2008

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Legal Studies Research Series, No. 08-18

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September 2008

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ETHICAL AND LEGAL ISSUES IN REPRODUCTIVE HEALTH

Prenatal management of anencephaly

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KEYWORDS

Abortion;
Anencephaly;
Induced birth;
Late-term abortion;
Lawful abortion;
Maternal health;
Termination of pregnancy

Abstract

About a third of anencephalic fetuses are born alive, but they are not conscious or viable, and soon die. This neural tube defect can be limited by dietary consumption of foliates, and detected prenatally by ultrasound and other means. Many laws permit abortion, on this indication or on the effects of pregnancy and prospects of delivery on a woman's physical or mental health. However, abortion is limited under some legal systems, particularly in South America. To avoid criminal liability, physicians will not terminate pregnancies, by induced birth or abortion, without prior judicial approval. Argentinian courts have developed means to resolve these cases, but responses of Brazilian courts are less clear. Ethical concerns relate to late-term abortion, meaning after the point of fetal viability, but since anencephalic fetuses are nonviable, many ethical concerns are overcome. Professional guidance is provided by several professional and institutional codes on management of anencephalic pregnancies.

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1. Introduction

Anencephaly is the most severe of fetal neural tube defects, resulting from failure of the neural tube to close at the base of the skull in the third or fourth week (day 26 to 28) after conception [1], leaving skull bones that usually surround the head unformed. The brain thereby lacks part or all of the cerebrum, and remaining brain tissue is often exposed to injury from amniotic fluid. Stillbirth is a common outcome of fetal anencephaly, but some affected fetuses are born alive with a rudimentary brain stem. However, lacking a functioning cerebrum, they are incapable of consciousness and of experiencing pain, although the brain stem may support

reflex actions such as breathing, and occasionally responses to sound or touch. Anencephalic newborns are not viable or treatable and their survival is usually measured in hours rather than days.

There is a long history of recognition of births, and in less severe cases, survival of grossly malformed products of human conception [2], and the historic Anglo-Saxon (English) Common law recognized them as "monsters," of uncertain human status. The medieval Christian church was in similar doubt, providing no more than conditional baptism, in the terms "If thou art a man, I baptize thee, etc" [3].

The modern incidence of anencephaly is difficult to assess in global terms. In the United States, estimates are variously set as one in a thousand pregnancies or live births. The incidence among live births is more easily determined than among pregnancies because, with prenatal detection, women frequently opt for abortion. In worldwide terms, the incidence tends to appear higher where abortion is

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legally restricted. In recent years, the abortion response to prenatal detection of anencephaly has come under legal challenge particularly in South America, notably in Argentina and Brazil, and recently in Ireland.

The failure of health and legal systems to deal humanely with anencephalic pregnancy was brought to international attention in November 2005, when the UN Human Rights Committee, in the case of *KL v. Peru* [4], condemned the defendant country for its multiple violations of the human rights provisions of the International Covenant on Civil and Political Rights. The case arose when a 17-year-old patient at a Ministry of Health hospital in Lima was diagnosed with an anencephalic pregnancy. Her gynecologist informed her of the risks this posed to her life, and advised termination, to which she and her mother agreed on confirmation of the diagnosis. The law in Peru allows abortion on this indication. However, the hospital's director, though aware of the finding of risk to life written by the hospital's gynecologist, refused the authorization that was necessary for this procedure [5].

The young patient was required to deliver and breast feed her newborn dying baby for the few days it survived, and suffered deep depression psychiatrically found to have severely affected her development and future mental health. The hospital director's callous indifference to the risk to the patient's life and mental health, and of her legal entitlement to termination of pregnancy, implicated the state's responsibility for violations of human rights. The Human Rights Committee found cruel, inhuman, and degrading treatment of KL and further violation of her privacy in obstruction of her lawful means to comply with her gynecologist's advice, and in denial of her adequate legal remedy for violation of her rights.

