II. Governance and biopolitics

3. Non-Invasive Prenatal Testing in Germany and Israel

A Matter of Course or a Matter of Discourse?

Tamar Nov-Klaiman, Hannes Foth, Yael Hashiloni-Dolev

Since its introduction into clinical practice in 2011, non-invasive prenatal testing/screening (NIPT/NIPS) has prompted concerns over its ethical, legal and social implications (Dupras et al. 2020; Haidar/Dupras/Ravitsky 2016). These concerns have intensified worldwide as many countries consider implementing NIPT in their national healthcare system, or have already done so (Ravitsky et al. 2021). Against the backdrop of this broad debate, we examine the local discourses of NIPT policymaking in Germany and Israel. These countries, related through a traumatic history, are both characterised by advanced medical technology and universal health coverage. Nonetheless, they are often opposed in terms of lay moralities, professional practice and healthcare policies, especially for genetic testing (Hashiloni-Dolev 2007; Raz/Schicktanz 2016). Israel is known as an early and enthusiastic adopter of biomedical technologies, whereas Germany is perceived as being relatively restrictive and cautious.

This study contributes to the comparative analysis of policymaking in healthcare. Cross-country comparisons are a powerful tool for understanding national variation in health policies and the moral and political assessment of biomedicine. Our focus on how NIPT policies are debated in Israel and Germany enables us to test the interplay of technological imperative in healthcare (McCoyd 2010) and cultural persistence/change. Raz (2018: 234) argues that in its genetic policies, “Israel is both reckless and pioneering – depending on one’s perspective”. Its early adoption of these technologies sometimes leads the way for other countries. Should we therefore expect the convergence of Israeli and German policies with the passing of time and advancement in techniques? Or rather, their divergence due to situated variables, such as previous approaches to screening for Down syndrome (Lôwy 2020)?

The case of NIPT highlights three major, inter-related challenges that are important for healthcare policy. First, NIPT policymaking provides a setting for considering various approaches to parental autonomy, selective abortion, embryo protection and disability rights (Haidar/Dupras/Ravitsky 2016; Heyd 1994). Second, it highlights different emphases in the context of care/prevention. While usually about prevention through abortion, NIPT may also be used to provide parents with early options of preparation (Kibel/Vanstone 2017; Lôwy 2020). Third, NIPT policymaking reflects different configurations of health governance that interconnect the State, the market, at-risk social categories, the family and the individual (Allyse et al. 2015; Lemke 2005; Ravitsky 2017).

These characteristics make NIPT a test case for stakeholder involvement. We compare the setting in which NIPT has been introduced in both countries: the legislative and regulatory framework as well as the socio-political context. This enables us to portray the discourses and stakeholders related to the use and potential implementation of NIPT in public healthcare in each country and their influence on decision making. Who is leading the debate? Which agendas drive the process? Do the decisions reached correlate with the legal and regulatory framework, and do they match former policies or take a new path?

Our analysis was done through systematic examination of policy documents and opinion papers issued by relevant stakeholders in Germany and Israel, such as medical organisations and advocacy bodies, in the period 2012–2021. It also involved an assessment of the legal framework with which this technology interrelates. Previous comparative studies between the countries, including in the field of biomedicine, were reviewed in order to establish the historical and social context in which the current debate takes place.

1. Foundations of the comparison

Non-invasive prenatal testing (NIPT) is a genetic test that targets placenta-derived cell-free DNA present in maternal plasma. It is used at present mainly to detect certain chromosomal aberrations with high accuracy in the detection of trisomy 21, which results in Down syndrome (DS) (Gregg et al. 2016). However, NIPT also enables the detection of single gene disorders as well as sequencing of the entire foetal genome (Kitzman et al. 2012; Lench et al. 2013). As the technology becomes cheaper, it seems plausible that such detailed prenatal testing will be commonly used (Dondorp et al. 2015).

The test can be used as early as 9–10 weeks of gestation. Unlike invasive diagnostic testing such as amniocentesis, it poses no risk of miscarriage. The accuracy of NIPT is higher than previous forms of prenatal screening for aneuploidy. However, being a screening test, upon abnormal findings, diagnostic testing should be offered (Gregg et al. 2016). The test's features – its non-invasiveness and ability to provide early in pregnancy an abundance of genetic information – are changing the field of prenatal genetics (Dondorp et al. 2015; van Schendel et al. 2014).

