

Moral Status of the Embryo in Professional Obstetric Ethics

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ABSTRACT

This paper addresses the moral status of the embryo based on the ethical concept of the embryo as a patient. This concept is explained by appealing to the ethical principles of beneficence and respect for autonomy and the professional virtue of integrity. The clinical implications of the ethical concept of the embryo as a patient are explored in both *in vitro* fertilization and nondirective counseling about a newly initiated pregnancy. The purpose of the counseling process should be to integrate beneficence with respect for autonomy to guide a professionally responsible counseling process that is designed to empower the woman to make informed decisions about initiating and continuing pregnancy.

Keywords: Embryo, Ethical principle of beneficence, Ethical principle of respect for autonomy, Ethics, Moral status, Patient.

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INTRODUCTION

The ethical concept of the embryo as a patient is an essential component of assisted reproductive medicine and obstetric management of early pregnancy as embryologic development transitions to fetal development and therefore in professional obstetric ethics.^{1,2} In this chapter, we provide an account of this ethical concept and identify its implications for clinical practice. To accomplish this goal, we begin with accounts of ethics and professional medical ethics, including a brief overview of their historical development. There then follows a section on definitional issues, which includes an account of the ethical concept of moral status. The material presented in these three sections of the chapter provides the basis for a practical examination of the clinical and research implications of the ethical concept of the embryo as a patient, a pragmatic, clinically applicable concept free of metaphysical baggage. These implications are separately identified for the *in vitro* embryo as a patient and for the *in vivo* embryo as a patient.

ETHICS

Ethics is the disciplined study of morality, our actual beliefs about right and wrong, good and bad. Ethics assumes that these beliefs—as well as behavior and character traits based on these beliefs—can be improved. Ethics uses two tools to do so. The first tool is a patient analysis of relevant ethical concepts to express them as clearly as possible. Unclear or confusing concepts disable ethical reasoning from its very start and therefore must be replaced with clear concepts. The second tool is identifying the implications of clearly expressed concepts for behavior and character. The goal of ethical reasoning is to reach well-reasoned ethical judgments that classify types of behavior and character traits as either ethically permissible, ethically obligatory, or ethically impermissible. Ethics accepts only well-reasoned judgment, i.e., those that are established based on ethical analysis and argument. Judgments made without this basis are to be considered “mere opinion”, as Plato had Socrates teach in the *Dialogues* two-and-a-half thousand years ago. “Mere opinion” therefore has no place in ethics and therefore no place in the professional ethics of obstetrics and gynecology.³

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Beginning in the world of ancient Greece and China, two fundamental methods of ethical reasoning emerged. The first method can be described as a quest for certainty.⁴ By grounding ethical reasoning in sources that are not of human making, one seeks to identify ethical judgments that are true and therefore transcultural, transnational, and transreligious. This philosophical tradition begins with Plato (427–347 BCE) and includes the most important philosopher of the German Enlightenment, Immanuel Kant (1724–1804 CE). One prominent example is the ethical concept of a natural right, a right that all human beings possess in virtue of shared human nature no matter their nationality, culture, or religion. The second method can be described as the quest for reliability.⁴ This philosophical tradition begins with Confucius (551–479 BCE) and Aristotle (384–322 BCE). Ethical judgments evoke ethical concepts that human beings have invented in a specific cultural setting but have become durable. This occurs when, over time, an ethical concept becomes transcultural, transnational, and transreligious. One prominent example is the ethical concept of a human right, which was invented shortly after World War II and, and has since then gathered persuasive power as it was repeatedly and successfully invoked utility to call governments to account for abuse of human beings. The discourse of human rights has been endorsed by the United Nations.⁵

PROFESSIONAL ETHICS IN OBSTETRICS AND GYNECOLOGY

Professional medical ethics undertakes to improve clinical practice, research, and health policy. Professional medical ethics accomplishes this goal of constant improvement by deploying the tools of philosophical ethics to reach reasoned judgments about how physicians should act and what character traits, or professional virtues, they should cultivate inpatient care, in scientific and clinical research, and in contributing to the formation and implementation of health policy.

