Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

A summary of publicly-funded services for fertility preservation for medical reasons in selected countries –

Appendix D: Extracted grey literature

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Table D.1 Extracted data for Australia (Storage Guidelines).

Australia		
Author(s) **Title [year]**	Department of Health and Aged Care, Government of Australia Assisted Reproductive Technology (ART) Storage Funding Programme[1] [2023] and Guidelines[2] [2024] (Note: Service commenced 1 July 2023)	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		Eligible patients are those who either: ▪ have a cancer diagnosis and the cancer treatment will affect their fertility ▪ are at risk of passing on a genetic condition and have had pre-implantation genetic testing (PGT) through Medicare. They must also hold a valid Medicare card and must consent to their ART clinic sharing their relevant personal information with the Department of Health and Aged Care and Services Australia in order to facilitate their participation in the programme. For embryo cryostorage, only one member of the reproductive couple needs to meet eligibility requirements. Someone is not eligible if they: ▪ access other Commonwealth, state or territory funded cryostorage services ▪ have opted to undergo PGT but are not a known carrier of a genetic disorder. Further information: **Cancer diagnosis:** must have evidence of a cancer (malignant neoplasm) diagnosis at the time of cryostorage. This programme excludes cancer-like conditions such as: ▪ benign tumours ▪ other medical conditions that require gonadotoxic treatment. A referral to fertility specialist from another doctor (for example GP, oncologist, endocrinologist, haematologist) may act as evidence of eligibility. **Pre-implantation genetic testing (PGT):** Medicare funds PGT for people who know they carry a serious genetic disorder and are therefore at risk of having affected children. The Medicare Benefits Schedule (MBS) items for PGT are: 13207 73384 73385 73386 73387.

		A person is eligible if they have received Medicare benefits for one of these MBS items. Evidence of the patient being billed for Medicare Benefits ART Storage Funding Programme Guidelines Schedule (MBS) items 13207, 73385, 73384, 73386 or 73387 may act as evidence of eligibility. **Exclusions (based on the patient) to the programme include:** ▪ For the purposes of this programme, cancer is considered a malignant neoplasm and excludes conditions such as benign tumours or other medical conditions where gonadotoxic treatment and fertility preservation may be required ▪ Patients who undertake pre-implantation genetic testing, who are not known carriers of genetic conditions, are ineligible for this programme. These patients will not satisfy eligibility requirements for claiming MBS items 13207, 73385, 73384, 73386 or 73387**.**
Preservation method(s) available		Each eligible patient can access up to two cryostorage services of different material type (that is egg or sperm, and embryo).
Organisation	***Referral pathways***	No referral for this service. If the patient is eligible, the clinic will invite the patient to take part in the programme.
	Service provider characteristics	**A cryostorage service is eligible for subsidy under the programme if:** ▪ the cryostorage service commenced on or after 1 July 2023, and ▪ it is a cryostorage service for eggs, sperm or embryos provided by an eligible ART clinic, and ▪ it is a cryostorage service provided to an eligible patient, and ▪ the cryostorage subsidy limit of 10 years has not been exceeded, and ▪ the patient has not been charged any additional, out-of-pocket costs for the cryostorage service, and ▪ the cryostorage service is not partly or fully subsided under any other Commonwealth, state or territory funded cryostorage service or programme, and ▪ it is not a duplicate cryostorage service. Note that one 'cryostorage service' would include all storage samples of the same type of genetic material that are saved in one container (that is, multiple storage of eggs from multiple cycles stored together would comprise one claim for one yearly payment under the programme, and so forth). A cryostorage service is not eligible for subsidy under this programme if: ▪ it was placed into cryostorage with any facility before 1 July 2023, or ▪ it is a cryostorage service stored on behalf of a patient who is not eligible for the programme, or ▪ the cryostorage subsidy limit of 10 years has been exceeded (see Section 4.1), or ▪ the patient has been charged any additional, out-of-pocket costs for the cryostorage service, or ▪ the cryostorage service has been partly or fully subsided under any other Commonwealth, state or territory funded cryostorage service or programme, or ▪ it is a duplicate cryostorage service. Subsidy under this programme is only available for eligible patients for up to two different types of cryostorage service. **An ART clinic is eligible for the programme if they:** ▪ hold a current licence from RTAC (Reproductive Technology Accreditation Committee),

		▪ register with Services Australia's Organisation Register, ▪ sign a Grant Agreement with the Department (see Grant Opportunity Guidelines, published on GrantConnect, for more information), and ▪ meet all requirements detailed in these programme guidelines. **ART clinics must be able to provide evidence:** ▪ that their clinic holds a current RTAC license, ▪ that the patients for whom the clinic is seeking a subsidy are eligible for the programme ▪ that the cryostorage services for which the clinic is seeking a subsidy are eligible for the programme, ▪ that the clinic has not charged the patient any out-of-pocket costs for cryostorage services being subsidised under this programme, and ▪ that the clinic has received consent from all eligible patients to seek a subsidy under this programme. **Exclusions (based on the service) to the programme include:** ▪ Cryostorage services for eggs, sperm or embryos which were placed in storage prior to 1 July 2023 are not eligible for subsidy under the programme, ▪ Where a patient's cryostorage service is partly or fully subsided under any other Commonwealth, state or territory funded cryostorage service or programme, it is not eligible for this programme, ▪ Only one subsidy may be claimed per eligible patient, per storage period and per eligible cryostorage service, and ▪ Any cryostorage service for which an ART clinic has charged any additional, out of pocket costs is not eligible for subsidy under this programme.
	Timelines to access services	No information identified (however cryostorage must have begun after programme launch – 1 July 2023).
	Any other organisational aspects	**Claim Process:** Every 6 months, ART clinics will lodge claims with Services Australia for all eligible cryostorage services they provided over the previous 6 months. The claim must itemise each eligible cryostorage service for which the ART clinic are seeking payment of the programme subsidy. Note that each 'cryostorage service' would include all storage samples of the same type of genetic material that are saved in one container (that is, multiple eggs from multiple cycles stored together would comprise one claim for one yearly payment of $600, and so forth). The first claim submissions under this programme will be lodged in January 2024, for the storage period 1 July-31 December 2023. Payment for these claims will be made in early 2024. Services Australia will: ▪ validate claim submissions, ▪ work with ART clinics to ensure the service information in the claim is complete and correct as required, ▪ make payment to each ART clinic for validated storage services, and ▪ provide a payment statement to the ART clinic with details of payment made.

