

Summary

Since the Health Council published its report on 'invasive diagnosis and treatment of the fetus' in 1990, significant developments have taken place in this field, mainly as a result of the new options now available in non-invasive (drug) and minimally invasive fetal therapy. This report, which is complementary to the update on the state of scientific knowledge (MTA report, 2008)³ published by the Health Council, contains an investigation of the normative (ethical and legal) aspects of the development of this field of healthcare and science.

The fetus as a patient?

In view of the greater opportunities for treating fetal abnormalities and development defects prior to birth, it is not surprising that the fetus undergoing such procedures is described as a 'patient'. This need not imply more than that the fetus is or can be the subject of medical treatment. But the word 'patient' is more than a descriptive term; it inevitably leads on to normative considerations that can come to play an independent role in the ongoing debate on what can be expected of physicians and pregnant women in this regard. The emphasis on the fetus as a separately treatable individual could imply that the pregnant woman is regarded mainly as a 'fetal environment' requiring optimum management. This approach threatens to sideline the pregnant woman herself and her experience of her pregnancy, and the bond she feels with her as yet unborn child. Moreover, regarding the fetus as patient could all too easily lead to the conclusion that, like every patient, the fetus is entitled to receive treatment. But whether that is so is a separate question that remains unanswered with reference to the greater treatment opportunities now available in this field.

In any case it is clear that physicians and other healthcare practitioners involved in prenatal care are responsible not only for the expectant mother and her well-being, but also for the well-being of her unborn child. If this is what is meant by references to 'the fetus as patient', then that appears to be a sensible message. However, the phrase 'responsibility to the unborn child' can refer to two things that need to be clearly distinguished from each other. The first is the well-being of the future child, and the second is that of the fetus as a fetus. There is no ethical or legal conflict with regard to the former issue healthcare practitioners must take account of the health interests of the future child. And also the pregnant woman herself can, at least from a moral perspective, be called to account in this respect. The aim is to prevent damage

to the fetus that, once born, could cause the child to suffer from health problems or a diminished quality of life.

But what about the fetus as a fetus? Are physicians and pregnant women obliged to do everything they can to save the life of a fetus that would otherwise be doomed to die before birth? From a legal perspective the answer is no: the fetus is not a person entitled to treatment. Ethically, it first of all depends on how you think about the status of the fetus. Those who believe that the status of a person with rights or interests that deserve protection is conferred to a human being only at birth will be of the opinion that interventions aimed exclusively at keeping the fetus alive should rather not be carried out. Those who believe that the fetus should be regarded as a person who deserves protection from the moment of conception or from some other point in development will have another view. However that may be, the point is that we are dealing here with philosophical convictions about which reasonable people can have different opinions. Recognising this would be a reason to refrain from imposing a particular course of action upon pregnant women in this respect.

Cautious development of fetal therapy

As indicated by the recent MTA report, fetal therapy is at the cutting edge of medical science. There are a few accepted treatments for which adequate scientific evidence is available, but most interventions are still experimental.

Fetal therapy should wherever possible be developed in the context of well-designed prospective scientific research aimed at obtaining data on the efficacy and safety of new therapies. Administering innovative but as yet unproven therapies can be justified in *ultimum remedium* situations under certain conditions (including informed consent from the pregnant woman), but needs to be the subject of scientific research at the earliest opportunity. It is vital to ensure that pregnant women are not used as test subjects without adequate protection of their interests (and those of their future children). The problem of having too few patients for comparative research can be resolved by means of international cooperation between centres, something that is increasingly occurring.

Essential elements for responsible future development of the field are central and uniform registration of procedures, scientific assessment and follow-up research. A longer-term view must also be taken. This research must not only focus on the development and well-being of children who underwent fetal treatment, but also on the well-being of women involved in such procedures during pregnancy.

The prohibition on non-therapeutic scientific research on fetuses, enshrined in Article 20 of the Embryo Act, recently came up for discussion. It has recently been announced that this aspect of the law is to be revised, allowing some opportunity for such research subject to strict conditions. One of the points made in the parliamentary debate on this issue was that the research

that will now be permitted must be 'without any risk to the fetus'. This criterion is stricter than that laid down in the Medical Research involving Human Subjects Act (WMO), which allows non-therapeutic research on mentally incompetent individuals subject to the requirement of 'negligible risk'. The question is: is this requirement too strict? What can be the reason for providing fetuses greater protection than mentally incompetent children or adults?

