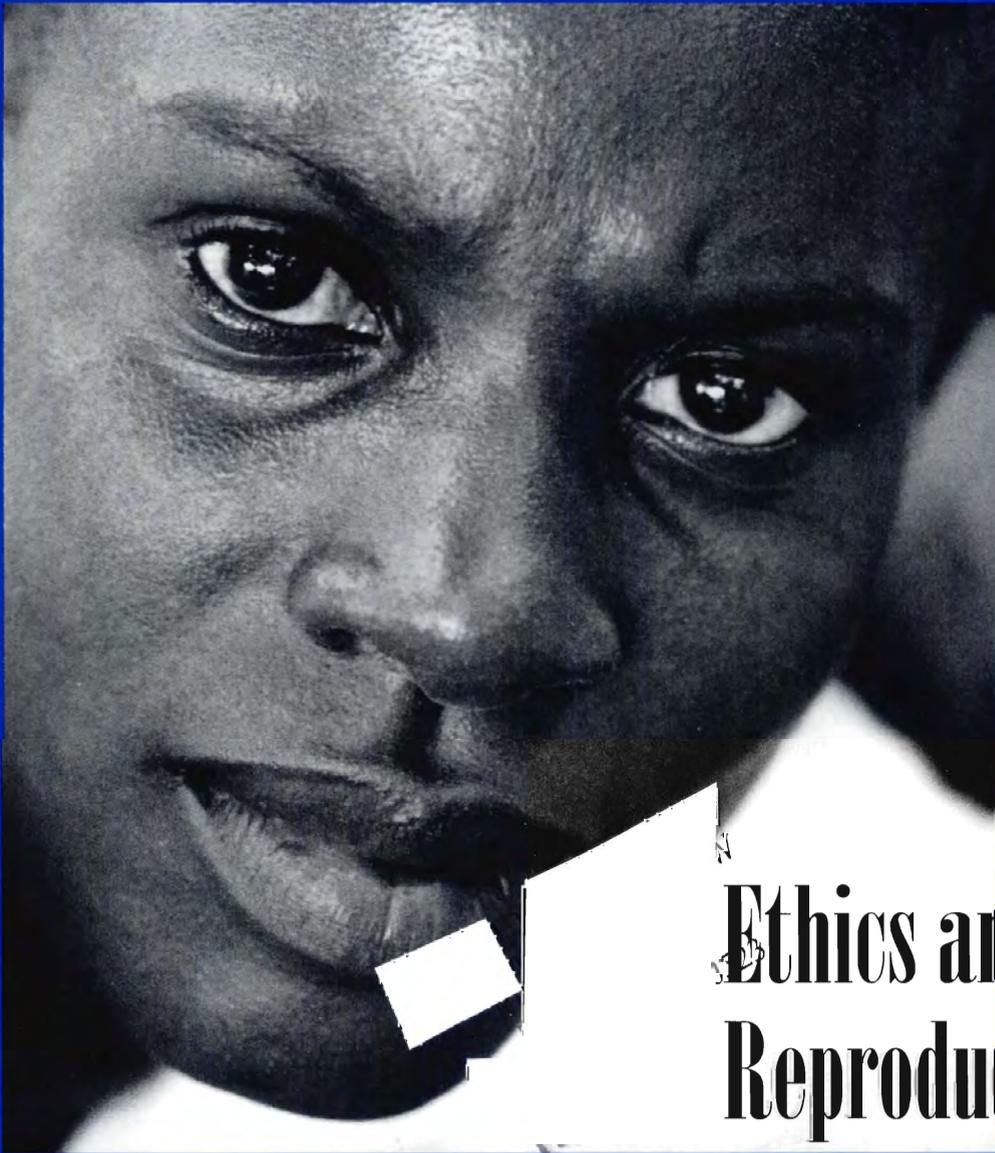


Network

FAMILY HEALTH INTERNATIONAL, VOLUME 21 NUMBER 2, 2001



**Ethics and
Reproductive Health**

News Briefs

NO TUBAL INFERTILITY RISK FROM IUD USE

Previous use of a copper intrauterine device (IUD), the most common type of IUD currently used, does not increase the risk of tubal infertility in women who have not yet had children, a new study by FHI and collaborating researchers in Mexico has shown. However, tubal infertility (infertility associated with blockage of the fallopian tubes) was found to be associated with *Chlamydia trachomatis* infection.

"This study suggests that copper IUD use is even safer than previously thought," says FHI senior epidemiologist Dr. David Hubacher, principal author of the study published in the August 23, 2001 issue of *The New England Journal of Medicine*. "Contemporary copper IUDs may be among the safest, most effective, and least expensive reversible contraceptives available. If not at risk for sexually transmitted infections, even women who have not yet had children are appropriate candidates for the copper IUD."

The study compared such factors as past use of contraceptives, previous sexual relationships, history of reproductive tract infections, and *C. trachomatis* infection among some 1,900 Mexican women divided into three groups: infertile, childless women with tubal blockage; infertile, childless women without tubal blockage; and women pregnant for the first time. Women who had chlamydia antibodies, indicating infection with *C. trachomatis*, were over twice as likely as women without antibodies to have tubal occlusion. Medical guidelines recommend that the IUD not be used by a woman with a current or recent sexually transmitted infection.

Previous studies involving IUDs, including some IUDs no longer in use, suggested they might cause pelvic inflammatory disease (PID), leading to tubal infertility. This concern has limited use of this highly effective contraceptive method. However, research suggests that the risk of

PID with IUD use is related only to the insertion process. If, during IUD insertion, microorganisms that cause sexually transmitted infections, such as *C. trachomatis*, are introduced from the cervix into the uterus and fallopian tubes, PID may develop. After the first month of IUD use, the risk of infection is not significantly increased. Worldwide, the IUD is the most widely used reversible contraceptive, with over 100 million women using the device.

LESS EXPENSIVE HPV EXAMS ARE EFFECTIVE

Direct visual observation of the cervix or genetic testing for types of human papillomavirus (HPV) strongly associated with the development of cervical cancer are more effective and less expensive than the traditional Pap smear in screening for this deadly cancer, a recent study suggests.

The study used a mathematical model involving a hypothetical group of black South African women to compare the cost-effectiveness of three approaches to cervical cancer screening: direct visual inspection of the cervix, an HPV DNA (genetic) test, and the Pap smear. When performed once at age 35, visual inspection followed by immediate treatment of women with abnormal findings was estimated to reduce cervical cancer incidence by 26 percent, compared with no screening. HPV DNA testing, followed by treatment in a second visit for women who tested positive for high-risk types of HPV, reduced the incidence of cervical cancer by 27 percent. In contrast, a Pap smear that was followed by treatment in a second visit for those women with abnormal results reduced the incidence by only 19 percent.

The researchers also estimated that visual inspection or HPV DNA testing cost less than U.S. \$50 per year of life saved, compared to U.S. \$81 for Pap smear testing.

In the study, published in the June 27, 2001 issue of *The Journal of the American Medical Association*, researchers also analyzed screening strategies, including frequency of tests, number of clinic visits, and optimal age for screening. They concluded

that the best way to balance clinical benefits and costs was to provide a single screening to previously unscreened women 35 years of age, followed by treatment for women with abnormal results.

Cervical cancer is a leading cause of cancer-related death among women in developing countries. The cancer is highly treatable in its early stages, but few women survive advanced cervical cancer. Most cervical cancer patients in developing countries already have advanced disease when diagnosed.

SIV VACCINE SHOWS PROMISE

A vaccine that protects monkeys against vaginal transmission of a virus closely related to HIV has been developed, and human clinical trials with an HIV version of the vaccine are planned.

The vaccine, developed by scientists from the University of California, San Francisco, and the University of California, Davis, was given to seven adult female macaque monkeys, all of whom remained healthy a year after exposure to a highly virulent strain of the simian immunodeficiency virus (SIV). The simian virus usually causes AIDS-like disease within a year. But two of the seven vaccinated monkeys showed no signs of infection, two were nearly free of any sign of infection, and the remaining three were infected but did not show any clinical signs of disease a year after exposure.

In contrast, six other monkeys exposed to SIV but not vaccinated developed a fatal form of simian AIDS 48 weeks after SIV exposure. The monkeys in this group were seriously ill with the disease, according to the study that was published in the August 2001 issue of the *Journal of Virology*.

The SIV vaccine combined elements of the Sabin oral poliovirus vaccine, which triggers a strong immune response, with genetic fragments of the simian virus. A proposed HIV vaccine would combine the Sabin vaccine with genetic fragments of the AIDS virus.

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The cover photograph, by Heldur Netocny of Panos Pictures, is a reminder that reproductive health care clients and research participants need protection. Principles of medical ethics have evolved over time to meet that basic need.



Human Research Must Protect Participants

Studies should be designed and monitored to protect the physical and psychological well-being of participants.

A provider who offers contraceptives or other products to clients should be confident that these products and services have been proven to be safe and effective through trials that were reliable, accurate, and had the welfare of the user as the ultimate goal.

This close relationship between research and clinical practice leads to better services and care for clients, as well as new or improved reproductive health options — better contraceptives, for example, or new treatments and preventive strategies for sexually transmitted infections (STIs).

An essential element of all good research is that it be done in an ethical manner, with careful planning and procedures to protect the individuals who participate.

“The basic principles of sound medical ethics have evolved over time to fulfill an essential need, and that is to protect people,” says Dr. Roberto Rivera, director of FHI’s Office of International Research Ethics. “These principles protect people who volunteer to take part in medical and behavioral research — both quantitative and qualitative studies. These basic principles shape the ethical safeguards for each study, but the specific protocols involved must come from close collaboration with several interested groups, especially from those who best represent the volunteers and who are members of the community where the research is conducted.”

The potential harm that can arise during a medical trial is often obvious. Volunteers in research involving contraceptives or devices or drugs to prevent or treat STIs may face some risk of physical harm, especially for products in early development. Potential harm to participants in qualitative studies may be less obvious, but is nevertheless real. An example would be if the confidentiality of a participant were not respected, especially during studies examining such sensitive issues as STIs (including HIV/AIDS), domestic violence, or sexual behavior and preferences. Such disclosure could expose participants to social stigma, job loss, or even violence and death.¹

Questions raised in social and behavioral studies may be controversial and often involve personal aspects of a subject’s life, says Dr. Nancy Williamson, who headed FHI’s Women’s Studies Project (WSP). During the 1990s, WSP sought a better understanding of family planning methods and the impact of services through interviews and discussion groups with women in 14 countries.

“Years ago, before I came to FHI, I was involved in a behavioral study in the Philippines,” she recalls. “When the questionnaires were entered into the databank, and the names of the participants were put into code, we told the staff to destroy the questionnaires. I guess we were not specific enough. We probably should have said, ‘burn the questionnaires.’ A week later, I was at the local fish market and bought a fish. I

was shocked when I saw that the man who sold the fish to me was carefully wrapping my purchase in a page from the completed questionnaire! Paper was so valuable in that culture that somebody must have sold the questionnaires rather than destroyed them." Such a flaw in the study's procedures might have widely exposed personal information about participants.

BASIC PRINCIPLES

It is now widely accepted that any type of study involving humans must be carefully designed and monitored to protect the physical and psychological well-being of the participants. In addition to obtaining informed consent from each participant (see article, page 16), scientists are required to monitor study participants closely, and have strict procedures for reporting any adverse experiences. Also, additional safeguards are needed to protect vulnerable populations, such as children, prisoners, and people with limited education or mental capacity.

Codes of ethical conduct have evolved from decades of analysis, debate, and international concurrence from research scientists, clinical practitioners, policy-makers, and academics.

Three widely accepted ethical principles should guide the protocols for any study involving humans. Research participants should expect:

- respect
- beneficence
- justice

In the United States, these principles were articulated in 1976 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.²

The commission stated that "respect" for participants incorporates at least two important ethical convictions. First, people who volunteer for research should be treated as autonomous agents — people who have self-rule. And second, people who have diminished self-rule due to age, marital status, mental or physical impairment, lack of education, incarceration, or financial instability are entitled to additional precautions.

Participants should also be protected from harm, with extensive efforts in procedures and study protocols to secure their well-being — the principle of "beneficence." Beneficence is a term that typically describes acts of kindness or charity, but is used in a stronger sense when guiding the ethical design of research. In the context of research on humans, "beneficence" is a strict obligation to maximize possible benefits and to minimize possible harm to participants.

