5. NIPT in Germany
Moral Concerns and Consumer Choice

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Policies and practices of prenatal diagnosis (PND) in Germany are characterised by an ambivalence of persistent public concern on the one hand and increasing routinisation on the other.[1] We will argue in this chapter that this ambivalence is in fact a pervasive feature of the (West-) German prenatal diagnosis dispositif (Löwy 2014; 2017).[2]

In German debates on prenatal testing, the legacy of Nazi eugenics and the concept of "life unworthy of life" have certainly played a role and have given rise to a certain sensitivity in politics and civil society towards eugenics and selection practices. Yet whether or how this sensitivity has actually shaped the ways in which PND is organised, regulated, diffused and performed, is a more complicated question. This ambivalence, of concern and unease on the one hand and moves towards normalisation and routinisation on the other, has also characterised the stance towards non-invasive prenatal testing (NIPT) in

1 A note on terminology: The term "prenatal diagnosis" in Germany commonly refers to examinations performed on the pregnant woman or the embryo or foetus in utero for the purpose of establishing foetal disorders, disease or malformation (Kolleck and Sauter 2019: 31; Wolf and Graumann 2016: 14). Conceptually, it forms part of antenatal care, but this as a whole is broader and also encompasses medical surveillance and review of the woman's health and wellbeing. NIPT refers to a low-threshold procedure based on the analysis of cell-free foetal DNA circulating in the woman's blood that serves to establish the probability of foetal genetic aberrations. Strictly speaking, NIPT and some other procedures are not diagnostic since they actually serve to establish a probability, even though a rather precise one. Abnormal findings must still usually be confirmed by invasive diagnostics (Kolleck and Sauter 2019: 81).

2 The prenatal diagnosis dispositif, as Ilana Löwy frames it, is the "heterogeneous assemblage of instruments and techniques, professional practices, and institutional and legal arrangements that, taken together, made it possible to diagnose fetal anomalies" (Löwy 2017: 2).

Germany over the past ten years (Braun and Könninger 2018). Interestingly, in some respects, the German policy approach to NIPT seems to be complementary to that taken in Israel: in Germany, public concern is comparatively strong and vocal but the costs of the test for the most common trisomies 13, 18 and 21 will be covered by the statutory health insurances without setting a specific risk threshold as access criterion. In Israel, in turn, NIPT is not in the national Basket of Health Service and accordingly not part of the universal coverage, but nevertheless partly covered by health funds; however, it has not been a matter of public controversy (Raz et al. 2021). On the contrary, PND is rather seen as a moral duty and more a collective responsibility than a moral concern, as Aviad Raz explains in this volume. In Germany, in contrast, it would be seen as inappropriate to say that NIPT, or any PND, is good because it helps to reduce the prevalence of children with Down syndrome; that would probably cause immediate public outrage. The possibility of using NIPT routinely to screen for Down syndrome is officially refuted. Yet, we will argue, the policy approach that has been taken up to now lacks any effective provisions to prevent exactly this situation.

In this chapter, we explore the controversy around NIPT against the background of previous controversies on abortion and preimplantation genetic diagnosis (PGD).[3] We argue that we see a recurring pattern, which we have termed the "No, but…" pattern. It is characterised on the one hand by a widespread moral unease about reproductive practices that, in effect, involve selective decisions about which children should be born and which should not, and on the other by a political disinclination to take binding decisions to effectively curb them. Since the 1970s, the traditional way of accommodating these countervailing tendencies has been to confirm the morally problematic character of such selective choices *in principle* while nevertheless allowing them under certain circumstances, which – theoretically – are defined as being exceptional and rare (Braun 2016). However, there is no general rule to determine whether such exceptional circumstances are present or not; thus, it becomes a matter of case-by-case decision-making or, as Dominique Memmi (2003) puts is, of delegated biopolitics. In practice, the decision is left to the

3 We are mostly drawing on policy document analysis and interviews of experts and policy actors in 2015–2017, supplemented by a review of recent events concerning the issue of reimbursement for NIPT. The empirical research for this article was partly funded by the German Federal Minister for Education and Research, funding number 16I1676.

individual. Thus, the responsibility for the diffusion of reproductive selection practices lies with the individual. Policy actors usually see the need to take fundamental social and ethical implications of such practices into account, but resort to the above-mentioned "No, but…" model to deal with the issue (Braun and Könninger 2018). To understand the structure of this policy pattern better, we will first take a look back at the so-called abortion compromise and the legal regulation of PGD. Subsequently, we will briefly recapitulate the controversy about PND in Germany and then show how the "No, but…" pattern plays out in the case of NIPT.

