

THE FETUS AS A PATIENT

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The Fetus as a Patient

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Edited by

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Foreword

Remarkable achievements in perinatal medicine in the last 20–25 years have benefitted many fetuses and newborns, mostly through the accurate diagnosis of their well-being. However, we all have been waiting long for prenatal diagnosis to be accompanied by therapeutic plans. The real progress of direct fetal therapy and surgery begins with introducing real-time ultrasonography. The potential for direct therapy of some fetal diseases has opened up a new era in perinatal medicine, and it is not overstating the fact to say that the fetus has become a patient. Treatments vary from indirect mode through the mother to direct manipulation of the fetus, including surgery. Fetal therapy, in fact, may represent one example where treatment is indeed prevention. It is therefore understandable that these recent therapeutic developments have received much attention by both the medical profession and the lay public. It was time for the experts from this youngest branch of medicine to reflect on the impact of fetal therapy on their own practice and society's response to them. Therefore the first international meeting was organized by the Medical Academy of Croatia in Sveti Stefan, Yugoslavia, from which selective papers are printed in this volume. For me it was a real pleasure to edit the proceedings; but without great help of Mr Uchida, and my secretary, Mrs Vesna Balijsa, this work would have been difficult.

Asim Kurjak

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Fetal therapy: ethical and legal aspects

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Our ability to diagnose fetal birth-defects has achieved considerable sophistication. However, new scientific knowledge and resultant technologies create complex ethical dilemmas for society. Society has a critical stake both in the successful treatment of fetal disorders and in the maintenance of respect for the human dignity of the fetus. Therefore, fetal therapy raises not only scientific issues but also ethical and legal ones which challenge many of our traditional concepts of the fetus. The availability of therapy for a defective fetus will cause more questions to be raised in the public conscience about who the fetus is. This complex problem may be considered from the point of view of beginning of human life, present attitudes towards early fetal life, some moral considerations, the problems arising from embryo transfer, the legal status of the unborn child, and fetal therapy.

THE BEGINNING OF HUMAN LIFE AND ITS ASSESSMENT IN UTERO

In spite of the tremendous scientific advances in the world today, when, where, and how life began has still not been conclusively established. Some authors say that in fact life as such does not exist – no one has ever seen it. Szent-Györgyi says that the noun 'life' has no significance, for there is no such thing as 'life'(1). Le Dantec holds that the expression 'to live' is too general, and that it would be better to say that a dog 'dogs', or a fish 'fishes' than that a dog or fish lives (1).

Be that as it may, a definition of life should include not only life as it is today, but as it might have been in its primordial form and as it will be in the future. That is to say, all present forms of life are the fruit of an uninterrupted continuity from its very inception. Not a single form of life appears as something completely new: life, then, is transferred, and not conceived in each new generation. Human life is no exception. Both the female ovum and the male sperm are human cells. Their merging (fertilization) is not the begin-

ning of human life, but just one, exceptionally important step in its continuity. True, the product of fertilization, the fertilized ovum or zygote, is a new form, but it is still not a new individual either by scientific or by general standards. This ovum still lacks any of the essential characteristics attributed to man. It does not have the rudiments of a central nervous system, nor does it react even to the simplest of stimuli.

Life, in the true sense of the word, begins when the chemical matter gives rise, in a specific way, to an autonomous, self-regulating and self-reproducing system. Life is connected with a living being, and it creates its own system as an indivisible whole. That is to say, it has individuality. Living beings transform matter, i.e. they create their own substance from matter obtained from outside, just as they break it down. The organism demonstrates a certain sensitivity in regard to some aspects of self-regulation. One of the most important characteristics of living beings is their reproduction, which is also connected with the inheritance of certain features (1).

Although the substance of living beings is composed of the same elements as make up inanimate nature, living beings have a specially complicated system of matter, such as does not exist in inanimate nature. Living beings demonstrate variability, individual development and harmony. It is exactly this individuality that constitutes one of the most essential characteristics of the human being. It includes bodily features, special behavior and the capability to recognize and adopt. These characteristics gradually develop into human fetuses.

