Draft - SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	11J/0234
Service	Assisted Conception Service
Commissioner Lead	NHS Dorset Clinical Commissioning Group
Provider Lead	
Period	01 April 2019 – 31 March 2022
Date of Review	To be reviewed Annually

1. Population Needs

1.1 National/local context and evidence base

In the general population (which includes people with fertility problems), it is estimated that 80% of women would conceive within one year of regular unprotected sexual intercourse. This rises cumulatively to 90% after two years and 93% after three years.

It is estimated that infertility affects 1 in 7 heterosexual couples in the UK. Since the original NICE guideline on fertility published in 2004 there has been a small increase in the prevalence of fertility problems, and a greater proportion of people now seeking help for such problems.

The main causes of infertility in the UK are (per cent figures indicate approximate prevalence):

- unexplained infertility (no identified male or female cause) (25%)
- ovulatory disorders (25%)
- tubal damage (20%)
- factors in the male causing infertility (30%)
- uterine or peritoneal disorders (10%).

Infertility can be primary, in couples who have never conceived, or secondary, in couples who have previously conceived. It is estimated that infertility affects one in seven couples in the UK. There has been a small increase in the prevalence of fertility problems and a greater proportion of people now seeking help for such problems.

Healthcare professionals should define infertility in practice as the period of time people have been trying to conceive without success after which formal investigation is justified and possible treatment implemented

1.2 Evidence Base

This specification is designed to sit alongside the legislative provisions of Infertility treatment and the Care Standards Act (2000), and is not designed to replicate these provisions, or to duplicate, replicate or supersede the following policies and guidelines, which may change over time:

- The Human Fertilisation and Embryology Act; 1990

- The National Institute for Clinical Excellence Infertility guidance (CG156 - "Fertility: assessment and treatment for people with fertility problems"); 2013
- NICE Evidence Update for Fertility March 2015 (Evidence Update 74)
- National Minimum Standards for Independent Healthcare; 2000
- Any Quality standard as determined by the Care Quality Commission
- Any Quality standard required under the terms of the Care Standards Act; 2000
- Any Quality Standard as published by NICE

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	**Preventing people from dying prematurely**	
Domain 2	**Enhancing quality of life for people with long-term conditions**	
Domain 3	**Helping people to recover from episodes of ill-health or following injury**	
Domain 4	**Ensuring people have a positive experience of care**	*
Domain 5	**Treating and caring for people in safe environment and protecting them from avoidable harm**	*

2.2 Local defined outcomes

The Human Fertilisation and Embryology Authority (HFEA) require licensed providers to submit their information including outcome information about every cycle of licensed treatment provided within specified timescales. These are published on the HFEA website and are available for patients and commissioners to view.

Success rates will be expected to align with current HFEA – national averages; taken from their website period 01/07/14-30/06/15:

Under 38 years of age
Births per embryo transferred 27%
Births per egg collection 39%

38 years old and over
Births per embryo transferred 11%
Births per egg collection 20%

All
Births per embryo transferred 21%
Births per egg collection 33%

Multiple birth rate – Target of 10% or less

3. Scope

3.1 Aims and objectives of service

- To help couples suffering from subfertility or confirmed infertility who meet the criteria to access licensed treatment to achieve a successful pregnancy
- To offer licensed assisted conception treatment for patients suffering from subfertility or confirmed infertility who meet the criteria to access treatment.
- To offer storage of gametes or embryos for patients who are on the NHS funded pathway or will be at risk of requiring Assisted Conception treatment in the future (e.g. patients receiving cancer treatment likely to impact on their future fertility).
- To provide a quality, safe, cost effective Assisted Conception Service ensuring that the risk of infection and other complications such as OHSS and multiple pregnancy to service users is minimised.
- To provide a personal service sensitive to the physical, psychological and emotional needs of service users. Including that patients will be offered counselling with a Specialist Fertility Counsellor in line with the HFEA Code of Practice.
- To ensure effective communication between commissioners and the service providers.
- To develop and implement a data collection and monitoring processes which provides fertility services intelligence to support the future commissioning of fertility services

3.2 Service description/care pathway

The Assisted Conception Service components are detailed in Appendix A.

