In Vitro Fertilisation (IVF) & Intracytoplasmic Sperm Injection (ICSI)

Information for patients
This booklet informs you how an IVF (or ICSI) cycle is managed at Leeds Fertility.

You can find further information at: www.leedsfertilityclinic.co.uk and at our regular, free, New Patients’ Information Open Evenings (see website or Reception notice board for up-coming dates and details).

How to contact us

Please turn to page 51 of this booklet for urgent and non-urgent contact details.
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What is IVF / ICSI treatment?

Natural conception and fertility
Assisted conception by IVF takes over the natural processes. During each natural female monthly cycle, a woman releases one egg from one ovary from the fixed supply that she was born with. The egg takes two weeks to get ready to be released (ovulated) when it is picked up by the Fallopian tube and carried towards the womb. It meets the sperm in the tube and fertilisation happens here. The embryo (fertilised egg) then attaches to the womb lining that has prepared to receive it. A baby then develops. The process is coordinated by hormones (natural chemical messages).

A woman’s fertility is quite closely related to her age. She is most fertile in her 20s and early 30s. For all women, fertility naturally falls in their later 30’s and 40’s. This makes it harder to get pregnant naturally, and with IVF assistance, because the quality and number of the eggs is reduced. IVF treatment does not affect (improve) egg quality but it can increase the number of eggs available to be fertilised at a given time.

Some women have fewer eggs than average at birth and some women lose their eggs more rapidly in their younger years. There may be inherited (genetic) reasons for this and/or it can be caused by past illness or lifestyle choices such as smoking. There are tests that can help to predict a woman’s egg reserve and her likely response to / success with IVF treatment. (See Preparing for treatment: Tests pages 14 - 15).
Natural conception

FSH and LH hormones released from the brain into the bloodstream to stimulate egg development and ovulation.

Oestrogen and progesterone released from the ovary into the bloodstream to stimulate the womb lining.

Sperm meet the egg in the Fallopian tube where fertilisation happens.

The embryo travels into the womb to implant 5-7 days later.
Common reasons why IVF is advised

There are a variety of situations where IVF / ICSI treatment is recommended to assist or speed up conception (achievement of a pregnancy). It is very common for there to be more than one single reason for the delay.

The most common are:

- Blocked or damaged Fallopian tubes
- Irregular monthly cycles (infrequent or absent egg release / ovulation) e.g. Polycystic Ovary Syndrome
- Reducing ovarian (egg) reserve (natural ageing, endometriosis, past surgery)
- Sperm problems (quantity and / or quality)

The IVF process

During IVF treatment, hormones taken by injections, cause the ovary to make several eggs at the same time. These are taken out of the woman’s body in a minor surgical procedure.

The eggs are put together with her partner’s sperm in the laboratory for fertilisation to take place. This is when the sperm enters the egg and the contents of both are combined to create a unique being.

If ICSI is advised, the sperm are injected individually into each of the mature eggs collected. This is done if it is felt that few or no sperm would enter the eggs if left to do so alone.

The laboratory allows the fertilised eggs, now called embryos, to grow under observation for two to six days.
A process of selection takes place during this time, to identify as far as possible, the embryo(s) with the best chance of continuing to develop into a baby.

This embryo is then separated from the rest and transferred to the woman’s womb in a procedure that feels similar to having a cervical smear test. After the embryo transfer, further medicines are taken to give the embryo every chance to attach (implant) and start the journey of pregnancy. A standard urine pregnancy test should be positive after two weeks if the treatment has been successful.

If so, the first pregnancy ultrasound follows about three weeks later. At this stage, the pregnancy sac is large enough to see on the scan, along with a flickering heart beat.
Success rates
Please see our website for our latest figures and the HFEA website for the figures for babies born in the last year. About 40-50% couples will have a positive pregnancy test. About three quarters of these will go on to see a heart beat on the first scan.

Many embryos do not have the ability to develop into a baby. This is usually related to the genetic quality of the egg and does not always show up during the short time the embryo is under observation in the laboratory. The process of human development is very complex and if the embryo is faulty, it is almost always stopped in it tracks, very early on. This natural process prevents abnormal pregnancies from reaching an advanced stage in their development only to be lost later on.

Embryo storage
If you produce more good quality embryos than can be used for one treatment (transfer), they can be frozen and saved for use later on. Human embryos generally cope well with freezing and thawing (90% will survive) and this does not affect their ability to grow into a healthy child, regardless of how long they are frozen.

See our separate information booklet / online called ‘Frozen Embryo Transfer’ for details about treatment with frozen-thawed embryos.
How do I get IVF treatment?

Referral & funding
You can be referred to Leeds Fertility for discussion and assessment by your GP or your local District Hospital. IVF and other treatments involving eggs, sperm and embryos require a special license and there are limited clinics available with the required facilities (see legal aspects section page 37).

Leeds Fertility is a large unit receiving referrals from a wide area. We treat both NHS and self-funding patients under the same roof because of the legal requirements of the facility. Each area (Clinical Commissioning Group, CCG) has its own criteria for accessing NHS funding for treatment.

Your GP should be able to tell whether you fit the criteria for NHS-funded treatment for your area or not. All patients are entitled to an NHS consultation and investigations as are felt to be appropriate. We will provide you with the current price list for your treatment if needed. (See website: www.leedsfertilityclinic.co.uk).

Timescales
Once the decision has been accepted that IVF treatment is needed, your treatment should be able to start within six weeks. You will know whether you are pregnant or not after about another six weeks.

