



*Family planners remain divided over whether the quinacrine sterilization pellets are safe. In Pakistan, researchers are experimenting with the method. Photo: Marie Stopes International*

## Risks and rewards: Family planners weigh quinacrine

By John M. DiConsiglio

To some family planners, quinacrine hydrochloride, a radical sterilization technique, is a contraceptive marvel that could save the lives of a quarter of a million women who die as a result of unwanted pregnancies each year.

To others, the nonsurgical, chemical method not only offers a unique opportunity for coercive use, but is also an untested risk that might damage women's health.

But if the quinacrine question is far from resolved, one aspect of the sterilization method is undisputed by both camps. Unlike past contraceptive controversies — like RU-486 — that have pitted family planners against government agencies, anti-abortion groups or even the public, quinacrine has divided the reproductive health community itself. The results of studies on the method, which involves inserting pellets into the uterus that cause a scarring of the fallopian tubes, have been both praised and vilified. A large-scale Vietnam trial that was sup-

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# Will quinacrine pellets ~~save~~ lives or put them at risk?

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posed to finally clear quinacrine's name among critics has instead caused even more debate.

And despite a recent special meeting at the Association for Voluntary Surgical Contraception (AVSC) to explore the incendiary issue, experts say the rift quinacrine has opened shows no signs of healing.

"It would be tragic to see [opponents of quinacrine] win out," said Dr. Stephen Mumford, president of the Center for Research on Population and Security. "For the women around the world who die of unintended pregnancy, quinacrine offers

Health Organization (WHO) and that some studies — which others discredit — have suggested the method may cause cancer. And while the latest trial undertaken by the Vietnamese Ministry of Health and published in *The Lancet* claimed positive results in 32,000 women, some are suggesting that questionable methodology makes that study unreliable.

"The conclusions drawn in that study were unwarranted," said Judy Norsigian, president of the Boston Women's Health Book Collective. "It didn't seem to do a good job in collecting follow-up data. I don't think there's any question that very retrospective work is needed on that

It was that version of quinacrine that the WHO rejected, the drug's supporters say. Although the chemical formulation has changed slightly, the quinacrine pellets remain roughly the same chemical that flunked the WHO exam. Supporters say the difference is the smaller dose and the new delivery system, which now makes quinacrine safe.

"It's looking as if it's very safe and effective," said Dr. Tim Black, director of Marie Stopes International. "Certainly, the relative risk of having a baby in a rural area is much higher than anything quinacrine presents."

The newer version involves dropping seven pellets into the uterus with an IUD inserter. The pellets dissolve within a few minutes. The seven-pellet process is then repeated a month later. Women reportedly have complained of only minor temporary symptoms like cramping and fever, and the method appears to be about 95% to 97% effective. In Pakistan, researchers are experimenting with a one-time insertion of seven pellets followed by three doses of a related drug called Brufen. Pakistani doctors claim a 1% failure rate.

Field trials are under way in 11 nations. Past studies have involved FHI and USAID. FHI had approached the U.S. Food and Drug Administration (FDA) with a plan to study quinacrine, but the application was withdrawn after several Chilean quinacrine users developed cancer.

While several researchers are not satisfied with recent unpublished FHI studies that suggest the cancer clusters were an unrelated phenomenon, others are confident that quinacrine's name has been cleared.

**"I am totally satisfied that it is safe,"**

***'I am totally satisfied that [quinacrine] is safe. I'd have no hesitation about using it.'***

Bhiwandiwala said. "I'd have no hesitation about using it."

While the Vietnam study was intended to make believers out of quinacrine skeptics, the results have merely fueled the controversy. Of the 32,000 women who were given quinacrine in Vietnam, only 818 pregnancies occurred, with no deaths and just eight serious complications. By contrast, similar trials using surgical sterilization would have yielded 30 deaths and as many as 1,800 serious complications, Vietnamese officials estimate based on past complication rates.

But skeptics — most notably AVSC officials — have contended that too few of

the women were followed up after the study. Information on failure rates and side effects are based on subsets of the 32,000 group, AVSC officials say, which the report then extrapolates to the group as a whole.

"I would continue to recommend going cautiously," said Dr. Alan Rosenfield, dean of the Columbia University School of Public Health. "At the moment, we don't have enough data for worldwide use."

