Q is for Questions

By Vinia M. Datinguinoo

Juliet is 25 and has four children one year apart, had kids early, and after the fourth child knew she and her husband could not afford one more. Once she tried taking pills but it made her forget things, so she stopped.

In late 1993, a worker from the local family planning clinic came and told her about a new method of sterilization that was permanent, free, and most of all, did not require her to be cut up.

Her husband's consent was sought. Three days later, Juliet came to the health center to be sterilized. The doctor explained how it works: pellets of a drug called quinacrine will be inserted into her uterus; she will return the next month for the next dosage, and the next for the third; the drug will close her tubes; she will never get pregnant again. She might feel a little nauseous after the procedure, said the doctor, but she should be alright. Juliet knew this was what she wanted, so she signed the consent form and lay down to be treated.

Over a year later, Juliet has never gotten pregnant again, and is happy she decided to get sterilized when she did.

What Juliet doesn't know—and what her doctors have not told her—is that the sterilization method she had undergone has been the subject of debate abroad for the past several years. The World Health Organization (WHO) itself has never recommended it, even after over two decades of research by its proponents.

Juliet's sterilization is part of a set of clinical trials being done to study the possibility of introducing in the Philippines a new method of nonsurgical female sterilization that uses the antimalarial drug quinacrine. When inserted into the uterus, the drug closes the woman's Fallopian tubes.

The ongoing clinical trials aim to test 600 women by January 1996. Proponents say the quinacrine method is cheaper, easier to administer, and is as safe and effective as surgical sterilization. It will provide women with one more good choice, they say.

But other sectors are sounding the alarm. Women's groups, as well as other family planning providers both here and abroad, say several questions on both quinacrine's safety and efficacy remain unsolved. They question the

80,000 Pregnancy Deaths Unlisted

by Diana G. Mendoza

Deaths due to pregnancy worldwide have been substantially underestimated, with nearly 80,000 more such deaths per year than what has been previously reported, said a major study by the World Health Organization (WHO) and the United Nations Children's Fund (Unicef).

According to the study some 585,000 maternal deaths occur yearly, 99 percent of them in developing countries.

More than half (55 percent) of these pregnancy-related deaths occur in Asia, which also accounts for 61 percent of the world's births.

Africa, which takes up 20 percent of the world's births, also accounts for 40 percent of all maternal deaths.

In contrast, progressive countries have less than 1 percent of total maternal deaths and an almost reasonable number of births at 11 percent.

Dr. Susan Holck of the WHO Reproductive Program said "maternal mortality is a particularly sensitive indicator of inequity."

"Maternal mortality offers a litmus test of the status of women, their access to health care and the adequacy of the health care system in responding to their needs," she said.

The WHO said it is extremely difficult to assess level of maternal mortality. Maternal deaths tend to be underreported even in developed countries with vital registration systems.

Few countries count births and deaths; even fewer register

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ethics of doctors who are administering drugs without warning women about its possible side-effects. They urge that clinical trials be paused, existing literature be evaluated, and gaps on toxicity issues be filled.

WHO's Special Program on Human Reproduction considers the evidence on the method's safety and efficacy "inadequate". Its position is that no clinical trials are even "justified" unless these questions are answered by a complete toxicological evaluation of the drug and the method.

In 1991, WHO's Toxicology Panel recommended that the study of quinacrine pellets for female sterilization not be pursued. The Panel said the toxicological data concerning the method was unsatisfactory," and that "full, classical" toxicological testing was required before the compound could be used for female sterilization.

Such tests are at present being done in the United States, according to WHO's Human Reproduction Unit.

But Dr. Rafael Esmundo, coordinator of the Quinacrine or Q Study here in the Philippines, is convinced there is nothing more to prove as far as the method's safety and efficacy are concerned. "It is safe. This is no different from what is used for malaria. *Yun nga iniinom pa e, ito sa* uterus *lang* (That one is even taken orally. This just goes to the uterus)." The objective, he says, "is really to find out how best to introduce it here."

He dismisses toxicity questions from others as "common sensical." "We have been taking oral quinacrine, so what else is there to test if it is placed inside the uterus and is absorbed? Common sense."

First used for malaria in the 1920s, oral quinacrine has been found toxic when given in large doses. Side effects associated with it include central nervous system excitation, skin rashes, dizziness, headaches, and rarely, aplastic anemia. When chloroquine became available, the use of quinacrine for malaria declined.

Quinacrine scars tissues, and it is this property that attracted researchers to its potential for permanent tubal sterilization. Its liquid form was first used in Chile in the 1960s by researchers of the Family Health International, a U.S.-based family planning organization involved with the development of contraceptive technologies.

But the liquid form was associated with "intense

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the cause of deaths; and fewer still systematically note the pregnancy status on the death form.

