FERTILITY POINT
IVF Clinic for Reproduction and Embryology

Patient Information Booklet

FERTILITY POINT
IVF Clinic
for Reproduction
and Embryology

This information booklet has been compiled to explain our clinic policies and procedures to ensure that you receive the best patient-centered care. If you have any questions regarding these policies and procedures, please feel free to ask any of the staff for assistance.

If you have any suggestions that may assist us in improving our service, please bring it to the attention of the staff.

Compiled and Edited by; Ayieta Lumbasyo
1st Edition

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INTRODUCTION

Welcome and thank you for choosing Fertility Point Kenya as your trusted partner in your fertility treatment. Fertility Point is a team of highly qualified and internationally trained IVF consultants and senior embryologists with proven expertise in successful treatment of infertility.

Fertility Point's state-of-the-art IVF laboratory is equipped with the most advanced and innovative technologies that ensure quality care and achieve high success rates. We take pride in bringing together some of the best IVF specialists and embryologists trained abroad and with a proven track record in all areas of infertility treatment. We are affiliated with Europe's largest fertility services provider to share technological know-how and medical expertise thus ensuring best international practices.

At Fertility Point, we consider every aspect of your journey to achieve your dream of parenthood. Our aim is to assess your needs accurately and offer a personalized treatment plan guiding you through every step of your fertility journey.

With the Fertility Point team, you can be assured of world-class reproductive care, underlined by a sincere commitment to your overall well-being.


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Informed Consent

Under the Kenyan laws, it is important that informed consent is given before any medical procedure that does not fall under Emergency Care is administered. It is therefore important that you read this booklet in its entirety and if, after consultation with the doctor and an assessment of potential risks, associations and benefits you choose to proceed with your treatment, our clinic staff will provide consent form(s) for you to fill up.

Some procedures may involve filling up more than one consent form and these to be signed before treatment begins. You are allowed to ask all and any questions about your particular procedure

The signed consent form(s) are valid for one year and in some instances, you may be required to complete a new consent for with each subsequent treatment cycle.

Privacy and Confidentiality

Our Centre is dedicated to maintaining our patients' privacy and confidentiality. All patient details and treatments are treated with the utmost privacy and confidentiality. To this end, we will not release any information without a patient's written consent.

Conversely, Fertility Point shall not discuss treatment with other family members, such as mothers, sisters, or even friends unless permission has been granted beforehand by the patient(s).

However, in normal course of medical practice, communication, either verbal or written, detailing the kind of therapy undertaken, may be made with the doctor(s) who referred you or is undertaking after treatment follow up. If you do not wish this information to be shared, then you must notify us in writing.

Financial Responsibility

Prior to initiating a treatment, we will conduct a financial consultation that is designed to provide you with information regarding Fertility Point's treatment fees, our package programs, and if applicable, to understand your individual financial situation and insurance coverage. Every effort will be made on our part to provide treatment in the most affordable and cost-effective manner, and to alleviate financial stress when possible.

You are solely responsible for all the costs associated with your treatment. Kindly note that most medical covers in Kenya do not cover fertility treatment, thereby, such expenses shall be paid directly by yourself /selves. You will be required to pay your account before start of treatment.

No new treatment cycles will be started if there is an outstanding balance on your account. All payments are to be made upfront. All fees are due and payable on the date of service. If you have a question regarding fees, please call our Accounts Department for assistance.

Treatments that come as package shall have no breakdowns and/or refunds as they are heavily subsidized. Kindly consult the staff on costing before starting your treatment protocol.

First Appointment Essentials

We have specialist registered nurses, who are dedicated to assisting new and existing patients. They can answer any questions you may have about visiting our practice, and can explain the forms and other information you will need to provide in advance of your first appointment. This information will provide your doctor with details that are important and relevant to your reproductive care.

Ideally, we would like to receive your information at least a few days before your first appointment. This will give your doctor time to review your records before you meet.

If you are not able to forward the paperwork in time for it to reach us before your appointment, please bring the information with you, and arrive at least 30 minutes before your appointment so we can prepare your folder.

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Getting Started

The aim of assisted reproductive technologies (ART) is to help achieve a healthy pregnancy and child. In general, ART is considered when reproductive problems affecting the female, male or both, make it unlikely or impossible to achieve a pregnancy through natural intercourse. An extensive evaluation will aid in directing your team of fertility specialists to recommend an optimal course of treatment including ART.

There are a number of variations of assisted reproduction, but all involve working with Ooctyes (eggs), sperm and/or embryos in the fresh or frozen condition outside of the body. Since the introduction of in vitro fertilization in the late 1970's there has been an on-going increase in the number and availability of related procedures. ART includes various processes such as in vitro fertilization (IVF) which is the mixing of sperm and eggs (gametes) to allow fertilization outside of the body. Intra-Cytoplasmic Sperm Injection (ICSI) is a procedure to assist fertilization in vitro.

The purpose of this Patient Information Booklet is to give you an overview of the many procedures available, their implementation, alternatives, risks and outcomes and terminology. This overview is supplemented by discussions with various clinicians that are all crucial in providing you with a clear and realistic picture of your own clinical situation.

Assisted Reproductive Technologies (Art)

1. In Vitro Fertilization (IVF)

IVF is the oldest ART procedure and still the most frequently used. The term “in vitro” refers to fertilization outside the body. In Vitro Fertilization literally means fertilization outside the body; generally this is done is a specific Petri-dish hence the commonly used term ‘test tube baby’.

Variations of IVF include donor egg, donor embryo, “natural cycle” IVF and gestational surrogacy.

An IVF cycle typically includes the following steps or procedures:

- Medications to grow multiple eggs
- Retrieval of eggs from the ovary or ovaries
- Insemination of eggs with sperm
- Culture of any resulting fertilized eggs (embryos)
- Placement (“transfer”) of one or more embryo(s) into the uterus
- Support of the uterine lining with hormones to permit and sustain pregnancy

2. Stimulated Cycle Oocyte (Egg) Development and Monitoring

A Woman’s body will naturally release a single egg for possible fertilization each month. IVF increases the chance for pregnancy by producing many eggs in one month. To accomplish this, patients are given fertility medications to help the body grow more than one egg from a pool of eggs that are available each month.