Self-funding patients do not take priority. We have the capacity to treat all patients fairly, equally and in a timely way. Self-funding does not speed treatment up.
What can I do to prepare for healthy pregnancy and boost my chances of success?

General lifestyle issues

• Stop smoking completely.
• Reduce alcohol intake to a minimum for both men and women. No safe limit has been identified so no alcohol consumption is advised.
• Women should have been vaccinated against german measles (rubella) or have confirmed immunity.
• Women should have an up to date, normal cervical smear test.
• Women should be taking folic acid (vitamin B) supplement at 400 micrograms daily before and during treatment, and for at least the first three months of pregnancy (buy over-the-counter ‘folic acid for pregnancy’ or ‘multivitamins for pregnancy’).
• Some women need to take high dose folic acid (5mg). Please speak to to your GP if you are diabetic, epileptic, overweight, have a gut condition that can cause reduced absorption, or have any history of spina bifida (neural tube defect) in a previous pregnancy.

• Both partners should aim for normal body weight for their height. Women in particular should aim for a body mass index ideally under 25kg/m\(^2\), and absolutely under 30kg/m\(^2\) to access NHS-funding. Treatment is less successful and more risky at heavier weights. Pregnancy is also less healthy with a higher risk of blood pressure problems and diabetes in heavier mothers. (See separate weight management guidance booklet or online).

• A healthy, varied diet and regular physical exercise are helpful for overall health, weight management and stress reduction.

• Discuss any other medication you take with your GP and specialist (s) to ensure any risks to yourself (from other medical conditions) and to your up-coming pregnancy / baby are minimised.

• Consider carefully the use of complimentary therapies, and please inform us what you are using / doing. Acupuncture is not known to be harmful and many patients find it helpful with managing stress. Other supplements that have not undergone conventional medicine testing will not be recommended.
Preparing for treatment: tests and support

- **Sperm analysis**: This is always done as part of the investigations work-up in the out-patient clinic. Even if you have had a sperm analysis done before (e.g. at your GP or District Hospital), it is often necessary to repeat it in the IVF clinic as our test is more detailed and can help to guide the best form of treatment we should be using (e.g. sperm injection or ICSI). Our samples are produced on site in discrete private rooms, by masturbation into a small sterile pot, which will be provided. If you are concerned that you may have difficulty producing a sample on the day of egg collection (not an uncommon anxiety) please ask about freezing a sample in advance as a back-up.

- **Hormone blood tests for the woman**: Day 1-3 of a cycle (whilst bleeding) **Follicle stimulating hormone (FSH)**, **Luteinizing hormone (LH)**, **Oestradiol (E2)** are required within six months of treatment starting (GP test).

  Anytime in the cycle **Antimullerian hormone (AMH)** is useful to guide the dose of hormones needed to stimulate your ovaries. This blood sample must be taken at Leeds Fertility and sent to a specialist lab for testing. It is not covered by the NHS and will incur a charge if you choose to have it (see price list).
• **Pelvic ultrasound baseline scan:** This is a screening scan that is performed internally (vaginally) to make sure there are no interfering factors such as fibroids (swellings in the muscle of the womb), polyps (overgrowths of womb lining), ovarian cysts (such as endometriosis) or swollen fallopian tubes. Any such findings may need further treatment before your IVF cycle can begin, in order to give you the highest chance of success. The scan will also assess ovarian reserve by looking for egg sacs (follicles) that are getting ready to develop mature eggs in the coming months. Polycystic ovaries have very many of these (more than 12 each side) and this makes them particularly sensitive to the IVF hormones. Women with polycystic ovaries will have a specially tailored treatment course to minimise the risk of producing too many eggs at once (**ovarian hyperstimulation syndrome** - see page 30).

• **Sexual health screen:** Both men and women are offered screening for common sexually transmitted infections and non-sexually transmitted vaginal infections that can reduce the chance of IVF treatment success if they are not treated. Often these infections can be present without obvious symptoms. We may refer on to the Sexual Health Service if necessary.
• **HIV, Hepatitis B, C and syphilis screen:** We must screen all patients whose sperm and eggs will pass thorough our treatment laboratories and/or into our freezing tanks in order to protect all patients from any possible contamination or new infection. No case of infection has ever occurred in this way but we continue to take precautions. Any patients found to have one of these infections will be counselled and referred to the appropriate specialist for on-going care. Leeds Fertility can not conduct the laboratory part of the cycle for these patients but we do have a partnership with another IVF unit that can. They provide laboratory space which is separate from their standard service.

• **New Patients Information Presentation:** All patients are kindly asked to listen to this talk that we provide just before your treatment cycle starts. You can access this, free of charge, in person at Leeds Fertility (see Reception or Notice Board or website for dates and time) or via the link on the website homepage. The talk will give you a rough time line and point out some important things that you need to understand clearly for your treatment to run smoothly. We will do all we can to support and help you to keep your treatment on track at home, in between the visits to Leeds Fertility.

• **Counselling and patient-to-patient support:** We recognise that struggling to conceive can be upsetting. We aim to provide supportive care for both partners through this process, regardless of the outcome. We have a highly-skilled team of counsellors who are all professionally registered (British Infertility Counsellors Association: www.bica.net).
• They provide support in dealing with the social and emotional aspects of fertility problems and help to find ways to cope with the on-going situation.

Counselling is free and usually delivered on Leeds Fertility premises. Some counsellors offer evening appointments. Please call **0113 206 3100** if you would like to make an appointment, or request a referral from the doctor or nurse attending to you.

