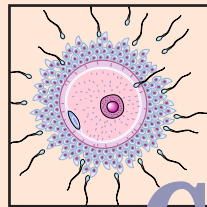
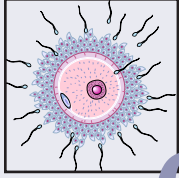


KAISER PERMANENTE®



THE ART OF
CONCEPTION
INFERTILITY SERVICES



THE ART OF CONCEPTION

INFERTILITY SERVICES

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DISCLAIMER

This guideline is not intended to establish a protocol for all patients with a particular condition. While the guidelines provide one approach to evaluating a problem, clinical conditions may vary significantly from individual to individual. Therefore, the clinician and patient must exercise independent judgment and make decisions based upon the situation presented.

While great care has been taken to assure the accuracy of the information presented, the reader is advised that The Permanente Medical Group cannot be responsible for continued currency of the information, for any errors or omissions in these guidelines, or for any consequences arising from their use.

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WELCOME TO THE INFERTILITY SERVICES AT KAISER PERMANENTE.

If you have been trying to conceive and, unfortunately, have not been able to, you are not alone. One out of six couples experience infertility problems at some time in their lives.

At Kaiser Permanente, we realize that coping with infertility can be a trying and frustrating experience. In order to provide high quality personalized care to our patients, we offer a team approach that includes physicians, nurse practitioners, nurses, medical assistants, and the receptionist. We strive to offer you the respect and quality of care that you deserve in order to reach your goal.

WHAT IS INFERTILITY?

Couples are considered to be infertile if they have not been able to conceive after 12 months of having sexual intercourse without using any form of birth control. If you are 35 or older, six months is considered the appropriate time to begin to consider that you might have a fertility problem.

WHO IS ELIGIBLE FOR SERVICES?

Kaiser Permanente members who meet the previous definition of infertility and do not smoke.

WHAT ARE THE INFERTILITY SERVICES AVAILABLE FOR KAISER PERMANENTE MEMBERS?

- ◆ Basic education and literature about fertility issues offered in the fertility group appointment
- ◆ Timed blood tests and semen analysis
- ◆ Pre-pregnancy screening tests
- ◆ Initial consultation with an Ob/Gyn physician or nurse practitioner. Through a review of the basic tests, semen analysis, and your history, this consultation will clarify if you have an infertility problem.

When indicated, treatment options can also include:

- ◆ Medications
- ◆ Inseminations
- ◆ Surgeries

All members should check with their local Health Plan Office and employer's benefits office to verify their infertility services, In Vitro Fertilization (IVF), and drug coverage.

Kaiser Permanente In Vitro Fertilization (IVF) program offers IVF and related services. For most members, IVF is not a covered benefit.

WHAT QUESTIONS SHOULD A KAISER PERMANENTE MEMBER ASK?

"HOW DO WE GET STARTED?"

First, a woman should have a routine gynecological exam. The next step is to attend a fertility group appointment, preferably with her partner.

Information and routine lab tests, semen analysis and questionnaires will be provided at that time. Depending on your individual medical history, certain steps should be completed before the initial fertility consultation with a physician or nurse practitioner. Previous infertility records should also be available at the consultation visit.

"ARE THERE INFERTILITY SUPPORT SERVICES?"

Individual and couple counseling is available through Kaiser Permanente. Infertility support groups may be available locally or through RESOLVE, Inc (The National Infertility Association, telephone 617.623.0744 or <http://www.resolve.org>). Additional information on the biology of reproduction, infertility, as well as nutrition and exercise, can be found in the *Kaiser Permanente Healthwise Handbook* and at the Kaiser Permanente Web site, www.kp.org.





OVERVIEW: THE BIOLOGY OF REPRODUCTION

FEMALE REPRODUCTIVE ANATOMY

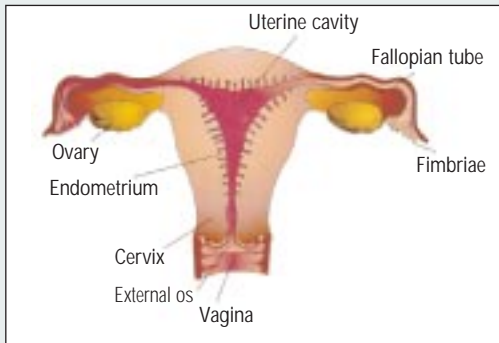


Figure from *Before We Are Born: Essentials of Embryology and Birth Defects, 5th Edition*, by Moore, Keith L. and Persaud, T.V.N. ©1998. Reprinted with permission of W.B. Saunders Company.