1.1 The global debate on public funding for NIPT

It could be argued that there are merits to the user paying for NIPT, at least partially. For instance, it is claimed that charging money for NIPT will promote informed choice, as it will signal to women that the test is optional and will facilitate their deliberation on whether to take it up. However, as Bunnik et al. (2020) argue, evidence for such effect is lacking. Rather, they claim, the fact that the test is paid for out of pocket mainly disadvantages women of lower socioeconomic status, resulting in inequality of access and therefore harming claims to justice and reproductive autonomy.

In its position statement on NIPS, the *American College of Medical Genetics and Genomics* recommended informing "all pregnant women that NIPS is the most sensitive screening option for traditionally screened aneuploidies" (Gregg et al. 2016: 1059). When a high-performance test is offered, but only a certain group of users can afford it, there are ethical implications that should be addressed in policymaking. The inequity applies to both the uptake of the (better) test itself and the accessibility of subsequent publicly funded prenatal services at an earlier gestational age. Women who cannot afford NIPT are denied this better-performing test, and also denied earlier access to related services, such as genetic counselling and pregnancy termination, which has both physical and psychological implications (Vanstone et al. 2014). Implementing NIPT in the national healthcare system with public funding could therefore alleviate concerns about inequality of access.

1.2 Establishing the comparison between Germany in Israel

Past research has shown Israel and Germany to have opposing policies in several relevant fields, such as genetic screening, stem cell research, and preimplantation genetic diagnosis (Hashiloni-Dolev 2007; Raz et al. 2017;

Raz/Schicktanz 2016). In all these cases, Israeli policy is permissive, whereas German policy is more restrictive. Israelis are considered to enthusiastically embrace medical technologies (Prainsack/Firestine 2006), especially those in the field of reproduction. Accordingly, genetic screening programmes are well established, and less subject to social or professional controversies than elsewhere. The limited public debate in Israel is in striking contrast to the thriving social, legal, and ethical debate concerning reproductive genetic technologies in other countries, especially in Germany (Hashiloni-Dolev 2007).

These differences have been attributed to a unique mixture of sociocultural, religious, and political features. Israel's unique stance has been related to its pro-natalism, familism, Jewish heritage, and its views on the beginning of life (Hashiloni-Dolev 2007), its state of conflict with neighbouring countries, and the trauma of the Holocaust leading to an emphasis on survival and abled bodies (Chemke/Steinberg 1989; Prainsack/Firestine 2006). Consequently, ideas that restrict genetic testing and abortion in other countries, mostly disability rights and the rights of the foetus, are less influential (Hashiloni-Dolev 2007; Raz 2005), even among disability rights activists and parents of children with disability who do not oppose testing (Nov-Klaiman/Raz/Hashiloni-Dolev 2019; Raz 2004).

On the other side, German restrictions/caution have been attributed to the view of the foetus as a potential person with at least some individual rights (and requiring protection) (Heinemann/Honnefelder 2002), as well as to the salient presence of disability rights activists in the public discourse (Hashiloni-Dolev/Raz 2010; Raz 2005). A universalistic lesson of the Holocaust on the value of diversity and dignity has propelled criticism of reproductive genetics as a "new eugenics" (Braun 2005; Hashiloni-Dolev/Raz 2010; Raz/Schicktanz 2016). Motherhood itself is also understood differently. Whereas Israeli mothers see themselves as being responsible for preventing suffering and disability in their families (Nov-Klaiman/Raz/Hashiloni-Dolev 2019; Remennick 2006), German mothers are more expected to welcome all children regardless of their condition (Hashiloni-Dolev/Shkedi 2007), although this might be changing with the growing use of prenatal testing (Graumann 2014).

Based on the characteristics emerging from these studies, one might have expected NIPT to be rejected in Germany and adopted in Israel. However, the complex reality is not in line with the initial expectations.

1.3 Mapping out the regulatory framework

We consider three dimensions of the regulatory framework that are crucial for the application of NIPT: the existing provision of prenatal testing; legislation on genetic testing; and abortion laws. Residents of both countries are entitled to services covered by mandatory health insurance. Likewise, an assigned committee approves the inclusion of any technology in the national health insurance scheme. This is the *Health Basket Committee* on the Israeli side and the *Federal Joint Committee* (*Gemeinsamer Bundesausschuss – G-BA*) for Germany.

