Care for the unborn child

Ethical and legal aspects of fetal therapy

Monitoring Report Ethics and Health 2009

CENTRE FOR ETHICS AND HEALTH

Care for the unborn child
Edition of the Centre for Ethics and Health
ISBN 978-90-78823-13-1

Preferred citation:
Health Council of the Netherlands. *Care for the unborn child*
Monitoring Report Ethics and Health, 2009/1. The Hague: Centre for Ethics and Health, 2009

Publicatienumber Health Council of the Netherlands: 2009/01E.

This publication can be downloaded from www.ceg.nl / www.healthcouncil.nl / www.rvz.net

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Centre for Ethics and Health

To the State Secretary for
Health, Welfare and Sport

Parnassusplein 5
NL-2511 VX The Hague
P.O.Box 19404
NL-2500 CK The Hague
Tel **+31 (70) - 340 50 60**
Fax **+31 (70) - 340 75 75**
E-mail **info@ceg.nl**
URL **www.ceg.nl**

Date
March 23, 2009
Your reference
-
Our reference
6106.5-006
Direct dial
+31 (70)-340 59 18
Subject
Presentation
Monitoring report

Madam Secretary of State,

The monitoring report that I hereby submit to you is related to the document published by the Health Council last year 'Fetal therapy: update on the current level of knowledge'. Whereas that publication provided an overview of medico-scientific developments in the field of fetal therapy, this monitoring report discusses the normative (ethical and legal) aspects associated with these developments.

The monitoring report addresses the nature of the responsibility of physicians, other healthcare professionals involved in prenatal care, and pregnant women for the well-being of the unborn child. What can be expected of them? In this context it is important to distinguish between the well-being of the future child and that of the fetus as a fetus. The monitoring report shows that physicians, other healthcare professionals and pregnant women must take account of the health interests of the future child. To this extent, their responsibility is not dependent on opinions and discussions on the moral and legal status of the fetus as a fetus.

This report also deals with normative questions related to the still largely experimental nature of fetal therapy, the difficult choices with which pregnant women and their partners can be faced in practice, and the challenge this signifies for counselling.

The monitoring report emphasises that many pregnant women are rather too much than too little inclined to expose themselves to considerable burdens and risks in the interests of their child. But, it may happen in exceptional cases that, in the opinion of healthcare professionals, a pregnant woman who refuses an accepted fetal treatment is seriously failing in her

responsibility for the future child. The question is whether measures involving coercion or even compulsion would be justified in such situations. In the monitoring report it is emphasised that protecting the interests of the future child is especially also important before 24-weeks, as preventable damage that can have consequences for the future child, often occurs early in pregnancy.

In the final Chapter a number of policy issues are raised for 'professionals and practitioners' and 'government and society', to which I should like to draw to your attention. This monitoring report is published in the series of the CEG's Monitoring Reports Ethics and Health. It was drawn up under the responsibility of the Health Council's Standing Committee on Health Ethics and Health Law. The Standing Committees on Medicine and Genetics discussed an earlier version.

Yours faithfully,
(signed)
Prof. J.A. Knottnerus

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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.

1 Introduction

Almost twenty years ago, in 1990, the Health Council issued an advisory report on 'invasive diagnosis and treatment of the fetus'.[1] This area of research and therapy was just starting to take off at that time.[2] This was made possible by improvements in ultrasound that allowed structural abnormalities in the fetus to be made visible during pregnancy.

The aim of fetal therapy is to improve the outcome of the pregnancy (in terms of death and disease) through early interventions. In the early days most of the procedures were carried out for conditions that often caused the fetus to die during pregnancy (or the child at birth). Examples include urinary tract obstructions (leading to impaired kidney and lung development), diaphragmatic hernia (a defect in the diaphragm threatening the normal development of the lungs) and certain fetal heart abnormalities.

The Health Council's advisory report was very cautious in its recommendations. Open surgery (in which the uterus is opened) was rejected as (still) being far too risky and requiring further investigation in the form of animal research. It also concluded that more research was needed into seemingly less risky 'closed procedures' (using laparoscopic and endoscopic techniques). Only one success was reported in the 1990 advisory report: fetal treatment of blood group antagonism, developed in the 1960s, by blood transfusion via a thin needle inserted into the uterus.

1.1 MTA monitoring report: update on the current level of knowledge

The Health Council's Medical Technology Assessment (MTA) Committee has recently published a comprehensive monitoring report about the medical and technical developments in this field over the past twenty years.[3] This showed that significant advances have been made in the reliability of diagnosis, insights into the natural course of fetal conditions, and the (further) development of minimally invasive (applicable by endoscopy) and non-invasive (drug) forms of treatment. The risks of these techniques to the pregnant woman herself are very small.

Involved physicians in the Netherlands have adopted a very cautious approach. In general, fetal treatment is chosen only if delaying treatment until just after birth is almost certain to lead

to a poor outcome. Improvements in neonatology (treatment of newborn infants) therefore help to determine the possible need for treatment during pregnancy. Of course, providing treatment after birth is preferable because the circumstances are then usually more favourable.

Accepted fetal treatments, alongside intra-uterine blood transfusion as referred to above, include:

— pharmacotherapeutic treatment (by administering drugs to the mother) of fetuses with heart rhythm disorders;
— using laser light to coagulate connecting blood vessels on the shared placenta of a twin with life-threatening twin-to-twin transfusion syndrome (TTS);
— inserting shunts in cases of abnormal fluid accumulation in the fetal chest cavity (hydrothorax and cystic lung tumours) that lead to heart failure and imminent death.

A new and very promising application is the treatment of fetal metabolic diseases by giving the pregnant woman a special diet or food supplements. In addition, clinical research is being carried out abroad into the treatment of diaphragmatic hernia by the temporary closure of the fetus' windpipe in order to promote lung growth, into treatment of fetal heart valve constriction by means of a balloon catheter, and into surgical closure of the exposed bone marrow in open spina bifida. Fetal stem cell therapy has hardly ever yet been attempted in humans, and fetal gene therapy is still completely in the animal experimentation phase.

The recent MTA monitoring report not only provides an update on the current level of knowledge, but also contains recommendations aimed at ensuring careful further development. It argues for (further) concentration in one centre or a small number of centres (partly also possibly in a European context) and for transparency. The monitoring report suggests that the concerned professional groups could draw up a quality standard that would help give shape to this. It emphasises that fetal therapy is a sensitive field in which good care for the pregnant woman is directly related to decisions that also have an impact on the life and health of her child. It is important to show that these decisions are taken carefully, on the basis of a multidisciplinary assessment of treatment options and after careful counselling of the pregnant woman (and her partner). It is also vital that the further development of indication determination is based on thorough scientific research.

1.2 Ethical and legal aspects

In contrast to the advisory report produced in 1990, the recent MTA monitoring report does not go into more detail on the normative (ethical and legal) aspects of medical research and therapy on the fetus. This is done in this follow-up monitoring report, published in the series of ‘Monitoring Reports Ethics and Health’.

Under what conditions is (experimental) treatment of the fetus acceptable? What does the possibility of fetal therapy mean for the responsibility of the physician and the position of the pregnant woman? How far can (or must?) she be expected to undergo more or less invasive medical procedures in the interests of the fetus and its healthy development?

1.3 Structure of this monitoring report

The structure of this monitoring report is as follows. First, (chapter 2) the concept of 'The fetus as patient' is addressed. As treatment options for fetuses with diseases or developmental defects increase, it becomes more common to also regard the fetus as a (potential) patient. But what does this mean for the normative context in which fetal therapy can be developed and offered? Chapter 3 investigates the still largely experimental character of fetal therapy. How can this form of medical treatment be carefully developed and introduced? Chapter 4 deals with the question of how careful counselling and decision-making are possible in this highly sensitive and morally charged area. The interests of both the as yet unborn child and of the pregnant woman come into play here. As any treatment that may be given to the fetus passes through her body, the final decision lies with the pregnant woman. Often she will be inclined to expose herself to considerable stress and risks in the interests of her child. But, it may happen in exceptional cases that a pregnant woman who refuses fetal treatment is, in the opinion of healthcare professionals, failing in her responsibility for the future child. These conflict situations are discussed in Chapter 5. Finally, chapter 6 contains agenda items for action for policy and regulations.

1.4 Acknowledgement

The Health Council's Standing Committee on Health Ethics and Health Law (see the Appendix for Committee composition) authored this monitoring report. Written comments on a previous version were received from Dr. D. Oepkes, gynaecologist/perinatologist at Leiden University Medical Centre (LUMC). The Standing Committees on Medicine and Genetics examined this report.

2 The fetus as a patient?

As diagnosis and treatment options for fetuses with diseases or developmental defects increase, it becomes more common to regard the fetus as a (potential) patient. The unborn child as a patient was also the title of the Health Council's 1990 advisory report. This is first a telling way of making clear what is medically and technically feasible in this area. But that is not all it implies. 'Being a patient' also has a normative dimension. It implies a relationship with a physician or other healthcare professional that is characterised by expectations and obligations with regard to care. In this relationship the patient is always entitled to good medical care and the physician is obliged to offer this good care. Does all this also apply to the fetus? Does the fetus have a right to treatment? What can be meant by this, and what is excluded? This chapter contains an investigation of the normative implications of talking about the fetus as a patient, first from an ethical perspective and then from a legal perspective.

2.1 Ethical perspective

In one of the first comments on the notion of the 'fetus as a patient', the American ethicist Fletcher warned against morally overloading this term.[4] It is a metaphor that can contain meanings that are not really pertinent in this context. The term 'as a patient' should not allow us to forget that diagnosis and treatment of the fetus takes place in the body of the pregnant woman and in the context of the already existing treatment relationship with her. In any event, the fetus is thus not a separate patient with whom the physician is able to maintain a treatment relationship outside the care provided to the pregnant woman. Any suggestion that this would be the case presents him or her with impossible dilemmas in practice.

Furthermore, as several authors have argued, talking about the fetus as patient threatens, precisely because of the connotation of separateness that this includes, to make the relational dimension of the pregnancy disappear from the picture.[5,6] A typical illustration of this, as recorded by Caspar in her sociological analysis of the history of fetal therapy, is the way surgeons speak about the pregnant woman as a 'natural incubator', 'fetal container' or 'fetal environment', of which it must only be hoped that this 'shell' will hold out for long enough after a surgical intervention for the fetus to come into the world without too much damage due to prematurity.[7] These kinds of phrases and images reduce the pregnant woman to nothing more than the background of the stage on which heroic medicine takes place for the benefit of the fetus.*

There is no place on this stage for the fetus' dependence on the pregnant woman, the physical and emotional investments that this demands of her, or the essential interconnectedness of their two lives. The critics are right that this is more than a semantic discussion. It is not surprising that where the pregnant woman disappears into the background follow-up studies still pay very little attention to the impact of an intra-uterine intervention on the health and well-being of the mother, also in the long term.[6]

This justified criticism of the ‘dividing of’ the pregnant woman and the fetus does not detract from the idea that physicians and other healthcare professionals involved in prenatal care are responsible not only for the well-being of the pregnant woman but also for that of her as yet unborn child. If this is what is meant by references to 'The fetus as patient', then that is a sensible message. Although the pregnant woman and the unborn child cannot be divided and although their interests will usually be the same, it will not necessarily always be the case that their interests will coincide.

Naturally, most pregnant women want a healthy child and are prepared to undergo a procedure necessary for this, even if the procedure would be burdensome and not without risk for themselves. This is indeed true in the broader sense for a variety of perinatal decisions, including bed-rest, cerclage (placing a band around the cervix to prevent premature birth), contraction inhibitors, Caesarean section because of imminent fetal oxygen deficiency, and so on. Even if all this is perhaps not strictly speaking in the interests of the pregnant woman, it is usually the case that they are indeed in her interests in the broader perspective of the outcome that she herself desires. However, the point at issue here is rather different. Namely, that the interests of the as yet unborn child are a morally relevant consideration regardless of whether the pregnant woman can see or experience these interests, in this broader sense, as also being her own interests.

