NHS
Bristol, North Somerset and South Gloucestershire
Integrated Care Board

Infertility Assessment & Treatment

Criteria Based Access/Prior Approval

Assessment of Infertility – Criteria Based Access
Treatment of Infertility – Prior Approval

Funding for the assessment and treatment of infertility will only be granted by the ICB for:

- Heterosexual couples who have not conceived after two years of regular unprotected sex (exceptions apply in certain circumstances as described within the policy).
- Single women who have not conceived after two years of regular unprotected sex.
- Single women who have not conceived after 6 unstimulated cycles of independently funded Human Fertilisation and Embryology Authority (HFEA) approved Intrauterine Insemination (IUI)
- Same sex couples who have undergone 6 independently funded unstimulated cycles of HFEA approved IUI and have not conceived.
- Men who have been shown to have low or zero sperm counts can also be assessed.

NOTE: For heterosexual and same sex couples, If either partner has living offspring, the couple is not able to access NHS fertility services including assessment
For single women, if they have living offspring, they are not able to access NHS fertility services including assessment.

Section A - General Principles for all Patients

Points that should be noted when considering whether patients are eligible to access NHS funded infertility assessment and treatments:

1. Fertility treatment should be offered in the least invasive format appropriate, namely investigation and assessment, followed by assisted conception. All referrals for assessment and treatment should be made on the form published on the BNSSG websites and accompanied by a referral letter setting out detailed clinical information and background.
2. Individuals who do not meet the eligibility criteria set out in the relevant section of this policy or have received NHS funded In Vitro Fertilisation (IVF) treatment elsewhere are not eligible for treatment under this policy.
3. The prospective mother must not be older than their 39th birthday at referral and the prospective father should be not older than their 54th birthday at referral.
4. Where a prospective mother has previously received NHS funded treatment as part of another couple, they will not be barred from accessing NHS funded treatment under their current relationship where they meet all criteria. They will not be managed as single women within the scope of this referral.
5. For heterosexual and same sex couples, If either partner has living offspring, the couple is not able to access NHS fertility services including assessment. For single women, if they have living offspring, they are not able to access NHS fertility services including assessment.
6. Individuals who have had unsuccessful NHS funded fertility treatment, or have a child, will not be eligible to have NHS funded consultations with fertility services to assess their condition and secure treatment advice.
7. For the purposes of this policy, the commencement of IVF/ Intracytoplasmic Sperm Injection (ICSI) cycle is defined as commencement of ovarian stimulation by fertility services, or if no drugs are used, when an attempt is made to collect eggs/oocytes. Any patient who completes this step, regardless of the outcome, is deemed to have had one full cycle of IVF/ICSI. Therefore, if a cycle is abandoned for clinical reasons this is still counted as the fresh cycle that the couple are entitled to. One frozen cycle using frozen embryos will follow a fresh cycle if deemed clinically appropriate. Patients will not be eligible for further NHS funded investigation and fertility treatment following completion of this cycle.
8. A full IVF/ICSI treatment cycle includes:
    - Diagnostic tests, scans and pharmacological therapy
    - Counselling for couples
    - Stimulation of prospective mother's ovaries to produce oocytes
    - Harvesting of the oocytes
    - Fertilisation using IVF or ICSI (assisted hatching is not provided)
    - One fresh embryo transfer
    - If unsuccessful, within twelve months of cryopreservation, one frozen embryo transfer from remaining frozen embryos [maximum of 2 embryos per cycle]

Continued below

Section A - General Principles for all Patients (cont'd)

- A follow up consultation with fertility services post IVF treatment.
- Where patients have completed their NHS funded full cycle of IVF treatment but have frozen embryos remaining in storage, they can elect to self-fund further treatment with the fertility services.

9. The individual's GP must have given their positive recommendation to proceed to treatment. Account must be taken of additional factors such as active hepatitis,

Section B - Investigation, Assessment and Advice on Infertility Issues
Criteria Based Access for Heterosexual Couples

For review and consideration by the GP at time of referral to the Fertility Service.
In order to access services to investigate and assess issues with infertility, individuals must meet all of the following criteria:

1 An individual maybe referred if:
   a. The individual has failed to conceive after two years of regular unprotected sexual intercourse
      Or
   b. If the individual has undergone 6 cycles of independently funded unstimulated IUI using sperm from an HFEA approved source.
      Or
   c. If there is a sexual health condition where the patient is unable to have penetrative sex. Individuals must have completed all relevant therapy provided by Psychosexual or Andrology services.