Many physicians believe that professional medical ethics was introduced into the history of medical ethics in the ethical texts of the Hippocratic Corpus, including the Hippocratic Oath. This common belief, however, is mistaken. There is no concept of medicine as a profession in the Hippocratic Oath. Instead, medicine was understood by the authors of the Hippocratic Oath and other ethical writings in the Hippocratic Corpus to be entrepreneurial and self-interested and thus dominated by the physician's concern for a good reputation (which was then in scarce supply). These texts are also shaped by the self-interests of physicians as a group, to maintain market share in a highly competitive and unforgiving market to medical services. This group's self-interest is evidenced in the dismissal of surgeons in the Hippocratic Oath and the prohibition of surgery because its frightful mortality rates would bring disrepute on all physicians.⁶

Professional medical ethics, including professional ethics in obstetrics and gynecology, was invented in the late eighteenth century. The ethical concept of medicine as a profession was introduced into the history of medical ethics by two British physician-ethicists, John Gregory (1724–1773) of Scotland and Thomas Percival (1740–1804). This ethical concept calls for physicians to make three commitments: to become and remain scientifically and clinically competent; to protect and promote the patient's health-related interests as the physician's primary concern and motivation, keeping individual self-interest systematically secondary; and to protect and promote the patient's health-related interests as the physician's primary concern and motivation, keeping group self-interest systematically secondary.^{3,6}

Gregory and Percival put forth this concept to correct three major problems. First, many practitioners were incompetent, given the absence of uniform training and state licensure. Second, many practitioners were "men of interest" who made money and fame their primary consideration, as one would expect of entrepreneurs (this was the true legacy of the Hippocratic texts). Third, many practitioners made the protection of the market share and power of the medical guild, known as the Royal Colleges, their primary consideration. The result was rampant distrust of the sick in physicians, surgeons, apothecaries, and other medical practitioners.⁶

Making the three commitments of the ethical concept of medicine as a profession transformed the relationship between physicians and the sick. The historical legacy of the Hippocratic texts was that this relationship was contractual and nothing more. Physicians did not commit other than to deliver promised services, just as in every other commercial enterprise. This had resulted in profound distrust of physicians. The relationship was a "the sick-the physician" (an admittedly awkward phrase) relationship of *caveat emptor* on the part of the sick individual contracting for medical services. The professional relationship is very different.

In this relationship, the sick individual is not on his or her own, always wary and distrustful, but protected by the physician's three commitments.⁶

Two ethical principles and one professional virtue are essential for undertaking professional medical ethics.³ Ethical principles provide general guides to action. Professional virtues shape the professional character of the obstetrician-gynecologist.

Ethical Principle of Beneficence

This is the oldest ethical principle in the history of medical ethics. It creates the ethical obligation of the obstetrician-gynecologist to identify and provide forms of clinical management that are reliably predicted to result in net clinical benefit for the patient. Beneficence-based ethical judgments should be evidence-based. The reliability of beneficence-based ethical judgment varies directly with the level of evidence for the prediction of net clinical benefit.

The ethical principle of beneficence is essential for understanding the clinical ethical concept of a medically reasonable alternative.³ A form of clinical management should be considered medically reasonable only when two conditions are met: (1) the form of clinical management is technically feasible; and (2) there is a sufficient evidence base for the prediction of net clinical benefit.

Ethical Principle of Respect for Autonomy

Gregory insisted that every patient has a "right to speak", one of the earliest expressions of respect for patient autonomy.⁶ In contemporary professional ethics in obstetrics and gynecology, the ethical principle of respect for patient autonomy creates the ethical obligation to empower the pregnant patient with information about the progress and current state of her condition, including pregnancy, the medically reasonable alternatives for managing her pregnancy, and the clinical benefits and risks of each medically reasonable. The obstetrician should support the pregnant woman as she evaluates this information and expresses a decision based on such evaluation. The obstetrician should also be alert to potentially controlling influences on the woman's decision-making process and protect her from such influences. The goal is to enable the woman to make informed and voluntary decisions.³

Professional Virtue of Integrity

Fulfilling the three commitments of the ethical concept of medicine as a profession sets the physician on the path of the pursuit of excellence in patient care, research, and health policy. The experience of such excellence integrates the physician's character in a life of service to patients. The professional virtue of integrity requires life-long, rigorous adherence to the three commitments of the ethical concept of medicine as a profession.^{3,6}

DEFINITIONAL ISSUES

Meaning of "Embryo" in Reproductive Medicine

The word "embryo" has two distinct meanings in reproductive medicine. The first meaning is: "The fertilized ovum after it has begun the process of cell division".⁷ This is the meaning used in *in vitro* fertilization (IVF). This first meaning is the *in vitro* definition of "embryo". The second meaning is the biological entity that comes into existence when the blastocyst implants in the uterine wall until the eighth week of development, after which it becomes a fetus.⁸ This is the meaning used in obstetrics and gynecology. This is the *in vivo* definition of "embryo".