Cautious decision-making

Treatments are available for some fetal conditions that entail minimum risk for the pregnant woman or the unborn child and that can improve the prognosis so greatly that the choice is not difficult. Examples include intra-uterine blood transfusion and some forms of drug treatment. However, in many other cases the expectant mother or the couple is faced with a more complex deliberation. The desired outcome is a child born alive with the best possible health prospects. Not all pregnant women or couples may take the view that fetal therapy, that increases the chances of survival but cannot necessarily prevent some of the surviving children being disabled, is necessarily a better option than abortion (if this is still possible) or taking no action for the time being. If the procedure involves surgery, there is also the risk of premature breaking of the waters and premature birth, and so the procedure itself could lead to perinatal death or neurological damage. Consequently, decisions often have to be taken under conditions of uncertainty, even in the case of proven treatments such as those for twin-to-twin transfusion syndrome. This is even more likely to be the case with experimental forms of fetal therapy. It is sometimes doubtful whether the treatment will provide a greater chance of healthy survival. In this situation some couples will want to do everything they can to save their child's life, even if there is a considerable risk the child will be facing a life of illness and handicap. Others will take a different decision for that very reason, and decide not to take action for the time being or to terminate the pregnancy.

These are clearly emotionally charged decisions in which a great deal is at stake for those involved from various points of view. Counsellors who help the pregnant woman or the couple to come to a considered decision face a challenging task. A key aspect is the strong bond of sympathy that many pregnant women feel with their fetus. Many pregnant women are prepared to make sacrifices at great cost to themselves for their child if this is necessary. Counsellors need to be very attentive here. Does the pregnant woman's choice fit in with her own experiences, values and ideals, or not? Another aspect is that some of these choices (abortion) require healthcare professionals to be as non-directive as possible, whereas for other choices this attitude would be too detached in view of the fact that healthcare professionals are also responsible for the well-being of the future child.

Conflict situations

It can be argued from an ethical point of view that good parenting starts before birth, and that expectant mothers may be reminded of this if necessary. This can be the case if a pregnant

woman would cause her future child to suffer from a serious deficiency if she failed to undergo a proposed fetal treatment. However, this would require an accepted treatment that would evidently save the future child from significant and irreversible damage without exposing the pregnant woman herself to a serious risk. In such cases, strongly directive counselling can be morally justified, as may also be the case for further-reaching forms of coercion or even compulsion.

Whether in such cases these measures may also be justified in legal terms, is a difficult question. The problem is that the child has not yet been born, and so there are no grounds for imposing restrictions on the pregnant woman's freedom. Some judicial verdicts have used a broader interpretation of existing legislation in order to justify measures involving coercion or compulsion applied to pregnant women who are addicted or mentally ill in order to protect the child prior to birth from health damage caused by their lifestyle. In the debate on this matter the assumption is that such measures would be legally justified only for pregnancies of 24 weeks gestation or more. The fact that developmental damage often occurs earlier in pregnancy raises the question of whether the health interests of the unborn child are adequately protected by this approach.

As an extension of this debate, the question of the justification of compulsory perinatal or prenatal interventions (Caesarean section, fetal therapy) arises. Compulsory treatment would seem to be difficult to defend from a legal point of view as we are generally dealing here with mentally competent pregnant women, which was not the case in the context referred to above. But the question of whether this option needs to be available is up for debate. Some authors argue from the principle that a viable fetus has certain rights that must be weighed against those of the pregnant woman. The question is whether the debate could perhaps be posed in terms of a less controversial argument: the future child's interest in good health.

Policy issues

FOR PROFESSIONALS AND CLINICAL PRACTICE

- Fetal therapy should wherever possible be developed in the context of well-designed prospective scientific research aimed at obtaining data on the efficacy and safety of new treatments;
- International cooperation is vital if research of this kind is to get off the ground;
- Essential elements for responsible future development of the field are central and uniform registration of procedures, scientific assessment and (long-term) follow-up research;
- Preventing fetal stress and possible fetal pain must be a major issue;
- The complexity of fetal therapy requires a multidisciplinary approach by a team of experts involved not only in the treatment but also in the pretreatment and posttreatment phases;
- Adequate counselling of the pregnant woman and her partner is a significant challenge. Further reflection on the normative framework for this counselling is needed, especially in the light of the many and varied kinds of decisions that may need to be taken in practice.

These decisions may sometimes require healthcare practitioners to adopt a non-directive approach, but there may be occasions on which it is important to emphasise to the pregnant woman that she has a responsibility for the well-being of her future child.

FOR GOVERNMENT AND SOCIETY

- Preclinical animal research is important in order to determine whether human trials would be justified. Non-human primates may have to be used in such research. This is permitted under the law subject to strict conditions, but is increasingly subject to societal controversy;
- Funding of long-term follow-up is a real sticking point in practice;
- The changes that have been announced to Article 20 of the Embryo Act still do not appear to offer enough opportunity for non-therapeutic scientific research on fetuses;
- A sustainable normative framework is needed for potential measures involving coercion or compulsion for the protection of the health interests of the future child, also with regard to cases where developmental damage is to be prevented in the early stages of pregnancy.