ISAF

QS

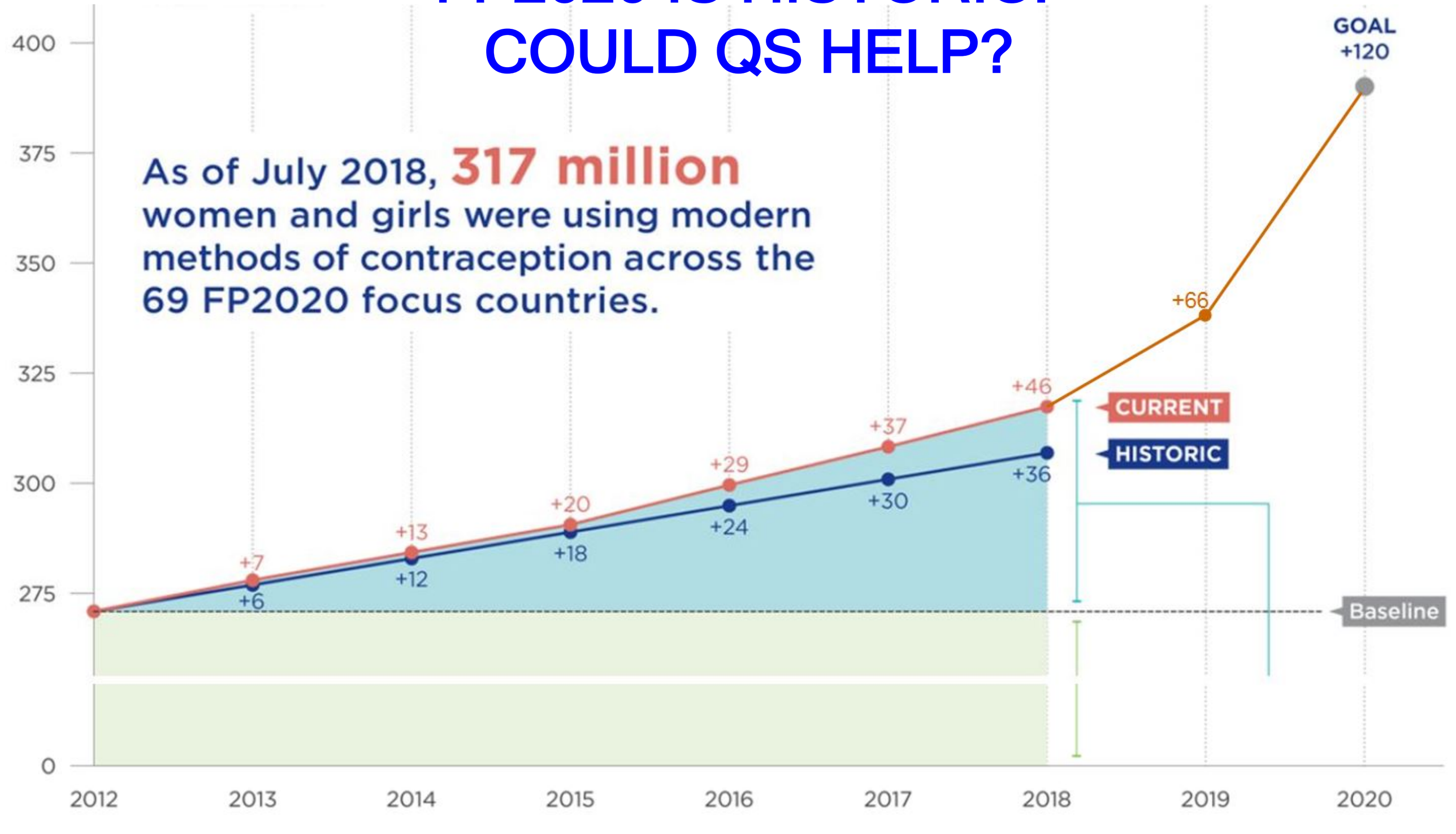
Permanent Contraception for Women ®

Will they survive?
Will they thrive?

PLEASE HELP
QS SAVE OUR
PLANET

QS COULD IMPROVE THE QUALITY OF LIFE FOR A BILLION FAMILIES

FP2020 IS HISTORIC!
COULD QS HELP?



Quinacrine Sterilization

What is Quinacrine Sterilization (QS)?

Quinacrine Sterilization (QS) is a permanent method of contraception. There is no surgery. Instead, a drug called quinacrine (originally taken orally to treat malaria) is inserted into the uterus. Researchers began to study quinacrine sterilization in humans in the 1970s. Since then, over 125,000 women in 30 countries have used QS as a method of sterilization.

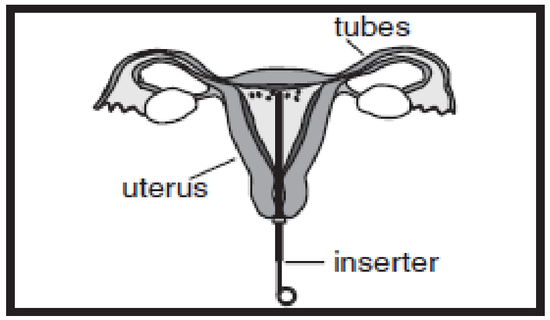
Because it is a relatively new method and many women do not know much about QS, this brochure is provided to answer some questions.

How safe is QS?

Research has been done around the world to find out how safe quinacrine is. What is known is that QS is safer in terms of complications than surgical sterilization especially in parts of the world where hospitals and clinics are poorly equipped.

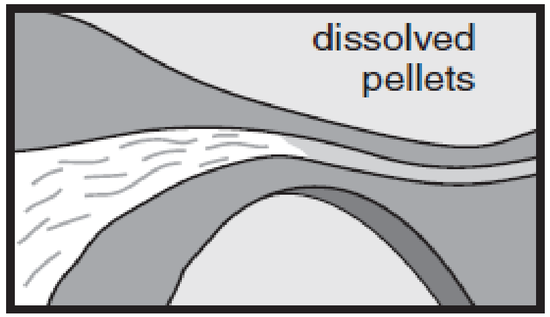
What happens during an insertion?

1



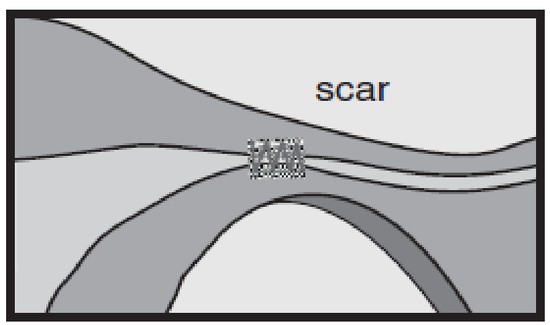
Using a modified IUD inserter, the healthcare provider (a midwife, nurse or doctor) places 7 small pellets (pills) of quinacrine in the uterus on two separate visits.

2



In half an hour, the pellets dissolve and the liquid quinacrine flows into the tubes. The quinacrine causes inflammation of the lining of the fallopian tubes.

