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Quinacrine Sterilization (QS): Informed Consent[1]

Informed Consent Working Group

Abstract

Informed consent is a basic human right for any medical procedure. It is particularly important that women know what is involved in any sterilization method, and how it will affect their health and their emotional life. Over 140,000 QS procedures have been performed in 34 countries. In no country has there been any formal effort to advance the acceptance of this method. Instead, satisfied users have been the promoters. Thoroughly informed consent is vital to patient satisfaction. A working group undertook an initiative to create an ideal consent form. The product of that initiative is presented.

Keywords: Quinacrine sterilization, female sterilization, non-surgical sterilization

1. Introduction

An informed consent is a fundamental human right for any medical procedure. It is critical for an elective procedure, particularly a permanent one like sterilization. Detailed knowledge of every aspect of a method on which a woman bases her decision is essential to her ultimate peace of mind.

Quinacrine sterilization (QS) providers have an additional reason to be deeply concerned, because success of their program depends on patient satisfaction. More than 140,000 women in 34 countries have chosen QS. Nowhere have practitioners made a formal effort to advance its acceptance. Instead, contented users themselves have been the promoters of this method. Thoroughly informed consent is vital to patient satisfaction. These women have been happy with the service they received and the results of their QS procedure. They recommend it to others because of their own experience.

One of the lessons learned in family planning over the past 40 years is that women who find fault with a contraceptive method can seriously undermine its acceptance, especially in regard to sterilization, because of its permanence. We have learned that incentives for sterilization usually lead to an increasing number of women (or men) in the population who are unhappy to have elected such a procedure. They have been tempted into choosing sterilization, before they were ready for it, by the incentive payment. They then become increasingly regretful of their decision, which had been made prematurely. They often complain bitterly about their sterilization and attribute any number of maladies to it. In their misery, they concoct rumors, which they spread abroad. Eventually, they go out of their way to discourage others from seeking sterilization.

The same applies to women who have second thoughts about their sterilizations because they lacked a

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[1] Note to Readers: This questionnaire had more than 30 authors. It is the product of an initiative to create the best possible consent form for quinacrine sterilization (QS). From the beginning, the goal of the designers of this document has been to do our best to insure that women are so well informed about the procedure and its sequelae that they will be content with their decision whether or not to undergo QS. One contributor to developing this consent form was the late Dr. Michael Burnhill, Vice President for Medical Affairs, Planned Parenthood Federation of America. He played a key role in advancing the acceptance of QS in the United States and bringing this method to American women and consequently to women everywhere. This article is dedicated to Dr. Burnhill.

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complete understanding of the procedure and the risks. You can count on them to frustrate your efforts to offer a QS program. The most effective way to minimize this trend is to insure that your patients are well informed. These satisfied QS users not only present the method in a positive way to others who may then seek it, but they also constitute a pool of accurate first-hand QS information in the community.

Well-informed women are more apt to comply with the protocol. They are more likely to use the necessary alternative contraception for 3 months following the first insertion and return to the clinic for a second one, without a pregnancy intervening between the first and second quinacrine insertion. Thus, failure of the QS procedure will be reduced. In the long run, program success depends on thorough informed consent. The more people who have reliable facts about the method, the greater the demand will be for QS services. Experience with QS in country after country has shown that satisfied QS users are sufficient for program success. No other promotion is needed.

Toward this end, a working group of more than 30 people undertook an initiative to create an ideal consent form. The product of that initiative follows. We realize that local conditions may necessitate alterations in the ideal informed consent procedure but every effort should be made to maximize understanding of the QS procedures. To facilitate alterations, this document is available in an electronic form and can be easily modified to meet local needs.

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 was first introduced in the 1930s to be taken by mouth to prevent and treat malaria. Since then, doctors all over the world have prescribed it for millions of people to treat and prevent malaria. It is also used to treat 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 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 to prevent malaria, 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 sometimes fail and you could become pregnant.

Permanent sterilization results when pellets of quinacrine are put into the uterus (womb). The pellets dissolve and some of the liquid makes its 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 about 1 month apart of 252 milligrams of quinacrine to be inserted into the uterus.

WHAT IS THE HISTORY OF QS?

The QS method was first developed in Chile in 1977. Since then, over 130,000 women in 34 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. For example, treating lupus with quinacrine is 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. Some women 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. Occasionally, some patients feel nauseated, weak or faint. After the inserter is removed from the cervical opening, the tenaculum and speculum will then be 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 one or two days after insertion you will likely have a discharge that is yellow or green and itching may follow. Itching can be prevented by douching as soon as you see the yellow discharge.

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

If you have any event that worries you, you should feel free to call us.

REPEAT OF PROCEDURES

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

Occasionally, for special reasons 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), an x-ray with instillation of a dye under pressure, but when it is used, 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 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 2%
No Method	85%

WHAT ARE THE PERMANENT STERILIZATION CHOICES?

SURGICAL STERILIZATION

The most common method is surgical sterilization. In terms of safety, quinacrine sterilization is safer.

QUINACRINE STERILIZATION

In over 130,000 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 three to ten per 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 130,000 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 3 to 10 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 related

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. If you believe there is any chance that you may regret your decision, QS might not be your best option. 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 or on the ovary instead of the uterus. As the tube will not grow, this is extremely dangerous.

Ectopic pregnancies also occur in women who have not been sterilized. Although QS (and surgical sterilization) prevents many ectopic pregnancies, a greater percentage of the pregnancies that do occur after sterilization failure 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. Ectopic pregnancies are also treated medically.

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 130,000 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.

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

Uterine perforation occurs once every 1000 to 1500 cases. 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. No deaths have ever been reported with QS. Nor has any QS complication ever required abdominal surgery in over 130,000 documented cases.

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 4 milliliters (about a teaspoon), the insertion may need to be repeated in the next cycle as an additional insertion.
- 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. This may cause itching which is relieved or prevented by douching.
- 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 130,000 cases. With surgery, 3 to 10 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 – 1/10th the cost of surgical sterilization.
- 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. Douching helps.
- 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. There was no increase in the incidence of cancer. No long term risks have been identified.
- 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 2% at the 2-year mark.
- 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

G6PD – Glucose 6 phosphate dehydrogenase. A metabolic disorder in which quinacrine is contraindicated

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 may 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 resulting 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 drop out of this program at any time and dropping out will not affect your receiving medical care now or in the future.

You may sign this form only if the following points are 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	_____	_____	_____