# ASSISTED CONCEPTION POLICY

## – Intra-Uterine Insemination (IUI), In Vitro Fertilisation (IVF) AND Intracytoplasmic sperm Injection (ICSI)

| Policy Number: | CLIN 5 |
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| Version: | 3 |
| Ratified by: | PCT Board |
| Name of originator/author: | Working Group- Commissioning |
| Name of responsible committee/individual: | Quality and Performance Committee |
| Date issued: | July 2008 |
| NHSLA Standard (if applicable): | N/A |
| Standards for Better Health (if applicable): | C18 |
| Last review date: | December 2011 |
| Next review date: | December 2012 |

## EQUALITY IMPACT ASSESSMENT TOOL

To be completed and attached to any procedural document as part of main document sited between version control sheet and contents page

| | | Yes/No | Comments |
|---|---|---|---|
| 1. | **Does the document/guidance affect one group less or more favourably than another on the basis of:** | | |
| | • Race | no | |
| | • Ethnic origins (including gypsies and travellers) | no | |
| | • Nationality | no | |
| | • Gender | yes | Please see comments relating to age |
| | • Culture | no | |
| | • Religion or belief | no | |
| | • Sexual orientation including lesbian, gay and bisexual people | no | |
| | • Age | yes | There is an upper age limit for Women with regard to treatment as recommended by NICE, this is line with clinical evidence of diminishing fertility in women as they age. This is not the case with Men and therefore there is no age restriction for Men |
| | • Disability - learning disabilities, physical disability, sensory impairment and mental health problems | no | |
| 2. | **Is there any evidence that some groups are affected differently?** | yes | The Policy impacts on couples who have children from previous relationship in that this disqualifies them from treatment |
| 3. | **If you have identified potential discrimination, are there any exceptions valid, legal and/or justifiable?** | | The PCT will consider individual case requests for treatment outside the Policy. |
| 4. | **Is the impact of the document/guidance likely to be negative?** | yes | The issue of previous children remains a contentious issue nationally; however NHS Surrey is consistent with SEC SHA PCTs. This is line with the guidance issued by the Secretary of State for Health when the guidance was published that priority should be given to childless couples. |
| 5. | **If so, can the impact be avoided?** | | The impact is in line with both local and national guidance; however revised guidance is expected during |

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| | | | this financial year. The policy will be reviewed at this point. |
| **6.** | **What alternative is there to achieving the document/guidance without the impact?** | | NHS Surrey is committed to accepting the South East Coast Policy Recommendation Committee advice, they have concluded that this exclusion should remain in the criteria following review by clinical staff and patient representatives. The Policy is consistent with recently published model criteria |
| **7.** | **Can we reduce the impact by taking different action?** | | The impact can be reduced by allowing couples with children from previous relationships access to treatment, however this is not consistent with specialist advice. |

For advice in respect of answering the above questions, please contact Tina Gull Equality and Diversity Lead E-mail: Tina.Gull@surreypct.nhs.uk Telephone 01932 723543 If you have identified a potential discriminatory impact of this procedural document, please contact as above.

| **Names and Organisation of Individuals who carried out the Assessment: Please give contact details** | **Date of the Assessment** |
|---|---|
| T Gull, E Stevens NHS Surrey | 12.08.2009 |
| S Lewis Jones Surrey Coalition of Disabled People | |

## VERSION CONTROL SHEET

| Version | Date | Author | Status | Comment |
|---|---|---|---|---|
| 1 | April 2008 | Working Group: Commissioning Niki Bartrop, Abigail Groves, Marion Heron, Anna Raleigh and Sue Waters | Draft | Out for consultation |
| 1 | July 2008 | Working Group: Commissioning | Final | Approved at Board |
| 2 | July 2009 | Niki Baier/ Avril Imison | Draft | Reviewed and agreed as part of specialist commissioning group for South East Coast |
| 2 | August 2009 | Niki Baier/ Avril Imison | Final | Approved at Risk and Clinical Governance Committee |
| 3 | Dec 2010 | Kelly Morris | Draft | Reviewed to include SEC policy recommendation re: cancer treatment and sperm retrieval |
| 3 | Dec 2011 | Amelia Whittaker/ Michael Baker | Draft | Reviewed and now includes:<br>- Paragraph on the Armed Forces Covenant added.<br>- Oocyte vitrification included and time limit for storage confirmed as 10 years<br>- Smoking: details of referral to Surrey Stop Smoking Service now included.<br>- BMI changed to reflect NICE classification of a healthy weight.<br>- Confirmation that the lower age limit (23 years) will not apply to patients that are accessing Assisted Reproductive Techniques for Fertilisation Preservation<br>- Update to current service providers<br>-Clarification of NHS provision for self funding patients<br>- Gamete/Embryo Storage guidelines |