Some patients choose to support each other through social media and there is a private Facebook page for patients from Leeds Fertility.

Infertility Network UK ([www.infertilitynetworkuk.com](http://www.infertilitynetworkuk.com)) is the leading national charity for people having difficulty conceiving. They also offer emotional and practical support with a wealth of personal experience.

There are circumstances where the clinical team calls upon the Leeds Fertility counsellors to discuss the implications of some of our treatments e.g. the use of donated eggs or sperm with the intended recipients. This is a legal requirement of our Licence and addresses some important issues you may not have thought of by yourselves.
The Leeds Fertility counsellors are also occasionally asked to meet with couples or individuals when a circumstance has given us cause to seek assurance, as far as we can do, as to the welfare of the child who may result from our treatment, within the intended family unit. Again, it is a legal requirement of our Licence to consider the wellbeing of the child who does not yet have a voice, and do all that we can to ensure that child will not be at risk of harm. The clinic does have the right to refuse treatment, having considered evidence from a wide variety of sources if necessary.

- Please speak to your consultant if you have any concerns in this area. Our Standard Operating Procedure is available on request.

How is IVF done?

Summary treatment cycle process
- Nurse consultation
- Stimulation
- Egg Collection
- Laboratory phase (Fertilisation and embryo monitoring)
- Embryo transfer
- ‘Two week wait’ to pregnancy test
- Follow-up (pregnancy scan or clinic appointment)
Nurse consultation

This one hour long appointment with a nurse specialist is the gateway into your treatment cycle. Both partners must attend.

Tasks:

1. **Planning calender:** You will be given a Treatment Diary explaining your individually-tailored treatment program and the expected dates when key parts of the process should fall.
   Please be aware that our bodies do not always ‘read the textbook’ and sometimes we have to reschedule for minor delays such as a period coming later than expected. This is quite normal and the service will stretch to fit you in.
   ![Calendar]

   Please bring your treatment diary to every visit after this.

2. **Medication injection teach:** The woman will be using medicines on a daily basis, some by injection. We will teach you both how to do this properly and safely. Many patients find this worrying to start with, but get the hang of it very quickly. The medicines are dispensed by a home-delivery pharmacy who will bring them to the address of your choice.

![Injection]
The nurse will show you examples of what will arrive and advise you how to store them. More information is available on our website e.g. injection teaching video.

3. **Consents:** Consent for treatment is an important and legally binding process. You will be registered with an online service called EngagedMD to guide you through the necessary information and signature process before your nurse consultation. The nurse will check your forms with you before they are approved for your records. You may have a copy for your own records if you wish.

Settlement of Invoice: If you are paying for your treatment, we respectfully ask that the bill is settled by the time of the nurse consultation. This can be done by card over the telephone **(0113 206 3157)** or in person on the day, with the Business Support Team on the unit.
Treatment protocols

The principle of IVF requires stimulation of the ovaries with hormone injections under the skin to produce many eggs at once. Egg release (ovulation) is controlled so that the eggs can be collected and removed from the body.

There are two commonly used ways of doing this, and a third process (the flare protocol) which is used less often:

1. **Long protocol**
   - This is where the natural ovulation mechanism is switched off for two to four weeks.

2. **Short protocol**
   - This is where natural ovulation is prevented for a shorter time (five to ten days).

3. **Flare protocol**
   - The natural ovulation mechanism is switched off for a medium time period.

The doctor will decide which one would suit your circumstances best. There are medical and safety reasons why one might be chosen over another and this will be tailored to your needs and explained individually.

We recommend that you choose a time of day to take your medicines and stick to it. Ideally, 21.00-22.00 is advised for the FSH stimulating injection.
Your medication plan will be carefully explained at your nurse consultation. Your personalised diary will set out your specific instructions. Please be prepared for some instructions to change depending on your response as the cycle progresses.

The treatment diary also contains further important information such as the use of other medicines, food intake (fasting), make-up, period of abstinence (no ejaculation) for the male partner before the treatment sperm is required. If you are particularly anxious, you may request a tranquiliser tablet to help you sleep the night before and remain calm on the day of the egg collection procedure.

**Egg collection**

The doctor reaches the eggs through the skin at the top of the vagina using the same kind of ultrasound machine that we use in the clinic to monitor egg development, but with a needle attached to a very gentle suction pump.

The egg collection procedure is done with fast-acting painkillers and sedatives given into a vein. It takes about half an hour. Most women do not remember the procedure happening (they are relaxed and comfortable) although they are not unconscious. This is not a general anaesthetic, which means that you can recover more quickly and get home sooner. A consultant anaesthetist will be close by, managing your comfort level.
You can expect to be heading home within four hours of the procedure once you have recovered and eaten, and the laboratory have reported the sperm sample to be satisfactory.

Progesterone supplements start on the night of the egg collection. You will be advised how and what to take before you leave Leeds Fertility. It is normal to experience some lower tummy discomfort (not severe pain or breaking through paracetamol pain-relief) and some light vaginal bleeding.

Please call the Leeds Fertility emergency phone if you are concerned and need advice (see page 51 for details).

**Laboratory phase**

The eggs and sperm will be mixed together on the afternoon of the harvest.

If ICSI (sperm injection) is required, this will be done at this time.
The need for ICSI is almost always known beforehand and you will be aware if this is planned for your treatment. Very occasionally, a sperm sample may be poorer than expected on the day of treatment.

The embryology scientists will discuss the possibility of injecting the eggs instead of the standard IVF insemination, with the consultant on duty and with you.

