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Quinacrine sterilization (QS): the ethical issues

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Abstract

QS has generated debates that are ultimately grounded in various principles, norms, and values. Through a careful analysis of opposing arguments, this paper focuses on two ethical principles claimed by both sides, namely: respect for life and beneficence. Though issues surrounding QS are complex, from the common ground of these two principles, this paper proposes a course of action that addresses many of the concerns from both points of view.

Keywords: quinacrine sterilization, arguments pro and con, beneficence, respect for life, ethics

Fighting behind the banners of protection of women's health and their reproductive rights, overpopulation and poverty, organizations and individuals argue their positions for and against the use of quinacrine as a non-surgical form of female sterilization (QS). QS sparks heated debates rivaling those that accompany the issues surrounding abortion. Similarly, discussions regarding QS are often painted with bold "black and white", right/wrong distinctions. However, the issues themselves are complex and tightly intermingled with various political, sociological, economic and religious agendas. Unfortunately, when discussions are polarized and ideologies are set up against one another, a great deal of energy is often expended in the argument itself and those whose lives are affected continue to suffer. This paper is designed to provoke thoughtful reflections on the ethical issues relating to QS and the plight of women who can be most helped or harmed by its utilization.

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Biomedical ethics is an inherently interdisciplinary field of inquiry, where we examine questions of morality: "What is right?" and "What ought to be done?" We also examine underlying principles and values. Ethical discussions and dilemmas highlight conflicts among competing goods, rights, principles and values. For example, proponents claim that QS is an option for reproductive freedom. They work to alleviate the high maternal mortality in the Third World, to address issues of overpopulation and to provide women throughout the world with the choice for non-surgical sterilization. On the other hand, QS opponents assert that their efforts are directed to protecting the rights of poor, often exploited groups, particularly women, and to preserve and maintain what they say is the integrity of medical research. While proponents argue that QS addresses urgent needs with a potential of minimal risk, opponents counter that the risks (not defined) which are associated with QS far outweigh any potential good. Thoughtful bioethical discussions begin with an understanding of the facts and of the various stakeholders[1] involved. Unfortunately, impassioned de-

[1] A stakeholder is any individual, local or international group or organization, that has an interest in, and is in some way involved with, the ethical issue under discussion.

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bates between stakeholders involved with controversial issues such as abortion and QS often become a barrier to clear perception and determination of the facts.

What the stakeholders view as relevant "facts", and their positions regarding QS, are influenced by: familial, societal, political, economic and religious factors. These also affect the principles, norms and values upon which they ground their arguments for or against QS. In his discussion on sterilization, Robert Veatch observes, "Decisions pertaining to sterilizations, just like all other medical decisions, must be made in the context of a set of fundamental value orientations." [1] Veatch would argue that it is logically impossible to make decisions regarding medical treatments, such as QS, without examining the value orientation of the various stakeholders inherent in their culture and society. The polarizing discussions regarding QS reflect multiple political, religious, economic and other influencing elements, and lead to the possibility of multiple motivations and principles for actions relating to this method.

To comprehend the ethical issues in a situation requires insights regarding the facts and the stakeholders involved. After presenting their differing perspectives on QS, this paper carefully analyzes several arguments, both for and against QS. Both sides in the debates put forth claims ultimately grounded in similar principles, namely: a respect for human life and beneficence. By focusing on this common ground, we are led to an understanding of a range of perspectives and then arrive at a multifaceted solution that attempts to stand between the "ban" vs. "use" positions currently being put forth for QS.