Commissioners understand that patient pathways will differ depending on their individual clinical needs and diagnosis - Fertility Policy and the Fertility Treatment Referral Pathway is detailed in Appendix B

3.3 Population Covered

The Assisted Conception Service will cover all eligible patients registered with a Dorset GP practice and those who meet the eligibility criteria in the Dorset Fertility Assisted Conception Service.

3.4 Any acceptance and exclusion criteria.

The Provider will ensure that they comply with current eligibility criteria set out in the DCCG Fertility – Assisted Conception criteria based access protocol (CBAP) document

Fertility – Assisted Conception criteria based access protocol

Services accessible regardless of age, disability, race, culture, religious belief, sexual orientation or income levels.

This specification covers NHS funded fertility treatment only. For clarity, patients will not be able to pay for any part of the treatment within a cycle of NHS fertility treatment. This includes, but is not limited to, any drugs (including drugs prescribed by the couple's GP),

recommended treatment that is outside the scope of the service specification or experimental treatments.

Individuals who choose to access private healthcare, for whatever reason, retain the right to access NHS healthcare which is normally funded within the individual's CCG on the same basis as any other individual. Commissioners will expect any transfer of care to follow locally agreed pathways of care and policies.

Individuals living in the UK and moving to the area will be either covered by the responsible commissioner guidance and will transfer to the local pathway of care at the point of transfer or within 3 months.

Individual moving from abroad will need to follow the local commissioned pathway of care.

Following any unsuccessful cycle, providers will assess the likely effectiveness and safety of any further assisted conception treatment.

3.5 Interdependence with other services/providers

The Provider will ensure that the service is planned and delivered in consultation with appropriate stakeholders including the Dorset Clinical Commissioning Group, Acute Trusts, and GPs within the locality.

4. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)

All relevant prevailing guidance and best practice recommendations including (but not limited to) that by NICE, NHSP, BSA, NHS England, MCHAS, BAAP, NDCS, DH, RCP, UKAS, RCS. The provider is required to meet the acceptable and work towards the achievable prevailing National Institute for Clinical Excellence (NICE) Clinical Guideline 2013, 156 (as detailed on - https://www.nice.org.uk/guidance/CG156) as relevant to the Assisted Conception Service

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator overseeing the use of gametes and embryos in fertility treatment and research. Treatment will only be supported at clinics holding the relevant HFEA licence (as detailed on https://www.hfea.gov.uk/ website)

4.2 Applicable local standards

The NHS Dorset CCG used existing guidelines and local clinical opinion in developing the Fertility and Assisted Conception Policy.

Treatment provided must be in accordance with the NHS Dorset CCG Fertility and Assisted Conception Policy.

The NHS Dorset CCG Fertility and Assisted Conception Policy may be reviewed and changed over the life of the contract and any changes will be communicated to the provider.

Direct Service Provision
Treatment commissioned and funded through this contract will include:

- Testing for viral status if not already performed.

- Procedures used during assisted conception, including drug regimes, oocyte and sperm retrieval and embryo transfer strategies, will be in line with the NHS Dorset CCG Policy.

- All the drug costs will be met by the provider as part of the commissioned service and must not be prescribed by a GP. The expectation is that if the following drugs are initiated that they are then continued within the service provided, and drug regime will comply with the NICE guideline 2013, 156:
    1. Progesterone
    2. Low Molecular Weight Heparins

5. Applicable quality requirements and CQUIN goals

5.1 Applicable national standards (e.g. NICE)

Applicable quality requirements (See Schedule 4 Parts [A-D]

5.2 Applicable standards set

Applicable CQUIN goals (See schedule 4 Part [E]

6. Location of Provider Premises

The Provider's Premises are located at:

7. Individual Service User Placement

Not applicable

8. Prices & Costs

Providers should detail separately costs associated with subcontracted services where appropriate

Appendix A – Key Service Components following receipt of referral

N.B please note this list is an overview and not exhaustive, services should align with HFEA regulations and guidelines for delivery of service components and best practice;

In line with the Dorset CCG Fertility Assisted Conception Policy the following assisted conception technologies and techniques are supported in Dorset:

- Intrauterine Insemination (IUI)
- In-Vitro Fertilisation (IVF)
- Intracytoplasmic Sperm Injection (ICSI)
- Surgical Sperm Recovery

The following fertility preservation techniques are supported in Dorset, in certain circumstances:

- Semen Cryostorage
- Oocyte Cryostorage;
- Embryo Cryostorage.