1.3.1 Prenatal genetic services

Israel

Since 1980 the Israeli *Ministry of Health* has run the "National program for the detection and the prevention of birth defects". This free-of-charge programme offers neonatal screening, prenatal testing, and population carrier screening for reproductive purposes. The prenatal component includes several ultrasound tests for all women, as well as biochemical blood tests that provide, among other information, risk assessments for DS. Women older than 35 or those referred by a medical geneticist due to increased risk are eligible for free amniocentesis (Zlotogora 2014). For every woman who undergoes an invasive test, due to her age or to abnormal findings in previous tests, a chromosomal microarray analysis (CMA) is performed free of charge. CMA, which is currently performed on samples taken in invasive procedures such as amniocentesis, is a high-resolution, whole-genome technique which detects submicroscopic deletions and duplications (Dugoff et al. 2016). In other words, currently, CMA covers a much broader spectrum of conditions than NIPT.

It is noteworthy that, unlike other countries in which a dramatic decrease in invasive testing has been reported since the introduction of NIPT (Hui/Bianchi 2017), such a trend has not been observed in Israel, according to A. Singer, MD, Head of the *Community Genetics Department* in the *Ministry of Health* (written communications, April 2020).

Germany

In the 1970s, prenatal services became an integral element of the *Motherhood Guidelines (Mutterschafts-Richtlinien)* (Kolleck/Sauter 2019). These binding rules set the prenatal care standards for the healthcare system. They include several basic examinations such as ultrasound for all pregnant women. Additional tests, e.g. invasive diagnostic testing, are subsidised if medically indicated. In a major difference from Israel, further tests like the First-Trimester Screening are not covered according to the guiding principles.

Moreover, unlike in Israel, the combination of invasive testing and CMA has never become routine in Germany and is not covered by mandatory health insurance (Müller-Egloff 2017). Instead, since 2004, the rates of invasive testing have decreased significantly (Kolleck/Sauter 2019). These data reveal a clear trend and priority towards avoiding invasive testing when possible.

1.3.2 Laws on genetic testing

Israel

In Israel, NIPT is subject to the *Genetic Information Law, 2000*, although this law does not explicitly mention prenatal genetic testing, except in relation to testing for kinship. The Israeli law does not explicitly regulate direct-to-consumer genetic testing (DTC-GT) either. This is particularly relevant for NIPT since the test is currently available only privately, with women being able to contact providers directly, without the involvement of a healthcare professional in the public system. DTC-GT, especially in the prenatal context, raises significant ethical and practical concerns, e.g. the quality of the information and counselling that patients receive, potentially affecting the process of informed consent and leading to patients misinterpreting test results (Allyse et al. 2013; Skirton 2015).

It could be inferred that pure DTC-GT is banned, as the law requires informed consent to be obtained, and explanations to be given by an authorised medical figure. However, without explicit clarification, the phrasing leaves room for bypassing the services of public health professionals and using only those provided by the marketing companies, with their inherent bias.

Germany

The German *Genetic Diagnosis Act* (*Gendiagnostikgesetz* 2009) contains a section on prenatal genetic examinations. It is updated when needed by the *Commission on Genetic Testing*, which includes experts as well as several representatives of patient and self-help organisations. The law aims to protect constitutional human dignity and the individual right of informational self-determination, either by protection against discrimination, or by sufficient information giving. This applies to pregnant women but also to the foetuses.

As in Israel, though not explicitly forbidden, pure DTC-GT does not match the required referral by a physician and comprehensive information and counselling. The German legislation emphasises women's right not to perform prenatal testing and not to know the associated findings.

1.3.3 Laws on abortion

The medical conditions that NIPT tests for are currently not treatable. Once one of these conditions has been detected, parents-to-be have two possibilities. They can either prepare themselves and their environment for a child with special needs or terminate the pregnancy. Such terminations are legally possible in both countries, but with several differences in their legislation and regulation.

Israel

Abortions are legal in Israel when performed according to the *Penal Law*, which specifies the circumstances in which a designated committee can authorise a termination request. These include, among other things, foetal handicap, as well as the physical and mental integrity of the woman (*Penal Law* of 1977: *Interruption of Pregnancy*). When legal, abortions are publicly funded.

The Israeli *Central Bureau of Statistics* collects and reports the yearly number of authorised abortions and specifies the numbers approved under each criterion, including those approved due to embryopathies.