The purpose of this section is to explain how drugs may be used and their advantages, disadvantages, side effects and risks.

Follicle Stimulating Hormone (FSH) is commercially available as Gonal f® or Follistim® and is a subcutaneous injection and approved for use in IVF. Human Menopausal Gonadotropins (hMG) namely, Repronex®, Menopur® are purified urinary or manufactured products that usually contain FSH and some LH hormone. Human Chorionic Gonadotropin (hCG) (Novarel®, Ovidrel®) is used to stimulate the final steps of egg maturation before egg retrieval. hCG and clomiphene citrate (Clomid®, Serophene®) are approved for ovulation induction in women who do not ovulate. Letrozole (Femara) is another type of oral medication used to induce ovulation.

Other medicines that may be utilized for ART include fertility pills (clomiphene, letrozole, etc) and patches (androgen, estrogen, etc). All of these medications are used extensively for assisted reproduction.

Additional medications may include supplemental estrogen, nutritional supplement, progesterone, aspirin, antibiotics, prednisone and others.

You will be given a daily schedule of when and how much medicine to take. It is important that you carefully follow these instructions. Please be sure that you take the prescribed dosage at the prescribed time. If in doubt, please call to ask questions.

You may experience mild reaction to these medication however, in some cases, serious pulmonary conditions and thrombi-embolic (blood clotting) events have been reported in conjunction with the use of ovarian stimulation medication.

Ovulation induction drugs are occasionally also associated with the risk of ovarian hyperstimulation syndrome (painful enlargement of the ovaries, See OHSS below).

Additionally, these drugs may cause the development of ovarian cysts (noncancerous, fluid-filled structures in the ovaries); in rare instances these may need to be removed surgically, possibly requiring short hospitalization. Though rare, the removal of an ovarian cyst can result in the loss of an ovary

It is inadvisable for such fertility medications to be used during pregnancy (except progesterone and estrogen).

In November of 1992, a published study addressed a potential risk of ovarian cancer associated with the use of certain medications for ovarian stimulation. Since that time, the consensus of medical opinion on the issue is that there is no conclusive evidence of this risk.

Monitoring of ovarian stimulation involves blood tests and/or ultrasound examination and is vital to proper fertility management. Inability to comply with scheduled office visits may necessitate rescheduling or cancellation of a cycle

Various complication may arise which may prevent the completion of an ART cycle, resulting in a cancellation, or delayed embryo transfer. Cancellation and cryopreservation of embryos for delayed embryo transfers will result additional expenses.

Alternatively, IUI may be performed instead of IVF when the ovarian response has been inadequate to proceed with egg retrieval, if a woman's fallopian tubes are open and there is adequate sperm function.

Overstimulation, a premature rise in progesterone, or a rise in estrogen that is too rapid, or retrieval of many more eggs than expected will sometimes require cancellation, the addition of other medications and/or delayed embryo transfer to a later month.

3. Ovarian Hyper-Stimulation Syndrome (OHSS)

The process of in vitro fertilization (IVF) involves the intentional, but controlled stimulation of the ovaries in order to obtain an optimal number of eggs. Mild symptoms related to the enlargement of the ovaries usually begin 5 to 7 days after ovulation (or egg retrieval) but may also occur after embryo transfer and pregnancy.

Mild symptoms which typically include: mild abdominal discomfort or distension, mild nausea, and diarrhea are fairly common and are usually managed by bed rest at home. However, a dramatic increase in the size of the ovaries may occur causing a number of symptoms collectively referred to as Ovarian Hyper Stimulation Syndrome (OHSS)

OHSS may be managed at home but in some cases, hospitalization will sometimes be necessary. In rare instances, removal of the ovaries may be required and other major complications such as internal bleeding, stroke and kidney failure are possible.

Warning signs of OHSS include; the following:

- Persistent nausea, vomiting or diarrhea
- Weight gain
- Persistent or constant pelvic pain
- Difficulty breathing
- Severe abdominal bloating
- Decreased urine volume despite usual fluid intake

If you experience any one or combination of these symptoms, contact the office immediately.

Egg Retrieval, Fertilization And Embryo Transfer

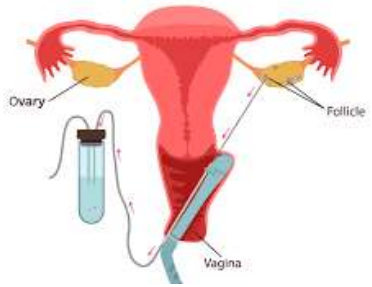
1. Transvaginal Oocyte (Egg) Retrieval or Ovum Pick Up (OPU)

Ovum Pick Up or Egg Retrieval as it's commonly known is usually done by use of an ultrasound guided needle that is passed through the right and the left corners of the vagina to enter the ovaries and follicles (egg sac). The needle is sequentially passed into each visible and accessible follicle. Fluid suctioned from within the follicles usually contains one egg per mature follicle. Notably, not all visualized egg sacs (follicles) will yield an egg

Retrieval of eggs is critically timed after the ovulation trigger because too early pick up, the eggs may not be mature; too late and the eggs may have been released.

In some instances, one or both ovaries may sometimes be completely or partially inaccessible through the transvaginal route, resulting in no eggs being retrieved or a lower number than expected.

Ovum Pick up is usually conducted under sedation or other forms of anesthesia which carries risks that include but are not limited to, allergic reactions to drugs and breathing problems. Cardiac arrhythmia / arrest and death are exceedingly rare complications.

