PATIENT INFORMED CONSENT IN PRENATAL SCREENING

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Abstract

Nowadays, informed consent, based on patient autonomy, is seen as necessary if medical interventions are to be seen as legally and ethically acceptable. Whereas informed consent protocols within antenatal care, including prenatal screening regimens are presumed to be adequate in developed countries, even with ongoing debates in improving guiding principle, in developing countries like Albania leaves much to be desired not only the actual condition but also the fact that there is no interest in looking into this matter.

Most pregnant women worldwide do not satisfactorily understand the medical purpose, limitations or potential ethical implications, such as selective termination, of the medical procedures consented to. Despite the fact that the consent given in these situations may well fulfil the minimal medico-legal criteria for informed consent, the required level of knowledge and understanding necessary to meet the ethical standards informed or understood consent often appears not to be met. The presumption that legally informed consent equates to morally informed consent within institutional protocols for prenatal screening must therefore be questioned, and the ethical integrity of these increasingly routine interventions demand further analysis.

The purpose of this article is to explore whether the problems identified in medical practice in western countries might also exist and at the mean time be a concern which must be looked after in Albania as well. The experiences of mother and health practitioners interviewed exposed a range of institutional, social, personal and philosophical constraints that reflected the abroad research findings and also illuminated how informed consent may be unintentionally undermined in the clinical setting in Albania as well.

Key words: *Informed consent, prenatal screening, ethics, patient education, protocols*

CHRONOLOGICAL BACKGROUND

In early late 1970 and early1980, in United Sates of America, the commission on ethics concluded in making a report on informed consent. This announcement called: “The Ethical Considerations Associated with Informed Consent," was subsequently approved and issued in 1980 as a Statement of Policy by American College of Obstetricians and Gynecologists-ACOG's Executive Board. The 1980 statement reflected what is now generally recognized as a paradigm shift in the understanding of the ethics of the physician–patient relationship. During the 1970s, a marked change took place in the United States of America from a traditional almost singular focus on the benefit of the patient as the governing ethical principle of medical care to a new and dramatic emphasis on a requirement of informed consent. That is, a central and often sole concern for the medical well-being of the patient was modified to include concern for the patient's autonomy in making medical decisions.

If in the 1970s informed consent was embraced as a corrective to paternalism, in the 1980s and 1990s shared decision making was increasingly viewed as a necessary corrective to the exaggerated individualism that patient autonomy had sometimes produced. At the same time, factors such as the proliferation of medical technologies, the bureaucratic and financial complexities of health care delivery systems, and the growing sophistication of the general public regarding medical limitations and possibilities continued to undergird an appreciation of the importance of patient autonomy and a demand for its promotion in and through informed consent.

In the early 21st century, there are good reasons for considering once again the ethical significance and practical application of the requirement to seek informed consent. This is particularly true in the context of obstetric and gynecologic practice because medical options, public health problems, legal interventions, and political agendas have expanded and interconnected with one another in unprecedented ways. The concern of ACOG for these matters is reflected in its more recent documents on informed consent and on particular ethical problems that arise in the context of maternal–fetal relationships, decisions about relationships, sterilization, surgical options, and education in the health professions [1–7]. Although a general doctrine of informed consent cannot by itself resolve problems like these, it is nonetheless necessary for understanding and responding to them.

Informed consent for medical treatment and for participation in medical research is both a legal and an ethical matter. In the recent history of informed consent, statutes and regulations as well as court decisions have played an important role in the identification and sanctioning of basic duties. Judicial decisions have sometimes provided insights regarding rights of self-determination and of privacy in the medical context. Government regulations have rendered operational some of the most general norms formulated in historic ethical codes. Yet, recent developments in the legal doctrine are few, and the most serious current questions are ethical ones before they become issues in the law. What above all bears reviewing, then, is the ethical dimension of the meaning, basis, and application of informed consent.

Although informed consent has both legal and ethical implications, its purpose is primarily ethical in nature. As an ethical doctrine, informed consent is a process of communication whereby a patient is enabled to make an informed and voluntary decision about accepting or declining medical care. There are important legal aspects to informed consent that should not be

overlooked. It is critical for physicians to document the contents of this conversation as part of the permanent medical record. A signed consent document, however, does not ensure that the process of informed consent has taken place in a meaningful way or that the ethical requirements have been met.