Eggs develop and are stored and matured in the *ovaries*. The *fallopian tubes* carry the eggs that are released from the ovaries during ovulation to the uterus. Fertilization of an egg by a sperm usually occurs in the fallopian tube. If an egg is fertilized, it will develop into a fetus in the *uterus*. The uterus has a specialized lining called the *endometrium* that allows an embryo to implant into the wall providing the developing baby with nutrients and support.

MENSTRUAL CYCLE AND OVULATION

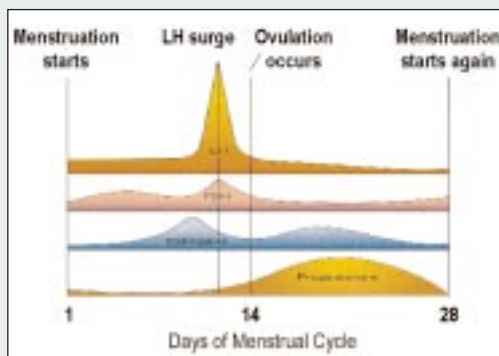


Figure from *Before We Are Born: Essentials of Embryology and Birth Defects, 5th Edition*, by Moore, Keith L. and Persaud, T.V.N. ©1998. Reprinted with permission of W.B. Saunders Company.

The entire menstrual cycle is controlled by the brain in concert with the ovaries. There are five main hormones involved in reproduction. *Follicle stimulating hormone* (FSH), *luteinizing hormone*

(LH), and *prolactin* are produced by the pituitary gland in the brain. FSH stimulates the growth of the egg within the ovary, while LH stimulates ovulation or the release of the egg. *Estrogen* and *progesterone* are produced in the ovary and help prepare the lining of the uterus so it will accept a fertilized egg.

The menstrual cycle is measured in days, starting with Day ONE as the first day of the menstrual period. Ovulation usually occurs at approximately Day 14. If the released egg is not fertilized, the lining of the uterus (the endometrium) is sloughed off as the menstrual period. Although a 28 day cycle is shown in the picture above, most women's cycles vary in length.

MALE REPRODUCTIVE ANATOMY

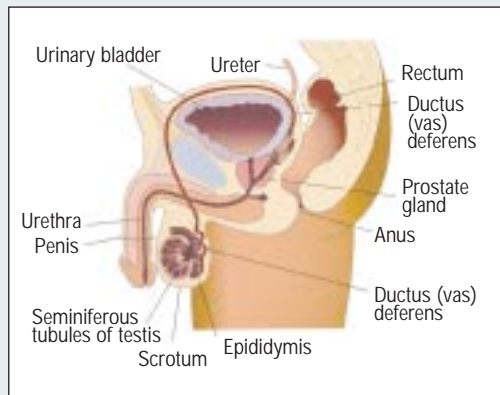


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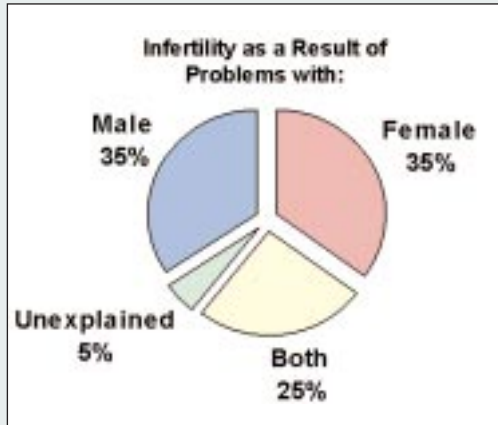
Millions of *sperm* are produced every day in the *testes*. It takes approximately 2 months for sperm to develop and mature. The *vas deferens* carry the sperm from the testicles to the urethra where the *seminal vesicles* and *prostate gland* add fluid to form semen. Semen moves out of the body through the *urethra* in the *penis*. Although approximately 40 million sperm are released at ejaculation, sperm are very small and most of the semen consists of fluid that provides nutrients and enzymes to nourish the sperm.