2 **Patients may be referred outside this timeframe if**:
   a. there is a known condition which is likely to affect fertility (e.g., severe oligomenorrhoea, low sperm count <1 million per ml taken on two occasions 3 months apart, bilaterally blocked fallopian tubes, azoospermia, stage 4 endometriosis or premature ovarian insufficiency)
      Or
   b. there is known premature ovarian insufficiency, defined as follicle-stimulating hormone (FSH) greater than 25, measured 2 months apart - coupled with oligomenorrhea or amenorrhea
      Or
   c. Alternatively, an anti-Müllerian hormone (AMH) marker of less than 1
      Or
   d. FSH > 25 on 2 occasions 3 months apart.

3 If the female being assessed will be older than their 39th birthday within the two year time frame, they can be referred after one year as long as they can still be referred before their 39th birthday.

4 Recurrent miscarriage is not an indication for patients to access fertility services although they may be referred for gynaecological investigations and treatments if appropriate.

5 Individuals, or if in a couple, both prospective parents must be registered with a BNSSG GP.

6 The individual must not have previously received a cycle of NHS funded fertility treatment to the level outlined in this policy.

7 Patients who have previously self-funded unsuccessful fertility treatment are eligible for NHS funded fertility treatment as long as they meet the criteria within this policy. Outcomes from previous fertility treatment will be considered as part of the clinical assessment and patients should be aware that multiple failures to conceive through fertility treatment is indicative of poor conception success rates.

Continued Below

Section B - Investigation, Assessment and Advice on Primary Infertility Issues for Heterosexual Couples. Criteria Based Access (cont'd)

8 Individuals must be non-smokers as confirmed in their primary care records. This includes prospective fathers or partners. Individuals who are smokers can be referred to a fertility service but should also be referred to smoking cessation services and be able to demonstrate by compliance with that service that they are non-smokers prior to commencing assessment. Prospective fathers and partners who smoke should be informed that there is an association between smoking and reduced semen quality and, although the impact of this on male fertility is uncertain, they should cease smoking prior to treatment to improve sperm quality.

9 The prospective mother's Body Mass Index (BMI) must be between 19 and 29.9 kg/m2 for a period of six months as evidenced from her primary care record. The evidence is clear that obesity negatively impacts upon successful natural conception and fertility treatment. Prospective mothers with a BMI of 30 and above should be offered a referral to weight management services to reduce their weight prior to assessment and treatment by fertility services (see NICE Recommendations).

10 Where the prospective mother is aged between 37 and up to her 39th birthday, her BMI must be between 19 and 35 kg/m2 prior to referral for assessment. Prospective mothers with a BMI above 29.9 in this age group should be referred to weight management services at the same time as being referred to fertility services to assist her to lose weight and aid fertility.

11 A prospective father is not older than their 54th birthday. Male fertility has been shown to decrease with age, with evidence of greater incidence of disability poor sperm function and DNA degradation.

12 Neither the prospective mother, nor any partner, has been sterilised in the past even if it has been reversed and the sterilisation is the cause of the fertility problems.

Section C - Investigation, Assessment and Advice on Infertility Issues for Same Sex Couples. Criteria Based Access

For review and consideration by the GP at time of referral to the Fertility Service.
In order to access services to investigate and assess issues with fertility, couples must meet all of the following criteria:

1. Same sex couples may be assessed if self-funded insemination on at least 6 non-stimulated cycles from an HFEA approved clinic has failed to lead to a pregnancy. NHS funding is not available for access to donor insemination facilities for fertile women or surrogacy.
2. Same sex couples where either:
   a. both partners have fertility issues, i.e., blocked fallopian tubes or anovulation
   Or
   b. where only one partner is sub-fertile, where possible, the partner who is fertile should try to conceive before proceeding to interventions involving the sub-fertile partner.
3. Recurrent miscarriage is not an indication for patients to access fertility services although they may be referred for gynaecological investigations and treatments if appropriate.
4. Both the individual being assessed, and their partner must be registered with a BNSSG GP.
5. The couple must not have previously received a cycle of NHS funded fertility treatment to the level outlined in this policy.
6. Patients who have previously self-funded unsuccessful fertility treatment are eligible for NHS funded fertility treatment as long as they meet the criteria within this policy. Outcomes from previous fertility treatment will be considered as part of the clinical assessment and patients should be aware that multiple failures to conceive through fertility treatment is indicative of poor conception success rates.
7. The prospective mother must be a non-smoker as confirmed in their primary care records. Patients who are smokers may still be referred to a fertility service, but should also be referred to smoking cessation services and be able to demonstrate that they are non-smokers prior to assessment. Partners of prospective mothers who smoke should also be offered a referral to smoking cessation services in order to improve their health and support their partner.
8. The prospective mother's Body Mass Index (BMI) must be between 19 and 29.9 kg/m2. The evidence is clear that obesity negatively impacts upon successful natural conception and fertility treatment. Prospective mothers with a BMI of 30 and above should be offered a referral to weight management services in order to reduce their weight prior to assessment and treatment by fertility services.
9. Where the prospective mother is aged between 37 and up to her 39th birthday, her BMI must be between 19 and 35 kg/m2 prior to referral for assessment. Prospective mothers with a BMI above 29.9 in this age group should be referred to weight management services at the same time as being referred to fertility services in order assist her to lose weight and aid fertility.
10. The partner of a prospective mother who has undertaken NHS funded fertility treatment, whether successful or not, will be deemed to have received their entitlement to NHS funded fertility treatment upon completion of this cycle in line with heterosexual couples and will not be eligible for a further NHS funded treatment with their partner.

Section C - Investigation, Assessment and Advice on Primary Infertility Issues for Same Sex Couples. Criteria Based Access (cont'd)

11. The prospective mother has not been sterilised in the past even if it has been reversed and the sterilisation is not the cause of the fertility problems.
12. Both members of the couple must accept joint legal responsibility for any child produced through fertility treatment.

Section D. Investigation, Assessment and Advice on Primary Infertility Issues for Single Women. Criteria Based Access

For review and consideration by the GP at time of referral to the Fertility Service.
In order to access services to investigate and assess issues with fertility, single women must meet all of the following criteria:

1. Single women may be assessed if:
    a. they have undergone 6 independently funded non-stimulated cycles of IUI from an HFEA approved source and have not conceived.
    b. The individual has failed to conceive after two years of regular unprotected sexual intercourse
2. Patients may be referred outside of the two-year timeframe if:
    a. there is a known condition which is likely to affect fertility (e.g., severe oligomenorrhoea, bilaterally blocked fallopian tubes, stage 4 endometriosis, premature ovarian insufficiency)
    Or
    b. there is a sexual health condition where the patient is unable to have penetrative sex. Individuals must have completed all relevant therapy provided by a Psychosexual or Andrology service
    Or
    c. there is known ovarian failure, defined as follicle-stimulating hormone (FSH) greater than 25, - measured 2 months apart - coupled with oligomenorrhea or amenorrhea
    Or
    d. they have an anti-Müllerian hormone (AMH) marker of less than 1
    Or
    e. their FSH > 25 on 2 occasions 3 months apart
3. NHS funding is not available for access to donor insemination facilities for fertile women or surrogacy.
4. Recurrent miscarriage is not an indication for patients to access fertility services although they may be referred for gynaecological investigations and treatments if appropriate.
5. The individual being assessed must be registered with a BNSSG GP.
6. The individual must not have previously received a cycle of NHS funded fertility treatment to the level outlined in this policy.
7. Patients who have previously self-funded unsuccessful fertility treatment are eligible for NHS funded fertility treatment as long as they meet the criteria within this policy. Outcomes from previous fertility treatment will be considered as part of the clinical assessment and patients should be aware that multiple failures to conceive through fertility treatment is indicative of poor conception success rates
8. The prospective mother must be a non-smoker as confirmed in their primary care records. Patients who are smokers may still be referred to a fertility service, but should also be referred to smoking cessation services and be able to demonstrate that they are non-smokers prior to assessment.

Continued below

Investigation, Assessment and Advice on Primary Infertility Issues for Single Women

Continued

9. The prospective mother's Body Mass Index (BMI) must be between 19 and 29.9 kg/m2. The evidence is clear that obesity negatively impacts upon successful natural conception and fertility treatment. Prospective mothers with a BMI of 30 and above should be offered a referral to weight management services in order to reduce their weight prior to assessment and treatment by fertility services.