3



Over the next 6-12 weeks, the quinacrine causes plugs of scar tissue to form at the first part of the tubes. These plugs close the tubes and block the egg's path to the uterus.

What are the advantages of QS?

The main advantages of QS are:

- no surgery, which means less risk of infection, injury or death
- no hospitalization
- less pain than surgical sterilization
- many types of trained healthcare providers, not just doctors, can perform the method
- requires no anesthetic

What are the disadvantages of QS?

The main disadvantages of QS are:

- it has never been successfully reversed (QS may be much less reversible than surgical methods)
- some women may still get pregnant even after they have a QS
- QS is still a new method; there may be risks which are not yet known
- it requires two visits to the clinic
- it does not completely protect against tubal pregnancy
- It does not protect against sexually transmitted diseases (STD's)

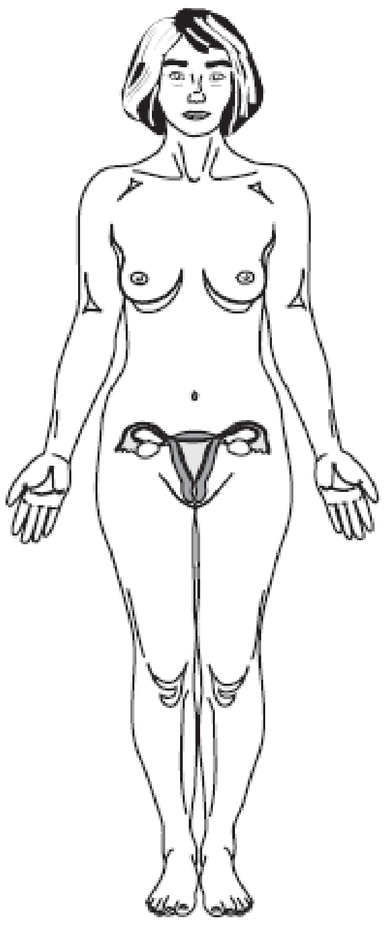
Is tubal pregnancy possible?

As with other methods of contraception, tubal pregnancy (a pregnancy which occurs outside of the uterus), though rare, can still occur. Tubal pregnancy may still occur after QS, but it is not caused by this method. The tubal pregnancy rate with this method is lower than the rate in women who use no contraceptive method. Tubal pregnancies are very dangerous. In some countries, 1 out of 20 women with a tubal pregnancy dies. If a woman believes she is pregnant and has any of these signs, she should call or go to her healthcare provider right away:

- a missed period
- severe pain in the lower abdominal area
- dizziness, fainting or weakness
- vaginal bleeding other than a normal menstrual period

How many insertions are necessary?

Two insertions greatly increase the chance that the quinacrine sterilization will be successful and are therefore always part of a QS insertion.



What happens after the first insertion?

Because it takes 6-12 weeks for the scar tissue to form, you must use another contraceptive method in addition to QS, starting the day of the first insertion. Examples of contraceptives to use are condoms, foam, pills, IUDs or injectables. To make sure that the scar tissue has formed and that the patient will not become pregnant, she must return for a second insertion one month later. She must continue using the other method for 2 more months after the second insertion.

Does QS ever fail?

Yes. QS fails if the tubes are not blocked completely after two insertions. However, it is becoming more effective with improved technique. Studies conducted 10-20 years ago reported higher failure rates than we see today. Since the adoption of a new insertion technique in 1993, the failure rates reported have been less than 2 out of 100 women after 2 years. Because of improvements in the technique, it is estimated that after ten years, fewer than 5 of 100 women will be become pregnant.

When must the insertions be done?

QS must be done 6-12 days after the onset of the woman's period. (To increase chances of success, there must be no blood in the uterus during the first or second insertion.)

1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28

days of menstrual period

days to have QS

What are the side effects of QS?

Nearly half of all women report experiencing at least one side effect. If there is a side effect, it usually goes away within a few hours to a few days. Here is a list of the most common side effects, and the number of women out of every 100 who get them:

Symptoms	Number of Women
menstrual pattern changes	20 to 29
lower abdominal pain	9 to 25
headache and dizziness	9 to 20
backache	1 to 21
vaginal itching or irritation	1 to 23
discharge	5 to 16
fever	9 to 10
pain during urination	≤ 1
pain during sex	≤ 1

Some women have menstrual changes after the insertions. This means that they either do not have their period or there is a change in the amount of flow of their period or the number of days it lasts. This usually lasts no more than a few months. In rare cases, it may last a year or more.

A potential QS client should be encouraged to consider the following:

1 Some questions to ask your healthcare provider

- Can I change my mind after the first insertion?
- Are there women in my community who have had QS? Can I contact them?
- What do I do if my side effects last longer than a few days?
- Can I return to all my normal activities right after QS?
- What kind of contraception do you suggest I use for the first 3 months?
- When can I start having sexual relations after QS?
- What happens if I find out I am pregnant?

2 Some questions to ask yourself

- Why am I having this procedure?
- Are there other methods of contraception I can use that will work better for me and my husband at this time?
- Most importantly, am I certain that I never want any more children?

3 Tell your healthcare provider

- if you know or think you might be pregnant
- if you have seizures (fits), cancer or any vaginal infections
- how long it has been since your last child's birth
- if you have doubts about being sterilized
- about any other concerns you have

A Brief History of QS

1976	1977 1980 1990 2000 2004	2006	2007	2009	2012	2015	2016
ISAF Founded	200,000 used QS in 50 Countries successfully - no reported deaths	Phase 3 Start	Phase 3 Halt	WHO Reject	FDRR Start	FDRR Reject	FDA Reject

In 1976, The International Services Assistance Fund, ISAF, a 501(c) (3) nonprofit organization was founded dedicated to family planning and contraceptive development research.

In 1993, ISAF focused on obtaining FDA approval of a nonsurgical method for female contraception called quinacrine sterilization (QS) developed in 1977 in Chile by Dr. Jaime Zipper, inventor of the Copper -T IUD.

In 2000, ISAF conducted a Food and Drug Administration (FDA) Phase 1 study of QS (IND 74802) by Dr. Jack Lippes, inventor of the Lippes Loop IUD, at the Women and Children's Hospital of Buffalo, a teaching hospital affiliated with the State University of New York at Buffalo School of Medicine. The hospital's investigational review board approved the clinical trial. Ten women who desired sterilization volunteered for QS and agreed to participate in the trial. This study was completed in 2003. There were no serious adverse events (SAEs) reported in this Phase 1 trial, the results of which were published in the ***International Journal of Gynecology and Obstetrics (IJGO)***.[28]

By 2004, QS was being used non-coercively and successfully by more than 200,000 women in 50 countries. Scores of peer reviewed publications highlight successful result for tens of thousands of women.[1-42]

In 2006, ISAF obtained FDA approval to commence a Phase 3 clinical trial of QS in the United States. Regional training was completed in the trial protocol of 40 physician investigators and their clinical staff which included 18 medical schools and a number of clinics.

