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]

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 counselling before and after the testing. For women who tested positive for HIV counselling was intended to help them cope with the disease, prepare for the future and reduce risky behaviours.

In addition to encouraging them to inform their partners HIV-positive women were asked to bring partners to the clinic for more counselling. 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 counselled (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 counselling. 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]

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 behaviour, 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."

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.

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 gynaecology 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.

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