Germany

Abortion law is part of the *German Criminal Code* (*Strafgesetzbuch* 1998), but is also regulated by the *Pregnancy Conflict Act* (*Schwangerschaftskonfliktgesetz* 1992), which determines the requirements for counselling. This expresses the constitutional tension between the mother's basic rights on the one hand, and the "unborn life's" dignity and basic right to life and bodily integrity on the other (WD 2017). Following the legislation of 1995, abortion was declared illegal, but is exempt from punishment until week 12 of the pregnancy, and after some obligatory counselling; but it is legal throughout a pregnancy if it results from a crime or endangers the physical or mental health of the mother. Only legal abortions are funded by the health insurance funds. Notably, the vast majority of abortions (96.1per cent in 2019) are officially illegal, but unpunished (Destatis 2020).

The former "embryopathic" (sometimes also called "eugenic") indication was dropped by the legislator in 1995 in order to clarify that a life with or without disability deserves the same protection. However, a child's disability can be interpreted as a threat to the physical or mental health of the mother and thereby serves as an indirect reason for a legal termination (WD 2017). The German abortion statistics do not specify the number of cases in which foetal anomaly was involved.

1.3.4 Findings from the framework comparison

Having reflected on the regulatory background of Israel and Germany, we can reconsider the question of health insurance coverage. The Israeli framework is characterised by more comprehensive provision of prenatal genetic testing, a lower level of regulation and restriction, and no specific friction between NIPT and the abortion law. Thus, it is in principle open towards an inclusion of this technology. The German framework presents significant reservations and conflicts with NIPT on the one hand, but on the other, NIPT fits into the German agenda of avoiding invasive testing (as indeed was the argument of the *G-BA*).

2. Discourses on implementation: the stakeholders involved and their positions

The implementation of NIPT involves various stakeholders, including medical professionals, policy bodies, advocacy groups, pregnant women, NIPT producers, and the media. Some of them markedly influence the related public discourse, while others are absent or less notable. In Israel, where there is traditionally less conflict between experts and the public, especially in the field of prenatal care, the process is mainly led by medical professionals and the policy body in charge, i.e. the *Health Basket Committee*. Other voices are hard to find. In contrast, the German discourse has provoked public statements by nearly all stakeholders, vital media reporting, and some related research. Thus, the difference between the discourses begins with the amount and range of easily accessible material. Our analysis focuses on medical professionals, policy bodies, and advocacy organisations.

Israel

NIPT has been marketed in Israel since 2013. The technology was submitted to the *Health Basket Committee* to be considered for public funding, in 2014 and 2019, and was rejected following evaluation in both cases. It is therefore not included in the current basket of health services. Since its introduction, only a few medical societies have addressed NIPT in their opinion papers to different extents. Critical reactions and public statements by advocacy organisations or others are rarely found, with the only statement by a disability advocacy group being supportive.

2.1 Medical associations

The *Israeli Society of Obstetrics and Gynecology*, in an opinion paper (ISOG 2018), refers to NIPT only in their list of tests that pregnant women should be informed of as part of routine follow-up.

Following a previous opinion paper by the *Israeli Society of Medical Genetics* (Michaelson-Cohen et al. 2014), in 2018 this organisation advanced its debate on the recommended use of NIPT. Since NIPT is better than the implemented biochemical screening at detecting the common chromosomal aneuploidies, they recommended using NIPT as a first-tier screening test for trisomies 13, 18 and 21.

It is noteworthy, however, that this society maintains that from a medical point of view, the preferred prenatal test in each pregnancy, including those with a priori low risk, is a diagnostic invasive test coupled with chromosomal microarray analysis (CMA), with its significantly broader scope compared to NIPT.

2.2 Policy body in charge

The *Health Basket Committee* in Israel is composed of representatives of the healthcare system (the *Ministry of Health*, health funds, hospitals), representatives of the *Ministry of Finance*, and representatives of the public (specialists in varied fields of medicine, as well as ethics, economy, social welfare, and others). This diverse composition, according to the *Ministry of Health*, aims to ensure that the decisions made by the committee take social perspectives into account along with the medical ones. In 2019 two scenarios of NIPT implementation were submitted for consideration for the 2020 Health Basket:

either for all pregnancies, or as a second-tier-test for high-risk pregnancies. In January 2020, the committee published its decisions. NIPT was rejected.