On January 10, 2007, FDA placed a clinical hold on ISAF's Phase III clinical trial. The basis for the clinical hold was and continues to be, 11 years and $8 million later, a fatally flawed rat cancer bioassay (CaBio) which the FDA offers as (the only) evidence that quinacrine is a genotoxic carcinogen. FDA staff at the Division of Reproductive and Urologic Products (DRUP) "directed" the team at Family Health International (FHI), now called FHI 360.

The International Conference on Harmonization of Technical Requirements for Regulation of Pharmaceuticals for Human Use (ICH) has determined the method that must be followed to set the doses in a CaBio. Determining the maximum tolerated dose (MTD) used in this CaBio was the most important step for this study. Yet, no one ever made any effort to determine the MTD. This CaBio never mentions the "MTD" in either the study protocol, the Final Report or in the published report, Cancel et al. (2010).[48] Yet, the FDA and FHI found the MTD of 350 mg/kg, 35 times as high as ISAF's 10 mg/kg (McConnell et al.).[3] ISAF's Haseman et al.[4] documented that using 350 mg/kg was responsible for all of the excess tumors in this CaBio. The FDA refuses to acknowledge the bad and dishonest science by FHI and the publisher of the CaBio, ***Regulatory Toxicology and Pharmacology.***

In 2008, members of a team of experts presented ISAF's position to the World Health Organization in Geneva[49], and to the US FDA DRUP in Washington, DC. Both organizations refused to acknowledge the bad science of the CaBio Study. Subsequent published papers[1-4] offered clear evidence of foul play by the FDA and FHI.

On December 26, 2012, ISAF submitted a formal dispute resolution request (FDRR) to the Office of Drug Evaluation III (ODE III), concerning the July 20, 2012, continued clinical hold action by DBRUP. On February 15, 2013, Dr. Julie Beitz, Director, ODE III denied the appeal.

On May 6, 2013, ISAF submitted a FDRR to the Office of New Drugs. Dr. John Jenkins, Director, Office of New Drugs (OND) denied the appeal on March 25, 2015.

On June 1, 2015, ISAF submitted an appeal to the FDRR to the Center for Drug Evaluation and Research to Dr. Janet Woodcock. Dr. Richard Moscicki, Deputy Center Director for Science Operations was chosen to be the deciding authority for the appeal. Dr. Moscicki requested a meeting with ISAF before rendering his decision on the matter. ISAF agreed to a meeting, and it was held on July 23, 2015. On December 18, 2015, Dr. Moscicki rejected our appeal.

On August 2, 2016, ISAF submitted our final appeal to the Commissioner of the FDA, Dr. Robert Califf, M.D. On December 9, 2016, we received a letter from Luciana Borio, M.D., Acting Chief Scientist for the FDA, acting on behalf of the Commissioner Dr. Califf, denying ISAF's request to reverse its previous decision. The FDA's final decision had been made!

On February 8th, 2017 ***The European Journal of Contraception and Reproductive Health Care*** published *Long-term risk of reproductive cancer among Vietnamese women using the quinacrine hydrochloride pellet system vs. intrauterine devices or tubal ligation for contraception*[1] an epidemiological study determining the long-term risk of reproductive tract cancer in women using the quinacrine hydrochloride pellet system of permanent contraception (QS) relative to the comparable risk in women using Copper T intrauterine device (IUD) or tubal ligation surgery (TL) for long-term or permanent contraception.

Methods: This was a retrospective cohort study, conducted in the Northern Vietnamese provinces of Ha Nam, Nam Dinh, Ninh Binh and Thai Binh. Women who had their first QS procedure, last IUD insertion or TL between 1989 and 1996 were interviewed regarding post-procedure health outcomes, particularly reproductive tract cancers.

Results: A 95% response rate resulted in 21,040 completed interviews. Reproductive cancer incidence rates were very low (5.77/100,000 women years of follow-up time; 95%CI¼3.72–8.94). No significant excess hazard of reproductive tract cancer was associated with QS.

Conclusions: No significant excess long-term risk of reproductive tract cancer was found after an average 16 years of follow-up among a large group of women using QS vs. IUD/TL for contraception.

This human study of 21,040 women renders any study of cancer in rats irrelevant.

On April 23, 2018, ISAF added another peer reviewed published work to its scores of scientific studies: ***The European Journal of Contraception and Reproductive Health Care*** published *Long-term risk of hysterectomy and ectopic pregnancy among Vietnamese women using the quinacrine hydrochloride pellet system vs. intrauterine devices or tubal ligation for contraception.*[2] This study determined the long-term risk of hysterectomy and ectopic pregnancy in women using the quinacrine hydrochloride pellet system of permanent contraception (QS) relative to the comparable risk in women using Copper T intrauterine device (IUD) or tubal ligation surgery (TL) for long-term or permanent contraception.

Methods: This was a retrospective cohort study, conducted in the Northern Vietnamese provinces of Ha Nam, Nam Dinh, Ninh Binh and Thai Binh. Women who had their first QS procedure, last IUD insertion or TL between 1989 and 1996 were interviewed regarding post-procedure health outcomes approximately 16 years post exposure.

Results: A 95% response rate resulted in 21,040 completed interviews. Overall incidence rates were low for both outcomes (91/100,000 women years of follow-up and 22/100,000 women years of follow- up for hysterectomy and ectopic pregnancy, respectively). After accounting for variations in baseline characteristics between women choosing QS vs. the other two contraceptive methods, no significant excess hazard of either hysterectomy or ectopic pregnancy was associated with QS.

Conclusions: No significant excess long-term risk of hysterectomy or ectopic pregnancy was found among a large group of women using QS vs. IUD or TL for contraception after an average 16 years of follow-up.

This study of 21,040 women showing no increases in QS vs. IUD or TL lays to rest any differences in the safety of these 3 methods.

On August 4th, 2017, ***ANSM***, ***The National Agency for the Safety of Medicines and Health Products of France***, "asked Bayer Pharma AG to recall the products in stock from all health facilities that may hold them. Consequently, it is requested as a precaution not to implant the Essure medical device as of now."[43]

On July 18th, 2018, the ***U.S. Food and Drug Administration*** was notified by Bayer that the Essure permanent birth control device will no longer be sold or distributed after December 31, 2018[44]. This decision follows the FDA's patient safety action in April, in which the agency issued an order restricting the sale and distribution of Essure; it was a unique type of restriction where the FDA used its authority to impose additional requirements to provide a reasonable assurance of the device's safety and effectiveness.

On July 20th, 2018 ***The Washington Post*** article, *Sales of Essure birth control implant to be halted by Bayer; U.S. last to sell controversial device*[45] stated that an "estimated 750,000 devices have been sold, mostly in the United States."

On August 6th, 2019 ISAF upgraded its website at http://quinacrine.org to solicit help to bring QS to fruition and submitted a plan to MacArthur Foundation 100andChange to save all species on earth while lifting all of humanity (voluntarily) to a U.S. level of quality of life by 2100AD.