Responsibility towards the future child

The term 'unborn child' does, however, need to be clarified.[9,10] It can be used to describe two very different things: the fetus as a future child or the fetus as a fetus.

In any event, healthcare professionals in this field have the moral obligation to prevent unnecessary fetal damage that could lead to post-birth (i.e. in the future child) health problems or an impaired quality of life.[1] After all, the child, born to a pregnant woman assigned to their care, would then suffer damage to his or her vital interests. Damage to the fetus can be the result of a certain lifestyle of the pregnant woman, such as smoking or drinking. It is then the task of the medical professional to make her aware of this (insistently if necessary).[11]

* The same criticism can indeed be made of terms such as 'fetal surgery', 'fetal therapy', and 'fetal medicine'. American publications often deal with this by using the adjective 'maternal-fetal'.[8] This is also not unproblematic: does 'maternal' suggest that the pregnant woman is already a mother? Is the fetus then already her child? Does this assume a certain view concerning moral status? However, this way of speaking does fit in with the perception of most pregnant women (see 4.4).

However, the fetus can also be damaged as a consequence of the physician's action, for instance, in the case of medical procedures incorrectly or irresponsibly carried out on the pregnant woman or the fetus. Or on the contrary by failure to perform an indicated treatment, such as medication for toxoplasmosis infection or an intra-uterine blood transfusion for anaemia caused by erythrocyte immunisation.

The principle in most cases will be that the duty of the healthcare professional to prevent unnecessary damage to the fetus is an extension of good care to the pregnant woman. But, the healthcare professional also has a direct responsibility to the as yet unborn child, just as the pregnant woman herself as a matter of fact. After all, the child's future interest in having good health can already be damaged by defective care, negligence or high-risk behaviour. The fact that the child has still to be born (and so does not yet exist) makes no difference to this. The child does not even has to be conceived yet Feinberg illustrates this using the example of a woman who had contracted syphilis from an infected blood transfusion, then became pregnant and had an affected child. The hospital where the blood transfusion had taken place was taken to court, and damages were awarded to the child.[12]

However, an essential condition is that the child will, in fact, eventually exist. If the fetus dies from whatever cause before birth, then the future interests of the child that might otherwise have existed are, of course, no longer relevant. It is thus also important in this context to know whether the pregnant woman intends to continue with the pregnancy. The perspective of the interests of the future child cannot, naturally, lead to the conclusion that the pregnant woman must not have an abortion. The relationship is reversed here: if she decides to bear the child, then she must also take its future interests into account. The same then also applies to the physician to whom she has entrusted the medical support of her pregnancy.

From the point of view of this responsibility towards the future child, it makes no difference whether the pregnancy has just started or not.[10] After all, significant damage can (in many cases, precisely) be caused at an early stage of embryonic or fetal development, or even (in cases such as damage to sex cells or IVF embryos) before a pregnancy exists. Even the fact that the pregnancy may no longer be legally terminated after 24 weeks does not mean that the interests of the future child weigh less heavily before that point.

Responsibility towards the fetus?

Recognising the obligation to prevent unnecessary damage to the fetus does not require assuming that the interests of the fetus would be harmed by such damage (or even merely that it has interests that could have been damaged), but only that it will be true for the child that the fetus will eventually become. Whatever views are held about the status of the fetus as a fetus (whether or not it is a person, whether or not it holds rights or interests), it is in any case relevant that the child’s future interests can already be an issue.[12]

However, this status debate will determine whether the physician and the pregnant woman also have a responsibility towards the fetus as a fetus, aside from their responsibility towards the future child.

Whatever one's views on the matter, the main issue in this context relates to the question of whether or not the physician and the pregnant woman have the moral duty to do everything reasonably possible to protect an affected fetus from intra-uterine death. The answer to this will be ‘yes’ if one regards the fetus as a person deserving protection as such, and ‘no’ if one does not ascribe any particular moral status to the fetus. Those who believe that only birth confers the status of a human being with rights and interests that deserve protection will hold that interventions aimed exclusively at keeping the fetus alive might better not be carried out. After all:

> Death to a fetus before it has any actual interests (...) is no harm to it. The (...) fetal preperson has no actual interests that can be harmed, and since it dies before any 'potential interests' can become actual, no harm can be done to these either.[12]

A life-saving intervention can still always be indicated on the grounds of good care for the pregnant woman, but not because the physician (and the pregnant woman) also owe this to the fetus. If a life-saving intervention of this kind might lead to a severely handicapped existence, then the interests of the future child might actually be an argument for refraining from this intervention. Actually, this entails a further difficult debate: if the child would not have existed without this life-saving intervention, how can his or her interests be damaged by it?[12-15]

There are various versions of the opinion that not only the future person (and his or her interests insofar as they can now be at issue) but also the fetus itself deserves protection. According to Roman Catholic doctrine, the fetus – and before that the embryo – must be regarded as a person from the point of conception. It is difficult to reconcile this view with the social acceptance of abortion, the creation of surplus embryos in *in vitro* fertilisation, and the use of the IUD as a means of preventing implantation.

Others take the view that the moral status of the fetus is initially small, but increases in weight as the pregnancy progresses. In this way of thinking (‘increasing entitlement to protection’), a responsibility towards the fetus as a fetus can only be said to exist in the case of an advanced pregnancy. Reaching the stage of independent viability (from a gestational age of about 24 weeks) is often regarded here as a morally relevant transition point. Reference is made thereby to the fact that a child born prematurely but after reaching the stage of viability is morally and legally regarded as being entitled to complete protection. Why should the viable fetus then not also be seen as a carrier of vital interests that deserve protection? The fact that abortion after reaching viability is broadly regarded as unacceptable (and forbidden in many countries, including the Netherlands) can also be seen as supporting this argument, although it is only one position in a philosophical debate with other possible moral views.

McCullough and Chervenak, authors of a series of joint publications presenting 'The fetus as patient' as an essential concept in the ethics of prenatal care, also see the viability threshold as a marker.[9,16,17] They say that the pregnant woman has the moral duty to make the fetus a patient ('present the fetus to the physician') from viability onwards, not only if the health of the future child is at issue but also if the life of the fetus is at stake. The physician may have the duty to strongly point this out to her if necessary or even as a last resort to try to obtain a court order for a life-saving intervention in the interests of the viable fetus.

The problem with this argument is not the position that these authors thereby take in the debate on the status of the fetus, which cannot be resolved purely on objective grounds. What is problematic is the suggestion that the concept they have devised of 'The fetus as patient' can help to bypass, and even render superfluous, the irresolvable (and therefore, according to them, frustrating and circular) debate:

> We need to ask not, "Does the fetus possess independent moral status or not?", but, (....) "How ought we to treat the fetus?"[17]

They thereby write as if it were possible to answer the second question ('How to treat…') without implicitly also answering the first question (that of status). In contrast to what McCullough and Chervenak suggest, this is an illusion. A recent comment on their work rightly emphasised that:

> Anyone who does not already believe that fetuses deserve protection (except as requested by the parents) will reject the authors' view that the clinician has duties of beneficence to it. The proposal to designate the fetus a ‘patient’ would change nothing.[18]

This is an important observation: except in the case of obligations that arise from the interests of the future child, all statements as to what the obligations of the pregnant woman or the physician towards the fetus may be from a moral point of view depend on an opinion as to the status of the fetus that is not necessarily shared by everyone (a 'philosophical' opinion in the broadest sense of the word). The suggestion that the concept of 'The fetus as patient’ can provide a more objective, and to this extent morally authoritative, foundation for such statements exposes pregnant women to the danger of moral pressure from physicians and others seeking agreement to treatments that are in (what others regard as) the interests of the fetus, but that are indeed risky to the pregnant women.[19]

2.2 Legal perspective

The question of whether the fetus can be regarded as a patient in the legal sense was raised in what is known as the Kelly case (Supreme Court of the Netherlands, 18 March 2005). This case involved a claim for damages filed by a child born severely handicapped and her parents against the midwife who had attended the pregnancy (and against the hospital as the employer).[*] It centred on, among other things, the question of whether concluding a treatment

agreement to attend a pregnancy gives rise not only to a contractual relationship between the practitioner and the pregnant woman, but also to one between the practitioner and the as yet unborn child. The Supreme Court stated in its judgement that it was generally possible for the pregnant woman to enter into contracts, not only for herself, but also on behalf of her as yet unborn child. However, the question of whether or not this is the case must be clarified when the agreement is concluded. If no reference to this effect is made, then it must be assumed that the pregnant woman has concluded the agreement only for herself. On this point the Supreme Court comments:

> It is *per se* correct that the as yet unborn child with which she is pregnant has its own interest in this agreement, but this circumstance alone is not sufficient to justify the child having to be regarded as a party to this agreement, or that the mother must be deemed to have concluded a separate agreement with the practitioner on behalf of her as yet unborn child.

Therefore, it cannot be deduced from the simple fact that the unborn child has an interest in the pregnancy being well attended that the fetus is a second patient with whom the practitioner can be said to have a separate practitioner/patient relationship. A separate practitioner/patient relationship comes into being only in the (exceptional) case where the pregnant woman expressly also enters into a contract for her as yet unborn child. However, the support for this option by the Supreme Court, namely with reference to art. 1:2 of the Civil Code (see below), shows that the fetus must in this context be thought of not as a fetus but as a future child. The interests that her child will have after birth can already be a reason why the pregnant woman wants to also enter into contractual arrangements for him or her.

The Supreme Court also states that although the unborn child is not in fact a party to the agreement, this does not detract from the fact that an agreement to attend the pregnancy entered into by the pregnant woman also includes providing the necessary care to the as yet unborn child. It is true that the practitioner's duty of care under Article 7:453 of the Civil Code is directed *primarily* towards the pregnant woman, but it also extends to the unborn child. If the practitioner falls short in fulfilling his duty of care towards the woman, then he is also acting 'contrary to what is regarded as fitting towards the unborn child in accordance with unwritten law in social intercourse'.

The Supreme Court's judgement dealt specifically with the child's interest in not having to go through life with severe handicaps. It is apparent from the judgement that the practitioner's duty of care also includes the health interests of the future child.

* The midwife had incorrectly judged that prenatal testing was not necessary. The mother would have had an abortion if testing during pregnancy had shown that the fetus she was carrying had a chromosomal abnormality. Both the parents' claim (a 'wrongful birth' claim) and that by Kelly (a 'wrongful life' claim), defended by her parents, were allowed. The child successfully made the negligent midwife (and the hospital) liable for the damage resulting from her handicapped existence.

However, the child cannot assert rights itself until it is born. It follows from the status attributed to the fetus in Dutch law that a fetus cannot hold subjective rights (see below). The unborn child is not a subject of the law. The Supreme Court also emphasised this by stating that the unborn child was not entitled to termination of the pregnancy.

The status of the fetus in Dutch law

Though there is little biological difference between a fetus one hour before birth and the child immediately afterwards, there is a great difference between the two in terms of legal status. This is because birth is the starting point of a legally human person. It is only by birth that the (born alive) child attains rights. The fetus has not yet reached this stage.

This does not mean that the fetus has no legal protection at all. In Dutch law, the fetus is regarded as a future human being, with protection that increases as it develops and grows. The increasing protection of the fetus is based on the view (referred to above; section 2.1) that the unborn human life deserves more protection as it (gradually) develops. In the theory of progressive legal protection, implantation in the uterus and reaching the stage of independent viability are regarded as legally relevant transition points. An early embryo (whether or not *in vitro*) enjoys a lesser degree of protection than a fetus that has implanted in the uterus. An implanted fetus is then in *'status nascendi'*: on the way towards birth. The degree of protection increases further once the stage of independent viability has been reached, while complete legal protection applies only from birth.