Obviously, the problem is not that of determining when actual human life begins but when the value of that life begins to outweigh other considerations such as the health or even the happiness of the mother. There is essentially no difference between euthanasia (terminating the life of a sick person) and teratothanasia (terminating the life of a malformed fetus), because in both cases life has been interrupted. Neither euthanasia nor teratothanasia have been legalized in any country in the civilized world, yet hundreds of pregnancies with malformed fetuses are interrupted annually. In mentioning all these problems, the authors wish only to point to the great need for international and multi-disciplinary consideration of this very delicate area (2).

Assessment of life in utero

The idea of a life in utero is by no means new. The Chinese, for example, have always considered themselves to be nine months older than their European cousins. The Ancients believed that in each ovum or sperm there was a complete but tiny adult. They imagined that the body and soul came into simultaneous existence at the time of fertilization. The theologians, however, introduced the idea that, in utero, we first existed in a pre-human, embryonic form, and subsequently after entrance of the soul we developed into the human fetus with which most people are familiar. Hippocrates believed that the entrance of the soul into the male fetus occurred on the thirtieth day of in-

trauterine life. It entered into the female fetus on the fortieth day. Actually, this idea was a considerable improvement on the scheme found in the Book of Leviticus, where it is suggested that the soul does not enter even the male fetus until the fortieth day, and does not enter the female until forty days after that.

With the development of embryological science, embryologists found themselves unable to confirm the notion that life in utero was divided into a pre-human and human era. Like the Ancients, they could discover only a continuum after fertilization. It now seems paradoxical that, for centuries, this idea of a continuum protected the early human fetus from violation by the unscrupulous until we, in our wisdom, saw such a liberalization in pregnancy termination.

The poets would have us believe that life in utero is a haven of peace and quiet, and that birth is equivalent to 'paradise lost'. But this is not so. We have our being there just as much as in the world we remember.

From the modern researches of Sir William Liley, it is now clear that the uterus is not even a sound-proof box (1). The noise of the maternal heart and the rumblings of the maternal gut produce as much sound as a busy high-street. It has been estimated that the sound level in utero may be as high as 90 decibels.

Nor is the uterus completely dark. Though the developing baby may not see objects distinctly, the light intensity within the uterus has been likened to the glow which appears through the cheek when a torch is placed inside the mouth.

It is also clear that the baby can taste the liquor which surrounds it. If chemicals are put into the liquor to render it bitter, the child swallows much less. By contrast, when the liquor is made sweet with saccharin, the child drinks much greater quantities.

The remarkable individuality which we develop at an early stage of our intrauterine existence comes about by the wonderful integration of a series of complicated events. This beautiful intrauterine conformity, however, is subject to the malevolence of disease and chance, just as much as in life after birth. In fact, because of our vulnerability in utero, after pregnancy and delivery we are not again subject to such risks of mortality until our old age.

In our view, the Chinese are correct. Life does not begin with birth. When born, we are already nine months old, and it is precisely because intrauterine life and neonatal existence constitute a continuum that medicine has a responsibility to learn how to study the life in utero, and subsequently how to care for it.

WHAT ARE THE MORAL ISSUES

Morals are the practice of ethics; and ethics are the principles which govern man's duty to his neighbor. Included in such principles are the concepts of natural and civil rights.

Natural rights

One remarkable feature of modern history has been man's struggle to make manifest certain fundamental rights and freedoms which are so intimately connected with his nature that to be separated from them would deprive him of a portion of his humanity. These natural rights are based on the idea that from conception, man has an inherent worth, an intrinsic dignity, a certain independence. He has an equal right to life, to liberty, to security of person, to freely exercise his mind, and to pursue contentment. These natural rights are independent of time, race, culture or social development. Moreover, from these rights of being, from the rights of mind, from these fair, just and due entitlements of all conceived individuals, no man has the natural right to exclude another without his prior consent.