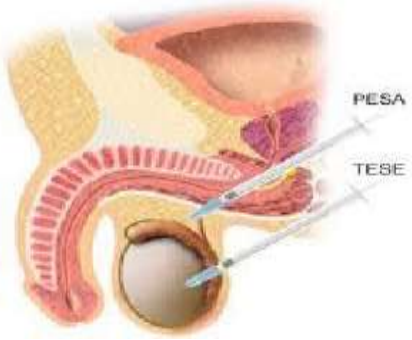


Mild to moderate discomfort may be experienced during the procedure. Other complications which are usually uncommon include but are not limited to; internal bleeding and/or puncture of blood vessels, injury to bowel, bladder, uterus, ovaries and/or any other abdominal organ. These are potentially serious and even life-threatening complications that may require immediate surgery and/or blood transfusion. If a serious injury is recognized during the retrieval, repair will usually be attempted immediately.

Rarely, will one get serious pelvic infections which shall requiring antibiotics and/or hospitalization and in even much rarer instances, removal of fallopian tube(s), ovary (ies), uterus (hysterectomy) or colostomy. Pelvic infection or surgery may cause formation of scar tissue, decreasing a woman's chance of conventional conception through intercourse. As with any procedure, transvaginal Oocyte retrieval may present other risks that have not yet been established.

2. Sperm Retrieval from Partner

The male partner will be required to supply semen, unless a sperm donor program has been indicated. However, in some cases healthy sperm cannot be obtained from the semen, or semen cannot be produced. Various techniques can, in most cases, successfully locate and obtain sperm for reproduction



avoiding the alternative of using donor sperm for reproduction.

In simple cases, sperm may be aspirated from the epididymis located adjacent to the testicle, called Percutaneous Epididymal Sperm Aspiration (PESA). Sperm may also be aspirated with a needle directly from within the testicle called Testicular Sperm Aspiration (TESA). In cases where very few sperm cells are produced within the tissue of the testes, a surgical extraction is recommended. This procedure entails a urologist making a surgical incision and biopsy on the testicle(s) to locate and remove sperm producing tissue and is referred to as Testicular Sperm Extraction (TESE).

Sperm obtained with these methods are usually few in numbers and may lack adequate motility as well. For this reason, microsurgical insemination, ICSI (Described below), is required to optimize the possibility and percentage of fertilization.

3. Insemination and Culture of the Embryos

In routine In Vitro Fertilization (IVF), fertilization is conducted between 2 - 6 hours after retrieval. Usually, sperm will be added to the dish containing all of the eggs for insemination and allow fertilization.

Some couples may NOT wish to use cryopreservation (freezing) of extra embryos and therefore may consider limiting the number of eggs inseminated and plan on method of any extra embryos created.

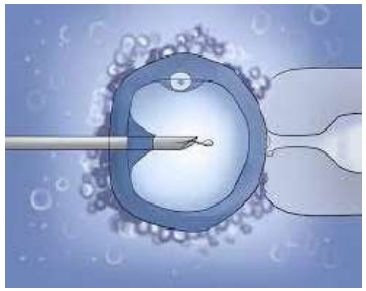
Assessment of fertilization is performed the next day, “Day 1” after egg retrieval and insemination. Under normal conditions, fertilization should have occurred in the majority of mature eggs. Problems with either egg or sperm quality may lead to a decreased number of eggs being fertilized and in some instances, no fertilization of oocyte (egg) will occur thus limiting the success of the cycle.

When normal fertilization is noted, the fertilized eggs (zygotes) are maintained in culture in the incubator for additional days. Some eggs will fertilize abnormally, with the most common being fertilization with more than one sperm. Such “polyspermic” fertilization cannot lead to normal embryos, and therefore these fertilized eggs are discarded. Occasionally, none of the fertilized eggs will cleave even after apparently normal fertilization.

4. Intra-Cytoplasmic Sperm Injection (ICSI)

In some cases, fertilization is achieved by injecting a single sperm into an egg using a technique called intractyoplasmic sperm injection (ICSI). ICSI, a specialized, microsurgical form of insemination, ICSI involves the direct injection of a single sperm into the interior of an egg using an extremely thin glass needle.

ICSI is most commonly used in cases with severe low sperm count, motility or other fertility problems which may cause conventional fertilization failure.



ICSI can be performed even in men with no sperm in the ejaculate and has to be retrieved directly from the testicle (vasectomy). ICSI is required for cases where genetic testing is planned for the resulting embryos.

Despite ICSI, failure to establish a pregnancy may result because of the following reasons: (1) inability of the eggs to withstand the injection procedure, (2) failure of the sperm to activate the egg in spite of injection inside the egg, (3) poor egg quality resulting in inability of the egg to achieve normal fertilization or subsequent cell division or growth, and/or (4) failure of the embryo to implant.

Risks of ICSI

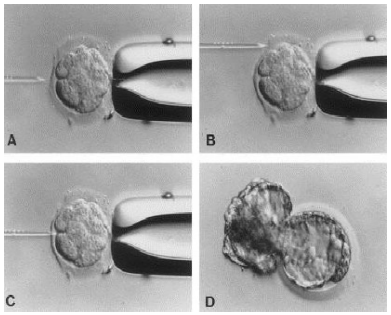
Although reports on the risk of birth defects associated with ICSI are inconclusive, ICSI is associated with an increased risk of certain major congenital anomalies. However, whether the association is due to the ICSI procedure itself, or to inherent sperm defects, could not be determined because the study did not distinguish between male factor conditions and other causes of infertility.

The reason for the increased prevalence of chromosomal anomalies observed in ICSI offspring is not clear. Whereas it may result from the ICSI procedure itself, it might also reflect a direct paternal effect. Men with sperm problems (low count, poor motility, and/or abnormal shape) are more likely themselves to have genetic abnormalities and often produce sperm with abnormal chromosomes; the sex chromosomes (X and Y) in the sperm of men with abnormal semen parameters appear especially prone to abnormalities. If sperm with abnormal chromosomes produce pregnancies, these pregnancies will likely carry these same defects

5. Assisted Hatching

An unusually thick shell may reduce the likelihood of timely hatching, implantation and pregnancy. Thinning or perforating the shell surrounding embryos immediately prior to transfer may be needed to increase implantation in certain cases.