This progressive legal protection is supported in a number of respects by positive law, including the fact that termination of pregnancy is indeed permitted in the event of what is regarded by the woman as an emergency situation (Termination of Pregnancy Act, Article 5 sub 2a), but that this is no longer the case once the fetus has reached the stage of independent viability (Criminal Code, Article 82a). On the grounds of medical opinion, an upper limit of 24 weeks is applied in practice. The viable fetus (over 24 weeks gestational age) is protected against being deprived of life through termination of pregnancy. Termination of pregnancy after 24 weeks ('late termination of pregnancy') can legally be justifiable only in exceptional cases, namely where it is already clear during the pregnancy that the fetus is practically certain to die before or shortly after birth, or if a hopeless postnatal prognosis is considered to be established in advance.

All in all, the model of progressive legal protection offers a global legal framework for attitudes to, and regulations governing, the status of the embryo or the fetus in its various phases of development. The fact that this legal protection increases as the embryo or fetus continues to develop means that there is more room in the earliest phases of development than in later phases for weighing the respect for the unborn human life against other values and interests.[20] The fact that the pregnancy may no longer be terminated after 24 weeks emphasises the greater legal protection that the fetus then enjoys. This does not, however, mean that the viable fetus has a 'right to life'. After all, rights only come with birth. It follows from this that the

responsibility of the healthcare professional with regard to the fetus as a fetus does not extend beyond the degree of protection that the law offers to a fetus, whether or not it is viable.

Protected status of the fetus in international conventions

The question of whether the fetus can derive a 'right to life' from provisions in international conventions has been discussed at length, particularly in the context of the permissibility of abortion. It concerns the Universal Declaration of Human Rights (UDHR), the International Covenant on Civil and Political Rights (ICCPR) and the European Convention on Human Rights (ECHR). These conventions do not themselves address the question of the possible rights of the fetus, nor can it be deduced from the history of their creation or their systematics that they were ever intended to relate to the fetus.[20]

According to some people, the jurisprudence of the European Commission and the European Court of Human Rights does in fact offer starting points that bring the fetus under the protection of Article 2 of the ECHR ('right to life') in particular circumstances. Although the embryo does not in principle come under the protection of the ECHR, the fetus may do so at a later stage of development. This would apply, in particular, to the viable fetus.[21]

However, a judgement by the European Court in 2004 (Case of Vo vs. France) confirmed that the 'right to life' protected in Article 2 of the ECHR does not extend to the unborn. It is true that the fetus (and earlier the embryo) must be protected in the name of human dignity because of its capacity to grow into a person. But this does not yet make the embryo into a person with a 'right to life' for the purposes of Article 2 of the ECHR.

The Court takes the view that – in view of the lack of a consensus in the Member States as to the nature and status of the embryo and/or the fetus – it is neither desirable nor possible to give an answer in the abstract to the question of whether the unborn child must be regarded as a person. As a consequence

> the issue of when the right to life begins comes within the margin of appreciation that the court generally considers that States should enjoy in this sphere.[2]

It is therefore left up to the Member States to decide the nature and status of the embryo or the fetus.

Article 2 Volume 1 of the Civil Code and the interests of the future child

What is the legal position concerning the responsibility of the healthcare professional towards the future child? After all, the future child does not yet exist and the fetus cannot be regarded as having rights. Article 2 Volume 1 of the Civil Code offers a possible starting point for this responsibility (though not only that of the healthcare professional but also of the pregnant woman and of all others whose actions may harm the interests of the future child). It is stated there that

> The child with which a woman is pregnant is regarded as having already been born whenever its interests require this. If it is stillborn, then it is regarded as never having existed.

Property law provides the context of this article. It creates the opportunity to take account of the property law interests that the child will have after birth (for example, as an heir). The discussion relates in the first instance to the question of whether this Article with its fiction ('act as if the child were already born') can apply in the same way to protect interests other than property law interests of the future child. In this case, this interest relates to the future child's health interests. Not all legal specialists agree that the Article can be interpreted in this broader sense, but there is considerable support for this view, including a number of court judgements (see 5.2).

Some authors also see a starting point here for re-opening the debate on the legal status of the fetus.[21,23] Is it not recognised here that an as yet unborn child has interests that deserve protection? In the *Handboek Gezondheidsrecht* [Manual of Health Law], Leenen *et al.* emphasise that this argument does not hold true:

> The legal fiction of this Article is linked to being born; …in addition, the relevant legal provision relates to property law claims that are implemented after birth. The legal fiction of that Article is suited to such claims, but offers no basis for the rights of the fetus.[20]

2.3 The fetus as a patient: an ambiguous concept

Where physicians are increasingly able to detect developmental defects and diseases in the fetus, and in some cases also correct or cure them by targeted intervention, it is understandable that the fetus is referred to by them, and subsequently by others, as a 'patient'. This does not necessarily say or mean any 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 as yet undecided debate on what can be expected in this regard from physicians and pregnant women.

Attention is thus correctly required for the connotation of separateness that is included in the term 'patient', and for the danger that the pregnant woman (and also the relational character of the pregnancy) may disappear from the picture as a result. Furthermore, it could be concluded from this that the fetus, like every patient, is entitled to be treated. That is of course a fallacy that rests on a dual use of the term 'patient': first, purely descriptive ('the fetus can be treated and to this extent we refer to it as a patient), and secondly also normative ('as a patient, the fetus has a right to treatment'). Whether the fetus 'has a right to treatment' is a separate question that is not answered by simply observing that fetal treatment is increasingly possible.

This Chapter has shown that it is important when answering this question to make a distinction between the future child and its interests, on the one hand, and the assumed interests of the fetus as a fetus, on the other hand. As far as the first case is concerned, there is an ethical

and legal consensus: healthcare professionals must take account of the interests of the future child. The pregnant woman also bears (at least moral) responsibility for this.

The situation is different when we are talking about the fetus as a fetus. Are the physician and the pregnant woman under an obligation towards the fetus to do everything possible to save its life? From a legal perspective the answer is no: the fetus is not a person who can independently make a claim for treatment. Ethically, it depends on how you start to think about the status of the fetus. The fact that opinions on this can fundamentally differ should, in any event, be a reason for not forcing anything on the pregnant woman.

3 Cautious development of fetal therapy

Last year's MTA monitoring report showed that fetal therapy is at the forefront of the development of medical intervention.[3] There are a few accepted treatments for which sufficient scientific evidence is available, including administration of corticosteroids in cases of imminent premature birth, intra-uterine blood transfusion to prevent severe fetal anaemia, and laser treatment for twin-to-twin transfusion syndrome. However, a significant proportion of the interventions are still experimental. Some of these interventions are also carried out in the Netherlands, such as inserting shunts for blocked fetal bladder outlets. The MTA monitoring report deals separately with fetal treatments that are still experimental and that are the subject of research in other countries, such as temporary blockage of the fetal windpipe in cases of diaphragmatic hernia, dilating a narrowed fetal heart valve, and closing a neural tube defect (spina bifida).

This Chapter discusses how the further development of this sensitive field may be responsibly shaped in medical, ethical and legal terms.

3.1 Preclinical animal research

The first experimental application of various forms of fetal therapy in humans was preceded by extensive animal research. This research focused on the efficacy and safety of these procedures. Various animal models have been/still are used.[7,24] As the uterus of the sheep is relatively insensitive to trauma, it is a good model for all types of physiological research. However, the sheep uterus is not appropriate for testing the risk of premature delivery following intra-uterine surgical procedures, and many experiments to investigate the effects of such procedures have instead been performed with rhesus monkeys. It has also recently been argued that apes (baboons) should be used as models for preclinical research into fetal stem cell therapy.[25] The development of fetal stem cell therapy is still largely at the stage of animal research, and there have been only a few reported cases of use in humans.[3]

The law on animal testing and the relevant European regulations allow non-human primates (with the exception of hominid apes) to be used for medical research under strict conditions of necessity, proportionality, subsidiarity and review by an Animal Ethics Committee (AEC). These requirements apply to all animal research and are, as such, not stricter for research with apes than for trials with sheep or rabbits.

However, research with apes is regarded as more socially sensitive, which means that the principle of 'subsidiarity' forbids the use of apes if the research can be carried out with other animals. Furthermore, research with apes is so expensive and (because of the long gestation and development period) time-consuming that there is no reason to fear imprudent use of apes as research material.

Fetal gene therapy is still regarded as too risky to take the next step to humans.[3] This view is based (in addition to the theoretical risks for the future child, including cancer, developmental defects, and loss of immunity to pathogens) on the theoretical (albeit unlikely) chance of the development of germ line modification.[26,27] This would result in both positive and negative gene therapy-induced changes to the genome being passed on to future generations, if the individual reproduced. The question is whether animal research can sufficiently remove the concern about these risks so that the next step to humans can eventually be responsibly taken.

Animal research involving genetic modification requires a licence under the Animal Health and Welfare Act and the Animal Biotechnology Decree. The Minister for Agriculture, Nature and Food Quality only issues these licences if there are no unacceptable consequences for the health or welfare of animals, and if there are 'no ethical objections' against the proposed activities.

3.2 Innovative medicine

New medical treatments are ideally only introduced into regular care once their value has been established in a prospective comparative study.[28] But the decision to launch a study of this kind is preceded by a phase in which a new treatment is often tested outside a formal study design on a small number of patients. This is described as innovative treatment, clinical innovation, informal research, etc.[29-31] Fetal surgery also developed along this path.[3,24,32] The first steps (experimental surgical interventions; off-label use of medicinal products) are always taken by physicians who did not want to simply accept that they could do nothing to save the pregnancy or improve the child's prognosis when faced with a pregnant woman with a severely ill fetus.[7] Looking back on the first applications of intra-uterine blood transfusion, the pioneer Liley (Auckland) wrote that, 'it was very frustrating to have to put a diagnosis on a baby which was virtually a sentence of death and then sit back and watch the baby die'.[33]

A recent example is the successful attempt by Utrecht physicians to start medication during the pregnancy to save a child from severe handicaps resulting from a congenital metabolic disease.[34] Prenatal diagnosis had established quite early in the pregnancy that the fetus had a genetic abnormality leading to 3-PGDH deficiency (a rare disease caused by a deficiency of the amino acid L-serine). The disease is characterised by congenital microcephaly (an excessively small skull circumference at birth), mental retardation and epilepsy. Postnatal administration of L-serine can prevent epileptic symptoms in patients, but cannot resolve the

developmental damage to the brain that developed prior to birth. When the pregnant woman said that she wished to continue with the pregnancy, the physicians faced the question of whether administering L-serine during pregnancy might prevent this developmental disorder. In the absence of data on possible positive and negative consequences, they did not venture to do so for as long as the fetus was developing normally. The decision to try administering L-serine was only taken (between 20 and 26 weeks) when the growth of the head circumference was clearly retarded. The treatment was a success: the brain again began to grow and the child was born without handicaps. The girl is now 8 ½ years old and attends a regular school. She has been developing normally, so far, and no neurological symptoms have appeared.*

Ultimum remedium

Harrison, the American pioneer of (open) fetal surgery, recalls the first surgical correction of fetal urinary tract obstruction as 'a desperate case' in which the cause of the problem could only be addressed by opening the uterus and inserting an artificial bladder outlet. Though the fetus did not survive (the intervention came too late and the kidneys were already too damaged), Harris wrote that the intervention was a technical success because it, in any case, demonstrated the feasibility and the initial safety for mothers.[24]

Harrison's description clearly shows that 'innovative medicine' is in the boundary area between clinical care and scientific research. This raises the question of how interventions of this kind relate to the usual ethical and legal framework for the assessment of medical procedures. An important element here is indeed precisely the distinction between care and science. As far as the care of the individual patient is concerned, his or her interests must take precedence. But when it comes to scientific research targeted at obtaining new understanding, then patients may only be subjected to such research under strict conditions of conscientiousness (methodically justified design, review, written informed consent).[35,36]

Innovative procedures can sometimes be perceived and justified as an *ultimum remedium*: the physician and the patient have their backs against the wall and decide, as a last resort, to attempt a procedure that has not yet been (sufficiently) proven.[1] If this choice is made in an isolated case, then it remains a form of patient care even if the one-off application of the procedure provides new knowledge. So long as the latter is an ancillary aspect and not the primary aim, it is not scientific research.[35] This is also stated in so many words in the Helsinki Declaration, which governs medical research: the physician has the freedom to choose new or unproven methods of measures 'if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering'.[37]

Treatment or research?