10. Where the prospective mother is aged between 37 and up to her 39th birthday, her BMI must be between 19 and 35 kg/m2 prior to referral for assessment. Prospective mothers with a BMI above 29.9 in this age group should be referred to weight management services at the same time as being referred to fertility services in order assist her to lose weight and aid fertility.

11. The individual who has undertaken NHS funded fertility treatment, regardless of previous relationship status, whether successful or not, will be deemed to

Section E - Assisted Conception. Prior Approval
The Fertility Service is required to secure funding from the CCG following assessment and before treatment commences under Sections E, F and G.

If IVF has been unsuccessful, patients will not be eligible for further IUI.

Assisted conception services include Intrauterine Insemination (IUI), ovulation induction medication and donor insemination. In order to access assisted conception services following investigation and assessment, couples must be assessed against the following criteria:

1. Each prospective mother will be offered up to three treatment cycles of IUI and up to a total of six treatments of the three techniques.
2. The BMI of the prospective mother must remain between 19 and 29.9 kg/m2 whilst accessing fertility treatment. This is because the success of fertility treatment is significantly reduced where the prospective mother is outside of these limits.
3. An assessment of a prospective mother's overall chance of successful pregnancy through natural conception or with IVF should be made with one of the following measures to predict the likely ovarian response to gonadotrophin stimulation in women who are considering treatment:
    a. anti-Müllerian hormone [AMH]
    Or
    a) b. timed follicle-stimulating hormone [FSH] and Estrogen.
4. The prospective mother must have;
    a) an AMH of greater than or equal to 5.4 pmol/l
    Or
    b) a FSH level less than or equal to 15iu/l.

Where AMH/FSH levels are outside of this, donor eggs will be the expected pathway.

5. If donor sperm is used the couple must be able to demonstrate in writing joint legal responsibility for any child born as a result of treatment.

Section F - In-Vitro Fertilisation or Intracytoplasmic Sperm Injection
PRIOR APPROVAL
For Fertility Service consideration when planning treatment – see above.
1. One full treatment cycle of IVF or ICSI (with oocyte donation and/or surgical sperm recovery if required) in line with Section A Points 7 and 8, will be offered to individuals where other assisted conception techniques have failed or carry a very low chance of success

In addition to all the criteria above, the following criteria must also be satisfied at the time of treatment:
1. The prospective mother's serum, if using their own eggs, FSH must be less than or equal to 12iu/l at the time of treatment or an AMH of greater than or equal to 5.4 pmol/l.

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2. The prospective father's serum FSH level must be less than 15 iu/l or testicular volume must be greater than 8ml (as assessed by a fertility specialist) for surgical sperm recovery and storage to be undertaken.
3. If donor sperm / oocytes are used the couple must be able to demonstrate in writing joint legal responsibility for any child born as a result of treatment.

Section F - Surgical Sperm Retrieval for Male Infertility - NHS England
This treatment is funded by NHS England please refer to the NHS England Clinical Commissioning Policy Surgical Sperm Retrieval for Male Infertility at:
https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2013/05/16040_FINAL.pdf
Or contact NHS England for more information.

NB: Patients must meet the criteria to access treatment under this policy in order to access treatment under the NHS England policy.

Section G - Sperm Washing – Exceptional Funding Request

Funding approval must be sought by the GP or the Fertility Service prior to referral by submission of an Individual Funding application form.

In cases where suppression of viral load is not possible then sperm washing could be available but only on recommendation from a specialist in communicable disease based on U=U guidelines.

BNSSG will approve funding for sperm washing with one full cycle of fertility treatment in conjunction with this policy where:

a. the couple qualify for fertility treatment under this policy, and
b. the prospective father is HIV positive.

Sperm washing is a technique used to decrease the risk of Human Immunodeficiency Virus (HIV) transmission in HIV positive prospective fathers, because the HIV infection is carried by the seminal fluid rather than the sperm. Research has shown that it can reduce the risk of transmission by 96%. However, there may still be a small risk of HIV transmission which some couples may find unacceptable.

Patients can be seen, assessed and treated by local fertility services although a sperm-washing service is only available at the Chelsea & Westminster (C&W) Hospital in London, and at the time of drafting this policy, no other clinics in the UK offer a sperm-washing service.