OVERVIEW: SOME CAUSES OF INFERTILITY

MEN OR WOMEN?

Infertility problems are associated equally with both men and women.



MALE FACTORS

Men are most likely to have a problem with their sperm (volume, count, shape, movement). Sometimes infertility can also be due to problems with testicles, prostate, varicocele (large vein), illness, medications, or hormones.

FEMALE FACTORS

Infertility can be caused by egg quality, ovulation factors, cervical factors, tubal factors, pelvic factors, or even weight. Both hormone functioning and reproductive anatomy must be “normal” for fertilization and fetal growth to occur.

EGG QUALITY

Egg quality refers to both the ability of an egg to become successfully fertilized and also the ability of that fertilized egg to develop into a healthy baby. Egg quality is most closely associated with age.

WHY IS IT HARDER TO GET PREGNANT AS WE GET OLDER?

Females are born with a certain number of eggs. As a woman ages, the number of eggs, as well as the quality of the eggs, declines. As a result, a woman over 35 years old has a lower chance of getting pregnant and a much higher chance of having a

miscarriage or a baby with congenital problems (such as Down’s syndrome) than a younger woman does.

HOW CAN I TELL IF MY EGGS ARE A PROBLEM?

Age alone is a strong predictor of successful pregnancy. There are also blood tests that can help your doctor/nurse practitioner determine the level of your fertility. Two blood tests that are commonly done are called FSH and Estradiol. If the results of these blood tests are high, your chances of becoming pregnant and having a baby are decreased.

Although your blood test results may change from month to month, the highest FSH and Estradiol results are used to predict your chances of success.

If your blood test results are normal, your doctor may order a Clomiphene Citrate Challenge Test (CCCT), that will involve drawing a blood sample before and after you take a fertility drug called Clomid®. These blood tests will help your doctor tell if your ovaries are working properly. A poor result generally predicts a decreased chance of conceiving and successfully maintaining a pregnancy.

Unfortunately, if blood tests indicate a diminished chance of conceiving, there are no drugs or treatment to help your own eggs. However, your doctor may prescribe fertility drugs if your test results are good. If you respond well to these drugs and/or if you are over age 38, your doctor may suggest moving quickly to an advanced fertility treatment called In Vitro Fertilization (IVF).

WHEN SHOULD I WORRY?

If a female is younger than 35 and has not become pregnant after trying for one year, or if she is 35 years or older and has not become pregnant after trying for six months, she should call her doctor/nurse practitioner. An infertility care provider will then start testing for infertility.



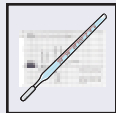
WHAT CAN I DO TO INCREASE MY CHANCES OF BECOMING PREGNANT?

WHAT SHOULD WE DO NOW?

Couples who are trying to conceive should be in good health, eating a well-balanced diet, engaging in moderate exercise and avoiding cigarette smoke, recreational drugs, and excessive alcohol consumption. *It is recommended that women take 400 mcg of folic acid daily while trying to conceive.*

HOW OFTEN SHOULD WE HAVE INTERCOURSE?

You should try to have intercourse every other day during the woman's fertile interval, near ovulation. Most, but not all women ovulate on or near day 14 of their menstrual cycle. (Remember: Day one of the cycle is the first day of a period.) Both Basal Body Temperature Charts and urine Ovulation Predictor Kits can help you determine when the woman is most fertile. It is best to have intercourse every other day instead of every day during this time in order to increase your chances of conceiving.



YOU CAN USE A BASAL BODY TEMPERATURE CHART

WHAT IS THE BASAL BODY TEMPERATURE?

The Basal Body Temperature (BBT) indicates your body's temperature while at rest. Hormone changes during a woman's menstrual cycle have an effect on her body temperature.

WHAT IS A BASAL BODY TEMPERATURE CHART?

The BBT is a record of your body's temperature before you get up in the morning. Your body's temperature is usually lowest in the morning when you have been at rest. It rises during the day because of your physical activity.

A woman's basal body temperature increases during ovulation. Therefore, BBT chart is a simple method that suggests whether or not she may be ovulating (releasing an egg). It will help you learn when your fertile times are.

HOW DO I USE THE BBT CHART?