Storage	***Arrangements and duration(s)***	Subsidised funding is provided for cryostorage of up to 2 types of material (eggs, sperm or embryos) for a maximum of 10 years. This means each type of material has its own 10-year limit. The same patient can get funding for: sperm storage for 10 years embryo storage for 10 years. The 10 years do not need to be continuous. Patients may continue to store their materials beyond the subsidy period. In this case, storage payment arrangements will be made directly between the ART clinic and the patient. If an eligible patient's eggs, sperm, or embryos are donated to another individual, reproductive partnership or organisation, then from the date of transfer the cryostorage service is no longer eligible for subsidies under this programme and cannot be claimed by the ART clinic; unless the other individual is also eligible for the programme. **Death of a patient** The death of a patient is a situation where sensitivity needs to be exercised and as such the following provisions will apply: 1. If a patient dies with one or more embryos in cryostorage, their surviving reproductive partner (the person who created the embryo with them) will become eligible for this programme and subsidies may continue in their name. If the surviving reproductive partner wishes to continue the cryostorage in their name, the ART clinic will need to: a. gain consent from the surviving reproductive partner to enter the programme, and to share their personal information with Services Australia and the Department of Health and Aged Care, then ART Storage Funding Programme Guidelines 16 b. lodge claim for subsidy for this cryostorage service under the Medicare number of the surviving partner as a new patient. c. In this case, the 10 year storage limit will renew under the surviving reproductive partner's name. 2. If a patient dies with embryo/s, sperm or eggs in cryostorage and legal arrangements are in place for transfer of ownership to another person, subsidies may continue until the first of the below takes place: a. ownership has been transferred, or b. for a grace period of up to 2 years, or c. until the material is donated or destroyed at the person's request, or d. until the original 10-year limit that applied to the deceased patient's cryostorage service is reached.

		3. If a patient dies with sperm or eggs in cryostorage and there are no legal arrangements in place for transfer of ownership to another person, in recognition of the time it may take for an ART clinic to become aware of the patient's death, subsidies may continue until the first of the below takes place: a. for a grace period of up to one programme storage period, or b. until the material is donated or destroyed at the family's request, or c. until the original 10-year limit that applied to the deceased patient's cryostorage service is reached.
	Access to stored materials	No information identified.
	Disposal of stored materials	If an eligible cryostorage service ceases due to the destruction of eggs, sperm, or embryos, the ART clinic's claim must reflect this (that is, they may only lodge a claim for the portion of the 6-month storage period that passed before the material was destroyed).
	Any other storage information	No information identified.
Governance		The subsidy amount will be periodically reviewed by the Department of Health and Aged Care in consultation with the sector. To facilitate payments, ART clinics will be required to register their details with the Services Australia Organisation Register prior to making any claim for eligible cryostorage services. Once they have registered, ART clinics will enter into a Grant Agreement with the Department. Initial grants will be in place until the end of FY2026-27. New grant agreements will be established to cover subsequent years. The Department of Health and Aged Care will evaluate the programme as part of the quality assurance process to ensure it is achieving its intended purpose. Any future changes to the programme will be reflected in updated programme guidelines, and stakeholders will be notified. **Clinic Obligations** All ART clinics registered to receive funding through the programme must: ▪ obtain and keep a record of consent from all eligible patients to seek a subsidy under this programme, ▪ ensure their information in the Organisation Register remains up to date, ▪ maintain a RTAC Licence as evidence that they are compliant with industry requirements for providing safe and high quality cryostorage services, ▪ notify Services Australia within 28 calendar days if they lose their RTAC Licence, ▪ meet eligibility requirements, ▪ ensure that none of the cryostorage services for which they claim the subsidy are ▪ subject to any exclusion criteria, ▪ follow the claim submission process and claim subsidies for eligible cryostorage services every 6 months, ▪ provide a statement to each patient every 6 months once they have received subsidy payments for that

		patient's eligible cryostorage service/s, ▪ engage fully in compliance activities undertaken by the Department or agents acting on the Department's behalf, and ▪ keep a copy of all documents relating to the ART Storage Funding programme requirements for a minimum of 7 years. **<u>Programme compliance</u>** The Department may undertake post-payment compliance activities at any time to ensure that ART clinics comply with these programme guidelines. Programme compliance activities may include a post-payment review of practice documents. If your practice is unable to provide information to support eligibility and the claims you have made, the Department may look to recover your past payments. Registered ART clinics must willingly engage fully in compliance activities undertaken by the Department or agents acting on the Department's behalf. This includes being able to provide evidence: ▪ to support eligibility of their each cryostorage service for which they have claimed subsidy under this programme, ▪ that they have an RTAC licence, ▪ that they have obtained consent from all eligible patients to seek the subsidy under this programme for their eligible cryostorage service/s and share their relevant personal information and that they have kept a record of this consent for each eligible patient, ▪ that no additional out-of-pocket fees for storage were charged for patients subsidised under this programme, and ▪ that they have provided statements to patients every 6 months, including details on subsidies paid by the Government for their eligible cryostorage service/s and information on how to cease the cryostorage. ART clinics must also: ▪ provide accurate, timely information to the Department as requested through programme compliance activities, ▪ keep a copy of all documents relating to the ART Storage Funding programme requirements for a minimum of 7 years. The Department reserves the right to recover any payments that have been inappropriately claimed.
Funding		**<u>Subsidy Amount</u>** The subsidy amount is up to $600 per year per patient and per eligible cryostorage service. Payments of up to $300 will be made in arrears on a 6 monthly basis. The first payment period will cover cryostorage of eligible services from 1 July to 31 December 2023. The first payments will be made in early 2024. The payment amount will be calculated on a monthly pro-rata basis: that is eligible cryostorage services will be subsidised for storage from the first day of the month in which they are placed in storage, to the last day of the month in which the cryostorage service ends.

