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NIPD in the system of medical care

Ethical and legal issues

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I. Introduction

The procedures of prenatal and preimplantation diagnostics are discussed critically again and again in our community [1-6]. In addition to the permanently controversial issues of embryo protection and abortion, considerations that discrimination on the basis of disability could occur with problematic consequences also for already born people with disabilities and their relatives now play a central role.

However, many of these reservations only take effect when the use of the relevant techniques and methods has reached a "critical mass". For example, the objection that prenatal diagnostics worsens the life situation of children with disabilities and puts their parents under pressure to justify their actions is plausible from the outset only on the condition that prenatal diagnostic procedures are used on a fairly regular basis; as long as only very isolated pregnant women prevent the birth of a child with a certain disability, nothing happens in terms of society as a whole.

In many cases, however, widespread use is not likely until the public health care system, i.e. in Germany the statutory health insurance (GKV), assumes the costs of prenatal diagnostic procedures. In this situation, one can now come up with the idea of solving a - real or supposed - social problem "in a cold way" by preventing exactly this financing. The temptation here is to shift the problem onto the SHI system and its players. This was also observed with regard to the new procedures of non-invasive prenatal diagnostics (NIPD) (cf. II.). Such attempts should be rejected (III. - V.).

II. the NIPD in medical device and constitutional law

The introduction of the so-called PraenaTest, a non-invasive method for determining fetal trisomy 21 and possibly other trisomies from the blood of the pregnant woman, has attracted considerable attention [7]. The great advantage of this test and other methods of NIPD is that they allow the determination of genetic defects on the one hand - unlike the invasive procedures of amniocentesis (amniocentesis) and chorionic villus sampling (placental puncture) - without major impairment for the pregnant woman and in particular without the risk of triggering a miscarriage and, on the other hand, this determination can be made relatively early (in principle from the 9th week of pregnancy). This means that - should the pregnant woman decide to terminate the pregnancy due to a detected defect - an abortion is less stressful (and many would say also less morally problematic) than at a later point in time. However, the low access barriers of the test have also attracted critics: Does this not open the door to a "selection" that overburdens parents and puts them under pressure to justify their decision to have a child with a disability in the first place [8]?

This criticism has not changed the fact that the PraenaTest has been available in Germany since 2012. As a medical device - and specifically as a method for detecting disabilities within the meaning of § 3 no. 1 b) MPG - it does not require approval, but only certification (CE marking, cf. § 6 MPG). The responsible state authorities saw no reason or no means to take action against the test, although they were requested to do so by a legal opinion [10]. In fact, the regulation of § 4 I MPG, according to which the placing on the market of medical devices is prohibited if there is a "reasonable suspicion that they directly or indirectly endanger the safety and health of patients, users or third parties when properly used, maintained and used for their intended purpose beyond a reasonable level according to the knowledge of medical science", is not relevant here: The test does not endanger anyone; this occurs at most through the subsequent decision of the pregnant woman to terminate the pregnancy. Conceivable indirect consequences of a social practice - namely the frequent decision to terminate a pregnancy in

the event of a positive test result - for the life situation of people who have already been born and future parents and pregnant women can hardly be subsumed under this standard, even if the test promotes this practice.

Thus, there is no legal basis for a general ban. Whether this could or even should be created is at least uncertain [9-13]. It will hardly be possible to say that the state's duty to protect human dignity, life and equality of disabled people from Art. 1 para. 1, 2 para. 2 p. 1 and especially 3 para. 3 p. 2 GG is violated if the test is not banned: The state does not discriminate against anyone by its inaction, but merely allows the pregnant woman to obtain information about the genetic constitution of the embryo more easily and earlier than before and to draw consequences from this, which may not infrequently consist in the decision to terminate the pregnancy, but also in the choice of a hospital with a children's clinic or a planned Caesarean section instead of a natural birth. An obligation to prevent this will not be able to be derived from constitutional law, if only in view of the legislative leeway. This applies in particular to the argument that the social practice promoted by the test jeopardizes the claim to inclusion of persons with disabilities who have already been born: empirical studies in fact tend to indicate that their legal and social situation has improved significantly in recent years despite all the progress made in prenatal diagnostics [14,15]. Of course, here and there there may be the frequently quoted contemporary who reacts to the sight of a child with a disability with the unspeakable remark that "such a thing is not necessary nowadays after all". The prenatal diagnostic possibilities, however, do not seem to have obscured the majority and politically the view that one can respect the assessment of a pregnant woman not to be able to carry and raise a child with a disability and at the same time advocate that the inclusion claim of people with disabilities is fulfilled. That NIPD will change something in this neither contradictory nor otherwise criticizable but thoroughly humane attitude is not very likely and in any case does not have to be assumed by the legislator.