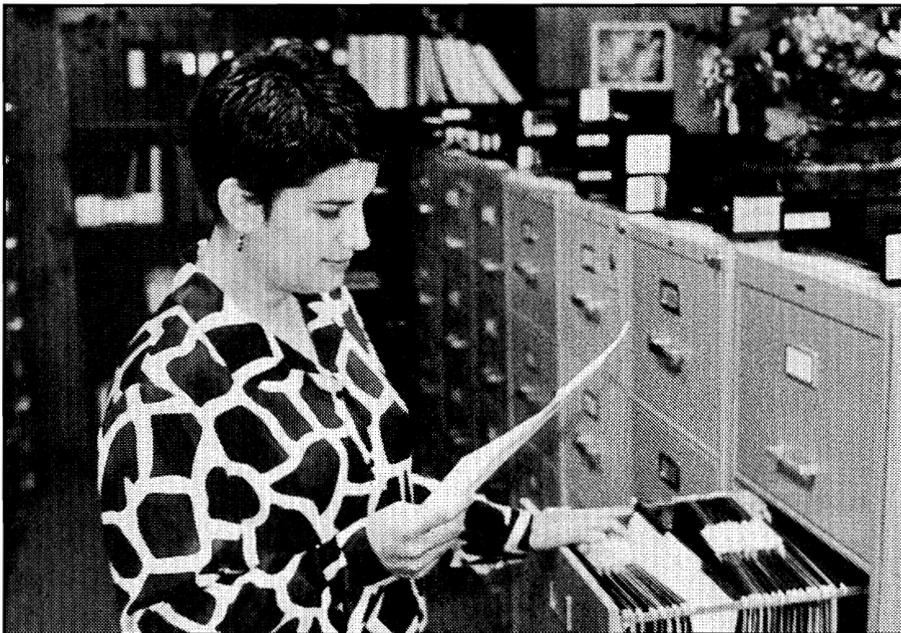
Beneficence places the responsibility of the well-being of the participant — physically, mentally, and socially — directly on the researcher conducting the study, and reinforces the ancient maxim of medical ethics: first, do no harm. Protecting the human research participant is more important than the pursuit of new knowledge. It takes precedence over the personal or professional gain of the researchers.

"Justice" is the third principle. Justice weighs such questions as who will benefit from the research and who will bear its burdens. Scientists are called upon to design studies that distribute equally the risks and benefits that participation in the research would bring. Justice mandates that recruitment and selection of research participants be done in an equitable manner, and that research not be done on disadvantaged or vulnerable people in order to benefit the privileged.

Conducting research largely among the poor in order to benefit people who are better off is an example of injustice. A widely publicized example in the United States involved syphilis research conducted on disadvantaged African-American men from 1932 to 1972. In the study, Alabama farmers were only told they were under study for "bad blood." Researchers allowed some participants to go untreated for syphilis for years after effective treatment had become available, in order to study effects of the disease on a long-term basis.³ In 1997, President Clinton apologized on behalf of the United States government to the surviving participants and their families.

Continued on page 8

NASH HERNDON/FHI



PROTECTING THE CONFIDENTIALITY OF PERSONAL INFORMATION ABOUT RESEARCH PARTICIPANTS IS AN ETHICAL RESPONSIBILITY. ABOVE, AN FHI STAFF MEMBER CAREFULLY HANDLES RESEARCH FILES.

INSTITUTIONAL REVIEW BOARDS HELP ENSURE SAFETY

An ethics review committee — sometimes referred to as an “institutional review board” (IRB) — helps ensure that people participating in a study are protected as much as possible from any harm resulting from the study. An IRB is composed of members who are not doing the actual research itself, and the membership should consist of people who are representative of the community in which the study is taking place.

The committee’s primary responsibility is to review study protocols before research begins to make recommendations concerning the safety and possible risks to human participants. It also reviews incidents during the study that could or do affect safety, and recommends how to resolve them.

In the United States, any research conducted using federal money must be reviewed by an independent ethics review committee to ensure that research involving human participants is clearly justified, safely performed, and complies with national and international codes of research ethics, such as the U.S. Code of Federal Regulations.¹

In 2001, a U.S. government commission made a series of recommendations to protect the participants in any research, regardless of whether federal funds were used. For example, it recommended that informed consent forms explain any benefits that would be available to participants when the study ends, and that participants receive an explanation of how any new, effective interventions will become available to the public. For research sponsored by the U.S. government in a developing country, the recommendations would require approval by ethics review committees in both the host country and the United States. New laws would be needed for the recommendations to take effect.²

WHO SERVES?

Generally, selection of IRB members should meet certain criteria. These criteria help ensure a diversity of professional backgrounds, gender, and ethnic groups. In the United States, federally funded research requires that at least one member come from a nonscientific background, and that at least one member not be affiliated with the institution conducting the research.³

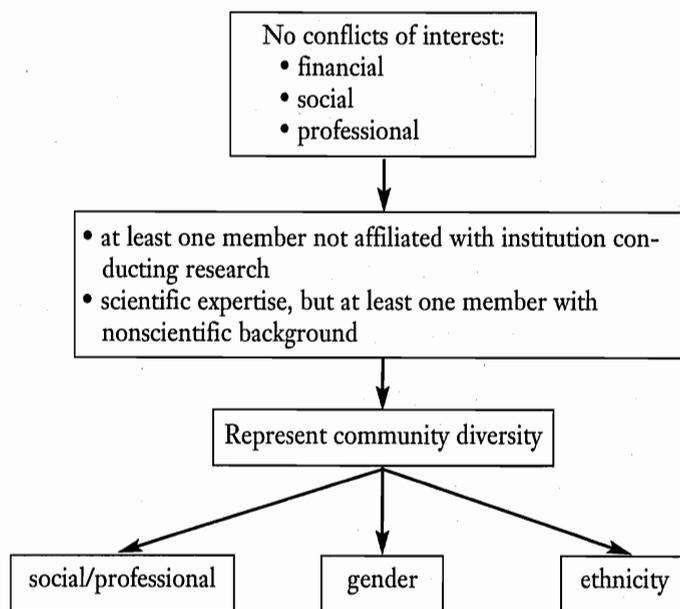
Each panel for U.S.-funded research must have at least five members from varying backgrounds. This diversity helps ensure that several areas of expertise are given equal weight in any decision that the committee makes. If the study involves participants who are particularly vulnerable, such as children, prisoners, or

physically or mentally disabled persons, it is strongly recommended that at least one member be knowledgeable about that particular group.

FHI has a panel to apply good ethical designs and safeguards to all of its human research. This panel, known as the Protection of Human Subjects Committee (PHSC), is additional to any ethics review committees in places where research is conducted. An FHI study at a U.S. medical center, for example, would require oversight from both FHI’s PHSC and the medical center’s own IRB.

“Our PHSC is made up of eight members and meets at least four times a year,” says David Borasky, institutional representative to the PHSC at FHI. No FHI staff can cast a vote in the independent PHSC’s deliberations. “I’m a member of our PHSC,” says Borasky, “but I’m not a voting member. Basically, the PHSC reviews proposed studies, and votes to either approve, disapprove,

GUIDELINES FOR SELECTING MEMBERS OF AN IRB



GRAPHIC: KAREN DICKERSON

or defer a particular project. It also reviews ongoing studies to ensure compliance with guidelines governing protection of human participants during study implementation.”

PHSC members come from varying professional or social backgrounds in order to ensure an appropriate range of perspectives. For example, the current PHSC chair is a theologian who is headmaster of a private school and previously was dean of the School of Divinity at Duke University in the United States. Other



COMMUNITY ADVISORY BOARDS, SUCH AS THIS ONE IN BLANTYRE, MALAWI, EVALUATE THE IMPACT OF STUDIES ON LOCAL COMMUNITIES.

members include several professionals who are not associated with FHI's work outside of their PHSC memberships — an epidemiologist, an obstetrician/gynecologist, a pediatrician, two sociologists, a specialist in internal medicine and bioethics, and an attorney who specializes in health law. The membership represents different ethnic groups and half of the members are women.

In addition to the PHSC, other panels are sometimes established to advise FHI scientists, including community advisory boards. For example, in FHI's Women's Studies Project conducted during the 1990s in 14 countries, local advisory groups were established that included scientists, women's advocates, and policy-makers. Some of the research focused on sensitive topics — such as domestic violence in Bolivia and the Philippines, covert use of contraceptives by women in Mali, adolescents seeking abortion in Brazil, and teenagers' attitudes about sexuality in Jamaica. Consequently, FHI and local researchers worked closely with local advisory groups to make sure study participants' privacy was protected. And at Iloilo University in the Philippines, an IRB established as part of the Women's Studies Project continues today, long after the FHI project concluded.

ETHICAL SAFEGUARDS WORLDWIDE

FHI's PHSC applies U.S. regulations strictly, even when conducting research in other countries, and even when U.S. government funds are not used. Coordinating the PHSC's activities with ethics review committees in other countries or at other institutions is part of the process to safeguard participants. "Usually, it is the

study's local investigator who has the most contact with the local panels," says Borasky.

Conducting research in other countries can be challenging. Differences in languages, including local dialects, levels of literacy, and a variety of local values and cultural systems must play a role in how to inform potential participants about the research and its risks, and in shaping other ethical aspects of a study. Certain cultures may prohibit women from serving on a local ethics review committee, thus defeating the U.S. standard that requires gender diversity. In most resource-poor countries, administrative expertise, well-staffed facilities, and access to information are limited, making it difficult for a local panel to perform effectively.⁴

"During the past few years, there has been an increasing recognition of the need to strengthen the capacity of developing countries to conduct the ethics review of projects," says Dr. Roberto Rivera, director of FHI's Office of International Research Ethics.

"FHI is now conducting a strong, well-organized effort to provide training and curricula that will help the staff of research organizations in developing countries to establish ethics review committees," he says. "I believe FHI is one of the first international organiza-

tions to do this." For example, FHI has prepared a training curriculum for developing country scientists and policy-makers. Devoting this issue of *Network* to the subject is another effort to encourage well-designed ethical oversight for human research.

"A competent ethics review committee cannot be established overnight," says Dr. Rivera. "Much care should be taken that the membership is selected carefully and mirrors the local population where the research is being conducted. Sometimes, membership is over-represented by physicians. Alerting the local people about the importance of membership diversity is the key to ensuring that as many viewpoints as possible are given equal weight for the benefit of human participants."

— Ellen Devlin

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The concept of justice also applies to the publishing of study results. Investigators are ethically obligated to present their findings accurately and fully — including results that may argue against the study's hypothesis — in order to protect both the study participants and people who volunteer for future research on the same topic, as well as the general public whose access to products or services may be affected by the outcome of the research.⁴

SINCE HIPPOCRATES

The first recorded application of ethical standards to medical practice is from Hippocrates, who practiced and taught medicine in ancient Greece. The Hippocratic oath, which is recited by most graduating medical students to this day, stipulates that physicians should “first do no harm,” that patient confidentiality must be respected, that physicians should not perform procedures for which they are not qualified, and that physicians should lead exemplary lives.

As medicine became more advanced over time, physicians and scientists confronted situations that were no longer neatly addressed by the oath. In order to develop safe and effective medical procedures and treatments to combat disease, scientific studies on drugs, devices, and procedures had to be performed. In recent times, this has meant conducting research first in the laboratory, then on animals, and eventually on humans if laboratory and animal studies involving safety issues were encouraging.

During World War II, German physicians forced concentration camp inmates and prisoners of war to take part in a variety of harmful experiments, most of which were medically useless. Many of the prisoners died from the experiments, or were permanently injured as a result.

Nazi war criminals, including some of the physicians who performed these experiments, faced a war crimes tribunal in Nuremberg, Germany. A result of these trials was the Nuremberg Code, which established 10 standards of ethical conduct for studies involving human subjects.

Since the drafting of the Nuremberg Code, other documents and declarations have amended those principles to include contingencies that the framers at Nuremberg could not foresee. The Nuremberg Code and other accords that followed have established international guidelines to help researchers protect the safety of their participants.

In 1964, the World Medical Assembly (now known as the World Medical Association) drafted the Declaration of Helsinki, which expanded on the basic

consent in cases where the participant is legally incompetent.⁵

The Declaration of Helsinki has undergone revisions since 1964. One supports a researcher's right to use new therapeutic measures to save a life, for example. Another amendment mandates the establishment of a committee, sometimes known as an institutional review board (IRB), to oversee studies involving human participants (see article, page 6). These committees must be independent of the organization conducting the research.⁶

Some of the amendments to the Declaration of Helsinki have been controversial. A revision added in 2000 states that the “benefits, risks, burdens, and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods.