		The subsidy amount is subject to indexation annually on 1 July in line with the Wage Price Index (WPI). Subsidies will be paid directly to eligible ART clinics via a payment system managed by Services Australia. No payments will be made directly to patients. ART clinics are not permitted to charge additional out-of-pocket fees for cryostorage services that are subsidised under this programme.
Communication and information provision		There is a fact sheet available for patients on the ART Storage Funding Programme.[3] This is available for clinics to provide to patients that they believe may be eligible. ART clinics must inform patients of the way their personal information will be collected and used by showing patients the ART Storage Funding Programme Privacy Collection Notice, which will be available on the Department of Health and Aged Care's ART Storage Funding Programme website. ART clinics are also required to ask patients at the end of each storage period whether they still want their eligible cryostorage service/s to remain in cryostorage. The method by which this is undertaken is a decision for each ART clinic. ART clinics must provide a statement to the patient every 6 months once they have received the programme payment, noting: ▪ that the federal Government paid for the cryostorage service rendered by the ART clinic, ▪ that $0 is owing for this cryostorage service, ▪ the period of subsidised cryostorage (that is, may be a portion of the 6 month period), ▪ which material/s storage was subsidised (that is, eggs, sperm, embryo/s), and ▪ instructions for the patient regarding how to proceed if they no longer require the storage service/s.
Ethical considerations		None explicitly outlined; however, they are aware of the sensitive nature of the death of a patient.
Relevant legislation (list)		No information identified.
Miscellaneous		No information identified.

Table D.2 Extracted data for Australia (ART Guidelines)

Australia		
Author(s) **Title [year]**	National Health and Medical Research Council (Australian Government) Ethical guidelines on the use assisted reproductive Technology in clinical practice and research[4] [2017, updated 2023] and Summary of 2023 update to the ART Guidelines[5] [2023]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		Ethical considerations are directed toward all those undergoing ART. However, specific groups are also included. Those which are of particular relevance are those undergoing ART for fertility preservation and children and young people.
Preservation method(s) available		Covers all ART.
Organisation	***Referral pathways***	No information identified.
	Service provider characteristics	No information identified.
	Timelines to access services	No information identified.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	**Maintain the safe storage and accurate identification of all gametes and embryos** Individuals and couples responsible for stored gametes or embryos are entitled to certainty about the safety and identity of the gametes or embryos. ▪ Clinics must have procedures in place to ensure all reasonable efforts are taken to maintain the safe storage and accurate identification of all gametes and embryos. All procedures should be consistent with current best practice. ▪ Clinics must ensure that all reasonable efforts are made to keep gametes and embryos in safe storage for the period of storage specified in the consent form. After this time, if the individual or couple responsible for the stored gametes and embryos cannot be contacted to provide further direction and consent, clinics may discard the gametes or embryos, in accordance with the clinic's policy. **Assess the suitability for continued (long term) storage of gametes and embryos** Decisions about the continued (long term) storage of gametes or embryos involve both personal and clinical considerations. The suitability of gametes or embryos for continued storage is a clinical determination; however, if there is no evidence of deterioration, decisions about the continued storage of gametes or embryos may depend entirely on the personal preferences of the responsible party(ies). ▪ Clinics should have policies that guide the clinical determination for continued storage of gametes and embryos. *Specific to fertility preservation*

		Manage the collection and storage of gonadal tissue or gametes for fertility preservation - Clinics should have a policy in place to manage the collection and storage of gonadal tissue or gametes for fertility preservation, including from persons unable to provide valid consent.
	Access to stored materials	No information identified.
	Disposal of stored materials	**Manage embryos no longer needed by an individual or couple for their own reproductive purposes** At any time during the period of storage of an embryo, the individual or couple for whom the embryo is stored, in consultation with their clinician, may decide that the embryo is no longer needed for their own reproductive purposes. - Clinics must have policies in place that document the basis of discussion about embryos no longer needed by an individual or couple for their own reproductive purposes. - Clinics must obtain a declaration in writing, from the individual or couple for whom the embryo is stored, that the embryo is no longer needed for their own reproductive purposes. The options listed should then be offered. **Manage stored gametes or embryos following the death of a gamete provider** The use of stored gametes or embryos for reproductive purposes following the death of a gamete provider requires the valid consent of the gamete provider or in some situations, their spouse or partner. - Clinics must have clear policies for the management of stored gametes or embryos following the death of a gamete provider. - Unless prohibited by law, if a clinic receives confirmation that a gamete provider has died, the gametes or embryos should remain stored and made available for use, or be discarded, in accordance with the wishes of the deceased expressed in the consent for storage. **Manage the discard of stored gametes and embryos** - Clinics must have policies and procedures in place for discarding stored gametes and embryos. These policies should provide for the responsible party(ies) to determine the means of removal or discard of the embryos from the clinic, including those which are legal, but are not available at the particular clinic. - Clinics may, in limited circumstances, and in line with the clinic's policy, discard stored gametes or embryos without the consent of the individual or couple for whom the gametes or embryos are stored. - Before a clinic may discard stored gametes or embryos without the consent of the responsible party(ies), clinics must make all reasonable efforts, and document all attempts, to notify the responsible party(ies) and allow reasonable time for the responsible party(ies) to take action.