"No, but…": The Abortion Compromise

In 1976, the German Constitutional Court determined that the liberalisation of abortion law that the German *Bundestag* had passed in 1974 was unconstitutional on the grounds that it violated the state's duty to protect human dignity as enshrined in Art.1 of the German Basic Law. Where human life exists, the Court ruled, it enjoys human dignity (Bundesverfassungsgericht 1975).[4] The development of human life was a continuous process that started with gestation at the latest; it was therefore unconstitutional to suspend the right to life and human dignity for a certain period of life, even if this period was the first trimester of pregnancy. However, the Court also established that under certain conditions, namely a threat to the woman's health (medical indication), birth defects on the part of the child (embryopathic indication), rape (criminal indication), or a general situation of need (social indication), the foetus' rights *could* be balanced against those of the woman. The Court thus established a general norm according to which the foetus' right to life would – normally – outrank the woman's right to self-determination. Simultaneously it established a list of exceptions for which this norm would not apply and the foetus' right to life would *not* outrank the woman's right to self-determination. The "malformed" foetus, as it was termed, thus constituted a case of exception that would suspend its entitlement to life and human dignity. The right to the protection of human dignity and right to life – the logical implication of the ruling – would not apply to foetuses expected to have a "defect"; the legal status of the presumably disabled foetus differed from that of the "normal" one. As a consequence,

4 An English translation is available at http://groups.csail.mit.edu/mac/users/rauch/nvp/german/german_abortion_decision2.html (accessed 31 August 2021).

the disabled foetus' rights became a matter of case-by-case decision-making. Note that the rationale for allowing abortions under certain circumstances was *not* based on a woman's fundamental right to bodily self-determination, but on a rule-and-exception thinking, a "No-but" figure that seeks to uphold strong normative principles grounded in a universalist deontological ethics but nevertheless allows for decision-making on the question of which children should be born and which not. This type of reasoning would eventually recur both in the legal regulation of pre-implantation diagnosis and in the approach towards NIPT.

Consequently, the *Bundestag* complied with the Court's instructions and passed an abortion law in 1976 that banned abortion *in principle*, but allowed it in cases of a threat to the woman's health, rape, a general situation of need, or "birth defects" of the child.

After German unification, a new law was passed in 1992 that, again, would legalise abortion in the first trimester of pregnancy. Again, the Constitutional Court ruled that it was unconstitutional and prescribed that abortion remain illegal – in principle (Bundesverfassungsgericht 1992). In response, the *Bundestag* passed a new law in 1995 stipulating that first-trimester abortions remain technically illegal, except in cases of rape or a threat to the woman's health, but they are not punishable if the woman has undergone proper counselling (Deutscher Bundestag 1995). In case of a criminological (rape) or a medical indication, abortion is not illegal and not punishable.

This law is still in place today. Thus, technically, it is based on the norm-and-exception or the "No, but…" model, except that the person making the decision is now the individual woman. Up to twelve weeks of gestation, it is she who determines whether she is in a situation of exceptional distress that cannot be averted in any other way than by terminating the pregnancy. The presumably disabled foetus, however, still constitutes a case of exception. The situation has also changed due to another significant change in the law: in 1995, the Parliament also decided to abandon the embryopathic indication in response to pressure from disability rights groups, who argued that it discriminated against people with disabilities (Deutscher Bundestag 1995). From a disability rights perspective, the decision backfired. *De jure* foetal abnormalities no longer constitute a case of exception that justifies an abortion; in practice, however, it is the individual woman who determines that the disabled foetus poses a serious threat to *her* health so that she needs an abortion. Hence, the medical indication has *de facto* substituted the former embryopathic indication (Nationaler Ethikrat 2003: 63). However, since the 22-week time limit for medi-

cal abortions was also abandoned, there is as a result *no* time limit on aborting a presumably disabled foetus. Hence, we see a policy that was motivated by moral concerns about selective abortion decisions but in effect individualised them.

