SCHEDULE 2 – THE SERVICES

A. Service Specifications

1. Service name	Fertility preservation service for service users with testicular tissue who are at high/very high risk of infertility and cannot store sperm.
2. Service specification number	1867-230902
3. Date published	18/09/2023
4. Accountable Commissioner	NHS England england.npoc-womenandchildren@nhs.net

5.	**Population and/or geography to be served**
5.1	**Population Covered** All ages This service specification covers the provision of fertility preservation services for service users with testicular tissue who are at high/very high risk of infertility and endocrine failure and cannot store sperm. It is one of three service specifications that describe an integrated single fertility preservation and restoration programme. The other two service specifications cover: - • Fertility preservation for service users with ovarian tissue who are at high/very high risk of infertility and cannot eggs • Fertility and endocrine restoration using cryopreserved ovarian tissue The fertility and endocrine restoration service specification does not include the restoration of testicular tissue as unlike ovarian tissue restoration, it is not currently clinically available for males. There are no lower and upper age limit criteria contained in this specification and the eligibility criteria is based on physiological potential of the testicular tissue.
5.2	**Minimum population size** Not applicable
6.	**Service aims and outcomes**
6.1	**Service aims**

The aims of the service are to: -

- Provide fertility preservation treatment for service users with testicular tissue who are at high or very high risk of reproductive and endocrine failure and who cannot store sperm.
- Provide specialist fertility expertise and advice.
- Provide surgery to remove testicular tissue.
- Provide a Tissue Establishment (TE) that can store and cryopreserve testicular tissue.
- Ensure compliance with the Human Tissue Authority Regulations.
- Ensure that service delivery is in line with national and international guidelines and established best practice.

6.2 **Outcomes**

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

Reference	Domain	Rationale	Indicator
FPS-Ov01	4,5	To understand the proportion of service users receiving tissue cryopreservation	Proportion of service users having treatment for a malignant and non-malignant condition that places them at high/very high risk of infertility who receive testicular tissue cryopreservation

The service will complete/upload data for all listed quality metrics to the national Specialised Services Quality Dashboard (SSQD). The full version of the quality metrics and their descriptions including the numerators and denominators can be accessed at https://www.england.nhs.uk/commissioning/spec-services/npccrg/specdashboards/

7. Service description

7.1 **Service model**

At birth, the testicles contain spermatagonial stem cells (SSCs) and Leydig cells, which after puberty, can produce sperm and testosterone respectively. Treatments such as chemotherapy, pelvic radiotherapy, total oophorectomy, and novel compounds (e.g., immunotherapy), can lead to the destruction of

	significant numbers of SSCs and Leydig cells leading to premature gonadal failure, infertility, and endocrine dysfunction. In some cases, this will occur before the patient has reached puberty and in advance of being able to store sperm. For service users whose treatment puts them at high/very high risk of reproductive and endocrine failure and unable to freeze/store sperm, testicular tissue cryopreservation (TTC) is the only treatment available to preserve fertility and endocrine function. TTC requires a surgical procedure under general anaesthetic to remove healthy tissue which is then cryopreserved and stored at a very low temperature to preserve the SSCs and Leydig cells within the tissue for use in adulthood to restore fertility and endocrine function. **Hub and Spoke/Tissue Establishment Model** The service will be delivered through an integrated hub and spoke model arrangement. The Hub is a hospital based clinical service and provides a fertility preservation programme, coordination of service provision across services, leadership and advice. The Hub also participates in and receives expert clinical and technical advice from a National Expert Group. This model centralises the specialist fertility expertise in the Hub whilst enabling testicular tissue collection surgery to take place in the service user's local surgical treatment centre (Spoke). The tissue is then processed, cryopreserved, and stored at an appointed TE licenced by the Human Tissue Authority. This model is similar to fertility preservation programmes operating in German speaking countries (FertiPROTEKT), Denmark and Nordic Countries (Nordfertil) and the Oncofertility Consortium in the USA. **The Hub** The Hub will: • Have a named Programme Lead who is responsible for ensuring compliance of the service across the Hub/Spoke/TE services in accordance with the service specification standards. • Put in place Service Level Agreements (SLAs) /Third Party Agreements (TPA) with the Spoke site and TE and agree and monitor quality assurance measures across the Hub/Spoke services. • Participate in a National Expert Group made up of experts from across the UK covering fertility, onco-fertility, oncology, haematology, endocrinology, psychology, genetics and ethics. • The Hub panel will oversee the fertility preservation programme and monitor quality assurance between Hub/Spoke and Hub/TE services. • Provide MDT advice on complex cases and on auto-transplantation. • Provide specialist fertility expertise, and advice to Spoke centres, service users and/or their parents/ person with parental responsibility (PPR). This will include the development and update of fertility