Harrison's description of the first application of fetal surgery does show that acquiring new knowledge was more than an ancillary aspect. This first 'desperate case' application had been

* Personal communication by Dr. T.J. de Koning, paediatrician specialising in metabolic diseases, Utrecht University Medical Centre.

preceded by extensive trials in animal models. The step to humans was therefore deliberately prepared and fitted in with his group's development and research agenda:

> We thought it would be the easiest disease to treat because all we had to do was decompress the bladder before birth in the same way that it was decompressed after birth, either with a catheter shunt or with a surgical opening.[24]

Can we still talk of care as an ultimum remedium? The experimental context of the treatment provision makes that problematic: 'In an application of this kind there is indeed a therapeutic goal alongside the experimental goal, but this does not detract from the fact that this first application of a new substance or new procedure is an experiment.[35] By continuing to talk of treatment, this aspect is lost from sight and threatens to expose the patient (in this case the pregnant woman) without her knowledge to risks that do not primarily coincide with her own interests, but arise from the research goal of the physician or the team.[31,35,38,39]

A recent revision to the Helsinki Declaration added the requirement that unproven medical procedures must 'where possible' be made the subject of scientific research aimed at assessing their safety and efficacy.[37] It is stated in the Belmont Report that such procedures must be submitted to scientific assessment 'at an early stage'.[36] Behind these formulations ('where possible', 'at an early stage') lies the concern that physicians may move away, under the pretext of innovative medicine, from the ethical and legal context for medical research that has been developed to protect subjects.

3.3 Scientific research involving fetuses

The normative framework for the assessment of the acceptability of medical research is laid down in international conventions, European legislation and regulation, and (at national level within the Netherlands) in the Medical Research involving Human Subjects Act (WMO). The Embryo Act contains an elaboration for the field of scientific research with fetuses. This is research wherein fetuses are the object of the research and pregnant women are trial subjects, and that may also have consequences for the health prospects of the future child.

According to the Embryo Act, such research is acceptable if the design and conduct are scientifically sound (Article 10, clauses c and d); the research complies with conditions of interest, proportionality and subsidiarity (Article 19); the research may also benefit the fetus or future child in question (Article 20); the pregnant woman has given her informed consent before the research is performed (Article 21); and if other requirements, which could include issues such as conditions of privacy protection, that can reasonably be imposed on such research are met (Article 10, clause e).

Scientific soundness, interest, proportionality and subsidiarity

The requirement for scientific soundness is self-evident. It is ethically and legally irresponsible to expose people to the stress and risks of research that cannot provide new scientific insights

because of poor design or performance. Among other things, this means that sufficient laboratory research must have first been carried out, especially in the form of animal testing, and that the researchers must be qualified and experienced. 'Interest', the second condition, refers here to the aim of the research (described in limitative terms in Article 19 as obtaining new medical knowledge about unborn or newly born children or the completion of pregnancies) and the likelihood that the research will contribute to this. 'Proportionality' refers to whether the interest to be served by the research outweighs the drawbacks and risks of the research for the fetuses and pregnant women involved in it. 'Subsidiarity' means that it must not be possible to achieve the aim of the research in a less invasive way (with fewer drawbacks and risks), with research that does not have to involve fetuses or, if this is impossible, using less invasive procedures.

Drawbacks and risks

'Drawbacks and risks' refers to negative consequences that the research might have for the fetus or the pregnant woman. Depending on the nature of the research, the fetus can be at risk of death or developmental damage, the future child may be in danger of handicap or disease, and the pregnant woman may be exposed to stress and risks associated with interventions of varying invasiveness, health effects caused by medication (such as anti-arrhythmics) targeted at the fetus, miscarriage, premature delivery, side effects of medication administered to prevent premature delivery, hospitalisation, Caesarean section, obstetric complications, pulmonary oedema, and an increased chance of obstetric complications in subsequent pregnancies. There have been no reports of maternal death as a consequence of fetal therapy.

The requirement in the Embryo Act that the interest of the research must outweigh the drawbacks and risks to both the fetus and the woman is essential.[1] It first serves to emphasise that research with fetuses is also inevitably research with pregnant women. Second, it prevents the advance creation of a conflict between fetal and maternal interests.

Fetal stress and pain

The drawbacks and risks that must be avoided as far as possible also concern fetal stress and pain. Until the 1990s the fetus was treated as if it could not experience pain. Research into stress reactions when treating neonates has changed this. Pain is a subjective experience and cannot be objectively measured, but neonatal and fetal stress reactions that may indicate pain can be so measured. In the case of the fetus, the question is from what point onward can the fetus experience pain. It is accepted that the neuro-anatomical structures and connections needed for this are not present before the third trimester.[40,41] This does not answer with certainty the question of whether a fetus at that stage of development actually experiences pain when it produces stress reactions.[42] However, on the basis of this hypothesis attention is paid to preventing possible fetal pain during intra-uterine procedures. As it cannot be ruled out that the fetus may feel pain, this is a reason for protecting the fetus against pain. Furthermore, there are indications that stress or pain reactions in the fetus may have long-term consequences for the development of the sensitivity of the nervous system:

> It is becoming increasingly clear that experiences of pain will be ‘remembered' by the developing nervous system, perhaps for the entire life of the individual.[43]

It is therefore in any event in the interests of the future child that fetal pain should be prevented as far as possible. General anaesthesia during pregnancy is risky, and so is rarely used except in the case of open surgical procedures. It is still insufficiently clear what the most effective and safe methods are for preventing fetal pain in minimally invasive endoscopic procedures.[40] It must be borne in mind that pain relief is itself also a form of fetal drug treatment, the longer-term consequences of which are often insufficiently clear or have not yet been investigated.

Research that may also benefit the fetus or the future child

Article 20 of the Embryo Act states that scientific research with fetuses is only permitted if it

> may contribute to the diagnosis, prevention or treatment of serious conditions in the fetus in question and that cannot be postponed until after birth.

The first part of this formulation means that only 'therapeutic' research is acceptable: research that may in any event also be beneficial to the development of the fetus or the health prospects of the future child. The background to this is the consideration that the fetus is not itself in a position to give consent, as is also the case with research involving children and incapacitated adults.

Room for non-therapeutic research with fetuses?

This restriction has recently been the subject of debate. It is pointed out in the Embryo Act evaluation report that the protection of fetuses is stronger on this point than that of incapacitated individuals under the WMO,[44] which allows non-therapeutic research involving incapacitated individuals in the context of 'group-based' research that presents negligible risks to the individual to be involved in the research and where the drawbacks are minimal (WMO Article 4). Why is it not possible to also make space under the same conditions for non-therapeutic research with fetuses, provided that it complies with the other aforementioned general requirements? 'Group-based' would then mean that the research cannot be performed otherwise than without fetuses. This kind of research is prohibited under the current wording of the Embryo Act, whereas it could provide important new insights with a view to improving prenatal and perinatal care. This also includes biomedical knowledge that can contribute to the further development of fetal therapy, including the natural course of fetal diseases and conditions.

The Embryo Act evaluation report refers to the room allowed for such research in the Additional Protocol concerning Biomedical Research of the European Convention on Human Rights and Biomedicine (CHRB). Article 18 of this protocol states that non-therapeutic research during pregnancy is acceptable if 'the research entails only minimal risk and minimal burden'.[45] This is also the criterion contained in recent American regulations: ('risk to the fetus (...) not greater than minimal').[46]

It has in the meantime become clear that the Embryo Act needs to be amended in this respect. Once the Central Committee on Research involving Human Subjects (CCMO) had indicated in its annual report for 2007 that this was indeed a real problem, the Secretary of State agreed that 'in any event, room (will) be created for risk free scientific research' (TK 27 428 no. 110). This qualification ('risk free') connects directly to the report by the CCMO of an observational ultrasound investigation affected by the prohibition in Article 20 that could be carried out 'without any risk' to the fetus. The procedure involved counting the number of coils in the umbilical cord. The aim was to conduct a prospective study to ascertain whether there was a relationship between an abnormal number of coils (too many or too few) and a greater chance of perinatal death.[47] Research of this kind will therefore be permitted in the Netherlands in the future. However, if 'risk free' is to be the new criterion, then the room for non-therapeutic research with fetuses will remain very limited. It will be smaller not only than it is in the aforementioned protocol to the CHRB and American legislation, but also smaller than if the WMO criterion of 'negligible risk' had been used. The question is whether the new criterion is not too strict, even if it is only because completely theoretical risks can never really be completely excluded.

One possible reason for not following the WMO here is expressed in the previous Opinion of the Secretary of State on the evaluation report. She stated here that the stricter conditions for research with fetuses

> (are) of course inspired by the wish to offer the unborn as much legal protection as possible, more protection in fact than minors and incapacitated individuals have under the WMO (TK 30 486 no. 3).

However, the 'more' is morally and legally dubious. For what reason would the fetus deserve more protection than a minor? How can this be reconciled with the fact that humans only acquire subjective rights at birth (see 2.2)? Does the fetus then deserve more protection than the pregnant woman? Might this not lead to highly undesirable outcomes in the event of conflicting interests (see Chapter 5)? That is why this also makes it seems reasonable to adopt the WMO wording ('negligible risk') during the proposed revision of Article 20, as was also argued in the evaluation report.

‘Delaying until after birth may not lead to a better prognosis’

The meaning of the final words of the current formulation of Article 20 of the Embryo Act ('and that cannot be postponed until after birth') is not entirely clear. Does it mean that only experimental therapy that can save the life of the fetus is acceptable?[44] The Memorandum of Explanation states that the research '(must) in the specific case be therapeutic in character, and must be a now-or-never choice', and refers in this context to the advisory report produced by the Health Council in 1990 (TK 27 423 no. 3). However, this advisory report contains a different statement, i.e. that treatment during pregnancy can only be acceptable if there is reason to expect that the intervention will lead to a better outcome than will postnatal treatment. It is not enough that a disease can be successfully treated prenatally, or a defect can be successfully corrected prenatally. If there is no prospect of a better eventual health prognosis than in the

case of treatment after birth, then experiments during pregnancy are not justified, as a result of the greater risks and also the need for the pregnant woman to take part.[1]

This is thus not so much an additional requirement (as suggested in the Memorandum of Explanation) as a clarification of the condition that the research must also be capable of benefiting the fetus or the future child. These latter words of Article 20 are also interpreted in this way in the Opinion of the Secretary of State on the evaluation report: 'if the intervention to be investigated improves the prognosis of the fetus if it takes place before birth, then the requirement is met' (TK 30 486 no. 3). In the meantime, it has become clear that this will often be difficult to assess in practice, specifically because of the uncertainties that still surround experimental intervention. The Health Council's advisory report addresses the matter in this way,

> If there are no alternatives and the prognosis [if treatment is delayed until after birth] is bleak, i.e. there is a high chance that the fetus will die or be severely handicapped, then it may be justified to accept the risks of the experimental procedure.[1]

The question of whether the first applications of a fetal intervention that has only been tested on animals are likely to be of benefit to the fetus or the future child, besides providing information on safety and efficacy, is a difficult one. If this is not the case because the uncertainties are still too great, or if (just as with phase I and II drug trials) it would always be wrong to regard such research as therapeutic, then the inevitable conclusion is that it may not be carried out on fetuses and must therefore not be performed. This was also the conclusion of the Health Council's 1990 advisory report, at least as far as it relates to the more risky procedure of open fetal surgery.[1]

In the discussion of the acceptability of the risks of experimental fetal therapy, a strong emphasis is often laid on the difference between lethal and nonlethal fetal conditions.[38] In the case of lethal conditions, there is a high to very high chance of the fetus dying before or around delivery if treatment is delayed. A small chance of an advantage (in terms of survival or a better postnatal prognosis) should then be sufficient to justify interventions with a large risk of fetal death. After all, the death caused by the intervention does not make the eventual outcome any worse than it might have otherwise been. In contrast, most untreated fetuses with nonlethal conditions survive. In this case, a greater chance of the fetus dying as a result of the procedure is an important reason to refrain from the procedure.[8]

Fetal death is, however, not the only risk that counts. Other important questions are what the consequences (for instance, premature birth caused by the procedure) might be for the health of the surviving children, and what risks (apart from the loss of the fetus) face the pregnant women taking part in the research. As far as these considerations are concerned, there is (of course) no difference between lethal and nonlethal conditions.