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| | | | | -FSH/AMH levels reviewed by clinicians<br>- Single Embryo transfer- HFEA guidelines added<br>-Guidance regarding women in same sex couples and women not in a partnership<br>-HFEA code of ethics added to criterion<br>Couples to take up funding offer within 6 months |
| 3 | Feb 12 | | Final | Approved by Quality and Performance Committee. |
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## EQUALITY STATEMENT

NHS Surrey aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. It takes into account the Human Rights Act 1998 and promotes equal opportunities for all. This document has been assessed to ensure that no employee receives less favourable treatment on grounds of their gender, sexual orientation, marital status, race, religion, age, ethnic origin, nationality, or disability.

Members of staff, volunteers or members of the public may request assistance with this policy if they have particular needs. If the member of staff has language difficulties and difficulty in understanding this policy, the use of an interpreter will be considered.

NHS Surrey embraces the four staff pledges in the NHS Constitution. This policy is consistent with these pledges.

## COMMISSIONING POLICY

The management of fertility includes both primary and secondary care support and intervention where appropriate, including advice on lifestyle changes that are likely to improve the probability of conception.

1. In Vitro Fertilisation (IVF) Intra-Uterine Insemination (IUI) and Intracytoplasmic Sperm Injection (ICSI) will normally be funded only in the context of the fertility care pathway recommended by protocol for the clinical management of infertility (Appendix 2).

2. Access to NHS funding for specialist assisted conception treatments will normally be on the recommendation of a local NHS Consultant Gynaecologist and on some occasions from local NHS Consultant Urologist.

3. NHS Surrey will provide, in line with South East Coast Policy Recommendation PR 2008-07:

    a. Up to 6 cycles of IUI, as clinically indicated and at the discretion of the referring gynaecologist, for eligible couples

    b. A maximum of four embryo transfers (including no more than two transfers for fresh cycles), for eligible couples

4. The current providers for treatment are:
   Nuffield Health Woking Hospital
   Croydon Health Services NHS Trust
   Queen Mary's Hospital, Roehampton (Kingston Hospital NHS Trust)

5. The specialist fertility units will be solely responsible for initial consultation, treatment planning, counselling and advising patients, consent all drugs, egg collection, semen analysis, embryo transfer, pregnancy test, all

consumables, pathology tests, scans and Human Fertilisation & Embryo Authority (HFEA) fees if required.

6. This policy should be read in conjunction with the NHS Surrey Criterion for Access to Intra-Uterine Insemination (IUI), In Vitro Fertilisation (IVF), Intracytoplasmic Sperm Injection (ICSI) (Appendix 1). Couples **must** meet all the criteria in order to be eligible for NHS funding of treatment.

7. **Pre-implantation genetic diagnosis** can avoid transmission of serious genetic disease. Funding of pre-implantation genetic diagnosis is separate from infertility treatment and is covered by the London Genetics Panel and South East Coast Specialised Commissioning Group. Referral is made by Consultant to this panel.

8. **Sperm Donation** - NHS Surrey does not fund sperm donation procedures.

9. **Egg Donation** - NHS Surrey does not fund egg donation procedures.

10. **Surrogacy** - NHS Surrey does not fund any element of surrogacy procedures.

11. **IVF treatment and drugs -** These elements are included in the cost of the package managed by the lead Consultant provided by the specialist unit and will not be funded as separate elements by Primary Care clinicians (GPs and/or Nurse Prescribers).

12. **Private/Self Funding Patients** - Patients who are undergoing treatment outside of an NHS pathway will not be funded or reimbursed for drugs or additional tests incurred as a result of self funded/private treatment.

13. **In vitro maturation** - will not be funded, due to limited evidence of effectiveness.

14. **Blood borne viruses and sperm washing** - Sperm washing for the prevention of transmission of blood borne viruses will not be funded, due to limited evidence of clinical and cost-effectiveness. However, the evidence will be kept under review.

15. **Cancer treatment** - NHS Surrey will fund treatment for people due to undergo cancer treatment that will affect their long term fertility, as long as they meet all applicable criteria (Appendix 1) for treatment. Patients with cancer seeking egg or sperm donation are not covered by this policy.

