SCHEDULE 2 – THE SERVICES

A. Service Specifications (B1)

Mandatory headings 1-4. Mandatory but detail for local determination and agreement
Optional heading 5-7.Optional to use, detail for local determination and agreement.

All subheadings for local determination and agreement

Service Specification No.	01_MRFH_0002
Service	Assisted Conception
Commissioner Lead	Maternity, Reproductive & Family Health Principal Programme Lead – Service Redesign and Delivery
Provider Lead	
Period	1 April 2014 to 31 March 2017
Date of Review	31 March 2017

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.

Infertility in the UK (2010) can equally be attributed to the male and female with both responsible in 30% of cases. Combined issues account for 10% and unexplained problems can account for as much as 25%.

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 (NICE clinical guidance 156 2013)

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 Fertility treatment 2010 trends and figures report published by the Human Fertilisation and Embryology Authority (HFEA) states that overall the pregnancy rate has remained steady between 2009 and 2010, but the multiple pregnancy rate has decreased.

The pregnancy rate (per embryo transfer) using fresh eggs has remained steady:
2009 – 33.4%
2010 – 33.4%

Multiple pregnancy rate (% of pregnancies) using fresh eggs has decreased:
2009 – 25.4%
2010 – 22.2%

Providers are required to devise their own 'multiple births minimisation strategy' and It is expected that for our local population we will be achieving the current HFEA target of 10% maximum multiple conceptions.

Providers are expected to have a successrate of at least 35% live births.

Providers will have a maximum rate of ICSI of 45% and 55% IVF for 1st full cycles

Providers will agree through the tender process a maximum rate for ovarian hyperstimulation syndrome.

3. Scope

3.1 Aims and objectives of service

To provide Assisted Conception Services (encompassing In Vitro Fertilization (IVF), Intracytoplasmic Sperm Injection(ICSI) and Intrauterine Insemination (IUI) for couples who meet the criteria set out in the Dorset Clinical Commissioning Group (CCG)Fertility and Assisted Conception Policy.

Objectives:

- To ensure equity of access, to Fertility and Assisted Conception services for patients registered within the NHS Dorset CCG General Practices
- To ensure effective communications between patients and the service providers
- To ensure effective communication between commissioners and providers
- To ensure a safe, cost effective service for the recipients of the services commissioned
- To provide a personal service sensitive to the physical, psychological and emotional needs of the patients
- To develop and implement a data collection and monitoring process to support the future commissioning of assisted conception services across Dorset

3.2 Service description/care pathway

All Couples receiving this service must meet the NHS Dorset CCG Fertility and Assisted Conception Policy referral criteria at the point they commence a treatment regime and at designated points throughout their treatment pathway.

The treatments and fertility preservation techniques which will be commissioned in line with the policy and are detailed below:

- In Vitro Fertilisation (IVF)
- Intracytoplasmic Sperm Injection (ICSI)
- Surgical Sperm Recovery
- Intrauterine Insemination (IUI)
- Semen Cryostorage
- Oocyte Cryostorage
- Embryo Cryostorage
- Donor gametes

Treatments for patients who do not meet these criteria and the following treatments are **not** commissioned: Any request for one of these treatments on grounds of exceptional individual circumstances should be submitted to the CCG for consideration.

- Surrogacy
- In Vitro Maturation (IVM)
- Gamete Intrafallopian Transfer (GIFT)
- Zygote Intrafallopian Transfer (ZIFT)
- Assisted hatching
- Cervical Mucus Testing
- Reproductive Immunology
- Variocele Surgery
- Sperm washing outside of NICE guideline 156, 2013

3.3 Service Model

Access

The Commissioners and providers will work together to develop and offer consistent referral arrangements. Providers of fertility services will maintain close working links with primary care, secondary care providers and maternity services, in order to ensure appropriateness of referrals for treatment, and optimal post discharge support and follow-up.