N.B *Before proceeding to treatment a* ***Funding eligibility check appointment*** *must be completed to ensure patients meets criteria before proceeding to treatment.*

Applicable to all treatments:

- All required consultation appointments for treatment planning, legal consent requirements, injection technique, if required and follow up appointments;
- All scanning requirements;
- All required blood tests;
- Semen analysis, transvaginal ultrasound scan to check the sperm and uterine cavity prior to treatment;
- Completing medication needs/requirements;
- Support for patients/couples throughout treatment in person (e.g. telephone, email, face to face);
- If required additional support counselling available, as per HFEA guidelines;

IVF:

As above with the addition of:

- Sperm freezing if required;
- Egg collection procedure;
- Embryo development procedure and monitoring;
- Consultant and embryologists involved in selection of optimum embryo/s to return to patient;
- Embryo transfer procedure;
- Freezing of any remaining suitable embryos;
- Support for patients/couples throughout treatment in person (e.g. telephone, email, face to face);
  Additional support counselling available, as per HFEA guidelines, if required;
- Blood test to confirm outcome of treatment two weeks after embryo transfer;
- Follow up consultation with a consultant;

ICSI:

- As above with the addition of microinjection of the sperm into the collected eggs by our embryologists at the stage of mixing the eggs with the sperm.

IVF/ICSI with Donor Eggs:

- As above with the addition of:
    - HFEA requirement that a couple attends a counselling appointment if using donor gametes to be counselled as to the implications of using these;
    - At treatment planning stage coordinate treatment with the egg donor;
    - Donor eggs are prepared and mixed with sperm to develop embryo.

Frozen Embryo Transfer, if there were suitable embryos for freezing:

- Thawing and monitoring confirmed embryos;
- Embryo transfer procedure.

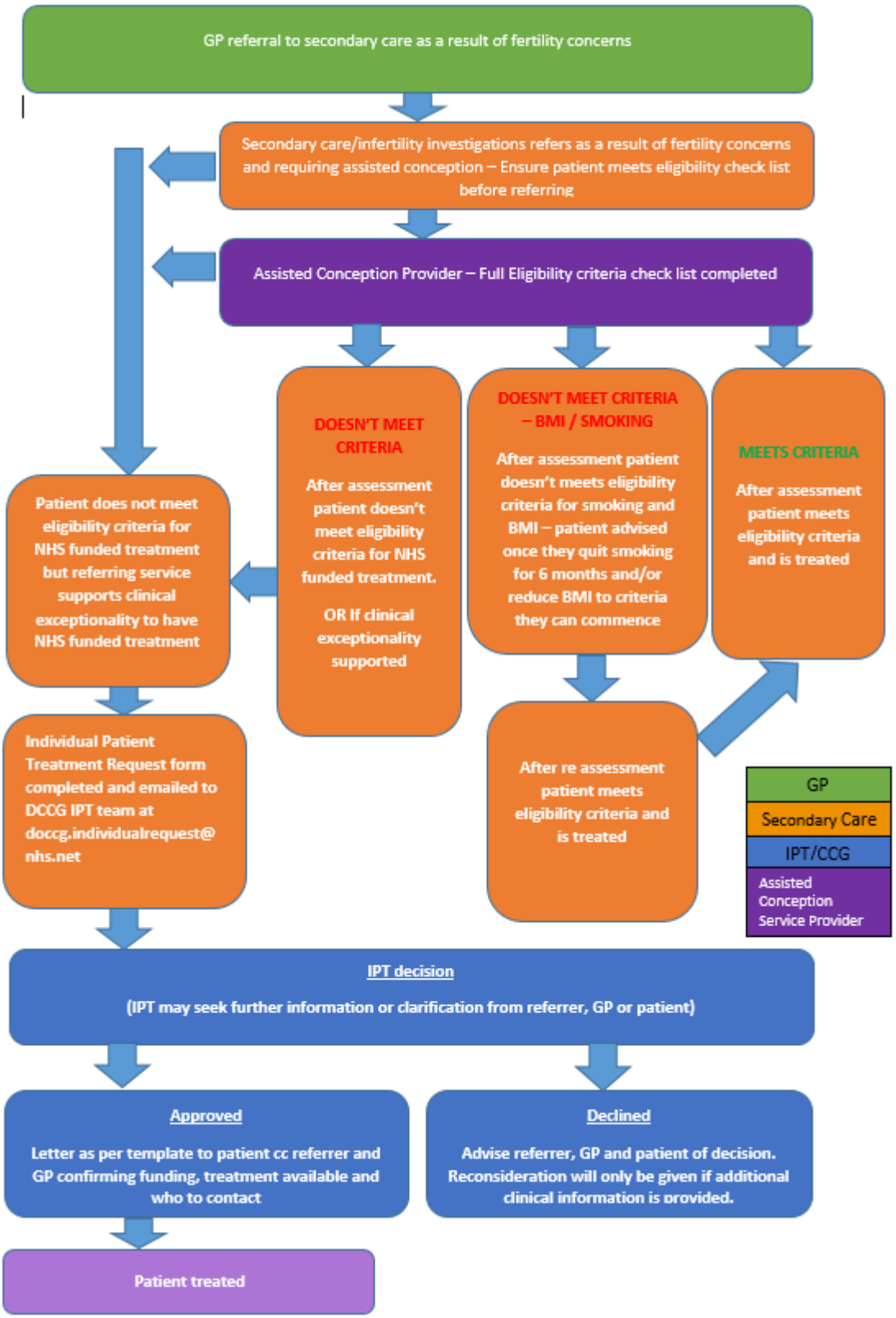
Intrauterine Insemination (IUI):