16. **The Armed Forces Covenant** - The Armed Forces community should enjoy the same standard of, and access to, healthcare as received by any other UK citizen in the area they live. Those serving personnel and veterans should receive priority assisted conception treatment where it relates to a condition which results from their service in the Armed Forces (such as serious genital injuries), subject to clinical need.

NHS Surrey

## NHS Surrey Criteria for Access to Assisted Conception
## Intra-Uterine Insemination (IUI), In Vitro Fertilisation (IVF) and Intracytoplasmic Sperm Injection (ICSI)

A. NHS Surrey will fund up to six cycles of IUI and two full cycles of IVF/ICSI treatment per eligible couple.
B. All couples will be expected to have completed the primary and secondary care pathways (as defined in Appendix 2) appropriate to them before eligibility for IVF, IUI or ICSI is considered. Sub fertility will be defined as no live birth following insemination at, or just prior to, the known time of ovulation, on at least ten documented non stimulated cycles or fertility problem demonstrated at investigation.
C. One cycle of IVF is defined as one full cycle including ovulation induction, egg retrieval, fertilisation and implantation including all appropriate diagnostic tests, scans and pharmacological therapy and embryo freezing (of appropriate embryos), storage and frozen embryo transfer .
D. NHS Surrey expects all service providers to follow the guidance of the Human Fertilisation and Embryology Authority (HFEA) supporting single embryo transfer to reduce the number of multiple pregnancies.
E. NHS Surrey will fund assisted conception treatment prior to cancer treatment that is likely to cause infertility if the couple meet the applicable criterion.
F. Couples must be registered with a general practitioner based in Surrey.
G. These criteria will be reviewed on a regular basis.
H. If the patient does not meet the criteria in this policy and the patient's clinical circumstances are considered by the requesting clinician to be exceptional the clinician is able to submit an individual funding request for consideration. The Individual funding request policy can be found on NHS Surrey's website: http://www.surreyhealth.nhs.uk/index.php/2011-09-21-11-07-58/individual-funding-requests-ifr

| Reference | Title | Criterion |
|---|---|---|
| 1 | Duration of Sub-fertility | IUI, IVF and ICSI will be funded in couples that have been attempting to conceive for at least 36 months unless they have an identifiable cause and unless clinical judgement dictates otherwise. |
| 2 | Age of woman | Funding is available for couples where the woman is aged 23 – 39 at the time of treatment.<br><br>Exceptions are made for;<br>• women who are aged 39 at the point of referral to an IVF unit but they must be |

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| | | treated within six months of their 40th birthday.<br><br>• women undergoing full cycles that include subsequent frozen embryo transfers (if the initial cycle was unsuccessful), then the same age stipulation applies, i.e. that they must commence the final frozen cycle within 6 months of their 40th birthday.<br><br>• the lower age limit (23 years) will not apply to patients that are accessing Assisted Reproductive Techniques for Fertilisation Preservation due to receiving clinical treatments that are likely to result in long term sub fertility. |
| 3 | Age of male partner | No upper age limit for male partner (as per adoption laws) |
| 4 | Women in same sex couples/and women not in a partnership | Sub fertility treatment will be funded for women in same sex couples or women not in a partnership if those seeking treatment are demonstrably sub fertile.<br><br>In the case of women in same sex couples in which only one partner is sub fertile, clinicians should discuss the possibility of the other partner receiving treatment before proceeding to interventions involving the sub fertile partner.<br><br>NHS funding will not be available for access to insemination facilities.<br><br>Women in same sex couples and women not in a partnership should have access to professional experts in reproductive medicine to obtain advice on the options available to enable them to proceed along this route if they so wish. |
| 5 | Previous infertility treatment | Couples will *not* be funded if they have already had three previous cycles of IVF/ICSI (irrespective of how these were funded).<br><br>This means that couples will be funded:<br><br>• For up to six cycles of initial IUI, as clinically indicated and at the discretion of the referring gynaecologist<br>• For **two** cycles of IVF or ICSI if no previous cycles have been funded by the NHS, or if they have already received one non-NHS funded cycle<br>• For **one** cycle of IVF/ICSI if the couple has already received one NHS funded cycle or two non-NHS funded cycles |