Few, if any, "facts" – even scientific facts – are pure, objective entities. Often the answer to the question "What are the facts?" depends upon the relative position of the individual responding. One's perspective influences not only what are deemed the pertinent "facts" of the case under examination, but also how they are to be interpreted. Thus, prior to discussing the facts associated with QS, it is necessary to consider the stakeholders involved. Examination of the disparate organizations and individuals who are in one way or the other concerned with QS, reveals a complicated web of interconnected lives. They constitute a long list, including all women of the world, particularly impoverished women living in Third World villages with only limited access to and means for healthcare. The existence of these women and their families often gets caught among the ideological arguments regarding overpopulation, reproductive freedom, family planning and human rights. The Pope and the Roman Catholic Church are powerful stakeholders who fight through a commitment to what they term "natural law" to protect "the family" as they perceive it. Physicians working in rural villages, or in industrial cities like New York, represent stakeholders operating under any number of motivations: from a desire to provide female patients with reproductive choices to ambition for recognition in promoting governmental policies regarding the number of children a couple may have. Stakeholders are also found among government leaders, members of international medical organizations, such as the Association for Voluntary Surgical Contraception, the Congress of the United States of America, pharmaceutical companies, non-governmental organizations (NGO) and many others. Those within these groups are concerned about freedom, reproductive choices, and the health of women, their families and communities. This web of stakeholders includes women and men, old and young and individuals from all levels of society.

Such a diversity of stakeholders, not surprisingly, leads to a multitude of perspectives and ideas regarding what are and are not the correct/acceptable facts of QS. Despite all the controversy surrounding this procedure, there is general agreement over the historical development of quinacrine (atabrine, mepacrine hydrochloride) as an anti-malarial drug and the way in which it came to be utilized for non-surgical female sterilization [2]. Additionally, both those who support and those who oppose the utilization of QS agree that it is inexpensive, simple to administer, and does not require surgical facilities or the expertise of physicians. However, these three facts, along with others emphasized or ignored, are at the heart of the ethical controversies surrounding QS. Perceiving a need for an inexpensive, non-surgical form of sterilization, physicians from a number of countries conducted clinical trials (to date approximately 140,000 women have undergone QS). They concluded that QS is a safe and effective option for women who want no more children [3–7]. On the other hand, opponents, keenly aware of the historical abuse of sterilization, specifically in developing countries, are highly suspicious of QS. Abuse of anything can occur anywhere. Opponents question QS' primary use where the world's most vulnerable populations live.

They claim the success rate of QS is low, its side effects daunting, and that the potential for its abuse is simply too overwhelming to allow its use [8–10]. Although there is agreement that QS is inexpensive, easy to utilize and requires neither specialized equipment nor intensive training, there are a variety of disputes concerning the implications of these facts.

So here is a situation rife with disagreements regarding the facts associated with the method. Respected, peer-reviewed journals such as *Contraception*, *Fertility and Sterility*, the *International Journal of Gynecology & Obstetrics* and *Lancet*, have published the results of a number of QS clinical trials. The conclusions of Drs. Zipper, Hieu, Bhatt and others, all indicate that QS is successful in preventing pregnancies, with minimal side effects [11,12]. But Drs. Carignan and Pollack, journalist Alix Freedman, and others view the clinical trials with great suspicion. They insist that this research is invalid due to what they consider irregularities. They question the manner in which data were calculated, and take exception to the ability of the investigators to conduct adequate follow-up programs. According to them, "It is not possible to conclude quinacrine pellets are a safe, effective non-surgical method of female sterilization", because the results varied too widely. Questions have been raised regarding lack of informed consent and inability to conduct follow-up studies because the women are from rural areas and difficult to find. These opponents claim that QS has not yet been approved by the US Food and Drug Administration (FDA) and call for a halt in its use in humans until questions regarding QS safety and efficacy can be answered, and it receives FDA authorization. However, the FDA has approved a phase I trial of QS which was completed as of 30 April 2003. Ultimately, medical concerns aside, these individuals argue that the potential for abuse is simply too high to support the method.