Section H - Pre-Implantation Genetic Diagnosis
This is funded by NHS England – please contact them for more information.

Section I - Funding of Surrogacy Arrangements and Treatments – Individual Funding Request
The CCG does not fund any element of surrogacy. Funding approval must be sought by the GP or the Fertility Service prior to referral by submission of an Individual Funding application form.

Maternity Care Arrangements
The Commissioner commissions maternity services to provide appropriate support, guidance and care to women during and after pregnancy and these services will continue to be available to surrogates.

BRAN

For any health- related decision, it is important to consider **"BRAN"** which stands for:

- **B**enefits
- **R**isks
- **A**lternatives
- Do **N**othing

Benefits

The primary benefit of fertility treatment is to provide the opportunity for people who are unable to become pregnant naturally to become pregnant.

This assessment stage can support the development of treatment of plans that can help to reduce some of the adverse elements of pregnancy. This can also enable patients to adopt health lifestyle practices that can optimise them for treatment and increase the likelihood of conception.

Risks

Fertility treatments are generally considered safe, carrying small risks to the patient. Fertility treatment, and the conditions described within this policy to support said treatment, will not completely negate the impact of pregnancy.

The main risks of fertility treatment are multiple pregnancy and Ovarian Hyperstimulation Syndrome (OHSS), which can happen if the ovaries are over-stimulated. This can make some women very ill, and they may need to spend time in hospital and have intensive treatment.

Women who receive IVF treatment are at a slightly higher risk of an ectopic pregnancy. The potential impact on the patient's mental health and wellbeing is likely to be impacted following ectopic pregnancy. Consequently, clinicians in primary care and those providing fertility treatment should recognise the potential risks and discuss with each patient as appropriate.

Similarly, IVF can become less successful with age. The risks of miscarriage and birth defects can increase with the age of the recipient.

It is likely that women may experience side effects to certain medications used during IVF. Due consideration should be given to the impact this might have on their general health and wellbeing, including the emotional impact of the process.

Alternatives

Studies exploring alternatives such as the use of Complementary and Alternative Medicine have concluded this is not associated with improved pregnancy rates. The National Institute for Health and Care Excellence (NICE) states further research is needed before such interventions can be recommended.

Adoption is a further alternative.

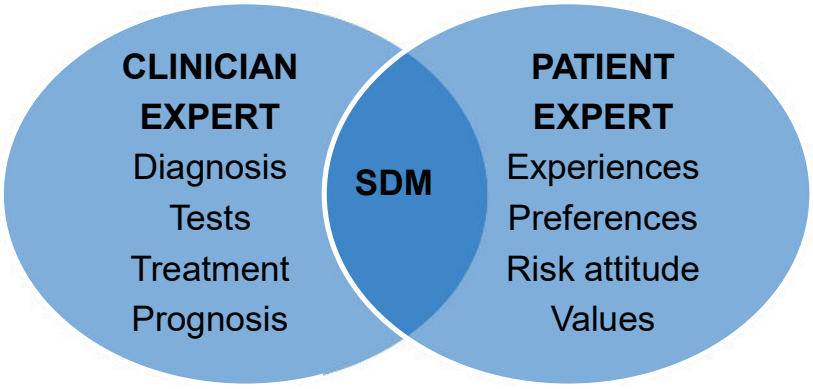
Do Nothing

Remember, you always have the option to do nothing. Doing nothing is an equally reasonable option to doing something. Sometimes "not yet" is a good enough answer until you gather more information.

Shared Decision Making

If a person fulfils the criteria for Infertility, it is important to have a partnership approach between the person and the clinician.

Shared Decision Making (SDM) is the meeting of minds of two types of experts:



It puts people at the centre of decisions about their own treatment and care and respects what is unique about them. It means that people receiving care and clinicians delivering care can understand what is important to the other person. The person and their clinician may find it helpful to use 'Ask 3 Questions':

1. What are my options? (see sections above)
2. What are the pros and cons of each option for **me**?
3. How can I make sure that I have made the right decision?

Infertility – Plain Language Summary

An estimated one in seven couples have difficulty conceiving. In the UK it is estimated that 84% of women would conceive within one year of regular unprotected sexual intercourse. This rises to 92% after two years and 93% after three years. This includes women with fertility problems.

