

to this method; too much has happened. Hence, it is unlikely that USFDA approval could be contemplated without an open public hearing.\* Opponents of quinacrine would undoubtedly attend to put the case against approval.

Further, even if the method were approved, the private sector might be unwilling to manufacture it. Possibly serious side effects have been

reported in women anecdotally, including **unexplained** bleeding, a sensation of burning **internally** and pain after insertion. Any serious adverse outcome, even in a few women – combined with the fact that the drug was shown to be mutagenic – could lead to law suits. **No** drug company in the US, for example, would be likely to take quinacrine on in today's climate.

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## References and Notes

1. See Berer M, 1994. The quinacrine controversy one year on. *Reproductive Health Matters*. 4(Nov):99-106 for a history of this controversy.
2. Jeffrey Spieler, Chief, Research Division, Office of Population, USAID. Personal communication. October 1995.
3. See Pollack A and Carignan C, 1993. The use of quinacrine pellets for non-surgical female sterilisation. *Reproductive Health Matters*. 2(Nov):119-22.
4. This paper analyses the main report of the Vietnam study by Hieu et al, which was published in the *Lancet* 1993; 342:213-17.
4. A retrospective study of quinacrine sterilization in Vietnam: for presentation at the Quinacrine Sterilization Dissemination Meeting in Hanoi, February 1995. Conducted by Ministry of Health, Vietnam and Family Health International. (Unpublished)
5. FHI quinacrine studies. *Network*. 1995; Sept:27. And: David Sokal, Family Health International, personal communication. October 1995.
6. Ralph Heywood, Consultant in toxicology, UK. Written communication. 13 November 1995.
7. Patrick Rowe, Medical Officer, Special Programme of Research, Development and Research Training in Human Reproduction, WHO, personal communication. October 1995.

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# Business as Usual for Quinacrine Sterilisation in Chile

*Lezak Shallat*

**C**HILE is the birthplace of female sterilisation with quinacrine. Contrary to what was reported in Chile's newspapers, however, it is almost 'business as usual' again for this controversial method of sterilisation, following a short-lived public outcry that led to a temporary suspension of provision late last year.

The good news is that scrutiny by local women's health activists stopped the Chilean Health Ministry from entering into expanded trials of the method and brought about the first-ever talks between feminists and quinacrine researchers, with the focus on informed consent.

Quinacrine sterilisation has been part of the

national contraceptive research landscape since the early 1970s, when it was first developed as a sterilisation method by Chilean scientist Jaime Zipper. Some 1,500 women have undergone quinacrine sterilisation to date in trials supervised by him in three public hospitals.

But it was not until late last year-when Health Ministry plans to participate in expanded trials came to light-that the facts about quinacrine use erupted into public controversy. The uproar began when women's health activists received copies of a September 1994 memo from the US-based Center for Research on Population and Security,' which stated (erroneously, as it turned

that the Chilean Health Ministry was recommending surgical sterilisation with quinacrine in the nation's two most populous regions. The memo presented this possibility as an already-decided policy, saying that Chile's support of quinacrine in the face of the World Health Organization's 'ridiculous position' against its clinical use until more is known about its safety and efficacy, was a landmark event that would pave the way for quinacrine sterilisation to be taken up throughout the region.

These bombastic assertions turned out to be false. But probing by activists determined that the Chilean Health Ministry was, in fact, studying plans to join the Zipper team in providing quinacrine sterilisation to up to 1,000 women in central and southern Chile.

The ironies of this plan are considerable. Female sterilisation is highly restricted in Chile under a 1975 decree by the pro-natalist Pinochet regime, which mollified the Catholic Church in the reproductive rights arena at a time of rampant human rights abuse. Sterilisation is available only to women over age 30 for medical reasons, and a woman must have four living children and spousal authorisation. In practice, these restrictions apply primarily to the public health services, since women with private physicians generally have no problem getting sterilised, particularly after caesarean delivery. Vasectomy, though technically legal, is viewed by the Catholic Church as a form of mutilation and is virtually impossible to get in the public health services. Abortion for whatever reason (including to save the woman's life) is strictly illegal.

Nonetheless, demand for female sterilisation is high, with public health services performing up to 15,000 surgical sterilisations a year. Unmet need is high too, due to exclusionary restrictions, complicated paperwork for allowable cases and the limited number of public hospital beds available for elective surgery.

While governed by the same restrictions as surgical sterilisation, the out-patient quinacrine sterilisation procedure provides Chilean women who cannot afford private medical care with a fast track to sterilisation that eliminates the long wait for a public hospital bed. Women who come to the public health services voluntarily seeking sterilisation and who agree to be treated with quinacrine are informed that it is definitive and irreversible, that it has a three percent failure

rate and that alternative methods exist to prevent pregnancy. Nowhere is it stated, however, that the treatment is classified as 'investigational'.

With women's health activists sounding the alarm over quinacrine safety and the spectre of experimentation on poor women, the Chilean Health Ministry withdrew its support for quinacrine research and in December 1994, the Minister of Health called for suspension of its use. More than a ban, however, this proved to be a short hiatus in which the three public hospitals providing the method were asked to review their internal ethical procedures. (In Chile's decentralised public health care system, ethical decisions about research are made by the Ethics Committee of each hospital.)