Complications from pregnancy and childbirth are the leading causes of death in developing countries among women of reproductive age. They constitute 99% of the approximately 600,000 women who die annually

during childbirth throughout the world.[47] About half of these women lose their lives as a result of an unwanted pregnancy because they either had no contraceptive choice or access to a method that was acceptable and effective. Surgical sterilization is the most widely used contraceptive method worldwide because it is reliable and cost effective. However, surgical sterilization services are difficult to deliver and unavailable to the majority of the world's women. **Regulatory approval of QS a decade ago may have saved the lives of millions of mothers in the world.**

Bottom Line: Over 42 years, hundreds of thousands of mothers, hundreds of doctors and researchers, and the team at ISAF have proven that QS is safer and more effective than any existing method of permanent female contraception in existence including surgical sterilization. The quality of billions of lives would be improved throughout the world if QS was made available today.

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European Society of Contraceptive and Reproductive Health

2010 MEDAL LECTURE

Jack Lippes, MD
USA

QUINACRINE HISTORY

- 100,000,000 people have taken quinacrine during the past 70 years to treat or prevent malaria
- Some were pregnant — no fetal abnormalities
- 3,000,000 Allied Soldiers took it during WW II without any serious adverse events
- Quinacrine is still used to treat tapeworm, giardiasis, rheumatoid arthritis, lupus
- 175,000 quinacrine sterilizations with no deaths and
- No complications serious enough to require surgery or hospitalization

COSTS

Quinacrine Sterilization		Laparoscopic TL	
No anesthesia	$0	General anesthesia	$300
Drug and inserter	$.53	US hospital charges	$3000-$4000
Office visits x 2 • in Asia • in US	 $2 $200	Surgeon's fee	$650-$900
Total	$4.50-$200	Total	$4000

700,000 laparoscopic tubal ligations are performed in US/year. Savings could equal $3800 x 700,000 > $2.5 billion/year in US.

Quinacrine Non-Surgical Female Sterilization (QS)

Introduction and Summary

You are considering a very serious decision.
Please read and consider everything you have been given.
Ask questions.
Take your time.

HOW DOES TUBAL STERILIZATION OCCUR?

One kind of sterilization occurs when there is no way for the egg and the sperm to meet. This happens when the Fallopian tube between the ovary and the uterus becomes blocked. Although there can continue to be normal ovulation, the egg cannot pass through the tube and cannot meet a sperm. Occasionally this blockage happens after an infection causing unwanted infertility. It also happens intentionally when the tubes are cut during surgical sterilization.

WHAT IS QUINACRINE?

Quinacrine is also known as Atabrine or Mepacrine. It is taken by mouth.

It was first introduced in the 1930s to prevent and treat malaria. Since then, doctors all over the world have prescribed it for millions of people who have malaria and also for treatment of giardiasis, lupus, tapeworm and other medical conditions.

It is the only drug in the United States approved by the FDA (Food and Drug Administration) to treat giardiasis.

There has been a great deal of research on oral quinacrine over the past 65 years. Oral use of quinacrine is very safe, especially in doses under 3000 mg per month. Millions of Americans have taken as much as 36,500 to 52,000 milligrams of it by mouth each year. In some cases they have done so for years as an anti-malarial, with few lasting side effects.

WHAT IS QUINACRINE STERILIZATION (QS)?

QS is a non-surgical sterilization procedure for women. It cannot be reversed. Do ***not*** agree to have this procedure done if you may want more children. On the other hand, although the QS method is intended to prevent pregnancies permanently, it can fail and you could become pregnant.

Permanent sterilization results when pellets of quinacrine are put into the uterus (womb). The pellet dissolves and some of the liquid makes it's way into the Fallopian tubes. The action of the Quinacrine that reaches the Fallopian tube causes scar tissue, which blocks the tube.

The QS method requires two doses of 252 milligrams of quinacrine. They are to be inserted into the uterus one month apart.

WHAT IS THE HISTORY OF QS?

The QS method was first developed in Chile in 1977. Since then, over 100,000 women in 20 countries have undergone the procedure.

Even though quinacrine is an FDA approved drug for giardiasis, the FDA has not approved its use for female sterilization. Using quinacrine for this purpose is considered an "off-label" use. Off-label use of drugs is legal, acceptable, and common practice by providers. Treating lupus with quinacrine is also an off-label use. The United States Pharmacopeia, a national text, lists female sterilization as a use of quinacrine.

WHAT HAPPENS DURING THE QS PROCEDURE?

QUINACRINE INSERTION

The quinacrine may only be inserted into your uterus between the 6th and 12th day of your period (beginning with the first day of your menstrual period). This reduces the risk that you may be pregnant and not know it. It is also that part of the cycle when the height of the endometrium, which may interfere with the action of the quinacrine, is the lowest.

Before insertion, your clinician will perform a pelvic examination. Its purpose is to determine the size, shape, and position of the uterus and to be sure that there are no contraindications. An instrument called a speculum will hold your vagina open so that the cervix (the entrance to the uterus) can be seen. You will probably feel pressure from the speculum throughout the insertion procedure.

The cervix is then cleaned with an antiseptic solution and an instrument called a tenaculum is attached to it. This instrument helps hold the uterus steady during insertion. You may feel pain or a pinching sensation as the tenaculum is attached. Then the clinician will guide a narrow instrument called a sound through the opening of the cervix into the uterus. The sound measures the depth and position of the uterus. You can expect to feel cramping similar to menstrual cramps as the sound is inserted and withdrawn.

Then the clinician will guide the inserter containing the quinacrine pellets through the vagina and the cervix into the uterus. The pellets are placed inside at the top of the uterus.

During insertion, you may have some pain or cramping. You may feel nauseated, weak or faint. After the inserter is removed from the cervical opening, the tenaculum and speculum will then be removed. You may feel pain or pinching when the tenaculum is removed. Following the insertion, you should remain lying down quietly for a while and rise slowly to avoid the possibility of fainting.

FOLLOW-UP PROCEDURES

For up to 24 hours after insertion you will likely have a discharge that is yellow or opaque.

You will have a follow-up appointment in a week.

If you have any event that you read in the Warnings section, call immediately.

REPEAT OF PROCEDURES

The insertion process will need to be repeated in one month.

It may be necessary to repeat the insertion a third time.

There is currently no reliable test to learn if the blockage is complete. There is one test called a hysterosalpingogram (HSG) but when it is used, it can disturb the fresh scar tissue. It can reduce the effectiveness of QS.

CONTRACEPTIVE BACKUP METHODS

Another contraceptive method should be used starting the day of the first insertion and continuing for two months after the second insertion or third if needed. In other words, it should be used for a total of at least 12 weeks. This ensures that during the period when the plug of scar tissue is forming, the chances of pregnancy will remain low. If you have already been using a contraceptive method that you are comfortable with before you had your QS, you should keep using it for the required time

HOW EFFECTIVE IS THE QS METHOD?