	Any other storage information	**Manage disputes between members of a couple for whom an embryo is stored** 7.4.1 Clinics must have clear policies for managing disputes that may arise between individuals for whom an embryo is stored. 7.4.2 When a dispute arises, a clinic may suspend the expiry of the period of storage specified in the consent form at the request of either party. Such a suspension should be notified in writing to both parties and should be reviewed by the clinic every 5 years. Any subsequent discard of the embryos, without the consent of both parties, must be in accordance with the clinic's policy, which should have been clearly articulated to the responsible couple before the storage initially occurred.
Governance		**Record keeping** <u>Maintain appropriate records – General requirements</u> - Clinics must have appropriate policies and procedures for the collection, storage and release of data related to ART activities. - Clinics must maintain records that are adequate to allow: ▪ monitoring of, and access to, data regarding the creation, storage, use and discard of embryos ▪ for the collation of clinic-specific and national statistics about reproductive treatments and procedures, to assist individuals and couples considering ART to make informed decisions ▪ where applicable, the exchange of information between a gamete donor, recipient and person born as a result of donation ▪ where applicable, the exchange of information between a surrogate, the commissioning parent(s) and person born as a result of the surrogacy arrangement. - Clinics must manage records so that the integrity and privacy of the records comply with all requirements of relevant Commonwealth, state or territory legislation and any requirements of applicable accreditation or regulation bodies. - Clinics should have procedures for record keeping that include: ▪ the collection, recording and reporting of data about persons, treatments, procedures and results ▪ arrangements to ensure transfer of records to a suitable person or location (for example a central register or another clinic) when a clinic closes, a clinician ceases to practice or gametes or embryos are transferred to a sperm, egg or embryo bank or another clinic ▪ provision to keep records indefinitely (or at least for the expected lifetime of any persons born), including the regular review of the format in which the records are stored to ensure their ongoing accessibility and preservation. As a minimum, the following information should be recorded for each ART activity: ▪ full names (including previous names) and contact details of all individuals and couples involved and, whenever possible, the names of any person born as a result of the activity ▪ consent forms, a record of participation in counselling services, and the information provided to fulfil the relevant requirements ▪ identification details of gametes and embryos so that the clinical status or outcome for each individual embryo, egg or sperm sample can be followed from the date of collection

		▪ the outcomes of the activity for the embryo, the person born and the individuals or couples involved. This data should be recorded in an easily accessible form that can facilitate the collation of national statistics about reproductive treatments and procedures. The recorded outcomes should include: ○ the live birth rate per treatment cycle commenced ○ the occurrence of single and multiple pregnancies, ovarian hyperstimulation syndrome, miscarriage, termination of pregnancy, ectopic pregnancy, stillbirth, genetic conditions or perinatal events ○ any serious adverse effects and other side effects for the individual undergoing ART or for the person born. ○ data to facilitate long-term follow-up studies of persons born as a result of ART activities, and the individuals or couples involved (for example rates of long-term adverse outcomes and subsequent fertility). Maintain appropriate records – Donor conception programmes and surrogacy arrangements [not extracted as not deemed relevant] **Reporting of data** <u>Ensure public accountability for all activities and procedures</u> Reporting of data must be adequate to ensure open communication of, and accountability for, the clinic's activities to all parties involved, including persons born as a result of ART and to the general public. - Clinics should make non-identified data, including data relevant to licensable activities, available to appropriate bodies, to enable subsequent collation of national statistical information - Reporting of data must comply with requirements of relevant privacy legislation, state or territory legislation, NHMRC guidelines, and any accrediting bodies. Any non-mandatory use or reporting of data is subject to the consent of the individuals or couples involved.
Funding		No information identified.
Communication and information provision		Decision-making must be supported by the provision of access to counselling by a professional with the appropriate training, skills, experience and competency to counsel in reproduction. **Information Giving** <u>Provide and discuss information - General requirements</u> Clinics must ensure that information is discussed in a way that is appropriate to, and sufficient for, informed decision-making. The information should be given: ▪ verbally, supported by written information in plain language ▪ with sensitivity to cultural diversity, religious beliefs and personal circumstances ▪ in a way that is accessible to those with low literacy or disability, or whose first language is not English ▪ in a way that avoids any undue pressure or inducement. Clinics must ensure that the following information is discussed, at a minimum: ▪ options for the use or discard of gametes or embryos, including options that are legal, but may not be

		offered at the particular clinic ▪ whether the proposed procedure or treatment is accepted practice or an innovative practice, acknowledging areas of uncertainty ▪ the experience of the clinic and the clinician with the procedure, any clinically relevant outcomes and success rates and, where applicable, an explanation that certain procedures may be undertaken by persons other than the individual's or couple's treating clinician ▪ whether any training activities are intended to be conducted in the course of the treatment, including where a member of the clinical team will be supervised by more experienced staff whilst undertaking a procedure ▪ any interests of the clinician, including any commercial, financial or personal interests, relating to services provided by the clinic or any treatment or procedure recommended by the clinician, which may reasonably be perceived as a conflict of interest ▪ an explanation of all costs involved for relevant parties. Clinics must provide individuals or couples with sufficient information regarding the likely fees and the associated out-of-pocket expenses so that they are able to make an informed financial decision ▪ the clinic's privacy and record keeping policies, including an explanation of any mandatory uses or reporting of data ▪ any planned or possible clinical follow-up ▪ options for participation in a current research study or any possibility of future requests for participation in research studies. Before gametes are collected or embryos are created, clinics must ensure that all responsible parties are provided with sufficient information to facilitate an understanding of the options they will have regarding the use, storage and discard of the gametes or embryos, including those which are legal, but are not available at the particular clinic. Options include: ▪ use in their own or their partner's reproductive treatment (including the potential for posthumous use) ▪ donation to another individual or couple for use in reproductive treatment and the potential for this donation to be reallocated to a subsequent individual or couple ▪ use in research ▪ use in training or quality assurance activities ▪ transfer to another clinic in cases where the desired option for the use or discard is not available at the initial clinic ▪ discard of the gamete or embryo. The provision of information should be separated from the process of seeking consent, to allow the individual or couple sufficient time to consider the information discussed and the opportunity to seek further information and or participate in counselling, before consent is provided. <u>Provide and discuss all relevant information – Specific situations</u> <u>Individuals and couples undergoing ART</u> ▪ In addition to the requirements outlined, clinics should ensure that the information discussed with