2.3 Advocacy organisations and additional stakeholders

In Israel, NIPT has not drawn much public attention or debate and is not discussed in parliament. The *Israeli National Council for Bioethics* has not addressed the issue either.

Moreover, since the introduction of the test into clinical use, no campaign against NIPT has been launched in Israel by disability advocates or by others. In fact, one of the DS advocacy organisations called the *Ministry of Health* as early as 2014 to make sure that NIPT would be affordable for all pregnant women (ATID 2014). They argued that this is important for parental autonomy. To support their claims, they noted that the costs of raising a disabled child, such as one with DS, are far higher than the costs of NIPT. They argued that Israeli society at large and family members alike carry the heavy burdens of supporting and financing these children for their entire lives.

Germany

The introduction of NIPT in Germany was pushed forward in 2012 by *LifeCodexx AG*, a private company that received public funding for the development of NIPT for the German market (Deutscher Bundestag 2015). In 2019, the *G-BA* concluded its assessment by adopting NIPT for trisomies 13, 18 and 21 in the public health insurance under certain conditions. Both the market introduction of NIPT and the involvement of the *G-BA* since 2014 activated numerous stakeholders, public protest, and media reporting (Kolleck/Sauter 2019). Advocates for persons with disabilities even denied the compatibility of NIPT with the German legal framework, but their view did not prevail.

2.4 Medical associations

In sharp contrast to Israel, many German medical organisations engaged in the debate and submitted comments to the *G-BA*, which published them in a collection (G-BA 2019a). This engagement may reflect the tradition of corporatism and self-governance of the German healthcare system, but also the controversial character of NIPT. A broad spectrum of positions was presented, ranging from calls for rejection to unrestricted coverage of NIPT. But most associations come down somewhere in between.

Several major associations welcomed the introduction of NIPT and its evaluation by the *G-BA*, including the *German Society of Gynecology and Obstetrics* (DGGG 2014), and the *German Society of Human Genetics* (GfH 2012). To them, NIPT – at least for trisomies – is not an ethical slippery slope but an advancement of prenatal testing that avoids the risks of invasive testing and should in principle be available to every woman. Both showed much support for a limited coverage, for women with an increased risk of trisomies (G-BA 2019a).

Other organisations representing prenatal-care specialists emphasised their concerns over the proper implementation of NIPT. They called for clear indications, without which, they warned, extensive and improper use could follow coverage (BVNP 2018; G-BA 2019a).

Others focused more on the possible social and psychological implications of NIPT. For instance, the *German Society of Psychosomatic Gynecology and Obstetrics* (DGPFG 2013) warned against discriminatory effects on people with disabilities, as well as putting greater pressure on women and delegitimising those who decline testing or choose to have a child with disability. Nonetheless, torn between these concerns and the arguments of risk avoidance and equal access, the organisation showed some acceptance of limited coverage, under careful implementation (G-BA 2019a).

2.5 Policy bodies in charge

Even before the market entry of NIPT, the *Commissioner for Matters relating to Persons with Disabilities* tried to prevent this step through a legal opinion stating its incompatibility with several laws (Gärditz 2012). The arguments presented became characteristic of the opposition to NIPT: Without available treatment, the test would be used as a tool for selection, and therefore carries a clear discriminatory message for people with disabilities. For similar reasons, the *Inclusion Council* considers NIPT to violate the *UN Convention on the Rights of Persons with Disabilities* (Staatliche Koordinierungsstelle 2013).

However, this view was not adopted by the *German government* (Deutscher Bundestag 2015) nor by the *German Ethics Council* (Deutscher Ethikrat 2013), which recommended a restricted use of NIPT for women with increased risk of a genetic condition but did not comment on public funding. The council also voiced concerns that the early applicability of NIPT might undermine the restrictions of the abortion laws, and recommended revising them.

Since 2015, a concerned inter-fractional group of parliamentarians has put NIPT on the agenda of the *German Bundestag* (Deutscher Bundestag 2015), and eventually promoted a parliamentary debate. The debate, held on 11 April 2019, presented a spectrum of positions (Deutscher Bundestag 2019; Foth 2021). Many deputies expressed their commitment to the values of dignity, diversity, and the struggle for inclusion of people with disabilities. Nonetheless, NIPT has often been acknowledged as a means to avoid invasive testing that should be equitably accessible to women at a higher risk for trisomies through public coverage.