Human eggs are surrounded by a 'shell' (zona pellucida or simply "zona") composed of a soft gel-like substance. Sperm must pass through this layer in order to fertilize the egg and the embryo must break out of this shell so that implantation and pregnancy can result.



To break out of the shell and implant in the lining of the uterus, the embryo must weaken and then push through the surrounding shell - an event similar to the hatching of a chicken from its egg. Because of the earlier analogy to "hatching", this procedure is referred to as assisted hatching. The evidence does NOT consistently suggest a benefit in all cases, deferring its use in individual cases.

The need and recommendation for assisted hatching may not become apparent until embryos are examined in the laboratory following insemination and fertilization. Assisted hatching is performed as part of all procedures for genetic testing of embryos.

Potential Risks and Benefits

Each step of an ART process that involves direct handling of embryos is associated with a risk of damage; the more times an embryo is handled in the laboratory, the higher the likelihood that some damage might occur. Assisted hatching involves direct handling of embryos and therefore adds to the risk that an embryo will be damaged in the laboratory. There are no published data to suggest that use of assisted hatching has any detrimental effect on the potential of the embryo to implant. For certain couples, the benefits of assisted hatching (potentially raising the chance of a successful pregnancy)

6. Embryo Transfer

The transfer of embryos into the uterus which is the final step in the ART process and it is ideally accomplished with great ease.

Embryos that have developed and cultured are loaded into a catheter that is then passed through the cervical canal into the uterine cavity

In some instances, ultrasound guidance or other instruments and occasionally dilating the cervix may be required.

Generally, Embryo transfer is easy and pain free although one may experience moderate to severe discomfort, cramping or significant bleeding. Embryo transfer, like any manipulation of the uterus involves a small risk of infection, which may require antibiotics

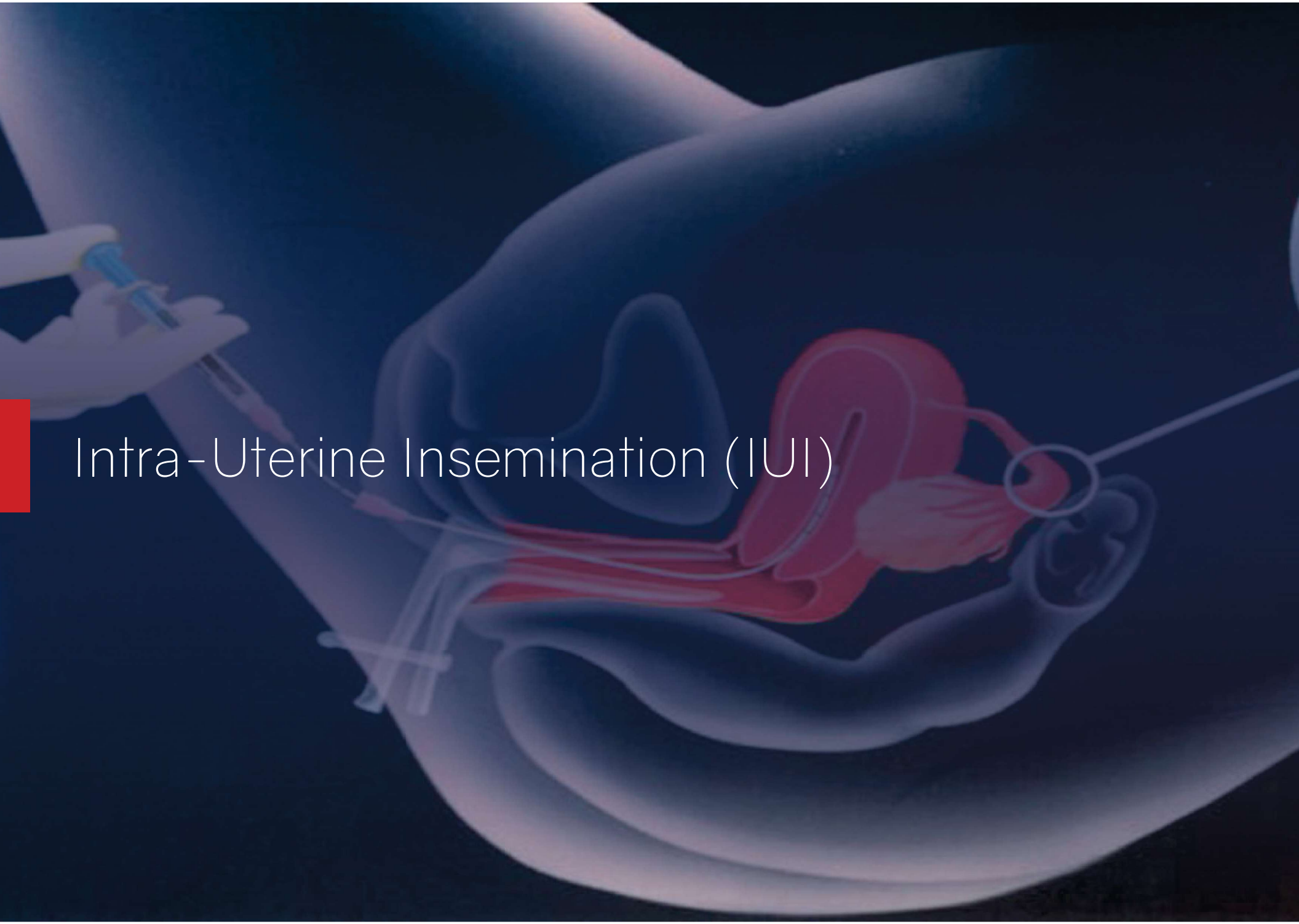
Number of Embryos to Transfer

Not every embryo transferred during ART will implant, and not every embryo that implants will result in a clinical pregnancy or a live born infant. The chance of implantation varies with each individual patient/couple, although statistical averages demonstrate that the age of the woman is a key factor, possibly the most important factor.