On the contrary, a legal ban on NIPD procedures would even meet with considerable constitutional concerns. For a "high-risk pregnant woman", this would mean that she would have to be referred to an invasive examination option and, if necessary, to a later abortion. The argument that this would protect her self-determination because she would then not be subject to "social pressure" to undergo an easily accessible and risk-free test cannot really be taken seriously either (on the applicability of the GenDG, § 15 of which regulates prenatal genetic counseling, to the PraenaTest: [16-18]): Since when is it best to guarantee self-determination in a difficult decision-making situation - despite all the need for education and counseling that undoubtedly exists here - by a total ban that simply takes away a decision-making alternative [19, 20]? Finally, one will have to consider that NIPD prevents miscarriages and in this sense saves lives: The number of abortions of embryos with a genetic defect may increase, but this is probably overcompensated by the avoidance of miscarriages, to which the invasive methods of prenatal diagnostics lead in a certain, in detail not uncontroversial percentage of cases. Especially representatives of a strict protection of life should think about this; this effect of NIPD can only be avoided if all methods of prenatal diagnostics are banned.

III NIPD and the SHI system

Neither simple law nor constitutional law therefore provide a comfortable basis for a ban on NIPD. However, it is now a completely different question whether SHI will cover the costs of these procedures. On the parallel question in state aid law, see [21]. Even if the tests are becoming cheaper and cheaper (according to the manufacturer, offers for the Praena test currently start at around 130 euros [22]), this question is likely to be of central importance for their widespread use for the foreseeable future. And so the discussion has shifted to this aspect [23].

1. the procedure at the G-BA

The Federal Joint Committee (G-BA) is initially responsible for deciding whether NIPD should be included in the SHI catalog. For it, this is a question of innovation regulation [24], or more precisely: whether NIPD procedures should be included in the maternity guideline (Section 92 (1) Sentence 2 No. 4 SGB V) and thus be available in SHI-accredited care.

In 2014, the G-BA initiated the consultation procedure for issuing a trial guideline for "non-invasive prenatal diagnostics to determine the risk of fetal trisomy 21 by means of molecular genetic tests" in accordance with Section 137e SGB V [25]. This provision, introduced by the GKV-VStG [26], allows the trial use of new examination and treatment procedures that have not yet proven their (additional) benefit but have the "potential of a necessary treatment alternative". The G-BA has already been severely attacked for this decision. The criticism misses the point, however, because an application was submitted by the manufacturer of the Praena test and the G-BA was obligated under Section 137e (7) sentence 3 SGB V to decide on this application within three months. And in view of the fact that NIPD is regarded as a major advance in medicine, there was nothing else to do in the matter but to assume a corresponding "potential".

The G-BA then went one step further in August 2016 by suspending this trial procedure and initiating a method assessment procedure in accordance with Section 135 of the German Social Code, Book V [27]; the reason for this is probably that numerous studies on NIPD procedures are now available, so that an upstream trial procedure has become unnecessary. In this method evaluation procedure, which as a rule must be completed within three years (cf. Section 135 (1) sentence 5 SGB V), "the recognition of the diagnostic and therapeutic benefit of the new method as well as its medical necessity and cost-effectiveness - also in comparison with methods already provided at the expense of the health insurance funds - must be examined

according to the respective state of scientific knowledge in the respective therapeutic direction" (Section 135 (1) sentence 1 no. 1 SGB V).

The G-BA is responsible for the Methods Assessment Subcommittee, which commissioned the Institute for Quality and Efficiency in Health Care (IQWiG, cf. Section 139a SGB V) with the evidence assessment of NIPD on January 26, 2017 [28]. At the same time, the commenting procedure was opened according to Section 6 (2) of the G-BA's Regulation.

In addition, the G-BA has now commissioned IQWIG to prepare information for insured persons on prenatal diagnostics, which is expected to include NIPD [29].

There could hardly be any doubt that the NIPD procedures fulfill these requirements in principle. However, it had to be clarified in which cases of a "high-risk pregnancy" which test should be used at the expense of the SHI - an application in every pregnancy should not be considered for cost reasons alone -, how information and counseling before and after the test should be designed and to what extent NIPD can replace invasive procedures. The latter question arises on the one hand because NIPD offers a very high, but not 100% certainty, so that in the case of a positive test result, clarification is currently still carried out by means of an invasive procedure (whereby it must be taken into account that the test result is negative in the vast majority of cases, so that invasive examinations can then be dispensed with). Secondly, NIPD so far only covers trisomies 13, 18 and 21; other malformations and developmental disorders can still only be detected by means of invasive procedures.