Civil rights

Less fundamental than natural rights are man's civil rights. Society depends for its survival upon an ordered liberty of the individual. Implicit in this concept are freedom from fear and from want, freedom of speech and to worship, and numerous basic cultural freedoms, including the right to be educated, to be safe within society, to work, to participate in the culture of life and to share in its scientific benefits. To safeguard such civil rights man has evolved the idea of civil liberties. These are the natural consequences of man's concern for every member of the human family, and civil liberties usually appear as the products of just government.

Concern for fetal life

Concern for fetal life has been expressed certainly since the time of Hippocrates. In the Hippocratic oath it is written that "I will not give a woman a pessary to produce abortion". Here concern is expressed not only for a potential human life but also for a human life which can not protect itself. In 1948 as mankind considered the horrors of a second world war, the Declaration of Geneva proclaimed: "I will maintain the utmost respect for human life from the time of conception". However, present attitudes to early fetal life can be divided into three different categories.

(i) There are those who consider the early fetus merely an organ of the mother and not a living human being. It has only those rights guaranteed to it by its mother and no moral problem arises, in regard to its removal. This view is obviously unjustifiable as it is not based on the nature of early fetal development. It takes no account of natural rights.

(ii) There are those who consider all forms of human life, including fetal life to be supreme. From the moment of conception, the fetus is a full human being with the same rights and same value as a baby at birth. This attitude

accepts only one view of fetal life, considering all individuals as equal whether they be born or unborn.

(iii) The view most commonly held is that a fetus is a potential individual, and that this potential increases throughout pregnancy to become actual at birth. This opinion accepts that there may be times when fetal life is less important than other issues. In this context, fetal life would be presented as a phenomenon which, though it be of secondary importance on occasion, always has a value which should not be underestimated.

THE ABORTION ACT IN THE UNITED KINGDOM

English law has, through the ages, fostered a similar concern for fetal life. In addition in 1837 a change in the law was proposed whereby a doctor would not be punished who, in good faith, undertook abortion to save a mother's life. This amendment was adopted in 1929. Law case *Bourne v. Rex* (1938) ultimately poured further testimony to a still more enlightened legal field regarding abortion (3).

However, so far as the unborn individual is concerned, there is conflict about the time from which he is entitled to enjoy his natural rights and the time from which he should be subject to the control and benefits of civil liberties. We should like to discuss this conflict from the point of view of the unborn child. The three aspects we shall consider are: (a) the interpretation of the Abortion Act in the UK; (b) the rights of the unborn child to seek redress for injuries sustained in utero; and (c) some legal problems associated with embryo transfer.

It is comforting to think that in the UK an Abortion Act exists which legally permits a pregnancy to be terminated when there is a risk of a child being born abnormal. By contrast, it is disturbing to realize how infrequently the Act is used to avoid the problem of handicap. To put the case into perspective, it is said that in the UK one child suffering from cerebral palsy is born every eight hours and 1000 children a week are born with some form of handicap. Restricting the situation to fetal abnormalities only, the incidence of significant malformations at birth is of the order of 20-30 per thousand. Nevertheless, of the 100,000 or so pregnancy terminations performed annually in the UK slightly less than 1 per cent are performed for fetal abnormality. The reasons for this are well known. Currently, less than one-third of all fetal malformations are amenable to detection; metabolic disorders may not become apparent until after birth; and the facilities for antenatal detection of handicap may fail, be too insensitive, or may simply be unavailable.

The minority of cases which are detectable are important, and for every child found to be abnormal it is estimated that another 30 will receive reasonable reassurance of normality. This, too, is important. Such attempts at prenatal diagnosis, however, are attended by legal problems for both the abnormal and the normal child.