- Backup sperm freeze if required;
- Preparation of sperm for treatment;
- IUI procedure;
- Support for patients/couples throughout treatment in person (e.g. telephone, email, face to face);
- If required additional support counselling available, as per HFEA guidelines.

Donor Sperm (use in any of the above treatments):

- As above with the addition of:
    - Selection of donor sperm;
    - HFEA requirement that a couple attends a counselling appointment if using donor gametes to be counselled as to the implications of using these;
    - The donor sperm is thawed and used in treatment as partner sperm would be.

Appendix B - Fertility Policy and the Fertility Treatment Referral and Funding Pathway



Appendix C – Guidance for General Practitioners: Assessment and treatment of Couples with Fertility Problems

NHS Dorset Clinical Commissioning Group

GP Guidance for Infertility Investigation



VERSION CONTROL SHEET:

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0.1	January 2014		Chris Parsons
0.2	January 2018	Guidance updated to reflect changes from CBAP review of Jan 2018	Hannah Nettle

Guidance for General Practitioners

Assessment and treatment of Couples with Fertility Problems

Whilst criteria apply to fertility treatments, it is appropriate for all people experiencing fertility problems to be investigated and, if necessary, referred to a specialist with an interest in fertility so that they can have more complex investigations and be informed as to the causes of their fertility problems. This will allow them to decide on the options they may wish to pursue.

- Infertility investigation can commence at any age, couples must be Dorset residents in a stable relationship and registered with a Dorset GP.
- Infertility Investigations should not be undertaken until couples have been attempting to conceive for at least a year (NICE Clinical Guideline156).
- Prior to this time general lifestyle advice should be offered; weight management, alcohol intake, smoking, frequency and timing of intercourse etc.
- Please do not refer patients who have undergone previous sterilisation or vasectomy.

NB: NHS funded assisted conception (IVF/ICSI) is not available for individuals that have children from current or previous relationships, this includes adopted children. Sterilisation or vasectomy excludes patients from assisted conception treatments.

Where there are treatments planned that may result in infertility, clinical causes or history of present or predisposing factors for infertility (e.g. undescended testes, known bilateral tubal disease) assessment may be undertaken sooner.

Where an urgent referral is required for a patient needing treatment for cancer that may affect fertility, this can be made directly to the Dorset CCG Commissioned provider of assisted conception. This would usually be referred via the oncology services.

Please note referral to Assisted Conception will be made by secondary services following infertility investigations for patients meeting the eligibility criteria as defined within the NHS Dorset CCG Assisted Conception policy

http://www.dorsetccg.nhs.uk/Downloads/aboutus/Policies/Clinical/Policies%20from%20Sept%202014/Criteria%20Based%20Access%20Protocol%20-%20Fertility%20Policy.pdf

To see NICE Clinical Guideline156 please click here:

http://www.nice.org.uk/nicemedia/live/14078/62769/62769.pdf

NICE Clinical Guideline 156: summary of the main points applicable to general practice when considering referral for fertility investigations:

Defining infertility

- Couples should be informed that over 88% of couples in the general population will conceive within 1 year.
- People who have not conceived after 1 year of unprotected sex intercourse (UPSI) should be offered further investigation.
- If there is a history of predisposing factors for infertility [such as pelvic inflammatory disease (PID), oligomenorrhoea, amenorrhoea, and undescended testes] investigation should begin immediately and early referral offered.