QS is not as effective in the first year as surgical sterilization or as some temporary methods of such as an IUD, the Pill (when used correctly), Norplant® and Depo-Provera.

QS is more effective than some well known birth control methods such as condoms, the diaphragm or spermicides (used alone).

Early studies reported that 9 out of 100 women who had QS, became pregnant: 3 in year 1, 2 more in years 2 to 5, and 4 more in the next 5 years. Changes in the insertion procedure have improved effectiveness.

To see how the failure rate of QS compares with all methods of birth control during the first year of use, see Table 1. A failure means that the woman has become pregnant in spite of using a particular method. Failures continue to occasionally occur throughout a woman's reproductive years with QS because the body never stops striving to repair itself, just as we see in women who have been surgically sterilized. With surgery, about two women out of 100 will become pregnant in the first 10 years.

Table 1 *Typical Failure Rates for All Methods during the First Year of Use*

Oral Contraceptives	less than 5%
ParaGard® T 380A (IUD)	less than 1%
Diaphragm + Spermicide	18%
Vaginal Sponge	18% to 28%
Condom alone	12%
Periodic abstinence	20%
Norplant	less than 1%
Injections	less than 1%
Surgical Sterilization	less than 1%
QS	1% to 3%
No Method	85%

There is a chance of pregnancy. It is strongly recommended that women who are faced with post-QS pregnancy obtain an abortion as soon as arrangements can be made. If you are opposed to abortion for yourself, QS may not be a good choice for you. You should consider either surgical sterilization or temporary contraception methods. You should carefully consider what action you would be prepared to take in the event that you were to be faced with either of these circumstances before deciding on the QS method.

WHAT ARE THE PERMANENT STERILIZATION CHOICES?

SURGICAL STERILIZATION

The most common method is surgical sterilization.

QUINACRINE STERILIZATION

In over 100,000 sterilizations, no deaths have been reported, unlike surgical sterilization, "tying the tubes," which requires surgery. In industrialized countries, the death rate for surgical sterilization is one to two for 100,000 women. In less developed countries, the death rate for surgical sterilization can be as high as 20 per 100,000 women. QS also has fewer serious complications that require hospitalization than surgical sterilization. The QS rate is 0.03% compared to 1.7% for laparoscopic sterilization. The risks of complications with the surgical method are even greater for women with certain health problems such as respiratory disease, diabetes, and obesity, or if they have had abdominal or pelvic surgery.

It is also much less risky to have a QS than to become pregnant, carry a child to full term, and give birth.

OTHER

There are a few other experimental methods. The safety and the effectiveness of these methods are not yet established.

WHAT ARE THE RISKS AND DISCOMFORTS TO BE CONSIDERED?

Death

In over 100,000 Quinacrine sterilizations, no deaths have been reported.

Surgical sterilization (tying the tubes) requires surgery and anesthesia. In industrialized countries, the death rate for surgical sterilization is one to two for 100,000 women. In less developed countries, the death rate for surgical sterilization can be as high as 20 per 100,000 women.

It is also much less risky to have a QS than to become pregnant, carry a child to full term, and give birth.

Available data from numerous sources have been analyzed to estimate the risk of death associated with various methods of contraception. The estimates of risk of death include the combined risk of the contraceptive method plus the risk of pregnancy or abortion in the event of method failure.

Table 2 *Annual Number of Birth-Related or Method-Related Deaths Associated with Control of Fertility per 100,000 Non-sterile Women, by Fertility Control Method, According to Age.*

Age	15-19	20-24	25-29	30-34	35-39	40-44
Method of control and outcome						
No fertility control methods*	7.0	7.4	9.1	14.8	25.7	28.2
Oral contraceptives,, nonsmokers**	0.3	0.5	0.9	1.9	13.8	31.6
Oral contraceptives,, smokers**	2.2	3.4	6.6	13.5	51.1	117.2
IUD**	0.8	0.8	1.0	1.0	1.4	1.4
Condom*	1.1	1.6	0.7	0.2	0.3	0.4
Diaphragm/spermicide*	1.9	1.2	1.2	1.3	2.2	2.8
Periodic abstinence*	2.5	1.6	1.6	1.7	2.9	3.6
Surgical female sterilization**	2.0	2.0	2.0	2.0	2.0	2.0
Surgical male sterilization**	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0
QS**	**<1.0**	**<1.0**	**<1.0**	**<1.0**	**<1.0**	**<1.0**

* Deaths are birth related only
** Deaths are method related or birth relate

Potential for Regret

Some women regret getting sterilized. This regret is almost always due to changing circumstances, usually divorce or remarriage. QS is not reversible. Surgical sterilization is sometimes reversible. If you believe there is any chance that you may regret your decision, QS might not be your best option. Surgical sterilization or a temporary method would be more appropriate for you. Before agreeing to be sterilized you should be comfortable with your decision. Ask yourself these questions.

- Am I sure that I never want any more children?
- What action would I take if I found myself pregnant?
- Would temporary methods or a surgical sterilization be better for me?
- Is my family or a clinician or anyone else pressuring me to get sterilized?
- Why am I choosing QS?

Ectopic Pregnancy

An ectopic pregnancy is one in which the fertilized egg implants in the tube instead of the uterus. As the tube will not grow, this is extremely dangerous.

Were the tube blockage incomplete after QS and were an egg to be fertilized, the scar tissue in the tube would interfere with the trip to the uterus. The fertilized egg could then implant in the tube.

Although QS (and surgical sterilization) prevents many ectopic pregnancies, a greater percentage of the pregnancies that do occur are ectopic.

If you have ever had an ectopic pregnancy, you have an increased risk of having another one. You also have an increased risk of an ectopic pregnancy if you have ever had certain types of infections. These infections include pelvic inflammatory disease (PID) or any venereal disease (VD) or sexually transmitted disease (STD) caused by, for example, gonorrhea or chlamydia.

Ectopic pregnancy can cause death, so it is very important to know the symptoms!

They are:

- Vaginal Bleeding
- Lower abdominal pain
- A missed period
- Dizziness
- Weakness
- Fainting
- Shoulder pain

If you have any of these symptoms or suspect that you may be pregnant because of a missed period you must immediately contact your doctor or nurse and go to a hospital or clinic to find out if it is an ectopic pregnancy. Ectopic pregnancy may require surgery to save your life.

Serious problems requiring hospitalization

QS also has fewer serious complications that require hospitalization than surgical sterilization. The QS rate is 0.03% (3 per 10,000) compared to 1.7% (1.7 per 100) for laparoscopic sterilization. The risks of complications with the surgical method are even greater for women with certain health problems such as respiratory disease, diabetes, and obesity, or if they have had abdominal or pelvic surgery.

Birth Defects

In over 100,000 QS sterilizations, no birth defects have been reported in any infant exposed to quinacrine in early pregnancy -- that is, when a woman was not aware that she was pregnant at the time of quinacrine insertion or when she became pregnant in the weeks following quinacrine insertion.