Services should be provided to couples that meet the NHS Dorset CCG Fertility and Assisted Conception Policy referral criteria and documented adherence to these criteria must be made available if requested.

Service Providers will ensure that the service offered is respectful and does not discriminate on grounds of age, gender, sexuality, ethnicity or religion. Services should be accessible to the needs of couples whose first language is not English, and those with hearing or visual disability.

All provider sites should be easily accessible by public transport and must provide information about parking. Provision should be made under the Disability Discrimination Act; to ensure that disabled patients are able to access the service.

Facilities should include adequate security arrangements to ensure the protection of

patients attending the premises. There should be clear and appropriate signs for the entrance from the public highway.

The service will be provided from a suitable venue, which:

- complies with appropriate health and safety legislation
- has disabled access
- has appropriate waiting and diagnostic/treatment areas
- is appropriately furnished and equipped with necessary equipment
- meets cleanliness and hygiene standards

The service will be available to patients at times and on days that reflect patients' clinical needs and the clinical needs of the service.

Patient Information

In line with NICE guideline 2013,156 providers will develop information to help patients understand:

- The likelihood of successful treatment
- Benefits and risks of assisted conception in accordance with current HFEA Code of Practice
- The long-term health outcomes of treatments, including consequences of multiple pregnancies.

Information sheets in non-technical language should be available to explain the proposed planned pathway including investigations and treatment, together with detailed information on drugs (and any possible side effects) prescribed by the centre. Information should be tested out with couples to ensure it is user-friendly and available in a range of languages/formats.
Information relating to clinical outcomes should be available for couples on request.

Patients will be given accurate and detailed information about possible side effects their treatment, including:

- Possible drug interactions
- Risks associated with multiple pregnancy

Ovarian hyper stimulation, which is a potentially fatal condition, is also a risk. The exact incidence of this has not been determined but the suggested number is between 0.2 to 1% of all assisted reproduction cycles. Patient information will be developed taking into account local district services. (Mild symptoms are common in women having IVF treatment. As many as one in three (33%) women develop mild OHSS. About one in 20 (5%) women develop moderate or severe OHSS.

The risk of OHSS is increased in women who:

- have polycystic ovaries
- are under 30 years
- have had OHSS previously
- get pregnant, particularly if this is a multiple pregnancy (twins or more).*
  SourceRoyal College of Obstetricians and Gynaecologists (RCOG) guideline on

Ovarian hyperstimulation

Referral

Referrals of couples for assisted conception can be accepted only from Primary Care, and specific NHS Gynaecologists. Self referrals and referrals from private fertility specialists will not be accepted.

Referrals for Military personnel and couples presenting for Pre-implantation genetic diagnosis (PGD) are not the responsibility of the CCG and will be covered by arrangements with the NHSCommissioning Board.

Couples presenting to primary care services must first be referred for assessment by NHS secondary care fertility services and be fully worked up prior to referral to assisted conception services.

All appropriate secondary care investigations should have been undertaken prior to referral for assisted conception, and the results should be made available to the service by the referrer. No investigation that should have been undertaken within primary or secondary care will be funded through this contract. Referrals should be returned to primary care or the named gynaecologist if further investigations are required.

Patients who do not attend (DNA) the service will be offered a single further opportunity to attend the clinic. The referral will be returned to the GP if the patient DNA's a second time. The provider will not be paid for DNA's.

People who require egg donation and their needs cannot be met by the provider (e.g. Ethnicity), will be supported to find a donor with other centres.

People who are known to have viral disease (e.g. HIV, Hepatitis B or Hepatitis C) should be referred to centres that have appropriate expertise and facilities to provide investigation and treatment.

It is expected that referrals to other centres will continue to be managed by the service provider by means of sub-contracting arrangements with these centres and to ensure that overall responsibility regards follow up arrangements and on-going treatment will remain with them under a shared care arrangement.