The main reason for suggesting ICSI is to give the eggs the best chance of actually achieving fertilisation, which is the first step towards embryo development.

Therefore it is worth all patients understanding some of the issues around this technique. *(See Risks of ICSI on page 34).*

Fertilisation happens during that night. Usually about 70% of the eggs accept the sperm. After this time, if they have not, there is no further chance of fertilisation. These eggs will be discarded the next morning at the fertilisation check. You will receive a telephone call from the embryologist informing you how many of your eggs have fertilised, and therefore how many embryos are now in the culture incubator.
The embryos will be supported in their further development for two to six days, until such time as the best quality one (or two) can be selected out for transfer into the womb. Embryos that reach the blastocyst stage of development (usually at day five) have a higher chance of attaching and producing a baby and it is the clinic’s ambition to transfer a blastocyst for you. However, if the number of embryos available to you is small (one or two only), it may be clear which is / are the best much earlier (day three). In this case, we would call you in for embryo transfer at this stage rather than keep the embryos in an artificial environment that will offer no further advantage over the woman’s womb. The policy of aiming for a blastocyst transfer does mean that for a small number of couples (2-5%), no suitable embryos may be available. This is discussed more in the risks of treatment section (see page 35 for details).

Leeds Fertility is pleased to be able to offer Embryoscope time-lapse imaging incubators. These machines allow the embryos to be cultured in a closed system (no opening of the ‘oven’ door while the ‘cake is rising’) because they have built-in cameras (microscopes) taking pictures of the embryos every 10 minutes. This means that details of the individual embryo’s development can be monitored throughout the culture period and pieced together in a short video clip. Without this technology, embryos are removed from a standard incubator and checked at snap shot time points (fertilisation, day three and day five).

The development in-between is never seen. As we come to understand more about the details of embryo development, so we expect to be able to select ‘good quality’ embryos more accurately and increase the success of treatment.
The latest data from our unit indicates that the use of Embryoscope results in a 1.3-fold increase in live birth rate per fresh embryo transfer and that the risk of early preterm birth and very low birth weight are reduced.

- Embryoscope incubation is separately funded so please check with the Team as to your position.

**If you wish to use Embryoscope you must declare this at the time of Nurse Consultation.** Please note that the maximum number of embryo slots available per couple is 12.

If you produce more than 12 embryos, the excess will be looked after in the standard incubators without time-lapse imaging.

*Images courtesy of The Association of Clinical Embryologists*
Embryo transfer

You will be called by the embryologist on the day of your transfer with news of your embryo development / quality and a recommendation of the proposed number of embryos to transfer. You will be given a time to attend (usually early afternoon) and advised to be filling your bladder in anticipation of the procedure. A comfortably full bladder helps the passage of the fine tube (catheter) containing the embryo that makes the procedure easier, quicker and safer.

The procedure itself does not require any pain relief or sedation. It is similar to having a smear test. We introduce the embryo through the vagina and cervix, guided by an ultrasound scan through the tummy. Partners are welcome to support the woman and watch from the side. After the transfer, you may empty your bladder immediately if necessary. There is no need to lie down and rest.

You will be given information about your pregnancy test timing and technique.
Two-week wait and pregnancy test
The wait after the transfer and before the pregnancy test is often described as the hardest time of an IVF treatment cycle. We will not usually need to see you during this time and generally recommend that you continue with your normal activities, in order to keep your mind off the uncertainty of the result. If you wish to exercise, we recommend low impact activity and not to swim.

Pregnancy test
We advise a urine pregnancy test is done 18 days after the egg collection. Instructions will be provided at the time of your transfer.

Pregnancy scan and follow-up
The first scan is done about five weeks after the egg collection when the pregnancy sac, fetal pole (baby) and a heart beat should be visible.

If all is well at this stage, we will discharge you back to your GP to make arrangements with the midwife and antenatal clinic. We shall look forward to the news of your new arrival in due course, and will then complete the information on your treatment with the HFEA register.
If your test is negative, you will be advised to book a follow-up appointment to discuss the cycle and your future plans.

**Treatment risks**

**Multiple pregnancy and the One at a Time initiative**

We all want to achieve a healthy pregnancy and live birth. This is more likely with a single baby at a time, rather than twins or more. IVF has a poor reputation for producing multiple pregnancies: these can be complicated for both mother and babies, sometimes with tragic outcomes. It is not wise to take unnecessary risks by transferring more than one embryo at a time in couples with a high chance of success. Therefore, it is our usual policy to transfer a single embryo in women under the age of 38 years, during the first or second cycle of treatment, where the embryo development has been good. This practice is consistent with the HFEA Code of Practice ([www.hfea.gov.uk](http://www.hfea.gov.uk)) and the One at a Time initiative ([www.oneatatime.org.uk](http://www.oneatatime.org.uk)). The chance of a pregnancy is closely related to female age (and egg quality) and to the performance of the clinic as a whole. Our figures show clearly that if we have two good quality day five blastocyst embryos, and we transfer both together, there is a 50% chance that if pregnancy results, it will be a twin implantation. If we only transfer one blastocyst, the chance of a pregnancy resulting is only about 1% lower than if two were transferred, but without the significant risks of multiple pregnancy. The Law permits the transfer of a maximum of two embryos in women under 40 years of age. Over 40 years, the maximum number of embryos permitted is three at any one time. We will be happy to discuss your embryo development and the context of your chances of pregnancy on the day of embryo transfer, if you have any concerns about the advice proposed.
Ovarian hyperstimulation syndrome (OHSS)

The purpose of IVF is to generate multiple eggs at once. All patients experience a mild form of hyperstimulation. A few (about 1%) will get significant symptoms and need special help or alteration to their treatment program. Patients with polycystic ovaries are particularly vulnerable and we take a number of precautions in planning the treatment to reduce the risk for these women.