The new estimates were developed by adjusting available country figures to account for underreporting and using a simple model to generate estimates for countries with no data or where there is concern about the adequacy of officially reported estimates.

Source: Today, February 27, 1996

IUD Not First Choice For Young, Never Pregnant Women

by Barbara Barnett

Young women and women who have not yet had children can generally use intrauterine devices (IUDs), but providers should be cautious. Because these groups face increased risk of IUD expulsion and pelvic inflammatory disease (PID), the IUD generally is not recommended as the first method of choice.

For adolescents who need family planning, the IUD does have distinct advantages: It is nonhormonal and requires minimal compliance after insertion. The risks of infertility, however, should be considered before recommending this method to younger women.

"Age by itself is not a contraindication for IUD use," says Dr. Roberto Rivera, FHI's corporate director of international medical affairs. "There is no biological reason to say a young woman is at higher risk

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mental irritability" and three deaths. Researchers then switched to the pellet form, which has since been tried on at least 80,000 women in 13 countries: Bangladesh, China, Costa Rica, Croatia, Egypt, India, Indonesia, Iran, Pakistan, Venezuela, Chile, Vietnam, and the Philippines. Vietnam is considered the biggest trial field so far, with over 31,000 women having undergone insertions by end-1992, beginning in 1989.

The Philippine quinacrine clinical trials began in late 1993, after Esmundo came back from a family planners' meeting in China. He set up the Q Study with the help of the International Federation for Family Health and the Center for Research on Population and Security, two U.S.-based organizations involved with the development of contraceptive technology. These groups are funding the study with a $10,000 grant.

Esmundo is special adviser to the health secretary on matters related to local governments. The Q study, however, is officially a project of the Movement for Development and Prosperity Foundation, a non-governmental organization (NGO) created by Esmundo in the 1970s.

The other investigators are Drs. Virgilio Oblepias of the Mary Johnston Fertility Care Center, Iva Anastacio of Makati City's family planning unit, and Roger Ramones of the Ramones Medical and Surgical Hospital. All four are reputable gynecologists and family planning providers.

Dr. Anastacio, for instance, is head of Makati's family planning clinic. She was founder of the NGO, Family Planning Organization of the Philippines, and was president of the Philippine Medical Women's Association.

Anastacio has been getting an average of one patient per week for the Q Study. "It's free, it's simple, and they do not want to be cut up." She says she has not received any serious complaints from patients so far, except for a common experience of yellowish discharge. She says some of the quinacrine is expelled. On her logbook, one patient was said to have had "mental stress" after the first insertion. This patient must have had that condition before, says the doctor.

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Anastacio says she is not aware of the controversy over the quinacrine method, neither of the WHO recommendations nor the positions taken by other local and international organizations. "The important thing is that we haven't experienced anything bad so far," she says.

Doctors at the Jose Fabella Memorial Hospital, the health department's clinical arm, were also approached by Esmundo for the study. But they declined to

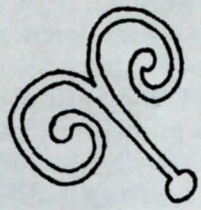
than an older woman. An older woman and younger woman with the same sexual behavior have the same risks."

While there is no medical rationale against IUD use by adolescents, demographic studies show that women under age 25 have a higher incidence of sexually transmitted diseases (STDs)than older women, who are more likely to be married or living in union. Younger women are not biologically more susceptible to STDs; however, lifestyles and sexual partners, may put them at greater risk.

For the majority of IUD users, fertility typically returns immediately or soon after the device is removed, and duration of use does not appear to affect a woman's ability to conceive. One study in New Zealand found that within 48 months of IUD removal, 91.5 percent of women, who had never before been pregnant, had conceived, while 95.7 percent of those who had been pregnant before IUD use had conceived.

Family planning providers should help clients understand how contraceptive use may affect their risks of PID and their future fertility. Inspite of risks of infertility to young women and nulliparous women, the decision about which method to use ultimately should be made by the woman.

Source: Network Family Health International, Winter 1996 Vol. 16 No. 2, p. 13



join the clinical trials because of reservations on both the study design and the drug's toxicity.

"We suggested that there be two insertions instead of three," says Dr. Rebecca Ramos, chief of Fabella's WHO collaborating center. They also thought a test should be made on the patient after two insertions to see if the tubes have been closed. The Q Study's design involves three insertions, and no tests. Reasons Esmundo: "*Mas matipid ito* (This is more economical)."

The Bureau of Food and Drugs (BFD), meanwhile, says Esmundo's group "deviated from standard procedures" in the conduct of the clinical studies. The group did not first seek BFAD's approval, says bureau director Dr. Quintin Kintanar. Clinical trial proponents have to submit an application to the BFAD. The bureau then either approves or denies the application through evaluation of the reliability of the investigators, the design of the protocol, and the absence or presence of "unusual hazard" for the subject.