Potential Risk of Cancer

QS researchers believe that if there is any risk of cancer with QS, that risk is very small. Quinacrine has been taken orally by more than 100 million people during its first 65 years of use, always in larger doses than for QS. There was never any mention that this drug might cause cancer because clinical experience did not indicate any link. No cancer clusters were ever reported in this vast human experience. One QS study in Chile that has followed 1500 women for 19 years, has found no increase in the risk of cancer.

Some studies done on microscopic organisms in a laboratory caused some concern. Quinacrine caused some cells to mutate. Many other drugs including tetracycline, acyclovir and metronidazole (Flagyl ®), can also cause some cells to mutate in laboratory tests. Some mutagens cause cancer. Others, such as coffee and grilled hamburger do not.

Severe Allergic Reaction to Quinacrine

Severe allergic reactions that could be life threatening are known to occur occasionally with every drug used by humans. Quinacrine is no exception.

Thus far, two severe allergic reactions with QS have been reported, or one per 50,000 cases. Both women had the allergic response within an hour of use and fully recovered within a few hours.

Uterine Perforation

Partial or total perforation through the wall of the uterus may occur as the quinacrine is put in the abdominal cavity. Perforation could result in abdominal adhesions (scars), severe pain, and loss of contraceptive protection. Perforation and its complications may require surgery and, in very rare cases, could possibly result in serious illness or death.

Side Effects

Side effects are those temporary and expected problems that accompany a treatment. Their severity ranges from almost nothing to severe, and they are not predictable.

Side effects in QS are common but they are usually minor, temporary and easily managed. It is extremely important that you know about these possible side effects before you decide to have the procedure, so you will know what to expect.

If any of these side effects bother you after QS is administered, you should contact your health care provider for treatment.

The following may occur during the insertion of the quinacrine and shortly afterwards.

- Pain, usually uterine cramps, low backache, headache, dizziness, vaginal itching or irritation and fever may occur at the time of insertion or shortly afterwards and may persist. If pain is severe, becomes worse, or persists, contact your clinician. Pain during sex is a rare side effect that disappears within a few months. Pain during urination is also rarely reported and disappears without treatment.
- Dizziness or fainting may occur at the time of insertion.
- A small amount of bleeding occurs following insertion in some women. If the amount of blood is more than 1 milliliter (a teaspoon), the insertion must be repeated in the next cycle as an additional insertion. Blood in the uterus interferes with the action of the quinacrine and will increase the risk of failure.
- Bleeding between menstrual periods may occur during the first two or three months after insertion. The first few menstrual periods after insertion may be heavier and longer than usual or they may be lighter and shorter. Some women will miss their period for as much as several months after the first insertion. If these conditions continue for longer than two or three months, consult your clinician.
- Occasionally, you may miss a menstrual period while using QS. It is important to determine if you are pregnant; report this immediately to your clinician.
- You will experience a bright yellow discharge from the vagina during the first 24 hours following insertion. The bright yellow color comes from the quinacrine itself. This side effect is harmless but will stain clothing and bedding, as quinacrine is also a dye.
- Abdominal adhesions (scar tissue)
- Backache
- Cervical infection
- Miscarriage

- Pelvic infection (PID), which may result in surgical removal of your reproductive organs, including hysterectomy
- Hematometra, accumulation of menstrual blood in the womb, an easily-treated condition

WHAT SHOULD YOU LET THE CLINICIAN KNOW?

The clinician needs the truth. You will be interviewed and a checklist will be used for all of these points.

Contraindications

There are 12 conditions that will prevent or delay your QS procedure. In some cases you can be treated for the condition and have the QS later.

- Pregnancy. You must be absolutely certain that you are not pregnant before QS can be performed. If there is any reason to suspect pregnancy, you will need a pregnancy test first.
- Infection - uterine or cervical
- Unexplained vaginal bleeding
- Tumor in the reproductive tract (fibroid, etc.)
- Severe uterine distortion (bicornate uterus, etc) that will not allow proper placement of the pellets
- Active pelvic inflammatory disease (PID)
- Psoriasis. Quinacrine may cause a severe attack of psoriasis
- Porphyria. Quinacrine may cause this condition to worsen
- Glucose-6-phosphate dehydrogenase (G6PD) deficiency
- Use of alcohol or alcohol-containing medications within 24 hours before the procedure and 24 hours after
- Use of primaquine
- Use of hepatotoxic (liver damaging) drugs

Information

There are many other conditions that the clinician should know about in order to better understand your health.

- Heart disease
- Heart murmur
- Hepatitis or severe liver disease
- Diabetes
- Leukemia
- Fainting spells
- Steroid therapy
  Anemia or blood clotting problems
- Current suspected or possible pregnancy
- Ectopic pregnancy (pregnancy outside of the uterus)
- Recent pregnancy
- Abnormalities of the uterus
- Bleeding between periods
- Cancer of the uterus (womb) or cervix
- Suspicious or abnormal Pap smear
- IUD in place now
- Heavy menstrual flow
- Severe menstrual cramps
- Multiple sexual partners
- A sexual partner who has multiple sexual partners, or is at high risk for acquiring HIV
- Pelvic infection (including pus in Fallopian tubes)
- Infection of the uterus (womb) or cervix
- Genital sores or lesions
- Sexually transmitted disease (venereal disease), such as herpes, gonorrhea,

chlamydia, or acquired immune deficiency syndrome (AIDS)

- Unexplained genital bleeding
- Uterine or pelvic surgery
- Vaginal discharge or infection
- I.V. drug abuse
- Alcoholism

A COMPARISON OF THE ADVANTAGES AND DISADVANTAGES

This is a list made up by someone else. You may have your own considerations to add to this list.

Advantages

- Less risky than surgical sterilization. No deaths or life-threatening complications have been reported in over 100,000 cases. With surgery, one to two deaths per 100,000 procedures have been recorded. No surgery means less risk of infection, injury and death.
- QS is an outpatient procedure. No hospitalization is needed. Usually you can leave the clinic or office in about an hour after the pellets are inserted.
- No general anesthetic.
- Less pain than with surgery.
- Recovery is faster.
- Many types of trained health care practitioners, not just doctors, can provide this method.
- It is the least expensive contraceptive method.
- It is permanent after the insertions are complete.
- There is no visible scar.
- It does not change the user's sex drive or interfere with her ability to feel sexual pleasure.
- No ongoing use of hormones is required.

Disadvantages

- It is not reversible, which means that a woman cannot expect or hope to undergo another procedure that would make her fertile again.
- Nearly half of all women having this procedure complain of a side effect. The most common are lower abdominal pain, headache, dizziness and backache. Sometimes users experience mild fever or vaginal itching. These symptoms usually stop a few hours or days after the treatment. Also, menstrual periods may be irregular for a few months after quinacrine sterilization.
- Some patients report a yellow vaginal discharge for up to 24 hours. This is not a sign of infection. It is due to the yellow color of the quinacrine, which is a brilliant yellow dye. It will stain clothing and bedding. Feminine protection should be used to prevent this staining.
- Quinacrine sterilization is still new at least in the United States; there may be risks that are not yet known. Only one study has tried to establish long term risks. For up to 19 years, it followed 1500 women who had had QS. No long term risks have been identified. But no definitive conclusions can be drawn from this research, which found no increased risk of cancer among quinacrine pellet method users. A final answer to whether QS increases the risk of cancer can only come after a study of 30 to 40 years on many more women.
- Life-threatening complications of QS are very rare. However, this does not mean that you will not experience a life-threatening complication. In such a case, it is possible that you would have to undergo major surgery for some

unforeseen reason, which could place you at risk of death.