"No, but…": The Legal Regulation of Pre-Implantation Genetic Diagnosis

A similar compromise was established for the issue of PGD. After longstanding, controversial public debate that peaked around the years 1999 to 2002 and again in 2010–2011, the *Bundestag* finally passed a law on PGD, the 2011 Pre-implantation Genetic Diagnosis Act (Bundesgesetzblatt 2011).[5] The debate had previously revolved around issues of a new eugenics, the status of the human embryo, the lessons learnt from the Nazi past, the social implications of PGD for women and people with disabilities, versus the desire of couples with an increased probability of having a child with a certain genetically related disease to have a child "of their own" not affected by the disease. The PGD Act inserted a new paragraph into the existing Embryo Protection Act that would allow PGD under certain conditions. The new paragraph stipulates, first, that performing PGD is illegal and can be punished with imprisonment of up to one year. Next, it stipulates that performing PGD is *not* illegal in two exceptional cases: if there is reason to assume that a couple has a "high risk" of having a child with a "serious hereditary disease", or if PGD is performed in order to establish whether the embryo is affected by "serious damage" that with "high probability" will cause a miscarriage or stillbirth. Neither the Act nor the amendments pertaining to it, however, define the terms "serious", "high risk" or "high probability". Instead, it postulates that demands to perform PGD shall be submitted to newly founded ethics committees at state level who then determine in case-by-case decisions whether a risk is "high" and the damage is "serious". In more than 80 per cent of cases, a request is approved (Albrecht and Grüber 2019: 88–89). Thus, the decision does not lie directly with the applicants but, in the vast majority of cases, their individual demands are approved.

At the same time, the Embryo Protection Act continued to ban the use of human embryos for any purpose other than its own preservation (Bundesministerium für Justiz und Verbraucherschutz 1990). PGD means that more em-

5 *Gesetz zur Regelung der Präimplantationsdiagnostik (PräimpG)*, hereafter PGD Act.

bryos are generated than will be implanted, so inevitably, some embryos will be discarded because genetic anomalies are detected, and this inscribes a contradiction into the law; it bans the destruction of human embryos in principle but allows it in case of genetic disease or damage.

This tension between moral unease about selective practices and the disinclination to take binding decisions to curb them also comes into play in the controversy about PND and NIPT in Germany, as we will argue below.

The Prenatal Diagnosis Dispositif in Germany

The prenatal diagnosis dispositif, as Ilana Löwy (2014; 2017) terms it, formed in the late 1960s and early 1970s in the context of intersecting developments in society, medicine and law. Formative events were the emergence of amniocentesis and obstetrical ultrasound, the decriminalisation of abortion, the shift in many countries from legislation that would allow involuntary sterilisation on eugenic grounds to a general legalisation of sterilisation on demand, based on individual decision-making, and the framing of Down syndrome as a major strain on public resources. In Germany, amniocentesis was first carried out in 1970. From 1976 onwards, PND was included in the catalogue of antenatal care services (*Mutterschaftsrichtlinien*) and covered by the statutory health insurances (SHI) in cases of so-called pregnancies at risk.[6] The same year, a revision of the Criminal Code allowed for abortion up to 22 weeks of gestation in the case of foetal birth defects, thus opening the way to having an abortion following the result of an amniocentesis. Subsequently, the number of amniocenteses performed increased sharply (Nippert 1999: 63; 2001: 294). In the 1980s and 1990s additional methods of prenatal testing were introduced, such as regular ultrasound examinations in 1979, the "triple test" in 1988, nuchal translucency (NT) measurement in 1996, and in 1999, the first trimester screening test (ETS), which combines NT measurement with analysis of certain markers in the maternal blood to detect trisomies 21, 13 or 18 (Netzwerk gegen Selektion durch Pränataldiagnostik 2002). Today, antenatal care regularly includes three ultrasound examinations, covered by the SHI. If there is an increased probability of