The Human Rights Committee's 2005 judgment sets the standard by which to measure other responses to prenatal diagnosis of anencephaly.

2. Prevention and detection

Anencephaly appears multifactorial in origin, including genetic and particularly dietary contributory causes. Studies show that a woman who has had one child with a neural tube defect (NTD) has about a 3% risk that a later pregnancy will be so affected, but evidence of hereditary origins is largely indirect [6]. More relevant is a woman's poor or inadequate dietary consumption of folates, such as fortified grains, spinach, lentils, chick peas, asparagus, broccoli, peas, corn, Brussels sprouts, bananas, and oranges. Because NTDs can originate before women become aware that they are pregnant, women are advised to consume foods that are rich in folic acid at least 3 months before they plan pregnancy, and to maintain an appropriate intake when of reproductive age and liable to become pregnant. It is estimated that up to half of all birth defects are preventable if women of childbearing age eat sufficient quantities of food bearing or fortified with folic acid, or by taking vitamin supplements [7]. Rates of NTDs are predictably higher in communities in which women suffer impoverished diets.

When pregnancy is diagnosed, women can be tested for NTDs by different means. Most common now is ultrasound examination, which is widely available in high-income countries and often accessible in larger centers in resource-poor

countries, and can detect absence of upper portions of a fetal head at 12 or so weeks of gestation. At a month or so later, amniocentesis may also show fetal spinal fluid in a woman's amniotic fluid, and maternal serum (alpha-fetoprotein) screening may disclose evidence in a mother's blood stream of leakage from the fetal neural tube.

Ultrasound examination is the preferred means to test prenatal neural tube or spinal status, since it allows for earlier termination of pregnancy if severe abnormality is detected. Maternal serum analysis is only a preliminary screening test, and requires subsequent confirmation of fetal status because it provides a high rate of false positive (and some false negative) results. Amniocentesis is more accurate, and may confirm the result of a serum screening test, but is more invasive than the blood test, involving insertion of a syringe through the uterine wall to withdraw a small volume of amniotic fluid for analysis of fetal cells. The test can show chromosomal or genetic abnormality of the fetus as well as any NTDs, but cannot be undertaken before 14 weeks of pregnancy. Results may not be known, and appropriate counseling be provided, until the middle of the second trimester, when abortion may be more difficult and invasive to undertake.

3. The law on abortion

Many historically restrictive abortion laws have been amended to allow abortion of a fetus that is not viable, or that, if born, would be affected by a severe anomaly incompatible with a significant period of survival. However restrictively worded a fetal health indication for lawful abortion may be, it is certain to be satisfied by a diagnosis of anencephaly, since the condition is inconsistent with viability and a meaningful life. The insensate fetus, capable of feeling neither comfort nor pain and lacking any prospect of survival on birth beyond at most a few days, may not be considered to possess legal rights or interests.

An analogous case in the highest court in England concerned a 21-year-old patient in a persistent or permanent vegetative state. He had suffered severe anoxic brain damage when crushed for several minutes under a crowd, unable to breathe, and relapsed into unconsciousness. He remained capable of spontaneous breathing, but required artificial nutrition and hydration by a nasogastric tube. After three and a half years, the hospital sought leave of the court to withdraw the tube, withhold antibiotic treatment in case of infection, and allow the patient, with his family members' consent, to die. The family court, Court of Appeal, and highest court, the House of Lords, all declared that such death would be lawful. The judges considered that death would not be contrary to his interests and intimated doubt whether, in his permanently insensate condition, he possessed interests in survival. Lord Goff observed that "if the question is asked, as in my opinion it should be, whether it is in his best interests that the treatment... should be continued, that question can sensibly be answered to the effect that it is not in his best interests" [8]. This observation reinforces numerous judgments finding that life-prolonging treatments of severely compromised newborns are not indicated, taking account of their best interests and human rights [9].