- QS requires 2 and possibly 3 insertions one month apart.
- The failure (pregnancy) rate has been variously reported between 1% to 3% in the first year.
- You may become pregnant in a tube (ectopic pregnancy). This condition has also been reported for women who are using no contraceptive method, or using temporary methods, and in those women who have been sterilized surgically or with the quinacrine method.
- Does not protect against AIDS or other sexually transmitted diseases.

WARNINGS

Call your clinician immediately for any of the following reasons:

- A missed period. You may be pregnant.
- Unexplained or abnormal vaginal bleeding or discharge. This could indicate a serious complication, such as an infection or ectopic pregnancy.
- A delayed period followed by scanty or irregular bleeding. You may have an ectopic pregnancy.
- Pelvic or lower abdominal pain or cramps or unexplained fever. An ectopic pregnancy or infection may have developed, requiring immediate treatment.
- Exposure to venereal disease (VD) also called sexually transmitted disease (STD).
- *QS does not prevent venereal disease.* If exposure to venereal disease is suspected, call for examination and prompt treatment. Failure to do so could result in serious pelvic infection. **QS does not protect against diseases transmitted sexually such as HIV (AIDS), chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B and syphilis.**
- If your relationship ceases to be mutually monogamous or if your partner becomes HIV positive or gets a sexually transmitted disease, you should report this change to your clinician immediately. It is advisable to use a condom as a partial protection against STDs.
- Genital sores or lesions, or fever with vaginal discharge. You may have an infection.
- Severe or prolonged menstrual bleeding.

Glossary

Adhesions – Scarring within a body cavity or between organs in the abdominal cavity

Cervicitis – Infection of the cervix.

Cervix – Lower portion of the uterus visible in the vagina

Contraceptive – Means of preventing conception

Ectopic or tubal pregnancy – Pregnancy outside of the uterus

Endometrium – Lining of the uterus. The endometrium is shed every month and expelled during the menstrual period.

Fallopian tubes – Tubes through which the egg passes from the ovary to the uterus

Fertilization – The process of the sperm penetrating the egg of the female

Genital – Referring to organs concerned with reproduction

Giardiasis – An intestinal infection caused by a protozoan parasite

HIV – Human Immunodeficiency virus that causes AIDS

Infection – Invasion of the body by microscopic (tiny) organisms, such as bacteria. Can cause illness.

Intermenstrual Bleeding – Bleeding between periods

Intrauterine – Within the uterus

Menstruation – A woman's monthly period.

Monogamous – Practicing sexual relations with only one partner

Mutagenic – The ability to cause genes to mutate (change)

Off-label use – When a doctor prescribes a drug for a treatment that is not indicated on the drug's package insert (or label). Any drug that is FDA approved can legally be used in this way. Approximately 60% of all prescriptions are for off-label uses

Ovary – Almond-shaped organ. One ovary is located on each side of the uterus. Produces and releases human eggs

Ovulation – Release of an egg by the ovary

Porphyria – A metabolic disorder

QS (Quinacrine pellet method for non-surgical female sterilization) – Name for the quinacrine sterilization procedure

Quinacrine (Atabrine) – A synthetic anti-protozoal drug. Originally used to treat malaria. When placed in the uterus, it can prevent pregnancy by scarring the Fallopian tubes

STD – Sexually transmitted disease - also called VD or venereal disease

Spermicide – Chemical that kills male reproductive cells (sperm)

Uterine Perforation – A tear, hole or puncture of the uterus

Uterus (womb) – Pear-shaped organ located deep in the pelvis that contains and nourishes a fetus during pregnancy

CONSENT TO HAVE QUINACRINE STERILIZATION

You have come to this clinic seeking information about permanent methods of contraception. You were given information about temporary methods of birth control and two methods of permanent sterilization: surgical and QS. You have had time to read and view the information. You read or viewed:

_____ QS brochure _____ QS video

_____ QS information sheet _____

There are some basic points you must understand before agreeing:

- Being sterilized is an irreversible choice. If you have any hesitation about wanting children at all you should not do this.
- It is not 100% effective. A pregnancy could be dangerous and you would be advised to have an abortion. If you are opposed to abortion, now is the time to think about this.
- Being sterilized does not protect you from sexually transmitted diseases, including Acquired Immune Deficiency Disease (AIDS), gonorrhea, chlamydia, syphilis and others.
- The FDA has not approved this use of quinacrine for female sterilization. It is however, a legal use of the drug.
- There is no money available from any source, including from the doctors or the clinic, to cover the cost of treating any complications or for any additional costs from the quinacrine sterilization method.
- There is no penalty for saying no at this point. You will still be treated in this clinic and receive its services.

You may sign this form only if the following points totally true.

- No one has forced or pressured me to undergo this procedure. I am making this choice freely.
- I feel comfortable that the information I have at this point about the risks, benefits and alternatives is sufficient for me to choose this method.
- I have had the opportunity to ask questions and all of my questions have been answered to my satisfaction.
- I have answered all of the clinician's questions truthfully, and as completely, and accurately as I can.

After reading the material checked above or viewing the video I, choose to be permanently sterilized by the quinacrine sterilization method.

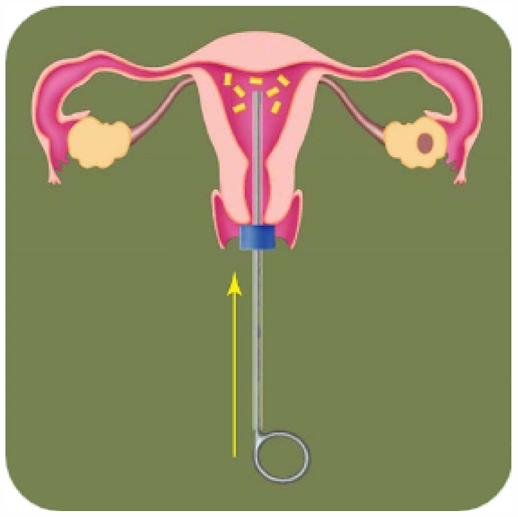
	Signature	Printed Name	Date
Patient	_____	_____	_____
Witness 1	_____	_____	_____
Witness 2	_____	_____	_____

Why QS?