		individuals and couples undergoing ART is sufficient to facilitate an accurate understanding of the following issues: ▪ the likelihood of the individual becoming pregnant other than through ART ▪ the likelihood of the individual becoming pregnant via the proposed reproductive procedures, referencing conditional factors including the individual's age, the number of cycles previously undertaken and recent and meaningful success and failure rates relevant to the particular individual or couple ▪ the potential that treatment will produce embryos that are considered unsuitable for transfer and the potential that such embryos may be used in training and quality assurance activities, or discarded ▪ any potential short or long-term physical and psychosocial implications for the person who would be born, the individual or couple, acknowledging that these may be uncertain ▪ the currently available published data on morbidity, and short and long-term outcomes for persons born through ART, including for future generations. <u>Individuals and couples involved in donor conception programmes [not extracted as not relevant]</u> <u>Individuals and couples seeking to store gametes or embryos</u> Clinics should ensure that the following information is discussed: ▪ the survival rate and suitability for transfer of gametes and embryos after freezing and thawing for the particular clinic ▪ the live-birth rate following the use of the thawed gametes, tissues and embryos for the particular clinic ▪ the currently available information about outcomes for persons born from stored gametes or embryos ▪ any limitations on use, specific to the clinic or the state or territory ▪ any limitations on storage times, specific to the clinic or the state or territory ▪ any circumstances under which the clinic may dispose of the gametes or embryos before the end of the consent period, including the clinic's policy for managing disputes that may arise between a couple for whom an embryo is stored ▪ the responsibilities of each party (including the clinic's) for stored gametes or embryos. <u>Individuals and couples seeking ART overseas</u> Overseas clinics may operate in an environment that does not adhere to Australian standards of care, and the clinical services available may perpetuate donor anonymity, or include treatments or procedures which are considered unethical under these Ethical Guidelines or are illegal under Australian legislation. ▪ Clinics and clinicians must not promote or recommend practices which contravene these Ethical Guidelines or Australian legislation, nor enter into contractual arrangements with overseas providers who offer such practices. ▪ Clinics approached by an individual or a couple for advice on undertaking ART overseas have an ethical obligation to advise the individual or couple of any concerns about the standard of care in the overseas clinic or acknowledge where the standard of care is unknown.

		▪ Where an individual or couple has made an autonomous decision to seek ART overseas, clinics may provide information aimed at the reduction of harm to the intended parent(s) and the person who would be born. This may include advice aimed at reducing the likelihood of ovarian hyperstimulation, the promotion of single embryo transfer and supporting the right of persons born from donated gametes or embryos to know the details of their genetic origins. ▪ Where an individual or couple has made an autonomous decision to seek ART overseas, a clinician may feel they have an ethical obligation to participate in elements of the treatment of the individual or couple in order to minimise potential harms, however: ▪ clinicians have no obligation to participate in such treatment ▪ clinicians should be aware of the relevant legislation in the relevant state or territory before participating in the treatment in such circumstances. **Counselling** <u>Provide counselling services – General requirements</u> Clinics must provide accessible counselling services from professionals with appropriate training, skills, experience and competency to support individuals and couples in making decisions about their treatment, before, during and after the procedures. Clinics should actively encourage participation and keep a record of participation. The counselling services should: ▪ provide an opportunity to discuss and explore issues ▪ explore the potential personal and social implications for the person who may be born and for the individual or couple ▪ provide personal and emotional support for the individual or couple, including help in dealing with adverse or undesired results ▪ provide advice about additional services and support networks ▪ reflect an integrated, multidisciplinary approach, including medical, nursing, scientific and counselling staff ▪ provide individuals or couples with information, when requested, about professionals who are independent of the clinic, who have specific expertise with appropriate training, skills, experience and competency to support individuals and couples in making decisions about their treatment. ▪ Clinics should be satisfied that each individual makes their own independent decision to participate in counselling and that this decision is reached without undue pressure. In some circumstances, participation in counselling is mandatory. ▪ Clinics should ensure that the time period between counselling and obtaining consent for treatment is sufficient to enable consideration of the issues. Conversely, the time elapsed should not be so great that the information discussed and the issues explored during counselling are no longer relevant or contemporary.

		Provide counselling services – Specific situations Individuals and couples involved in donor conception programmes [not extracted as not relevant] **Valid consent** Obtain consent from all relevant parties for each specific procedure – General requirements Clinics must ensure that valid consent for each specific procedure is obtained from all relevant parties and remains current. For consent to be valid: ▪ the person giving consent must be considered to have the capacity to provide consent ▪ the decision to consent to the treatment or procedure must be made without undue pressure ▪ all relevant requirements regarding the provision of information and counselling requirements must be satisfied ▪ the consent must be specific, and is effective only in relation to the treatment or procedure for which information has been given consent must be sought for all training and quality assurance activities conducted on embryos, including where an embryo is deemed unsuitable for transfer. The process of seeking consent should include: ▪ provision of all relevant information about the proposed treatment or procedure to the individual or couple, and discussion of this information ▪ provision of access to counselling by a professional with the appropriate training, skills, experience and competency. - Clinics must have procedures to verify the identity of those providing consent and to ensure the validity of the consent. - Consent must be obtained in writing and documentation must include a signed statement by the treating clinician confirming that all relevant provision of information and counselling requirements have been satisfied - All relevant parties must be provided with a copy of the signed consent form for each specific treatment or procedure. Obtain consent from all relevant parties for each specific procedure – Specific situations Individuals and couples involved in donor conception programmes [not extracted as not relevant] Individuals and couples seeking to store gametes or embryos In addition to the requirements for obtaining consent, clinics must obtain specific consent from each relevant party before gametes or embryos are stored. Consent must include consideration of: ▪ the duration of storage ▪ the use, storage or discard of gametes or embryos if either or both the person(s) for whom they are stored die(s), become(s) incapable of varying or withdrawing consent, or fail(s) to give further