Furthermore, fetal survival is not necessarily a better outcome than fetal death (as a consequence of the condition or because of a decision to terminate the pregnancy). In their discussion of research into fetal gene therapy, the British ethicist and obstetrician Noble and Rodeck remarked that,

> It is tempting to conclude that a fetus should be given a 'chance for life' (...)• This runs on the concept that any chance of life is better than none. However, a partial success in such cases might lead to greater prolonged suffering in the offspring and greater psychological and socioeconomic burdens on the parents.[19]

3.4 The pregnant woman as a test subject

The pregnant woman can be a subject in medical research that is focussed primarily on her own health or that is – as discussed in this monitoring report – mainly investigating the healthy development of the fetus.* In both cases, the research can only be carried out with her explicit written consent and she, as a potential subject, must be given beforehand all the information that is needed to allow her to come to a well-considered decision as to whether she wants to take part. The information must be balanced and give a realistic picture of the possible advantages and disadvantages both for herself and for the fetus or the possible future child. The information must be given in such a way that it is 'reasonably certain' that she has understood it properly.

Sufficient time for reflection must be allowed as necessary for her to come to a well-considered decision. However, there is little opportunity to give this time for reflection in the acute situations that often arise in this context. Good information is important as well as adequate counselling. In the complex considerations that may be at issue here, the pregnant woman must be allowed to take a decision that is in line with her own values and ideals (see further Chapter 4).

Under recent American legislation, it is also necessary to seek the informed consent of the father in the case of decisions relating to research that can only provide a direct benefit to the fetus (and that is to this extent not also carried out for the benefit of the mother).[38,48] Of course, it is still the case that the research cannot be performed without the pregnant woman's consent, but this does give the father a clear voice in the decision-making process. This right is expressly not conferred in the Embryo Act. Although it is his child that is involved, and in most cases the pregnant woman herself will take his views into account, the procedure does – as is emphasised in the Memorandum of Explanation (TK 27 423, no. 3) – take place via her body and so it is only from her that consent must be requested.

* The former type of research with pregnant women comes under the WMO in the Netherlands, while that latter comes under the Embryo Act. In her Opinion on the evaluation of the Embryo Act, the Secretary of State has indicated that both types of research may be brought under the WMO in the future. (TK 2006-2007, 30 486, no. 1).

The Embryo Act does (in Article 21, clause 2) offer the option of deputising consent (by parents, legal representative or partner) in the case of pregnant women who are incapacitated. This is in line with the rules on other forms of medical research with incapacitated individuals (WMO, Article 4). If the pregnant woman is not able 'to reasonably judge her interests in the matter', she cannot be involved in scientific research unless the research may also benefit her (or, in the case of non-therapeutic research, under the conditions referred to above).

The perspective here is therefore clearly on the interests of the pregnant woman and not those of the fetus or the future child, expect where that coincides with the interests of the pregnant woman. That means that this Article can never be used to involve a incapacitated pregnant woman in scientific research purely by appealing to the interests of her unborn child. Only when it is clear that participating in this research is also in her own interests, having regard to the ratio of advantages and disadvantages that this would entail for herself, can it be carried out on the basis of deputising consent.

It is important to emphasise this, because the broader context of this statutory Article (research with fetuses) might suggest the opposite reading. Moreover, the Memorandum of Explanation insufficiently takes the edge off this suggestion. It states therein that 'it (may) be undesirable in connection with the therapeutic nature of the research that the research is not carried out, solely because the pregnant woman in question is incapacitated' (TK 27 423, no. 3). Therapeutic here means: (also) in her interests.

3.5 Prospective comparative research

Comparative research, if possible in the form of randomised controlled trials (RCT)*, or if this is not possible with alternative designs that are as strong as possible, is necessary to determine the value of new interventions. Relatively little such research has so far been carried out in the field of fetal therapy. This is true both for surgical interventions and drug treatments.[3,32] Since a trial carried out with the support of the National Institutes of Health (NIH) in the 1990s demonstrated that open surgical correction of congenital diaphragmatic hernia (CDH) was not better than the standard postnatal treatment, there has been an increased awareness of the importance of such research. Deprest's group in Leuven conducted consecutive trials investigating the possible benefits of a less invasive endoscopic method of treating CDH for a strictly defined 'poor prognosis' group.[49] Also from the Netherlands pregnant women are referred to Leuven for this treatment, which is still regarded as experimental. The successful introduction of laser treatment of twin-to-twin transfusion syndrome was possible as a result of the favourable outcomes of a large European randomised trial.[50] An RCT has been taking place since 2003 in the United States into the value of intra-uterine treatment of spina bifida (performing open fetal surgery to close the neural tube defect). The NIH is also funding this trial. An impor-

* In a prospective comparison, the health outcome – in terms of death, disease or quality of life – in an intervention group are compared with those in a control group that has undergone the standard treatment. In a randomised trial, the participants are randomly allocated to the intervention group or control group.

tant motive was to put an end to the uncontrolled performance of this experimental procedure in a growing number of American centres.[51] The trial aims to compare the outcomes of prenatal and postnatal repair of the neural tube defect up to one year after delivery. Primary endpoints include fetal death and the need to insert drainage tubes to prevent hydrocephaly, but the study also looks at motor development and intelligence.[51]

The initiative has also been taken to clarify, via a randomised trial, the value of endoscopic insertion of shunts for a blocked bladder outlet.[52] As the MTA monitoring report states, recruitment for this latter trial is slow.[3] This is one of the problems of research in this field: the rarity of many of the conditions and the often large variation in the syndrome can make it difficult to set up a study of a sufficient size in order to show a significant difference in outcome for what is moreover often a highly selected patient group. It is therefore always important that all centres performing the procedure do so in the context of the study.[32,53] This requires cooperation at the European level.

Acceptability of clinical trials

The first CDH trial was a non-randomised prospective comparative study. The researchers considered randomisation to have been unjustified and stated that, 'the ethical considerations and highly personal decisions surrounding fetal surgery preclude a prospective randomised trial'.[54] In an earlier publication they discussed the need for a study design 'that minimises the ethical and emotional problems of assigning or withholding a potentially life-saving fetal treatment'.[55] In a randomised trial, chance determines which participants receive the experimental intervention and which receive the standard treatment (control group). Is this morally problematic? Only if it were clear in advance which treatment is better. But in that case, all comparative research would have to be abandoned, not only randomised trials.[56]

A somewhat different point is that researchers may themselves be so convinced of the superiority of the intervention they have developed that they see any trial only as a way of proving this to the outside world. If this is also the implicit message to the potential female participants, it can then become rather difficult to explain that participation might mean them being assigned to the control group. But this touches not so much on the ethics of the trial design as on that of responsible information and counselling when recruiting participants for the research. Care must also be taken with the term 'therapy' in the case of research into the value of fetal interventions. This term can incorrectly rouse the suggestion that this value has already been established.[19] For the same reason, it is desirable that healthcare professionals who are responsible for handling the pregnancy should not themselves be involved in the trial.

As a matter of fact, it may be too soon or too late for a clinical trial. So long as little is known about the safety and efficacy of a new treatment, it is not acceptable to withhold the standard treatment from trial subjects.[19,57] But it can also be too late. If the delay is too long, a new treatment may have become so established in regular care that everyone assumes, also without sound scientific foundation, that it is better than what was until then regarded as the stand-

ard. It is then very difficult to get a trial off the ground, even if the basis of this consensus is and remains very thin. The uncontrolled way in which various forms of fetal drug therapy have been introduced in practice has, according to Koren *et al*., led precisely to this situation, and this has had the consequence that it is difficult to obtain proper answers to important questions about the efficacy of various pharmacotherapeutic fetal treatments.[3,52]

Clinical trials and abortion

If pregnant women taking part in a trial in this area decide, for whatever reason, to terminate the pregnancy, this leads to a loss of data. It is, for example, then no longer possible to compare the outcomes of prenatal and postnatal treatment. Of course, it cannot be expected from pregnant participants to continue with the pregnancy, come what may. But could this problem perhaps be dealt with by only asking pregnant women who have said in advance that they are opposed to abortion to take part in the research? It is debatable whether this approach is necessarily in conflict with the principle of respect for autonomy.[57] Nevertheless, a situation can easily arise in which pregnant women who take part in the research feel under an obligation towards the researchers to continue with the pregnancy.[19] Chevernak also refers to an opposite scenario in his discussion of this question. In this scenario, one of the criteria by which female participants would be recruited is their intention to abort a fetus with serious handicaps caused by the procedure.[57] Of course, the point here is not to prevent loss of data but to prevent the birth of a child that would have to life with serious health damage as a consequence of the research. Here, too, there is the potential danger that the pregnant woman's room to take her own decision as to whether or not to continue with the pregnancy would be restricted beforehand.

Selection for participation on the basis of abortion preferences must be excluded on moral grounds. Both selective abortion and the birth of handicapped children must be regarded as 'endpoints' of the trial. It must be stressed in counselling that the pregnant woman's participation in no way detracts from her freedom to decide herself (within the limits of the law) whether to continue with the pregnancy or to terminate it.

Long-term follow-up

As was also emphasised in the MTA monitoring report, long-term follow-up of children who underwent fetal treatment is an important condition for careful development of this area. Not only is it vital to see whether fetal therapy leads to better outcomes in the immediate perinatal period; this follow-up must also investigate the possible impact on the further development and health of the child in question. This chiefly applies to more or less invasive forms of fetal surgery. A major problem in practice is that it is often difficult to find funding for such follow-up research. This is also the experience of Dutch researchers.