Kessel, Mumford, Lippes and others, however, point out that quinacrine has been prescribed as an antimalarial for over 70 years and has been ingested in large doses by over 100 million people. In all these years, there has been no report of long-term side effects or any increase in cancer. They argue that quinacrine is in fact an FDA-approved medication, and utilizing it for QS is considered an "off-label" use. The toxicology testing and clinical trials available in the 1942 Winthrop Corporation publication indicate the safety of the drug. Proponents apply the results of these earlier tests to QS, arguing for its safety. Opponents reject this assumption and insist that the tests for the oral consumption of quinacrine are not applicable to its transcervical uterine administration for QS. In order to gain FDA approval specifically for the procedure, Family Health International estimates it would require eight years and eight million dollars [13]. Pharmaceutical houses usually provide the financial backing for drug testing. However, quinacrine is in the public domain and cannot be patented, thereby decreasing, if not removing altogether, the profit incentive. Perhaps it is for this reason, and the fear of litigation, that many of these companies are unwilling to conduct the studies and have even abandoned further research and development for contraceptives [14].

While Pollack, Freedman and others claim QS clinical trials lack follow-up studies, Suhadi, Soejoenoes, Bhatt, Sokal and others have conducted, and published, studies that monitored patients anywhere from 6 months to over 19 years following the procedure. Some of these studies reported a success rate of 97%. All the research has found that QS was a safe, effective, non-surgical form of female sterilization [15–17]. While proponents of QS maintain that past testing and current clinical trials are applicable and reliable, opponents reject these conclusions. These are but a few examples of the disputes concerning the facts relating to QS and how the positions of the stakeholders influence both their presentation and interpretation.

Having discussed the various stakeholders and facts, let us now examine several arguments for and against QS. Arguing against QS, Brinda Karat, general secretary of the All India Democratic Women's Association, claims that her group is fighting to assure respect for the lives of poor, uneducated Indian women by attempting to protect them from the possible harms of QS. According to Ms. Karat, QS in India is the product of white, imperialist men who are "motivated by a political agenda that smacks of racism", whose "politics are questionable" and whose bottom line is to control, if not exterminate the poor, vulnerable Third World populations, all for the better good of this planet. Ms. Karat led the call that resulted in India's governmental ban on QS. According to her, "Indian women are not guinea pigs to be used ... I don't think any doctor could ever believe that a drug without adequate testing should be used on human

beings." [18] This opposition to QS may be indicative of several influencing elements, political, economic and perhaps religious, to name a few. However, the opinion itself may be reflecting a sincere concern of many who fight to protect the lives of those often abused and overlooked, the poor and uneducated. Opponents maintain that past governmental actions regarding sterilization are deplorable and caution needs to be exercised as sterilization methods are proposed.

Dr. Naseem Rahman, a gynecologist who has performed over 3,000 QS procedures on women in Bangladesh, also fights for the lives of poor, uneducated women. However, her conclusions regarding QS are the antithesis of Ms. Karat's. Motivated by the urgency of the high rate of maternal mortality, overpopulation and the need for an accessible, inexpensive, non-surgical method of sterilization, she enthusiastically supports QS. When asked about the possible cancer risks with QS, Dr. Rahman responded: "She's [women living in the villages] probably going to die next year or the year after in childbirth. Do you still think she's bothered about cancer, which can take place – may or may not – after twenty or forty years? She won't live that long." [18] Due to the critical circumstances in which she functions, Dr. Rahman's response is pragmatic: perhaps additional FDA pharmaceutical testing could be done, but she is satisfied with the already published results. Her patients are suffering under a multitude of burdens and have requested sterilization. Because the current situation is characterized by insufficient funds, lack of trained surgeons and proper facilities (operating room, anesthesia etc), tubal ligations, the method of choice for women seeking sterilization in industrialized societies, are not feasible. According to Dr. Rahman, QS is a method of choice. If there was a full FDA approval, we would no longer need clinical trials or put another way – to gain FDA approval, we must have clinical trials.