This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic, or therapeutic method exists.” Another section adds, “At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic, and therapeutic methods identified by the study.”⁷

The stipulation regarding the use of a placebo arm* when a known treatment may indeed exist has resulted in ethical debate, particularly in countries where the HIV/AIDS epidemic has taken a terrible toll.⁸ For example, some antiviral medications, such as zidovudine, reduce HIV transmission from an infected mother to her newborn. However, in some

U.S. DEPARTMENT OF DEFENSE/WEBSHOTS



NUREMBERG TRIALS: THE NUREMBERG CODE, A RESULT OF THESE TRIALS OF NAZI WAR CRIMINALS, ESTABLISHED STANDARDS FOR ETHICAL CONDUCT IN HUMAN RESEARCH.

points of the Nuremberg Code to include concepts such as the distinction between clinical research combined with professional care, and nontherapeutic clinical research. The declaration also stated that informed consent should be obtained in writing, and that a legal guardian may give written

* In research using a placebo arm, only some of the participants receive the drug or treatment being studied. Other participants receive a “placebo,” an inert compound or treatment that is identical in appearance to the experiment drug or treatment. The purpose is to analyze the experimental approach more accurately, since the suggestion of receiving any drug or treatment could have an effect. Comparing experimental treatment with a placebo arm helps remove this effect.

studies that sought to determine the efficacy of reduced doses of the drug, there was a placebo arm that withheld all treatment. Critics argue that there should be no placebo arm, and that participants engaging in such trials should be provided with the highest accepted standard of care or treatment, even when that level of care is not readily available in the country where the study is conducted.⁹

However, a placebo arm is sometimes the only way to test whether or not a treatment is effective. Consequently, a ban on a placebo arm could prevent the development of a more effective, less costly treatment since conclusive research needed to obtain regulatory approval might not otherwise be possible.

The international codes of ethical conduct in research have been evolving in a climate of worldwide change in attitudes regarding vulnerable populations. The rights of children, the elderly, indigenous people, and persons with disabilities are more widely embraced, and this public recognition of their fundamental rights has resulted in better family planning and reproductive health care, as well as additional safeguards for research involving reproductive health.

One example of this changing worldwide attitude can be seen in the United Nation's 1994 International Conference on Population and Development, held in

Cairo. Representatives from 179 countries endorsed a number of statements seeking to protect women and other vulnerable groups and to enhance their opportunities for equal treatment and better education. Many of the concepts have been embraced by nongovernmental organizations and other groups that provide family planning services or conduct reproductive health research.¹⁰

— Ellen Devlin

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Health Services Raise Ethical Questions

Reproductive health providers routinely face ethical issues, including those with conflicting principles.

Providers of reproductive health services struggle daily with ethical decisions that can have profound consequences for the well-being of their clients.

Serving adolescents, HIV-positive clients, and women whose partners are violent or who oppose contraception are among the many ethical issues that reproductive health service providers routinely face. So, too, is balancing pressures to help reduce population growth with clients' rights to make contraceptive decisions freely.

There is no correct approach that fits every case. At the very least, the ethical delivery of reproductive health services must begin with providers carefully considering the possible consequences of their actions, based upon three well-established cornerstones of medical ethics: respect, beneficence, and justice (see article, page 4). And providers should remember that clients make the final decisions about the services they receive.

Not uncommonly, however, providers face situations in which these ethical principles are in conflict with each other. For example, respecting the confidentiality, and thus privacy, of clients is considered to be the ethical duty of all health professionals. However, providers may feel that disclosing confidential information is ethically correct in order to maintain societal norms or protect the health of the public at large.

ADOLESCENTS

As with all clients, adolescent clients' specific circumstances should be carefully considered when providing reproductive health services. For example, particular care must be taken in the case of a young adult who wishes to be sterilized, since the procedure is permanent. Sterilization is inappropriate for young teenagers, and thorough counseling is needed for young adults who are older, in their early 20s. Studies show that up to 20 percent of women sterilized at a young age (younger than 25 years old, in one study) later regret this decision.¹

Providers should respond to adolescents' requests for reversible contraceptive services with courtesy, while maintaining confidentiality. Research has demonstrated that adolescents are more likely to seek such services from providers they feel they can trust and from providers who respect their right to privacy.² "Youth are sensitive to the idea that the information they share about their sexual behavior will not be held in confidence, but instead will be shared with their parents or other adults," says Dr. Cindy Waszak, an FHI senior scientist with expertise in adolescent reproductive health. "They feel they lack control, that their behavior will be particularly scrutinized and judged by adults, and they realize that the consequences of such information being disclosed may be severe.

"They have good reason to be concerned," she adds. "Many providers do not

see adolescents as having the same rights as adults, and may be reluctant to serve them without parental consent, even when policies spell out the right of adolescents to receive non-permanent contraception or treatment for sexually transmitted infections (STIs) without such consent. Many providers either deny services to adolescents or fail to provide confidentiality because they sincerely worry that freely making contraceptive methods available to adolescents will encourage them to be sexually active, although research indicates that this is not the case.³ Finally, many providers choose to deny the fact that adolescents are sexually active."

However, the decision not to provide reproductive health services to adolescents in a confidential setting can cause far more harm than good. "Providers need to ask themselves whether they are providing the best possible care to their clients, regardless of age," says Dr. Waszak. "An adolescent who is turned away or whose reproductive health information is not held in confidence may well end up with an unplanned pregnancy, STI, or ostracism from parents or others in the community. Any of these outcomes can have life-long adverse consequences for an adolescent."

In cases where the law, administrative policies, or guidelines require parental consent for certain reproductive health services, the provider must follow the law. However, the provider can recommend options that do not require disclosure, such as buying condoms at a pharmacy rather than getting pills at a clinic. Also, the provider can either encourage the client to talk with her or his parents or offer to talk to the parent and adolescent together.

"Providers also need to keep in mind that some girls are in situations in which they find it difficult, if not impossible, to refuse sex," says Dr. Waszak. "In such cases, it is important for providers to respect an adolescent's courage and resolve even to seek reproductive health services. It is unethical for providers to turn away or betray the confidence of adolescents who have made such an effort to get help."

HIV-POSITIVE CLIENTS

Many clients who are HIV-positive or have other STIs do not know they are infected. In many settings, testing is unavailable. In others, clients who suspect

they are infected may be reluctant to be tested. They may fear receiving a positive test result, particularly if treatment is unavailable. They also may worry that a positive test result will not remain confidential, leading to severe social consequences.

Confidential and anonymous HIV testing services are slowly becoming available, and providers should promote the use of such services, most experts agree. (In confidential testing, a person's identity is known but test results are kept confidential. In anonymous testing, the identity of the person being tested is not recorded or required.)

"People who learn that they are not infected will be encouraged to maintain their HIV-negative status," says Dr. Eric van Praag, an FHI expert on HIV/AIDS care and support services. "Meanwhile, those who learn they are infected will become aware of the urgent need to adopt safe sexual behaviors to avoid infecting others, receive contraceptive counseling that takes their HIV status into account, and be actively referred for medical care and social support if needed. Pregnant women can receive treatment to reduce the risk of transmission of HIV to their unborn children. A diagnosis also allows infected individuals to obtain appropriate counseling and to plan for the future, anticipating how to care for surviving children and to make wills."

In Kenya, Tanzania, and Trinidad, a study conducted by a group that included FHI and involved some 4,200 people between 1995 and 1998 showed that HIV counseling and testing reduced risky behaviors associated with the sexual transmission of HIV. Over six months, individuals receiving HIV counseling and testing were more than twice as likely to report declines in unprotected intercourse with non-primary partners than individuals who received only basic information about HIV transmission



PROVIDERS HAVE AN ETHICAL DUTY TO PROVIDE THE BEST POSSIBLE CARE TO CLIENTS, REGARDLESS OF AGE.

and correct condom use. Self-reported behavioral changes were confirmed by STI incidence rates. However, the study showed that clients were reluctant to disclose test results for fear of stigmatization and discrimination.⁴

Their fears are well-founded in most settings. In developing countries, people usually depend on their families and communities for support and care. But, where stigmatization is associated with HIV/AIDS, disclosure can lead not only to rejection by family members, but loss of work and friends, physical and sexual assaults by male partners, and even deadly attacks.⁵

The Joint United Nations Programme on HIV/AIDS and the World Health Organization (WHO), which jointly provide surveillance of the global HIV/AIDS and STI epidemic, have stated that all such surveillance programs "should have policies that protect the privacy of patients and the confidentiality of disease control data."⁶ Furthermore, health care providers are bound by their profession to maintain the confidentiality of client information. And many do so.

However, positive test results often are disclosed, either carelessly or on purpose. Reports of such breaches have come from many countries. For example, HIV/AIDS reporting is supposed to be confidential in Sri Lanka, but some people have reported being stigmatized after their

HIV status was carelessly disclosed and became publicly known against their wishes. Some health staff in Sri Lanka have been accused of demanding money from people who tested positive in exchange for not disclosing their HIV status to the community.⁷

A small study in Russia concluded that confidentiality is not well understood by physicians. "There is little evidence that principles of confidentiality have received much consideration," the researchers concluded. For example, even at sites promising anonymous HIV testing, little effort was made to conceal patient identity on laboratory or insurance forms.⁸

Even well-intentioned providers sometimes disclose confidential information about HIV status. They argue that the confidentiality afforded infected people may jeopardize the well-being of uninformed, healthy partners. By guarding such deadly secrets, some providers fear that they may lose the trust of the community.

These concerns are so acute that partner notification against client wishes — although usually qualified by a long list of conditions — has been accepted in some countries. In the United Kingdom, for example, the doctor who believes an HIV-positive patient has not informed his or her sexual partner (and cannot be persuaded to do so) may notify the partner, but must be prepared to justify such a decision. In Thailand, where husband and wife are legally considered to be the same person, either must be informed of their spouse's HIV status.⁹

"In general, however, if a client is not ready to disclose his or her HIV-status to anyone, there is little a provider can do except repeatedly discuss with the client when and how to disclose and to whom," says FHI's Dr. van Praag. Notably, HIV counseling and testing services have been developed in Uganda, Rwanda, and other African countries to facilitate partner communication about HIV status. FHI researchers in Kenya and Tanzania found

couple HIV counseling to be more difficult than individual counseling, but more likely to reduce high-risk sexual behaviors.¹⁰

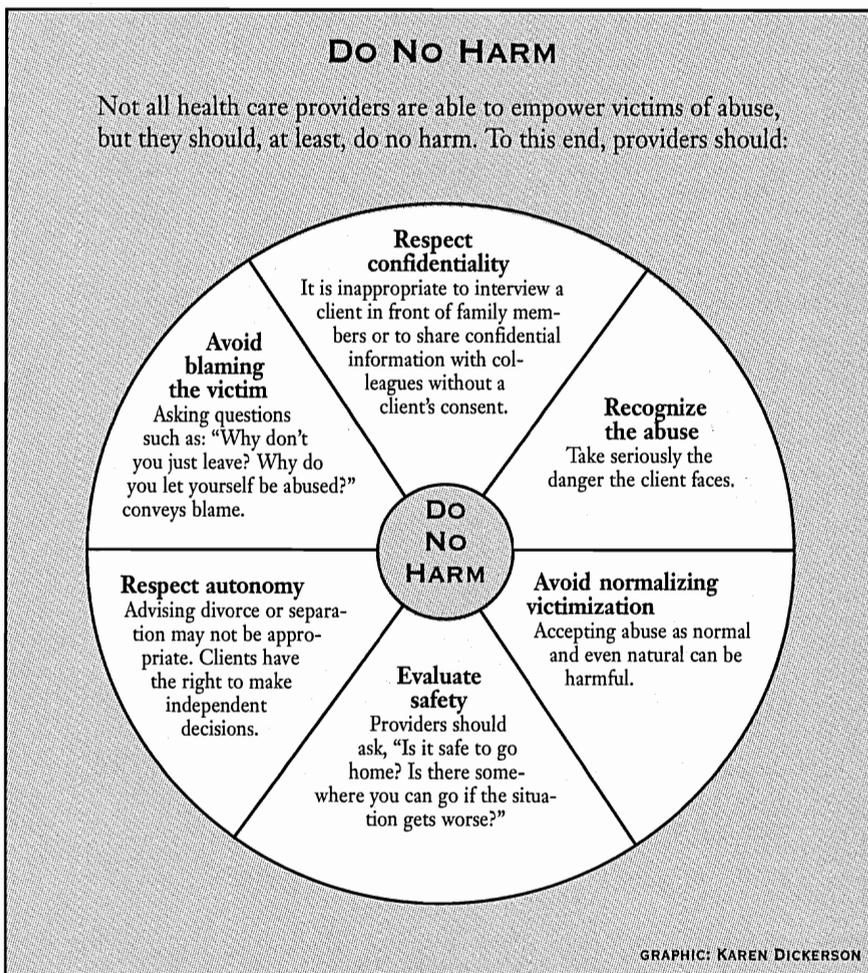
Despite the ethical duty of health professionals and reproductive health providers to care for HIV-infected patients or clients, some do not fulfill this obligation. In India, for example, 22 of some 100 doctors interviewed said they did not treat patients with STI complaints. "It is most regrettable that the medical profession, which should be the first to offer care and support to HIV-infected people, actually discriminates against them and rejects HIV/AIDS patients in India," researchers concluded.¹¹

Discrimination against HIV-positive patients not only threatens their well-being, but can also jeopardize the safety of other health professionals. Dr. María Eugenia González, an obstetrician and gynecologist at the General Hospital of Mexico in Mexico City, recalls how staff there could have been endangered because a woman in labor lied about her HIV status to gain admission to General Hospital, after being denied admission to other hospitals because of her HIV-positive status. "By the time she reached our hospital she was desperate for medical attention," says Dr. González, chosen for a research fellowship under FHI's Fellowship in Contraceptive Technology Research. "Immediately after being admitted, she gave birth." Although General Hospital routinely uses precautions to protect staff from HIV infection, staff at some hospitals might not be as careful if they did not know a patient was HIV-positive.