The German counterpart to the Israeli *Health Basket Committee* is the *G-BA*. Its decision-making body is composed of neutral chairpersons, and representatives of the statutory health insurance funds and healthcare providers. In addition, patient representatives have the right to participate in its discussions.

In its decision of September 2019, the *G-BA* rejected a routinised use of NIPT in the sense of mass screening. Instead, it decided that NIPT could be funded in individual cases for pregnancies with particular risks or suspicious findings. According to the updated *Motherhood Guidelines* coverage is possible when it aims to avoid invasive testing and "is necessary to enable the pregnant woman to address her personal situation regarding the presence of a trisomy under medical supervision" (G-BA 2019b: 3). This is explained by the heavy burden a woman may feel if she might be expecting a child with a trisomy (G-BA 2019c: 4). The request of the patient representatives in the *G-BA* to withhold NIPT until week 12 of pregnancy, while abortions are easily accessible, was rejected.

Although the G-BA explained its decision in an additional statement (G-BA 2019c), it left many commentators unsure about its implications (Rehmann-Sutter/Schües 2020). To finalise the new provisions, however, the G-BA had to "translate" them into an easy-to-understand brochure for insurance fund members, attached to the *Guidelines*. This process required another round of consultations with several stakeholders. According to the brochure's final version, NIPT is covered for a pregnant woman "when other examinations have raised the suspicion of a trisomy, or she, together with her doctor, comes to the conclusion that the test is necessary in her personal situation" (G-BA 2021: 11). In this way, the decision introduces a strongly subjective component and could be widely interpreted in practice.

The regulation came into force in 2022. There was no objection from the legislator, the German Bundestag, although the public debate is not entirely settled.

2.6 Advocacy organisations and additional stakeholders

The discourse on the implementation of NIPT has largely been shaped by civil society involvement and augmented in the media. Some civil society stakeholders that have long been critical of the growth of prenatal genetic testing opposed the market introduction of the test from the outset. However, their opposition has diverse backgrounds (Braun/Könninger 2018).

Some criticism is inspired by Christian values and is often combined with objection to abortion. Thus, several charitable organisations, representatives of the *Roman Catholic Church*, and groups which engage in the protection of (unborn) life opposed the implementation of NIPT (CDL 2012; Zimmermann 2019). The *Protestant Church in Germany*, however, supported limited coverage (EKD 2018).

Another criticism is stressed by some disability advocacy groups and networks with a strong feminist commitment, such as the *Network against Selection by Prenatal Diagnosis* (G-BA 2019a; Netzwerk gegen Selektion durch Pränataldiagnostik/Gen-Ethisches Netzwerk/BioSkop 2014). They believe that NIPT strengthens eugenic practices and the medicalisation and commodification of pregnancies; it undermines the wellbeing and self-determination of pregnant women; and runs counter to the goal of an inclusive society. They claim that prenatal testing should be supported only when it enables a medical treatment. Thus, they also demand a revision of the existing framework of genetic testing, insofar as it can be criticised for similar reasons. From their point of view, NIPT is a major step in an expansive dynamic of genetic testing that is not sufficiently reflected on, discussed, or legitimised by the public or by parliament.

However, the introduction of NIPT received support from other civil organisations, most prominently from *pro familia*, which advocates for sexual and reproductive health and rights. They supported coverage of NIPT for so-called risk pregnancies, stressing the reproductive rights of prospective parents, which should guarantee their access to the means for informed decision-making, but also a right not to know (pro familia Bundesverband 2019).

3. Discussing key themes

So far, we have presented the regulatory and legislative circumstances in which NIPT has been introduced into clinical practice in Germany and Israel, and the discourse of different stakeholders around the use of this technology and its implementation using public funding. While we can learn much from examining the actors involved in medical policymaking, we can equally learn from examining which actors' voices are not heard. Indeed, major differences can be found not only between the regulatory frameworks of Germany and Israel, but also in their discourses about NIPT: their extent, the type of participating actors, and their views.

Several key themes have emerged from the comparison: the balancing of parental autonomy and embryo protection; prevention vs. support; and the extent of public deliberation. In these regards, Germany and Israel approach NIPT from different directions and are concerned with different implications, thus demonstrating the interplay between cultural norms and technology in the shaping of concrete health policies.