Ms. Karat and Dr. Rahman are both stakeholders from the Indian subcontinent's elite; Ms. Karat is a politician and Dr. Rahman is a physician. Undoubtedly their positions regarding QS are influenced by various elements. Dr. Krishna Jafa, a physician working with others who support the use of QS, considers Ms. Karat's position a political reaction. Dr. Krishna Jafa admits she was skeptical about QS at first. However, after interviewing over one hundred women who underwent QS, discussing the side effects and their experiences, she concluded that QS was an appropriate option. She is convinced that the rationale for India's ban on QS was purely political and had nothing to do with science. When asked if QS may have had a different fate had it been distributed by an Indian woman's movement and not by two white American men, Dr. Krishna Jafa answered with a definite, "Yes, that's a forgone conclusion!" [18]

While Ms. Karat's position is criticized on political grounds, Dr. Pollack, president of EngenderHealth (formerly known as Association for Voluntary Surgical Contraception – AVSC), charges Dr. Rahman and others in favor of QS with setting a dangerous precedent regarding healthcare. Doing a risk/benefit analysis, Drs. Kessel and Mumford (the two above-mentioned "white, imperialist men") argue that developing nations "with low contraceptive prevalence, high population growth and high maternal mortality benefit greatly from increased contraceptive prevalence." Dr. Kessel, along with many others, cites the statistics: worldwide 500,000–600,000 women die each year from pregnancy-related complications. According to the World Health Organization (WHO), 98% of these deaths occur in developing countries [19]. With every maternal mortality, another fifteen women, men and children are left handicapped in some way. In view of the magnitude of these losses, Dr. Kessel argues that the benefits provided by QS far outweigh the possible potential risks. As far as Dr. Kessel is concerned the risks are minimal to nil. Dr. Pollack disagrees with this conclusion insisting "that [QS] sets up a big double standard for how we live in this world. It's like saying 'that's another world ... we don't have to be worried about quality or safety or efficacy over there'." [18] According to her, performing QS prior to its full FDA approval is unethical and setting a double standard of healthcare.

Dr. Pollack's comments indicate a disregard of the numerous published clinical studies on QS. Her comments also imply that there is equity in healthcare and its distribution. Although her desire for a worldwide healthcare system that is equal in its availability and distribution is a noble and ethical goal, her arguments against QS fail to acknowledge the realities of the great disparities in that care around the world. Consider the statistics cited above, that, while maternal deaths are rare in industrialized countries, they are a major

cause of mortality for women of childbearing age in the Third World [20]. In this context, is supporting QS promoting a double standard or addressing different realities? In the majority of situations world-wide, if individuals are gainfully employed, have some means and health insurance, then they have a greater access to healthcare than those who are unemployed, and have neither money nor coverage. Combining elements of Kant's categorical imperatives and agent-centered utilitarianism, Denise Cooley posits that there are certain situations where it is morally permissible to support something like the distribution of QS even if it is lacking full FDA approval [21].

Drs. Malcolm Potts and Giuseppe Benagiano, two physicians directly involved with pharmaceutical clinical trials in developing countries, understand how QS could be misinterpreted as promoting a "double standard". However, they suggest that the "differences are quantitative not qualitative." [22] According to them, QS is a safer choice over surgical sterilization for women living in the United States as well as in India. It is safer than surgery for women who are heavy smokers, anemic or otherwise not appropriate candidates for surgical, voluntary sterilizations. QS could also be a method of choice for those who desire sterilization but are afraid of surgery [23].

Drs. Kessel and Mumford agree that overpopulation is an issue they are attempting to address. During the 1994 Cairo conference, direct connections were made between population growth, reproductive health strategies and economic and environmental conditions. Many speaking from a Malthusian perspective, see the reduction of population growth as the panacea for poverty. Advocates of this position believe QS is an answer to a nation's overpopulation concerns. However, many Third World nations see the "Western focus on population control as a way to avoid discussing such causes of underdevelopment as inadequate access to capital, exploitative investment strategies and unfair trade practices." [24] It is well known that while industrialized nations contain only 25% of the world's population, they consume 75% of the earth's energy and 85% of its forest products. This same 25% is responsible for generating 75% of the world's pollutants and wastes.