In response, the Sotero del Rio Hospital - Dr Zipper's research base and home to the country's largest maternity ward - stopped doing quinacrine sterilisations for three months. The hospital has since re-instated its programme, however, and is conducting a privately-financed trial with up to 700 women. As of October 1995, the quinacrine sterilisation programmes in the two other hospitals were still under internal review. Plans to reclassify the Sotero del Rio programme from 'investigational' to 'procedural' (routine), a move that would pave the way for wider use, were also put on hold.

Despite the decision to distance the Ministry from the use of the method, it would appear that Health Ministry officials continue to view quinacrine as a promising option to satisfy the unmet need for elective sterilisation.

Leading the public scrutiny of quinacrine use in Chile is the Santiago-based **Foro Abierto de Salud y Derechos Reproductivos** (Open Forum for Reproductive Health and Rights), a coalition of activist groups. The group has three basic concerns regarding the continuing 'trials': first, unresolved issues of safety, including the internationally agreed recommendation to delay clinical use until toxicology trials are satisfactorily completed; second, the need for improved informed consent procedures in this interim period before these trials are completed; and third, the need for greater transparency of information and improved access to hospital ethical committees.

In June 1995, the **Foro** met for the first time with Dr Zipper and his team, including experts from various medical specialties, midwives, the head of the Sotero del Rio Hospital women's

health services and the top Health Ministry official for the zone. Citing the backlog of women requesting sterilisation and the danger of unwanted pregnancy while they are waiting for surgery, the Zipper team defended its decision to resume quinacrine use before the results of the toxicology studies are known.

As for the Ministry's decision to hold off reclassification of the method from investigational to procedural status, Dr Zipper said his team had envisioned a compromise so as to increase the number of patients enrolled (up to 700), as if it were a routine hospital procedure, while maintaining the level of follow-up required with investigational treatments. Interestingly, Dr Zipper's team acknowledged the weakness of existing informed consent protocols and broached the possibility of holding additional meetings with the Foro to discuss this issue.

Foro members were pleased at the efficacy of public pressure in obtaining this long-denied interview with Dr Zipper and his team. But the coalition has yet to decide how to proceed. If they explore the possibility of improving the informed consent procedure, does this implicitly mean they support the provision of the method? Or, if they refuse to do so because they disagree with provision of the method until more is known

about its safety, does this mean they are doing a disservice to the women **who** are already receiving it, or to those who could benefit from it in the future?

One possibility the **Foro** has discussed is to enlist the support of the Pan American Health Organization's Latin American and Caribbean Regional Program on BioEthics, created in 1994 and headquartered in Santiago. The Program's head, Dr Julio Montt, a former Chilean Health Minister, has already expressed reservations about the unresolved issues of quinacrine safety and informed consent to the national health authorities. However, the Program views its role **as** educational, not activist, in monitoring ethical issues concerning reproductive rights in Chile.

Thus, it would appear that the Foro must assume the activist role in addressing the ethical issues surrounding the use of quinacrine, one way or the other, nearly 30 years after its first appearance in Chile.

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## Reference

1. Progress Report: Quinacrine pellet method for nonsurgical female sterilization. Letter dated 30 September 1994, from Stephen Mumford, Center for Research on Population and Security. North Carolina, US.

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## RESUME

L'administration de quinacrine est une **méthode** non chirurgicale de **stérilisation** féminine qui n'a encore **été approuvée nulle** part par les autorités de réglementation pharmaceutique, faute d'**études** sur son **efficacité** et sa **sécurité** d'emploi. Un petit nombre de **médicins** persistent (**individuellement**) à appliquer cette méthode à des femmes pauvres dans des pays en développement, en **dépit** des avertissements lancés à l'**échelle** internationale par l'**OMS**, l'**IPPF** et d'autres experts **médicaux** et scientifiques **sur** le terrain. On trouvera dans ce rapport: **1)** un résumé des **événements** de l'**année écoulée**, au premier plan desquels la constatation d'une **mutagenicité** par trois des quatre essais **précliniques**, **avec les** questions que de tels **résultats** posent pour **les** recherches futures; **2)** un document sur la poursuite de l'application de **cette** méthode à des femmes de Santiago (Chili).

## RESUMEN

**La** quinacrina es un **método** no quirúrgico de esterilización femenina. No ha sido aprobado por las autoridades de **regulación de fármacos** de **ningún país** ya que **los** estudios no han demostrado **aún** su seguridad y efectividad. A **nivel** individual, un **número** reducido de médicos han seguido suministrando este **método** a mujeres pobres en países en desarrollo, en contra de **los** consejos a **nivel internacional** de la OMS, la **Federación Internacional de Planificación Familiar** y otros expertos médicos y científicos en este terreno. Este informe **incluye:** **1)** un resumen de **los** acontecimientos **del** año pasado, **el más** importante de **los** cuales es la presencia de mutaciones causadas por el **fármaco** en tres de **las** cuatro pruebas **pre-clínicas**, y lo que dichos resultados implican **para** las investigaciones **futuras**; **2)** un ensayo sobre la continua **provisión** de **esterilización** por medio de quinacrina a mujeres en Santiago de Chile.