Esmundo says he wrote Kintanar to inform him of the quinacrine study plans and ask him of regulations they needed to follow. He showed PCIJ a copy of the letter. But it doesn't show it as received by BFAD because, according to Esmundo, the letter was mailed and not hand-delivered.

Still, some think there is an ethical case to be made against doctors engaging in clinical trials of quinacrine, when the WHO has said such studies were "not justified."

"WHO's position should serve as guidelines," says Dr. Sylvia Estrada Claudio of the women's group GABRIELA, especially because WHO's reservations concern the toxicity of the drug in question.

Claudio also thinks private medical practitioners should keep abreast of developments in their field, and keep tabs of controversial discussions such as those on quinacrine.

Princess Nemenzo of the NGO WomanHealth wants the clinical trials stopped. She says she is alarmed because the quinacrine trials are being done on women, "in a clandestine manner." Nemenzo also says the WHO's word should be followed as "procedural guidelines."

Esmundo disagrees. The only ethical consideration he and his team have, he says, is ensuring that the patient is allowed informed consent. "What my patient and I have agreed upon is what's important," he says, "and not what the WHO dictates. The oath that I took is with my patient."

Neither does Esmundo accept as official the position of the WHO Special Program on Human Reproduction. "The supposed WHO position on quinacrine was issued by one adviser, and not by the organization."

The WHO itself refuses to say whether the clinical trials are unethical despite its position. "That is best answered by Philippine authorities rather than by WHO," says Dr. Giuseppe Benagiano, chief of WHO's Special Program on Research, Development and Research Training in Human Reproduction.

BFAD's Dr. Quintin Kintanar thinks the same. "They are professionals, they are licensed. It's an old drug already approved for marketing, and they can use it in the way they see fit."

Manila-based WHO consultant Dr. Marilen Danguilan asks as well: "Why should the WHO keep these doctors from performing the tests?" What is more important, she says, is ensuring that "the woman's rights are not violated, her body not trampled upon." Danguilan suggests that women be "open to technology, and see that it could further our interests."

But Juliet was not subject to a thorough physical exam before the procedure, contrary to what her doctor told PCIJ. "Nothing, I was just asked if I had pains during my period or with giving birth."

And Juliet never knew the method was still on trial. "No one said it was just an experiment," she says. "I was just told it was free, I was not going into surgery, I would not be hospitalized."

Nor was she told of the method's possible failure, including the risk of ectopic pregnancy. She laughs: "*Pero wala namang nangyaring ganon. Basta hindi na ako kinakabahan ngayon na baka mabuntis pa ako ulit.* (But nothing like that happened. The important thing is now I have no worries that I will ever get pregnant again)."

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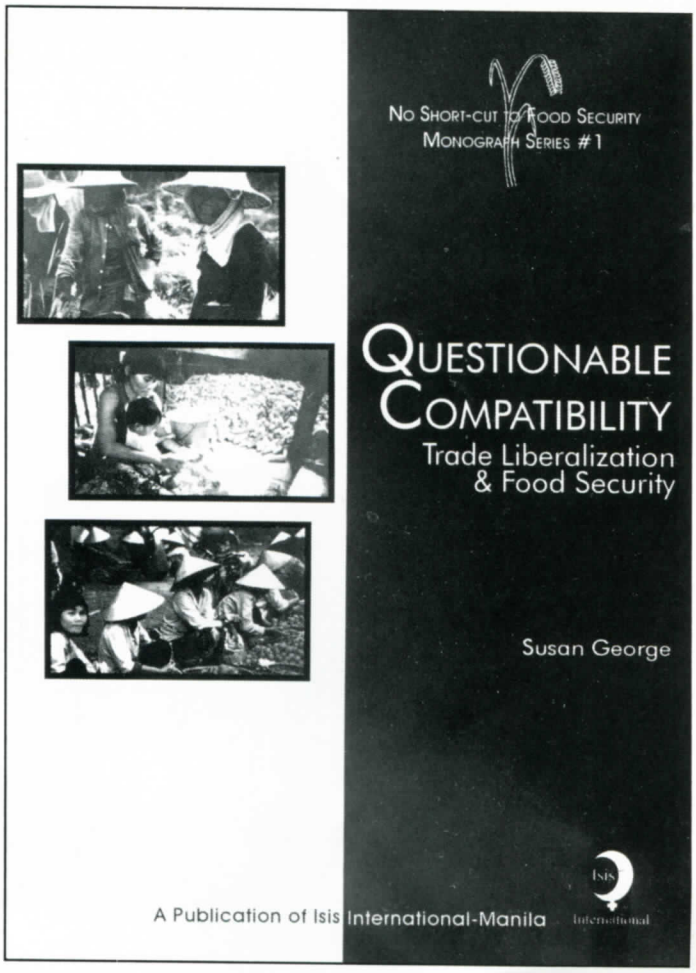

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