

The Professional Responsibility Model of Ethics in Perinatal Medicine

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Abstract

Objective: To describe the professional responsibility model of ethics in perinatal medicine, based on the fetus and pregnant woman as patients, to guide the deliberative practice of perinatal medicine.

Methods: We describe secular medical ethics and its two fundamental principles, beneficence and respect for autonomy. We articulate the ethical concept of the fetus as a patient on the basis of the ethical principle of beneficence.

Results: In the deliberative practice of perinatal medicine guided by the professional responsibility model, the perinatologist should always identify and balance beneficence-based obligations to the fetal patient and beneficence-based and autonomy-based obligations to the pregnant patient. Directive counseling is appropriate when the fetus is a patient. Non-directive counseling is appropriate when the fetus is not a patient.

Conclusion: Counseling pregnant women about the clinical management of their pregnancies should always identify and balance beneficence-based obligations to the fetal patient and beneficence-based and autonomy-based obligations to the pregnant patient.

Keywords: Perinatal medicine; Ethics; Directive counseling

Introduction

Ethics has become an integral dimension of perinatal medicine [1-3]. In this paper, we will present an ethical framework to guide clinical judgment and decision-making in the perinatologist-patient relationship [4]. We call this framework the professional responsibility model of ethics in perinatal medicine [5]. We will emphasize a preventive ethics approach. Preventive ethics is based on the recognition of the potential for ethical conflict in patient care and adopts ethically justified strategies to prevent those conflicts from occurring. As a result, preventive ethics helps to sustain a strong physician-patient relationship in perinatal medicine.

We begin by defining ethics, medical ethics, and two core ethical principles of medical ethics, beneficence, and respect for autonomy. Second, we show how these two principles should interact in perinatal judgment and practice, guided by the core ethical concept of the fetus as a patient.

Key Definitions

Ethics has been understood for centuries in global cultures as the disciplined study of morality. Medical ethics is the disciplined study of morality in medicine and addresses the obligations of physicians and health care organizations to patients as well as the obligations of patients [5]. Medical ethics should not be confused with the many sources of morality in a pluralistic society. These include applicable law, the political heritage of self-government, the world's religions, ethnic and cultural traditions, families, personal experience, and the traditions and practices of medicine.

Medical ethics since the eighteenth century European and American Enlightenment has been secular [6]. Secular medical ethics makes no reference to divinity or revealed tradition, but to what reasoned discourse requires and produces. At the same time, secular medical ethics is not intrinsically hostile to religious beliefs. Therefore, ethical principles and virtues should be understood to apply to all physicians, regardless of their personal religious and spiritual beliefs [7]. Secular medical ethics is thus transnational, transcultural, and transreligious. In short, secular medical ethics is global medical ethics.

The traditions and practices of medicine constitute an indispensable source of morality for physicians, because they are based on the obligation to protect and promote the health-related interests of the patient. This obligation tells physicians what morality in medicine ought to be in very general, abstract terms. Providing a more concrete, clinically applicable account of that obligation is the central task of medical ethics, using ethical principles [5].

The ethical principle of beneficence requires one to act in a way that is expected reliably to produce the greater balance of benefits over harms in the lives of others [7]. Putting this principle into clinical practice requires an account of the benefits and harms relevant to patient care and of how those goods and harms should be balanced against each other when not all of them can be achieved in a particular clinical situation, such as a request for an elective cesarean delivery [8]. In medical ethics, the principle of beneficence requires the physician to act in a way that is reliably expected to produce the greater balance of clinical benefits clinical over harms for the patient [5].

Beneficence-based clinical judgment has an ancient pedigree, with its first expression found in the Hippocratic Oath and accompanying texts [9]. Beneficence interprets reliably the health-related interests of the patient from medicine's perspective. This perspective is provided by the deliberative (rigorous, evidence-based, and accountable) clinical judgment [10]. Beneficence-based clinical judgment is thus mere opinion based merely on the clinical impression or intuition of an

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individual physician. In deliberative clinical judgment, beneficence-based reasoning identifies the clinical benefits that can be achieved for the patient. The benefits that medicine is competent to seek for patients are the prevention and management of disease, injury, disability, and unnecessary pain and suffering, and the prevention of premature or unnecessary death. Pain and suffering become unnecessary when they do not result in achieving the other goods of medical care, e.g., allowing a woman to labor without effective analgesia [5].

