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Ethics and the reproductive process

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RESUMEN

Los cambios en la tecnología reproductiva y en la accesibilidad de los anticonceptivos han producido reconsideraciones éticas en muchos países. Los Estados Unidos de Norteamérica no han sido la excepción. Aquí se presenta una discusión de los principios éticos aplicables para la investigación anticonceptiva y los programas de planificación familiar. Cada país debe decidir su propia respuesta a un problema ético determinado. Este manuscrito no propone soluciones, pero está diseñado para motivar las preguntas necesarias.

SUMMARY

Changes in reproductive technology and contraceptive availability have resulted in ethical reconsiderations in many countries. The United States has been no exception. A discussion of the applicable ethical principles for contraceptive research and family planning programs is presented. Each country must decide its own individual response to a given ethical problem. The paper does not propose solutions but is designed to raise the necessary questions.

The advent of numerous, interrelated reproductive technologies is forcing a fresh look at old ethical systems, religious systems, and the role of government in regulation by law and policy. The United States has to this time made the approach to such changes not by governmental means, but through the academic and private sectors. Whether this is appropriate for other

countries depends upon each individual society's beliefs and upon the type of government involved.

It is also difficult to present and discuss these matters without intruding one's own ethical and cultural biases. This was most recently explored when FHI was invited to assist the Indonesian government in solidifying the ethical approach to informed consent and patient rights in a society which embodies Muslim, Buddhist and Christian ethics in an unresolved mix. The major issue to be resolved was that of informed consent; the Indonesian researchers did not believe that their population was ready to be fully informed about any scientific matters and would be too frightened to participate in any studies.

I am going to consider ethics from two separate, but intimately related aspects:

- The ethics of contraceptive research, and
- The ethics of family planning programs.

The United Nations as a body recognize and emphasize that:

"All couples have the basic right to decide freely and responsibly the number and spacing of their children and to have the information, education and means to do so; the responsibility of couples and individuals in the exercise of this right takes into account the needs of their living and future children, and their responsibilities towards the community." (Isaacs, 1981).

But, what are the LIMITATIONS to the moral right to reproduce? These might include:

- A. Transmission of disease to the offspring.
- B. Unwillingness to provide proper prenatal care.
- C. Inability to rear children.
- D. Psychological harm to the children.
- E. Overpopulation.
- F. Non-marriage (singles, homosexuals).

Certainly, points A through D are reasonable to the

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observer, but not necessarily to the couple participating. Who has the right to decide that Overpopulation (in the world, region, country, etc) requires limitations of the INDIVIDUALS right to reproduce? And...

Who makes the ethical decisions?

The mother, potential or actual
Husband and wife
Physician/Counselor/Professional Groups
The Clinic

Ethical Committees:

Local or National
The Legislature/Law Makers
Religious Groups
The Media
Religious Groups
The Media

Which of these SHOULD make the decisions and WHICH actually do?

In today's climate of "individual" rights, the medical profession is no longer considered as the sole guardian of the public health, and there is a tendency to lay the necessity for informed consent and information provision on the medical group while ignoring the necessity for recognizing and ACCEPTING autonomy and responsibility on the part of the patient/subject. This is similar to a parent appearing to allow a child to make a serious choice and then shielding it from any serious consequences.

What is the legal Status in the United States currently? No. U.S. state has ever attempted to impose "No Childbearing" laws. The U.S. assumes the "Right to Procreate". All mandatory sterilization laws for habitual criminals and the mentally handicapped have been voided by the Supreme Court.

Informed choice and subject protection in research began for the United States with the work done on Yellow fever while the Panama Canal was under construction. The Nuremberg trials detailing Nazi medical atrocities led to further U.S. and World concern, resulting first in the Helsinki Declaration and later a U.S. Congressional interest produced the Belmont Report, which has been the basis on which we have developed our system of Informed Consent and the Institutional Review Boards for research projects.