HARM FROM PARTNERS

Women are more likely to be injured, raped, or killed by a current or former partner than by any other person. In reliable, large-scale studies, results indicate that between 16 percent and 52 percent of women have been physically abused by a partner. Surveys in a number of countries show that from 10 percent to 15 percent of women report being forced to have sex by their intimate partner.¹²

Common as it is, domestic violence often remains hidden. The spouse was the aggressor in three of every four reported



RESPONDING TO VICTIMS OF DOMESTIC VIOLENCE INCLUDES DISPELLING POPULAR MYTHS

Many health workers do not have the time, training, resources, or support to help victims of domestic violence.

However, the World Health Organization states that, at a minimum, health workers can do the following:

- Be attentive to possible symptoms and signs of abuse — such as pelvic infections, recurrent sexually transmitted infections (STIs), physical injuries, and depression — and follow up on them.
- Where feasible as part of history-taking, routinely ask all clients about their experiences of abuse.
- If abuse is suspected or evident, be sympathetic and do not blame the victim since this can reinforce isolation and self-blame.
- Provide appropriate medical care and document in the client's medical records instances of abuse.
- Identify available community resources and refer clients there.
- Maintain the privacy and confidentiality of client information and records.¹

"When working with a victim of domestic violence, the provider's first priority probably should be to evaluate the woman's safety in terms of risk of recurrence of violence,



A man can do whatever he wants to his wife.

adverse reproductive health outcomes, or death through homicide or suicide," says Alessandra Guedes, a gender-based violence program officer at International Planned Parenthood Federation/Western Hemisphere Region (IPPF/WHR) in New York. "Obviously, it is essential for providers to take immediate action if the woman is in serious danger." This may mean helping victims of domestic violence to prepare an escape plan — knowing where to go and what to take with them if the danger becomes too great.

The provider should also keep in mind the credo "do no harm." This includes not blaming a woman for the domestic violence she has suffered. "Health workers, for example, may blame a woman for remaining in an abusive situation without understanding the economic and social constraints she faces or the fact that many abused women love their partners and do not want to leave them ... they just want to stop being beaten," says Donna

McCarraher, an FHI research asso-

ciate who has studied intimate partner violence. "Providers of family planning also may blame a woman who fails to follow their advice to use condoms. But if the woman knows that trying to

It's their business. It's not right to interfere with the private affairs of a couple.



negotiate condom use will lead to a beating, giving her another condom lecture will only succeed in further shaming her."

In many settings, domestic violence is accepted by women as well as men and will only be reduced as basic human rights are recognized. Until that time, while providers should not condone such abuse,



It is best for the children if she stays with him. He can still be a good father to them.

they will be limited in what they do by the institutional support they receive. "In general, a provider who wishes to take the first step of trying to identify victims of domestic violence should have a specific goal," warns McCarragher. "Is it to enable the provider to give better care? Is it to provide women with an opportunity to discuss their situation and reinforce the fact that the abuse they suffer or have suffered is no fault of their own? Or is it to refer an abused spouse to the appropriate services? If the goal is referral, providers must be aware of what resources exist for violence victims. The point is that, if you ask a victim if she or he has been abused, be prepared to act. Otherwise, you may do more harm than good."

To be prepared to act, providers need substantial guidance and training, coupled with institutional support. One source of guidance is an IPPF/WRH newsletter on integrating gender-based violence into sexual and reproductive health, available at <http://www.ippfwhr.org/whatwedo/basta.html>. The winter 2001 newsletter describes

how to create a protocol for implementing screening and services for victims of gender-based violence. The summer 2000

newsletter tells how to create a referral network and begin implementing client screening and staff training. Guidance for ways to end violence against women also is available from The Johns Hopkins School of Public Health Population Information Program at <http://www.jhuccp.org/~pr/11edsum.stm>.

— Kim Best

Only poor, ignorant men beat their wives.



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ILLUSTRATIONS, COURTESY OF THE HESPERIAN FOUNDATION, DEPICT COMMON MYTHS THAT CONDONE ABUSE.

cases of abuse among 179 women using health services in Santo Domingo, Dominican Republic. Yet, half of the interviewed women who had suffered physical or emotional abuse — with over three-quarters of those experiencing sexual abuse — said they had told no one about the violence before being interviewed for the study on violence.¹³ “Many abused women never tell,” said L.J. Payán of PROFAMILIA’s Santo Domingo clinic, where many of the women were interviewed.

Why should reproductive health providers consider it their ethical obligation to help clients who are victims of domestic violence?

“Violence is a reproductive health issue,” says Donna McCarragher, an FHI research associate who has investigated intimate partner violence in Bolivia. “It can endanger pregnant women, and directly jeopardize the use of family planning and STI prevention and treatment. Also, for many women who are abused, health workers are the main and often the only contact for support and information.” (See article on page 13 for how providers can help.)

Meanwhile, a married woman’s life and health also can be seriously threatened if her spouse vetoes her use of family planning services. In many countries, providers need to follow spousal authorization requirements that are found in laws, regulations, clinic guidelines, and national ministry of health regulations. However, some providers require spousal consent simply because they fear that not getting such authorization will defy cultural values and bring reprisals against them.

Studies conducted in Kenya, Botswana, Burkina Faso, Senegal, and Tanzania (Zanzibar) by the Population Council found that some providers reported imposing more restrictions on contraceptive use than required by policy or service protocols. Spousal consent is not required for provision of combined oral contraceptives, condoms, intrauterine devices (IUDs), injectables, or Norplant in these countries. But, depending on the method and country, from 6 percent to 57 percent of some 2,000 providers in the studies still required it as of 1998. “For all countries, the level of spousal consent requirements for condoms is discouraging,

particularly since many of these regions have a high prevalence of HIV and other sexually transmitted diseases,” the study researchers observed. In Kenya, for example, 41 percent of some 444 providers reported restricting condoms without spousal consent, “suggesting an unwillingness to recognize the frequency of HIV transmission within married couples or a fear that the women would use the condoms in extramarital relationships.”¹⁴

In the absence of legal requirements for spousal consent, providers have an ethical obligation to allow women to make independent decisions about contraception. The right of couples and individuals to decide freely on the number and spacing of their children has been repeatedly recognized throughout the world as a matter of principle: in 1974, at the World Population Conference in Bucharest; in 1984, at the Mexico City World Population Conference; and, in 1994, at the International Conference on Population and Development in Cairo. Furthermore, courts of several countries have held that spousal veto practices violate principles of personal privacy and autonomy and the right to health care. Courts in general agree that one partner may not compel the other to reproduce.¹⁵

PRESSURE

FHI and many other international health organizations believe that pressuring clients to use contraception is ethically wrong. Most countries uphold this position.

Nevertheless, there have been efforts in some countries to curtail rapid population growth, which can strain resources and lower the quality of life for all. For example, doctors may be offered incentives to meet quotas for IUD insertions and consequently pressure women to accept this method. Women in indigenous regions where language and cultural barriers exist between health providers and patients may be particularly vulnerable to pressure to use contraception.¹⁶

Clients’ contraceptive preferences also may be overridden when providers — believing they know what is best — make decisions on behalf of clients. “One must remember that, in some settings, women themselves may prefer providers to make reproductive health decisions for them,” says Dr. Irina Jacobson, an FHI assistant

medical director who conducts contraceptive technology training for developing country providers. “In fact, they may feel that a provider who is supposed to know what is best for them — yet still does not make a decision for them — simply does not care. Ideally, though, a provider should explain to the client that, while the provider knows what methods the woman can use, only the woman will know, based on her personal circumstances, what method is best for her.”

In general, providers of contraception — particularly long-acting methods — should offer methods without pressure as part of a wider menu, offering removal upon request of such methods as IUDs and the Norplant implant.

— Kim Best

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IS FEMALE GENITAL CUTTING ETHICALLY JUSTIFIABLE?

Just because certain practices have existed for centuries, are widespread, and are widely accepted in some cultures does not make them ethically justifiable.

Such a practice is female genital cutting (FGC) or female circumcision, which involves the partial or total removal of the external female genitalia or other injury to the female genital organs. The prevalence of FGC is estimated to be at least 90 percent in some African and Middle Eastern countries. In such cultures, FGC is often accepted by both women and men. Many women believe that FGC ensures that they will be accepted by their community. They do not know that it is not practiced in most of the world.

The World Health Organization (WHO), the United Nations Children's Fund, and the United Nations Population Fund have jointly stated that FGC causes unacceptable harm and have called for its complete eradication.¹ Immediate complications of FGC include hemorrhage, shock, infection, urine retention (often leading to urinary tract infections), and injury to adjacent tissue (sometimes resulting in incontinence). Long-term complications include bleeding, anemia, difficulty urinating, recurrent urinary tract infections, incontinence, chronic pelvic infections, infertility, vulval abscesses, scarring, difficulties menstruating, sexual dysfunction, and problems in pregnancy and childbirth.

It has been suggested that these harmful health consequences could be reduced while maintaining the deeply-rooted FGC tradition were the procedure performed by trained medical professionals in hygienic settings. This trend to "medicalize" the procedure is arising in several settings, including Egypt and Kenya.

However, WHO has consistently and unequivocally advised

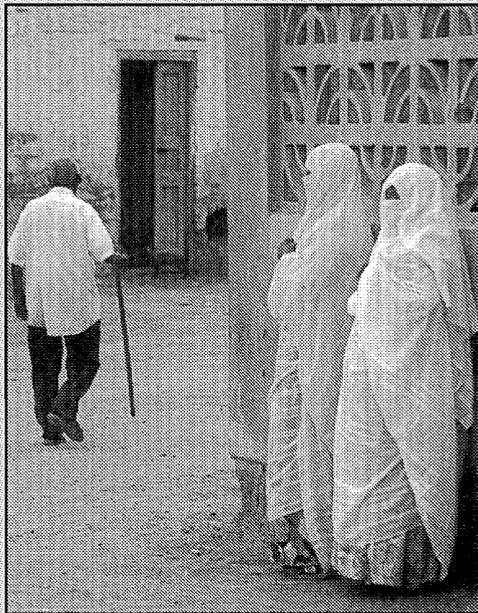
that FGC, in any of its forms, should not be practiced by any health professional in any setting — including hospitals or other health establishments.² "If an individual reaches the age of consent and wants to have the procedure done in a country where it is legal, then that is her decision and her right," says Dr. Ian Askew, a senior program associate with the Population Council, which seeks to eradicate the practice. "But FGC is usually performed on children or women too young to give consent, and performing FGC without consent is a clear violation of their basic human rights.

"In Kenya and Mali, the ministries of health have explicitly banned the practice in their facilities and by their staff, but the impact of these policies is not clear," says Dr. Askew. "Whether directives banning FGC will lead to clandestine cutting by health professionals, renewed use of traditional FGC practitioners, or elimination of the practice is not known."

Institutions working to eliminate FGC generally think that changing beliefs that perpetuate FGC should be the focus of interventions seeking to eradicate this harmful practice, says Dr. Laila Nawar, a regional advisor to the Population Council in Cairo, Egypt. In Mali, the Population Council has encouraged health practitioners to cease practicing FGC, and urged them to persuade clients to discontinue the practice.

— Kim Best

HELDUR NETOCNY/PANOS PICTURES



MUSLIM WOMEN IN ERITREA, WHERE FGC IS PREVALENT.

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Choices Must Be Informed, Voluntary

To make informed decisions, clients and research participants need reliable and complete information.

Everyone should have the right to make fully informed and voluntary decisions about reproductive health care. For medical providers and research scientists, ensuring this basic human right involves two related concepts: informed choice and informed consent.

Informed choice refers to ensuring that each client has the information about methods and services – including their risks and benefits – that enables clients to make a fully informed decision about whether to obtain or decline treatment or services; which contraceptive method, treatment, or service to select; and whether to seek and follow up on a referral. The process of ensuring informed choice for contraceptive use involves considering a wide range of factors that could affect the person's method choice.