In men, a fertility problem is usually because of low numbers or poor quality of sperm. Female fertility decreases with increasing age. For women aged 35, about 95% who have regular unprotected sexual intercourse will get pregnant after three years of trying. For women aged 38, only 75% will do so.

Other factors which affect fertility success rates include obesity and social factors such as alcohol and drug misuse and therefore this policy has criteria on these subjects.

In vitro fertilisation (IVF) is one of several techniques available to help people with fertility problems have a baby.

During IVF, an egg is removed from the woman's ovaries and fertilised with sperm in a laboratory.

The fertilised egg, called an embryo, is then returned to the woman's womb to grow and develop.

It can be carried out using your eggs and your partner's sperm, or eggs and sperm from donors.

Intracytoplasmic sperm injection (ICSI) is a type of IVF treatment that involves drawing up a single sperm into a very fine glass needle and injecting it directly into the centre of the egg. The fertilised egg (embryo) can then be transferred into the womb of the woman as in a normal IVF cycle. The live birth rates for ICSI and conventional IVF are similar.

The major development of ICSI means that as long as some sperm can be obtained fertilisation is possible.

Intrauterine insemination (IUI), also known as artificial insemination, is a fertility treatment that IUI involves separating sluggish, non-moving or abnormally shaped sperm and injecting directly into the womb.

This policy has been developed with the aid of the following:

1. NICE (2017) Fertility Problems: Assessment & Treatment (Clinical Knowledge Summary) www.nice.org.uk
2. National Library of Medicine (2015) 'Live Birth Rate Associated with Repeat Invitro Fertilisation Cycles'.

Due regard

In carrying out their functions, the Bristol, North Somerset and South Gloucestershire Clinical Policy Review Group (CPRG) are committed to having due regard to the Public Sector Equality Duty (PSED). This applies to all the activities for which the CCGs are responsible, including policy development and review.

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Support

If you would like further copies of this policy or need it in another format, such as Braille or another language, please contact the Customer Services Team on: **0117 900 2655** or **0800 073 0907** or email them on BNSSG.customerservice@nhs.net.

Glossary

AMH	Anti-Müllerian hormone (AMH) - Comparison of an individual's AMH level with respect to average levels is useful in fertility assessment, as it provides a guide to ovarian reserve and identifies women that may need to consider either egg freezing or trying for a pregnancy sooner rather than later if their long-term future fertility is poor.
Azoospermia	Azoospermia is where he testicles are either producing no sperm or very low numbers of sperm and sperm is not present in the ejaculate.
Embryos	Refers to a fertilised Oocyteoocyte. It is called an embryo until about eight weeks after fertilisation and from then it is instead called a foetus.
Endometriosis	Endometriosis is a condition where tissue similar to the lining of the womb starts to grow in other places, such as the ovaries and fallopian tube.
FSH	Follicle-Stimulating Hormone (FSH) regulates the development, growth, pubertal maturation, and reproductive processes of the human body.
ICSI	Intracytoplasmic Sperm Injection is a variation of in-vitro fertilisation in which a single sperm is injected into the inner cellular structure of an egg.
Infertility	In the absence of known reproductive pathology, infertility is defined as failure to conceive after regular unprotected sexual intercourse for 2 years.
IUI	Intrauterine Insemination (IUI) involves timed insemination of sperm into the uterus. This can be completed as part of a natural unstimulated cycle (unstimulated IUI) or following stimulation of the ovaries using oral anti-oestrogens or gonadotrophins (stimulated IUI).
IVF	In-Vitro Fertilisation (IVF) is a technique whereby eggs are collected from a woman

	and fertilised with a man's sperm outside the body.
Ooctye (Eggs)	Refers to a female gametocyte or germ cell involved in reproduction. In other words, it is an immature ovum, or egg cell.
Oligomenorrhoea	Oligomenorrhoea is infrequent menstruation defined by a cycle length between 6 weeks and 6 month
Regular Unprotected Sex	Unprotected sex is sex without any contraception or condom. The NHS recommends that people trying to get pregnant have sex every 2-3 days across the days mid cycle around the time of ovulation.
Sperm	Refers to the male reproductive cells
Sperm, Oocyte or Embryo Cryopreservation	Sperm, Oocyte or Embryo Cryopreservation is the freezing and storage of Sperm, Oocyte or Embryos that may be thawed for use in future in-vitro fertilisation treatment cycles.