A. RESEARCH AND ETHICS

The establishment of FHI's IRB/PHSC in November, 1975 followed the requirements of the Belmont Report. Since that time, our PHSC has reviewed ALL protocols involving human medical research. The reviews are primarily from the standpoint of subject or patient safety, but they often deal with scientific validity and feasibility, too. The standards of the Belmont Report were adopted by the US Department of Health and Human Services (HHS), and, consequently, by the Food and Drug Administration (FDA). ALL human research studies in the US and ALL studies conducted outside the US which are expected to be submitted to the FDA must follow the rules of informed consent and the ethics propounded in the Belmont Report or the study data will not be considered acceptable.

One of the overriding principles in research which is related to informed consent is that of **FREE CHOICE**. This means **NO** coercion to enter or to stay in a study. The subject is free to leave at any time for any reason. This may be especially pertinent in a study of a new contraceptive which results in greater amounts or frequency of bleeding than the subject considers all right for HER. The Investigator can explain and attempt to persuade, but he cannot threaten or withdraw services in the event of leaving. Even the "persona" or the image of the investigator may be threatening to the subject.

One of the more recent changes in all drug research in the U.S. is the withdrawal of prisoner populations. For years, most U.S. pharmaceutical houses had research buildings on the grounds of major prisons which provided good meals, superior recreational facilities and more than usual privacy. It was decided that such **ADVANTAGES** constituted coercion for the prisoners and as such, the units were closed. Payment for participation in a research project is also a sensitive subject. Obviously, paying \$10,000.00 to someone would be a serious coercion to enter a study, almost regardless of the risks. Payment to reimburse for travel expenses (legitimate) and time lost from work is almost universally accepted, but between these two extremes where is the line to be drawn ethically?

The ability to study the mentally handicapped or children in research projects is severely limited by their inability to give adequate informed consent. The non-use of children makes the development of pediatric drugs a very difficult chore in the U.S. To the best of my knowledge, all drugs cleared by the FDA in the last 10-15 years for adult use not received clearance for pediatric dosing. Only drugs specifically designated for children, such as growth hormone, have made it through the triple problems of IRBs, informed consent and the FDA.

The issue of confidentiality in ANY research is a vital ethical problem. The medical profession's view of confidentiality extends far back into the past and has been clarified, at least for U.S. legal purposes, within the recent past. And yet, how is this to be handled in contraceptive studies when the woman does not want her partner to know or be aware that she is attempting to contracept. If the woman is below "the age of consent", what are the rights of the parents to know versus the necessities of both the subject and society to prevent unwanted and unnecessary pregnancies?

In randomized studies, subjects are assigned to groups, either control, placebo, standard medication or device or experimental method. Obviously, the outcomes for the individual participant depend upon the group assigned and there may be an as yet indefinable risk of pregnancy. In this situation, informed consent, understanding of the risks and lack of coercion are ethically vital! The subject must know what help is available in case of failure and what the possible damage to the fetus may be. A balance must be struck between fearful disclosure and unknowing innocence. In the U.S. signed informed consent is a must; in some

societies oral consent with adequate impartial witnessing may serve the ethical needs.

The subject should ALWAYS have someone available to contact at the study site in case a problem develops.

One complication which has arisen in the U.S. is the "feminist view" of research. Most publications devoted to this view of research insist that it is male-dominated and dedicated to harming women. A recent article purported to find a direct collegial link between the NAZI experiments and modern research into contraceptive uses. As in the rising protests concerning "animal rights" in research, this may make future studies more difficult and rational results harder to obtain.