A risk of OHSS may become apparent during the early scanning phase before egg collection. Your medication may be altered. Very occasionally, the stimulation may be abandoned altogether to be started again at a later date on a much lower dose. If the number of eggs harvested is very high, we may recommend that all the embryos created are frozen to allow you to get back to normal before a transfer is attempted.

Separate information will be provided on treatment with frozen / thawed embryos in due course.

The main reason for this is because a positive pregnancy test on top of OHSS can make the syndrome much worse and last for longer. This is unpleasant for the woman but also can be medically risky. Severe OHSS has been associated with blood clots (thrombosis), dehydration and kidney problems, on top of the bloating discomfort, nausea, vomiting and diarrhoea that occur with milder forms of the condition.
Some women need hospital admission to manage the symptoms and prevent complications. Most can be managed as out-patients with regular monitoring at Leeds Fertility. The condition eventually rights itself over a period of weeks. Further written information will be provided if you appear to be at risk of OHSS or indeed have signs of the condition. See separate OHSS leaflet.

If you suspect you may have symptoms of OHSS, please contact us directly at Leeds Fertility for advice (not your local hospital or GP). See back cover for contact details.

Miscarriage
The risk of miscarriage after a positive pregnancy test is approximately 20-30%, whether the pregnancy has been assisted through IVF or occurred through natural means. Once the pregnancy sac has been seen and the heart beat identified then the risk of miscarriage falls (<5%). The risk of birth defects in babies born after IVF is no greater than in naturally conceived pregnancies. Your personal risk is more likely to relate to your age, your family history and whether or not you have a multiple pregnancy.

Ectopic pregnancy
Embryos do not implant immediately upon transfer. There is a small chance that an embryo may drift up and settle in the Fallopian tube. This is an ectopic pregnancy which, if unidentified, may burst and cause serious internal bleeding. Women whose tubes have been identified to be less than perfect are at higher risk of ectopic pregnancy after natural or IVF conception.
We will perform your first pregnancy scan early (6+ weeks) if you are at risk. The standard first pregnancy scan is done at 7 weeks (3 weeks after your pregnancy test).

**Please note**

It is important to take a pregnancy test even if you have bled, and attend for the scan after a positive test. If a pregnancy sac is not seen on scan, a blood test is taken to measure the pregnancy hormone (hCG) level in your blood. You may be asked to attend for more tests after a few days.

If this hormone level is steady or slowly rising, then we may need to perform further investigations which may include a laparoscopy (surgery).

**Risks of the egg collection surgical procedure**

At the time of the egg collection a needle is carefully passed through the skin of the vagina into the ovary under ultrasound vision. The risks are rare and include the following:

- **Infection**
  
  The needle can transfer germs from your vagina into the pelvis and lead to an infection. The risk of this is higher:
  
  - If you already have infected tubes or an active vaginal or pelvic infection.
  
  - If you have endometriosis and especially if it is affecting the ovary in a cyst.
  
  - If you have internal scarring involving the bowel.
Pre treatment sexual health screening of both partners, Dalacin antibiotic vaginal cream and clean surgical technique all minimise the infection risk.

- **Bleeding or internal injury**
  The needle could also enter a blood vessel leading to internal bleeding or damage the bowel leading to internal infection. Further treatment, including surgery may be appropriate. The risk of this complication is quite remote and less than 0.001%.

**Risk of equipment failure**
Leeds Fertility maintains service contracts for all our equipment. There are also many safety checks in the laboratory to give early warning of any possible problems. Despite all our efforts, and very uncommonly, equipment failure may sometimes lead to loss of eggs or embryos. This is a ‘Category A’ incident that will be immediately notified to our licensing body (HFEA), the Leeds Teaching Hospitals Trust and to you. There would usually be a thorough investigation and steps taken to prevent a recurrence of similar problems. The HFEA also operates an Alert system which all clinics use to learn from incidents elsewhere and can then reduce risks locally.

**Other risks**
Although it has been suggested that the use of IVF hormones may increase the risk of ovarian cancer, these medicines have been used in treatment for over 50 years. There have not been any cases of ovarian cancer that can be directly liked to the use of fertility treatment hormones. The available evidence suggests that there is no increase in your risk over and above that which exists naturally.
Risks of ICSI

Intracytoplasmic sperm injection, ICSI has been used worldwide for over 20 years in the assistance of male factor infertility.

The risks described in this section reflect the current state of our knowledge and the guidance provided by the Human Fertilisation and Embryology Authority.

ICSI is an artificial, invasive technique and may also use sperm that would not otherwise be able to fertilise an egg. For these reasons, concerns about the potential risks to children born as a result of ICSI have been raised. The concerns mostly involve the risk of passing on a genetic problem that would not be transmitted under normal conception circumstances. The potential result is a fertility problem in the child, especially if it is a boy. The studies of ICSI children published so far have involved relatively small numbers of children and do not yet include effects that may be seen in older children or in the next generation. Work is on-going and we would encourage patients needing ICSI to participate in long term follow-up studies.