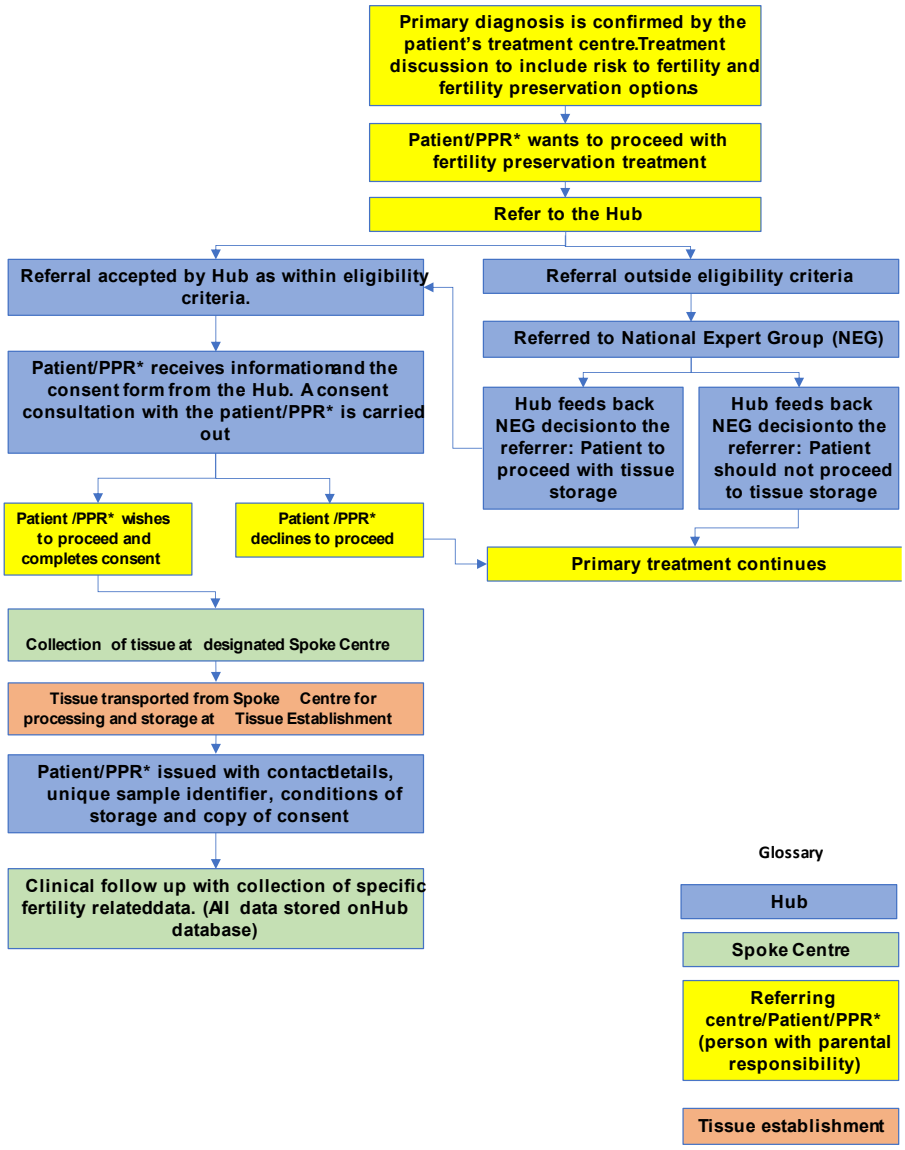
	information leaflets/video /website for service users and clinicians on all aspects of fertility and treatment options. • Develop and maintain a Hub Quality Management System which will include details of Hub and Spoke services management and governance arrangements which will be detailed in shared standard operating procedures. These procedures and documents will be detailed in the Hub/Spoke and TE (SLA)/(TPA). These will cover all areas within the patient pathway and will demonstrate compliance with the Human Tissue Authority Human Application Licence for the associated Tissue Establishment • Ensure all service users, parents and PPR have adequate information to give informed consent for the storage of testicular tissue. • Store data on all referrals and tissue procurement episodes and report data as required to NHSE and other regulatory authorities. • Ensure that serious adverse events/ reactions associated with the fertility preservation treatment are reported by Spoke sites to the Hub and that these are notified to the TE. • Have in place arrangements to enable the reconsenting of service users at the age of 18 years for ongoing storage of testicular tissue if testicular tissue consent was originally given by a parent or person with parental responsibility. • Have in place arrangements to enable contact with service users and Spoke services to ensure service users are aware of the tissue stored and to collect clinically relevant information. • Collect data on deceased service users and pass this information onto the TE so that the TE can ensure that tissue is either disposed or made available for research as per the patient's pre-collection or over 18-year-old consent. • Carry out an annual review of Spoke centres to ensure their compliance with the service specification standards and HTA regulations and to ensure that any areas of concern are addressed, and corrective and preventative plans are completed and effective. • Have in place a system for obtaining patient feedback to inform service evaluation and development. • Ensure that all patient data complies with the United Kingdom Data Protection Action (UKDPA) regulations. • Hold a register of all relevant Hub and Spoke personnel detailing their roles and delegated responsibilities, including a named individual trained to undertake fertility preservation counselling. • Use their job planning, appraisal, and revalidation system to ensure that all members of the team are appropriately trained and competent to carry out their designated roles. • Coordinate with adult fertility services providing fertility preservation treatment, auto-transplantation, menopause, and counselling services to ensure adequate transitional care arrangements