It is correctly emphasised that research must look not only into the consequences for the children but also the consequences for the woman, both in the shorter term (after the procedure) and in the longer term. Examples include physical consequences of invasive treatments, such

as complications in subsequent pregnancies, but also the longer-term psychosocial impact.[8,58]

3.6 Accepted treatment

When can fetal therapy be offered to pregnant women as accepted treatment? According to Noble and Rodeck, the following conditions must in any case be met: 1) there is a reasonable certainty that the fetus will suffer irreparable and significant damage without the intervention; 2) the intervention has been proved to be effective; 3) the risk to the health and well-being of the pregnant woman is negligible; and 4) the pregnant woman can give consent to the intervention in an appropriate manner.[19] These conditions are in line with the Health Council's earlier report, except with regard to the requirement of negligible risk. According to that report, accepted treatment

> (…) must be able to guarantee a therapeutic success with not excessively great risks to the pregnant woman and the unborn child, and the prenatal intervention must be preferable on medical grounds to interventions carried out after birth.[1]

Negligible risk to the pregnant woman does indeed appear to be an unnecessarily strict requirement in the case of a mentally capable woman who can decide herself to accept certain risks in order to protect the fetus (her future child) from irreparable and significant damage. It seems hard to argue that she should not be able to make such a choice or that physicians should not cooperate with it. Live kidney donation is an analogy, where the donor also exposes him or herself to a more than negligible risk in the interests of treating another person. Of course, this does not mean that the extent of the risk to the pregnant woman is irrelevant simply provided that she 'has given consent in an appropriate manner'. Fetal therapy that exposes her to disproportionate risk is morally and legally irresponsible, and can form no part of the professional standard.

4 Cautious decision-making

As is emphasised in the MTA monitoring report, the complexity of fetal treatments requires a multidisciplinary approach by an entire team of specialised experts who accompany not only the treatment itself but also the period before and after treatment. In addition to the woman's gynaecologist, these would include experts in neonatology and, depending on the nature of the condition, genetics, paediatric cardiology, paediatric neurology, and so on.

Multidisciplinary consultation between the concerned disciplines is often necessary in order to answer the question of whether fetal treatment in a specific case should be medically preferred to possible alternatives, such as postponing treatment until after birth or sometimes also having the child born prematurely so that it can be treated outside the uterus. The possible treatment, any alternatives and their likely consequences are, of course, discussed with the pregnant woman and her partner (the expectant parents). The aim is a cautious decision-making process wherein all involved parties are engaged.[59,60] The most important normative aspects of this decision-making process are discussed in this Chapter.

4.1 Multidisciplinary assessment: various perspectives

The team assessing a situation will first weigh up the medical facts: the nature of the condition and its expected course; the therapeutic options both before and after birth; the advantages and disadvantages of alternatives; and the eventual prognosis. This medical focus does not detract from the fact that moral or philosophical assumptions play an important role in all these deliberations.[61] For example views on how much protection the fetus deserves, and the meaning of pregnancy, parenthood, handicaps, and so on.

These views can be coloured by, in addition to factors such as experience and personal history, the specialism in which the physician was trained as a medical practitioner. In her research into the development of fetal therapy in the United States, referred to above, Caspar found that gynaecologists and obstetricians looked at the possible advantages and disadvantages of fetal interventions mainly from the point of view of the pregnant woman, while neonatologists tended to concentrate first of all on the interests of the fetus or the future child.[7] A study into the views of the Medical Ethics Committees of the (American) professional associations of both disciplines appears to point in the same direction ('subtle but telling differences').[62] One of the advantages of a multidisciplinary approach is that it prevents a moral

'monofocus'. However, the difference in perspective referred to here can also give rise to differences of opinion that cannot be resolved simply by appealing to the medical facts.[7]

For that matter, a Dutch study into multidisciplinary perinatal decision-making found no systematic differences between the views of the representatives of the disciplines involved (including obstetricians, neonatologists and paediatricians).[59] The researchers noted that the participants had already been working together in the team for a prolonged period, which may have contributed to the formation of a common 'language'. It is precisely here that the value of a multidisciplinary approach may then lie. In addition, the researchers wrote that the team also has an educational function, whereby young clinicians from various disciplines are initiated into this common language and shared perspective.[59]

In her investigation of decision-making practices in British multidisciplinary fetal medicine units[63,64] Williams emphasised that this type of shared perspective is not necessarily free from blind spots or one-sidedness. She found a strong focus on the interests of the child, shared by the whole team, and much less attention to the pregnant woman and what the intervention might or might not mean for her. In the words of one of the obstetricians interviewed: '... the discussion is very fetus oriented and there is little mention in those discussions ever about the mother'.[63]

Research into the attitudes of professionals is important because it challenges the practitioners concerned to account for the fact that they are guided not only by medical knowledge but also by normative assumptions and perspectives. It is particularly important for practitioners to reflect on their own role and their own perspective precisely where complex decisions in a morally sensitive area are concerned.

This is just as much the case for a more general aspect that can play a role in this context: the urge felt by practitioners to be able to do something in every case. This imperative just to do something may be a factor in the team's eventual preferred option when the alternative to fetal intervention is often taking no immediate action but waiting to give treatment after birth, and with an often real chance of prenatal death of the fetus. Borrowing a phrase from the noted sociologist Parsons, Williams speaks of 'medically ritualised optimism' and a bias in favour of active intervention.

4.2 Information and consent

As fetal therapy always also involves a procedure on the pregnant woman, her consent is necessary. Written consent is required for all scientific research (see 3.4).

The physician treating the pregnant woman has the responsibility of providing her with the information that she needs to take an independent and well-considered decision on the proposed treatment. Besides being sufficient, this information must also be balanced and com-

prehensible. As it is her body that is involved, it is the pregnant woman – and she alone – who can consent to the performance of a fetal treatment, and it is therefore also to her that the necessary information must be provided. This does not detract from the fact that she will in most cases want to take this decision together with the father of the future child, and that he will in most cases also feel strongly involved.[58]

Sufficient information

The information provided to the pregnant woman (and her partner) regarding possible fetal therapy must relate to

— the nature of the treatment: drugs, surgery, degree of invasiveness;
— its purpose: preventing intra-uterine death, improving the health prospects of the future child;
— the possible advantages and disadvantages, both for the pregnant woman herself and for the fetus or the future child (in the case of a twin, as with twin-to-twin transfusion syndrome: for both fetuses or children), also in comparison with
— possible alternatives, which in many cases might be postnatal treatment. Termination of pregnancy may be an alternative to be considered and so also discussed, depending on the values and philosophy of the pregnant woman (and her partner).

Under the Medical Treatment Agreement Act (WGBO), the healthcare professional is required to be guided by what 'the patient should reasonably know' when providing information. The common interpretation of this criterion is that it refers to what 'a reasonable person in the given circumstances can be expected to consider before taking a decision'.[20] Among other things, this moves away from the idea that all available information must be given about the aspects mentioned, if this would be possible at all. However, it does not mean that the physician may ignore the specific information needs of the individual patient, insofar as this is different from or goes beyond what a 'reasonable person' would want to take into account when deliberating.[65] In the light of the great complexity of fetal therapy, including from a moral and emotional standpoint, the physician can be expected to actively ascertain whether the information is in fact sufficient for the involved persons, taking account of their specific situation (prior history, capacity) and views on life.

Balanced information

The information about advantages and disadvantages of the proposed treatment must be balanced, including in the light of the pros and cons of any alternatives. The possible advantages (reduction in mortality and morbidity) may not be presented as greater than they are, and the disadvantages (inconvenience and risks for the pregnant woman and the future child) may not be trivialised. Unbalanced information makes it difficult for the pregnant woman to take an independent and well-considered decision.

Comprehensible information

Finally, a well-considered decision requires that the provided information is comprehensible. In contrast to the WMO, which deals with information provided to potential medical research subjects, this aspect is not explicitly covered in the WGBO. It does, though, state that the patient must be given information 'in a clear manner'. Jurisprudence shows that the healthcare professional is (to a certain degree) obliged to ascertain whether the information has actually been understood.[66] This particularly applies in the case of information that is needed for a decision on which much may depend for the involved individual, which is usually the case with fetal therapy. Leaving time for reflection, which is also not explicitly referred to in the WGBO but is contained in the WMO, is also part of the care provided by a good healthcare professional in such cases. However, the opportunity to do this is also dependent on the sometimes extreme time pressure under which decisions as to whether or not to start fetal therapy have to be taken.

4.3 An emotionally loaded and complex consideration

The pregnant woman and her partner (the expectant parents) are confronted with information about chances and risks at an emotionally loaded time. In most cases, they have only just heard that something is wrong with their child. If the mother's prior history (for example, immunisation in a previous pregnancy) or the family history (for example, congenital metabolic diseases in the family of the pregnant woman or her partner) was a reason for prenatal research, this should (to a certain extent) have prepared them. But the news more often comes as a complete surprise, for example, if abnormal findings in a pregnancy check up or an abnormal echogram led to prenatal diagnosis.[67] This kind of bad news often comes relatively late in the pregnancy. It was recently discovered that the introduction of the standard ultrasound examination (SUE) around 20 weeks has led to a larger number of serious abnormalities detected in the second trimester, and also to a larger number of pregnancy terminations because of a fetal defect in the period between 20 and 24 weeks.[68] This means that the expectant parents have already made a significant emotional investment in their child. The information that the pregnant woman or the couple then have to process is wide ranging and complex, whereas a decision often has to be made under time pressure.

As the MTA monitoring report shows, treatments are available for some fetal conditions that entail minimum risk for the pregnant woman or the future child and that can improve the prognosis so greatly that the choice is not difficult. Examples of this include intra-uterine blood transfusion and some forms of drug treatment. In many other cases, the pregnant woman (and her partner) are faced with a more complex deliberation. The desired outcome is a child born alive with the best possible health prospects. Some pregnant women or couples make take the view that fetal therapy that increases the chances of survival, but cannot necessarily prevent some of the surviving children being disabled, is not necessarily a better option than abortion (if this is still possible) or taking no action for the time being, with death as the eventual result. If the procedure involves surgery, there is also the risk of premature rupture of the

membranes and premature birth, and so the procedure itself could lead to perinatal death or neurological damage. Decisions are therefore often taken in uncertainty, even with accepted treatments. In the case of a twin pregnancy, another factor is that the effect of the treatment is not necessarily equally good for both fetuses. Where laser treatment is carried out for twin-to-twin transfusion syndrome featuring unequal sharing of the placenta between the twins, it may lead to one fetus being saved but the other dying.

The uncertainty over the ratio of advantages to disadvantages is still greater with experimental forms of fetal therapy. One example is fetuses with a blocked urinary passage outlet.[3] This condition can cause serious damage to the lungs and kidneys. If no action is taken, the infant will often die immediately after birth as a result of pulmonary hypoplasia (underdeveloped lungs). Fetal treatment consists of inserting a drainage tube (vesico-amniotic shunt). This procedure is carried out a few times a year in the Netherlands, but it is not certain whether the treatment can lead to a greater chance of healthy survival.[52] In this situation, some couples will want to try everything to save their child's life, even if there is a strong chance that it would then face a life of illness and handicaps. Others will take a different decision for that very reason, and decide not to undergo treatment or to terminate the pregnancy.

4.4 Challenges for counselling

In complex decision-making situations such as these, the healthcare professional or the team can be expected to do more than simply provide information about the possible advantages and disadvantages of the treatment and possible alternatives. Good medical care here also requires that multidisciplinary support, tailored to the individuals asking for help and their situation, be offered to help the pregnant woman and her partner decide on a course of action (counselling). This support must be available as often as the expectant parents need it. Sufficient time must be set aside for this, and the provided information should ideally be confirmed in writing shortly afterwards. This puts a heavy burden on the entire perinatology team.

Non-directive counselling or joint decision-making?

The support in question is far from simple, not only in technical and logistical terms. Developing a responsible counselling practice in this context is a major challenge in normative terms as well.[69] In the case of fetal therapy, decisions sometimes have to be made that require a non-directive attitude on the part of the healthcare professional, but sometimes the choices are such that he or she can be expected to play a part in the deliberation process.