Keep your thermometer at your bedside and shake it down the night before you use it. Put the

thermometer under your tongue for five minutes every morning before you get out of bed. Record the number on the chart. It is easiest to use a special thermometer called a basal thermometer because it covers a much smaller range of temperature than regular thermometers and is a lot easier to read. You can find a basal thermometer in most drugstores.

Other helpful information such as intercourse, factors which might affect the temperature (i.e., taking the temperature earlier or later than usual, or illness) and other signs such as increased vaginal mucus or sharp ovarian pain should also be recorded on the charts.

Please bring your Basal Body Temperature chart with you to each office visit for review.

YOU CAN USE AN OVULATION PREDICTION KIT

WHAT IS AN OVULATION PREDICTION KIT?

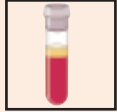
Ovulation prediction kits are easy-to-use test kits that you can buy without a prescription to help determine when a woman is about to ovulate.

About 12 to 14 days before a menstrual period, the brain releases its supply of luteinizing hormone (LH). This is called the LH surge and can be detected in your urine. The LH surge happens about 1 to 1½ days before an egg is released and triggers the egg's release from the ovary. You are fertile around the time the egg is released. Generally, you should have intercourse the day of, and the day following, the color change of the predictor kit.

Names of kits include: OvuQuick, Conceive, Q Test, Clearplan Easy, Assure, and EZ-LH.

HOW DO I USE THE OVULATION PREDICTION KIT?

Be sure to carefully follow the directions from the kit you are using. It is best to test your urine in the morning after you have already urinated one time. You should begin testing on the 10th day of your menstrual cycle unless your doctor/nurse practitioner tells you to start on a different day.



IF I DON'T BECOME PREGNANT AFTER TAKING THESE FIRST STEPS, WHAT TESTS WILL DETERMINE THE CAUSE OF MY INFERTILITY?

There are four main questions that will be evaluated by your physician or nurse practitioner. These include:

- ◆ Are there enough moving, normally shaped sperm?
- ◆ Is ovulation occurring? If so, how often?
- ◆ Is anatomy normal? Can the egg and sperm meet?
- ◆ What are the quality of the eggs? What is the role of age?

FEMALE TESTS : BLOOD TESTS FOLLICLE STIMULATING HORMONE (FSH) & ESTRADIOL

WHAT IS FSH?

FSH is a brain hormone that stimulates the development of the follicle (egg) in the ovary.

HOW IS FSH MEASURED?

Your FSH level is measured by taking a blood test on day two or three of your menstrual cycle (day one is the first day of your period).

WHAT DO THE TEST RESULTS MEAN?

FSH levels measure ovarian reserve, or how well the ovary is working. A low FSH means the ovary is working well. An elevated FSH (greater than 10) is an early chemical indication of decreased fertility.

Your doctor/nurse practitioner will receive the results of your FSH test and will determine if you fall into the normal, borderline, or abnormal (decreased fertility) range.

- ◆ **Normal:** A FSH of 10 or less (in our regional laboratory) indicates that pregnancy is possible. However, it does not guarantee that you will become pregnant, nor does it predict how well you may respond to fertility medication.

- ◆ **Borderline:** A borderline FSH of 11-13 suggests that you have declining egg quality or ovarian reserve. A borderline FSH indicates that your chances are low with or without treatment.

- ◆ **Abnormal:** An abnormal FSH (14 or higher) indicates poor egg quality. The chance for a successful pregnancy (using the woman's own egg) and a live birth is rare. If you have an abnormal FSH, your provider can counsel you about alternative ways to become a parent. FSH levels can vary from cycle to cycle. It is the highest FSH level that predicts egg quality. Any one FSH level that is abnormal predicts a poor response to fertility medications and a decreased ovarian reserve.

WHAT IS ESTRADIOL?

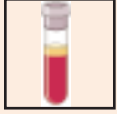
Estradiol is made by the egg follicles as they grow in the ovary. Estradiol, in addition to progesterone, prepares the uterine lining to receive the fertilized egg.

WHEN IS THE ESTRADIOL TEST DONE?

The blood test to measure estradiol is taken at the same time as your FSH level (on day two or three of your menstrual cycle).

A low estradiol level indicates that pregnancy is possible.

A high estradiol level (greater than 80) shows that egg quality (ovarian reserve) is poor and a successful pregnancy is unlikely.



PROGESTERONE BLOOD TEST

WHAT IS PROGESTERONE?