There is no clear evidence that ICSI results in more birth defects than occur randomly with natural conception. There is also no clear evidence to give cause for concern regarding the on-going physical and intellectual development of ICSI children.
Treatment failure

Possible reasons

- Failure to produce enough eggs in response to the hormone injections (weak ovaries).
- Failed release of the eggs before the egg collection (very uncommon).
- Unexpected illness in either of the partners.
- Failure of any eggs to fertilise: This may be due to problems with either the eggs, the sperm or both.
- Occasionally fertilised eggs fail to divide and continue their development. Not all fertilised eggs will divide to form embryos. If embryos do not reach the blastocyst stage of development in the laboratory, and none are available for transfer, it is clear that a pregnancy would not have resulted even if they had been transferred earlier e.g. on day 3. It is, of course, very disappointing, but the inevitable outcome is revealed earlier than might have been expected (after a negative pregnancy test). This does not necessarily mean that IVF treatment will never work and a follow-up appointment with a doctor will follow.

Although these circumstances do occasionally arise, they are not common.

It is more common for a pregnancy not to result, even when everything has apparently gone well. Sometimes we may not have an explanation for why a pregnancy fails to occur. We suspect that in most of these cases, the embryos were, in fact, faulty in their genetic make-up and were never destined to produce a baby.
Unfortunately, the time that the embryos spend under observation in the laboratory is short and we can not identify everything about their (genetic) chances of continuing to develop normally, and as far as a baby. When IVF embryos do undergo genetic testing, they are found to carry the same rate of genetic faults as naturally conceived miscarriages. This can be as high as 50%, and gets more common in women over the age of 40 years. There are often no signs of these faults at the early stages of development that we are able to observe (such as in the Embryoscope). There is still much work to do to try to overcome what can often feel like a lottery. You may rest assured that we will not stop trying.

We welcome feedback on the various aspects of our service. We use it to ensure that we are maintaining a high standard of patient experience and to try to improve the service that we provide. We would be grateful if you would spend a few moments to complete our questionnaire once your cycle is over.
Legal aspects of treatment: HFEA, confidentiality, consent, welfare of the child

The Human Fertilisation and Embryology (HFE) Act (1990, amended 2008) and the HFE Authority (HFEA) regulate all treatments involving human eggs, sperm and embryos.

The HFEA issues the Code of Practice that we work by and it inspects us regularly to ensure standards are maintained before renewing our License.

All UK clinic results are reported to them and are publically available (www.hfea.gov.uk).

HFEA register
The Authority keeps a confidential register of identifying information on all patients, their treatments, donors, recipients and children born after HFEA licensed treatments.

Since 2008, adults may request information from the HFEA as to whether they were conceived with donor material and the HFEA may disclose such identifying information as was available at the time of the treatment.

Confidentiality of fertility treatment
All information regarding your FERTILITY treatment is strictly confidential under our HFEA License and is subject to both the HFE Act and the general Data Protection Act.

We may only communicate with your general practitioner, referring consultant and other carers with your written consent.
Once we have disclosed treatment information to individuals who are not subject to the HFEA Licence (e.g. your GP) such information can no longer be controlled by us in its onward travel. It will still be regulated by the Data Protection Act and General Law of Confidentiality, as for all private medical information. In general practice, information will be accessible to other GPs and staff working within the practice even if your consent specifically named only one of the several GPs in your practice. When changing GPs, your medical records will be transferred to your new GP practice without any regard for any specific named consent you gave us in the past. The General Law of Confidentiality will apply.

From time to time your notes may be inspected at Leeds Fertility for audit (standards checking) by other officials e.g. HFEA members, Care Quality Commission, Patient Safety Agency and National Care Standards Commission.

You have the right to decline consent to share your fertility information but we need to consider your reasons for declining consent in our assessments. Generally, it is advisable for us to keep your GP informed of the progress of your treatment in case you need them in an emergency.

**Welfare of future children**

The Law states that ‘a woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father), and of any other child (other children in the household or the family) who may be affected by the birth’.
It is therefore our legal responsibility to have a written procedure for assessing the Welfare of the Future Child and that of any other existing child who may be affected by our treatment.

**Factors considered in assessment include**

- The couple’s commitment to having and bringing up a child.
- The couple’s ability to provide a stable and supportive environment for the child/children.
- The couple’s medical history and that of their families, considering factors that may risk the child’s wellbeing.
- Both partner’s health (including their ages) and their ability to provide maternal and paternal nurturing to the child.
- The couple’s ability to meet the needs of the children in the event of a multiple birth.
- Any risk of harm e.g. that of inherited disorders, transmissible disease, neglect or abuse.
- Any risk a new born may put on the welfare of the existing child with in the family.

Our protocol has been approved by our local ethics committee. Under specific circumstances, we may also need to contact your GP, other medical specialists, authorities and agencies e.g. social workers, police etc for information. This is to enable the members of the team at Leeds Fertility or the Clinical Ethics Committee in The Leeds Teaching Hospitals Trust to formally consider the welfare of the future child when appropriate.
Consents

Fully informed consent to the different aspects of fertility treatment takes quite a long time but it is critical to ensuring you and we understand our respective responsibilities in all possible circumstances. Further relevant information will be provided through the process in written and spoken forms. Please do not sign until you are completely clear and satisfied with your stated position. **Both partners must sign all of the consent forms before we can proceed with your treatment.**

Your consent advises us of your informed choice but does not commit you to undergo any form of treatment. **You have the right to change your mind until, but not after the event.** It is vital that all the issues are thoroughly considered beforehand and that snap decisions are not regretted afterwards.

You will have the following issues to consider at the start of treatment:

- Fresh IVF treatment.
- Freezing of eggs / sperm / embryos.
- Research on eggs / sperm / embryos.
- Long -term storage of eggs / sperm / embryos.
- Use of eggs / sperm / embryos after death.