As implantation is a necessary first step to achieve a clinical pregnancy, or a live birth, pregnancy rates generally decrease with age as well. In general, more embryos can be safely transferred as maternal age increases. Most commonly, patients wait to make the decision when more information is available on the day of transfer.

The chance of multiple births and the risk of premature birth and complications from multiple pregnancies increase with an increased number of embryos transferred.

In addition to maternal age, transfer number may be determined for individual case based on diagnosis, number/quality of embryos, physician's judgment, prior attempts and comfort level.



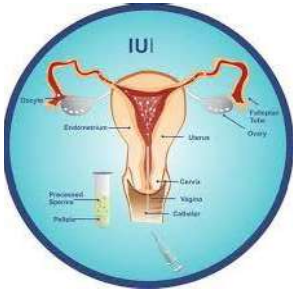
Intra-Uterine Insemination (IUI)

Intra – Uterine Insemination (IUI)

ntra – Uterine Insemination involves placing sperm directly into the female's uterus through a catheter. As it is a relatively low-tech solution to infertility problems, IUI is usually one of the first techniques used to assist a couple who is having difficulty becoming pregnant.

Sperm can be provided by the woman's husband or partner or by a known or anonymous sperm donor This procedure is done around the time of ovulation to give the best chance of conception.

In some cases, hormonal (fertility) medications might be used in conjunction with the treatment to enhance conditions for a pregnancy, either by increasing the number of follicles and eggs produced with a cycle, or triggering release of the egg(s) at a precisely known time to coordinate better with insemination.



If menstrual cycle is regular, IUI will be performed about Day 12 to Day 15 of the cycle when ovulation – release of the egg – is taking place. You will be asked to work out when ovulation will occur by tracking basal body temperature (your temperature increases during ovulation) and changes in vaginal mucus, or by using ovulation kits. Alternatively, you may be monitored through regular ultrasounds or blood tests administered by your medical team or clinic.

Depending on your particular situation, your doctor may recommend that you take hormonal medication (also known as 'fertility drugs') to help stimulate ovulation. If fertility drugs are used, monitoring of the ovarian stimulation levels will begin with the onset of cycle and includes blood tests and periodic ultra sound examinations

On the day of scheduled IUI, a semen sample is obtained from the male partner (by masturbation, collected at home or collected on site), or by thawing previously cryopreserved (frozen) sperm. The semen sample is then processed ("washed") to isolate motile sperm. Next the isolated motile sperm are loaded into an insemination catheter which is then inserted past the cervical canal and into the uterine cavity, where the sperm are deposited.

Possible side effects of IUI include but are not limited to abdominal and/or pelvic pain, fever and/or a vaginal discharge following IUI. Pelvic infection following IUI may lead to tubal disease and scarring, and may require antibiotic treatment.

IUI is not effective when there is; bilateral/blocked or damaged fallopian tubes, ovarian failure severe male factor infertility and severe endometriosis. In such cases IVF is advised.

Art Treatment Related Procedures

Cryopreservation (Freezing and Storage) of Embryos

Freezing (Cryopreservation or "Cryo") of living cells has been successfully used in research laboratories for many years with the first birth results after the freezing and thawing of a human embryo occurring in Australia in 1985

Data suggests that the chance of birth defects in children born following the cryopreservation of embryos is the same as the rate observed in an age-matched group of pregnant women. There is no further evidence of an increased risk of birth defects or obstetrical problems in these pregnancies compared to fresh, non-frozen embryos.

Generally, the purpose of cryopreservation with ART is to optimize the stimulation to obtain good quality eggs without the obligation to transfer too many embryos at one time if several good quality embryos develop. Also, a deferred embryo transfer is sometimes desirable or required if an impairment of implantation is suspected for a fresh transfer.

In instances where more normally dividing embryos result than the couple desires to transfer, the couple is given the choice before starting the cycle to cryopreserve any excess embryos for later attempts.

In some cases, it may be preferred to "freeze all" embryos and schedule the embryo transfer in a non-stimulated menstrual cycle.

Embryos are frozen using a process called "vitrification". During thawing, embryos are usually thawed one at a time and after an initial thaw, poor quality or survival may suggest the need to thaw one or more additional embryos, if available.

The chance of pregnancy and birth resulting from the transfer of cryopreserved embryos depends on a number of factors specific to the patient, most importantly the woman's age when the embryos were generated. Pregnancy rates with frozen embryos, in general, remain slightly less than that with fresh embryo transfer.

Embryos that fail to develop during an ART cycle are more likely to be genetically abnormal and are ideally not frozen.

The number of cryopreserved embryos available will be important in determining the best way to proceed with a subsequent ART cycle. When there are only one or two frozen embryos available, the physician may suggest a new stimulation and retrieval cycle, prior to using the cryopreserved embryos.

Legal concerns regarding Cryopreservation

The law regarding cryopreservation and the ownership, control and disposition of cryopreserved embryos has not yet been developed in Kenya.

It is thus our policy that any decision regarding the embryos shall be the joint decision of the partners receiving ART services (the responsible parents). And this decision

shall be contingent upon their mutual consent or upon a legally binding and enforceable agreement, in writing, signed by both of them. If such embryos are legally determined to be property, the couple shall hold them jointly with all rights in the survivor.

Embryos cannot be donated unless the donating couple has fully assumed the responsibility of being screened for genetic or infectious diseases. This would allow the embryos to be donated anonymously to another infertile couple.

These screening tests need to be obtained at least 6 months after the cryopreservation of the embryos. If the embryo(s) is/are donated, the donating couple, their successors and heirs waive any and all rights that they may have in the donated embryos and in any child born as a result of their transfer.