Nonmaleficence means that the physician should prevent causing harm and are best understood as expressing the limits of beneficence. This is also known as "*Primum non nocere*" or "first, do no harm." This commonly invoked dogma is really a latinized misinterpretation of the Hippocratic texts, which emphasized the primacy of beneficence while avoiding harm when approaching the limits of medicine to alter the course of disease [5]. When the physician approaches the limits of beneficence-based clinical judgment, i.e., when the probability of clinical benefit diminishes and the risks of clinical harm increase, then the physician should proceed with great caution. The physician should be especially concerned to prevent serious, far-reaching, and irreversible clinical harm to the patient.

It is important to note that there is an inherent risk of paternalism in beneficence-based clinical judgment. By this we mean that beneficence-based clinical judgment, if it is considered to be the sole source of moral responsibility and therefore moral authority in medical care, invites the unwary physician to conclude that beneficence-based judgments can be imposed on the patient in violation of her autonomy. Paternalism is a dehumanizing response to the patient and, therefore, should be avoided in the practice of perinatology.

The preventive ethics response to this inherent paternalism is for the physician to explain the diagnostic, therapeutic, and prognostic reasoning that leads to his or her clinical judgment about what is in the interest of the patient so that the patient can assess that judgment for herself. This general rule can be put into clinical practice in the following way: The physician should disclose and explain to the patient the major factors of this reasoning process, including matters of uncertainty. In neither medical law nor medical ethics does this require that the patient be provided with a complete medical education [11]. The physician should explain how and why other clinicians might reasonably differ from his or her clinical judgment. The physician should then present a well-reasoned response to this critique. The outcome of this process is that beneficence-based clinical judgments take on the rigor required by the deliberative practice of medicine. Beneficence-based clinical judgment will frequently result in the identification of a continuum of clinical strategies that protect and promote the patient's health-related interests. Awareness of this feature of beneficence-based clinical judgment provides an important preventive ethics antidote to paternalism by increasing the likelihood that one or more of these medically reasonable, evidence-based alternatives will be acceptable to the patient. All beneficence-based alternatives must be identified and explained to all patients, regardless of how the physician is paid, especially those that are well established in evidence-based perinatology.

In the past four decades, there has been increasing emphasis in medical ethics on the principle of respect for the autonomy of the patient [7]. This principle requires one always to acknowledge and carry out the value-based preferences of the adult, competent patient, unless there is compelling ethical justification for not doing so, e.g., prescribing antibiotics for viral respiratory infections. The pregnant patient increasingly brings to her medical care her own perspective on what is in her interest. The principle of respect for autonomy translates

this fact into autonomy-based clinical judgment. Because each patient's perspective on her interests is a function of her values and beliefs, it is impossible to specify the benefits and harms of autonomy-based clinical judgment in advance. Indeed, it would be inappropriate for the physician to do so, because the definition of her benefits and harms and their balancing are the prerogative of the patient. As a consequence, autonomy-based clinical judgment is strongly anti-paternalistic in nature [5].

Three steps implement this principle in clinical practice. First, the patient pays attention to and absorbs and retains information about her condition and alternative diagnostic and therapeutic responses to uncertainty. Second, she understands this information, by acknowledging and evaluating the clinical benefits and risks of medically reasonable alternatives. Third, on the basis of this understanding, she expresses her authorization or refusal of authorization. The physician has a role to play in each of these. First, the physician should recognize the capacity of each patient to deal with medical information (and not to underestimate that capacity), provide information (i.e., disclose and explain all medically reasonable alternatives, i.e., supported in beneficence-based clinical judgment), and recognize the validity of the values and beliefs of the patient. Second, the physician should not interfere with but, when necessary, assist the patient in her evaluation and ranking of diagnostic and therapeutic alternatives for managing her condition. Third, the physician should elicit and implement the patient's value-based authorization or refusal of authorization [5,12].

In the United States, the legal obligations of the physician regarding informed consent were established in a series of cases during the twentieth century. In 1914, *Schloendorff v. Society of The New York Hospital* established the concept of simple consent, i.e., whether the patient says "yes" or "no" to medical intervention [11,13]. "Every human being of adult years and sound mind has the right to determine what shall be done with his body, and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages" [13]. The legal requirement of consent further evolved to include disclosure of information sufficient to enable patients to make informed decisions about whether to say "yes" or "no" to medical intervention [11].