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| | | Overall, eligible couples will be funded for a maximum of 6 cycles of IUI and **four** embryo transfers (including no more than two transfers from fresh cycles)<br><br>Couples must take up the offer of IUI/IVF/ICSI within six months of being referred to the IUI/IVF/ICSI service provider<br><br>If a cycle is abandoned for reasons of poor response or failure of fertilisation this will count as one cycle and embryo transfer<br><br>If a cycle results in a miscarriage, this will counted as one embryo transfer<br><br>Women who have attempted IVF/ICSI will not be offered subsequent IUI |
| 6 | Childlessness | Neither partner in a couple could have a living child from their relationship or any previous relationship. A child adopted by the couple or adopted in a previous relationship is considered to have the same status as a biological child. |
| 7 | FSH Level | FSH levels should be checked between day 1 and 4 of the menstrual cycle with an LH and Oestradiol level. Only women whose FSH has never exceeded a level of 11.9 iu/l or less when an oestradiol level checked on the same day is 249 pmol/l or less will be eligible for treatment with the sample timed within 6 months of date of referral. For those with no periods the sample can be timed at any date but the same maximum levels apply. |
| 8 | AMH | This is under review, awaiting publication of the forthcoming NICE Guidance (April 2012). Currently there is no clinical consensus to move to AMH. |
| 9 | Gamete/Embryo storage | Sperm storage will be funded for post-pubertal males under the age of 55 years who are about to undergo medical treatment which is likely to result in long term sub fertility. Subsequent assisted conception procedures using the sperm will not be funded unless the other eligibility criteria are met by the couple.<br><br>Embryo storage and Oocyte (egg) vitrification will be funded for female patients who meet criteria and who are about to undergo medical treatment which is likely to result in long term sub fertility. Subsequent assisted conception procedures using the eggs will not be funded unless the other eligibility criteria are met by the couple.<br><br>Funding will be provided for storage up to the maximum of 10 years (statutory storage period: Human Fertilisation and Embryology (HFE) Act 1990 (as amended). |

| 10 | Storage of surplus embryos following a fresh cycle of NHS funded IVF/ICSI | Freezing and storage of viable embryos from NHS funded IVF will be funded for up to 2 years (or the female partner's 40th birthday if this is sooner). NHS Surrey expects all frozen cycles to be completed prior to commencement of a second fresh cycle. |
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| 11 | Surgical Sperm Retrieval | Surgical sperm retrieval will be commissioned in appropriately selected patients, provided that the azoospermia is not the result of a sterilisation procedure or the absence of sperm production, providing the couple meet all areas of criteria. |
| 12 | Sterilisation | Assisted conception will not be provided to couples if their sub-fertility is the result of sterilisation in either partner |
| 13 | Body Mass Index | Women must have a BMI of between 18.5 and 29.9 inclusive for a period of 6 months or more before receiving any assessment treatment. They must be informed of this criterion at the earliest possible opportunity in their progress through infertility investigations in primary and secondary care. GPs are encouraged to provide unambiguous and clear information about BMI criteria to infertile couples. |
| 14 | Smoking | Only non-smoking couples (both partners) will be accepted for IVF treatment inclusive for a period of 6 months or more before assessment for treatment.<br><br>Smoking couples must be referred to NHS smoking cessation services (www.surreyquit.net or telephone 0845 602 3608) and demonstrate that they are non smokers for a period of 6 months or more prior to any assessment for treatment.<br><br>They must be informed of this criterion at the earliest possible opportunity in their progress through infertility investigations in primary care and secondary care. GPs are encouraged to provide unambiguous and clear information to infertile couples.<br><br>A statement should also be issued at the time of publishing the eligibility criteria, emphasising the importance of an active, healthy lifestyle and highlighting the dangers of smoking and passive smoking, obesity, alcohol and caffeinated beverages as important causes of infertility. |
| 15 | HFEA Code of Ethics | Couples not conforming to the HFEA's Code of Ethics, will be excluded from having access to NHS funded assisted fertility or other treatment. This includes consideration of the 'welfare of the child which may be born' which may take into account the importance of a stable and supportive environment for children as well as the pre-existing health status of the parents. |

## APPENDIX 2 –NICE Pathway for Fertility Treatment

### Assessment and treatment for people with fertility problems

**Initial advice for people concerned about delays in conception:**
- Cumulative probability of pregnancy in general population:
  - 84% in 1st year
  - 92% in 2nd year
- Fertility declines with a woman's age
- Lifestyle advice:
  - Sexual intercourse every 2–3 days
  - ≤ 1–2 units alcohol/week for women; ≤ 3–4 units/week for men
  - Smoking cessation programme for smokers
  - Body mass index of 19–29
  - Information about prescribed, over-the-counter and recreational drugs
  - Information about occupational hazards
- Offer preconceptional advice:
  - Folic acid
  - Rubella susceptibility and cervical screening