6 "Pregnancy at risk" is defined as a pregnancy in which there is reason to anticipate an increased risk to the life and health of the mother or child based on anamnesis or findings obtained (Kolleck and Sauter 2019: 25).

genetic aberration or anomaly, the SHI will also cover an amniocentesis, chorionic villus sampling (CVS), ETS or additional ultrasound examinations. In the absence of increased "risks", ETS is offered as a private service.[7]

Prenatal testing has been a controversial issue in Germany since the 1980s (Achtelik 2015). Criticism and concern are not limited to genetic or invasive testing methods but refer to the purpose of selectively identifying foetuses that are likely to be born with certain impairments or undesired variations from standards of health and normality. In the absence of therapeutic treatment options, critics argue, PND *de facto* operates as a selection technology, serving to decide who should be born and who should not. Criticism comes from pro-life actors, disabilities rights organisations such as the *Bundesvereinigung Lebenshilfe* or the *Aktion Mensch*, and feminists who are in favour of the right to abortion but nevertheless concerned about prenatal selection. One of the most outspoken and longstanding organisations problematising PND, the Network against Selection through Prenatal Diagnosis (*Netzwerk gegen Selektion durch Pränataldiagnostik*), takes a decisively anti-eugenic *and* feminist stance.

The motives of this rather unusual alliance are diverse and overlap only partly. They overlap mainly regarding their concerns about the reinforcement of ableism in society, and otherwise range from anti-abortion attitudes to concerns about an increasing focus on the foetus and its features in prenatal care rather than on the woman and her needs, concerns about social pressures on women to produce healthy and "valuable" children, to a more fundamental, anti-capitalist stance against a lack of solidarity in society and increasing norms of productivity and fitness imposed on individuals, a trend towards further dismantling of the welfare state and shifting responsibility for health, education and wellbeing onto the individual instead.

All these issues have resurfaced in recent discussions on NIPT. In addition, there is increased concern that, due to its low-threshold nature, NIPT might become standard practice in all pregnancies. Furthermore, it is likely to yield significantly more information about the foetus than conventional methods and thereby produce an information overload that cannot possibly be managed by practitioners, genetic counsellors, or pregnant women (de Jong et al. 2010: 275; Schmitz 2016).

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7 For practices and discussions of prenatal testing in Germany, see Baldus (2006); Waldschmidt (2006); Bundeszentrale für gesundheitliche Aufklärung (2010); Bundesarbeitsgemeinschaft der Freien Wohlfahrtspflege e.V. (2013); Achtelik (2015); Wolff and Graumann (2016).

NIPT: An unsolvable dilemma?

NIPT was introduced in Germany in 2012 and has remained controversial since. At present, it is available to detect trisomies 13, 18 and 21, some sex chromosome aberrations such as Triple-X syndrome and Klinefelter syndrome, some microdeletions such as Cri du chat syndrome, and for foetal sex determination[8] (Kolleck and Sauter 2019: 59; Stumm and Schröer 2018). Data on the uptake of NIPT are hard to obtain since there are no publicly available statistics on the matter. According to LifeCodexx, the most prominent German test provider, 80.000 PraenaTests were performed in 2017, half of them on pregnant women in Germany – equivalent to one in 10.000 pregnancies – and the number of gynaecological clinics performing NIPT increased from 70 in 2013 to over 3.000 in 2018 (Kolleck and Sauter 2019: 145).[9]

Conflicts erupted around market approval, public funding, and most of all around the issue of reimbursement by the SHIs. What sparked these conflicts and what was at stake?

A central issue of contention was the question whether NIPT would lead to further normalisation and routinisation of selective abortions and thereby indirectly to reinforcing negative attitudes in society against people living with disabilities. When LifeCodexx announced the upcoming release of its PraenaTest in 2011, a series of articles in the print media discussed concerns about a trend towards the tentative pregnancy (Katz Rothman 1986), "eugenics from below", and an increasing number of abortions of children with Down syndrome.[10] A legal opinion commissioned by the Federal Government Commissioner for Matters Relating to Persons with Disabilities (Beauftragter der Bun-

8 Technically, however, it is illegal in Germany to reveal the sex of the child during the first twelve weeks of gestation.

