the same respect and dignity as any other human being. Kantian ethics emphasizes that humanity is not determined by any particular characteristic or trait, but rather by status as a rational and autonomous being. Therefore, Kantianism argues that it is morally impermissible to discriminate against individuals with Down syndrome or treat them as less than fully human (24). Selective abortion of fetuses that test positive for Down syndrome is unethical in the same way as it is treating the fetus as a means to an end. Rather, one should value the fetus for what it is.

The Kantian argument demonstrates many parallels to the Disability Rights Movement. As the name implies, disability advocate groups seek to ensure that individuals with disabilities are treated with equal respect and dignity and are not discriminated against based on their disabilities. One such group, which has gained traction in the fight against NIPT for Down syndrome, called “Don’t Screen Us Out,” aims to “create a world where people with Down syndrome are equally valued” (25). They promote inclusion, equality, and respect for individuals with Down syndrome, and they challenge the notion that individuals with disabilities are less than fully human. Protesters of NIPT associated with the “Don’t Screen Us Out” movement offer sentiments such as “NIPT? No, I’m perfect, thanks” and “Prenatal testing cannot predict this type of love” (25). These powerful slogans serve as a reminder that the value of a person’s life cannot be reduced to genetic markers.

i. Counterargument to Kantianism

A counterargument to Kantianism promoting dignity of human beings may stem from Kant’s definition of a human. Rather than using humanity to describe the species *Homo Sapiens*, Kant “considered the term ‘person’ to be applicable to beings with certain capacities” (26). Here, he offers a perception that humanity is not defined by one’s biological species, but rather by one’s rational capacities. From this line, some may infer that neither fetuses, which are not fully developed humans and thus incapable of rationality, nor individuals with intellectual disabilities are human. This being the case, some may argue that selective

abortion and/or discrimination against individuals with Down syndrome is not unethical.

However, this counterargument can be challenged by pointing out that it is based on an incomplete understanding of Kant's philosophy. While it is true that Kant believed that humanity is defined by rational capacities, he also argued that all human beings possess inherent dignity and worth, regardless of the weight of their capacities (24). Furthermore, even if fetuses and individuals with intellectual disabilities cannot be considered human beings according to Kant's definition, it does not necessarily follow that selective abortion or discrimination is morally permissible. Kant's philosophy emphasizes the importance of treating all beings, including animals, with respect. He delineates that "violent and cruel treatments of animals" (27) is forbidden and that "he who is cruel to animals becomes hard also in his dealings with men; we can judge the heart of a man by his treatment of animals" (28).

Therefore, while some may argue that selective abortion and discrimination against individuals with Down syndrome is not unethical based on Kant's definition of humanity, this counterargument can be challenged by pointing out that it is based on an incomplete understanding of Kant's philosophy and does not align with his emphasis on treating all beings with inherent worth and dignity.

V. CONCLUDING REMARKS

In conclusion, the use of non-invasive prenatal testing (NIPT) raises important ethical questions. On one hand, I have shown how supporters of NIPT argue that it can help parents make informed decisions about their pregnancy and provide an opportunity to prepare for a child with potential health concerns. I first explained how proponents of natural rights theory may argue that parents have a right to access this technology in order to protect the health and well-being of their child. I dispute this point by showing that NIPT is in direct violation of the inalienable right to life. Next, from a utilitarian perspective, I showed how it can be thought that NIPT helps reduce suffering and promotes the greatest good for the greatest number of people. However, I then argued that utilitarianism is a faulty argument because it does not consider individual rights and collapses the spectrum of intellectual disability of Down syndrome.

Following the argument for the continuation of NIPT, I then offered compelling arguments against the use of NIPT. From a natural law perspective, I showed how the use of NIPT violates the principle of double effect (PDE), as invasive follow-up diagnostic testing carries significant risks to the health of the fetus and pregnant

individual, and the decision to selectively abort a fetus with Down syndrome constitutes an evil that cannot be justified by any potential good. From a Kantian perspective, I explained how the promotion of human dignity is paramount, and the use of NIPT to selectively abort fetuses with Down syndrome undermines this fundamental principle. Moreover, the use of NIPT may perpetuate ableist attitudes and contribute to the stigmatization of individuals with disabilities.

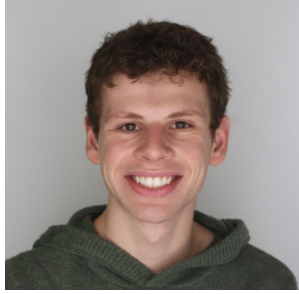
Given these ethical considerations, it is clear that the use of NIPT is a complex issue that requires careful consideration. In light of the FDA warning and ACOG statement about the limitations and potential harms of NIPT, it is important for healthcare providers and policymakers to take a critical look at the use of this technology. Rather than promoting the widespread use of NIPT, efforts should be made to educate healthcare providers and patients about the potential risks and lack of practical benefits of this technology. In effect, I call on the FDA and ACOG to provide more nuanced warnings of NIPT's ethical and scientific challenges for Down syndrome.

Moving forward, it is important to consider the broader implications of NIPT for the field of genetics and reproductive medicine. If NIPT becomes more widely available, it is likely that the use of this technology will continue to raise important questions. It is essential for ethicists to further engage in thoughtful and nuanced discussion about the appropriate uses of genetic screening technologies in order to ensure that it is used in a way that upholds the dignity of all human beings. Furthermore, continued research into alternative approaches to genetic testing and counseling may offer new solutions that can help parents make informed decisions without perpetuating harmful attitudes and practices. Similar to the landmark progress shown by Mattel, Inc. in introducing a Barbie doll with Down syndrome, my appeal for expanded research and ethical deliberation to safeguard the rights of individuals with Down syndrome and to question the implications of NIPT echoes the necessity of advancing a society founded on inclusivity and empathy.

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