Ethical Concept of Moral Status

The attribution of moral status to an entity means that others have the ethical obligation to recognize the existence of that entity and to protect its interests or stakes that it has in the present and future. There are two kinds of moral status.

Ethical Concept of a Person

In philosophy, the first kind of moral status is known as “independent” moral status: some property or properties constitutive of the entity that has independently of all other entities originate moral status.³ In philosophical ethics, a paradigm of independent moral status is known as a “person”. The word “person” thus has a distinctive meaning in philosophy. There are, to be sure, different meanings of the word, “person”, with different implications for moral status. These concepts of being a person, especially in religion, are explored elsewhere in this volume.

The ethical concept of independent moral status and therefore the ethical concept of being a person apply only to individuals. In Western metaphysics, an entity becomes an individual if and only if satisfies two criteria (which can be thought of inclusion criteria for being an individual). The first criterion is that the entity is distinct from other entities: we can pick it out separately from other entities. The *in vitro* embryo and the *in vivo* embryo are distinct, thus satisfying the first criterion for being an individual. The second criterion is indivisibility: the entity cannot divide into two entities of the same species. In embryological development, this division is known as twinning. Twinning, a phenomenon with which obstetricians are already familiar, has important metaphysical implications, which we now, briefly, explore.

As long as the embryo retains the potential to a twin, it is divisible, not indivisible, into two human beings. It follows necessarily that an embryo that can twin is not an individual and therefore cannot have independent moral status. It also follows necessarily that the ethical concept of being a person cannot apply to the embryo with the potential to twin. No *in vitro* embryo is a person.

The embryo that no longer has the potential to twin is indeed an individual because it has become indivisible. However, while it is metaphysically necessary for being a person that one is an individual, it is metaphysical insufficient for being a person, by itself, that one is an individual. One must also be an entity that self-generates the constitutive property that is the basis for independent moral status as an individual. In Western metaphysics, it is generally accepted an entity with the constitutive property of rational self-consciousness, which is a function of highly developed sensory and nervous systems. Neither the *in vitro* embryo nor the *in vivo* embryo has such sensory and nervous systems. It necessarily follows that neither the *in vitro* embryo nor the *in vivo* embryo is a person.

Some Western philosophers hold that the capacity for awareness of pain establishes the basis for the independent moral status of an individual as a person. Awareness of pain is a function of highly developed sensory and nervous systems. Neither the *in vitro* embryo nor the *in vivo* embryo has such sensory and nervous systems. It necessarily follows that neither the *in vitro* embryo nor the *in vivo* embryo can be aware of pain. It also follows that neither has independent moral status and that neither, therefore, can be a person.

The ethical concept of being a person provides no applicable ethical guidance for the professionally responsible management

of clinical practice and research on *in vitro* embryos or the clinical management of *in vivo* embryos. The ethics of the clinical management of and research on *in vitro* embryos or the clinical management of *in vivo* embryos is therefore free the metaphysics of being an individual and being a person. Finally, the metaphysics of being an individual and being a person is distinctively Western, calling into serious question whether the ethical concept of the embryo as a person is a transnational, transcultural, and transreligious concept. The ethical concept of the embryo as a person, therefore, has no place in the professional ethics of obstetrics and gynecology.

Ethical Concept of Being a Patient

The second kind of moral status is known as “dependent” moral status: an entity occupies a social role that has been created to protect all entities in that role.³ In philosophical ethics, a paradigm of dependent moral status is a child: a human entity in a social role that creates ethical obligations of parents to protect and promote the interests of their child. The concept of dependent moral status is pragmatic: it is a concept invented and sustained over time because of its utility, in this case, its utility for the professional ethics of obstetrics and gynecology. The concept is therefore not metaphysical, freeing it from the metaphysical baggage that burdens the ethical concept of being a person.

The Hippocratic texts and the later Latin texts in the Hippocratic tradition do not use the word “patient” but instead the word for “the sick one” or “the sick individual”. This discourse signals the ethics of the marketplace.