The former is the case when the pregnant woman and her partner are faced with the question of whether or not they want to terminate the pregnancy in view of the severity of the conditions found to be affecting the fetus. This is and must remain a highly personal decision for those concerned. This is why the tradition of counselling in clinical genetics and prenatal diagnosis has always strongly emphasised the ideal of non-directivity.[70] This means that healthcare professionals must, as far as possible, avoid imposing their own moral views on the involved indi-

viduals. It must, of course, be borne in mind here that non-directivity in the sense of completely 'value-neutral' counselling is an illusion.[71] Furthermore, the ideal of non-directive counselling does not imply that the practitioner must do no more than offer purely technical information about chances and prospects.[72] Non-directive counselling can also involve helping the patient (here the pregnant woman and her partner) to understand and interpret the information in the light of her own views, and to reach an independent, well-considered decision on the basis of this.[73] This approach is in line with the recent emphasis in reproductive counselling on making an 'informed choice' possible, where 'choice' is understood as a broader term than 'consent'.[74] An informed choice is only possible if the decision matches the values and ideals of those concerned.

But, the field of fetal therapy often involves decisions that are similar to the choices that parents and physicians can face in neonatology: decisions as to whether or not to carry out treatment, with consequences that can be far-reaching in terms of the quality of the child's subsequent life. As healthcare professionals bear their own responsibility for the well-being of that child (next to that of the parents), it is understandable that the aim in neonatology is not non-directive counselling but joint decision-making. This process must be based on an investigation of the values at issue, carried out jointly by the healthcare professionals and the parents, and the implications of various choices in the light of this.

Two different counselling traditions therefore come together in fetal therapy decision-making situations. The tension between these two perspectives is not necessarily irreconcilable, but there is a need for further reflection on the challenges for responsible counselling in this specific area. In which situations must the physician limit his or her action to helping the pregnant woman (and her partner) to make an 'informed choice', and when, because of his or her professional co-responsibility for the well-being of the future child, is it responsible or even desirable for the physician to make an active contribution? A closer ethical analysis of this area of tension is needed.

As decision-making about fetal therapy is directly connected to moral and philosophical views, the increase in cultural and religious diversity also poses an important challenge to counselling. Offering adequate decision-making support to pregnant women and couples from very different backgrounds requires not only engagement and empathy, but also knowledge of these backgrounds and the outlooks on life that can be associated with them.

The pregnant woman and her child

One of the aspects of the challenges to counselling in this field is recognising what is described in Chapter 2 as the essential connectedness between the pregnant woman and her as yet unborn child.[8] The terminology used is already an important point for consideration. Technically and legally, one is speaking of a fetus until birth, but the pregnant woman (and her partner) finds this a detached term that does not necessarily match her (their) own experience. The pregnant woman is likely to talk about her baby or her child, and so lends an emo-

tional, relational and also moral significance to the life growing in her abdomen.[75] Various researchers have emphasised that being able to see the fetus on an echogram is a significant trigger for this kind of investment of meaning, and that as a result (in a certain sense) the birth takes place socially before it takes place biologically:

> For many women it is the first time they relate visually to the living fetus inside – and intermittently, co-relate that imagery with their own intensely intimate bodily sensings of the fetus growing in them.[76]

Many expectant parents feel the dependence and vulnerability of the future child, already present, as a call for care and protection, especially if something appears to be wrong with the fetus. This is confirmed by the aforementioned research among pregnant women in specialised fetal medicine units in the United Kingdom and the experience of American counsellors in a centre where experimental fetal surgery for spina bifida is carried out.[64,76] Pregnant women attending these centres showed a high degree of willingness to expose themselves to considerable risks for even a small chance that this might save the life of the child (the fetus) or, in the case of spina bifida, that it would improve the health prospects of the child after birth. The cited publications show that many pregnant women and couples feel a strong urge to be able do something rather than nothing, especially if they have already decided that they do not want to terminate the pregnancy. The feeling that they do after all have a choice, and can still exert some influence over the emergency situation that has arisen for them and their child, is an important motivating factor for them.

It is repeatedly shown in the cited publications that many pregnant women are prepared to set themselves aside for the benefit of the fetus, that this can easily be abused (even with the best intentions), and that the counsellor has the task of protecting the pregnant woman against this by inviting her (and her partner) to look clearly at the choices facing her (them) in the light of her (their) own experiences, values and ideals. The role of 'heroic mother' who will naturally make any sacrifice for her child must never be imposed on her. Rather, the counsellor must be alert to the pressure that pregnant women can feel to do what her circle expects of her in this respect.

5 Conflict situations

Healthcare professionals and pregnant women will often be in agreement as to what the best decision is in the given situation: delaying treatment, performing fetal therapy, or – if this is the choice of the pregnant woman – termination of the pregnancy. If this agreement does not exist, this does not necessarily have to lead to a conflict situation. If the physician thinks that fetal therapy would be irresponsible in a particular case, a pregnant woman who wants to have the therapy carried out despite this can ask for a second opinion, but will otherwise have to accede to that decision. Reversing the situation, it may be that the pregnant woman decides to refuse a treatment option proposed by the physician or the team. The healthcare professionals must then accept this. After all, the situation affects her body, her child, and her view on advantages and disadvantages that are often impossible to objectively compare. But this is not the final word in exceptional cases. It can sometimes be thought that the pregnant woman is wrongly refusing a proposed fetal treatment and consequently failing in her duty towards the future child in a serious manner. This can only be the case if she does not choose to terminate the pregnancy (or if this option is no longer available). Furthermore, the type of fetal therapy that she has rejected must be an accepted treatment that is known to be capable of preventing considerable and irreparable damage to the fetus, without exposing the pregnant woman herself to serious risk. The fact that these are (to date) exceptional situations when described in terms of these conditions, does not eliminate the question of what can and should be done when they occur. Can the pregnant woman be put under pressure to undergo treatment against her wishes in the interests of her future child? Or is it perhaps even the case that this must be done? In addition to pressure, is compulsion also permitted or necessary?

5.1 Appealing to the pregnant woman's responsibility

Good parenting does not start only at birth. Expectant parents have a moral responsibility towards their future child during pregnancy and even before (think of preconception advice to couples wishing to have a child), and healthcare professionals can appeal to this if necessary.[11] Might this not also mean that they must consider, or even have to accept, certain forms of fetal therapy (that meet the conditions set out above)? The damage to the fetus that would be prevented must be damage that has direct consequences for the health prospects of the future child. If the procedure only leads to a reduction in intra-uterine death, then it does not serve the interests of the future child, although such a procedure may of course be indicated in the interests of the pregnant woman herself.

Fetal therapy as a moral duty?

According to Beaufort, the fact that the child depends entirely on the pregnant woman for his or her (future) well-being means that it deserves more protection 'with a view to later' than is often given in practice.[77] But does it also follow from this that the pregnant woman has a positive duty to do everything that is necessary to protect it from harm, even including undergoing a medical intervention? Following on from Thomson's famous 'In defence of abortion', this is problematic.[78] The physician, the expectant father and others in the pregnant woman's circle also have the duty in their relations with her to ensure that they cause no damage to the future child. For the pregnant woman, on the other hand, the burden of causing no damage, in view of what she must give up to this end, is incomparably greater than that of all these other parties. In her article on abortion, Thomson concluded that even if the fetus were a person deserving complete protection, it does not necessarily follow from this that the pregnant woman is under an obligation to that person to continue with the pregnancy. It could be argued in the same way here that the responsibility of the pregnant woman towards the future child does not, of course, also include the duty to undergo fetal therapy.[79]

But (as Thomson emphasises) another important issue is whether or not the pregnant woman has accepted responsibility for the creation of the dependency relationship that now presents her with a moral challenge. By deciding to continue with the pregnancy and so to give the as yet unborn child an existence, the pregnant woman makes herself responsible for its (future) well-being. Under certain circumstances (serious and irreversible damage to the future child, effective intervention, low risk) this means that she has no good reason to refuse fetal therapy.

Directive counselling

The classic example of successful fetal therapy is intra-uterine blood transfusion for red cell allo-immunisation. The combination of a very poor prognosis if treatment is delayed and the strong chance of a healthy child if blood transfusion is performed have led to this treatment becoming standard care.[3] The poor prognosis to be prevented includes not only intra-uterine death but also severe neurological damage in surviving children. Not performing the intervention means that the child has a high chance of brain damage if he/she is born alive. As the risks of the procedure both to the fetus and to the pregnant woman herself are low, it can be argued that the pregnant woman has a responsibility here. This is a responsibility that specialist healthcare professionals not only may, but even must remind her of. Directive counselling is then indicated.

Other examples of fetal therapy of which the same may be said include administration of corticosteroids for imminent premature delivery between 25 and 34 weeks, and administration of antiviral or antiparasitic medication.[3] The situation is less clear when it comes to the use of laser beams to seal vascular anastomoses between fetuses in the case of twin-to-twin transfusion syndrome. This is because, even though this procedure has been proven to be useful, the uncertainties are greater.

Much better survival rates here are associated with what is still a considerable percentage of serious neurological abnormalities (despite better neurological outcomes in surviving fetuses).[80] It therefore does not seems self-evident that the pregnant woman would be failing in her responsibility if she were to decide to continue with the pregnancy without undergoing this laser treatment. Of course, the extent of the risk for the pregnant woman is also an issue. The risk is greater with treatment for twin-to-twin transfusion syndrome than with intra-uterine blood transfusion.[3]

Moral acceptability of pressure and compulsion

Directive counselling is a form of pressure. As such, it is the first step in a continuum that runs from rational exertion of influence via limiting choices to physical compulsion. Measures from this spectrum ('pressure and compulsion') can be justified if the criteria of efficacy, subsidiarity and proportionality are met. Appropriateness (or necessity) refers to the probability of the goal being achieved. In this case, the goal is to prevent serious health damage in the future child without thereby exposing the fetus or the pregnant woman to serious risk. Subsidiarity means that the least invasive effective measures in the spectrum of pressure and compulsion must be chosen, and proportionality means that there must be a reasonable relationship between the end and the means.

In the context of fetal therapy, could there be situations in which, apart from directive counselling, more far-reaching forms of pressure, or even compulsary treatment, would be justified? As fetal therapy of whatever kind involves interfering with the physical integrity of the pregnant woman (this also applies to drug therapy), treatment against her will is, to say the least, problematic in view of the criterion of proportionality. But does this mean that interference of this kind in the interests of the future child can never be justified?

Fetal distress at full term is a well-known example from perinatal care. The only way of preventing serious damage caused by lack of oxygen is a Caesarean section performed at short notice. Imagine that the pregnant woman refuses this procedure, even after being strongly urged to agree. Can a compulsive Caesarean section then be acceptable? In view of the strong interest that the child would have in not being born handicapped, and the low risk to the woman when set against this, then it seems that this cannot be automatically ruled out from an ethical point of view. Should this then not, in principle, also apply to forms of fetal therapy with the same ratio of advantages and disadvantages for the future child and the pregnant woman? One important difference is that there is, as a rule, much greater uncertainty as to the expected outcomes of fetal therapy, even in the case of accepted treatments. The greater this uncertainty is, the more difficult it is to justify compulsion (or strong pressure).