Follow-up arrangements

- On positive outcome: Early pregnancy scan undertaken at 6/7 weeks then patient discharged to ante-natal care under GP
- On negative outcome(last cycle): follow-up appointment with medical specialist at the provider and discharge summary sheet sent to GP
- Appropriate drug regimes will be provided by the service, and GP's should not be asked to prescribe drugs for these patients.

Sharing of information between professionals

Providers are required to hold an annual seminar with the referring secondary care services to discuss referral protocols, communication and pathways. Commissioners are to be invited to these events. Commissioners may include representation from the patient representatives involved in the relevant clinical commissioning programme.

The General Practitioner, referring doctor / nurse and doctor providing follow-up care should be informed in writing of treatment provided and any follow up needs. If follow up is required within an obstetrics service this service will make direct arrangements with the local obstetrics service and inform the GP.

Notification of major complications must be provided to the GP and if necessary direct contact with the relevant obstetrics service.

Confidentiality

A written Confidentiality Policy should be prominently displayed and made available to service users. The policy needs to clearly state the circumstances in which other agencies may need to be informed. Staff should be able to demonstrate an understanding of the Policy and process and be able to communicate this to patients using the service.

The Service Provider will be expected to demonstrate that the collection, storage and transfer of information to other services, including that in electronic format is secure and complies with any data protection requirements.

Consent

The Service Provider will be expected to operate a policy for obtaining consent that complies in all respects with the requirements of National Minimum Standards and the Private And Voluntary Healthcare (England) Regulations 2001 and any other relevant guidelines.

Competent consent is understood in terms of the patient's ability to understand the choices and their consequences, including the nature, purpose and possible risk of any treatment (or non-treatment). In assessing competence the Service Provider needs to refer to the Department of Health (DOH) Reference Guide to Consent for Examination or Treatment (2001).

The provider will have secure IT systems in place for recording patient information and activity.

Service User Experience

As a minimum all patients should be asked to complete an anonymous post treatment patient experience survey using the HFEA patient questionnaire. The survey results should be used by the provider to review and reflect on the service being delivered and should be forwarded to the Commissioner on annual basis. The information gathered by the patient experience survey should be taken into account when reviewing standards as part of clinical audit, and when reviewing commissioning arrangements.

Monitoring Staff Quality

Clinical audit should be undertaken regularly. Professional and support staff should be

involved in the audit of organisational care. Professional staff should undertake interdisciplinary clinical audit and receive clinical supervision.

Education, training and staff development should be an integral part of service provision. All staff should receive appropriate training in patient care and support for adults who are defined as being infertile. The provider should ensure that these programmes integrate with the continuing professional development of relevant professionals involved in the care of patients who are defined as having fertility problems across organisational boundaries. The provider should co-host regional and postgraduate training programmes with other designated fertility services providers.

Description of the service to be provided

The service provider must hold a current Human Fertilisation and Embryology (HFEA) licence for the provision of IVF.

Providers are required to meet all HFEA standards for facilities, staffing and service infrastructure.

The provider must have a multiple birth reduction policy as required by the HFEA, and must demonstrate that they are working towards a multiple conception target of no more than 10%. The provider will have an embryo and blastocyst transfer policy compliant with the NICE guideline 2013, 156.

Providers should work in collaboration with primary and secondary care services to provide a seamless service.

The provider must ensure all referrals meet the criteria indicated in the NHS Dorset CCG Assisted Conception Policy and document adherence to these criteria.

The provider must check and ensure guidance is given on alcohol and caffeine consumption. The smoking status will be assessed for all referrals using a carbon monoxide breath test or similar to demonstrate compliance. People will be discharged from the service if they are smoking and care can be delayed for 3 months for those where other lifestyle factors need to be addressed.

Patients who choose not to commence treatment within 3 months from being called for treatment will be referred back to their GP.

