

Ethics in Obstetric Ultrasound: The Past 25 Years in Perspective

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ABSTRACT

Ethics is an essential component of obstetric ultrasound, an area in which the authors have collaborated for the past 25 years. The authors describe their collaboration. They then present one of the core ethical concepts of obstetric ultrasound: The ethical concept of the fetus as a patient. Next, they present one of the clearest clinical applications of ethics to obstetric ultrasound: Autonomy-enhancing strategies. The authors hope that these two paradigms will convince the reader that ethics is an essential dimension of obstetric ultrasound and stimulate further interest.

Keywords: Ethics, Fetus as a patient, Beneficence, Respect for autonomy.

INTRODUCTION

In the past 25 years, ethics has established itself as an essential dimension of obstetric ultrasound.¹⁻⁵ In 1985, we published the first ethical framework for perinatal medicine and our partnership has thrived for the past quarter-century.⁶ Our collaboration began in the spring of 1983. At that time, Dr Chervenak was a fellow in maternal-fetal medicine at Yale-New Haven Medical Center and Dr McCullough was the medical faculty at Georgetown University. Dr Chervenak came to Georgetown in the spring of 1983 to participate in one-month medical ethics elective, taught conjointly by ethics faculty of the Washington, DC medical schools. Dr Chervenak heard Dr McCullough presentation on the concepts and language of ethics and Dr Chervenak realized that there was a direct relevance to the role of cephalocentesis and at the end of the elective proposed that they continue collaboration. Their work continued when Dr Chervenak joined the medical faculty of Mt. Sinai Medical School in 1983 and moved to Weill Cornell in 1987, and after Dr McCullough moved to Baylor College of Medicine in 1988. Their regular meetings were first supplemented by telephone and mail communication, then fax and then modern electronic media.⁷ Their collaboration has resulted in more than 160 peer-reviewed publications and the first book on ethics in obstetrics and gynecology, published by Oxford University Press.⁸

It is clearly beyond the scope of this article to provide a comprehensive account of ethics in obstetric ultrasound. We will first present one of the core ethical concepts of obstetric ultrasound: The ethical concept of the fetus as a patient. We

will then present one of the clearest clinical applications of ethics to obstetric ultrasound: Autonomy-enhancing strategies. We hope that these two paradigms will convince the reader that ethics is an essential dimension of obstetric ultrasound and stimulate further interest.

THE ETHICAL CONCEPTS

A key component of the ethical framework that we have developed and used is the ethical concept of the fetus as a patient.⁸ We therefore begin with an elaboration of this concept, utilizing two key ethical principles. These come from the history of medical ethics. Throughout the history of medical ethics, an important starting point for reflection on ethics in clinical practice and research has been the clinician's obligation to protect and promote the health-related interests of the patient. This commitment defines what it means to be a health care professional, but at the same time is quite general in its nature. To make it clinically relevant and applicable, this general guideline needs to be made more clinically specific, reflecting two basic perspectives; that of the clinician and of the patient.

The Ethical Principle of Beneficence

The ethical principle of beneficence translates into clinical practice medicine's perspective on the health-related interests of the patient. This ethical principle obligates the clinician to seek the greater balance of clinical benefits over clinical harms for the patient as a consequence of clinical management of the patient's condition. On the basis of rigorous clinical judgment, informed by current science, especially evidence-based

medicine and a commitment to excellence in clinical practice, the clinician should identify the clinical strategies that are reliably expected to result in the greater balance of clinical benefits (i.e. the protection and promotion of health-related interests) over clinical harms (i.e. impairments of those interests).⁸ The principle of beneficence has a long and illustrious history in the global history of medical ethics. In Western medical ethics, for example, it dates back at least to the time of Hippocrates.⁹ Indeed, the Hippocratic oath enjoins physicians to prescribe diet and exercise in a manner that will “benefit the sick according to my ability and judgment”.⁹

The principle of beneficence should not be confused with the principle of nonmaleficence. The latter principle is also known as *Primum non nocere* or “First, do no harm”. It is worth noting that *Primum non nocere* appears neither in the Hippocratic oath nor in the texts that accompany the oath. Rather, the principle of beneficence was the primary consideration of the Hippocratic writers. For example, the Hippocratic text, *Epidemics*, reads, “As to diseases, make a habit of two things—to help or to at least do no harm”.¹⁰ Thus, the historical origins of *Primum non nocere* remain obscure. This seemingly arcane historical point is not only historical, but also conceptual and clinical. If *Primum non nocere* were to be made the primary principle of clinical ethics, then virtually all invasive aspects of health care, including many aspects of the diagnosis and management of genetic disorders, such as invasive prenatal diagnosis, would be unethical because of the clinical risks they involve for patients. If the primary goal of clinical management is to avoid harm, even drawing blood becomes ethically suspect, especially for patients with a dread of needles.