The couple understands if any dispute arises between the two partners regarding disposition of the embryos, the physician or practice is authorized, in its sole desecration, to refrain from taking any action unless and until otherwise directed by a final judgment of a court of competent jurisdiction.

Options for disposition of cryopreserved embryo(s), include transfer to the uterus of the woman attempt pregnancy, transfer to another ART program or facility, physical delivery of the embryo(s) to the couple, disposal of the embryo(s) in an appropriate manner, or, with appropriate testing, donation to another couple.

Currently, couples do not have the option of offering embryos for research, but may have in the future

Uterine Abnormalities and ART Outcomes

Obstetrical complications occur more frequently in ART pregnancies and particularly if uterine abnormalities exist. Examples of uterine abnormalities include uterine polyps, fibroids and congenital uterine defects such as a septum or double cavity. Acquired uterine abnormalities may arise as scars from a D&C, myomectomy, C-sections and other uterine surgeries.

Women with these types of abnormalities appear to be at greater risk for miscarriage, premature delivery and other pregnancy complications such as breech presentation and placental abnormalities.

Ectopic pregnancies occur more frequently in ART pregnancies possibly due to uterine or tubal factors. The chance of multiple pregnancy is increased with ART and it is well recognized that multiple pregnancy (twins, triplets, etc.), whether occurring naturally or through medical intervention, increases the risk of complications and birth defects.

Careful counseling prior to conception will help a woman to understand what these risks might be and to modify the number of embryos transferred to optimize outcomes.

Pregnancy Outcome after Conception with ART

Chances of an ART procedure resulting in a clinical pregnancy and/or a live birth depends on many factors which include; the age of the woman, the quality of the eggs, the quality of the sperm, the number of eggs/embryos retrieved/transferred and the condition of the uterus.

There are many steps, or phases, to a cycle of ART, and the achievement of a live birth requires that each phase be successfully completed however, there are no guarantees of success at any ART program.

It is therefore realistic to consider that multiple attempts may ultimately be needed or that none of the treatment may be successful eventually.

Because infertile couples have risks above that of fertile couples, genetic screening by maternal blood (Non-Invasive Prenatal Testing, NIPT) and/or testing by chorionic villus sampling (CVS) or amniocentesis is recommended for all ART pregnancies and for women ≥35 years of age.

ART may not result in a normal pregnancy, even though a full ART cycle is successfully completed.

Some of the reasons for this are as follows;

- A majority of attempted ART cycles result in the transfer of at least one egg or embryo. However, only a small percentage of embryos will implant in the woman's uterus or continue development. Some early embryos fail to progress even after a missed menstrual period and a positive pregnancy test early embryos may fail to progress.
- Embryos may not develop normally and may be spontaneously aborted (miscarriage). Miscarriage rates increase with a woman's age. ART pregnancies miscarry at similar rates to non-assisted pregnancies in women at the same age.
- Ectopic or tubal pregnancies (where the embryo begins to develop outside the uterus) occur in a small percentage of pregnancies following ART. However, it occurs with greater frequency in infertile couples than the general population. Tubal pregnancies may be treated medically or surgically. Surgery may result in the loss of a fallopian tube, which, in turn, can further impair fertility. In rare instances, a tubal pregnancy may present a medical emergency in which the patient may go into shock as a result of blood loss and/or require transfusions and other treatment. Early diagnosis is essential for safe management.

Even an apparently normal ongoing pregnancy presents risks to both the mother and the baby, and does not guarantee a normal delivery at term of a normal infant. In ART pregnancies, as in pregnancies resulting from intercourse, serious unforeseen obstetrical complications occur. Such complications may result in miscarriage, the loss of the child in advanced pregnancy (stillbirth) or delivery of a baby too premature to survive.

A prematurely born infant may experience serious or life threatening complications or permanent medical disability. The chance of premature labor and delivery is increased with multiple pregnancies, which is a common possibility while using ART.

However in recent times, the rate of multiple pregnancies with ART has steadily declined as newer technologies, including Pre-Implantation Genetic Testing/ Screening (PGS) and Diagnosis (explained below) allow fewer but healthier embryos to be transferred, hence reducing the risks associated with multiple gestation.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Preimplantation Genetic Screening (PGS) And Diagnosis (PGD)

Preimplantation Genetic Screening (PGS) and Preimplantation Genetic Diagnosis (PGD) are specialized techniques designed to screen embryos for chromosomal or genetic disorders. The PGS and PGD techniques are relatively new investigational procedures requiring removal of one or more cells from the embryo.

The blastomere(s) or TE cell(s) is/are genetically evaluated to determine the presence or absence of specific chromosomal abnormalities and/or genetic diseases. After the genetic evaluation of embryos, they are selected for embryo transfer into the uterus, or frozen (cryopreserved) to be used later, to achieve pregnancy. The advantages of using PGS/PGD are to greatly reduce the risk of miscarriage or having a child with the chromosomal/genetic problems.

Normal human cells have 23 pairs of chromosomes; one of each pair came from each parent. Eggs and sperm have half of these. Abnormal chromosome number, called aneuploidy, is known to be the most common cause of miscarriages, and believed to be the most likely reason for an unsuccessful ART cycle. One example of aneuploidy is Down syndrome (an extra chromosome 21, or trisomy).

PGS is used to select and replace embryos that are less likely to have chromosomal abnormalities, e.g. missing one chromosome (monosomy) or extra chromosome (trisomy).

Potential benefits from the use of PGS/PGD are:

- Decreasing the number of embryos transferred thereby reducing the chance of high multiple pregnancy,
- Increasing the chance of a normal pregnancy,
- Reducing the chance of miscarriage,
- Gaining information that may be applicable to your future care and fertility treatments and decisions.