9 The diffusion of NIPT might further a development that has been occurring for some two decades now: the increased use of early-stage non-invasive testing and a concurrent decline in invasive testing (Kolleck und Sauter 2019: 44). For Bernhard Wieser (2017: 62–63) this indicates that instead of one dramatic testing event, we typically see a testing cascade that starts with low-level, non-invasive tests, such as ultrasound and/or ETS, early in the pregnancy and proceeds to amniocenteses or CVS if the results are anomalous. Some scholars, however, expect that low-threshold NIPT might also lead to more tests and consequently more positive results that need be confirmed through invasive methods (Dondorp et al. 2015).

10 Articles appeared in *Die Zeit*, *die Tageszeitung* (taz), *Süddeutsche Zeitung*, *Frankfurter Rundschau*, *Frankfurter Allgemeine Zeitung*, *Spiegel online* and several regional papers.

desregierung 2012) argued that prenatal testing for non-treatable conditions such as trisomy 21 was incompatible with the UN Convention on the Rights of Persons with Disabilities. Article 8 of the Convention stipulates that governments have a duty to "combat stereotypes, prejudices and harmful practices relating to persons with disabilities" (UN CRPD Art.8 1(b)). In addition, the opinion held, it was incompatible with the German Genetic Diagnosis Act, which allows prenatal genetic testing for medical purposes only. In the absence of therapeutic treatment options, the opinion argues, testing cannot and does not serve a medical purpose. LifeCodex in return commissioned another legal opinion arguing that the meaning of "medical purpose" should not be restricted to "therapeutic purpose" (Hufen 2013).

Nevertheless, the PraenaTest received approval from the authority in charge, the Regional Council in Freiburg in the state of Baden-Württemberg, who evaluated it in terms of safety and efficacy according to the Medical Devices Law (*Medizinproduktegesetz*), not in terms of ethical or social implications (aerzteblatt.de 2012). In that context, the Premier of Baden-Württemberg at the time, Winfried Kretschmann (Greens), set the tone for the developments to follow by framing NIPT as a matter of individual rather than political responsibility:

> Ultimately, the question is "abortion yes or no". […] These are very rare cases of a virtually unsolvable dilemmas and moral problems the state cannot solve. This question of conscience […] has to be left to the woman concerned (dpa 2012).[11]

In the course of this controversy, it became known that LifeCodexx had previously received government funding to develop the test. Critics argued that this funding *was*, after all, a political decision, for which the government was accountable. LifeCodexx had been granted some 300,000 euros from the Federal Ministry for Research and Education for NIPT development (Bahnsen 2011) – a fact that caused considerable outrage, particularly among disability rights organisations (Deutsches Down-Syndrom InfoCenter 2011; KIDS Hamburg 2012; Lebenshilfe 2011; Bündnis zum Welt-Down-Syndrom-Tag 2012; Netzwerk gegen Selektion durch Pränataldiagnostik 2012). Later, in the course of an inquiry by an interfactional group of parliamentarians in the *Bundestag*, it turned out that the government had provided further funding of some 500.000 euros to develop an NIPT for the early detection of trisomy 21. The

11 All translations from German to English by the authors.

group of MPs demanded to know precisely how much money the government had allocated to NIPT development and on what grounds. They also asked explicitly what, in the government's view, the medical purpose of the test was (Deutscher Bundestag 2015: 5, 10). The government, however, never really addressed this question. In their response, the government merely conceded that "[m]edical progress constantly poses fundamental ethical questions. This holds particularly true for the possibilities of prenatal and genetic diagnosis" (Deutscher Bundestag 2015: 3).

They did not, however, specify *what* questions these were or in what sense NIPT, in their view, was a case of medical progress. They merely proclaimed *that* fundamental issues existed that should be addressed, but they did not address them. In that sense, the response again exemplifies the ambivalence that characterises the political take on NIPT in Germany in general; a lingering sense of moral unease regarding practices of detecting and aborting disabled foetuses, and at the same time a refusal to renounce these practices.

NIPT: Serving a Medical Purpose?