Informed consent is a more formal, legal process in which the individual is first fully informed and then gives consent, usually in writing, to receive a method or service or to participate in a research study. Informed consent is typically required for volunteers who participate in human research and patients who undergo an invasive medical procedure, such as sterilization.

For either informed choice or informed consent, great care must be taken to be sure each individual understands the information provided and voluntarily agrees to receive the service or participate in the research study.

UNDERSTANDING INFORMATION

Each research participant must be informed about the nature of the research; foreseeable risks and expected benefits; potentially advantageous alternatives to participation; confidentiality; compensation for transportation, lost time, or injuries; and whom to contact with any questions. Each participant should also understand that participation is voluntary. Any research funded by the U.S. government must meet these criteria.¹

Simply providing information does not necessarily ensure participants will understand. Common barriers to understanding include illiteracy; language differences; class or power inequalities among scientists, research staff, and participants; and the nature of the consent form itself.

For many years, FHI has advocated the use of readability tests and other measures to ensure that consent forms are comprehensible; that is, they do not use unnecessarily long sentences and complicated words, and are otherwise appropriate. The consent form for research involving volunteers who have little formal education should be understandable to an illiterate or semiliterate person.² The sentence: "If there is a history of hypertension, alternative methods of contraception are indicated" could become "If you have high blood pressure, use some other kind of method." Also, the form would need to be read aloud to people who cannot read.

Consent forms are legal documents, often long and complex. Some forms “appear to be more concerned about legal implications for sponsor agencies than ... with the welfare of the volunteers,” Dr. Jean Pape, who works with research studies in Haiti, said in recent testimony before the U.S. National Bioethics Advisory Committee. “We cannot read them to volunteers because the only time a volunteer had a document like this read to him was when he was in a court of law and had to sign some kind of papers. So this is changing the trust relationship that we have with our participants and, therefore, we have to explain it step-by-step.”³

Even when participants understand an informed consent document, they typically have selective recall of its contents, according to an analysis involving 70 women who participated in a contraceptive clinical trial in Latin America, Africa, and North

study participants and users of contraceptive methods about the absolute and relative effectiveness of different methods,” says Dr. Judith Fortney of FHI, author of the study. Participants also need to understand clearly that participation is voluntary and that other contraceptive methods are available to them if they choose not to participate, she says.⁴

Studies in both developing and developed countries indicate a potential lack of understanding of informed consent forms. In Bangladesh, a study of informed consent among 105 pregnant women participating in a community-based study of iron supplementation found that while most women understood the objectives of the study, many did not understand they could decline to participate. Eighty-seven percent said they participated “because they believed that doing so might carry such great advantages, primarily in terms of medical

IS IT VOLUNTARY?

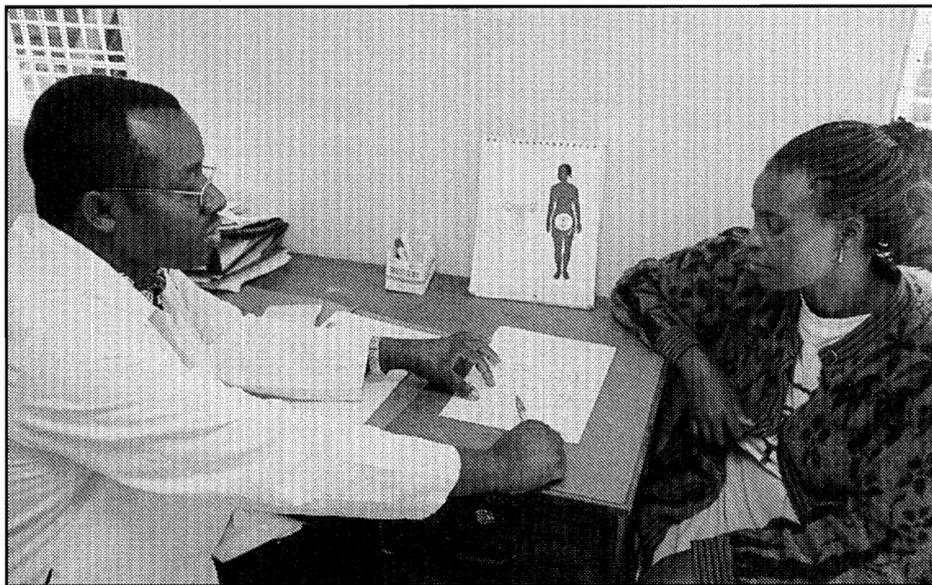
Ensuring that a person agrees voluntarily to participate in a study can be difficult. Many variables of culture and specific study circumstances affect whether consent is voluntary. Potential volunteers can get confused about the difference between experimental research and regular treatment. They may feel unable to withdraw from a study.

A perinatal HIV transmission study at a clinic in South Africa obtained the women’s permission to participate in the study prior to testing them for HIV. An analysis found that women clearly understood the nature of the research, so consent was informed. However, more than one fourth of the 112 women in the analysis agreed to the HIV test because they thought a refusal could limit their hospital care. “Many patients perceive that the hospital staff expect them to participate in the studies; this perception seems to have added a subtle element of coercion to ostensibly voluntary consent,” concluded Dr. Quarraisha Abdool Karim and colleagues.⁷

The AIDS epidemic has prompted difficult ethical issues regarding informed consent for research, including participation in HIV vaccine-related trials, and voluntary counseling and testing services. A research team in South Africa, where HIV rates are among the highest in the world, has developed proposed guidelines for culturally sensitive approaches to informed consent in such areas. One of the most important aspects in the process of obtaining consent, the researchers say, is to involve the community. “All decisions regarding participation should be shared decisions of the research team and volunteers, and their representatives,” the researchers proposed. “Full consultation should take place with the community, in order to foster a sense of partnership with respect to the research project.”⁸

Involving the community can be a delicate matter, however. A study designed to improve reproductive health services among Aymara women in an isolated area of Bolivia attempted to involve the women in developing research priorities. A culturally sensitive research team that included an Aymaran anthropologist and Latino social scientists examined the lessons they learned in an initial, unsuccessful effort. In a community meeting, the researchers

RICHARD LORD



AT THE MAJENGO CLINIC IN NAIROBI, KENYA, THE NATURE OF AN AIDS VACCINE STUDY IS CAREFULLY EXPLAINED TO A STUDY VOLUNTEER TO ENSURE THAT HER CONSENT TO PARTICIPATE IS FULLY INFORMED.

America. Most women correctly recalled such details as the number of visits, tests, and examinations that would be involved.

But the women did not correctly recall aspects of the study that affected their choice of contraception. Only 23 percent recalled the correct risk of pregnancy associated with the method. “The most immediate concern is how better to inform

treatment for themselves or improved health care for their babies, that is was difficult to say no.”⁵ A study in Italy tested understanding of informed consent by interviewing 250 patients at four national health service clinics to see if they would participate in a clinical trial. Fewer than six of 10 people interviewed understood the meaning and value of informed consent.⁶

explained the research project, hoping to have the women draw up a mutually agreed upon document.

However, the women did not want to make suggestions. They wanted to give unlimited and unconditional consent. As one woman said, "We'll just sign a blank piece of paper." The researchers determined that their initial approach had not worked because, in Bolivia, international research projects often lead to grants for development activities. "The anticipation of material benefits can motivate participation, despite explicit and repeated denial that such prospects exist," the researchers concluded.⁹

Informed consent documents developed in one country might not work well in another country or cultural setting. In-depth interviews with more than 100 researchers and oversight committee members in eight countries found that informed consent forms developed in another country can be inappropriate in some settings. The study by Duke University in Durham, NC, USA, and FHI recommended that

informed consent documents be developed in collaboration with local colleagues, giving special attention to cultural situations and potential problems of translation of particular concepts.

For example, national guidelines for conducting human research in one African country reject a requirement for written informed consent, based on the country's recent experiences of political torture and persecution that were linked to a person's affiliation to various organizations. Just the name of a person could be used to link them with an organization. Consequently, instead of signing research consent forms, individuals are allowed to put an "X," thus concealing the person's identity while following the requirement for written consent within a culturally sensitive context.¹⁰

Consent forms approved in English have to be translated accurately into local languages. Incorporating local concepts into translations and explanations can convey even complex scientific issues in creative ways. For example, the idea of an immune response is challenging to many

participants who do not understand the concept that something in their blood can attack bacteria or viruses. To overcome this problem, researchers in one country likened the body's immune response to a village with guards. They talked about "a particular kind of watchman" in the person's blood.¹¹

Another example of using local ideas to explain complicated research concepts can be found in a randomized vaccine trial in Senegal. During community meetings, the concept of "randomization" was explained successfully by using agricultural terms involving different seed varieties, ideas that were familiar to farmers in the area. "Communicating information about a choice and its implications can be difficult and time-consuming, but it allows valid, informed decisions," the authors concluded. "We found that widespread illiteracy is not a barrier to comprehension, especially since informed consent is more an interactive process than one that depends on reading."¹²

INFORMED CONSENT INVOLVES MANY STEPS

Ensuring that the informed consent process is implemented fully in FHI research studies typically involves many steps. Below are some of the key steps taken in one recent study involving sexually transmitted infections (STIs):

- Researchers converted a standard consent format to a booklet with simple illustrations, suitable for the reading level of people in the communities where volunteers would be sought.

- Two institutional review boards (IRBs) approved the exact wording of the booklet as well as the study protocol: FHI's Protection of Human Subjects Committee and the national ethics committee for research in the country where the study was conducted.

- Study coordinators trained staff who would counsel the women during the consent interview and throughout the study. While the counselors had to follow the exact wording of the consent booklet, they needed to make the information culturally appropriate.

- During each interview with a prospective volunteer, both the counselor and the volunteer referred to the booklets. If the woman could not read, a witness attended the session with her to be sure the counselor read the booklet correctly. The counselor

read each paragraph, one at a time, stopping to ask the participant to explain complicated information. Discussing the paragraphs helped the counselor determine if the woman understood details such as when she would be tested for STIs, what would happen if she had an infection, what she would be asked in follow-up visits, how her confidentiality would be protected, and that she could leave the study at any time she wished.

- Screening involved two steps. First, women interested in the study were examined to see if they currently were infected. Women found to be infected were treated but were not eligible to participate in the study. Those potentially eligible for the study went through another informed consent interview later.

- Volunteers who qualified for the study needed to understand randomization. Because lotteries are popular in the country where the study was conducted, the counselors found a way to explain randomization in terms of a lottery.

- Monitoring of informed consent continued after the women signed the form and entered the study. At each monitoring visit, investigators interviewed study participants in order to see if the women continued to understand the study and the key elements of their participation.

— William R. Finger

INFORMED CHOICE

The process of informed choice provides a larger context for thinking about informed consent as well as decisions that do not involve legal documents, such as consent forms.

"When a person freely makes a thought-out decision based on accurate, useful information, this is an informed choice," explain Dr. Robert Hatcher and colleagues in *The Essentials of Contraceptive Technology*, a handbook designed for clinic staff. "Informed" means that "clients have clear, accurate, and specific information that they need to make their own reproductive choices," as well as an understanding of their reproductive needs through person-to-person counseling, mass media messages, and other sources of information. The term "choice" means that clients have a range of family planning methods from which to choose and that clients can make their own decisions.¹³

Studies have found that family planning clients often do not get the information they need to make an informed choice. In a study in 12 African countries involving some 7,000 client exit interviews and about 7,000 client-provider observations, researchers concluded that "counseling on family planning is broadly lacking across all study sites, in terms of both information taken from the client and information given to the client about her method. These activities are particularly important because they are directly related to client satisfaction, appropriateness of method selected, continuity of use, and sexually transmitted disease/HIV risk."¹⁴

If a client receives the contraceptive method she needs and prefers, she is more likely to be satisfied with the method. A study in Indonesia among nearly 2,000 women found that receiving the method they desire resulted in much higher continuation rates. Among the nearly 1,700 women granted their method choice, 91 percent continued using the method a year later. Among the 266 women who did not get their first choice, only 28 percent were using the method a year later.¹⁵

To strengthen informed choice, family planning programs have encouraged providers to discuss a full range of contraceptive method choices. Without focusing

counseling to the needs of the client, however, discussing all methods can waste time and does not improve method choice or continuation.