Potential risks of PGS/PGD include but are not limited to:

- Recognized and unknown detriment to embryos,
- A decreased number of excess embryos that may otherwise be cryopreserved and stored,
- An error in diagnosis due to biological and laboratory technology issues,
- A missed genetic abnormality due to limitations of technology,
- Assignment of a genetically normal embryo as “abnormal”

Limitations of PGS/PGD

Technical issues may prevent testing or reporting in some cases. For example, embryo biopsy may not be possible or some cells from embryos may not result in DNA amplification, preventing genetic analysis. In these instances, the genetic status may be unknown. It is assumed that DNA from the biopsied cell(s) represents the DNA of the remaining cells of the embryo. While true in theory, there are exceptions where embryos may contain a mixture of cells with different DNA (mosaic).

Further some chromosome abnormalities can be missed with current technology. Thus,

embryos with “normal” test results may still contain other abnormal chromosomes that were in cells not tested. Therefore, when a couple conceives after PGS, direct chromosome analysis by chorionic villus sampling (CVS) or amniocentesis remains recommended as standard of care, particularly for women ≥35 year of age. This is particularly true when an embryo with “unknown status” or embryos of mixed genetic status are transferred.

The fees for PGS/PGD are additional expenses to ART treatment and client is responsible for payment.

As genetic testing is relatively new, insurance rarely provides payment and you may be asked to make a deposit in advance

Third Party Reproduction

The phrase "third-party reproduction" refers to involving someone other than the individual or couple that plans to raise the child (intended parent(s)) in the process of reproduction. This includes using donated eggs, sperm, or embryos and gestational-carrier arrangements.

Third-party reproduction can be socially, ethically, and legally complex. As egg donation has become more common, there has been a reconsideration of the social and ethical impact this technology has had on prospective parents, their offspring, and the egg donors themselves.

Surrogacy arrangements are controversial, and are subject to both legal and psychosocial scrutiny.

This section will discuss the options for third-party reproduction, reviewing sperm donation, egg donation, embryo donation, and gestational-carrier arrangements.

1. Oocyte (Egg) Donation

The first pregnancy resulting from egg donation was reported in 1984. Since then, egg donation has helped many struggling with infertility to conceive. With egg donation, the intended parents will have a genetic link to the child only if they contribute the sperm used to fertilize the egg. Egg donation requires in vitro fertilization (IVF), as the eggs are removed from one woman, fertilized in the laboratory, and the resulting embryo is transferred to the recipient's uterus.

If pregnancy is established, the mother then becomes the "gestational" and legal mother and experiences the pregnancy and birth, although she is not the genetic mother. Her partner providing the sperm is the genetic father.

Working with egg banks and egg donor agencies, Fertility Point has made available an Oocyte (egg) donation service to treat infertility arising from the absence of ovaries or the inability of ovaries to produce healthy eggs. The service can also be used to help couples with potential genetic abnormalities.

The basic steps of egg donation with IVF are as follows;

- The first step is to find an egg donor. This can be either someone known to the intended parent(s) or an anonymous donor.
- The donor takes medication to stimulate her ovaries to produce multiple eggs and the eggs are collected. Sometimes, to share costs, the eggs from an egg-donation cycle are split among several recipients.
- Sperm from either the recipient's male partner or a sperm donor are used to fertilize these eggs in the laboratory.
- An embryo (fertilized egg) is chosen and transferred to the uterus (womb) of the intended carrier and, hopefully, a pregnancy is established. The intended carrier can be the intended parent or another woman (gestational carrier), depending on the circumstances.

Participants, both the donor and the recipients, are subjected to preliminary screening procedures, including review of medical records, physical examination, blood testing, screening for familial genetic and infectious disease, and psychological evaluation.

Oocyte (Egg) Donor Categories

There are several ways of obtaining donor eggs:

1. **Anonymous donors:** Women who are not known to the recipient(s). Donors may be found through egg donation programs or through agencies. Many women opt to undergo the egg donation process as anonymous donors. These individuals donate eggs to infertile couples whose identities also remain anonymous.
1. **Known (directed donors):** Women who are known to the recipient(s). In this case, the donor is generally a close relative or friend.
1. **IVF programs:** Women undergoing IVF may agree to donate their excess eggs to infertile patients.

Limitations Of Oocyte Donation Program

Participants in the Oocyte donation service must understand that there are limitations to relying on medical and family history in an attempt to exclude the possibility of genetic disease in a potential offspring.

It is likely that it will never be possible to test for all of these genes in either the egg donor or the genetic father.

It is also not possible or reasonable for Fertility Point Kenya to notify donors and recipients of a genetic disease in either the donor or the offspring developed or recognized in the future.

Currently, since there's no requirement for a donor registry in Kenya, there is no requirement for donors to notify the Egg Bank of their whereabouts or subsequent medical history.

2. Sperm Donation

nsemination using donor sperm has been practiced for over a century, although the first published reports of such were in 1945. Since the late 1980s, with the emergence of HIV, donor insemination (DI) has been performed only with frozen and quarantined sperm to allow for time to test the donors. International guidelines recommend that sperm be quarantined for at least six months before being used.

Reasons for Sperm Donation

Use of Sperm donor is necessary when the male partner has severe abnormalities in his semen and/or reproductive system, which may be present at birth (congenital) or develop later (acquired) and in other situations. These abnormalities include;

- Azoospermia (absence of sperm) can be due to a blockage (obstructive azoospermia), such as congenital bilateral absence

of the vas deferens (CBAVD) or previous vasectomy. Alternatively, azoospermia can be due to testicular failure (non-obstructive azoospermia) resulting from exposure to toxins like pesticides, radiation treatment, or chemotherapy.

- Severe oligozoospermia (decreased sperm count) or other significant sperm or seminal fluid abnormalities also are indications for DI.
- Ejaculatory dysfunction, such as inability to achieve or maintain an erection or to ejaculate, is a scenario where DI can be helpful.
- DI in place of an affected male's sperm can help bypass significant genetic defects that can be passed to children.
- When there is no male partner, such as with single women who wish to become parents or lesbian couples who desire a pregnancy, but who lack a male partner, DI is needed for pregnancy.