	The Tissues Establishment (Cryopreservation services) The tissue establishment: • Must operate in compliance with the HTA Quality and Safety Standards and hold a Human Tissue Authority Human Application (HTA HA) Sector Licence for procurement, processing, testing, storage, distribution, and disposal of testicular tissue. • Must have the capacity, supported by a capacity plan, that details how the TE will manage the variable clinical demand such that cases are not delayed or deferred and fertility preservation care can be delivered to coordinate with all aspects of the patient's primary treatment and concomitant surgical procedures. • Must have in place quality assurance measures and associated key performance indicators to ensure compliance with all parts of the TE Preparation Processing Dossier (PPD). These will be required by the HTA for regular inspections and should be shared with the HUB as detailed in the SLA/TPA. • Must have third party agreements in place with Spoke centres (third party sites) for the delegation of procurement activities in compliance with HTA Licence regulations. • Must have access to a dedicated courier for transfer of tissue samples in a traceable and compliant way as detailed in the PPD. • Must have capacity in the cryostorage tanks to quarantine samples until the mandatory HTA virology testing is reported and to divide service user samples between separate liquid nitrogen tanks, to mitigate the risk of total loss of a service user's tissue due to liquid nitrogen tank failure. • Must ensure that all patient data complies with the UKDPA regulations. • Must have arrangements in place to use their job planning, appraisal, and revalidation processes to ensure that all members of the team are appropriately trained and competent to carry out their designated roles. • Must have arrangements in place to monitor quality control of processing between technicians and over time to ensure that the quality of tissue stored is maintained. • Will report quality measures to the Hub site and discuss them with the Hub at an annual review meeting. • Must have arrangements in place to keep patient records/data to ensure traceability for a minimum of 30 years after clinical use or disposal of tissue, in an appropriate and readable storage medium (including an electronic format) as per HTA standards. **Spoke Centres (local surgical services)** The Spoke Centre: • Will have a nominated named Clinical Lead who is responsible for ensuring compliance with the requirements set out in the SLA with the Hub and the TE TPA, document control and Spoke Centre standard operating procedures.

	• Will ensure that all service users have fertility risk discussed and recorded as part of the primary treatment planning MDT. • Will, as part of the service user's treatment planning process, discuss in outline fertility risk and potential preservation options with PPR and where appropriate the service user. • Will, if storage of sperm is not appropriate, the Spoke Site will refer service users who wish to discuss fertility preservation and potential treatment options to the specialist fertility experts at the Hub site who will provide detailed information and arrange consultations with the service users. • Will, where TTC as fertility preservation treatment is agreed to be appropriate, the Hub and Spoke sites and TE will coordinate care and surgery times. • Will, whenever possible, arrange surgery for testicular tissue collection under the same general anaesthetic as other surgical procedures (such as central venous line insertion, gastrostomy, bone marrow aspirate). • Will ensure that consent for fertility preservation treatment involving storage of testicular tissue has been taken following consultation with a named person on the Hub/Spoke Consent Log prior to surgery. • Must have a named surgeon responsible for carrying out surgery to remove the testicular tissue. The lead surgeon must be listed in the Hub/Spoke delegation log. • Must ensure that there is a named individual trained in the requirements of the HTA to ensure that the consent form for testicular tissue collection, processing and storage is available and has been signed by the service user or PPR. • Must have a named person responsible for the coordination and liaison with the TE to collect the Tissue Box from a dedicated courier service pre- and post-surgery. The named person will be responsible for handling the testicular tissue in theatre, packaging of the tissue, completion of all essential paperwork and the return of the testicular tissue to the courier for transport to the TE. • Will be required to collect pre and post tissue clinical data for submission to the Hub and participate in audit exercises and the sharing of audit reports as agreed between the Hub and the Spoke Centre. • Must ensure that all patient data complies with the UKDPA regulations. • Will report serious adverse events or reaction (SAE/R) associated with testicular tissue collection to the Hub as soon as identified. The Hub will inform the TE to allow all parties to fulfil their legal requirements. • Must have in place arrangements for obtaining patient feedback to inform service evaluation and development. • Must use job planning, appraisal, and revalidation processes to ensure that all members of the team are appropriately trained and competent to fulfil their designated roles.