The Ethical Principle of Respect for Autonomy

A rigorous clinical perspective on the patient’s health-related and other interests are not the only legitimate perspective on such interests. The patient’s perspective on her own health-related and other interests must also be considered by the clinician.⁸ This is because adult patients have developed a set of values and beliefs, according to which they are capable of making judgments about what will and will not protect and promote their health-related and other interests. In particular, all adult pregnant women not in an emergency situation should be assumed to possess the decision-making capacity to determine which clinical strategies for the clinical diagnosis and management of their pregnancies are consistent with their interests and which are not, unless there is reliable evidence of significant clinical deficits in their decision-making processes. In making decisions about their medical care, pregnant women may use values and beliefs that go far beyond health-related interests (e.g. religious beliefs or beliefs about how many children she wants to have). Inasmuch as beneficence-based clinical judgment is limited by the scientific and clinical competencies of medicine, beneficence-based clinical judgment provides the physician no authority to assess the worth or meaning to the pregnant woman of her own nonhealth-related

interests. Such are matters solely for the pregnant woman to determine.

The patient’s perspective is translated into clinical practice in the ethical principle of respect for autonomy. This principle obligates the clinician to respect the integrity of the patient’s values and beliefs, to respect her perspective on her interests, and to implement only those clinical strategies authorized by her as the result of the informed consent process. The informed consent process is typically understood to have three elements: (1) Disclosure by the physician, or other relevantly trained and experienced clinician, to the patient of adequate information about the patient’s condition and its management; (2) understanding of that information by the patient; (3) a voluntary decision by the patient to authorize or refuse proposed treatment.^{8,11}

The Ethical Concept of the Fetus as a Patient

The clinician’s perspective on the pregnant woman’s health-related interests and the commitment to protect and promote her health-related interests create the clinician’s beneficence-based obligations to her. At the same time, the woman’s own perspective on her interests and the clinician’s commitment to respect her values and preferences create the clinician’s autonomy-based obligations to her. In contrast, because of its insufficiently developed central nervous system, the fetus cannot meaningfully be said to possess values and beliefs. Thus, there is no valid basis for saying that a fetus has a perspective on its interests. It follows that there can be no autonomy-based obligations to any fetus.⁸ The clinician nonetheless has a perspective on the fetus’s health-related interests, and therefore can have beneficence-based obligations to the fetus, but only when the fetus is a patient. Because of its centrality for the ethical management of pregnancies complicated by fetal anomalies, the topic of the fetus as patient requires careful consideration, a task to which we now turn.

One can become a patient without having rights. An important advantage of the concept of the fetus as a patient is that the language of fetal rights or personhood has no meaning, and therefore no application to the fetus in obstetric ethics, despite its popularity in public and political discourse in many countries. Thus, current controversies about “right to life”, especially its possible limited application to patients from non-Western cultures, can be avoided in clinical judgment and decision making about the management of pregnancies complicated by fetal anomalies. A major advantage of an ethical framework based on the concept of the fetus as a patient is that it keeps the ethics of the diagnosis and management of genetic disorders free from divisive disputes about fetal rights and about the fetus as an “unborn child.”¹²

Beneficence-based obligations to the fetus exist when the fetus can later, after birth, become a child and still later achieve independent moral status as a person.⁸ The fetus is a patient when two conditions are met: (1) The fetus is presented to the physician or other clinician; and (2) there exist medical and

other clinical interventions, whether diagnostic or therapeutic, that can reliably be expected to result in a greater balance of clinical goods over clinical harms for the fetus in its future. The ethical significance of the concept of the fetus as a patient, therefore, depends on links to its later becoming a child and, later still, achieving independent moral status.