2. the consideration of ethical reservations in the method evaluation process?

The G-BA has also been criticized for its decision to initiate the method assessment procedure: Here, a controversial medical technology with possible social effects and ethical problems is anchored in the health care system without prior discussion [30]. However, the fact that the

Federal Joint Committee may not block or delay a method assessment "arbitrarily or for irrelevant reasons" is not taken into account here either, if it does not want to produce a "system failure" - with the consequence of a cost reimbursement claim by the insured according to Section 13 (3) of the German Social Code, Book V: New methods are also part of the scope of services provided by the SHI system (cf. Section 2 (1), Sentence 3 of the German Social Code, Book V); insofar as they fulfill the legal requirements, the Federal Joint Committee must decide on their inclusion in the benefits catalog [31].

The impartial chairman of the G-BA has attempted to counter this inaccurate but expected criticism with the assurance that the G-BA is aware that "in addition to the standard medical aspects to be examined, this procedure touches in a special way on fundamental ethical issues that must also be considered" and that it therefore intends to involve "in addition to the scientific societies, other social organizations, for example the German Ethics Council" in the consultation procedure [32]. If this is not to be merely an inconsequential appeasement, it must mean that the G-BA at any rate considers it conceivable that NIPD will not be included in the SHI supply catalog, or only very restrictively, because of "fundamental ethical" aspects. However, this now raises the question of whether the ethical and social justifiability of a medical procedure can be the subject of the method evaluation pursuant to Section 135 (1) SGB V. Even at first glance, this would be peculiar: Why should a body of joint self-administration in SHI suddenly decide on the ethical aspects and sociopolitical effects of a method? Even if one were to see a special need for ethics here, it would be the medical associations that would come into view in this respect, as they traditionally deal - and with their own problems - with questions of professional law and ethics in reproductive medicine [33].

However, there is no need to discuss the much-discussed [34-39] legitimacy of the G-BA here, because the answer can be found in the law: Section 135 (1) of the German Social Code, Book V (SGB V) conclusively defines the criteria - diagnostic and therapeutic benefit, medical

necessity, and cost-effectiveness - on which the evaluation of methods must be based. The view that non-invasive prenatal diagnostics procedures cannot have any benefit within the meaning of the German Social Code, Book V, because no therapeutic interventions are possible to correct the genetic defect, which is also occasionally expressed in the political debate, is completely absurd. The suggestion that the G-BA should be particularly critical of the benefits of NIPD from the point of view of the ethical and social reservations about it [30] misses the point of the structure of the method assessment procedure: the G-BA does not assess the benefits itself, but must "obtain an overview of the published literature and the opinion of the relevant professional circles and then determine whether there is a consensus, adequately supported by scientific studies, on the quality and efficacy of the treatment method in question" [40].

This is exclusively a matter of quality assurance [41]; neither Section 135 (1) of the German Social Code, Book V (SGB V) nor any other norm authorizes the G-BA to conduct an ethical or social justifiability review in the method evaluation procedure. However, such a legal basis would be required already because of the relevance to fundamental rights of the regulation to be decided by the G-BA, which affects the conditions of realization of the professional freedom of the test manufacturers, the freedom of therapy of physicians, and especially the reproductive autonomy of women. In other areas of law with special reference to ethical issues, the examination of ethical justifiability (cf. § 7a para. 2 no. 3 TierSchG) or the involvement of an ethics committee (cf. §§ 40, 42 AMG) are then also expressly regulated. A "freehand" addition of ethical and social aspects to the legal program of action in order to appease political concerns and arrive at an exclusion of benefits is not permissible: The G-BA is also subject to the binding force of law (Art. 20 (3) GG).

The further development was therefore not surprising. The Institute for Quality and Efficiency in Health Care (IQWiG), commissioned by the G-BA, soon came to the conclusion that there

was little to criticize about the test to be evaluated from a technical point of view: its sensitivity and specificity were widely convincing [42]. On this basis, the G-BA took the decision in September 2019 to include NIPD in the maternity guideline - albeit limited to "justified individual cases", i.e. cases of - albeit unspecified - "high-risk pregnancies" (whereby a purely statistically increased risk of trisomy should not be sufficient) [43]. Since education and counseling of the affected persons play a central role for this review of the use of the test in the respective individual case, this decision will only come into force when IQWIG has developed a corresponding information for insured persons. This has been submitted in December 2020 [44], so that nothing stands in the way of a final decision by the G-BA, which would then finally anchor NIPD in the maternity guideline. An orientation debate in the Bundestag in April 2019 [45] has not yet led to any concrete legislative initiatives.