**Infertility:**
Failure to conceive after regular unprotected sexual intercourse for 2 years in the absence of known reproductive pathology
*This guideline does not include the management of people who are outside this definition, such as those with sexual dysfunction, couples who are using contraception and couples outside the reproductive age range.*

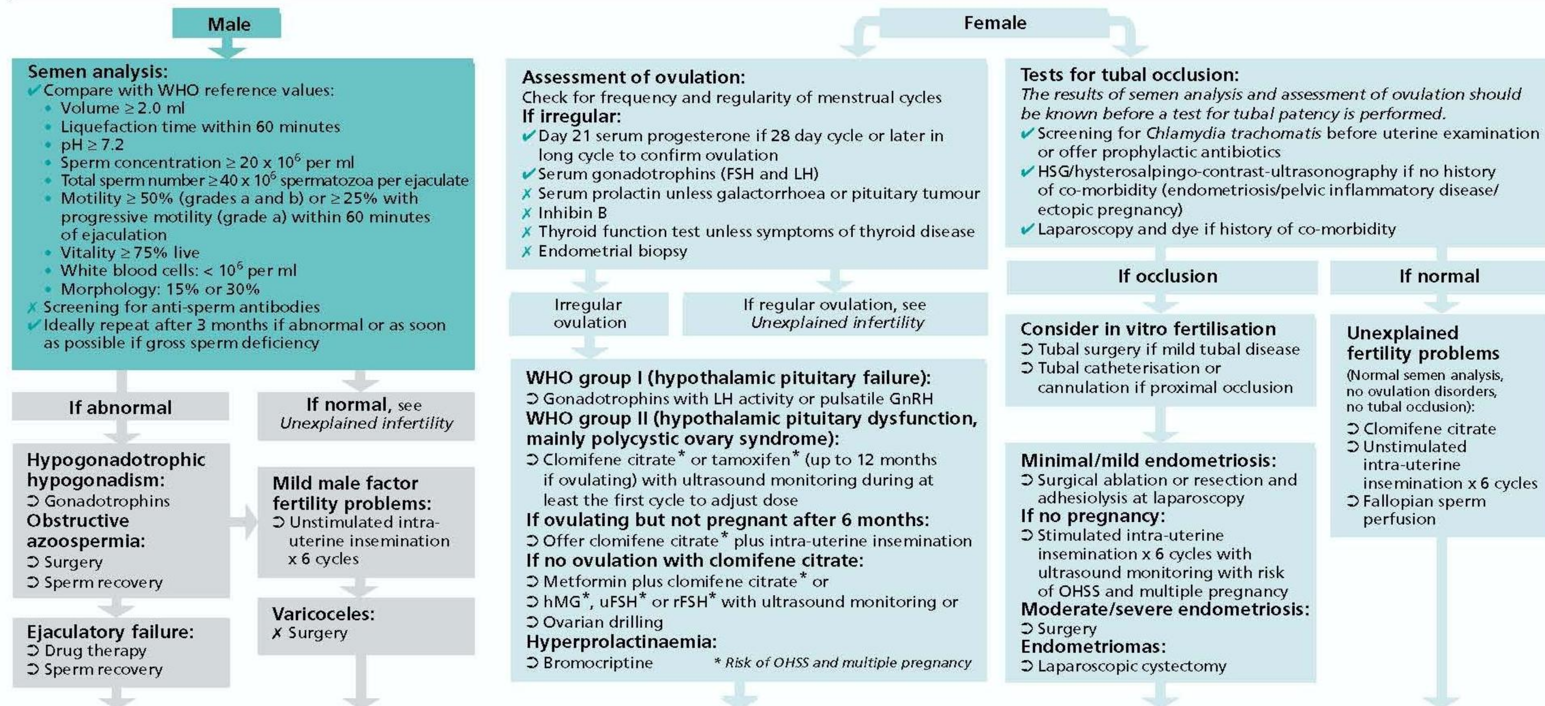
**Early investigation if:**
- History of predisposing factors (such as amenorrhoea, oligomenorrhoea, pelvic inflammatory disease or undescended testes); woman's age ≥ 35 yrs; people with HIV, hepatitis B and hepatitis C; prior treatment for cancer