The question of whether NIPT serves a medical purpose has remained a matter of contention. Critics argue that it does not serve a medical purpose, since currently it cannot open up any therapeutic options for the foetus. An organisation for people living with Down syndrome argued that it would instead reinforce the idea "of allowing socially desirable, well-standardised life only" (Deutsches Down-Syndrom InfoCenter 2011). From this perspective, the government had effectively funded the development of selection technology. Proponents, in contrast, contend that NIPT will reduce the number of invasive tests performed and thus the number of test-induced miscarriages, which in their view counts as a medical purpose – this was also the view of the Federal Government at the time (quoted in Deutscher Bundestag 2015: 4). Therefore, some proponents argue, it should be made available to all pregnant women (e.g. pro familia Baden-Württemberg 2012). This line of reasoning was eventually adopted by the Joint Federal Committee, the G-BA (*Gemeinsamer Bundesausschuss*), the body that decides which medical treatments, pharmaceuticals and medical devices are covered by statutory health insurance in Germany. It establishes a method's or a device's diagnostic and therapeutic usefulness, its cost-effectiveness and its medical necessity. In 2019, the G-BA established that NIPT for trisomies 13, 18 and 21 should be included in the catalogue of services

covered by the SHI. This was preceded in 2013 by LifeCodexx applying to the G-BA to include NIPT in the so-called trial procedure so that the test could become an SHI benefit, which was accepted in 2014 (Gemeinsamer Bundesausschuss 2014). The implementation of the decision in 2019, however, was contingent upon the existence of "patient information", which was finally presented to the public in August 2021. Provided that the Federal Minster of Health does not reject the decision from a legal point of view, reimbursement can start in early 2022 (Gemeinsamer Bundesausschuss 2021). We will come back to this point.

In Germany, some 90 per cent of the population are covered by statutory health insurance funds. These are not direct state bodies but self-governing entities in the corporatist tradition. The underlying idea is that the members together form a "community of solidarity" (*Solidargemeinschaft*), the purpose of which is to guarantee that every individual member will receive the medical treatments, services and benefits they need, regardless of income or social status. This is called the solidarity principle. The emphasis, however, is on *medical* treatments and *medically* necessary applications; the community of solidarity is not obliged to provide just any goods or services members need or desire; it is explicitly not committed to reimbursing the cost of lifestyle products. Accordingly, the G-BA is not in charge of assessing these. In practice, some health insurers nevertheless offer reimbursement for NIPT to their members on a goodwill basis (Krankenkasseninfo.de, n.d.).

The question of coverage by the SHIs, therefore, has important practical and symbolic implications. Many experts and policy actors we interviewed in our empirical study told us they expected the usage of NIPT to increase dramatically once it was covered. Furthermore, many argued that coverage would send a strong symbolic message to society that detecting foetuses with trisomy 21 or other chromosomal aberrations was a perfectly normal and acceptable thing to do, and therefore supported by the *Solidargemeinschaft*. The decision in favour of reimbursement would be a signal to pregnant woman to use NIPT. In this vein, for instance, the leader of a large self-help organisation for people with learning difficulties told us:

> Well, what I consider the main issue is that it may induce an attitude in society that it is a matter of course, that it is completely normal […] to do the test for Down syndrome, that it completely goes without saying that you don't give birth to a child with Down syndrome. […] That there is such a test is a signal to people with Down syndrome.

Another interviewee, a pregnancy counsellor, expected that cost coverage would lead not only to routine screening for Down syndrome but moreover to a whole new range of tests to follow:

> However, this is about something else: Do we really want to test our offspring for all disabilities that can possibly be discovered […] is this what we want? Since this is what is at stake.

Therefore, we contend, the question of whether or not NIPT serves a medical purpose would fall squarely within the purview of this panel. Yet they never addressed this issue directly, but avoided it.

After LifeCodexx submitted the application to the G-BA in 2013, the committee accepted it and launched an assessment procedure. By doing so, the G-BA implicitly stipulated that NIPT would count as a medical method serving a medical purpose; if it had found it would not serve a medical purpose, the matter would not fall within its remit. The decision met with vocal criticism from disability rights groups, pro-life actors, and feminist and anti-eugenic critics of PND. An alliance of civil society organisations and parliamentarians issued position papers, statements and open letters, voicing concern that providing the test for free would pave the way to routine screening for Down syndrome and other chromosomal or genetic aberrations, and demanding that G-BA take social and ethical aspects of the matter into account.