IV. Options for action

The G-BA could not be trusted to "deal with" the - real or perceived - ethical and social problems of NIPD in the method evaluation process. If it had done so, it would have exceeded its competences.

What would this mean for the regulation of NIPD? The legislator could try to ban their procedure completely in Germany. However, this would be constitutionally tricky and would also hardly be politically acceptable to a majority; moreover, it would only be likely to induce those affected to circumvent this ban by sending a blood sample abroad and then being left without any information and counseling before and after the test.

If one wants to avoid this and instead regulate SHI financing, two options are conceivable. One could consider providing the G-BA - for method evaluation or on an even more general level - with a legal basis for considering ethical and social consequential problems in its decisions. However, already in view of the anyway disputed legitimacy of the G-BA, this is not seriously

considered; also the G-BA itself should not be happy about such a politicization and "ethicization" of its activities.

This leaves only an explicit legal exclusion of NIPD from SHI care. This would represent a certain break with the general rules and procedures that otherwise guide the composition of the SHI coverage catalog, but the legislature would undoubtedly be authorized to do so in principle; after all, it has already made individual exclusions of benefits in other cases - from lifestyle drugs to vision aids to non-prescription drugs (cf. §§ 33, 34 SGB V). There are also no substantive constitutional concerns in this respect: NIPD is not part of basic medical care that is constitutional. The phrase that there is no right to a healthy child is not infrequently misused, because this is usually not the issue at all when those affected complain about the prohibition of a medical method; rather, they object to their self-determination being impaired. In the context of SHI financing, however, the sentence gains a certain justification: There is no claim that the solidarity community will bear all procedures available to fulfill the desire for a child. Comparable to this is, for example, the restrictions on the entitlement to benefits for artificial insemination measures in § 27a SGB V [46-49]. It will also be difficult to claim arbitrary unequal treatment if the legislator points to the aforementioned ethical and social consequential problems of NIPD as justification. From a purely medical perspective, however, it cannot be justified why NIPD is not included in the catalog of services, while riskier methods of prenatal diagnostics remain there. This objection of a certain inconsistency could only be completely refuted by the legislator if it were to remove all prenatal diagnostic measures from the SHI benefits catalog - which (as far as can be seen) no one wants to do.

V. Conclusion

The real problem is not NIPD, which is to be evaluated now, but the possible development that in the future numerous genetic characteristics of the embryo can be easily determined via non-

invasive testing [50]. Here, the community will indeed have to consider whether it makes sense that information about all possible characteristics - perhaps up to physical characteristics that have little to do with disease and health, but a great deal to do with ideals of beauty - is available and can be used as a basis for the decision to continue or terminate a pregnancy. In this respect, § 15 Para. 1 Sentence 3 GenDG prohibits, for example after a prenatal diagnostic examination, the communication of the sex of the embryo before the end of the twelfth week of pregnancy, so that an abortion without penalty (§ 218a StGB) cannot be used to select the sex. According to Section 15 (2) GenDG, prenatal diagnostic testing for late-manifesting diseases is generally inadmissible; this is rightly met with criticism [10, 51].

On the one hand, however, this is still future music to be decided on when it is played out; such fears do not allow a procedure to be banned now that does not provide any more information than the tests that have already been available for some time, but only does so much more gently. The boundaries between disease prevention and efforts to "perfect" may not be easy to draw here on occasion, but that does not mean that there are no boundaries and no clear cases here. If the politicians do not want to trust the citizens here and leave them extensive freedom of decision - which would speak for something, because apocalyptic developments do not seem to be just around the corner - the legislators themselves must take action in any case.

On the other hand, such considerations, which address the consequences of comprehensive knowledge about genetic characteristics of the embryo for social coexistence, touch on social and political issues that go far beyond traditional bioethics and medical ethics [50]. This makes it even more implausible that they would be well served by a body such as the G-BA, which is entirely focused on controlling the system of medical care. In this respect, too, the following therefore applies: If the funding of NIPD by the health insurance funds is to be generally excluded, this can only be done by the legislature itself. This does not, of course, answer the question of what one would think politically and morally about the procedure of denying SHI

funding to a medically superior procedure that is unpopular for ideological and extremely speculative reasons and then hoping that there will be enough women who cannot or do not want to afford the test and then run the risk of miscarriage. Perhaps this would be more of a topic for a social and ethical justifiability test.

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