		instructions at the expiry of the period of storage specified in the consent form. **Non-mandatory uses of data** ▪ In addition to the requirements for obtaining consent outlined, clinics must ensure that specific consent is obtained from individuals or couples involved in ART for any planned or future non-mandatory uses or disclosures of identifying information or data collected about them. **Recognise the right of individuals or couples to withdraw or vary their consent** ▪ Clinics must recognise that, with the exception of some specific issues relating to the donation of gametes and embryos, individuals and couples have the right to withdraw or vary their consent for ART activities. Section 5 *Use of donated gametes in ART activities* and Section *6 Additional guidelines for the use of donated embryos* is not extracted as not deemed relevant. *Specific to fertility preservation* **Information giving, counselling and consent** <u>Provide relevant information and counselling</u> ▪ Clinics must ensure that those considering the collection and storage of their gonadal tissue and or gametes are provided with all relevant information ▪ Clinics must provide those considering the collection and storage of their gonadal tissue and or gametes with access to counselling by a professional with appropriate training, skills, experience and competency to support their decision-making. **Obtain valid consent** ▪ Clinics must ensure that valid consent for each specific procedure is obtained. *Specific to children and young people* **Provide relevant information and counselling and obtain valid consent** ▪ Clinics must ensure that person(s) authorised to consent to the collection and storage of gonadal tissue or gametes from a child or young person are provided with all relevant information and have access to appropriate counselling services ▪ Clinics must ensure that valid consent for each specific procedure is obtained from the person(s) authorised to consent to the collection and storage of gonadal tissue or gametes from a child or young person. **Respect the developing capacity of a child or young person to participate in decision-making** ▪ Clinics must respect the developing capacity of children and young people to be involved in decisions about the collection or ongoing storage of their gonadal tissue or gametes. When the child or young

		person is not legally competent but sufficiently understands the issues, clinicians should encourage the child to take part in the decision-making process. ▪ Where appropriate, clinics must ensure that the child or young person is also provided with all relevant information and has access to appropriate counselling services. ▪ When the child or young person reaches the appropriate age of consent, as determined by relevant legislation, clinics must manage the transition of responsibility for the stored gametes from the person(s) authorised to consent, to the individual. The individual's valid consent must be obtained for the continued storage of their gonadal tissue or gametes. *Specific to people with impaired decision-making* **Provide relevant information and counselling and obtain valid consent** Clinics must ensure that the collection and storage of gonadal tissue or gametes from a person with impaired decision-making ability, such as with a cognitive impairment, intellectual disability or a mental illness, is conducted in accordance with the principles outlined in [sections relating to children and young people] **[Information specific to surrogacy, sex selection, preimplantation genetic testing not extracted as not deemed relevant.]** *Specific to the collection and storage of gametes from a person who is dying and has the capacity to provide valid consent* **Obtain valid consent** ▪ Clinics may facilitate the collection of gametes from a person who is dying if the person has the capacity to provide valid consent and consents to the storage of gametes and their use for reproductive purposes after their death. *Specific to the collection and storage of gametes from a deceased person or a person who is dying and lacks the capacity to provide valid consent* **Obtain valid consent from a spouse or partner** The acceptability of a spouse or partner making decisions regarding the collection of gametes warrants serious ethical consideration because of the enduring consequences of these decisions on any person who would be born and the potential for the spouse or partner to have a conflict of interest (that is a grieving spouse or partner may be focussed on their own desire to have a child, rather than the broader implications for the person who would be born, or the wishes of the person who is deceased or dying). For these reasons, court authority is required before a clinician may facilitate the collection of gametes from a person who is deceased or is dying and lacks the capacity to provide valid consent. With appropriate legal authority, clinics may facilitate the collection of gametes from a deceased person or a person who is dying and lacks the capacity to provide valid consent if: ▪ the request to do so has come from the spouse or partner of the deceased or dying person, and not

		from any other relative ▪ the gametes are intended for use by the surviving spouse or partner for the purposes of reproduction ▪ there is some evidence that the dying or deceased person would have supported the posthumous use of their gametes by the surviving partner, or at the very least, there is no evidence that the deceased or dying person had previously expressed that they do not wish for this to occur ▪ the surviving spouse or partner provides valid consent for the collection and storage of the gametes ▪ the proposed collection and storage has been approved by an appropriate court authority.
Ethical considerations		These Ethical Guidelines cover all activities associated with ART as they occur in clinical practice, including: ▪ routine practice associated with ART ▪ practices that raise specific ethical issues ▪ licensable activities under the Research Involving Human Embryos Act 2002 (RIHE Act) that occur in the clinical practice setting. For example, the use of excess ART embryos for training purposes. research involving: ▪ individuals or couples involved in ART activities, including donors of human gametes or embryos involved in embryo research ▪ embryos that are intended for implantation ▪ excess ART embryos ▪ other human embryos. The following guiding principles and their application are outlined: 1. **ART activities must be conducted in a way that shows respect to all involved:** A range of parties may be involved in ART, including the intended parent(s), gamete or embryo donor(s), a surrogate, persons who may be born as a result of ART and any child within the family unit(s) who may be affected by that birth. The interests of these parties are invariably interrelated and interdependent and may be competing. In decision-making about ART every effort should be made to consider the interests of all relevant parties in order to reconcile, as far as possible, these individual and collective interests. 2. **The interests and wellbeing of the person who may be born as a result of an ART activity must be an important consideration in all decisions about the activity:** All competent adult participants exercise a choice about their involvement in ART activities. The person who may be born as a result of the activity does not. Although the same can be said when conception is natural, some ART activities offer the potential for greater influence of the desires of the intended parent(s). Some argue that the child would not exist without the desire of the intended parent(s) to become parents and that it is in a child's best interest to be born. Nevertheless, ART may have serious consequences for the person born. Therefore, ART activities should not commence without serious consideration of the interests and wellbeing of the person who may be born as a result of that activity.