As a woman or family who wish to have no more children, you are looking for a safe, reliable, permanent contraception. The QS procedure does not require surgery or hospitalization, is performed on an outpatient basis in a doctor's office or clinic, and allows you to commence your normal duties immediately. . .

more

How QS Works



A healthcare provider (doctor, nurse or midwife) places seven small pellets of quinacrine up through the vagina and into the uterus with an inserter, immediately following the woman's monthly period and then again one month later. . .

more

Papers

Invented in Santiago, Chile in 1977, QS has undergone rigorous scientific study, producing scores of peer-reviewed articles attesting to its safety and efficacy. In clinical trials globally, more than 200,000 women in 50 countries have chosen QS as their method of permanent contraception, with no serious side effects. . .

more

About ISAF

ISAF

QS

Permanent Contraception for Women

Our Mission is to encourage and work for women's reproductive health, rights and empowerment, both domestically and internationally, through research, education, and facilitating the global availability of safe, inexpensive, non-coercive family planning methods. . .

more

ISAF Introduces QS 2016

QS video

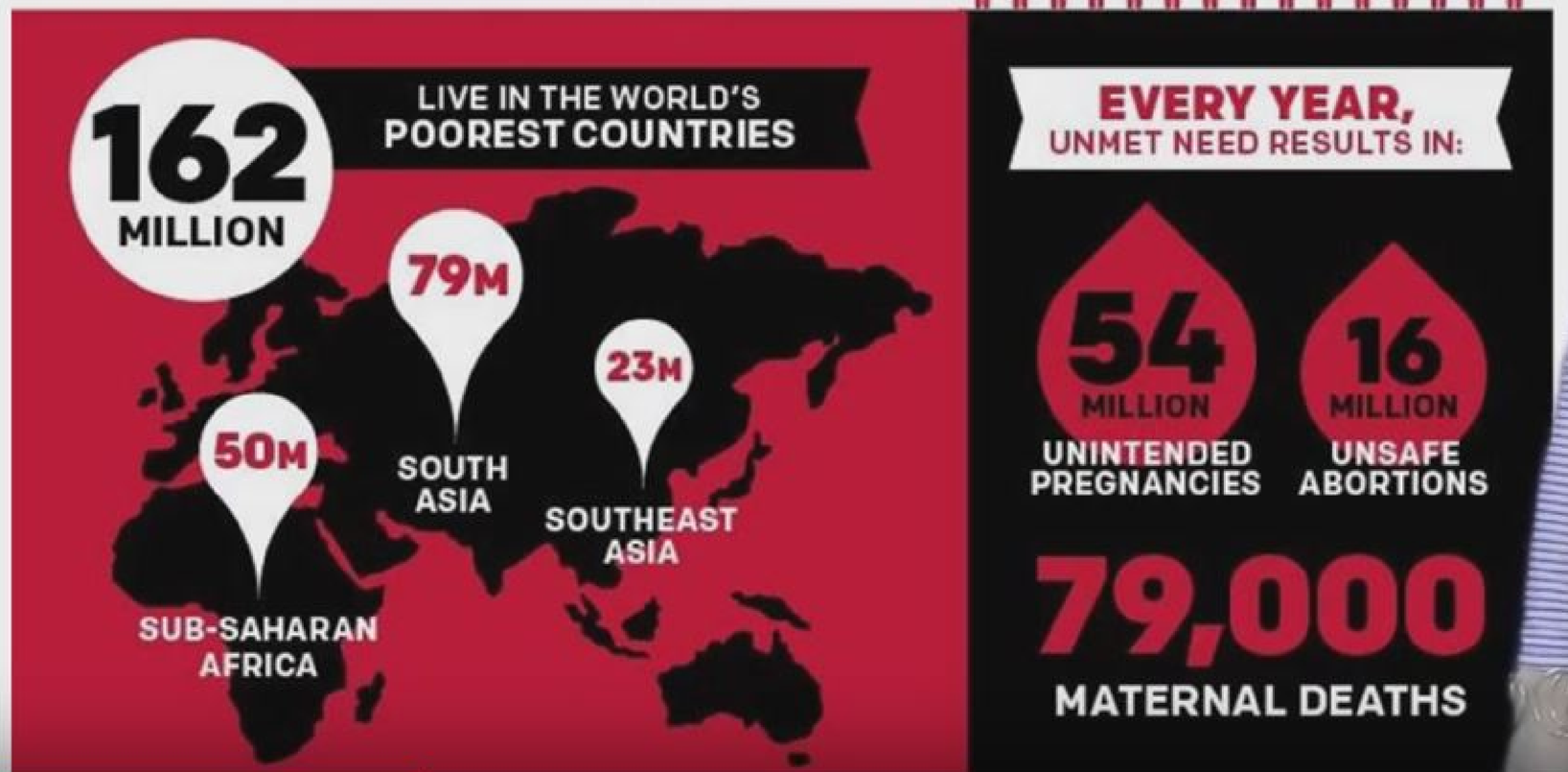
IN THE DEVELOPING WORLD,

222 MILLION WOMEN

WHO WANT TO PLAN THEIR FAMILIES AND THEIR LIVES
HAVE UNMET NEED FOR MODERN CONTRACEPTION.

Sources: Guttmacher Institute & UNFPA

UNMET NEED IS GREATEST AMONG WOMEN UNDER 20



EVERY YEAR,
UNMET NEED RESULTS IN:

54 MILLION UNINTENDED PREGNANCIES

16 MILLION UNSAFE ABORTIONS

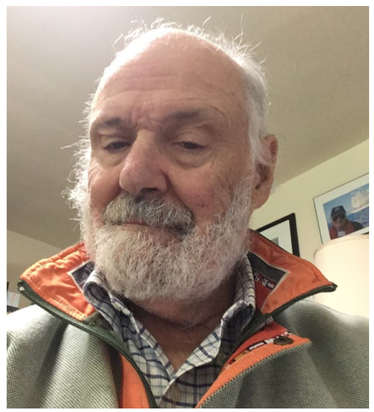
79,000 MATERNAL DEATHS

0:17 / 1:29

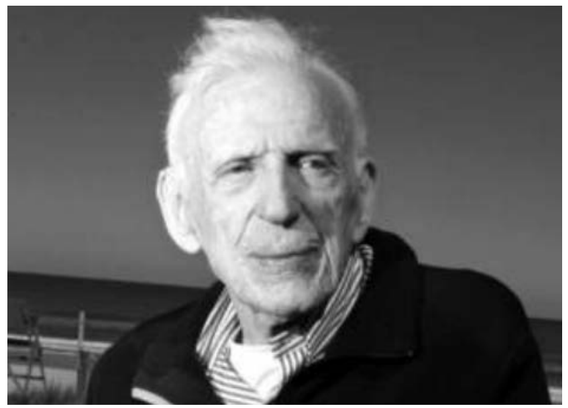
ISAF MANAGEMENT TEAM WITH OVER 200 YEARS OF EXPERIENCE HELPING WOMEN

Mumford
(CEO)

Epstein
(Secretary)



Collins, Sr.
(Founder & Treasurer)



Dr. Lippes
(Medical Advisory Committee Chair)

Collins, Jr.
(President)

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QS
Permanent Contraception for Women ®

WE ONLY HAVE ONE PLANET