The Viable Fetus as a Patient

One link to becoming a patient is viability, the ability of the fetus to exist *ex utero* with full technological support. Viability should not be viewed as an exclusively biologic property of the fetus, but in terms of both biologic and technologic factors. Only by virtue of both factors can a viable fetus exist *ex utero* and subsequently become a child, and later achieve independent moral status. Viability is closely correlated with access to technologic capacity. When access to such technology is present, as is the case in the United States and other developed countries, viability occurs at approximately the end of 24 weeks of gestational age.^{13,14} This understanding of viability as having a technologic component is not unique to obstetrics, but applies throughout medicine. For example, a patient with massive internal injuries with uncontrolled bleeding but without timely access to rapid transport to surgery is almost certainly nonviable, while the same patient with such access is viable.

The Preivable Fetus as a Patient

The only possible link between the preivable fetus and the child it can become is the pregnant woman's autonomy. This is because technologic factors cannot result in the preivable fetus becoming a child. This is simply what preivable means. When the fetus is preivable, the link between a fetus and the child it can later become is established only by the pregnant woman's decision to confer the status of being a patient on her preivable fetus in a decision to continue her pregnancy. The preivable fetus has no claim to the status of being a patient independently of the pregnant woman's autonomy. The pregnant woman is therefore free to withhold, confer or, having once conferred, withdraw the status of being a patient on or from her preivable fetus according to her own values and beliefs. Having made a decision to continue a preivable pregnancy, the woman remains free to revoke that decision. This has direct clinical application to the management of pregnancies complicated by fetal anomalies, as we shall see next. The preivable fetus is presented to the clinician solely as a function of the pregnant woman's autonomy.⁸

AUTONOMY-ENHANCING STRATEGIES FOR FIRST- AND SECOND-TRIMESTER ULTRASOUND

Second-trimester ultrasound screening,² invasive genetic diagnosis,³ and first-trimester risk assessment⁴ have become important autonomy-enhancing strategies in diagnosis of genetic disorders. When these concepts were initially introduced in

1989, 1993 and 2001 respectively, they were considered controversial.^{5,15} With the publication of the American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin, "Screening for Chromosomal Abnormalities", in January, 2007, guidelines now endorse the concept of offering risk assessment and invasive genetic diagnosis to all pregnant women: "screening and invasive diagnostic testing for aneuploidy should be available to all women who present for prenatal care before 20 weeks of gestation regardless of maternal age".¹⁶ In addition, ACOG has provided useful guidance on the information that should be provided to all pregnant women about the modalities available for screening and testing: "Regardless of which screening test you decide to offer your patients, information about the detection and false-positive rates, advantages, disadvantages and limitations, as well as the risks and benefits of diagnostic procedures, should be available to patients, so that they can make informed decisions".¹⁶

Given the wide variety of screening strategies and their potentially confusing names, such as 'integrated screening', 'stepwise sequential screening', and 'contingency screening',¹⁷ a natural response is to doubt the feasibility of obtaining truly informed consent. This is a reasonable concern because having too many options can confuse clinicians who in turn will present confusing information to patients, which will impair their exercise of their autonomy. Recent research in psychology has indicated that in many areas of human experience, such as career choice and shopping, providing individuals with too many choices can generate confusion and seriously impair their decision-making processes.¹⁸ Along these very lines, Menutti and Driscoll have suggested that patients have too many choices for first-trimester risk assessment.¹⁹ Recently, the lay press has reported on the challenges of having too many options for effective and informed decision making. While there is skepticism that one can make sounder decisions with less information, researchers have shown that this is indeed the case.²⁰

The commitment to autonomy-enhancing strategies should guide offering risk assessment and invasive diagnosis in a way that prevents having too much options about risk assessment.²¹ We identify a two-step process that enhances patient autonomy by dealing effectively with the challenge of patients apparently having too many choices. We show that patients can meaningfully exercise their autonomy in the informed consent process in response to the offer of risk assessment and invasive diagnosis and in response to the results of risk assessment.