Many laws that do not accommodate a fetal impairment indication for abortion allow the procedure to protect a pregnant woman's life, and her physical and mental health. The human rights violation in the KL case rested in part on disregard of the effect on the woman's future mental health of her being compelled to deliver and nurse her anencephalic newborn. There is a history, however, of judicial suspicion of claims of harmful psychological or mental health effects, because of the uncertainty of professional criteria and assessments and of longer-term prognoses, and the ease of simulation for self-serving purposes. Judges, predominantly male, have tended to discount the effects on women's mental health of stressful pregnancy, and their mental anguish, trauma, grief, guilt, and depression, after 9 months of gestation, at delivering a grossly disfigured, dying newborn [10]. The bland supposition that these effects can be resolved by counseling is dismissive and ignorant of a woman's emotional commitment in pregnancy to deliver a child capable of living.

Leading courts have justified legal restrictions on abortion because they protect state and individual interests in the developing fetus as "potential life." For instance, when in 1973 the US Supreme Court addressed the point in pregnancy at which the state's interest in unborn life becomes compelling, Justice Blackmun observed that "[w]ith respect to the State's important and legitimate interest in potential life, the 'compelling' point is at viability. This is so because the fetus then presumably has the capability of meaningful life outside the mother's womb" [11]. Similarly, in the Supreme Court of Canada, Justice Wilson spoke of "the value to be placed on the foetus as potential life" [12]. When a fetus has no potential for meaningful life, because it is unconscious and not viable, the state cannot justify placing fetal interests, or its own, above a woman's interest in safe termination of her futile pregnancy.

Different interests, namely of women requesting terminations of anencephalic pregnancies, of their fetuses, and of their states, are not infrequently raised in the courts particularly of Argentina and Brazil, where women are often required to obtain judicial approval before physicians will terminate their pregnancies. At the close of 2007, for instance, there was heated news media discussion in Argentina because of recent decisions on the scope of abortion under the national Criminal Code. In 2001, the Argentine Supreme Court had ruled, in a leading judgment, that inducing premature birth of an anencephalic fetus, doomed quickly to die, did not offend the abortion law. The fetus had no interest in prolonged gestation, and would die on delivery due to its pathology, not due to any lethal act [13].

The Supreme Court majority referred approvingly to the judgment given by Justice Maier in the court below, the Tribunal Superior de Justicia de Buenos Aires, who divided termination of pregnancy into abortion, meaning termination before 28 weeks of pregnancy and intended to achieve fetal death, and premature delivery, which is induced later in pregnancy and aims to produce a live, even if nonviable, child. This majority approach prevailed in the Supreme Court, but dissenting judges objected that the fetus would remain living in utero but would die on premature delivery, and was therefore denied the right, as long as nature would allow, to life. Life commences, under Article 70 of the Civil Code and Argentina's declaration on adherence to the international Convention on the Rights of the Child, at concep-

tion. The dissenting opinion was given despite the significant number of anencephalic fetuses that suffer death late in pregnancy or during natural delivery.

A feature of the Supreme Court's majority judgment was the importance it attached to evidence of continuation of pregnancy harming the applicant woman's physical and/or mental health, and also that of her family, which included a young daughter. A dissenting judge considered it unjustifiable to deprive the fetus of the weeks of life remaining to it merely to mitigate harm to the mother, which he considered could be alleviated with psychological support, but a majority judge found that forcing the mother to face the physical and mental health risks of continuing pregnancy and delivering a fetus with no chance of life outside her body resembles torture. This perception reflects the judgment in *KL v. Peru* [4], and appears to have reinforced decisions of later courts to follow the reasoning of the Supreme Court majority [14].