Progesterone is the hormone made in the ovary after ovulation and is responsible for maintaining the lining of the uterus. This is important because the fertilized egg must attach to the lining in order to grow. Progesterone also causes the small rise in body temperature that happens after ovulation. This is the rise in temperature that you measure if you are checking your basal body temperature.

HOW IS PROGESTERONE MEASURED?

Progesterone is measured by taking a blood test, during the second part of your menstrual cycle, usually a week following ovulation (around day 21, day 22, or day 23). If ovulation has occurred, your doctor/nurse practitioner will see a rise in your progesterone level.

PROLACTIN & HYPERPROLACTINEMIA

WHAT IS PROLACTIN?

Prolactin is a hormone made in the pituitary gland, in the brain. It is a hormone that stimulates milk production in women. Small amounts of prolactin normally circulate in the blood of non-pregnant, non-lactating (nursing) women.

WHY DO WE TEST FOR PROLACTIN?

Too much prolactin (hyperprolactinemia) can cause you to have irregular periods, trouble ovulating and/or getting pregnant and can cause non-pregnant women to have a milky secretion from their breasts.

HOW DO WE TEST FOR PROLACTIN?

A blood test to measure your prolactin level is taken in the middle of the morning, several hours after you eat. If your initial test is high, you may be asked to repeat the test. Sexual intercourse and breast stimulation should be avoided the day before prolactin testing.

WHAT CAUSES A HIGH PROLACTIN?

In some cases, high prolactin is caused by low levels of thyroid hormone (hypothyroidism), by some types of surgeries or by a small, benign (non-cancerous) growth in the pituitary gland (prolactin-secreting adenoma).

IF PROLACTIN IS HIGH, HOW IS IT TREATED?

First, the cause of the high prolactin level must be identified. You may be asked to take more blood tests and to get a special x-ray, called an MRI, of the pituitary gland to try to determine the exact cause. In most cases there is simple oral medicine that can be taken to reduce prolactin. Once prolactin levels are in the normal range, menstrual periods will usually become more regular and egg release (ovulation) will become more normal.

FASTING BLOOD SUGAR

Fasting blood sugar is a common laboratory test that measures the level of your blood sugar after you have not eaten for at least eight hours. It is used to determine if you have diabetes mellitus.

WHAT IS DIABETES MELLITUS (DM)?

DM is a condition in which the pancreas is unable to manufacture enough insulin. Insulin transports sugar from the blood stream into the tissues. Low insulin results in high blood sugar, which can cause serious symptoms.

WHY DO WE TEST FOR DM?

DM can affect your ability to conceive and maintain a healthy pregnancy.

HOW CAN HIGH BLOOD SUGAR BE TREATED?

In some cases, it can be controlled by a specific diet alone. However, it is sometimes necessary to use insulin injections to control blood sugar levels.

RUBELLA

WHAT IS RUBELLA?

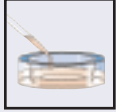
Rubella is a viral infection also known as the German measles.

WHY DO WE TEST FOR RUBELLA?

If you are exposed to rubella during pregnancy, and do not have immunity to the disease, your baby can have serious birth defects.

HOW DO WE TEST FOR RUBELLA?

Before you attempt pregnancy, blood will be drawn to measure your immunity to rubella.



WHAT DOES RUBELLA NON-IMMUNE MEAN?

Non-immune means that you have no protection against rubella disease. If you are not immune you should speak to your doctor/nurse practitioner to receive a vaccination prior to trying to get pregnant. You should not be pregnant when you receive the vaccine. You will be instructed to use birth control to avoid pregnancy for 28 days after you receive the rubella vaccination.

FEMALE TESTS: IMAGING STUDIES HYSTEOSALPINGOGRAM (HSG)

WHAT IS AN HSG?

HSG is an x-ray dye procedure used to view the inside shape of the uterus and fallopian tubes. This shows whether the tubes are open or damaged, and whether the uterine cavity is normal. Problems in these areas may make it difficult to become pregnant.

HOW IS AN HSG DONE?

A liquid, dye-like solution is injected through the cervix and its progress as it flows up through the uterus and tubes is viewed on x-ray. Spillage of the dye from a tube indicates that a tube is open. The inner shape of the uterus is also checked for abnormalities.