Principles of care

- The management of infertility should involve the couple. The care should be sensitive, informed and backed by patient information literature, and couples should be informed of a patient support group.
- A specialist team should treat couples. An expert not directly involved with the infertility management should offer counselling before, during and after treatment.

General advice

- Couples should be advised to have regular UPSI every 2 – 3 days.
- Couples should be advised to limit the use of alcohol.
- Couples should be advised to stop smoking.
- Couples should be offered specific advice in relation to recreational drug use where appropriate.
- Men should be advised to avoid tight fitting underwear and avoid testicular hyperthermia.
- Women should be advised to lose weight if their body mass index is greater than 29 kg/m2.

Preconception advice

- Women should be advised to take 400 mcg folic acid before conception and up to 12 weeks' gestation. Women on anticonvulsants, or with diabetes, or with a history of a child with a neural tube defect should be offered 5 mg folic acid per day.
- Attention should be paid to any medication e.g. statins, ACEI (changing medication if needed) to ensure risk is minimised
- Optimise physical and mental health conditions prior to conception e.g. diabetic control, stopping smoking, ensuring BMI within normal range
- Rubella status should be determined and if seronegative, they should be offered immunisation and should avoid pregnancy for 1 month.

Initial assessment prior to referral to infertility investigations

- Semen analysis should be performed on behalf of all couples presenting with infertility. If the first sample is abnormal a second sample should be taken 3 months later.
- For the assessment of ovulation, a menstrual history should be taken. If women have regular menses, they should be informed that they are ovulating. Confirm ovulation with mid- luteal (Day 21 of a 28-day cycle) progesterone. Depending on the timing of the menstrual periods, this test may need to be conducted later in the cycle (e.g. Day 28 of a 35 – day cycle).
- Temperature charting is not recommended.
- Follicle-stimulating hormone (FSH) can be used to predict the likely ovarian response to gonadotrophin stimulation.
- Women with irregular cycles should have serum FSH and luteinising hormone measured. High levels may indicate ovarian failure.
- Women who have symptoms of thyroid disease or oligo/amenorrhoea should have their thyroid function checked.
- Women who have galactorrhoea, a pituitary tumour or oligo/amenorrhoea should have their serum prolactin measured.
- Before undergoing uterine instrumentation, women should be offered chlamydia trachomatis screening and treatment where necessary.
- For the assessment of tubal damage, women who are not known or thought to have co-morbidities (such as PID, previous ectopic pregnancy, known endometriosis or symptoms suggestive of endometriosis eg dysmenorrhoea, dyspareunia, pelvic pain) should be offered hysterosalpingography or hysterosalpingo-contrast-sonography (HyCoSy). Women with co-morbidities should be offered laparoscopy and dye as other pelvic pathology can be assessed at the same time.

Fast Track Early Referral to infertility investigations

- Early specialist referral should be offered where the woman is aged ≥36 years, or there is a known cause or history of predisposing factors for infertility.
- For women to be eligible for assisted conception treatment they have to complete a cycle of IVF treatment before age 43.

For GPs: Please look at the Information required column and consider if you should refer or need to offer additional advice