To remind you of the situation in the UK, the Abortion Act of 1967 legally

permits a pregnancy to be terminated when continuation of the pregnancy would be more dangerous than abortion, to the mother's life, to the mother's health, and to the life or health of the existing children; also, if there is a risk of fetal abnormality. In each of these four cases the degree of unacceptable risk is not specified. Furthermore, in the case of fetal abnormality, before termination is legally justifiable, account must be taken of the corrective measures which could be offered to the child after its birth in order to provide it with a life of reasonable quality. All these matters are open to wide medical interpretation, and unfortunately the Law offers the doctor little guidance.

A further problem arises from the methods used to detect fetal malformation. The results of such tests are sometimes not available until the fetus is at least 20 weeks of age or even older. In England, the late detection of fetal abnormality can be further aggravated by a mother who fails to attend the clinic in early pregnancy.

Late pregnancy termination poses a legal problem in England. This is related to the three documents already mentioned. The Abortion Act of 1967 is already described. This Act, however, must operate in relation to the earlier Act of 1929 called the Infant Life Preservation Act. In summary, this earlier Act states that "Any person who, with intent to destroy the life of a child capable of being born alive shall be guilty of child destruction". A proviso confirms that when it is necessary to kill the fetus to save the mother's life, the operation may be considered legal: and it may be that a court would construe life to include cases where there was a very serious risk to the mother's health.

The relationship between the Infant Life Act of 1929 and the Pregnancy Termination Act of 1967 is important in English law. In particular, it is stated that nothing in the Abortion Act shall affect the provisions of the Infant Life Preservation Act. Thus, when in 1967 parliament declared the four reasons for pregnancy termination, it was also saying that once a fetus is capable of being born alive, the only justification for termination is saving the mother's life.

The phrase "capable of being born alive" does not mean viable (i.e. capable of survival), nor does it mean 28 weeks mature. The legal fact is, therefore, that whenever a fetus is capable of being born alive, procuring abortion for reasons other than saving the mother's life is to be considered child destruction, and illegal. Plainly, with the advance of modern medical techniques the fetus is capable of being born alive at earlier and earlier age. Therefore, the potential for the crime of child destruction is expanding, at the expense of what might otherwise be lawful abortion. Perhaps this situation needs legal modification.

There is one further implication of the phrase "capable of being born alive". It is immaterial whether the child is born alive or dead. If, in late abortion, a doctor employs a technique to ensure that the child will be born dead, it is automatically conceded that the doctor knew he was dealing with an infant capable of being born alive. By willfully acting to cause the child to

die before birth – in a non proviso case – the doctor becomes guilty of the crime of child destruction. The law regards feticide just as seriously as the crime of homicide.

If we turn now to the fetus which is born alive but which dies thereafter, it is self-evident that no matter how premature it may be, the child was capable of being born alive. In such an instance, it may be imagined that child destruction can hardly be alleged against the doctor, but this is not the case. If the doctor meant the child to die while in utero but the child survives only to die when fully born, in law two crimes have been committed. Firstly, the doctor has committed the crime of "attempted child destruction", as this is what he originally intended. Secondly, he has committed the crime of actual homicide because the death of a human being has been achieved. Perhaps this situation too, needs some modification.

However paradoxical it may seem, the legal situation is absolutely clear. A doctor who turns a safe uterine existence into a hopelessly premature human being is liable to be charged with homicide unless he does everything in his power to support the child's life after birth. The presence of gross fetal abnormality does not alter this. Even then the question of attempted child destruction remains.

To emphasize the medical importance of the present situation, the Medical Committee under Justice Law stated in 1974 that

"It is unlawful for termination of pregnancy to be carried out by a method which destroys a fetus capable of being born alive, even if its chances of survival are slight or non-existent, unless this is done in order to preserve the life of the mother. If a live and apparently viable fetus emerges from the termination there is a statutory duty to try and keep it alive, however unwanted or abnormal it may be, and for the mother and child to be cared for by a midwife for ten days.

Further, if, after delivery, a fetus shows signs of life an offence is committed if its birth and death are not registered or if it is incinerated elsewhere than in a crematorium".