There are two accepted legal standards for such disclosure. The professional community standard defines adequate disclosure in the context of what the relevantly trained and experienced physician tells patients. The reasonable person standard, which has been adopted by most states in the United States, goes further and requires the physician to disclose "material" information, what any patient in the patient's condition needs to know and the lay person of average sophistication should not be expected to know. Patients need to know what the physician thinks is clinically salient, i.e., the physician's beneficence-based clinical judgment. This reasonable person has emerged as the ethical standard, and we therefore urge perinatologists to adopt it in the decision-making process with patients. On this standard, the physician should disclose to the patient her or the fetus's diagnosis (including differential diagnosis when that is all that is known), the medically reasonable alternatives to diagnose and manage the patient's condition, and the short-term and long-term benefits and risks of each alternative.

The Roles of Ethical Principles Deliberative Perinatal Clinical Judgment and Practice

The ethical principles of beneficence and respect for autonomy play crucial roles in the professional responsibility model of ethics in perinatal medicine [4]. There are obviously beneficence-based and

autonomy-based obligations to the pregnant patient: the physician's perspective on the pregnant woman's health-related interests provides the basis for the physician's beneficence-based obligations to her, whereas her own perspective on those interests provides the basis for the physician's autonomy-based obligations to her. Because of an insufficiently developed central nervous system, the fetus cannot meaningfully be said to possess values and beliefs. Thus, there is no basis for saying that a fetus has a perspective on its interests. There can therefore be no autonomy-based obligations to any fetus. Hence, the language of fetal rights has no meaning and therefore no application to the fetus in obstetric clinical judgment and practice despite its popularity in public and political discourse in the United States and other countries [4]. Obviously, the physician has a perspective on the fetus's health-related interests, and the physician can have beneficence-based obligations to the fetus, but only when the fetus is a patient [5].

The ethical concept of the fetus as a patient is indispensable in deliberative perinatal clinical judgment and practice. When the fetus is a patient, directive counseling, recommending a form of management, for fetal benefit is appropriate. When the fetus is not a patient, nondirective counseling, offering but not recommending a form of management for fetal benefit, is appropriate.

In medical ethics generally, being a patient means that one can benefit from the applications of the clinical skills of the physician. A human being becomes a patient when two conditions are met: a human being 1) is presented to the physician, and 2) there exists clinical interventions that are reliably expected to be efficacious, in that they are reliably expected to result in a greater balance of clinical benefits over harms for the human being in question [4,5].

The authors have argued elsewhere that beneficence-based obligations to the fetus exist when the fetus is reliably expected later to achieve independent moral status as a child and person [5]. That is, the fetus is a patient when the fetus is presented for medical interventions, whether diagnostic or therapeutic, that reasonably can be expected to result in a greater balance of goods over harms for the child and person the fetus can later become during early childhood. The ethical significance of the concept of the fetus as a patient in perinatal medicine depends on links that can be established between the fetus and its later achieving independent moral status.

The viable fetal patient

One such link is viability. Viability, however, must be understood in terms of both biological and technological factors. It is only by virtue of both factors that a viable fetus can exist *ex utero* and thus achieve independent moral status. When a fetus is viable, that is, when it is of sufficient maturity so that it can survive into the neonatal period and achieve independent moral status given the availability of the requisite technological support, and when it is presented to the physician, the fetus is a patient.

Viability exists as a function of biomedical and technological capacities, which are different in different parts of the world. As a consequence, there is, at the present time, no worldwide, uniform gestational age to define viability. In the United States, we believe, viability presently occurs at approximately 24 weeks of gestational age [14,15].

When the fetus is a patient, directive counseling for fetal benefit is ethically justified, which involves one or more of the following: recommending against termination of pregnancy; recommending against nonaggressive management; or recommending aggressive

management. Aggressive obstetric management includes interventions such as fetal surveillance, tocolysis, cesarean delivery, or delivery in a tertiary care center when indicated. Nonaggressive obstetric management excludes such interventions. Directive counseling for fetal benefit, however, must take account of the presence and severity of fetal anomalies, extreme prematurity, and obligations to the pregnant woman.

The strength of directive counseling for fetal benefit varies according to the presence and severity of anomalies. As a rule, the more severe the fetal anomaly, the less directive counseling should be for fetal benefit. In particular, when lethal anomalies such as anencephaly can be diagnosed with certainty, there are no beneficence-based obligations to provide aggressive management. Such fetuses are dying patients, and the counseling, therefore, should be nondirective in recommending between nonaggressive management and termination of pregnancy, but directive in recommending against aggressive management for the sake of maternal benefit [16]. By contrast, third trimester abortion for Down syndrome, or achondroplasia, is not ethically justifiable, because the future child with high probability will have the capacity to grow and develop as a human being [17,18].