A study in Peru found that information for method choice improved when counseling sessions increased from between two and eight minutes to between nine and 14 minutes, but had no impact beyond 14 minutes. "Offering a wide range of contraceptive options took up most of the consultation time and was highly correlated with the session length," the study concluded. "Discussion of the chosen method's side effects and screening for contraindications did not vary by session length ... It is important that providers use the available time more efficiently; that they be more practical in assessing clients' needs; and that they avoid providing too much information about irrelevant methods."¹⁶

Another factor in informed choice is the counseling style of the provider. A study among 7,800 reproductive-aged rural women in Bangladesh found higher first use of contraceptives and continuation rates when quality of care was better. Women who were not using a method and who perceived quality of care to be very good were 27 percent more likely to adopt a method, compared with women who perceived quality of care to be poor. And those who perceived a high quality of care were more likely to continue using their method than contraceptive users who perceived quality of care to be low. "The results strongly imply that what may be most critical is not the absolute number of methods offered to the client, but rather the degree of trust, rapport, and confidence established between the field-worker and the client," the authors concluded.¹⁷

— William R. Finger

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CASE STUDIES

Editor's Note: The following are selective examples of ethical questions that have been raised in scientific journal articles and similar sources. Some are based on actual events, while others are hypothetical.

CONFLICTING OBLIGATIONS

Doctors who treat HIV-infected patients and who also serve as investigators for clinical trials of HIV therapies may find that these two roles sometimes conflict, posing ethical problems.

In Australia, a small group of doctors — six general practitioners and four hospital doctors — were interviewed during the course of a clinical trial of an HIV vaccine about the tensions of being both clinicians and research investigators in the context of HIV medicine. The patients' interests and the research goals were sometimes at odds.

As a clinician, the doctor's priority is to care for the immediate welfare of his or her patients. As a research investigator, the doctor's priority is to identify the potential benefits of experimental medication and weigh them against potentially harmful effects. The usual way of doing the latter is through a double-blind randomized placebo-controlled clinical trial where neither doctors nor patients know whether the patients are receiving an experimental treatment or a placebo.

Such trials offer hope, especially to those people whose health is deteriorating. As one doctor remarked, there is a belief among patients "that trials are not trials but are access to new and innovative therapies." But a physician's ethical duty is to explain clearly that trial participation is an experiment: that new treatment may be effective, but this is by no means guaranteed. In fact, the experimental product may prove to be ineffective or more toxic than anticipated.

Also, some patients attempted to move from one trial to a newer trial to obtain the latest therapy. Doctors did not encourage this. But, as clinicians, they felt that their first responsibility was to their patients. Working "in the patient's best interest," some admitted to withdrawing patients from an ongoing trial and sometimes enrolling them in another.

In general, it appeared that the doctors wanted to be good scientists. But they were sometimes overwhelmed by the immediate needs and desires of their patients, and all the doctors interviewed ultimately placed the immediate interest of their patient before the outcome of the trial.¹

— *Kim Best*

THE RIGHT NOT TO KNOW

During research to find ways of preventing the transmission of HIV from an infected mother to her newborn, volunteer pregnant women who tested positive for HIV were encouraged to inform their partners about their HIV status. However, some women who did so were chased from their homes or beaten as a result.

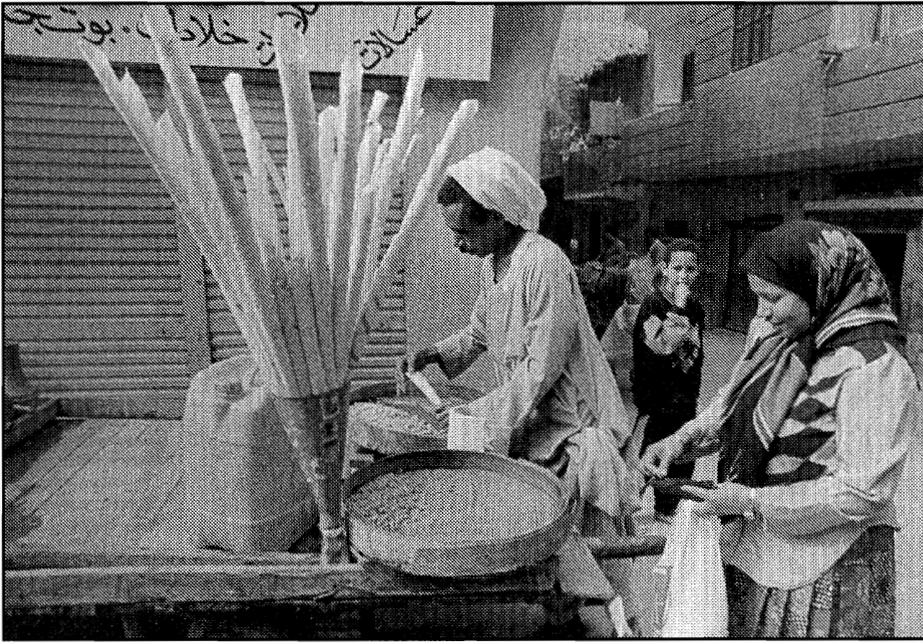
After giving their informed consent, volunteers for the three-year study were tested for HIV, and received counseling before and after the testing. For women who tested positive for HIV, counseling was intended to help them cope with the disease, prepare for the future, and reduce risky behaviors.

In addition to encouraging them to inform their partners, HIV-positive women were asked to bring partners to the clinic for more counseling. During the first two years of the study, 243 HIV-positive women participated and 66 of them shared test results with their partners. Twenty-one of those 66 returned with their partner to be tested and counseled (only five of the men were HIV-negative). However, as a result of revealing their status to their partners, 11 women were chased away from their home or replaced by another wife, seven were beaten, and one committed suicide.

Alarmed by the violence against women, the researchers changed their policy on counseling. During the final year of the study, women recruited for the research continued to receive information about HIV but were not given an appointment to receive the results of their HIV test. Instead, they were told that they could ask for the results, if they wanted to know — and only 109 out of 311 women with a positive HIV test did so. The scientists reasoned that the change was a safer, more ethical approach, since it helped protect the women from violence or stigma.

On the other hand, by not requiring the women to learn about their HIV status, it is conceivable that some HIV-positive women who did not learn about their status might spread the disease. The study's authors reasoned that most women in the study (about 80 percent) came from stable relationships in which the women were presumably faithful to their partners, and their partners were likely to be infected already. For these women, encouraging them to disclose to their partners that they were HIV-positive might only provoke abuse from the men, who might also take another wife and continue to spread the disease.²

— *Ellen Devlin*



A VENDOR OF CHICK PEAS IN CAIRO, EGYPT.

ECPS IN ADVANCE OF NEED

Emergency contraceptive pills (ECPs) should be included routinely among contraceptives that providers discuss with clients, including adolescents, say medical researchers from the University of Chicago, Illinois.³ The researchers offer the following hypothetical illustration of how failure to discuss ECPs might cause more harm than good:

Ms. Green is a 16-year-old who has been sexually active for about a year and started using birth control pills about six months ago. She tries to take the pills regularly, but admits to forgetting them sometimes. She says that, if she were to become pregnant, she would not have an abortion because she believes abortion is morally wrong.

In considering whether to tell Ms. Green about ECPs in advance of her needing them, several ethical issues arise. Because Ms. Green is not yet an adult, she may not be legally old enough to make an informed decision by herself about using ECPs. Second, since adolescents tend to use contraception sporadically, a provider might worry that telling Ms. Green about ECPs would decrease her adherence to her oral contraceptive regimen. This would put her at greater risk of an unplanned pregnancy.

But Ms. Green's previous use of birth control pills suggests that she is fairly responsible, and it seems unlikely that she would suddenly change her behavior, the researchers said. (There is no evidence that women who know about emergency contraception are less likely to use a regular form of birth control.) Also, it is precisely because of their irregular use of contraception that adolescents like Ms. Green can benefit from being told about ECPs before needing them.

A final compelling reason to discuss emergency contraception with Ms. Green is "her belief that abortion is morally wrong," the researchers noted. "For this patient and others who do not find abortion compatible with their moral framework, knowing that emergency contraception works as a contraceptive and not as an abortifacient provides another chance to avoid an unwanted pregnancy after unprotected intercourse."

— *Kim Best*

WHEN TO INTERVENE

In studies designed to identify problems in reproductive health service delivery, researchers may visit delivery sites and witness poor quality care that seems, for ethical reasons, to require their intervention.

A provider, for example, may drop an intrauterine device on the floor, pick it up, and — without sterilizing it — prepare to insert it in a woman.

The observer, in this case, might hesitate to act, since intervening might influence the research results. However, the safety of any client who is clearly at risk outweighs researchers' needs, and the observer in this case should intervene to protect the client, write the authors of a Population Council handbook about using situation analysis to assess family planning and reproductive health services.⁴ As stated in the Helsinki Declaration, "in medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society."⁵

Such a case is relatively rare. But troubling ethical concerns can still arise when observers witness less serious service quality problems. In fact, observers often are aware of mistakes, lapses, and misinformation, and interviewers often find that clients are not told essential information about their selected contraceptive.

In such cases, should observers intervene? "Clearly, doing so [in every service delivery situation] would prove so intrusive and detrimental to rapport with staff as to ruin the possibility of gathering useful information for program and policy decision-making and thus would greatly lessen the ability to make needed improvements," conclude the authors of the Population Council handbook.

Given the ethical dilemmas that observers may face in these cases, the Population Council authors recommend that a list of situations that might require some form of intervention be developed and discussed with relevant local authorities before such studies begin.

— *Kim Best*

RESPECT

In many cultural settings, lack of clear ethical guidelines and protocols for use in medical education and clinical practice — coupled with the high status that physicians enjoy — can result in providers disregarding women's autonomy and compromising their right to receive fair treatment in matters of reproductive health.

A study conducted in 1997 and 1998 at the teaching hospital of one of the major medical schools in Cairo, for example, clearly demonstrated that women's autonomy and right to information were neglected in the teaching process.⁶ The following exchange, observed during the study, is illustrative:

Doctor (to a woman listed on that day's surgery list for a hysterectomy): *Do you want any more children?*

Patient: *I have three, thank God.*

Doctor (to attending staff and students): *That is enough of consent. If she is calm and rational, you can explain the operation to her, or better just tell her husband.*

Besides belittling women, medical staff and students commonly excluded them from conversations about their health by speaking in English, a language unknown to the patients. The study found that the women, often treated as instruments of learning, were denied the right to participate and share their knowledge, as illustrated here:

Doctor: *How many children do you have?*

Patient: *Three, and thank God they are all well.*

Doctor: *I didn't ask you that.*

Patient: *I am sorry.*

Doctor: *And do you use a method (contraceptive)?*

Patient: *I wanted to tell you that I breastfeed.*

Doctor: *Did I ask you that?*

Patient: *Sorry.*

In fact, this woman had a reproductive tract infection. She wished to tell the doctor that she does not use or want to use contraception because she is breastfeeding and does not menstruate during lactation. Instead, he refused to listen to her and insisted that she come back to be fitted for an intrauterine device, despite her infection.

The project investigated how clinical instruction in obstetrics and gynecology influences students' perceptions of women's reproductive health and rights, and focused on interactions between female patients and male physicians. Fifth-year students and their instructors were observed during 100 clinical teaching rounds. The research also included interviews with 50 medical students and 14 of their instructors. Members of the Reproductive Health Working Group of the Population Council and other colleagues undertook the study, which was financed by a grant from the Dutch Overseas Development Corporation.

Egyptian medical students who were observed and interviewed in this study often received no instruction or inappropriate instruction about consent for reproductive health examinations and procedures. Nor did they provide their patients with information about physical examinations by the teaching faculty or clinical rounds where their case histories might be presented. Patients were expected to be passive and were believed to be incapable of understanding their own health and disease conditions. Three of every four students interviewed thought that women are indecisive and need help in making choices (particularly contraception), and nearly two of every three students thought that women could not handle complicated information. Most important, in 87 percent of cases reviewed in clinical rounds, patients were not informed of their diagnoses, although a similarly high percentage did receive follow-up and treatment.