It comes reasonably understandable, when this issue is faced in most developed countries; in my opinion, in Albania we face immeasurable problems with informed consent. Albania went thru dramatic changes in beginning on 1990 when the regime was changed from dictatorship to democracy, where these over two decades have been made a lot of changes in legislation and medical regulation, yet there is not a poor developed discipline and much need to be done in coming years.

CONSENT IN OBSTETRICS AND GYNECOLOGY AS A UNIQUE FIELD OF PRACTICE

The practice of obstetrics and gynecology has always faced special ethical questions in the implementation of informed consent. How, for example, can the autonomy of patients' best be respected when serious decisions must be made in the challenging situations of labor and delivery? What kinds of guidelines can physicians find for respecting the autonomy of adolescents, when society acknowledges this autonomy by and large only in the limited spheres of sexuality and reproduction?

In the context of genetic counseling, where being "non-directive" is the norm; is it ever appropriate to recommend a specific course of action? How much information should be given to patients about controversies surrounding specific treatments? How are beneficence requirements, regarding the well-being of the patient, to be balanced with respect for autonomy, especially in a field of medical practice where so many key decisions are irreversible?

These and many other questions continue to be important for fulfilling the ethical requirement to seek informed consent.

When this concern continue to arise in developed countries with high standard of health care service where the world is guided by their indicators, in developing countries like Albania, where the reliability of undergraduate, graduate and post graduate programs do not offer adequate theoretically and practically knowledge to address the need of exploration of this sensitive field.

Progress in the ethical doctrine of informed consent regarding, for example, the significance that relationships have for decision making, have helped to focus some of the concerns that are particularly important in the practice of obstetrics and gynecology [1]. Where women's health care needs are addressed and especially where these needs are related to women's sexuality and reproductive capacities, the issues of patient autonomy and its relational nature come to the forefront. Perspectives and insights for interpreting these issues are now being articulated by women out of their experience, that is; their experience specifically in the medical setting, but also more generally in relation to their own bodies, in various patterns of relation with other individuals, and in the larger societal and institutional contexts in which they live. These perspectives and insights offer both a help and an ongoing challenge to professional self-

understanding and practice of obstetricians and gynecologists, whether they themselves are women or men.

In western countries with well high standard health care system, new models for the active participation of health care recipients have been created in obstetrics and gynecology. Some of these developments are the result of arguments that pregnancy and childbirth should not be thought of as diseases, although they bring women importantly into relation with medical professionals and, in some cases, carry a potential for morbidity or mortality. Even when women's medical needs pointedly require diagnosis and treatment, their concerns to hold together the values of both autonomy and their relationships have been influential in shaping not only ethical theory but also medical practice.

Women themselves have questioned, for example, whether autonomy can really be protected if it is addressed in a vacuum, apart from an individual's concrete roles and relationships. But women as well as men also have recognized the ongoing importance of respect for autonomy, although they suggest it should be reconceptualised as less individualistic and more "relational" [8,9]. They call for attention to the complexity of the relationships that are involved, especially when sexuality and parenting are at issue in medical care, while upholding the importance of bodily integrity and self-determination.

The difficulties that beset the full achievement of informed consent in the practice of obstetrics and gynecology are not limited to individual and interpersonal factors. Both health care providers and recipients of medical care within this specialty have recognized the influence of such broad social problems as the historical imbalance of power in gender relations and in the physician–patient relationship, the constraints on individual choice posed by complex medical technology, and the intersection of gender bias with race and class bias in the attitudes and actions of individuals and institutions. None of these problems makes the achievement of informed consent impossible. But, they point to the need to identify the conditions and limits, as well as the central requirements, of the ethical application of this doctrine.

AIMS OF ANTENATAL TESTING

Antenatal screening services are based on population screening to identify people with a genetic risk, or a risk of having a child with a congenital or genetic disorder. In the genetic screening, the major aim is defined as: To enable people to decide upon a course of action that is acceptable for them .