		3. **ART activities must be undertaken in a manner that minimises harm and maximises the benefit to each individual or couple involved in the ART activity, any persons who may be born as a result of the activity, and any other child within the family unit who may be affected by that birth:** Decisions regarding any procedures or the use of gametes or embryos should take into account any potential harm to any relevant party, the views of the intended parent(s), any medically relevant factors, and the likelihood of a successful live birth. In deciding whether to proceed, clinics should carefully consider potential harms to the person who may be born, or any child who may be affected by that birth. Clinics may refuse or delay treatment (pending further review by the clinical team) if there are concerns about the physical, psychological and or social wellbeing of any relevant party. 4. **Decision-making in the clinical practice of ART must recognise and take into account the biological connections and social relationships that exist or may be formed as a result of the ART activity:** The significance ascribed to a biological connection varies considerably from person to person. For some people, their connection to their biological parents, surrogate, siblings or other biological family members is very significant. For others, some or all of these biological connections have little or no significance. If a person born as a result of ART is deprived of knowledge about their biological connections, they are also deprived of the ability to decide the level of significance these connections will hold for them. When a person born from donated gametes or an embryo wants to establish contact with their biological parent(s) and or their other biological family members, but is unable to do so, the effect on that person may be substantial. Consideration of biological connections and social relationships is important for prospective gamete donors or providers, and for those considering the use of donated gametes, donated embryos, surrogacy, or the posthumous use of gametes or embryos. In each of these cases, counselling by a professional with the appropriate training, skills, experience and competency to counsel in reproduction is required to assist those involved in their decision-making and to explore the possible implications of such decisions. 5. **Decision-making in the clinical practice of ART must recognise and respect the autonomy of all relevant parties, promoting and supporting the notion of valid consent as a fundamental condition of the use of ART:** Individuals and couples involved, or considering involvement in, ART activities have the right to decide for themselves whether or not to take part in the proposed activities. To support their decision-making, individuals and couples seeking ART are entitled to the provision of detailed, accurate, contemporary and relevant information about proposed procedures or treatment and access to counselling about the potential consequences or risks, by a professional with the appropriate training, skills, experience and competency to counsel in reproduction. Valid consent must be obtained from all relevant parties for each specific procedure or treatment. The process of obtaining consent for ART activities is ongoing and not a single event. When the individual involved does not have the capacity, or is not able, to provide valid consent (for example children, people with impaired decision-making capacity, or the deceased), a representative (as defined by relevant legislation, or as identified by the Ethical Guidelines) must be involved in the

discussions and decision-making. Although it is important to respect autonomy, an individual's or a couple's autonomy may be constrained by ethical and legal parameters.

6. **Decision-making in the clinical practice of ART must recognise that social relationships and social context may affect an individual's or a couple's decision-making and be sensitive to cultural and spiritual differences:** It is important to recognise that social relationships and social context may enable, shape, or constrain an individual's or a couple's autonomy (that is autonomy is relational). Attitudes towards some of the more controversial practices and aspects of ART differ considerably, and are shaped by an individual's own particular set of values, preferences, and beliefs, or those of their family and or community. Whilst it is important that the clinical team recognise the role that social factors play in decision-making, assumptions should not be made based on the personal circumstances, cultural background or spiritual beliefs of an individual or a couple seeking ART.

7. **Processes and policies for determining an individual's or a couple's eligibility to access ART services must be just, equitable, transparent and respectful of human dignity and the natural human rights of all persons, including the right to not be unlawfully or unreasonably discriminated against:** In determining an individual's or a couple's eligibility to access ART services, there must be no unlawful or unreasonable discrimination, for example, on the basis of:

- race, religion, sex, sexual orientation, relationship status, gender identity or intersex status, social status, disability or age
- the reason(s) for seeking assisted conception
- refusal to participate in research.

The right of an individual or a couple to accept or reject specific procedures or treatments should be respected. However, where the choice of an individual or a couple is in conflict with current clinical evidence and practice, is likely to have an adverse effect on the person who would be born, or has demonstrable adverse social impacts (for example the transfer of multiple embryos at the one time), then it is appropriate that these factors are taken into account in decision-making regarding the procedure. There are circumstances where it is reasonable for a clinician to delay treatment or decline to treat an individual or couple.

Conscientious objection

A member of staff or a student who expresses a conscientious objection to the treatment of an individual patient or to an ART procedure is not obliged to be involved in that treatment or procedure, so long as the objection does not contravene relevant anti-discrimination laws and does not compromise the clinical care of the patient (for example the patient is referred to someone without a conscientious objection and is willing to accept their care). The clinic must allow a member of staff or a student who expresses a lawful conscientious objection to withdraw from involvement

and ensure that the member of staff or student is not disadvantaged because of their lawful conscientious objection.

8. **The provision of ART must be underpinned by policies that support effective and efficient practices that minimise interventions not supported by evidence of successful clinical outcomes:** The principle of effectiveness requires that waste is reduced, practices that clearly do not work are not used, and proven measures that are likely to succeed are implemented. Effectiveness is linked to the concept of efficiency, which requires that limited resources be used in the most productive manner possible.

9. **The provision of ART must be transparent and open to scrutiny, while ensuring the protection of the privacy of all individuals or couples involved in ART and persons born, to the degree that is protected by law:** Clinics must practise an open and consistent approach to ART activities. Clinics must maintain policies for each treatment and procedure available at the clinic. These policies must identify the line of responsibility in each circumstance. For example, specific policies should be developed and implemented in relation to:
   - the range of treatments and procedures available
   - access to, and eligibility for, treatment
   - gametes and embryo donation (including allocation, counselling and eligibility of both donors and recipients)
   - use, storage and discard of gametes and embryos
   - provision of information and counselling to assist decision-making
   - obtaining consent for treatment
   - record keeping and data reporting
   - investigation and resolution of complaints.

   Detailed records must be maintained so that the short- and long-term outcomes of ART activities can be assessed in order to document benefit and harm. The objectives of this are to maximise the availability of data for research, monitoring and professional oversight and to identify risks — and facilitate their correction — in order to minimise harm to all parties, including to the persons born. Clinics must also have processes in place for the audit and or peer review of clinical decisions.