**People preparing for cancer treatment:**
- Follow Royal College of Physicians and Royal College of Radiologists guidance
- Cryostorage of gametes and/or embryos

**Principles of care:**
- Couple-centred management
- Access to evidence-based information (verbal and written)
- Counselling from someone not directly involved in management of the couple's fertility problems
- Contact with fertility support groups
- Specialist teams

### Clinical investigation of fertility problems and management strategies

For people who have not conceived after 1 year of regular unprotected sexual intercourse



## If no pregnancy with azoospermia, bilateral tubal occlusion or 3 years' infertility *and* the woman is aged 23–39 years, offer up to 3 stimulated cycles of in vitro fertilisation treatment

**Additional principles of care for people undergoing in vitro fertilisation treatment:**
Access to evidence-based information (verbal and written) on risks/implications of assisted reproduction, including health of resulting children; genetic counselling; consideration of welfare of the child

**Factors affecting the outcome of in vitro fertilisation treatment:**
- Salpingectomy before in vitro fertilisation treatment for women with hydrosalpinges
- Optimal woman's age is 23–39 years at time of treatment
- Increased success with previous pregnancy and/or live birth
- Ideal body mass index is 19–30
- Increased success with low alcohol/caffeine intake
- Increased success in non-smokers
- Consistent for first 3 cycles of treatment, effectiveness after 3 cycles is uncertain

**Procedures for in vitro fertilisation treatment:**

**1. Offer screening:**
✔ HIV, hepatitis B, hepatitis C; specialist referral if positive

**2. Ovulation induction:**
✗ Natural cycle
✔ Pituitary down-regulation with GnRH agonist long protocol
✔ GnRH agonist with gonadotrophins with consideration to minimising cost
✗ GnRH antagonists
✗ Growth hormone adjuvant
✔ Monitor follicular development with ultrasound: clinics should have protocols for management of OHSS
✔ Oocyte maturation with human chorionic gonadotrophins
✔ Oocyte retrieval: offer conscious sedation (follow Academy of Medical Royal Colleges guidance)
✗ Follicle flushing
✗ Assisted hatching

**3. Embryo transfer:**
✔ No more than 2 embryos to be transferred during any 1 cycle
✔ Offer cryostorage of supernumerary embryos if more than 2 embryos
✔ Frozen embryos to be transferred before further stimulated cycles
✔ Ultrasound-guided embryo transfer on day 2 or 3, or on day 5 or 6

**4. Luteal support:**
✔ Progesterone

**Women should be informed of the risks of OHSS and multiple pregnancy**

### Management options associated with in vitro fertilisation treatment and other forms of assisted reproduction

**Intracytoplasmic sperm injection – for couples with:**
- Severe semen quality deficits
- Azoospermia
- Poor in vitro fertilisation treatment response

**Screening:**
- Male karyotype

**Donor insemination – for couples with:**
- Azoospermia
- Genetic/infectious disease in male partner
- Severe rhesus isoimmunisation
- Severe semen deficits

**Screening of sperm donors:**
- Follow British Andrology Society guidance

**Assessment of female partner:**
✔ Confirm ovulation
✔ HSG if no pregnancy after 3 cycles

**Donor insemination:**
✔ Time insemination with either urinary luteinising hormone or basal body temperature changes
✔ If regular ovulation, offer 6 unstimulated cycles

**Oocyte donation – for women with:**
- Premature ovarian failure
- Gonadal dysgenesis including Turner syndrome
- Bilateral oophorectomy
- Ovarian failure following chemotherapy or radiotherapy
- Certain cases of in vitro fertilisation treatment failure
- Genetic disorder transmission to offspring

**Screening of oocyte donors:**
- Follow Human Fertilisation and Embryology Authority guidance

**Oocyte donors:**
- Risks of ovarian stimulation and oocyte collection

**Egg sharing:** counselling

**This algorithm should, where necessary, be interpreted with reference to the full guideline**

**Key:** FSH follicle-stimulating hormone; GnRH gonadotrophin-releasing hormone; HIV human immunodeficiency virus; hMG human menopausal gonadotrophin; HSG hysterosalpingography; LH luteinising hormone; OHSS ovarian hyperstimulation syndrome; rFSH recombinant FSH; uFSH urinary FSH; WHO World Health Organization