Antenatal screening includes:

I. Screening for sporadic conditions affecting the fetus such as; infections, chromosomal disorders, malformations, maternal diabetes.
II. Family history for genetic risks.
III. Population screening for carriers of common recessively inherited diseases.

Different health authorities in different countries have pointed out various aspects of antenatal screening. While some health councils consider screening as a community-based form of help

based on the obligation to help the weak, other health authorities point out that; although the primary aim seems to be to improve the health of persons suffering from genetic disorders, the benefits should include enabling individuals to take account of the information for their own lives, and empowering them as prospective parents to make informed choices about having children [3,4.5].

Although the screening test is not usually in itself diagnostic, it detects a subgroup of those tested who are at higher risk of having the disease or disorder than the original population screened, in many cases it is possible to make diagnoses with considerable accuracy.

There are three different types of antenatal screening methods widely used;

A. Biochemical screening. In this technique, a single specimen of blood taken from a pregnant women at about 16-18 weeks of her pregnancy, used to screen for Down's syndrome and open neural-tube defects. This can detect about 60% of pregnancies with Down's syndrome, about 90% of pregnancies with open spina bifida, and virtually all cases of anencephaly [3]. Biochemical screening tests are used to identify those women who are at high enough risk to justify the hazards and costs of the diagnostic procedures.

B. Genetic screening. The sensitivity and the specificity of genetic screening is fairly high. The test is carried out either by amniosentesis or by chorionic villus sampling (CVS) at 14-16 weeks and 8-9 weeks respectively. Using standard cytogenetic techniques it is possible to culture amniotic fluid cells from as little as 10 ml. of amniotic fluid at 12 weeks, although successful culture before this time is currently less reliable. In CVS chorionic tissue obtained via endoscopic biopsy is used to make the types of fetal diagnoses by culture of amniotic fluid cells

In general the objectives of genetic screening are to:

- Allow the widest possible range of informed choice to women and couples at risk of having children with an abnormality.
- Allow couples to embark on having a family knowing that they may avoid the birth of seriously affected children through selective abortion.
- Ensure optimal treatment of affected infants through early diagnosis [3,8,9].

C. Ultrasound screening. The objectives of ultrasound screening are defined as:

   - Reduce the prenatal mortality and morbidity
   - Allow the identification of a group of babies for whom treatment in utero may be appropriate by defining structural abnormalities.

Antenatal Diagnosis

Antenatal diagnosis has four main purposes;

1) Inform and prepare parents for the birth of an affected infant;
2) Allow in utero treatment, or delivery at a specialist centre for immediate postnatal treatment
3) Allow termination of an affected fetus;
4) Provide information so that parents may choose between 1, 2 and 3.

Evidently, the goal of antenatal diagnosis is to help couples make an informed choice, one which they feel is best for themselves and their families. Antenatal diagnostic tests can be divided into those involving measurements of chemicals in maternal blood, imaging the fetus, and invasive tests to remove tissue of fetal origin. The tests in the last group may be carried out before 14 weeks' gestational age but after implantation, beyond 14 weeks' gestational age, or in the pre-implantation period. The tests, which are carried out in the preimplantation period are embryo biopsy and polar body analysis. The tests in the second group are fetal blood sampling, fetal tissue biopsy, amniocentesis, and transabdominal chorion biopsy. The tests in the first group, that are the most widely used at present, are early amniocentesis, transabdominal chorion villus biopsy or sampling (CVS) and transcervical CVS.

Benefits of antenatal testing

There can be a little doubt, on the face of it, that the techniques just described were devised to help people, and aim to enable parents to plan their future family knowledgeably. However, many authorities from various fields have expressed some serious concerns about them. It is important to define the 'real' aims of these techniques, and see how they work in practice. It is thought that these techniques may not necessarily have been developed with the interests of women primarily in mind, nor are necessarily applied to further women's interests [8,9,10,11]. A governmental document issued by one of the western countries, may help us to clarify our thinking about the 'real' aim of these technologies. It reads: "...because caring for the handicapped can impose great burdens on our society the prevention of handicaps...in addition to its other benefits may save money. The costs of providing amniocentesis for all expectant mothers over the age of 40 years, and maternal serum AFP screening for all pregnant women, would be more than offset by the economic benefits in terms of savings of expenditure on children and adults with Down's Syndrome and spina bifida" [12-18].