**Consent to fresh IVF treatment**

Both partners must consent to the use of their eggs / sperm and creation of embryos with them, for the treatment of their current partner.
Please note that you have to decide the fate of your spare eggs / sperm and /or spare embryos and that we act as per your written consents.

**Consent to freeze eggs**
Eggs may be frozen to preserve fertility in single women likely to have an early menopause (usually due to chemotherapy for cancer treatment).

**Consent to freeze sperm**
Your sperm may be in storage if it has been banked before treatment. Not all the sperm stored may be used in one treatment cycle leaving some surplus to your immediate needs.

**Consent to freeze embryos**
The best quality embryo (s) is / are selected at the time of fresh transfer. Further good quality embryos may be stored. Poor grade embryos have a low chance of surviving the freeze-thaw process such that freezing is not a sensible option. Approximately 90% of good quality embryos survive the process and have a good chance of resulting in a pregnancy if they are intact. Embryo freezing can only be performed with your prior written consent. The legal storage limit for embryos is 10 years from the date of freezing. The period of storage can be extended under exceptional clinical circumstances, with the agreement of a fertility specialist doctor. You also have to decide the fate of the embryos in the event of death or mental incapacitation. We strongly advise you to maintain current contact details with us and recommend that you consider replacement of your frozen embryos at the earliest opportunity.
Consent to embryo donation

You can consider donating your embryos to help another couple. Before we can accept them for this purpose, you would both be required to have counselling to ensure all the implications have been considered, and the necessary screening tests would need to be completed. You might opt to do this if / when you have completed your family, or decided not to pursue treatment further yourselves.

Consent to egg / sperm / embryo research

All human embryo research requires specific permission (License) from the HFEA for the project in question. All research is experimental and embryos used or created during the project cannot be transferred for treatment after the project has finished. They must be allowed to perish. You may be offered the option to donate embryos for research, only if there is an active project running during the remaining time period available for your embryos to be in storage. Once the legal storage period is up, the embryos will have to be discarded. Embryos destined for research are anonymised which means that there will be no feedback to you of the outcome of the experiments.

Occasionally, embryos may be specifically used in genetic projects. If the results could have implications for your or your family’s future, you will receive more information and counselling before you agree to your embryos taking part. Offering to take part in a research project is always voluntary and will never affect your own treatment. You can change your mind and pull out at any time before your embryos are used.
Consent to training of embryology scientists at Leeds Fertility
Leeds Fertility is part of the Leeds Teaching Hospitals Trust and as such, is involved in the training of junior scientists. As part of training in techniques such as egg and embryo handling, freezing, thawing or injection, it is necessary to use real eggs, sperm and embryos. These will only ever be those that are not required for your treatment and would be otherwise discarded (e.g. unfertilised eggs, surplus sperm or poorly developed embryos). Your consent will be requested for this, in order to train junior staff, improve our service and develop new techniques.

Consent to humane discarding of spare embryos
Only good quality embryos can be successfully frozen, donated to another couple or used for research. If you do not wish prolonged culture with a view to freezing then you must instruct us to humanely discard your spare embryos.

Consent to the use of eggs / sperm / embryos after death
Men can opt to permit their female partner to use their sperm or embryos created with them after their death. There are ethical and legal concerns that you must consider very carefully before making this choice.

We will require you to have a discussion with the counsellor to consider the implications to all parties fully, if you are considering this.
Glossary

- **Biochemical pregnancy:** This is a pregnancy where the embryo has tried to implant but has not continued to develop. Pregnancy hormone reaches the bloodstream and urine to make a pregnancy test positive but the level is invariably low / weak and falls to zero within days.

- **Blastocyst:** This is a particular stage of development of an embryo which should be reached by day 5-6 after egg collection. A blastocyst has 50-60 cells and they have begun to separate into those that will form the baby and those that will form the placenta (afterbirth). A small area of fluid separates the two types of cells. Shortly after this stage the embryo will hatch and should implant into the lining of the womb.

- **Cleavage:** Cleavage is the term used to describe the multiplication of the cells of the embryo.

- **Down-regulation:** This is the first phase of treatment in a long cycle where the natural cycle is switched off.

- **Ectopic pregnancy:** This is when the pregnancy implants somewhere other than the heart of the womb where it should be. The commonest location is in one of the fallopian tubes but ectopics can also occur in the cervix and the top corners of the womb where the tube comes into the main cavity (cornual ectopic) even when the tubes have been removed.

- **Eggs:** A woman’s lifetime supply of eggs is present in the ovary at birth. They reduce in number and quality with time. They pass on the woman’s half of the genetic instructions to the embryo / baby.
• **Embryo:** Once the fertilised egg begins to cleave (multiply its cells) it is called an embryo.

• **Fertilisation:** Fertilisation is when the genetic material from the egg and sperm combine to create a new and unique cell which may go on to develop into an embryo and then a baby.

• **Follicles:** These are the sacs in the ovary that contain the egg. One follicle develops in every natural monthly cycle. The IVF process should cause several to develop at the same time which makes the ovaries larger for a short time (several weeks).

• **FSH:** Follicle stimulating hormone causes the eggs to mature in the ovary.

• **GnRH Agonist:** A hormonal drug that first stimulates and then inactivates the pituitary gland e.g. Prostap, Buserelin, Naferelin. These can be used to block ovulation during long IVF cycles and cause ovulation in short IVF cycles.