Patients to be treated with respect and their dignity to be safeguarded regardless of age, sex, ethnicity, religion, culture and sexuality. Services provided should be culturally sensitive

All staff will respect the confidentiality of the patient as required by the NHS document: The Care Record Guarantee (DoH, 2007).

Patients will be offered counselling with a Specialist Fertility Counsellor in line with the HFEA Code of Practice.

Patients should be informed that they may find it helpful to contact a fertility support group.

For continuity of care delivery, the patient will have a named Clinician, who will take

responsibility for the patient during this pathway of care.

In line with NICE guideline 156 ovarian reserve testing will inform treatments.

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 serviceand must not be prescribed by a GP. The expectation is that if the following drugs are initiated thatthey are then continued within the service provided, and drug regimes will comply with the NICE guideline 2013, 156:
    1. Progesterone
    2. Low Molecular Weight Heparins
- All ultrasound scans and hormone assessments during the treatment cycle.
- Oocyte recovery - by vaginal ultrasound guided by aspiration under sedation or local anaesthesia or laparoscopy as appropriate. General anaesthesia will be provided when necessary.
- All embryology including sperm analysis, preparation and sperm retrieval where indicated.
- A pregnancy test and a maximum of two scans to establish the viability of the pregnancy.
- Donor insemination in line with NHS Dorset CCG Policy including screening of donors.
- Cryostorage for sperm, oocyte or embryos as part of urgent medical treatment will be in line with the NHS Dorset CCG Policy.
- Cryostorage of embryos following assisted conception is commissioned for 1 year after the fresh cycle.

It is the responsibility of the provider to bear the cost of all ultrasound scans and any additional outpatient appointments, which may include other tests or observations, until the woman is referred to maternity services.

Hospitalisation will normally be dealt with on a day case basis. If, however, this requires to be extended for clinical requirements, for a maximum of 24 hours, no further charge will be raised.

If the length of stay is likely to be extended more than 24 hours the Provider must contact the on-call gynaecologist at the nearest District General Hospital to discuss appropriate management. This may require the patient to be transferred to an appropriate District General Hospital.

3.4 Any acceptance and exclusion criteria and thresholds

The provider must ensure all patients meet the referral criteria in the policy. Where a couple does not meet criteria where there are exceptional circumstances the Clinician can submit an Individual Patient Treatmentrequest.

Specialist assisted conception services form part of the infertility care pathway described in the 2004 NICE clinical guideline. Patients must have undergone appropriate investigation and treatment at primary and secondary care level before they can be referred for specialist assisted conception.

Referrals of couples for assisted conception can only be accepted from Primary Care and specific NHS Gynaecologists. Self referrals and referrals from private fertility specialists will not be accepted.

Couples presenting to primary care services must first be referred for assessment by NHS secondary care fertility services and be fully worked up prior to referral to assisted conception services.

Where a patient does not meet the eligibility criteria but secondary care makes a case for exceptional circumstances these patients should be prior approved and treated within the contracted activity.

All appropriate secondary care investigations should have been undertaken prior to referral for assisted conception, and the results should be made available. No investigation that should have been undertaken within primary or secondary care will be funded through this contract.

- The receiving clinician will ensure that the patient meets the NHS Dorset CCG Fertility and Assisted Conception Policy referral criteria and document adherence to these criteria.
- The provider will have the ability to undertake a carbon monoxide breath test or similar to show non smoking status.
- Consent will be gained from patients and relevant information sought from the referring GP and/or consultant as necessary.
- Referrals to other required services will be requested through the patient's own GP.

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.

Individuals cannot choose to depart from the pathway commissioned for social, cultural or religious objections to IVF.

Following the first 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)

The services described in this service specification have been considered in line with National Institute for Clinical Excellence (NICE) Clinical Guideline 11 "Fertility: Assessment and treatment for people with fertility problems" issue date Feb 2004,

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.

4.2 Applicable local standards

The NHS Dorset CCGused 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.

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

5.2 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.