Despite dissenting judgments in the courts of Argentina, the position seems considerably clearer than in Brazil, where an overview of court decisions shows disarray and judicial indulgence of personal moral beliefs, giving equal weight to judicial majority and dissenting approaches seen in Argentina. It was observed in 2007 that "[t]he debate surrounding the right to selective abortion has intensified in Brazilian medical and judicial circles in the last decade... The Brazilian Penal Code does not include fetal malformation as an acceptable case [for lawful abortion]; however, it is estimated that since 1989, 3000 law suits have resulted in the authorization of the interruption of pregnancies in the case of anomalies that are incompatible with life outside the womb" [15]. Intensification appears associated with increasing availability of ultrasound in public healthcare facilities in the 1990s. This exposed the background to the relatively high incidence of anencephaly at birth. According to WHO data, Brazil has the fourth highest newborn incidence worldwide, after Mexico, Chile, and Paraguay [16].

Most recently drafted in 1940, the Brazilian Penal Code punishes abortion with up to 10 years' imprisonment when done without the woman's consent, or causing her death or physical injury, and up to 3 years each when the performer and woman agree. This is relatively lenient, since English law, for instance, punishes performers with up to life imprisonment, even when unlawful abortion is undertaken safely and with consent. Brazilian law allows exceptions only when pregnancy resulted from rape, or when necessary to save the woman's life.

As in many other countries, the Penal Code abortion provisions in Brazil, drafted when anencephaly became apparent only at stillbirth or live birth, were designed to protect interests in fetal gestation and viability. When viability is recognized to be denied by nature, however, courts may reflect the leading 2001 case in Argentina, and approve premature delivery, such as in the Brazilian 2005 Leandra case, as falling outside the scope of abortion [17]. The Court observed that "[w]hen the fetus is incompatible with life... there is no affront to the values of life, protected by the Constitution and the Penal Code." Courts have indeed invoked the Constitution to approve abortion of anencephalic pregnancies on grounds of preservation of the lives and dignity of women [18]. Further, courts have also found preservation of women's mental and physical health to be

within the Penal Code's exception allowing abortion to preserve women's lives [19].

Nevertheless, prevailing jurisprudence in Brazil cannot be considered necessarily sympathetic to abortion of nonviable pregnancies. The Penal Code is often interpreted restrictively [20], and reinforced by provisions of the Constitution on the right to life, from conception, even of a fetus not destined to survive longer than a short time after birth. Although courts avoid use of moral or religious language, and express judgments through construction of terms of the Penal Code and Constitution, this legal craftsmanship often appears directed to reach conclusions that would be anticipated on the application of concepts of ensoulment and related teaching of the Roman Catholic church, which retains a strong hold on the Brazilian legal tradition. The Brazilian Federal Supreme Court is presently considering the constitutionality of abortion in cases of anencephaly without prior judicial authorization or other special permission from the state [21].

4. Ethical aspects

Early detection of neural tube defects is a wind that fans the flames of the well-rehearsed debate on the ethics of abortion. The special challenge of anencephaly arose before ultrasound detection became common, when the condition was detected prenatally only late in pregnancy. Late-term abortion is contentious because gradualistic approaches to abortion, which have inspired much liberal legislation, recognize that fetal interests, and interests in fetal life, grow in strength as gestation advances. A common point at which fetal interests may prevail is viability, often taken to occur at 24 weeks of gestation. This approach is confounded, however, when a particular fetus is nonviable.

Late detection of anencephaly has long been a medical concern where women lack access to prenatal services, such as in resource-poor countries and communities and, for instance, among residents of remote areas. Late-term abortion is also a professional ethical concern, perhaps with legal implications, in economically developed countries, even though its incidence may be very low [22]. However, there is little controversy, where medicine is practiced according to professional, secular principles, about late termination of anencephalic pregnancy, on grounds of sparing women particular hazards to physical and mental health of prolonged gestation and delivery of a stillborn or dying fetus. In the United States, physicians may be prohibited from undertaking what Congress named "partial birth abortion," but not medically indicated late-term abortion by other means [23].

In 1996, the government of the Netherlands appointed a commission to address management of late abortion. Its 1998 report [24] stated that where death of a child is expected to be inevitable during or immediately after birth, due for instance to anencephaly, late-term abortion would be ethically permissible with the parents' request or consent [25]. The report accepted third trimester abortion in such cases as morally permissible as the lesser of two evils.