• **GnRH Antagonist:** A hormonal drug that inactivates the pituitary gland e.g. Orgalutran, Cetrotide, only used to prevent ovulation in short IVF cycles.

• **Gonadotrophins:** Hormones produced naturally by the pituitary gland to stimulate the ovary to produce and release eggs e.g. FSH, LH. These drugs are produced as medicines to over-stimulate the ovary during IVF to get lots of eggs ready at once e.g. Merional, Menopur, Gonal F, Puregon.
• **HCG:** Human chorionic gonadotrophin is also a gonadotrophin but it is not produced in the pituitary. Normally, it is only produced by the placenta (afterbirth) during pregnancy. It is able to act like LH, but is stronger. We often use it in injection form to begin the ovulation process (trigger) before the egg collection. It can also help to prepare the womb lining for implantation.

• **LH:** Luteinising hormone is a gonadotrophin which causes the release of the egg at ovulation and prepares it for fertilisation by the sperm.

• **Luteal phase:** This is the phase after egg collection (or ovulation), including the embryo transfer, up until the pregnancy test.

• **Miscarriage:** Any positive pregnancy test which does not reach 24 weeks of pregnancy and the potential for a live-born child is a miscarriage. Miscarriage is as common after IVF as it is after natural conception. Bleeding in early pregnancy is not always bad news, especially if there is no cramping pain. Unfortunately some pregnancies miscarry without any outward signs (bleeding) and are not identified until a scan is done.

• **Oestrogen:** This hormone is naturally produced by the follicle in the ovary as the egg is growing. Its main job is to thicken the lining of the womb for the pregnancy to implant. It can also be given in tablet or skin patch form e.g. Progynova, Elleste.
• **OHSS:** Ovarian hyperstimulation syndrome is a risk of IVF treatment which can be serious if not recognised and treated. It happens when the ovaries are over-sensitive to the stimulation (FSH) injections and produce too many follicles. It can cause pain, abdominal bloating, sickness, diarrhoea, dehydration and rarely, serious blood clots. You will be warned if you are at risk, for the symptoms and signs to look out for and report to us for further advice.

• **Ovary:** Stores all the woman’s eggs for her whole life and produces hormones.

• **Pituitary gland:** In the head, behind the nose, produces many hormones including those that control the ovary and testis.

• **Progesterone:** This hormone is naturally produced by the follicle after ovulation and is also responsible for preparing the lining of the womb for implantation. It can also be given as a vaginal pessary e.g. Cyclogest or as an injection e.g. Gestone, Prontogest, Lubion.

• **Sperm:** The sperm develop in the man’s testes and continue to do so throughout adult life. They do not suffer the same deterioration with age as the woman’s eggs, as they are constantly being replaced. They pass on the man’s half of the genetic instructions to the embryo / baby.

• **Stimulation:** This is the phase where the daily injections stimulate the ovaries to produce multiple eggs.

• **Trigger shot:** (Also known as the “Late Night Injection”). This is usually hCG, however, can also be buserelin. This injection begins the release of the egg 35h before the egg collection. The timing is specific to you and you should follow your personalised instruction.
Useful resources

Human Fertilisation and Embryology Authority, HFEA
• www.hfea.gov.uk
  The regulatory body website has lots of information for patients.

Fertility Network UK
• www.fertilitynetworkuk.org
  The UK’s leading infertility support network offering extensive information and support through treatment. They provide advice regarding funding and a variety of factsheets.

British Fertility Society
• www.britishfertilitysociety.org.uk
  The UK professional society promoting high quality practice and research.

British Infertility Counselling Association
• www.bica.net
  The professional association of infertility counsellors in the UK.
Multiple birth matters
• www.oneatatime.org.uk
  This site provides information behind the drive to reduce multiple pregnancies during assisted conception treatments.
• www.multiplebirths.org.uk
• www.tamba.org.uk
  These two sites offer a wealth of information on twins and multiple births / pregnancies.

Health information for before and during pregnancy
• www.nhs.uk/conditions/pregnancy-and-baby/
  This is a comprehensive NHS resource on preparing for and achieving a healthy pregnancy.

The Miscarriage Association
• www.miscarriageassociation.org.uk
  If you have been affected by miscarriage, ectopic pregnancy or molar pregnancy you will find information and support here.

The Daisy Network
• www.daisynetwork.org.uk
  This charity provides support and information for women who are facing premature ovarian insufficiency (premature menopause) and its consequences.
Endometriosis UK
• www.endometriosis-uk.org
  Leading UK charity providing information and support for those with endometriosis.

Polycystic Ovary Syndrome (PCOS)
• www.nhs.uk/conditions/polycystic-ovarian.../Pages/Introduction.aspx
• www.verity-pcos.org.uk
  An NHS resource for information and a reputable patient support group.
Contact us

By post
• Leeds Fertility, Leeds Teaching Hospitals NHS Trust, Seacroft Hospital, York Road, Leeds, LS14 6UH

By email
• leedsth-tr.leedsrmuenquiries@nhs.net

Online
• Web: www.leedsfertilityclinic.co.uk

By telephone

Mon-Fri 08.00-17.00:
• For all NHS appointments: 0113 206 3100
• For clinical queries: 0113 206 3102

Sat-Sun 08.00-12.00
• Clinical queries only: 0113 206 3102

In an Emergency

During working hours
• Please call appointments or clinical queries as needed on the above numbers.

Outside working hours
• Please call Leeds Teaching Hospitals switchboard on 0113 243 3144 and ask to be put through to the Duty Nurse / Doctor for Leeds Fertility.
• If necessary, attend your local Accident & Emergency department.