At the heart of the controversy, which is still ongoing at the time of writing, was and remains the question of medical purpose. Advocates stress NIPT's potential to reduce the number of invasive tests performed and thereby of test-induced miscarriages – implicitly meaning miscarriages of *non-affected* foetuses, while critics deny that the tests can open up any other option than to terminate the pregnancy. One interviewee, a disability rights official, put it like this:

> This test serves exclusively, in my view, the purpose of selection. And when someone says, it is just so that one knows, then one wonders why a health insurance fund is possibly going to spend millions just so that anybody can know anything?

Similarly, an open letter to the G-BA in 2016 by a number of feminist and anti-eugenic civil society organisations objected that the concept of medical necessity in antenatal care had increasingly adopted the meaning of "screening for foetuses with disabilities" (Gen-ethisches Netzwerk e. V. et al. 2016). Critics called for a broader societal debate on NIPT and its social and ethical impli-

cations, rather than treating it as a matter of safety and efficacy in a merely technical sense.

The G-BA conceded that NIPT "touched upon fundamental ethical questions that had to be taken into account" (G-BA 2016). Members repeatedly expressed their concern but nevertheless decided against addressing social and ethical issues. The G-BA, in their view, was not the right body to deal with this type of issue; they did not consider themselves responsible for addressing the social and ethical implications of NIPT. The question remained, however: Who else was?

In August 2016, the G-BA decided to clear the way for reimbursement of NIPT for detecting trisomy 13, 18 and 21. The decision was preceded by a surge of position papers, statements, and open letters from civil society organisations and parliamentarians who were concerned that reimbursement would pave the way to routine screening for Down syndrome and other chromosomal or genetic aberrations. Nevertheless, the G-BA commissioned a so-called "patient information"[12] on NIPT for trisomies 13, 18 and 21, which formed the prerequisite for implementing the decision. Patient information is a brief brochure for patients and doctors that informs them about the scope, purpose and possible risks of the treatment or drug in question. Nevertheless, unease about fundamental ethical issues at stake persisted in civil society, in the Parliament, and in the G-BA itself. This became apparent when the chair of the G-BA approached the Health Committee of the *Bundestag* in March 2018 with a letter pointing out that the scope of NIPT would expand in the near future and raise fundamental ethical questions (Beeck et al. 2018). Therefore, he demanded, it was "imperative to launch a parliamentary discussion and consensus-building on the question of whether and to what extent molecular genetic testing procedures can be used in pregnancy" (Hecken, quoted in Fricke 2018: 2). In response to this letter, a group of ten MPs from different political factions issued a position paper in October 2018, also demanding a public and parliamentary debate on the matter (Beeck et al. 2018). Questions to be addressed in such a debate would include:

> What could a procedure look like that would serve to assess ethically contested diagnostic and therapeutic procedures in the future? Which body

12 The correct translation would be an "information leaflet for the members of the statutory health insurance schemes" (*Versicherteninformation*), but for the sake of briefness, we use the term "patient information".

> should deal with these ethical questions, and within which framework? […] What can we do to counteract prejudices against people living with disabilities, and how can we further improve the participation of disabled people and their families? (Beeck et al. 2018: 2)

The *Bundestag*, in fact, did address the matter and held an "orientational debate" in April 2019. It took two hours and focussed mainly on ethical questions (Deutscher Bundestag 2019), but remained inconclusive; it did not touch upon institutional issues of how to govern NIPT in the future, or produce any decision.

In 2021, following the production of the patient information, a new online campaign was launched by civil society organisations, demanding that prenatal selection through reimbursement for NIPT be stopped. The campaign primarily addressed the *Bundestag*, demanding that they enforce a return of the SHI to its "actual task under §1 SGB V", i.e. the provision that it cover the costs of medically necessary treatment. In addition, the campaigners demanded that the *Bundestag* curb unrealistic promises made by test producers. The test, they insist, cannot guarantee a healthy child, nor can it offer any treatment options for children with disabilities.