On top of parental autonomy, the Israeli framework seems to enhance prevention of disability. This is reflected most prominently in the name of the "National program for the detection and the prevention of birth defects" and the fact that embryopathy is one of the explicit criteria in Israel's abortion law.

However, some changes over recent years might also be interpreted as hints of a growing awareness of disability concerns. Israel ratified the *UN Convention on the Rights of Persons with Disabilities* in 2012. According to Mor (2014), rising disability advocacy had an effect on the Israeli jurisdiction when they barred "wrongful life" lawsuits in 2012. Moreover, with a push from Israeli DS advocacy organisations, Israel's social security organisation changed its policy in 2018 and now gives a "disabled child allowance" to all parents of children with DS at a rate of 100 per cent, at least up to the age of 6. Until 2018, the rate had been determined by an assigned medical committee on a case-by-case basis. This move shifts the "prevention vs. support" balance towards more support. However, both this move and the abolition of "wrongful life" lawsuits, although driven by disability advocacy, do not necessarily reflect a shift toward an agenda of opposing preventive measures in the form of prenatal testing. Indeed, the critical view coming from disability advocacy is absent from the discourse on NIPT. These moves can therefore be seen as another manifestation of the twofold view of disability: the aspiration to prevent it on the one hand, and the sense of duty to support those already born disabled on the other, in line with Raz (2004) and Nov-Klaiman, Raz and Hashiloni-Dolev (2019).

Cost-effectiveness calculations are at the heart of the "prevention vs. support" balance and are a morally sensitive issue (Kibel/Vanstone 2017; Ravitsky 2017). The Israeli case is unique. Even a DS advocacy organisation used the high costs of raising a disabled child, which fall on family members and society at large, as an argument in favour of subsidising NIPT. In Germany, however, even among those who favour public funding of NIPT, reference is not made to the societal costs of supporting affected children. Such economic considerations would be perceived by the German public as implying that a person's value is based on their economic contribution to society, which is a violation of the dignity of individuals with disabilities and would pave the way for discrimination against them. Similarly, an official aim of preventing disability would be perceived as discriminatory, and contradictory to the political agenda of inclusion, which has been pushed forward since Germany's signing of the *UN Convention on the Rights of Persons with Disabilities* in 2007. Indeed, some German proponents of the test use the opposite argument and claim that prospective parents can benefit from the test in terms of preparedness rather than prevention.

The German legislative and regulatory frameworks reflect a stronger emphasis on further groups beyond the women who are the direct consumers of prenatal testing, namely individuals with disabilities (protection against discrimination) and foetuses (their right to live). In Israel, however, foetuses have no legal rights (Hashiloni-Dolev/Weiner 2008), and therefore the implications of genetic testing are not viewed from the angle of their protection. Instead, the focus in Israel is more on the personal implications to the woman (her right to reproductive autonomy). However, the sheer existence of a comprehensive prenatal testing programme with public funding, coupled with the recommendation from professional organisations to test and supported with a permissive abortion law, implies a view that society benefits from prevention as well.

In Israel, NIPT has raised only limited deliberation and hardly any public debate. Engagement in the process is mainly professional and focuses on the test's technical performance. It does not refer to the potentially negative implications of the test, such as the effects on people with disabilities, or connect such large-scale screening of the population with eugenics. Lay people, religious representatives, political parties, or other groups did not spur debate on the test, leaving the process to be led by medical professionals.

It would therefore have been reasonable to expect Israel to adopt the test. However, its rejection is in fact not counter to the known Israeli logic. In the *Health Basket Committee*, NIPT competed with other technologies from diverse fields of medicine over a small and rigid budget. NIPT would thus come at the expense of other, non-related, medical technologies. Moreover, it was proposed to replace or to be integrated within a well-established, publicly funded prenatal screening programme. In other words, the gain from including NIPT in the Israeli *Health Basket* would not be as great as in a country that has not implemented a broad public screening programme, such as Germany. Furthermore, in a country that highlights maximal detection, the inclusion of NIPT with its relatively limited scope would be a step in the wrong direction. As Israeli professionals argue, and as common practice suggests, invasive testing combined with CMA is the goal, rather than NIPT. Therefore, the rejection of NIPT is actually not surprising.