5.2 Legal justification of pressure and compulsion

An intense debate is currently taking place on the question of whether pressure and compulsion to protect the health interests of the as yet unborn child can be legally justified as well,

mainly in the light of a few recent court judgements. These judgements relate to preventing prenatal health damage to fetuses as a consequence of addiction or mental impairment in the pregnant woman. In some cases, partly on the basis of the broader interpretation of Article 1:2 of the Civil Code discussed in Chapter 2, it was decided that certain child protection measures, such as a temporary guardianship or a temporary supervision order, should be introduced even before the child was born.[81] These measures allow compulsory instructions to be given to the expectant mother (such as undergoing the necessary checks by a midwife/gynaecologist, checks in connection with the addiction, and stopping drug use).[81,82]

In another judgement, the Court of Amsterdam decided that an addicted pregnant woman must be admitted to a psychiatric hospital because her mental impairment put the unborn child at risk. The court's view was that it was unacceptable to withhold protection from the child until after its birth, as it needed this protection earlier. However, the Psychiatric Hospital Special Admissions Act (BOPZ) states that a patient suffering from mental impairment can only be admitted by compulsion in order to prevent danger to him/herself or another person. By way of deviation from the conventional view whereby a human being only forms part of the legal community from birth (see 2.2), this judgement regards 'the unborn fetus' as 'another person' in the sense of the BOPZ.[83]

As an extension of this debate, the question arose of whether compulsary treatment of an addicted pregnant woman could be acceptable.[84,85] This involves not merely a restriction of freedom but also a violation of physical integrity. The WGBO permits this only if the pregnant woman is mentally incapacitated. Furthermore, the treatment must be necessary in order to prevent serious disadvantage to herself (Article 7:465 clause 6 of the Civil Code). Interests of third parties, as might be the case for the as yet unborn child, are insufficient grounds to apply compulsary treatment, something that is perceived as a problem in practice in the provision of care to this specific group.[84,85] Furthermore, it is possible that pressure or compulsion might cause a woman to avoid contact with healthcare professionals during any subsequent pregnancies. This would be a perverse effect that needs to be taken into account in this debate.

Compulsary treatment of mentally capable pregnant women?

The debate on pressure and compulsion in the case of addicted or mentally impaired pregnant women relates to a completely different context than that involved in decisions about fetal therapy. Again, one difference is the greater uncertainty as to the desired positive outcome. As has already been said, the degree of this uncertainty is one of the factors that may or may not justify pressure or compulsion. Another crucial difference is that the women involved are usually mentally capable. The paternalistic view that it is also in the interests of the pregnant woman herself to have a healthy child cannot therefore be a valid argument justifying compulsary treatment. A procedure of this type would therefore seem to be legally impossible in this context. After all, compulsary treatment is at odds with the requirement for consent that is enshrined not only in the WGBO (Article 7:450, clause 1, of the Civil Code), but also in Article 11 of the Constitution, which protects physical integrity. A preg-

nant woman may also present arguments based on other articles of the Constitution and international conventions in which the right to privacy and physical integrity is laid down.[21] In the Manual of Health Law, Leenen *et al*. concluded that there are no legal grounds for undermining the physical integrity of a mentally capable pregnant woman:

> Pregnancy does not undermine the rights of the woman. The interests of the fetus are subordinate to the rights of the woman. If the woman does not agree to fetal treatment, then the woman's freedom means that it must be accepted that no treatment is possible'.[20]

Still, this is not the only view that is being expressed in this debate. Some authors believe that a violation of the rights of the woman can (perhaps) be defensible in exceptional cases.[21,86] Kalkman-Bogerd formulates this cautiously: though it appears under current law that the pregnant woman cannot be coerced to undergo certain treatments in the interests of the unborn child, a different conclusion might be reached 'if the basic rights can also be considered as applying to the fetus'.[21] She does not rule out the possibility that this might be the case, and refers thereby to Article 2 of the ECHR ('right to life'; see 2.2). If a claim can be made on the basis of this Article with regard to the viable fetus,

> then right to life of the fetus can come into conflict with the rights of the pregnant woman, and the judge would have to weight up the interests on both sides in order to decide which right should, in the circumstances of the case, take precedence.[21]

Compulsary treatment could be a conceivable outcome of this deliberation in exceptional circumstances. The case would have to involve a life-threatening situation for the viable fetus that can effectively be resolved by an intervention that involves only a limited violation of the rights of the pregnant woman.

The judgement of the European Court referred to in Chapter 2 (Vo vs. France) does not support the reading of the ECHR that underlies this. Forder consequently states that the Court missed an opportunity to 'protect the interests of a party that does not have the opportunity to defend his or her own interests'.[87] Very recently, Kottenhagen, referring to the opportunity left to Member States by the Court to define the status of the fetus in more detail, argued that Dutch law offers enough grounds for the view that the pregnant woman has a legally coercive duty to offer adequate care to her as yet unborn child. He takes the view that the law must recognise that the viable fetus is a 'full human being' and that there can therefore be 'conflicts in rights between mother and unborn child'.[21,23]

Three lines of reasoning

To summarise, there are three lines of reasoning in the legal debate over pressure and compulsion in pregnancy. According to the first of these, measures aimed at preventing prenatal health damage that limit freedom can never be justified as the person whose interests would eventually be affected does not yet exist. Therefore, there are no legal grounds for taking such measures to protect these interests.

The second line of reasoning does attempt to create some room for this by taking the well-established legal status of the viable fetus as a starting point. After all, the interests of the child that is to develop from this fetus are at issue here. Furthermore, the viable fetus, though it is not yet itself a person, is very close in its development to the moment – birth – at which it will eventually become a person. The law recognises this by giving the viable fetus at this stage a legal status whereby the pregnancy can, in principle, no longer be terminated. In the light of this legal status, it could then be strongly argued that the interests of the child that will result from the fetus should be protected even prior to birth. In order to make this possible, existing legislation (Article 1:2 of the Civil Code, BOPZ) is interpreted broadly, as was the case in the court judgements cited above. This jurisprudence has so far dealt only with protecting the future child against possible damage caused by the lifestyle or behaviour of an addicted or mentally impaired pregnant woman.

The status of the viable fetus is also the starting point for the third line of reasoning, put forward by Kalkman-Bogerd[21] and Kottenhagen[23] among others. The difference is that these authors are not addressing the future interests of an as yet non-existent person, but the current interests of the fetus itself, including its interest in possible (life-saving) medical interventions. Both authors see an opportunity for weighing up the rights of the pregnant woman and of the fetus. Kalkman-Bogerd sees an opportunity of granting the fetus some legal protection on the basis of Article 2 of the ECHR (right to life), which would mean that certain forms of compulsary treatment of the pregnant woman (such as administering blood or medication) might be permissible in exceptional cases. Kottenhagen takes Article 1:2 of the Civil Code as a basis for permitting compulsary treatment in the interests of the fetus under certain circumstances.

5.3 Need for further discussion

Insofar as an opportunity is seen in the legal discussion summarised briefly above for prenatal protection measures, these are limited to the period of viability (pregnancy of 24 weeks or more). In the second line of reasoning described above, this limitation arises from the fact that the status of the viable fetus is used as a starting point for measures intended to protect the future person. In the third line of reasoning, the same restriction arises from the fact that the fetus already has, from the point of viability, its own vital interests that deserve protection. Neither of these arguments provide any justification for measures being taken earlier (before the viability threshold has been reached). After all, arguing for this would imply that the fetus has the legal status before becoming viable that, under the doctrine of progressive legal protection, is only attributed to it after that point. As has been noted in this context, this would immediately lead to conflict with abortion law.[20,81] A second, separate argument for limiting this to advanced pregnancies could furthermore be that the limitation on freedom contained in measures of pressure and compulsion must not last for longer than is strictly necessary (criterion of proportionality).[21]

However, limitation to after 24 weeks is problematic from the point of view of protecting the interests of the future child,[84,85] as damage to the fetus with consequences for the health of the future child can arise earlier in pregnancy. For example, it is the first trimester that is the critical period for fetal abnormalities caused by exposure to alcohol. If the aim is to prevent such damage to the child of an addicted pregnant woman, then protection after 24 weeks is too late, and so is automatically inappropriate and disproportional. The same could apply to any fetal therapy, as not all such treatments can or must only be carried out after 24 weeks. In fact, it is likely that treatments will in future be more often carried out in the early stages of pregnancy (for example: drug treatment of immunological or genetic conditions).

This raises an important challenge for further debate. Why should the ability to take account of the interests of the future child be dependent on the status of the fetus? It makes no difference to the future child at what point during the pregnancy any health damage that he/she now has to live is caused. Does the law really offer no opportunity to protect these interests earlier in pregnancy as well, if this is necessary? Why could not Article 1:2 of the Civil Code (‘The child with which a woman is pregnant is regarded as having already been born wherever its interests require this') also be used as an argument in the event of imminent harm in early pregnancy? In brief, the question is whether or not a fourth line of reasoning is possible, in which damage to the health interests of the future child can of itself be a sufficient reason for any measures involving pressure or compulsion, subject to the conditions referred to above (necessity, subsidiarity, proportionality). If the status of the fetus does not need to be considered here, then there is no reason to fear that abortion legislation could be undermined.

6 Policy issues

For healthcare professionals and practice

Fetal therapy should, wherever possible, be developed in the context of well designed prospective scientific studies focused on obtaining data on the efficacy and safety of new treatments. Administering innovative but as yet unproven therapies can be justified under certain conditions in *ultimum remedium* situations (including informed consent of the pregnant woman), but needs to give way to application in the context of research as rapidly as possible. It is vital to ensure that pregnant women do not become 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 trial centres, something that is increasingly happening.

Essential elements for responsible future development of the field include 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.

Preventing fetal stress and possible fetal pain must be an important point of interest.

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. The MTA monitoring report published last year argued for the development of a quality standard for the entire trajectory, expressing what is currently regarded as best practice.

Counselling is an important aspect that would certainly have to appear in this quality standard. Putting the pregnant woman (the couple) in a position to make a truly informed choice is a challenge that should not be underestimated. Furthermore, some of these choices (termination of pregnancy) require healthcare professionals to be as non-directive as possible in their attitude, while in the case of some choices this would be too meagre an approach in view of their co-responsibility for the well-being of the future child. Normative reflection is needed on the possible tension between these two perspectives and what the best way of dealing with it in practice might be.

A key aspect for counselling is the strong bond of sympathy that many pregnant women feel with their fetus. Even though the disease or developmental defect for which they have sought medical help affects the fetus, not themselves, this does not (in their perception) make the fetus a separate patient whose treatment they may or may not facilitate. 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 is there a reason to protect her from expectations imposed from outside?

On the other hand, it cannot be excluded that there may sometimes be very good reasons to clearly remind a pregnant woman of her responsibility. In this context, an example might be if a pregnant woman would fail in her duty towards her future child if she failed to undergo a proposed fetal treatment. The treatment in question must be acceptable, i.e. one that has been shown to be able to save the fetus from significant and irreversible damage without exposing the pregnant woman to a serious risk.

For government and society

Preclinical animal research is important so that it can be determined whether the step to humans 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 controversial.

One problem encountered in practice (though not only in the context of fetal therapy) is that it is not easy to find funding for follow-up research among women and children, although all parties concerned agree that such research is very important.

In response to the Embryo Act assessment, the government has announced that it intends to review the prohibition on non-therapeutic scientific research with fetuses in Article 20 of the Embryo Act. It has been suggested in parliamentary debate that the proposed relaxation must remain limited to research that is 'without any risk' to the fetus. The question is whether this requirement is still too strict. It might be possible to follow the principle of 'negligible risk' applied for non-therapeutic research with children and incapacitated adults.

The search for a tenable normative framework for protecting the future health interests of the unborn child has been going on for some time. The debate on this topic is complex, especially in legal terms. A small number of legal judgements have used a broader interpretation of existing legislation in cases of pressure 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. The debate on this matter has been conducted on the assumption 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 medical interests of the unborn child are adequately protected by this approach.

The question of the justification of compulsive perinatal or prenatal interventions (Caesarean section, fetal therapy) arises as an extension of this debate. Compulsary treatment would appear legally problematic because most of these cases involve mentally capable pregnant women. However, the question of whether room should be created for this is under discussion. Some authors argue from the principle that a viable fetus has certain rights that must be weighed against those of the pregnant woman. The debate could perhaps be posed in terms of a less controversial argument: the unborn child's interest in good health. Closer reflection is desirable on the question of whether, and to what extent, the law can allow for this interest and what this might mean for pressure and compulsive options in this area, also with regard to the prevention of developmental damage in a fetus that is not yet viable. After all, from the point of view of the interests of the future child, it is not important when such damage occurred, but whether it could reasonably have been prevented.

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Annex 1

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