

## The Future of Prenatal Diagnosis

### Summary



It is fair to assume that within a few years new methods of prenatal diagnosis will be developed, enabling the pregnant woman to obtain a great deal of information about the fetus early on in the course of pregnancy. The Danish Council of Ethics thinks that this development calls for discussion and, if necessary, some change to the legislative framework surrounding the area. In Chapter 4 of this report the Council presents recommendations on organizing and regulating the future of prenatal diagnosis. The report also contains chapters on the historical development of prenatal diagnosis in Denmark (Chapter 1), future technologies (Chapter 2) and ethical dilemmas in conjunction with such technologies (Chapter 3). There is also an appendix to the report with some legal deliberations. The following is a summary of the key topics in the report. Particular emphasis has been placed on presenting the Council's recommendations, though only the most central ones have been included.

### The Future of Prenatal Diagnosis

A few years down the line it is probably going to be possible to perform prenatal diagnosis with the aid of methods other than those primarily in use today. There is genetic material from the fetus, for example, in the pregnant woman's blood, which can be used to conduct prenatal diagnosis and obtain investigative results before week 12. Currently, it is not possible to obtain very much information about the fetus in that way, though for the most part determining gender on the basis of a blood sample from the expectant woman is feasible, for example. If, at some point, sufficiently large amounts of the fetal genetic material can be successfully isolated from the woman's blood sample, new methods may possibly be able to provide the same information about the fetus as is currently obtainable with the aid of amniocentesis or chorionic villus sampling. However, such methods will not be marred by the increased 0.5-1 percent risk of miscarriage associated with invasive investigations (amniotic fluid sample analyses or placental (CVB) biopsies). Non-invasive methods are more attractive than invasive methods, therefore: they supply information about the fetus early on in the pregnancy without increasing the risk of miscarriage.

### Ethical dilemmas and issues

The use of new methods also spawns fresh ethical dilemmas, however.<sup>[1]</sup> In the Council of Ethics' view, a position needs to be adopted on these dilemmas even at this stage in order to ensure that prenatal diagnosis is conducted on an ethically defensible and democratically grounded basis in the future.

### New methods and induced abortion

New methods of prenatal diagnosis will make it possible for the woman to access information about the fetus before the end of the 12-week time-limit for abortion on demand. The woman can therefore have an induced abortion if the fetus has characteristics she perceives to be undesirable. The question is whether this is acceptable in all cases, e.g. on the grounds of normal attributes, hereditary dispositions or less serious disorders. The way people relate to this issue depends on how they perceive and weight the ethical values relevant in the context of prenatal diagnosis. Among other things, it involves consideration for the woman's self-determination and consideration for the fetus. There are also more general, social values involved, such as ideals of avoiding sex discrimination and promoting good parenting or supporting social cohesion.

As the Council's recommendations will show, its members agree that induced abortion appears not to be acceptable in all instances, for example on the grounds of the fetus's gender or other normal characteristics. By contrast, in other contexts, the members do not arrive at the same conclusions. Inter alia, there is disagreement as to how severe a fetal disorder or malformation has to be before it is acceptable for the woman to have an abortion for that reason alone. Some members lay great store by the woman's autonomy and consider that the decision ought largely to be made by the woman herself. Conversely, other members ascribe greater weight to more general, social values and/or consideration for the fetus, and on that basis find that the use of new methods of prenatal diagnosis ought to be regulated to a greater extent, so as to preclude the existence of information on less severe disorders and malformations that may engender a desire to have an induced abortion.

## **Counseling and the woman's self-determination**

The pregnant woman herself makes a large part of the decisions in connection with prenatal diagnosis and possible termination. It is important that she is able to make those decisions on an informed basis, understanding the ins and outs of her particular situation and being able to take in the consequences that different decisions will have for herself and others involved. It is also important that she not be pressurized into making particular decisions by, say, the situation or the health-care professional advising and counseling her.