Couple Question	Information required prior to referral	Supporting comments/information
Are the couple both registered with your GP practice?	Gain agreement from other practice to be lead on the referral. Lead practice to obtain relevant information from other practice to include in the referral. Provide both names and DOBs Please ensure that you have documented in the referral medical histories for both parties including all medications and any known allergies	Yes/No Yes/No Yes/No Advise the couple need to attend the initial consultation appointment together.
Has the couple been attempting to conceive for one year (defined as regular unprotected intercourse) in this relationship? i.e. not taking contraceptive	Duration of attempting to conceive Consider earlier referral if any of the following apply: 1. Has there been previous cancer/other treatment that may affect fertility? 2. Have you evidenced anovulation? 3. Is there evidence of severe/bilateral tubal disease? 4. Have you evidenced severe male factor deficiency? 5. If there is a history of sexual dysfunction – consider referring to psychosexual services	Time frame: Tick if applicable and provide details
Has history of existing children from current or previous relationships been documented in referral (for both individuals)?	Include details Please document any obstetric problems **NB: NHS funded assisted conception (IVF/ICSI) is not available for individuals that have children from current or previous relationships, this includes adopted children.** **Sterilisation or vasectomy excludes patients from assisted conception**	Yes/No
If there has been previous fertility treatment? Is this documented? This is for both individuals.	Amend referral and include details, including private investigations and treatments and include full details	Yes/No Details:
Have you RISK assessed for Sexually Transmitted Infection?	Think about offering test prior to referral and document any previous chlamydia, HIV, or other screening test performed	Yes/No

Female factors		
Is the woman's BMI: • below 30 • over 19 19	**Do not refer** until BMI is under 30 - Consider referral for weight management If BMI is lower than 19, discuss exercise and moderate this if there are high levels of exercise If BMI is lower than 19 but the woman is ovulating, then this is considered physiologically ok in terms of normal fertility.	State weight, height and BMI:
Are they a Non-Smoker? Alcohol intake should be moderate	If no eating disorder discuss referral with secondary care **Do not refer** unless they are a non-smoker for a period of 3 months (must be non-smoker for 6 months before referral to fertility assisted conception service). **Do not refer** until intake decreased for three months. Discuss the importance of no binge drinking and discontinue all alcohol consumption at conception	Tick if applicable:
Has assessment of ovulation in line with best practice guidance (NICE 156) been undertaken and documented in the referral?	Irregular menstrual cycle see NICE 156. p19 for hormone profile. This could include one of the following measures to predict likely ovarian response to gonadotrophin stimulation in IVF: • mid luteal progesterone (day 21 of a 28-day cycle) this might be conducted later if there are longer cycles • FSH level take day 2- 5 of cycle • Oestradiol take day 2-5 of cycle	If irregular menstrual cycles perform serial progesterone. Results:
Is the woman's rubella status documented in the referral?	Ascertain status and amend referral including details. If rubella susceptible, offer vaccination and advise not to become pregnant for a month following vaccination	Yes / No
Has folic acid been commenced?	• Advise to commence 400 mcg daily. • Women who have had a baby with neural tube defect, who are receiving antiepileptic treatment or are diabetic should be offered a higher dose of 5mg folic acid daily (NB: consider referral to epilepsy specialist for advice on drugs pre-conceptually.	Yes / No Yes / No
Co-existing long term conditions	• Consider diabetic specialist referral if control is not optimal (normal HBA1C) • Patient on teratogenic drugs e.g. statins, ACEI should have medication reviewed and changed prior to conception	Yes / No Yes / No

If there has been a history of miscarriage, is it documented in the referral?	Include details of any miscarriages	Yes / No
Male Factors		
Is the man's BMI: BMI < 30?	BMI over 29 can affect semen quality **Do not refer** until BMI under 30 - Consider referral for weight management	Yes / No Yes/No
Are they a Non-Smoker?	Should be a non-smoker for at least 3/12 months (must be non-smoker for 6 months before referral to fertility assisted conception service). Men who smoke should be informed that there is an association between smoking and reduced semen quality (although the impact of this on male fertility is uncertain), and that stopping smoking will improve their general health	Yes/No
Alcohol intake should be moderate	Excessive alcohol intake is detrimental to semen quality. Alcohol intake should be less than three/four units per day.	Yes/No Results:
Has semen analysis been undertaken in line with best practice guidance NICE 156 and is recorded in the referral? The results of semen analysis conducted as part of an initial assessment should be compared with WHO reference values (NICE Guideline 156 p 18): •Semen volume: 1.5 ml or more •Ph: 7.2 or more •Sperm concentration: 15 million spermatozoa per ml or more •Total sperm number: 39 million spermatozoa per ejaculate or more •Total motility (percentage of progressive motility and non-progressive motility): 40% or more motile or 32% or more with progressive motility •Vitality: 58% or more live spermatozoa	Do not refer until analysis taken and recorded Repeat Semen analysis if very low values within 1 month, and at 3 months following lifestyle advice if borderline	

•Sperm morphology (percentage of normal forms): 4% or more		
Any additional supporting information		