Gregory and Percival rejected the discourse of “the sick” with the ethical concept of being a patient. The professional relationship becomes the physician–patient relationship. The ethical concept of being a patient derives from their invention of the ethical concept of medicine as a profession. Being a patient means that one has been presented to a physician and there exist forms of clinical management that are reliably predicted to protect and promote the patient’s health-related interests (in reducing the risk of mortality and morbidity).

The physician’s three commitments to professionalism create the social role of being a patient. Being a patient, therefore, is a form of dependent moral status. This has a crucial clinical implication: having independent moral status, or being a person (in the philosophical meaning above) is not required to become a patient. This is why the embryo can sometimes be considered a patient.

Ethical Concept of the Embryo as a Patient

An embryo becomes a patient when it is presented, *in vitro* or *in vivo*, to a physician and there exist forms of clinical management that are reliably expected to protect and promote the embryo’s health-related interests. For the *in vitro* embryo, this presentation occurs in the IVF laboratory, unmediated by any other human being. This is not the case for the *in vivo* embryo, the presentation of which is mediated by the pregnant woman. This means that whether the *in vivo* embryo becomes a patient is a function of the pregnant woman’s autonomous decision to present for obstetric management and to continue her pregnancy to live birth. The dependent moral status of the *in vivo* embryo is, therefore, more complex ethically than the dependent moral status of the *in vitro* embryo. This difference requires that the clinical ethical implications of the embryo as a patient differ for the *in vitro* embryo and for the *in vivo* embryo.

CLINICAL AND RESEARCH IMPLICATIONS OF THE ETHICAL CONCEPT OF THE *IN VITRO* EMBRYO AS A PATIENT

Transferring Embryos to Initiate a Pregnancy

The *in vitro* embryo can become an *in vivo* patient only with the informed consent of the woman into whose uterus it is to be transferred to confer this dependent moral status. The *in vitro* embryo can become a research subject that will not be transferred only with the informed consent of the couple from whom the *in vitro* embryo was derived. When the woman is initiating pregnancy with *in vitro* embryos, her gynecologist and the *in vitro* team have a beneficence-based ethical obligation to the future fetal patient(s) not to transfer a number that will result in high-order pregnancy that will increase *in utero* and perinatal risks to the fetal patient(s).⁹ The gynecologist and *in vitro* team also have a beneficence-based obligation to the woman to prevent the biopsychosocial risks to her of a high-order pregnancy. Existing guidelines from such organizations as the American Society for Reproductive Medicine (ASRM),¹⁰ the American College of Obstetricians and Gynecologists (ACOG),¹¹ or the European Society of Human Reproduction and Embryology (ESHRE)¹² should be followed. The informed consent process should include information about the IVF group's outcomes, including both percent of pregnancies initiated and percent of live births.

Preimplantation Diagnosis

If a preimplantation genetic or genomic diagnosis is to be performed, the woman should be provided information about the categories of results. These include results pertaining to each embryo: (1) a genetic or genomic diagnosis of an embryo; (2) risk assessment, i.e., the increased likelihood of disease in a future child or genetic kinfolk; (3) pharmacogenomic information about medication of the future child; (4) alleles of uncertain clinical significance, i.e., not previously reported alleles in genes known or suspected to be pathogenic; and (5) previously unreported alleles in healthy genes, the clinical significance of which is unknown.¹³ These also include results to the sources of gametes, either by implication or when they are also genomically assessed (e.g., in "trio" testing). The results will fall into the same five categories.

Counseling the woman and her partner about the interpretation of results must recognize that reports from genome laboratories can be cognitively demanding for the physician and will be even more cognitively demanding for the woman and her partner. The results should be organized into the above five categories and presented in order of clinical significance for which embryo(s) are considered appropriate for transfer. The likelihood of there being no results in any of the five categories is very low, given the inherent errors of human reproduction. This should be explained so that the woman and her partner are disabused of the search for the "perfect baby".¹⁴ It should be made very clear from the outset that the decision about which embryos she considers appropriate to transfer is the woman's decision and that the gynecologist's professional judgment may differ, in which case the differences will need to be mediated. The IVF laboratory should have the policy to guide such mediation that expressly states the laboratory's exclusion criteria, which should be consistent with guidance from ASRM, ACOG, or ESHRE.

Responding to Requests for High Number of Embryos to be Transferred

A request from a woman to depart from these guidelines should be managed by informing her of the risks of high-order pregnancy and recommending that the guidelines be followed for her benefit and the benefit of future and neonatal patients. If this attempt to transform her request into the informed consent process fails to persuade her to withdraw her request, then the gynecologist and *in vitro* team should, as a matter of professional integrity, should refuse the request. The gynecologist should document this process in detail.