Others, however, suggest that quinacrine opponents are becoming too bogged down in cautious procedural steps while the number of women who die in childbirth or unsafe abortions increases each year.

"They all want more information. But we won't have those answers for 20 years," Mumford said. "Meanwhile, people are denied a life-saving method.\*"

Several quinacrine supporters have suggested that some groups may oppose the pellets because they can be inserted by nurse practitioners or trained medical staff and may lessen the role of physicians.

"This is much more exciting than methods that get the medical community involved," Stopes' Black said. "As far as I'm concerned, it moves sterilization to a supply method, like condoms or pills."

## Coercion controversy

Meanwhile, quinacrine's opponents feel that more research should be completed on the potential for coercive use of the pellets. Most methods, including Norplant and Depo-Provera have raised questions about forcing women to give up their fertility, but quinacrine may be a particularly dangerous tool in the hands of some government population workers, critics say.

Inexpensive, permanent and easy to insert, quinacrine could be the ideal coercive technique.

But supporters of the method maintain that denying quinacrine because of coercion fears is irresponsible medicine. Mumford suggested that groups opposed to quinacrine because of coercion fears have taken the same view as the often-quoted American military official during the Vietnam war who said, "We had to destroy the village in order to save it."

"The position of those opposed to this method because they are concerned about it being used coercively," Mumford said, "is 'We had to destroy 200,000 women each year in order to save them from the risk of coercion.'"

While quinacrine supporters continue to insist that access to the pellets could save lives, opponents claim that there are safer ways to reform world health care systems than introducing what they consider to be a risky chemical.

"First let's provide women with an array of contraceptive options" and safer abortions, Norsigian said. "I'd rather spend my resources on methods that don't cut off a woman's fertility."

## Unmet sterilization need in selected countries

% of women wanting no more children

Country	Women (%)
Peru	73
Colombia	69
Thailand	67
Ecuador	67
Egypt	64
Mexico	64
Dominican Republic	63
Tunisia	58
Trinidad and Tobago	57
Indonesia	51
Kenya	49
Morocco	48

Source: United Nations Fund for Population Activities, 1991

their only hope."

Developed in the 1970s by a gynecologist in Chile, quinacrine may be the most important contraceptive development since the birth control pill, its supporters say. With United Nations numbers reporting that roughly 23% of reproductive-age women in the developing world have already chosen sterilization, the contraceptive method currently ranks as the most common in the world. But with a staggering unmet need in several countries (see chart), proponents of quinacrine say the pellets could bring sterilization to previously unreachable populations. Many developing nations lack the trained personnel, the surgical facilities and the financial resources for sterilizations. Even critics of quinacrine agree that the method is easy to perform, likely to be effective and, at a price of less than U.S.\$1 for two insertions, startlingly cheap.

"Quinacrine is remarkably inexpensive and easy to manufacture. It is as simple to administer as an interuterine device," reports an AVSC technical statement on the method. "[But] there are several safety and efficacy issues regarding quinacrine."

Some critics say the unanswered questions surrounding quinacrine make it too great a health risk to even continue clinical trials. They note that the chemical has failed past toxicological tests by the World

study."

Others worry that quinacrine may be used coercively. The ease of introducing the method could allow health care workers in some countries to sterilize women during routine exams without their knowledge. Indeed, one report, attributed to a Vietnamese publication called *The Woman*, said that more than 100 women in *The Lancet* study had quinacrine inserted in their uterus without their consent during a pelvic checkup. The authors of the study vigorously deny this charge.

"For everything there is a good and potentially bad use," said Dr. Pouru Bhiwandiwala, the former medical director of Family Health International (FHI). "It pains me that people would try to obstruct an important method because someone, somewhere might use it the wrong way."

## Waiting for more tests?

Although quinacrine has only recently reinserted itself into the contraceptive debate, the method has been used in nearly 100,000 women over the last decade. Originally developed to treat malaria, quinacrine was first used as a sterilizing agent by contraceptive researcher Jaime Zipper in the 1970s. The first quinacrine trials involved a liquid version, but that mode was abandoned because it delivered the drug too rapidly into the blood stream.