It is surprising that, in recent occurrences which have reached the press, doctors, hospitals and even health authorities in England seem to be in ignorance of the Infant Life Preservation Act of 1929. The only legal proviso which justifies child destruction is saving the mother's life. Fetal abnormality, or the risk of fetal abnormality, is not a proviso.

The third legal document which is of importance in the UK is the Law Commission Report on Injuries to Unborn Children. In essence this publication makes it clear that although the child in utero is not invested with legal rights, when born alive the child can bring an action retrospectively in relation to its intrauterine existence. Of course, a fault must first be proved, usually the fault of negligence and a direct cause, and effect must be shown between this fault and the substance of the child's complaint.

In practice the obstetrician has no need to be alarmed by this law so long as he acts with reasonable care and has due regard to the received professional opinion applicable to the particular class of case. Two examples will help to illustrate this point.

An obstetrician now prescribing thalidomide for a mother would undoubtedly be in trouble because there is a known cause and effect between this drug and phocomelia. Also the fault of negligence could easily be proved. By contrast, an eye injury caused, perhaps, by amniocentesis is unlikely to result in a successful legal action. The cause-and-effect relationship even if proved can hardly be the result of negligent practice when there is no received professional opinion to indicate how such an accident might be avoided.

Finally, we should like to turn to the problem associated with embryo transfer: this too has implications for fetal abnormality. In 1978, Steptoe and Edwards (10) announced that they had re-implanted in a woman an ovum which had been fertilized under laboratory conditions and that delivery of a normal child had been the successful outcome. Since that time, it has become clear that an ovum donated by one woman may be fertilized and re-implanted into a second woman. The legal issues raised by such a procedure could be analyzed through three different aspects. In the first situation the biological mother, that is the donor of the egg, is married to the father, but the fertilized ovum is implanted into a host mother. In the second situation, the egg from the biological mother is fertilized by the husband of the host mother. In the third situation, the egg from the biological mother is fertilized by a male who is not married to either the host or biological mother.

In each example the question is the same: who would the law regard as the mother of the child? Very probably the answer would be the woman who gave birth to the child, that is, the host mother. However, this will create a number of legal problems. For example, the host mother may not register the child in accordance with the wishes of the biological mother. The host mother may refuse to hand back the child to the biological mother or the biological mother may refuse to accept the child if it is malformed. If a malformed baby is detected early enough by means of ultrasound, there may also be disagreement about termination of pregnancy.

Obviously, we have reached a strange social situation when motherhood – with all that term implies for the child – is probably to be determined not only by nature but by the law or even by general agreement between two women. Undoubtedly, the problems arising from embryo transfer are complex and if they are to be resolved, doctors need to play a prominent part in legal reform. This will necessitate informing themselves of what the present law says and pressing for improvements which they believe to be necessary. Here, international cooperation would be of tremendous importance.

In conclusion, it seems fair to say that the present state of affairs is unsatisfactory. Many people are uncertain of the law, and although the law itself is reasonably clear, it is in need of urgent reform to take account of the modern facts of life. In particular, it is important to clarify the problems sur-

rounding late termination of pregnancy and to ensure that both the Abortion Act and the Infant Life Preservation Act are consistent with regard to protecting the embryo and fetus.

A meeting of the kind which is being held here is obviously invaluable in this regard.

LEGAL STATUS OF THE UNBORN CHILD AND FETAL THERAPY

Following on from the above considerations is the problem of the legal status of the unborn child. Thanks to modern technology, especially to real-time ultrasound, we now have proof that human life begins much earlier than we believed. The criteria for the beginning of life, therefore, should not be taken as the day of birth as specified in Roman law but from the time the fetus is able to exist independently. However, with the advance of modern medical techniques, the fetus is capable of being born alive at an earlier and earlier age. The crime of child destruction is, therefore, expanding at the expense of what might otherwise be lawful abortion. Obviously, this situation needs legal reconsideration. Such reconsideration should make it clear that although the fetus is not invested with legal rights, when born alive the child can bring an action retrospectively in relation to its intrauterine existence. Of course, a fault must first be proved, usually the fault of negligence, and a direct cause and effect must be shown between this fault and the substance of the child's complaint (3).