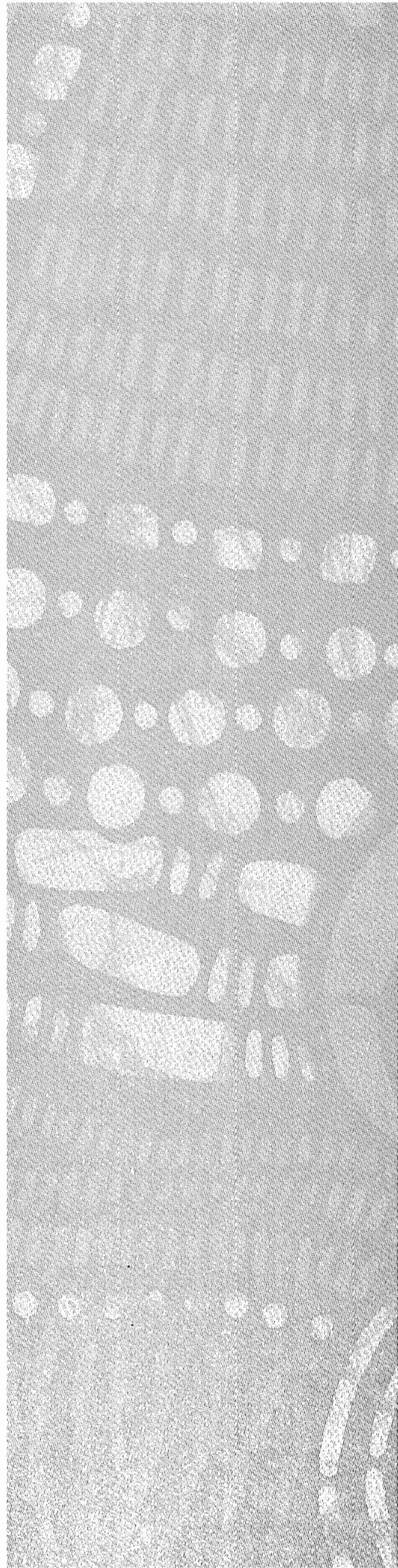
The study showed that explicit instruction about the ethics of clinical practice and patients' rights was rare. Most students learned by watching teaching staff interact with patients. This often led students to believe that providing a medical intervention was their primary mission, while respectfully interacting with patients was irrelevant.

— Kim Best and Dr. Hania Sholkamy

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Technology Raises Ethical Concerns

Providers must help ensure that emerging technologies are used ethically, with the client's best interest in mind.

Emerging technologies that involve reproductive health offer the promise of better care and services, and improved quality of life. However, new technology can often raise unanticipated ethical concerns, including the potential for abuse and misuse.

One central question is whether scientific advancements will be equally available to rich and poor individuals and in rich and poor nations. Another ethical concern is how technologies will be used — for altruism or profit.

Relatively new reproductive health technologies that are becoming more widely available include the use of ultrasound for determining the sex of an unborn fetus, new ways to achieve long-term or permanent contraception, treatments for people living with HIV/AIDS, and the use of in vitro fertilization (IVF).

Some emerging technologies involving reproductive health matters may not appear to affect developing countries directly. Yet these new ideas may shape health research policies in developed countries like the United States, which eventually could affect public health services or public policies in other countries. For example, the current debate in the United States over allowing embryonic stem-cell research is closely linked to an ongoing worldwide debate about elective abortion and IVF, since the specialized cells are

removed from human embryos that are being destroyed for other reasons. As U.S. research policy is shaped regarding embryonic stem-cell research, the thinking in other countries about abortion could change. And a decision to allow or prohibit stem-cell research will determine how soon new cures and treatments can be found for a number of diseases and illnesses, including options that may be better or cheaper for use in developing countries.

Reproductive health providers, clinic managers and policy-makers should be aware of ongoing ethical debates about these new technologies. As with any existing technology, health providers must work to ensure that tomorrow's technologies are used ethically, with the client's best interest in mind.

SEX SELECTION

Throughout the world, ultrasound technology has been used to produce images of the fetus in the womb, aiding in the diagnosis of genetic disorders. Ultrasound scans also can reveal the sex of a fetus, and some couples have used this information to abort unwanted female fetuses.

Abortion is a controversial procedure even in countries where it is safe, legal, and widely available. When abortion is used for sex selection, the controversy intensifies.

Several studies have shown that induced abortion has been used for this purpose.

FHI's Women's Studies Project found that in China, where government policy limits urban couples to one child and rural couples to two children, preference for sons remains strong. A survey of residents in six counties in north Anhui, south Jiangsu, and central Yunnan provinces found that some couples said daughters were good, but sons were better. "Without sons your husband will dislike you, and you will have low status," one 25-year-old woman said. An older woman said, "My mother-in-law said it is inferior to have daughters. If you have a son, even your house will look higher."

In China, many pregnant women use ultrasound to determine the sex of their fetus. Using ultrasound for sex selection is illegal, but study participants in the FHI study acknowledged it does occur. "People use an ultrasound machine," one woman explained. "If it is a female fetus, they don't want it. . . . No matter how much money they have to spend, they think it is worth it [to determine fetal sex]."¹

A Population Council study found similar results. Researchers interviewed 820 women in central China and found that nearly half of the pregnancies were subjected to an ultrasound scan for sex selection. About a third of 301 induced abortions were done to abort a female fetus.

In the same study, researchers learned that couples were most likely to abort a pregnancy when the previous children were girls and the current fetus was female. If the first child was a girl, 92 percent of the second pregnancies were aborted if the fetus was female. If the first child was a boy, 5 percent of second pregnancies were aborted if the fetus was female. However, when women were questioned about sex-selective abortions, 92 percent said they did not believe it was right to abort female fetuses. Many explained that they had an abortion because they felt pressured by family members; others said it was their duty to have a son who would carry on the family line. "I must have one son, no matter how many measures are taken," a woman said.

In analyzing study results, researchers urged stricter enforcement of laws and policies against sex selection. "More strenuous enforcement of the regulations forbidding prenatal sex determination and sex-selective abortion, and close monitoring of the uses of ultrasound" at hospitals and family planning stations might change the situation, said study author Chu Junhong.²

Some organizations and governments have taken steps to discourage sex-selective abortions. The government of India banned abortion of healthy female fetuses identified during genetic prenatal testing.³ A national convention of religious leaders

recently condemned sex selection.

However, the practice continues, and census figures show that the male-to-female ratio has dropped to 1,000:793 in the state of Punjab and 1,000:820 in Haryana.

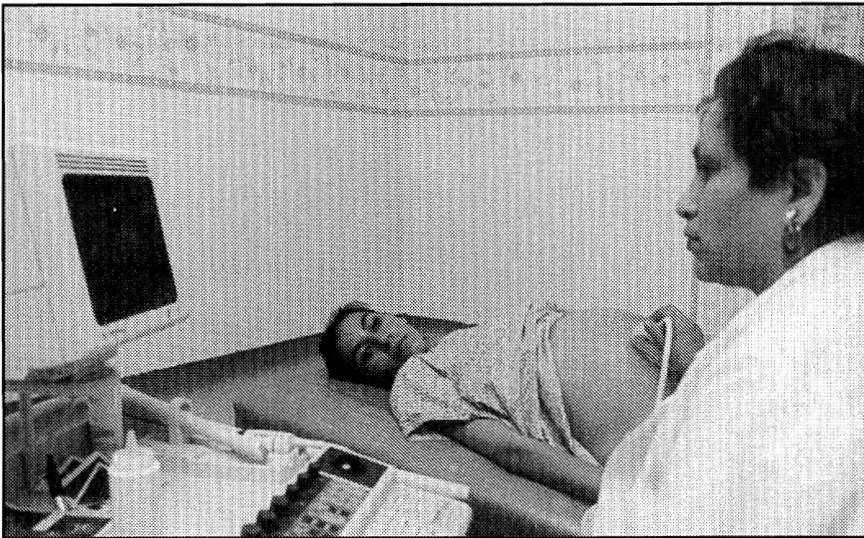
In Vietnam, where the government has implemented a two-child limit, son preference is strong, especially in rural areas. Couples who have more than two children risk steep fines and low priority for land allocation. While sex-selective abortion has not been widely documented, son preference apparently affects women's contraceptive use. An analysis of data from the Kien Xuong district found that women with one or two daughters reported higher rates of intrauterine device (IUD) expulsion than did women with at least one son. After the third year of IUD use, one-third of women with two daughters reported IUD expulsion, compared with 21 percent of women with two sons or a son and a daughter. Researchers suggested that women may have removed their own IUDs and reported it as an expulsion, hoping they would become pregnant and have a son.⁴

LONG-TERM METHODS

While long-term contraceptive methods are highly effective in preventing pregnancy and require little action on the part of the user, clients must rely on providers to obtain them and to discontinue their use. Consequently, some women's advocates have expressed concerns about the potential for abuse and coercion, with existing long-term or permanent methods such as IUDs, implants, and sterilization, as well as for newer options being developed.

In India in the 1960s and 1970s, family planning workers were encouraged to attract new contraceptive users. The Tamil Nadu state exceeded others in recruiting IUD acceptors, but research showed that some health workers were routinely inserting IUDs postpartum — often without women's knowledge or permission. Some women sought health treatment for unexplained bleeding and cramping — routine side effects of IUD use — apparently unaware that they were using IUDs.⁵ In 1996, India implemented a "target-free" approach to contraceptive service delivery, designed to focus health workers' attitudes

RICHARD LORD



ULTRASOUND IS ONE OF MANY TECHNOLOGICAL ADVANCES THAT POTENTIALLY RAISES ETHICAL CONCERNS. A ROUTINE, PRENATAL ULTRASOUND IS CONDUCTED IN MATAMOROS, MEXICO.

on quality care and reduce concern with numbers of clients served.

One of the most controversial contraceptive technologies is sterilization. Reports of coerced sterilization have surfaced in several countries. Women resisting sterilization have been jailed, and women refusing to undergo sterilization have been threatened with a suspension of food and milk programs if they did not submit.⁶ Meanwhile, research on nonsurgical methods of sterilization, such as drugs that block fallopian tubes, has generated concerns. Among the many ethical questions about these experimental sterilization technologies is the potential for use without a woman's consent or knowledge. Supporters say these new ideas may improve access to contraception and could save lives by avoiding pregnancy-related deaths.⁷ Because sterilization is permanent, health experts stress that informed choice and informed consent are critical (see article, page 16).

Because of the potential for abuse, some health advocates have asked that researchers cease work on other long-term experimental methods, including immuno-contraceptives or antifertility vaccines. Some women's health groups have suggested that family planning programs should promote only methods that are controlled by the user and are not dependent upon the provider, such as condoms and diaphragms. International health organizations, including the World Health Organization, have responded by saying that men and women deserve a variety of contraceptive choices and quality services and that research on a variety of long-acting methods should continue.⁸

HIV/AIDS TREATMENTS

The development of antiretroviral drugs has improved the life expectancy of many people living with HIV/AIDS and has reduced the incidence of mother-to-child transmission. Yet, these drugs are often too costly for governments and individuals in developing nations. AIDS advocates say that drug companies have an obligation to make drugs more widely available in geographic regions where the need is critical.

In 2001, the Pharmaceutical Manufacturers Association of South Africa

and 39 international pharmaceutical companies ended three years of legal action contesting a South African law that allows the government to ignore patent protection and to manufacture the drug without paying the patent's owners, if deemed appropriate by the government. While viewed as a victory for HIV/AIDS activists, some health experts have suggested that low-cost drugs will not become widely available in South Africa. Meanwhile, a conflict has arisen in Brazil over the nation's right to import or manufacture low-cost generic forms of HIV/AIDS drugs. At the heart of this debate is an important ethical question: whether expensive new health technologies should be available to those who cannot afford to pay and, if so, who should pay.

Women and men who are HIV-positive face other ethical issues. If an unintended pregnancy occurs, should the woman risk giving birth to an HIV-infected child or have an abortion?

Dr. Willard Cates, Jr., FHI president, recommends that to help HIV-infected women make informed choices about contraception and childbearing, voluntary counseling and HIV testing – if available – should be linked to family planning services. He recommends several options, including: referral to family planning programs if a woman does not wish to become pregnant; education about infertility and prenatal services for women who do wish to become pregnant, as well as information about drugs that might be available to prevent HIV transmission to infants; and antiretroviral therapy for women who are already pregnant and wish to continue their pregnancies.⁹

Women who decide to use contraception should be advised that male latex condoms can protect them and their partners from pregnancy and from further transmission of sexually transmitted infections (STIs), Dr. Cates says. However, they also should be encouraged to consider whether their male partner will be able to or will want to use condoms consistently. Women also should be informed about local availability of the female condom, and should be cautioned that other methods offer protection from pregnancy but no protection from STIs. Ultimately, the woman must be allowed to decide which method she will use, Dr. Cates says.

OTHER EMERGING TECHNOLOGIES

In industrialized nations, "assisted reproductive technologies" (ART) involve the use of expensive equipment and tests to help infertile couples conceive a child. One of the technologies is in vitro fertilization, in which egg and sperm cells are united outside the body, then fertilized eggs are implanted in a woman's uterus. While the technique has helped many couples give birth to healthy children, it also has raised serious questions. Should such technologies be available only to married couples or to single women as well? Should fertile women and men be allowed to donate eggs and sperm so that infertile couples can have children? Should these donors be paid? Once an egg is fertilized, is the resulting group of cells a potential person, or a person with the same rights as any other?