Rational as this sounds, this kind of rational-economic thinking may degrade society's willingness to accept and care for abnormal children, while at the same time enlarging the category of unacceptable abnormality and narrowing the range of acceptable normality. If Down's syndrome and spina bifida are “too” expensive today, what will become “too” expensive if the economic climate becomes gloomy [12-15]? Whether and how far it is right to accommodate cost-benefit analysis in the medical field has always been problematical. As has the question of whether economical considerations should affect clinical decisions [12].

Some reports have compared, for populations with varying incidence of neural tube defects, the benefits of a antenatal screening programme, in terms of number of births with neural tube defects prevented, against them physical costs, in terms of the number of normal fetuses

harmed by amniocentesis, the cost-benefit ratio becomes progressively less favourable as the population incidence of neural tube defects decreases. This, together with the fact that around 85 per cent of babies with neural tube defects are either still-born or die within the first year of life, means that, in regions with a low incidence of neural tube defects, it is possible that more unaffected pregnancies may be harmed than handicapped children avoided [13,14,15,16]. Another recent report has also indicated the possible cost of antenatal diagnosis.

According to the recent report published a debate outline on ethical issues in fetal diagnostics. It consists of a report on the past, present and future of fetal diagnostics, commissioned from a science writer, and a discussion of the council's deliberations on the issue. The report reads "Just under 120,000 fetuses examined. Over 2,200 sick or deviant fetuses identified and aborted. Loss of some 1,100 presumably healthy fetuses as a side-effect of the examination used" [10-13, 16-18]. The council sums up that "it is essential to stress that, irrespective standpoint taken on fetal diagnostics; it will be problematic for either one or the other party involved in fetal diagnostics".

Having noticed the problematic of the informed consent in obstetrics in western countries, where the patient education is presumed to be to a satisfied level, and also the frame work policy continuously improves in respect of patient rights and best interest, how is this topic handled in other countries where the standard of medical care and medico legal frame work policy is not satisfactory? In Albania, where the patient education in regards of their health status, in general, leaves to be desired, as the three level system of health care namely; primary, secondary and tertiary one, do not work as an integrated whole body. Thus, patients are influenced tremendously by physician’s opinion and decision made on their best interest, not participating in adequately in decision making in regard to the approving non invasive and invasive antenatal testing procedures during their pregnancy.

CONCLUSIONS AND AUTHORS OPINION

Since informed consent in general admits of degrees of implementation, there are limits to its achievement. These are not only the limits of weak knowledge or lacking communication, but rather they are limitations in the capacity of patients for comprehension and for choice. Assessment of patient capacity is itself a complex matter, subject to mistakes and to bias, consequently, a great deal of attention has been given to criteria for determining individual capacity, legally defined characteristic of "competence", and for just procedures for its evaluation. When individuals are entirely incapacitated for informed consent, the principles of respect for persons and beneficence require that the patient be protected. In these situations, someone else must make decisions on behalf of the patient.

Finally, although there are different views in the wide bioethics community, antenatal screening and antenatal diagnosis are new technologies developed to contribute to our happiness and welfare, but like many other new technologies, they are accompanied by new moral controversies. So, deciding the issue is dependent upon the views of the person, and a case-by-case approach can be suggested. If any embryological stage is defined as the beginning of a human individual, only testing but not termination may be allowed. We have stressed the vital importance of providing the parents with good counselling before and after antenatal test. The

aim of good quality counselling is to inform and enable parental understanding and choices with respect to their unborn child; health care professionals should not impose their own beliefs upon the parents. What they can and must do is to debate the issues among themselves, to review their criteria for advising antenatal testing procedures, and for the choices that may follow, so that they are providing the best possible service to their patients who are, of course, "persons", a category which the prenates may also belong, at least in the minds and hearts of their parents.

In Albania, well defined screening antenatal started in early 1990, and since then, we do perform antenatal screening test to the same standard as in western countries, however since then, not much is done in medico legal aspects of these tests. Consequently, more attention and energy to this component must put in order to bring our medico legal service, especially in delicate discipline of obstetrics and fetal medicine, in order to make sure we deliver the superior high quality health care service to our patients.

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