WHEN IS AN HSG PERFORMED?

A hysterosalpingogram is performed after all menstrual bleeding is done, but before ovulation. In women with a 28-day cycle this is usually between cycle days 8 and 12.

PELVIC ULTRASOUND

WHAT IS A PELVIC ULTRASOUND?

An ultrasound is an instrument that uses high frequency sound waves. The sound waves reflect off your internal organs and are “read” by scanners, that create pictures of your internal organs. A pelvic ultrasound scans your uterus and ovaries.

HOW DOES IT WORK?

There are various types of ultrasound that all work on the same principle. Sound waves, are directed into a specific area of your body through a microphone-

like device called a transducer. In an abdominal pelvic ultrasound a special gel, which helps to conduct the sound waves, is applied to your abdomen. The transducer glides across your skin to scan your pelvis. In early pregnancy or infertility, it is easier to view the embryo, or developing egg, and pelvic organs through the vagina. This procedure is called a *transvaginal ultrasound*. A transvaginal transducer is inserted into your vagina to produce sharp, clear images of the pelvic organs.

WHEN IS IT USED?

Ultrasound is often used in gynecology, as well as in pregnancy. It can help detect uterine fibroids, ovarian cysts, and early pregnancy. It can also examine the thickness of the endometrial (uterine) lining. In infertility, it can help monitor egg (follicle) growth and ovulation. Transvaginal ultrasound is also used for egg retrieval in In Vitro Fertilization (IVF).

WHAT ARE THE RISKS?

Ultrasound has been used for over 30 years and no harmful effects have been noted from its use. No radiation, dyes, drugs or chemicals are used in ultrasound. An ultrasound is not painful.

FEMALE TESTS: SURGERY HYSTEROSCOPY

WHAT IS A HYSTEROSCOPY?

A hysteroscopy is a way of looking at the inside of a uterus. A small lighted telescope is placed through the vagina, up into the uterus. This view is helpful in diagnosing problems within the uterus such as polyps, scar tissue, abnormal shapes or membranes, as well as fibroids.

WHAT IS A LAPAROSCOPY?

A laparoscopy is a surgical procedure that allows the doctor to look inside the female’s pelvis. By directly visualizing the pelvic organs, the doctor may be able to see if scar tissue or endometriosis may be present. These conditions may be treated during the same surgery.



WHAT TESTS ARE AVAILABLE FOR MEN?

SEMEN ANALYSIS

WHAT IS SEMEN ANALYSIS?

The semen analysis is one of the most basic laboratory tests of a couple undergoing an infertility work-up. The male partner is asked to produce a semen specimen to determine if the quality or quantity of the sperm is a contributing factor to their infertility.

WHAT IS A NORMAL SEMEN ANALYSIS?

The World Health Organization (WHO) suggests the following for normal values; (these should be seen as rough guidelines only)

- ◆ Volume: 2.0 ml or more
- ◆ Sperm Count: 20 million/ml or more
- ◆ Motility (% of moving sperm)
 - ◆ 55% or more with forward progression
 - ◆ 25% or more with rapid progression
- ◆ Morphology (the shape of the sperm)
 - ◆ 30% or more should be normal
- ◆ White blood cells: less than 1 million/ml

Remember these are only guidelines. Your provider will be able to interpret whether your results are within acceptable parameters, even when the numbers do not fall within these specific guidelines. The combination of volume, percentage of motile sperm, and the count determines the amount of active sperm and may provide an informative way to interpret the data.

$$\text{volume} \times \text{count} \times \% \text{ motility} = \text{total motile sperm}$$

HOW DO YOU COLLECT SEMEN FOR THE ANALYSIS?

- ◆ Obtain a container for collection from your provider.
- ◆ Abstain from any ejaculation for two to three days before your collection date.

- ◆ The specimen should be collected by masturbation directly into the container.
- ◆ Do not use a condom for collection because these contain agents that will kill sperm.
- ◆ The specimen should be kept warm by keeping the container directly next to the body. Deliver the specimen within an hour to the laboratory.

Please check the address and laboratory collection times prior to obtaining the specimen. These vary from clinic to clinic.

HOW ARE LOW OR ABNORMAL SEMEN ANALYSIS COUNTS TREATED?

Your provider will discuss the results with you.