Seamless Transfer of Patient Care

The gynecologist has a strict professional obligation to ensure a seamless transfer of care to the woman's obstetrician after transfer. The referring obstetrician should receive a clinical report, especially detailing any complications or poor prognosis, so that her obstetrician has the clinical information that he or she needs to create an appropriate care plan with the pregnant woman.

Research with *In Vitro* Embryos

In vitro embryos should be used for research (an experiment undertaken with a group of subjects to create generalizable knowledge) only under a protocol approved by the appropriate Institutional Review Board (IRB) or Research Ethics Committee (REC). Failure to obtain IRB or REC approval for research on human embryos constitutes an egregious failure of scientific and professional integrity and is therefore ethically impermissible. There are no exceptions.

CLINICAL IMPLICATIONS OF THE ETHICAL CONCEPT OF THE *IN VIVO* EMBRYO AS A PATIENT

The *in vivo* embryo can become a patient only with the informed consent of the pregnant woman to confer this dependent moral status. The pregnant woman is free to confer, withhold, or, having once conferred, withdraw the moral status of being a patient from the *in vivo* embryo.³

Counseling about the Termination of Pregnancy

There are a number of clinical circumstances in which it is ethically obligatory to offer (but not recommend) termination of early first-trimester pregnancy.¹⁵ The first occurs when a woman expresses ambivalence or uncertainty about remaining pregnant, raises the issue directly. The second occurs when her pregnancy has resulted from rape or incest. The second occurs when noninvasive risk assessment indicates an increased risk of a fetal anomaly, provided that the obstetrician explains that risk assessment is not diagnosis, which requires invasive assessment. For some women, the increased risk, by itself, will be unacceptable. The third occurs when invasive assessment results in the diagnosis of a fetal anomaly, in which circumstances it is exclusively the woman's decision about whether she wants to continue her pregnancy. The fourth occurs when a high-order pregnancy is diagnosed. Selective feticide is known to improve the perinatal outcomes for a twin or singleton pregnancy, information that a pregnant needs to make an informed

decision about continuation of a high-order pregnancy. The fifth occurs when the pregnant woman has a serious medical condition the mortality and morbidity risks of which a coexisting pregnancy could increase. This is information that a pregnant needs to make an informed decision about continuation of her pregnancy. Termination of an early first-trimester pregnancy remains legally permissible in most legal jurisdictions.

This counseling should focus on assisting the woman to have the clinical information that is salient to her decision. This information should be presented free of bias. It is ethically impermissible to limit information based on the obstetrician's personal beliefs or statutory law. It is also ethically impermissible to make any recommendation of any kind, especially one based on the obstetrician's personal beliefs. Counseling therefore should be strictly nondirective. A shared decision-making process should be adopted and driven by the patient's informational needs, values, and beliefs. She should be encouraged to draw on her social supports as she deems valuable. She should be supported in her decision about whom to involve and she is assured that the professional of confidentiality will be adhered to without exception and as required by law.

Counseling about Obstetric Management

Pregnant women should be routinely informed that 2–3% of pregnancies are affected by fetal anomalies. If one is diagnosed later in pregnancy, the pregnant woman may confront a decision about continuation of her pregnancy (subject to applicable legal restrictions).¹⁵ Pregnant should also be informed that a normal, low-risk pregnancy can become high-risk quickly and without warning, especially during the intrapartum period. In this case, when evidence-based clinical judgment supports doing so, her obstetrician may recommend cesarean. To prevent the effects on decision-making in a high-stress, time-compressed environment, the obstetrician should take advantage of prenatal visits to discuss intrapartum management in such clinical circumstances and document the results in the patient's record, so that decision-making intrapartum can be guided by the patient's expressed values and beliefs.¹⁶

CONCLUSION

The ethical concept of the embryo as a patient plays a foundational role in professional obstetric ethics^{3,17} and therefore in both IVF and nondirective counseling about a newly initiated pregnancy. This concept is beneficence-based and autonomy-based. The purpose of the counseling process should be to integrate beneficence with respect for autonomy to guide a professionally responsible counseling process that is designed to empower the woman to make informed decisions about initiating and continuing a pregnancy and to implement the professional virtue of integrity.

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