Sperm donors should be of legal age and ideally less than 40 years of age to minimize the potential increased risks of older male parents. Like egg donors, sperm donors can be anonymous or known (directed). It is important that both anonymous and known donors undergo the same initial and periodic screening and testing process, whether or not they are intimate sexual partners of the recipient.

Sperm donors, both known and anonymous should also be screened for risk factors for, and clinical evidence of, communicable disease agents or diseases. A donor is ineligible if either screening or testing shows the presence of a communicable disease or a risk factor for a communicable disease.

3. Embryo Donation

Embryo donation makes it possible to have a child when one or both partners are not able to contribute their own sperm, eggs, or embryos. Using donated embryos may be considered by women with untreatable infertility that involves both partners, untreatable infertility in a single woman, recurrent pregnancy loss thought to be related to the embryo, and genetic disorders affecting one or both partners. Donation can also be used for social reasons such as same-sex couples or for single men or women

The process of embryo donation requires that the recipient(s) undergo(es) the appropriate medical and psychological screening recommended for all gamete-donor cycles. In addition, the female partner undergoes an evaluation of her uterine cavity and then her endometrium is prepared with estrogen and progesterone in anticipation of an embryo transfer.

Embryo donors are required to provide a detailed medical history and be tested for communicable diseases including HIV, hepatitis, syphilis, gonorrhea and chlamydia at the time of donation. If the donors are unavailable or refuse to be tested at that time, the recipients are warned about the chances of transmission of disease.

Evaluation of the recipients is similar to that of patients undergoing routine IVF or donor egg/sperm. This includes a thorough medical history of both partners.

Recipients are encouraged to speak with a mental health professional about the decision to use donor embryos and potentially parent children that are not related to them genetically. The recipient should have a pelvic exam and an assessment of her uterus (womb).

Embryo Donation Categories

Potential embryo donors fall into two categories:

1. **Known donors** - the donors selected agree to transfer their embryo(s) to a recipient previously known to them, as with a relative or friend.
1. **Anonymous donors** use the service to donate their Embryo(s) to unknown recipients.

Legal and Ethical Issues of Embryo Donation

Embryo donation can be a controversial process from both an ethical and legal standpoint. Of paramount importance is that informed consent and counseling be provided to both the donors of the embryos and the recipient(s) to address the potential issues that embryo donation might raise.

In addition, due to the absence of explicit laws regarding embryo donation in Kenya, all parties should consult with legal counsel regarding a pre-donation agreement and whether recognition of parentage by the courts is needed for the intended parent(s).

Pregnancy following embryo donation, just like in other forms of ART treatment, depends on the quality of the embryos that were frozen, the age of the woman who provided the eggs, and the number of embryos transferred.

4. Gestational Surrogacy

Gestational Surrogacy (GS), also called a gestational carrier, is an arrangement where a woman carries and delivers a child for another couple or person (intended parent(s)). When using a GS, the eggs used to make the embryos do not come from the carrier. Because the eggs will be retrieved from one woman and implanted in another, this technique requires the use of in vitro fertilization (IVF).

A Gestational Surrogate is used when an intended parent wants to have a child and either does not have a uterus or has a medical condition that would prevent carrying a pregnancy safely. Also, a GS may be considered for women who have a history that suggests a problem with her uterus such as recurrent miscarriage or IVF failure or when a female partner is absent (single male or gay couple).

In Kenya, an ideal Gestational Surrogate or rather the requirements for a gestational surrogate are;

- A healthy woman between the ages of 25 and 45yrs old
- She must have had a successful term pregnancy
- The carrier should have no more than five previous vaginal deliveries or two previous cesarean deliveries. Prior to becoming pregnant, the GC should talk about the risks of pregnancy with her healthcare provider.
- Medically and psychologically screened

The Gestational Carrier will have a complete history and physical examination performed to ensure that there are no reasons for her to avoid pregnancy.

The embryo recipient, her partner (if applicable) and the genetic parents will also be screened for sexually transmitted diseases.

It is important that the Gestational Surrogate and her partner (if appropriate) undergo clinical psychological counseling with a mental health professional. This and subsequent interviews will cover the potential psychological risks associated with the process including managing relationships with her partner, her children, her employer, and the intended parents. Psychological testing may be performed at the discretion of the counselor.

Psychological counseling with a mental health professional is also recommended for the intended parents. The counselor shall evaluate the couple for any unresolved or untreated addiction, abuse, or mental illness. The evaluation also shall include an exploration of the couple's expectations and relationship with the carrier and her family, plans for any relationship with the carrier after delivery, and plans to disclose the use of a carrier to the child that is born.

Compensation

A Gestational Surrogate is generally compensated for the time and effort involved in fulfilling this role. Compensation to the GS should be agreed upon before any treatment begins. The amount of compensation can be prorated based on the procedures performed. The compensation agreement should be documented in the contract between the carrier and the intended parents which should be drawn by an advocate knowledgeable in reproductive health laws.

The laws regarding Gestational Surrogacy are not yet established in Kenya and thus it is recommended that the GS and the intended parents have independent representation by lawyers who are experienced with GS prior to start of treatment.

Legal and Ethical considerations for third party reproduction

Third-party reproduction involves several legal and ethical issues. Written informed consent should be obtained for any and all procedures. In situations of known sperm or egg donors, both donors, as well as intended parents, are advised to have separate legal counsel and sign a legal contract that defines the financial obligations and rights of the donor with respect to the donated gametes.

With embryo donation, in the absence of statutes defining rights and responsibilities, a pre-donation agreement and a judicial determination of parentage either before or after the procedure are recommended.

With gestational carrier arrangements, legal contracts, in addition to delineating financial obligations, may include details regarding the expected behavior of the carrier to ensure a healthy pregnancy, prenatal diagnostic tests, and agreements regarding fetal reduction or abortion in the