Bonnie Johnson, in her article "Overpopulation and Reproductive Rights", claims that contraceptive technologies do not provide solutions to poverty, overpopulation or even the subordination of women. As she sees it, one needs to look at economic inequities, women's roles in economic and political decisions, traditional roles in the relationships between the sexes, food production and the healthcare delivery system [25]. In Dr. Mahmoud Fathalla's estimation, the focus needs to shift away from the "problems of overpopulation" to the goal of empowering women. Increase a woman's level of education and improve her status, and she will most likely bear fewer children if given the opportunity to curtail her fertility. Working to improve the child survival rates, as well as providing care and protection for the elderly, would also go a long way in decreasing the need for having many children [20]. These are arguments that must be taken seriously as individuals work to provide all women with the option of QS. The need for amelioration of these problems is recognized by many, and most are in favor of solving them.

Drs. Kessel and Mumford have taken up Ms. Karat's challenge, where she implored them to "experiment on their white women first and then come tell us its for our good." [18] Dr. Kessel admits that perhaps they committed a tactical error in not pursuing FDA approval in the USA prior to taking QS around the world. The two pioneers, along with Dr. Lippes and others, have worked toward obtaining FDA approval and to making QS accessible to women in the United States of America[2]. In 1999, the Planned Parenthood Federation of America (PPFA) convened an ad hoc committee meeting to discuss QS. This committee voted to recommend PPFA's involvement in a clinical trial. Paradoxically, opponents of QS have militated to prevent QS testing in the United States. Judith A.M. Scully argues that the United States trials should be banned so as to not affirm previous studies [26]. However, others, like Potts and Benagiano, look forward to these FDA clinical trials there. By the end of April 2003, Dr. Lippes had completed a Phase I clinical trial with 10 women at the Children's Hospital, Buffalo Medical School, in Buffalo, New York.

Ms. Karat and Dr. Pollack accused Drs. Kessel and Mumford of acting unethically toward the poor, uneducated women of India and out of particular

[2] Interview with Dr. Elton Kessel.

political agendas. Mumford claims Ms. Karat and Dr. Pollack's objections to QS are motivated more by a desire to promote their own political and economic ideologies, rather than to protect the lives of the poor and uneducated. According to Mumford, Ms. Karat's crusade against QS provided her husband's communist party with a controversial platform issue. Mumford also suggests that Dr. Pollack's objections stem from the need to defend the interests of her organization, EngenderHealth, and he has presented his position in detail [27]. Undoubtedly, all the positions mentioned regarding QS are influenced by a variety of political, economic and religious elements.

Despite their conflicting opinions and the mutual attacks on each other's probity, one can find that their claims share a commitment to common ethical principles. One can propose that the unfavorable attitudes of Ms. Karat, Dr. Pollack and others arise from a commitment to respect for human life and beneficence. According to their point of view, all lives, poor, rich, educated or not, deserve safe, effective, healthcare. They raise questions and voice concerns that originate from their firmly held beliefs, so the good thing to do, the beneficent action, for Ms. Karat and Dr. Pollack, is to prevent QS from being performed. One can also propose that Drs. Rahman, Kessel, Mumford and others desire only to relieve the suffering associated with high maternal mortality. Their position in favor of QS may also be grounded in a commitment to respect for human life and beneficence. According to these doctors, the beneficent action is to provide a safe, effective method of sterilization for those women who would desire no more children. Taking all the above arguments at face value, one could contend that although their positions regarding QS are antithetical, the two camps share the principles of a respect for life and beneficence.