Directive counseling for fetal benefit in cases of extreme prematurity of viable fetuses is appropriate. In particular, this is the case for what we term just-viable fetuses, those with a gestational age of 24 to 26 weeks, for which there are significant rates of survival but high rates of mortality and morbidity. These rates of morbidity and mortality can be increased by nonaggressive obstetric management, whereas aggressive obstetric management may favorably influence outcome. Thus, it appears that there are substantial beneficence-based obligations to just-viable fetuses to provide aggressive obstetric management. This is all the more the case in pregnancies beyond 26 weeks of gestational age. Therefore, directive counseling for fetal benefit is justified in all cases of extreme prematurity of viable fetuses, considered by itself. Of course, such directive counseling is appropriate only when it is based on documented efficacy of aggressive obstetric management for each fetal indication. For example, such efficacy has not been demonstrated for routine cesarean delivery to manage extreme prematurity.

Any directive counseling for fetal benefit must occur in the context of balancing beneficence-based obligations to the fetus against beneficence-based and autonomy-based obligations to the pregnant woman. Any such balancing must recognize that a pregnant woman is obligated only to take reasonable risks of medical interventions that are reliably expected to benefit the viable fetus or child later.

Directive counseling for fetal benefit must be open to the possibility of conflict between the physician's recommendation and a pregnant woman's autonomous decision to the contrary. Such conflict is best managed preventively through the informed consent process as an ongoing dialogue throughout a woman's pregnancy, augmented as necessary by negotiation and respectful persuasion [19].

The previable fetal patient

The only possible link between the previable fetus and the child it can become is the pregnant woman's autonomy. This is because technological factors cannot result in the previable fetus becoming a child. The link, therefore, between a fetus and the child it can become when the fetus is previable can be established only by the pregnant woman's decision to confer the status of being a patient on her previable fetus. The previable fetus, therefore, has no claim to the status of being a patient independently of the pregnant woman's autonomy. The pregnant

woman is free to withhold, confer, or, having once conferred, withdraw the status of being a patient on or from her pre-viable fetus according to her own values and beliefs. The pre-viable fetus is presented to the physician as a function of the pregnant woman's autonomy [5].

Counseling the pregnant woman regarding the management of her pregnancy when the fetus is pre-viable should be non-directive in terms of continuing or terminating the pregnancy if she refuses to confer the status of being a patient on her fetus. If she does confer such status in a settled way, at that point beneficence-based obligations to her fetus come into existence, and directive counseling for fetal benefit becomes appropriate for these pre-viable fetuses. Just as for viable fetuses, such counseling must take account of the presence and severity of fetal anomalies, extreme prematurity, and obligations owed to the pregnant woman.

For pregnancies in which the woman is uncertain about whether to confer such status, the authors propose that the fetus be *provisionally* regarded as a patient. This justifies directive counseling against behavior that can harm a fetus in significant and irreversible ways, e.g. substance abuse, especially alcohol, until the woman settles on whether to confer the status of being a patient on the fetus.

Non-directive counseling is appropriate in cases of what we term near-viable fetuses, that is, those that are 22 to 23 weeks of gestational age, for which there are anecdotal reports of survival [14,15,20]. In our view, aggressive obstetric and neonatal management should be regarded as clinical investigation, not a standard of care. There is no obligation on the part of a pregnant woman to confer the status of being a patient on a near-viable fetus, because the efficacy of aggressive obstetric and neonatal management has yet to be proven [15].

Conclusion

We have provided an ethical framework for deliberative perinatal clinical judgment and practice, the professional responsibility model of ethics in perinatal medicine. Implementing this framework on a daily basis is essential to sustaining a professional physician-patient relationship in perinatal medicine. Perinatal ethics emphasizes preventive ethics, i.e., an appreciation that the potential for ethical conflict is built into clinical practice, and the use of such clinical tools as informed consent and negotiation to prevent such conflict from occurring. Counseling pregnant women about the clinical management of their pregnancies should always identify and balance beneficence-based obligations to the fetal patient and beneficence-based and autonomy-based obligations to the pregnant patient.

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