In August 2021, a preview of the patient information on NIPT for trisomies 13, 18 and 21, which forms the precondition for implementing the reimbursement policy, was published. Pending its approval by the Federal Minister of Health, the reimbursement policy is scheduled to start in early 2022. From then on, women can be reimbursed for an NIPT for trisomies 13, 18 and 21 – "in well-founded exceptional cases" and after obtaining medical counselling (Gemeinsamer Bundesausschuss 2021). The policy does not define what "well-founded cases" are, but leaves this decision up to the individual woman and her doctor. This scheme, as Christoph Rehmann-Sutter and Christina Schües (2020) argue, differs from that of many other countries in that it does not specify a quantitative risk threshold as an entry requirement for NIPT (or reimbursement) – which is remarkable since the G-BA has stated explicitly and repeatedly that reimbursement should be limited to exceptional cases and not lead to routinisation of NIPT. In effect, however, the policy amounts to NIPT on demand: it is sufficient for the woman to expresses anxieties about possible foetal Down syndrome or trisomy 13 or 18 to have free access to the test.

The related press release from the G-BA again sums up the characteristic combination of moral concerns and an individualisation of decision-making and accountability. Here, the chair of the G-BA again justifies the committee's

reimbursement decision: "It is rationally as well as medically right to offer a safe alternative to those pregnant women for whom the knowledge of a trisomy is personally important" (Gemeinsamer Bundesausschuss 2021: 1). Yet at the same time it calls for legislation, shifting the responsibility for NIPT policy to the Parliament:

> If we are serious as a society and consider a clear set of legal rules for dealing with non-invasive prenatal diagnostics to be appropriate, the Parliament must address these ethical and moral questions in light of the ever-evolving innovations (Gemeinsamer Bundesausschuss 2021: 1).

At present it seems highly unlikely that the Parliament is inclined to respond to the demand and enact binding legislation. *De facto*, we can conclude, NIPT in Germany is governed by a combination of consumer choice and public cost coverage: the producer offers tests on the market, the individual woman chooses to take them, and the statutory health insurance covers the cost. This arrangement, we would hold, sets high incentives for private sector companies to develop and market further tests for further conditions; the current policy provides no clear rationale or criteria for confining reimbursement to trisomy 13, 18 and 21.

Conclusion

NIPT is still a matter of controversy in Germany, evoking a sense of moral unease and some outright protest. Nevertheless, the policy approach that has emerged to date effectively results in a combination of individualised decision-making and public reimbursement. It thus shows a pattern that has already characterised the German policy approach towards selective abortion and pre-implantation genetic diagnosis. We have termed it the "No, but…" approach here. It stipulates that selecting which kind of children are desirable and should be born and which not is morally wrong or at least problematic *in principle*, but permissible under certain conditions. Whether these conditions apply or not is then a matter of case-by-case decision making by professionals in consultation with the individual – or, in practice, the other way round. With NIPT the decision is delegated to the individual woman, although she is advised to seek counselling. Thus, we see a tension between a moral unease towards selective practices on the one hand, and a reluctance to impose effective restrictions on the other. In effect, the tension is being resolved

through individualised decision-making, loosely coupled with professional consultation.

Early on, NIPT in Germany was defined as a deeply personal matter, akin to abortion. By doing so the responsibility for dealing with it in a morally and socially acceptable manner was shifted onto the individual, away from the level of policy-making. This move, however, also obscured policy decisions that had effectively been taken, namely the decision to support the development of the test through public funding. Moreover, we contend, the decision by the GBA to launch an assessment procedure and open the way to reimbursement, the decision to commission a patient information before the assessment procedure was completed, the decision to reimburse NIPT for trisomies 13, 18 and 21 on demand and without specifying further requirements – these were political decisions as well. In short, the decision to leave decision-making to the individual is a political one. This is all the more important as reimbursing NIPT on demand provides a strong incentive for manufacturers to further promote, diffuse and expand their products. Thus, a politics of individualising NIPT inevitably has social and economic implications that may reinforce a self-propelling dynamic of normalisation and routinisation, whether politically intended or not.

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