Having discussed the complex web of stakeholders and facts, and pointed out two ethical principles upon which all the above arguments can be based, let us now consider potential courses of actions. After all, ethics is about making decisions and acting toward what is good and right, for the individual and for society. First, one could do nothing. In terms of QS, this would mean the continuation of debates and controversy with little or no actual change in the way things were done, or in the lives of individual women and men who are suffering the most. In a broader scope, inaction is not only accepting mediocrity, it is allowing the inequities and injustices in the world to continue. Societies world-wide continually evolve and develop as they rise to meet the challenges placed before them. Inaction is an inappropriate response, for ultimately too much is at stake.

A second course of action could be to call for an absolute, international ban on QS. For those ideologically opposed to the method, or for that matter any other form of contraception, this is the only ethical option. No number of tests and studies, and no amount of money would ever make QS acceptable to the Roman Catholic Church or others who are firmly against any form of artificial contraception. However, the very attributes that make quinacrine attractive, and at the same time feared, make banning it impractical. It is inexpensive, easy to make, to obtain and to administer. Banning it may make it illegal, but not unavailable. Also, if QS is banned, protocols, policies and reviews for its use and distribution would neither be developed nor enforced. Although some would argue this action could feasibly protect women from the potential harms of QS, it definitely leaves them with fewer legal reproductive choices. This alternative, along with the first, does not positively address their contraceptive needs.

Another alternative along the above course of action, is to ban QS, but present a different, proven, safe, effective, inexpensive, accessible, non-surgical method of sterilization. This is a good idea, but again highly unrealistic. As already mentioned, pharmaceutical companies are backing away from the research and development of new forms of contraception. Also, although the voices of the opponents to QS are loud and firm, they are not offering a comparable alternative. If such research were actually implemented, then perhaps the reproductive needs of individuals could be met. However, QS is much farther along in testing, development and acceptability than any new idea for non-surgical sterilization.

If one's primary focus is overpopulation, then one may propose a third option: an immediate approval for world-wide distribution and use of QS. This same course of action may be chosen by those whose primary concern is poverty and reproductive freedom. Statistics demonstrate that poverty and overpopulation go hand in hand. Many studies indicate that sterilization is the contraceptive of choice in many countries, thus a

reason to support this alternative. Because of its cost, need for expertise and facilities, surgical sterilization alone cannot meet the demands [28]. QS could be an answer for overpopulation and poverty. However, with over-arching goals such as these, individual desires and choices can too readily be overlooked. Focusing exclusively on goals such as overpopulation almost invites abuse. Additionally, this narrow emphasis on contraception ignores other very powerful causes of overpopulation and poverty.

Among the options mentioned is a full range of other possible alternatives. Perhaps a foundation or government could provide the necessary funding and facilities with which to perform the required FDA drug studies. This action would directly address the fears related to the risks of cancer, effects on the fetus, and the like. One needs to remember that quinacrine itself has had FDA approval for decades; it is the "off-label" use that has not been officially approved. If money and time were not an issue, additional trials could be conducted – following FDA protocols to the letter. This could answer the questions and criticism of the studies already completed. However, time and money are important issues for those stakeholders dealing with the reality of high maternal mortality in developing countries and concerns with the results of overpopulation.

An ideal ethical alternative would address the concerns discussed above, and the actual needs of those living in the present and future. Since a multi-faceted issue such as QS requires a multifarious response, this final alternative incorporates a variety of elements and by its very nature is complex. This alternative has long- and short-term goals, mindful of both the fears and abuses associated with the history of sterilizations, as well as the years of research already conducted on QS. This view implements an ethical policy that works towards justice, safety and protecting from, even preventing, abuses. Influenced by conclusions reached at international conferences such as the 1994 Cairo International Conference on Population and Development and the fourth UN World Conference on Women held in Beijing in 1995, the focus of this alternative is to improve and ensure the health of all women, their children and families. Thus, it is called the "*whole family health*" ethical alternative. This focus ensures the ethical principles of respect for human life and beneficence [29].