7.2	**Pathways** **Overall patient pathway**

Fertility preservation – tissue procurement pathway



Consent

In accordance with HTA and General Medical Council (GMC) regulations, service users, parents/PPR must be provided with sufficient information and counselling to be able to give fully informed consent prior to surgery for the collection of testicular tissue for fertility preservation. This must include the clinical rationale for tissue storage, risks and benefits of the treatment, and details of tissue procurement, processing, testing and storage. The consent must also contain instructions for the disposal or donation to research of stored

	tissue in the event of service user's death or if the service user no longer plans to use the tissue.
	
	Where service users are too young to provide their own consent, it is a person with parental responsibility who will provide consent on behalf of the patient.
	
	The consent from the person with parental responsibility must be obtained voluntarily with full disclosure of information and will therefore be deemed both appropriate and ethical. The process of informed consent is dynamic, ongoing and should be adapted as new information becomes available.
	
	Once the patient has reached adulthood, and has gained capacity to consent for themselves, they should be counselled, and consent should be sought for the ongoing storage or removal from storage of their testicular tissue.
	
	Service Eligibility and Exclusion Criteria
	
	TTC requires the removal of healthy tissue for storage and potential usage in the future. This treatment is only appropriate for those service users where the risk of loss of testicular function and resultant infertility exceeds 50% (i.e., where storage of tissue gives the service user a greater chance of future fertility than leaving the tissue in situ.) The thresholds for high/very high risk of infertility acknowledges that success rates (defined as live births) for all types of fertility preservation are less than 100%. Infertility risk thresholds within this service specification are in line with the Children's Cancer and Leukaemia Onco-Fertility Guidelines for patients receiving chemotherapy and radiotherapy. The service will be informed by similar guidelines for other service users and will rely upon diagnostic expert advice to the Hub and the National Expert Group.
	
	Eligibility criteria
	• service users who cannot store sperm whose treatment places them at a high* or very high* risk of infertility.
	  ○ high risk* (60-80%) tissue storage gives best chance of future fertility.
	  ○ very high risk* (>80%).
	OR
	• service users undergoing total orchidectomy.
	AND
	• who must be medically fit for fertility preservation surgery under general anaesthesia AND
	• not in reproductive failure and whose testicular tissue, has a physiological potential to ensure sufficient reserve for future use.
	
	Exclusion criteria
	Service users not included in the service specification are those:
	
	• who can successfully store sperm

	• who are at low** or medium** risk of infertility as defined by international guidelines and peer reviewed tools.
	  ○ low risk** (<10%: i.e., in line with the background population infertility risk),
	  ○ medium risk** (10-60% - tissue in situ gives the best chance of future fertility)
	
	• who are in reproductive failure with testicular tissue that lacks the physiological potential to ensure sufficient reserve for future use
	• where TTC could delay their primary treatment and cause detrimental harm
	• where surgery or a general anaesthetic would carry undue risk
	
	Transition
	All healthcare services are required to deliver developmentally appropriate healthcare to service users and families. Children and young people with ongoing healthcare needs may present direct to adult services or may be required to transition into adult services from children's services.
	