As emphasized above, the purpose of the informed consent process is to enable patients to exercise their autonomy in a meaningful fashion.¹¹ The key to an effective informed consent process is to provide an adequate, but not overwhelming, amount of information to patients, tailored to the patient's education and knowledge. Brody²² and Wear²³ have argued that the guiding clinical concept for the clinician's role in the informed consent process should be transparency. The ethical standard of transparency requires the clinician to make an expert

judgment about what is clinically salient and then present this clinically salient information to the patient. Transparency requires the clinician to prevent over disclosure of information, i.e. too much information that could only confuse the patient and prevent her from exercising her autonomy in a meaningful fashion. Transparency requires clinicians to identify and present to patients the medically reasonable alternatives for the diagnosis and clinical management of their condition or problem.

In decision-making about risk assessment for genetic disorders clinicians should be guided by transparency about such risk assessment. It is now well established that first-trimester risk assessment, for which nuchal translucency and biochemistry are now accepted as the standard, is a reliable tool for assessing the risk of trisomy 21.¹⁶ First-trimester risk assessment is thus medically reasonable and should be offered to all pregnant women who present during the first-trimester for their prenatal care. To respect the patient's autonomy in making the offer, the clinician should not express or imply any expectation of acceptance of risk assessment and in no way imply that either refusal or choice of invasive diagnosis is any less acceptable than accepting risk assessment.

Respect for autonomy also has implications for the type and amount of information that patients should be provided about clinically significant scientific controversies, and the timing of such disclosure. Such information should be provided to patients only when it is relevant to the decision at hand. When decisions are made in sequence, as can be case for risk assessment of trisomy 21, and when scientific controversies are relevant only to later decisions, information about such scientific controversies should not be provided at the beginning of the decision-making process.

Step One: The Woman's Response to a Nondirective Offer of Risk Assessment and Invasive Diagnosis

An ethically justified decision tree for risk assessment of trisomy 21 should be based on and implement the informed consent process as an autonomy-enhancing strategy. Three options should be presented to all pregnant women in a strictly nondirective manner: First-trimester risk assessment; invasive genetic diagnosis; and continuation of pregnancy without first-trimester risk assessment or invasive diagnosis. Information meeting the recommended disclosure standard in the ACOG practice bulletin should be provided about these three options but the clinician should not make a recommendation about which one the pregnant woman should elect, even if asked to do so. Nondirective counseling is the ethical standard in this context because clinicians lack moral authority to decide for a pregnant woman whether she should accept any of these options or reject all of them. Clinicians, physicians and genetic counselors alike, are not empowered to weigh the many nonmedical factors that shape the exercise of the woman's autonomy, including how religious, moral and cultural beliefs should shape a judgment that the risk of learning whether a fetus has an anomaly is worth the risk of pregnancy loss from invasive testing.²⁻⁴

Nondirective counseling means that the clinician should emphasize that the decisions to be made are patient-directed,

not clinician-directed. At the same time, it is consistent with nondirective counseling to ask the patient what is important to her and then help her to identify options that support her values. The pregnant woman should be given adequate time to digest the information provided and be encouraged to ask any questions that she thinks appropriate, without fear of embarrassment. Adequate time should be given to ensure that information is conveyed in an effective and respectful manner.

In response to this offer of these options, patients will exercise their autonomy in one of four ways. First, some women will refuse both risk assessment and invasive diagnosis. Respect for the patient's autonomy requires clinicians to recognize that some women will not consider termination of pregnancy as acceptable under any circumstances, and therefore will find risk-assessment and diagnostic information irrelevant to their decision to continue the pregnancy. Religious and other moral beliefs will play a central role in such decisions and must command respect from clinicians.

The concept of moral risk is important to appreciate in these circumstances. Moral risk occurs when a patient obtains information that opens an option that is, for that patient, morally unacceptable to elect. The concept of moral risk in the setting of risk assessment means that some women will not want to confront having to make a decision about termination or continuation of pregnancy based on risk-assessment and subsequent invasive testing, and they will decline both. Based on their religious or other moral beliefs they will be rational to do so.

Second, at the other end of the spectrum, some women will elect invasive diagnosis without risk assessment for a variety of reasons, such as unwillingness to accept the birth of a child with any detectable chromosomal abnormality, including trisomy 21. Such women should be informed that opting for risk assessment first could provide information relevant to opting for invasive diagnosis but will take some time. Some women will nonetheless elect invasive testing, because it can rule out such an outcome promptly, and consequently accept the risks of invasive testing. Their reasons for making such a decision are their own, and should therefore command respect from the clinician. Once such women have made an informed decision for invasive diagnosis, it should be performed or a referral made. For these women and for those in the first group, once they have made an informed decision, recommending risk assessment should be regarded as unjustified paternalism, i.e. an attempt to interfere with the exercise of the woman's autonomy¹ based on the clinician's judgment that she has made a bad choice.