The question of an embryo's status has become the focal point of recent debates on the ethics of stem-cell research. Stem cells — the body's "master" cells that can produce millions of genetically identical cells and transform themselves into any type of cell in the body — might be used to regenerate damaged tissue or organs, or to find new cures for a variety of illnesses and diseases. Stem cells can be taken from adults, but scientists have said that cells from embryos are more useful and versatile.

While some critics have suggested that taking cells from embryos would be the equivalent of destroying a human life, some scientists have argued that the cells would be taken from surplus embryos created in laboratories for infertile couples wanting children. Because more embryos are created than are actually implanted, researchers say they could use cells from embryos to improve treatment or cures for Alzheimer's disease, diabetes, or other debilitating ailments.

In addition to affecting how quickly new cures or cheaper health treatments might be developed, the outcome of the stem-cell debate in the United States could affect developing countries in other ways. For example, if embryonic stem-cell research were banned in the United States, research might be done instead in other countries, perhaps in the developing world.

Another controversy in assisted reproductive technologies is "selective reduction." Because several embryos are

implanted to increase the couples' chance of having a baby, multiple births can occur. Some couples have chosen selective reduction instead — the destruction of a certain number of embryos by injection of potassium during the first trimester of pregnancy.

In the future, scientists predict they will be able to screen human embryos for chromosomal abnormalities and genetic diseases prior to implantation. They also expect to be able to alter genetic material. While some scientists suggest this could prevent diseases such as diabetes, hypertension, and schizophrenia, others say the procedure could be misused by parents seeking children with specific features, such as eye and hair color or higher intelligence.¹⁰

A new technique developed at the Genetics and IVF Institute in the United States may be able to guarantee a child's sex. The technique involves isolating sperm that will produce a female embryo (the sperm that carry an X chromosome). Currently being evaluated in clinical trials, the technique has the advantage of allowing couples to determine the sex of their child before the egg is fertilized, not after, and could potentially be used to prevent genetic disorders such as hemophilia or muscular dystrophy. These conditions are caused by defects in the X chromosome and primarily affect male children. Other scientists have speculated that the new

technique could become a tool for sex selection. "Ultimately we have to wonder whether [you will] ever have sex selection kits available at your chemist," says Ian Craft, a professor at the London Fertility Clinic in the United Kingdom.¹¹

Cloning has been used to produce human cell tissues and to split embryos in animals, allowing scientists to make identical genetic matches of sheep, cows, pigs, goats, and mice. Some researchers have been concerned that the process will be done in humans, allowing people to pre-terminate characteristics of the new cloned individual. For example, a family might request an individual be cloned to produce an organ donor. Other researchers have suggested cloning might be an option for infertile couples trying to have a child.

— Barbara Barnett

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Briefs

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OC STUDY ON BLOOD CLOTS

The risk that a woman taking oral contraceptives will develop potentially fatal blood clots is very small. But women taking third-generation pills are more likely to develop clots than women taking the older, second-generation pills, according to a recent analysis of previous research.

In most of the world, the risk of death associated with pregnancy is at least 100 times higher than that associated with the third-generation pills, which include Femodene, ED, Triadene, Minulet, Tri-minulet, Marvelon, and Mercilon. Nevertheless, the risk of taking the newer pills should be considered when women — especially first-time users — choose an oral contraceptive, caution the Dutch scientists who conducted the analysis.

Overall, women taking third-generation pills, which contain the hormones desogestrel or gestodene, have nearly twice (1.7 times) the risk of developing blood clots as women taking the second-generation pills, which contain levonorgestrel. The blood clots develop in the deep veins of the legs or the pelvis and can be fatal if they move through the circulatory system into the lungs.

Women who already use third-generation pills should not abandon their contraceptives altogether and risk pregnancy. Instead, they should seek medical advice and consider switching to another brand. Four deaths per million women could be prevented by switching from third- to second-generation pills, the scientists estimated in their report, which appeared in the July 21, 2001 issue of the *British Medical Journal*.

U.S. STUDY PANEL CONFIRMS CONDOMS ARE EFFECTIVE AGAINST HIV/AIDS

In July 2001, a National Institutes of Health (NIH) study panel in the United States issued its report on condom effectiveness in preventing sexually transmitted infections, including HIV/AIDS.¹ Family Health International distributed this concise list of typical questions and answers about the report to health providers and scientists worldwide, to help explain key findings.

Q: What were the report's major findings?

A: The NIH report concluded that correct and consistent use of male latex condoms effectively reduces transmission of HIV/AIDS in women and men; and gonorrhea in men; and prevents pregnancy. The report also found that evidence is insufficient to determine the effectiveness of condoms in preventing the six other sexually transmitted infections (STIs) it reviewed.

Q: What did the panel say about these six other STIs?

A: The panel concluded that epidemiological evidence is currently insufficient to provide an accurate assessment of the effectiveness of condoms in preventing spread of gonorrhea in women, or chlamydial infection, syphilis, chancroid, trichomoniasis, genital herpes, and genital human papillomavirus (HPV) infection in women and men. "Because of limitations in study designs," the report says, "there was insufficient evidence from the epidemiological studies on these diseases to draw definite conclusions" about the effectiveness of condoms. However, it noted that "the absence of definitive conclusions reflected inadequacies of the evidence available and should not be interpreted as proof of the adequacy or inadequacy of the condom" to reduce the risk of these other infections.

Q: What is FHI's professional opinion about the study's implications?

A: "The data clearly show that condoms prevent HIV/AIDS, which is the most deadly STI, and

gonorrhea, the most easily transmitted infection," says Willard Cates, Jr., MD, MPH, president of FHI. "We believe the male latex condom is also highly effective in preventing pregnancy, when used correctly and consistently. These are three excellent reasons for actively promoting the use of male latex condoms. Also, lack of research data on some STIs does not mean condoms are ineffective against these diseases. When used correctly and consistently, we should expect male latex condoms to be highly effective in preventing the risk of the other discharge diseases — gonorrhea in women, chlamydia and trichomoniasis. Condoms should also be effective, but not necessarily highly effective, in reducing the risk of genital ulcer diseases — genital herpes, syphilis, chancroid — and HPV infection. However, the study concluded that "condom use might afford some reduction in risk of HPV-associated diseases, including genital warts in men and cervical neoplasia [cancer] in women."

Q: Was any significant recent research not included in the panel's report?

A: Yes. In a study published June 27, 2001 in the Journal of the American Medical Association, scientists concluded that condom use during more than 25 percent of coital acts was associated with protection against genital herpes transmission to susceptible women. Other encouraging recent studies that are nearing publication include research in Peru that found consistent condom use protected sex workers against gonorrhea and, to a lesser extent, against chlamydia. And more recent follow-up data have become available from an important study that led the panel to conclude that consistent condom use protects men against gonorrhea. The more recent findings also suggest substantial protection against chlamydia.

Q: How was the panel selected, and how did it reach its conclusions?

A: Cosponsored by the National Institutes of Health, the Centers for Disease Control and Prevention, the U.S. Food and Drug

Administration, and the U.S. Agency for International Development, a 28-member panel of scientists and other experts analyzed more than 138 peer-reviewed studies on the properties and user patterns of the male latex condom during penile-vaginal intercourse.

Q: Precisely what risk reduction was found for gonorrhea and HIV/AIDS?

A: Meta-analysis of several studies showed an 87 percent decrease in risk of HIV transmission among consistent condom users versus non-users. However, three of the best-designed studies showed that HIV infection rates were less than 1 percent per year among consistent condom users. These data provide compelling evidence that consistent use of the latex male condom is a highly effective method for preventing HIV transmission, the report says. Studies also show a 49 percent to 100 percent reduction in risk of gonorrhea among men reporting condom use compared with non-users.

Q: What are the long-term health consequences from STIs?

A: In addition to death and other serious illnesses associated with HIV/AIDS, many of the other STIs can cause infertility, problems with pregnancy, and transmission from a mother to her infant. Long-term infection with certain types of HPV can cause cervical cancer if not diagnosed (through annual Pap smears) and treated. In addition, most STIs increase substantially the likelihood of transmitting HIV infection. While most STIs can be treated successfully, no vaccine is currently available to prevent infection by organisms that cause STIs, except for hepatitis B.

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Resources

FHI ETHICS TRAINING

Research Ethics Training Curriculum, a teaching aid produced by FHI, presents basic ethical issues that must be considered when human participants are included in research. Designed for biomedical and social science researchers, the curriculum covers the foundations, principles, responsible conduct, and oversight of research involving human participants. It includes a narrative, copies of overhead slides, case studies, pre- and post-test questionnaires, audience handouts, reprints of key ethical guidelines, and various resources and references. The package is available in English in a binder (a notebook) or on CD-ROM, and is free to developing-country providers and trainers upon written explanation of need. For others, pricing details are available upon request. To obtain a copy or information about pricing, please contact: Office of International Research Ethics, Family Health International, P.O. Box 13950, Research Triangle Park, NC 27709, USA. Telephone: (919) 544-7040. Fax: (919) 544-7261. E-mail: ethics@fhi.org.

FHI ADOLESCENT HANDBOOK

A reprint of *Young Clients: Meeting Their Needs, A Guide to Providing Reproductive Health Services to Adolescents* is available. The handbook for providers, program managers, educators, and others who work with adolescents outlines reproductive health services for young women and men, and focuses on: prevention of unplanned pregnancies and sexually transmitted diseases, including HIV. The 100-page handbook contains role plays that providers can use to help young people negotiate condom use and say no to sex. A Spanish edition is also available, and a French version is being prepared. A single copy is free to those working with adolescents in developing countries. For more than one copy, please

specify how copies would be used. To obtain the guide, write to: Publications Coordinator, Family Health International, P.O. Box 13950, Research Triangle Park, NC 27709, USA. Telephone: (919) 544-7040. Fax: (919) 544-7261. E-mail: publications@fhi.org.

INFORMED CHOICE MATERIALS

Materials about various aspects of informed choice and informed consent are available through EngenderHealth. *Informed Choice* is a folder of materials that cover emerging informed choice issues, human rights, medical ethics, and the challenges of informed choice in family planning. *Informed Consent and Voluntary Sterilization: An Implementation Guide for Program Managers* is a booklet that explains the nature and elements of informed consent and offers practical guidelines for implementing and supervising informed consent procedures. Copies in English, Spanish, or French of *Informed Choice* can be obtained for U.S. \$4, and copies of *Informed Consent* cost U.S. \$5. Contact: EngenderHealth Material Resources, 440 Ninth Avenue, New York, NY 10001, USA. Telephone: (212) 561-8000. Fax: (212) 561-8067. E-mail: info@EngenderHealth.org.

PAHO PAPERS ON AIDS AND ETHICS

Ethics and Law in the Study of AIDS is a collection of papers by experts in bioethics, law, and medicine. Offered by the Pan American Health Organization (PAHO), the papers explore some of the ethical and legal dilemmas arising from the epidemics of HIV infection and AIDS, and propose solutions. The 284-page compilation, available in both English and Spanish, includes a detailed analysis of AIDS- and HIV-related legislation in Latin America and the Caribbean, and discussions of ethical issues (such as confidentiality and the allocation of scarce resources) and public health policy. Cost: U.S. \$19 in Latin America and the Caribbean; otherwise, U.S. \$26. To order, mail or fax orders to: PAHO Sales and Distribution Center, P.O. Box 27, Annapolis Junction, MD 20701-0027, USA. Fax: (301) 206-9789. E-mail: paho@pmds.com.

USAID AWARD PROMOTES YOUTH REPRODUCTIVE HEALTH

The U.S. Agency for International Development (USAID) recently awarded FHI \$85 million to lead a five-year program to promote the reproductive health of youth in selected developing countries. FHI will implement the program, called YouthNet, through a partnership with CARE USA, Deloitte Touche Tohmatsu Emerging Markets, Margaret Sanger Center International, and Research Triangle Institute.

"There are 1.7 billion youth worldwide, many of whom are at risk of infection with human immunodeficiency virus, unplanned pregnancy, and sexually transmitted infections," says JoAnn Lewis, MPH, FHI senior vice president for reproductive health. "The goals of this program are to increase community and political support for youth reproductive health; to improve knowledge, attitudes, and skills related to healthy reproductive practices, including strategies to help young adults delay sexual

activity; and to expand access to quality reproductive health products and services for youth."

Strategies to achieve the program's goals include: designing interventions that recognize that youth have different needs depending upon such factors as their age, sex, life stage, and culture; providing practical tools to implement research and policy; using technology to increase access to information; and monitoring and evaluating interventions to better understand how to replicate and sustain successful efforts.

"We also believe that, for these initiatives to have an impact, youth must be full partners in the development, implementation, management, and evaluation of strategies and programs," says Ms. Lewis. "We view youth as assets, not problems. By recognizing their strengths and resiliency, we can help them to build skills that they can apply to all areas of their lives."