A further problem arises from the introduction of techniques for antenatal diagnosis. These techniques are complex and require considerable expertise. If a mistake is made and the child is born with a serious deformity, are those individuals who carried out the tests likely to be the subject of litigation?

There is still doubt whether a child with an injury caused before birth by someone's negligence can sue for damages. A baby may be born and survive in an injured condition after damage caused in utero by surgical procedures. The injury may be evident at birth or become so in childhood or not appear until adult life. If the fetus has the right to sue, obstetricians will face a fresh risk of action for damages for negligence in the treatment given to a pregnant woman either for her benefit or for the benefit of the fetus.

There are also a number of other problems. For example, what if high-risk patients are told of the possibility of amniocentesis and ultrasound examinations, but for religious or other reasons take no action. Would they have any defence against an action by an affected child? Where negligence, by an operator during amniocentesis, for example, causes harm to the fetus, the operator would be liable. Where the mistake results in an existing defect being missed he would not, but in this situation the parents themselves might have a case.

While medicine is international, law is not, and different countries have different laws. However, there are at least four universal problems. These are:

injury to the mother, death of the fetus, non-fatal injury to the fetus and failure to diagnose a defective fetus.

In daily practice, it is important to differentiate between three levels of malformation: (i) incompatible for any type of independent life; (ii) malformation requiring the life-time aid of another person; and (iii) malformation correctable by minor surgery or physical therapy. The first problem depends only on the decision of the mother. There should be no dilemma since in the interest of the family, a child incompatible for life should not be born. Opinions vary in the second case since this type of malformed child can have a relatively normal life after habilitation. The third case causes the greatest dilemmas as to whether the pregnancy should be terminated or not.

We believe, therefore, that a team should be responsible for the decision to interrupt a pregnancy. In Zagreb, our group of professionals has been working as a team for the last four years. We meet to make the final diagnosis which we then discuss with the mother or parents. We have worked with about 1000 patients in this way, and the information we have collected will be presented in a separate paper (2).

Some problems associated with embryo transfer should also be taken into account. In this procedure an egg is removed from an ovary, fertilized with sperm and surgically implanted in the uterus. Is the newly fertilized egg, incubating in its Petri dish, a person? What sort of legal obligations does that place on the technician who examines it for its suitability for implantation? Fewer than 15% of implanted embryos actually develop to term. Have the rest been murdered?

The majority of scientists, however, found research on early embryos acceptable, but some legal protection of the embryo is essential. It was recently recommended that research may be undertaken on embryos within a time limited to 14 days from fertilization, beyond which period it would become a criminal offence. The 14-day limit was chosen because primitive streak appears at 14 days and establishes whether the embryo will develop into a single identity, or twins, triplets, or more (4).

Fetal therapy

Fetal therapy raises complex ethical questions about the rights of the mother and fetus as a patient (5-7). Is the obstetrician to view the fetus or the mother as his patient? Usually there is no need to make the distinction, but what if the physician believes a procedure, such as fetal surgery, is indicated and the mother refuses to consent? To what extent is the mother responsible by accepting treatment? The life and health of the mother have traditionally always taken priority over that of the fetus if the circumstances of the case reach the extremity of choice. What then is the relation between a child who has been injured in utero by medical treatment and its mother?

Whether we call the fetus a person, a patient, or a fetus, what rights will we accord to it? When will we leave all decisions regarding its health to its

mother, and when, if ever, will we as a society decide to restrict the autonomy of pregnant women for the sake of their fetuses (8)?

Undoubtfully, there is a need for involvement of not only individual patients but also society as a whole in setting rules and priorities for fetal therapy. In the meantime, the responsibility of those undertaking fetal therapy includes an obligation to report to the medical profession all results, good or bad, so that the merits and liabilities of fetal treatment can be established as soon as possible (9).

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