A recurring theme in the Council's discussions has been whether there are special aspects relating to prenatal diagnosis that can make it difficult for the pregnant woman to take independent and properly informed decisions. One group of members is of the opinion that, in this respect, decisions on prenatal diagnosis do not differ substantially from other decisions citizens have to make when they come into contact with the health sector. Another group of members takes the opposite view, pointing out that, among other things, many pregnant women think of prenatal diagnosis as having been rubber-stamped by the health services and public authorities because all pregnant women are offered prenatal diagnosis. The members in question view this as problematic, because most pregnant women take up the offer for that reason without further deliberation and without making up their minds whether they might be better off saying no. Another factor which, in some members' opinion, limits women's self-determination is the proliferation of complex medical data and risk assessments involved with prenatal diagnosis. Since many women find it hard to fathom these data, it is flawed in some members' view to believe that the majority of women make the relevant decisions on a sufficiently informed and independent basis.

The Council of Ethics considers it essential for pregnant women to have an adequate basis on which to make the relevant decisions. The individual members have proposed various initiatives, which in their view can contribute to providing pregnant women with an adequate decision-making basis. These recommendations are set out in Chapter 4.

## **Parliament's role in formulating prenatal-diagnostic services**

Prenatal diagnosis works on a legislative basis that includes the abortion laws and the provisions of the Danish Health Act stating that the health services must safeguard respect for the individual, including his or her integrity and autonomy. The latter provisions are part of the basis for the National Board of Health's formulations on the purpose of prenatal diagnosis: "The purpose of prenatal diagnosis is-within the framework of Danish legislation-to assist a pregnant woman wishing for such assistance to make her own choices."<sup>[2]</sup>

In practice, however, the current prenatal diagnosis services on offer have been articulated primarily by the National Board of Health in collaboration with other players like the counties/regions and a variety of boards and committees specially set up for the occasion. It is a moot point whether parliament should be more involved in formulating prenatal-diagnostic practice than has been the case to date, though the validity of this point can be justified by the fact that the concrete form taken by the

prenatal diagnosis services offered is hugely important to essential, social questions like our understanding of parenthood and the meaning of human life.

The Council of Ethics has adopted a position on whether a new purpose for prenatal diagnosis ought to be formulated - and, if so, which formulations that new purpose should contain. Similarly, the members have taken a stance on whether parliament ought in future to be more actively involved in regulating the use of prenatal diagnosis than hitherto.

## **Recommendations**

### **Recommendations on the regulation of future, non-invasive methods**

All members of the Danish Council of Ethics endorse the following three recommendations:

1. The Council of Ethics does not think information should be recorded about the results of prenatal-diagnostic investigations to which the woman herself does not have access. Therefore, if it is considered inappropriate or ethically unacceptable to give the woman specific types of information in person concerning the fetus, this should be safeguarded against by ensuring that such information is not generated in the first place.
2. Prenatal-diagnostic investigations should exclusively generate information of relevance on health-professional grounds. That is to say that such investigations must either be aimed at identifying severe fetal disorders and malformations (or risk of such) or relate to disorders which it is possible to treat either in the fetal state or post-partum. The members recommend not offering all pregnant women a detailed examination of fetuses' genomes but having any genetic examination target severe disorders only.
3. The Council would qualify this by saying that joint rules concerning prenatal diagnosis must exist for the public sector and the private health system - also with regard to authorization and quality control. Thus it must not be feasible to conduct an investigation in one system that is not permitted in the other.

The members of the Council of Ethics do not feel it is possible to make exhaustive positive or negative lists that can form the basis for targeting and directing investigations. On the other hand the members do not consider that such evaluations can be entrusted entirely to individual judgment and have different recommendations as to how prenatal diagnosis should be organized:

- 7 members recommend putting in place a practice in connection with future prenatal diagnosis, ensuring some control and coordination of what new prenatal diagnostic methods are used to examine for. The members do not wish to exclude the possibility of new methods of prenatal diagnosis being integrated into the existing screening offer.
- 10 members do not feel that the management of future prenatal-diagnostic services can merely be entrusted to "practice". According to these members there is an impending risk of the new diagnostic technologies gradually being included in the offer presently available to all pregnant women purely on the basis of administrative decisions taken in the health services, which will lead to extensive eugenic practice. The members therefore recommend a political decision not to offer all pregnant women new, information-maximizing investigative technologies but to implement them following a medical referral only.
- 7 members think a negative list ought to be made up, listing characteristics for which it is basically unacceptable to check. The list must be regularly reviewed, and members are sensitive to the fact that it is scarcely possible to draw up a complete list.
- 4 members think a positive list should be compiled with guideline examples intended to form the basis for evaluating what to examine for in any given situation. The list cannot entirely eliminate the need for a hands-on assessment from case to case and must be regularly reviewed and revised.

### **Recommendations on the purpose of prenatal diagnosis**

12 members of the Council of Ethics recommend formulating a new purpose for prenatal diagnosis. In the members' opinion the description of purpose ought to make it clear that considerations other than the woman's interests are involved in prenatal-diagnostic practice. The point of reformulating the purpose is essentially twofold: it must be a controlling force in regulating new methods of prenatal diagnosis, and it must be instrumental in ensuring that the pregnant woman does not erroneously entertain the idea that she can make all the decisions regarding prenatal diagnosis herself.

## **Recommendations on the workings of the consultative abortion councils and the Appeals Board**

Under Danish legislation the consultative abortion councils and the Appeals Board in Cases of Abortion and Sterilization can grant permission for termination of pregnancy after the end of the 12th week of pregnancy if "owing to hereditary genetic predisposition or damage or disease in the fetal state, there is a danger that the child will sustain serious bodily or mental suffering". The members of the Council of Ethics agree on the importance of the greatest possible openness regarding the consultative abortion councils' and the Appeals Board's decisions, since the institutions are a sort of steward of society's ethics. This is precisely why it is important to have ongoing, public debate on such decisions. As the situation is now, the consultative abortion councils or the Appeals Board, as appropriate, can only take a stance on whether an application for termination of pregnancy after week 12 should be approved or rejected once some fetal disorder or malformation has been demonstrated. In order to provide greater scope for the couple to predict and monitor the course of the pregnancy, therefore, 12 members of the Council of Ethics recommend contemplating giving the consultative abortion councils an opportunity to present advance rulings on any possible, late abortions in special cases. This could be relevant if, among other things, a couple is considering having a child and some hereditary complaint in the family appears that will be passed on to the child with some degree of probability. Advance notification might also be of relevance if crucial in determining whether there is even any point in continuing to investigate the fetal state.

## **Recommendations on parliament's role in formulating prenatal-diagnostic services**

As mentioned previously, the role to be played by parliament in formulating the prenatal-diagnostic service offering is open to discussion. The members of the Council of Ethics polarize into two groups of views on this issue:

- 10 members of the Council think that parliament should regulate the use of prenatal diagnosis in Denmark more actively, including whether new methods of investigation are to be offered to all pregnant women, or whether they may only be used in special cases with a well-defined objective.
- 7 members, on the other hand, are of the view that even now parliament has key influence on the way prenatal diagnosis is performed in practice, because it establishes the legislative framework within which prenatal diagnosis functions. Against this backdrop the members consider it reasonable that the National Board of Health is involved in making concrete changes to prenatal-diagnostic practice.

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### **Footnotes**

<sup>[1]</sup> In the discussions of the Council and the working party, it has been repeatedly mentioned that decisions about prenatal diagnosis and induced abortion are normally made by the pregnant woman and the father of the child jointly. The Council wishes to signal that it agrees with and is aware of this fact, but in most cases has nevertheless opted to use formulations like "the woman and her partner, if any" or just "the woman" in the report. These formulations have been chosen partly because the pregnant woman does not always have a partner and legally speaking, moreover, is ultimately the one who makes the decisions.

<sup>[2]</sup> See National Board of Health, Denmark: Memorandum concerning new guidelines for prenatal diagnosis, 10 October 2003, page 13.