The established screening programme could also explain the lack of public controversy over the test. From a public point of view, NIPT might not be perceived as big news or represent a new approach in principle, but rather a technical improvement to an existing system (Lôwy 2020; van Schendel et al. 2017).

By contrast, the introduction of NIPT into clinical practice and its assessment for public funding has prompted much debate in Germany. This debate involves various actors, including health professionals, religious groups, political parties, disability advocacy groups, and the media, and covers a wide spectrum of views. The opposition to NIPT can be described as a mixed group with some overlapping criticisms and a strong basis in civil society as well as some representation in public institutions and medical professions. Their opposition is twofold. On the substantive level, they consider NIPT a questionable tool in terms of its meaning for women's health, the integrity of pregnancy, the foetus, persons with disabilities, and society in general. The criticism is reinforced by an expected expansion in testing as a result of the decision by the *G-BA*, and by special features of the German abortion law, which tolerates abortions without a medical indication up to 12 weeks. Since NIPT enables earlier testing, the legal and technical barriers to selective abortion due to foetal anomaly are reduced (Heinrichs/Spranger/Tambornino 2012). On the procedural level, the *G-BA* is repeatedly criticised for its limited scope of investigation. It is important to recognise that the opposition is not just directed against the addition of NIPT, but is also an attempt to revise significant aspects of prenatal care, including the rules relating to genetic testing, their interplay with abortion, and the governance of the field.

This is one major difference between the countries' discourses on NIPT. While in Israel it is limited to an expert discourse on a specific adjustment in the field of prenatal testing, in Germany it extends to a societal discourse on pivotal rules governing prenatal testing, including matters of abortion. While the Israeli assessment of NIPT is a matter of course within a rarely questioned scheme of prenatal testing and its governance, the German discourse on NIPT questions the pre-existing prenatal care regime and functions as a matter of deep controversy.

The *G-BA*'s decision on the inclusion of NIPT under public health insurance was big news. Non-invasive tests for trisomies are explicitly included within the public services for the first time in certain, somewhat flexible cases, which may reflect a shift by the German policy toward other Western countries' policies, including the Israeli one, which encourage prenatal testing.

The *G-BA's* explicit goal is not to screen (out) as many pregnancies as possible, but to avoid invasive testing. However, under the rules adopted, it leaves much room for interpretation, as criticised by some medical professionals. They have stated potential problems and predicted high uptake rates, which seems to contradict the initial idea of a restricted inclusion of NIPT and which could generate high costs for the healthcare funds (G-BA 2019a; Scharf et al. 2019). Further German stakeholders feared that this might undermine the aim of protecting women's right not to know and push towards the prevention of disability. Since the *G-BA* did not comply, it could be argued that the flexible phrasing is deliberate. Such phrasing could serve to reconcile both ends of the spectrum: those who saw Germany lagging behind in the coverage of prenatal testing, and those who oppose the routinisation of testing.

4. Conclusion

Seemingly counterintuitive decisions were reached both in Israel and in Germany. Given the differences between the countries – based on previous studies and in terms of the actors involved and the legal and regulatory background – an opposite scenario, in which NIPT is included in the Israeli *Health Basket* but rejected from the German health insurance scheme, seemed realistic.

Cultural norms have arguably played a crucial role in these societies' attitudes thus far toward reproductive technologies that have led Israel to adopt them eagerly and Germany to lag behind. Returning to the question of whether convergence in policies occurs over time, we conclude that the answer is not straightforward. The two countries seem to move toward one another in some regards, but not in others. Israel moves toward Germany in its growing awareness of disability advocacy in some policymaking. However, in the realm of policy related to reproductive technologies, the influence of disability critique is not apparent and rather maintains Israel's embracing approach. At the same time, Germany is moving closer to Israel in its growing coverage of genetic services, which have so far been lagging behind. By doing so, Germany is moving closer to other European countries as well, e.g. the Netherlands, in which the coverage of prenatal testing, including NIPT, is more comprehensive (Ravitsky et al. 2021). This change in German policy is justified by the wellbeing of pregnant women and is not, as in the Israeli setting, also associated with preventing disability or prioritising large-scale testing. Thus, we could say that the convergence observed remains ambiguous and may even serve to highlight the differences between Germany and Israel. The German adoption of the technology, justified by avoiding the risk of miscarriage and safeguarding women's health, might have unintended consequences. Time will tell how NIPT is implemented and used by women, and what its long-term effects are.

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