The focus of this option must be on the well-being of the whole family, not exclusively on the reproductive health of women or men, which may obscure the whole picture. Sterilization is not always *the* answer. Sterilizing a woman does not inevitably protect her or provide the basic needs for her family's survival. Unfortunately, in cases where the focus has been exclusively on sterilization, the basic health needs of the family are not always met [29]. Thus, this alternative would present a *whole family health* package. A comprehensive healthcare program would include access to nutrition, clean water, safe general medical assessments for children, adults and the elderly, as well as reproductive/contraceptive care for women and men.

A serious problem in most, if not all, societies is that women have had to carry the primary responsibility of contraception (and its failures) without the power to make their own reproductive decisions [30]. This is unacceptable. As a long-term goal, this *whole family health* alternative respectfully challenges religious, cultural, societal and political systems. As Fathalla stated, "No society, primitive or advanced, no culture, no religion, and no legal code has been neutral about reproductive life. The health of women is to no small extent determined by certain males of the species, moralists, politicians, lawyers and others ..." [31] Women and men have equal rights within the society and the family, and they should share the responsibility of contraception. It is unacceptable that women carry the primary responsibility for contraception, but do not have the power to make their own choices regarding reproduction and contraception. Even policy experts at the 1994 Cairo Conference realized that empowering women was the primary means to achieving their central goal of stabilization of the world population growth. Again, the focus would not be population reduction. That may be a by-product of empowering women, but it is not the focus of this alternative. Another goal involves increasing the level of education in the society. Once the focus is on the stories of the lives of women, their children and men, patterns of subordination can be uncovered and corrected [32].

The *whole family health* package offers QS as one of its many services. Women requesting permanent sterilization are to be fully informed of the risks and benefits of QS and provided with other long-term contraceptives options such as Norplant and condoms.

Only after informed consent is given, is QS to be administered. Additionally, to guard against abuse and coercion, the offer of QS is to be totally independent of any other needed medical assistance. It is not to be a condition for receiving medical assistance with pregnancy, childbirth, or any other medical need. This approach provides healthcare for the whole family.

This *whole family health* alternative also accepts the facts associated with QS. Drs. Malcolm Potts and Giuseppe Benagiano go so far as to say that "the unreasoned passion about QS is making evidence-based decisions difficult to reach." In their article "Quinacrine Sterilization: A Middle Road," they acknowledge that while they have had different stances regarding QS policies, they now "wish to help broaden the range of fertility control options available, especially for low income women around the world." They demonstrate an understanding of the complexities involved with the testing of new drugs or devices and they understand the desire for certainty. However, they are mindful that "the introduction of any new drug must necessarily take place on the basis of balanced judgment and, almost inevitably, incomplete information." They also recognize that "as with all new family planning methods at this stage of development, there are insufficient data to answer all possible questions about rare but potentially important long-term risks." Nonetheless, they argue "the experience to date has shown that QS has a low risk of serious, immediate side effects. We deplore hasty judgments and biased comments, and we ask all those who are interested in the welfare of women around the world to recognize the difficulty and inevitable uncertainty surrounding the introduction of any new method of fertility regulation." They conclude that QS should be available for "women who ask for sterilization and for whom existing methods are not available or present unacceptable risks." [22]

The *whole family health* approach is clearly the action of choice. It is mindful of the concerns raised by an examination of the historical context of sterilization in developing countries. By moving forward with an emphasis on the health of the entire family, it addresses the legitimate concerns regarding abuse, and takes into account the data obtained from the clinical trials conducted over the past twenty years. The primary values, principles and concerns critical for QS are incorporated. It is a compromise between doing nothing and a complete ban or full-scale implementation. Its central focus is the health of the individual, not merely reproductive health of women, but the general health of the whole family. This broader perspective calls for the enhancement of the lives of the whole community. It allows us to go behind Rawl's "veil of ignorance", where, based on respect, care, and concern for others, we make decisions that will affect us all.

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