	Transition is defined as a 'purposeful and planned process of supporting young people to move from children's to adults' services. Poor planning of transition and transfer can result in a loss in continuity of treatment, service users being lost to follow up and disengagement, poor self-management, and inequitable health outcomes for young people. It is therefore crucial that adult and children's NHS services, in line with what they are responsible for, plan, organise and implement transition support and care (for example, holding joint annual review meetings with the child/young person, their family/carers, the children's and adult service). This should ensure that young people are equal partners in planning and decision making and that their preferences and wishes are central throughout transition and transfer. NICE guidelines recommend that planning for transition into adult services should start by age 13-14 at the latest, or as developmentally appropriate and continue until the young person is embedded in adult services. This service covers children and adults and therefore addresses all transition needs of service users.

7.3	**Clinical Networks** There is a requirement for providers of this service to comply with the provisions of *Schedule 2A (Clinical Networks) of the NHS Standard Contract 2022/23 The Particulars.* This includes meeting the requirements of the *relevant* Specialised Services Clinical Network Specification.
7.4	**Essential Staff Groups** **The Hub** • Fertility Preservation Programme Lead responsible for the delivery of the service across the Hub/Spoke services and nominated deputy. • Specialist fertility expert • Paediatric and young adult oncology/haematology consultant • Consultant paediatric surgeon

	• Consultant in reproductive medicine/fertility/gynaecology • Consultant endocrinologist • Clinical nurse specialist/key worker • Programme administrative coordinator and deputy • Data manager • Psychologist/counsellor • Ethicist as required. • Geneticist **National Expert Group – drawn from Hub/Spoke site and specialty experts.** • Clinical Lead/Fertility experts from Hub sites, spoke sites and auto-transplant sites. • Specialist and onco-fertility experts • Endocrinologist • Experts from Clinical Reference Groups/fertility services where patients are deemed to be at high risk of infertility • Clinical nurse specialist representative from the Hub site • Patient and public voice representative **The Tissue Establishment** • HTA designated Individual and deputy. • HTA licence holder contact • Quality manager • Technician(s) trained in processing and cryopreservation of ovarian and testicular tissue. • Technician (s) trained in thawing cryopreserved tissue • Consultant histopathologist • Consultant microbiologist • Molecular biology and genetic expertise to assess safety of tissue • Administrative support **The Spoke Centres** • Lead consultant responsible for the fertility preservation treatment activities undertaken at the Spoke centre. • Paediatric/adult surgeon/gynaecologist with an interest in fertility preservation (as appropriate) • Third party coordinator/person trained to attend theatre. • Administrative coordinator • Clinical nurse specialist/key worker • Data manager
7.5	**Essential equipment and/or facilities**

	The Hub requires access to: • Histopathology for quality assessment of tissue stored. • Microbiology for clinical management of service uses. • IT support from data management and Hub/Spoke systems. **The Tissue Establishment requires access to:** • A facility that meets the requirements of the HTA and has a HTA Human Sector Application Licence for the procurement, processing, storage, testing and distribution of reproductive tissue and has sufficient capacity to meet clinical needs of the associated Hub/Spoke services • Tissue Storage facilities which meet HTA standards and are of sufficient capacity to meet clinical need. • Histopathology, molecular biology and genetics expertise for quality assessment of tissue stored. • Microbiology for sterility testing of tissue and processing. • Environmental monitoring of processing facility • Testing for mandatory markers of infection as per relevant regulations/legislation • Dedicated courier for transport of testicular tissue in appropriate temperature monitored boxes. **The Spoke Centres require:** • Day case and inpatient paediatrics and/or, adult facilities to enable surgery under general anaesthesia. The facilities must be able to manage complex medical issues. • Access to theatre lists for procurement of testicular tissue and, other treatment related surgery such as insertion of a central venous line or gastrostomy. • IT and data management support
7.6	**Interdependent Service Components – Links with other NHS services** Not applicable
7.7	**Additional requirements** Not applicable
7.8	**Commissioned providers**
7.9	**Links to other key documents** NHS England Service Specification - Children's Cancer Services - Principal Treatment Centres. This service specification sets out standards for specialist cancer services including fertility preservation linked to cancer treatment that can impact on fertility. NHS England » Children's cancer services: Principal treatment centres service specification

	Children's cancer services; paediatric oncology shared care unit service specification NHS England » Children's cancer services: Paediatric oncology shared care unit service specification NHS England » Teenage and young adult cancer clinical network specification This service specification describes the arrangements in place to ensure that service users get access to the right care, in the right place at the right time as part of a network approach to service delivery, including access to fertility treatment Fertility preservation for service users with ovarian tissue who are at high/very high risk of infertility and cannot store mature eggs service specification. [link to follow] Fertility and endocrine restoration using cryopreserved ovarian tissue; service specification. [Link to follow]