Some women decline termination and continue pregnancy [26]. Religious reasons may support this decision, and in the late 1980s an altruistic incentive was the prospect of salvaging the lives of other children by dedicating organs of the

deceased newborn for transplantation into others capable of survival. However, if the anencephalic newborn is left to natural death, its process of natural demise is liable to leave its organs unusable for transplantation, and it cannot be certified as dead by neurological criteria of total brain death while its brain stem supports spontaneous respiration and cardiac function, however compromised. Instances did occur at this time, such as at Loma Linda University Medical Center, in California, in which organs were transplanted from anencephalic newborns, but with immense ethical controversy aggravated by medical and legal apprehensions about the propriety of treatment strategies on determination of fetal brain death that could be employed to maintain tissue quality [27]. A prominent medical ethicist in 1988 wrote an article on the possibility of transplantation entitled "Organs from anencephalic infants: an idea whose time has not yet come" [28]. Twenty years later, however, it appears that the time for this idea has passed.

5. Professional responses

In its 2005 judgment in the KL case, the UN Human Rights Committee required the government of Peru to take measures to prevent its hospitals from repeating the human rights violations the case disclosed, including cruel, inhuman, and degrading treatment by denial of lawful abortion of an anencephalic pregnancy. The Committee indicated that Peru should adopt a national protocol for the provision of therapeutic abortion services based on the WHO 2003 handbook "Safe Abortion: Technical and Policy Guidance for Health Systems" [29]. Peru has reported to the UN Human Rights Committee that its Health Ministry has proposed a protocol, although this has not yet become official policy.

Guidance may be more narrowly tailored to address, for instance, only medical management of anencephaly. For example, in 1990 a US ad hoc Medical Task Force on Anencephaly published a statement, "The Infant with Anencephaly," [30] that was approved by the American Academy of Pediatrics, the American Academy of Neurology, the American College of Obstetricians and Gynecologists, the American Neurological Association, and the Child Neurology Society. The statement addresses management in utero and postnatally (pointing out that about 65% of affected fetuses die in utero), risks of dysfunctional labor and complicated delivery, newborn care until death, and reasons for failures to transplant organs with much success. The statement provides information on medical issues that would assist analysis of social, legal, and ethical concerns.

Several statements of the FIGO Committee for the Study of Ethical Aspects of Human Reproduction and Women's Health relate to management of anencephalic pregnancy [31], including Ethical Issues Concerning Prenatal Diagnosis of Disease in the Conceptus, Ethical Aspects in the Management of the Severely Malformed Fetus, Ethical Aspects of Termination of Pregnancy following Prenatal Diagnosis, and, in 2007, a statement on Anencephaly and Organ Transplantation that notes that local legal definitions of death are binding [32]. The 1995 statement Ethical Aspects of the Management of Severely Malformed Newborn Infants recognizes that, when parents and physicians agree that it is in the best interests of such infants, they should be allowed to die with dignity, without inappropriate or futile medical intervention.

In light of this guidance, medical professional associations and institutions such as hospitals may develop guidelines for management of anencephalic pregnancy, and/or for (late) termination of pregnancy on this and associated indications. Such guidelines should include indications for abortion on grounds of pregnant women's physical and mental health [10]. Professional guidance may also assist practitioners to address potential legal and ethical liabilities, particularly to patients, for their failure or refusal to offer or advise medically indicated lawful termination of pregnancy [33]. Further, initiatives to clarify appropriate practice may be taken at governmental levels. In Argentina, for instance, provincial and municipal health agencies in Buenos Aires have begun to formulate protocols for termination of anencephalic and other pregnancy, including by induced labor and premature delivery, that would take account of recent jurisprudence and not offend laws against abortion [34]. This is consistent with recent judicial requirements that, on human rights grounds, governmental agencies specify the conditions under which abortion services are legally available [5].

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