Third, some women will be uncertain about what to do. The clinician should explore the reasons for their uncertainty with them and be especially attentive to incomplete understanding of information that has been provided and confusion about the distinction between a risk assessment and a diagnostic test. If, as a result of a thorough informed consent process, the patient wishes to postpone her decision, she should be informed about the time-limited nature of such postponement.

The clinician should be sure to point out that, if she postpones her decision too long for first-trimester risk assessment to be performed, her only options will become second-trimester risk assessment, invasive diagnosis, or neither.

The fourth group is defined by those women who accept risk assessment. They understand that screening is not diagnostic and accept risk assessment, preferring a revised risk for fetal Down syndrome prior to proceeding. The potential responses to this group's approach are detailed below.

Step Two: The Woman's Response to the Results of Risk Assessment

Essentially, the fourth group will be women who accept first-trimester risk assessment as the outcome of the informed consent process. In response to its results they will sort themselves into three groups.

One group will judge the estimation of risk to be acceptable and will elect to continue the pregnancy without further risk assessment or invasive genetic diagnosis. At the other end of a spectrum, another group will judge the estimation of risk to be unacceptable to them and will elect invasive genetic diagnosis. The clinician should either perform, or refer the patient for invasive genetic diagnosis with the patient's informed consent for the procedure.

Still another group will be uncertain about whether the estimation of risk is acceptable. These women should be provided with information about available additional, noninvasive tests that could be performed during the first and second trimesters to better define their risk. The ACOG practice bulletin provides information on these alternatives.¹⁶ This is the only group for whom the informed consent process should present information about current controversies about first-trimester and second-trimester further testing to better evaluate assessment. In our view, for all other groups in this step and in the first step information about controversy is irrelevant and, if provided, can unjustifiably undermine the informed consent from information overload. We therefore differ from those who hold that all pregnant women should be offered all screening.¹⁷

A careful reading of the ACOG practice bulletin and the relevant scientific and clinical literature supports the judgment that a high-quality informed consent process is essential in implementing this two-step autonomy-enhancing strategy. Clinicians should ensure adequate time and personnel resources to conduct an informed consent process. There are mounting time pressures on clinicians, especially but not only from managed care organizations. If a clinician cannot make time available for a high-quality informed consent process, then referral should be made to a center that can do so.

Reservations have recently been expressed about the ability of patients and clinicians to interpret screening test results.²⁴ There is a reliable evidence base to warrant serious disagreement. There is evidence that the consent process that we have described results in patients' using sophisticated clinical risk-assessment information to make decisions that are

scientifically rational. That is, as the risk of chromosomal aneuploidy diminishes, the rate of election of invasive testing diminishes.²⁵ It is possible that this may not be the case for the more complicated consent process that will be required when all screening options are offered to all patients.

In the past, the use of a cut-off for invasive testing based on maternal age, though well intentioned and based on the best data available at the time, was at risk of being paternalistic because it unjustifiably assumed that there was no role for the patient's autonomy in decision-making other than to accept or refuse testing.³ In the past, those who argued against second-trimester ultrasound screening or first-trimester risk assessment were similarly paternalistic.^{5,15} Fortunately, these disputes have been resolved,¹⁶ but the risk of being paternalistic that erodes the autonomy of pregnant women has evolved. The ethical peril of the emerging consensus and widespread utilization of risk assessment is that patients will be perfunctorily stratified into risk groups without taking account of the values and beliefs that shape the exercise of pregnant women's autonomy. This outcome, should it occur, will simply substitute a new for the old paternalistic approach. The antidote remains keeping the ethical principle of respect for autonomy front and center in the increasing implementation of risk assessment and invasive diagnosis.

CONCLUSION

The past quarter-century has seen ethics become an essential dimension of ultrasound. Important conceptual work has been accomplished as well as extensive clinical applications. We have this progress by examining the ethical concept of the fetus as a patient and the clinical application of autonomy-enhancement. We hope that the reader is stimulated to explore the myriad dimensions of ethics in obstetric ultrasound.

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