B. FAMILY PLANNING SERVICES AND ETHICS

The same problems exist for the delivery of family planning services to consumers as exist for research into contraception. However, the application of informed choice and subject protection have slightly different aspects. Here, coercion and free choice are limited by five things:

a. Availability of methods — what mix of methods are available or provided in the area or country. Local customs, beliefs and religious practices may markedly affect not only what is acceptable to the consumer, but what is even offered. Consider that only in March, 1987 did the Italian Supreme Court decide that vasectomy was NOT a criminal offense and acquitted a physician who had fought the case for 5 years! In France, a resolution passed by the National Medical College of Physicians permitting voluntary sterilization for "very serious reasons", other than medical, has been ignored and NOT implemented! An article by G. Cave-Bondi in the journal *Zacchia*, 1987 discusses 45 cases of sterilization during cesarean sections and observes that recent guidelines in the area of jurisprudence seem to have cleared away all doubts concerning the lawfulness of such procedures, including those performed for CONTRACEPTIVE purposes. Consider that similar doubts and problems are still expressed in many developing world countries. In some, even the need and legality of ANY contraceptive program is still under discussion.

b. Attitudes of providers, imposition to beliefs and training

c. Attitude of government

d. Differing religious, cultural effects

e. Temporary vs permanent effects: that is; sterilization (reversible or not) versus steroid contraceptives (implants, monthly injectables, daily oral, barriers, etc.)

f. Financial availability of private versus public provision of methods.

Acceptability to individuals cultures plays a large role. The contraceptives offered certainly must fit within the role models and cultural taboos of:

a. The woman

b. Her husband. In many countries only the hus-

band can decide whether contraception can be undertaken and only what is acceptable to him.

There is also the question of the ethics of providing contraception or more specifically, sterilization, to those unable to control their own destinies. Consider the severely mentally handicapped woman, institutionalized or not, at the mercy and forbearance of those who provide care and with whom she comes into contact. Experience shows that pregnancy for these persons is not infrequent and the future costs of care for a normal or abnormal offspring are considerable. The obvious and simplest decision is to surgically sterilize, but who makes that decision? A study was done at the University of Michigan and a Model Clinic for the Reproductive Health Concerns of Persons with Mental Retardation was developed. An advisory committee, made up of community advocates for the mentally handicapped, clergy, special education professionals, parents, nurses and hospital administrators, is used to decide whether sterilization is appropriate. This committee and its processes have been favorably reviewed by regional attorneys, judges and social agencies. This report is the first I've seen that deals with the coercion and informed consent issues in a reasonable and useful way for the mentally handicapped female.

Confidentiality has been discussed with the research problems but the same difficulties exist for the delivery of family planning and for physicians the same background of patient confidentiality applies, if anything, even more strongly. In the U.S. the major ethical problem remains — do you provide contraceptive advice and techniques to underage persons without their parents knowledge and consent. About 18 U.S. states have ruled/legislated that is permissible for the provider to do. This means that 32 others either insist on parental knowledge or have not decided one way or another. This situation does just one thing well: In the U.S. it makes lawyers rich!

Finally, what is the effect of the incidence of sexually transmitted diseases and the AIDS epidemic on choice? There is evidence that the use of barrier methods of contraception reduce the transmission of STDs; there is a lesser body of evidence, but growing, that these same methods can reduce the transmission of AIDS. However, by custom, use, compliance and method, these are not particularly effective contraceptives, especially when compared to steroids and IUDs. Other evidence implicates oral contraceptives as at least a cofactor in the increased transmission of STDs (though some studies show lesser incidence of gonorrhea with steroid use). The situation with IUDs, pelvic inflammatory disease and ectopic pregnancy is not yet resolved and there is no evidence one way or the other concerning AIDS, only speculation that the endometrial injury may promote infection.

Any contraceptive or STD that promotes ectopy or genital ulcers increases the chance of AIDS infection.

Under these conditions, is it ethical to advise consumers to use only one contraceptive method or must we suggest a combination of methods? Here we are led

back to the necessity for more research in such areas so that family planning can help to provide protection not only against pregnancy but infectious disease.

A survey was done in an internal medical practice which shows that even in that milieu 30% of patients seen were found to present an ethical difficulty; the ethical problems encountered involved:

- a. Psychological factors- denial of condition
- b. Competence and capacity to choose
- c. Informed consent
- d. Refusal of treatment
- e. Confidentiality
- f. Cost of care

These six factors seem to cover well the ethical problems arising in both contraceptive research and delivery.

SUGGESTED READING

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