He/she may ask you to repeat the semen analysis to confirm an abnormal count. If needed, you may be referred to a specialist called a *Urologist*.

Usually the treatment for a mildly low count is to do intrauterine insemination. The process of preparing the sperm to be placed directly into the woman's uterus is called sperm washing.

If counts are extremely low, your provider may suggest using donor sperm or Assisted Reproductive Technology (ART), such as IVF with Intracytoplasmic Sperm Injection (ICSI).

Your provider will discuss the options you may have if male factors are identified as a contributing factor to your ability to conceive as a couple.

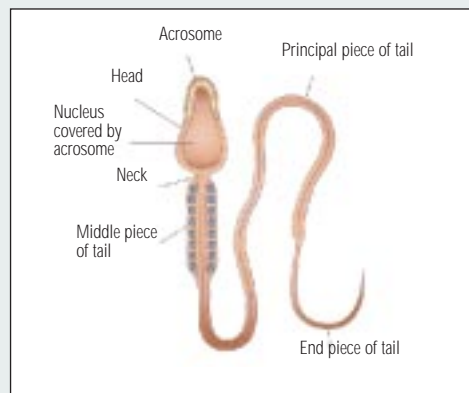


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WHAT TREATMENTS ARE AVAILABLE?

Depending on the results from your initial work-up, including lab tests, physical examination, and history, your physician or nurse practitioner will decide what treatment will be most effective for you and where you should start. Every patient is an individual and will most likely have to try a number of different treatments or combinations of treatments to achieve a successful result. Below is a brief introduction to some of the treatments you may hear about or need to undergo.

FERTILITY MEDICATIONS

The use of fertility medication ranges from non-invasive oral medications with little or no side effects to injections and more significant side effects.

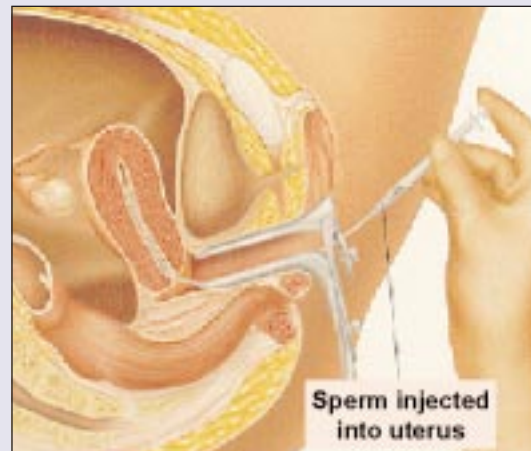
- ◆ **Clomiphene Citrate (Clomid®):** an oral medication which has been used for many years and has been very effective for women with irregular or no ovulation. Clomiphene Citrate can help women ovulate better by increasing the production of hormones that stimulate egg development.
- ◆ **Gonadotropins:** provide an extra supply of FSH and LH, helping to stimulate the development of eggs. Taking these medications is an intense process which involves daily injections at home and frequent blood estrogen level and ultrasound evaluations.
- ◆ **Endocrine Medications:** Medications such as: *Bromocriptine* (for an elevated prolactin), *Thyroid* medication (for an over or under active thyroid), *Insulin* (for diabetes), *Metformin* (for selected polycystic ovarian syndrome patients)—may help improve fertility.

INTRAUTERINE INSEMINATION

WHAT IS AN INSEMINATION?

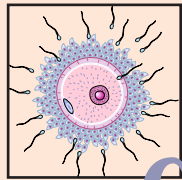
An insemination is a procedure that places washed sperm into the uterus using a small flexible tube attached to a syringe. An intrauterine insemination

(IUI) is done after a sperm wash has removed prostaglandin, bacteria, and unwanted debris from the collected sperm. The washed sperm are placed through the cervix, directly into the uterus, closer to the ovulated egg. Inseminations can be done with sperm from a male partner, or sperm from a known or anonymous donor. Insemination is helpful when there is a problem with the male partner's sperm, when the female has problems with her cervix, or when pregnancy is desired without a male partner. Although Kaiser performs donor inseminations, Kaiser benefits do not cover the sperm or cost of transport of sperm for a donor insemination.



IN VITRO FERTILIZATION

Through In Vitro Fertilization, a woman's own eggs can be fertilized outside her body and placed back in her uterus to develop. This process can also be done by using donor eggs (often from a younger woman).



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