Conflicts of interest

There is a need to ensure that the safety and wellbeing of patients takes priority over the commercial, financial, personal or other interests of the clinic or clinician. Clinics and clinicians should therefore avoid interactions that do not further patient care and which have the potential to bias professional judgment. Clinics should ensure that the clinical team discloses any interests, including and commercial, financial or personal interests, relating to the services provided by the clinic or any treatment or procedure recommended by the treating clinician(s). Disclosure of interests is necessary in order to assess any relevant conflicts; however, disclosure alone does not resolve a

		conflict. Clinics must maintain documented practices and procedures for the disclosure of interests and management of conflicts of interests. **Privacy** The right to privacy is not absolute in Australia. However, all individuals and couples involved in ART activities, including gamete and embryo donors, and persons born, are entitled to privacy to the degree that is protected by law. ART clinics hold large amounts of personal, sensitive or health information. Where an ART clinic operates as a private sector health service provider, it is considered an 'Australian Privacy Principle (APP) entity' under the Privacy Act 1988 (Cth) and is required to comply with the Privacy Act and the Australian Privacy Principles (APPs). It is a requirement for APP entities to take reasonable steps to secure this information from misuse, interference, loss and from unauthorised access, modification or disclosure. ART clinics in the private sector should seek advice from the relevant federal body in order to understand best practice and how to comply with the APPs when it comes to handling and storing this information. ART clinics that operate as a public health service provider must comply with the relevant state or territory privacy legislation. Clinics must have a privacy policy that ensures compliance with the relevant legislation. *Specific to fertility preservation* **Persons unable to provide consent** There may be situations in which it is ethically acceptable to collect and store the gonadal tissue or gametes of persons who are unable to provide consent. Assessments should be made on a case-by case basis. *Specific to children and young people* **Assess the ethical acceptability of the proposed collection and storage of gonadal tissue or gametes for a child or young person** The collection and storage of gonadal tissue or gametes for a child or young person may be ethically acceptable if: ▪ storage of the gonadal tissue or gametes is the best means of preserving the fertility of the child or young person ▪ the risks and discomfort of the procedure to the child or young person can be minimised ▪ the child or young person, if capable, and their parent(s), guardian or otherwise authorised person consents to the proposed collection and storage ▪ the collection and storage is not for the reproductive needs of another individual ▪ Where there is any doubt about the ethical acceptability of the proposed collection and storage of gonadal tissue or gametes for a child or young person, a clinician should seek advice from an independent body. *Specific to posthumous use of stored gametes or embryos* **Respect the wishes of the person for whom the gametes or embryos were stored**

		Regardless of the relevant individual's position on the posthumous use of their stored gametes or embryos, there may be a legal impediment to such use in some states or territories and a court order may first be required. ▪ Where permitted by law, clinics may facilitate the posthumous use of stored gametes or embryos to achieve pregnancy, if: ▪ the deceased person left clearly expressed directions consenting to such use following their death ▪ the request to do so has come from the spouse or partner of the deceased person, and not from any other relative ▪ the gametes are intended for use by the surviving spouse or partner ▪ the conditions around allowing sufficient time before attempting conception and/or pregnancy are satisfied. ▪ Where the deceased person has left clearly expressed directions that object to the posthumous use of their stored gametes or embryos, clinics must respect this objection and not facilitate the posthumous use of the stored gametes or embryos to achieve pregnancy. ▪ Where the deceased person has not left clearly expressed directions regarding the posthumous use of their stored gametes or embryos, where permitted by law, clinics may facilitate the posthumous use of stored gametes or embryos to achieve pregnancy, if: ▪ the request to do so has come from the spouse or partner of the deceased or dying person, and not from any other relative ▪ the gametes are intended for use by the surviving spouse or partner for the purposes of reproduction ▪ there is some evidence that the dying or deceased person would have supported the posthumous use of their gametes by the surviving partner, or at the very least, there is no evidence that the deceased or dying person had previously expressed that they do not wish this to occur ▪ the surviving spouse or partner provides valid consent ▪ the conditions around allowing sufficient time before attempting conception and/or pregnancy are satisfied.
Relevant legislation (list)		All activities referred to in these Ethical Guidelines must be carried out in compliance with existing laws and regulatory frameworks. The activities must also comply with relevant professional and accreditation standards. Where an ART clinic operates as a private sector health service provider, it is considered an 'Australian Privacy Principle (APP) entity' under the Privacy Act 1988 (Cth) and is required to comply with the Privacy Act and the Australian Privacy Principles (APPs).
Miscellaneous		No information identified.

Table D.3 Extracted data for Australia (ART Services).

Australia		
Author(s) **Title [year]**	Australian Government Assisted reproductive technology services (Services Australia) and Medicare Benefits Schedule Book Operating from 1 July 2024 (Department of Health and Aged Care)[6]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		The Medicare Benefits Schedule (MBS) provides a rebate for out-of-pocket costs for out-of-hospital services (including GP and specialist attendances). The Extended Medicare Safety Net (EMSN) provides an additional rebate for those whose costs go over an annual threshold. Medicare rebates are available to all those with a valid Medicare card. Medicare is funded primarily though taxation (2% of income) and there are different eligibilities depending on nationality. These rebates are not means tested and are available to all holders of a current Medicare card. There are no limits to the amount you can claim. Medicare benefits are claimable only for 'clinically relevant' services rendered by an appropriate health practitioner. A 'clinically relevant' service is one which is generally accepted by the relevant profession as necessary for the appropriate treatment of the patient. When a service is not clinically relevant, the fee and payment arrangements are a private matter between the practitioner and the patient. ART services are clinically relevant when accepted by the medical profession as necessary to appropriately treat a patient's medical infertility. Services performed must also comply with relevant state and territory laws.[7]
Preservation method(s) available		**Fee 13200:** Assisted reproductive technologies superovulated treatment cycle proceeding to oocyte retrieval, involving the use of drugs to induce superovulation and including quantitative estimation of hormones, ultrasound examinations, all treatment counselling and embryology laboratory services but excluding artificial insemination, transfer of frozen embryos or donated embryos or ova or a service to which item 13201, 13202, 13203 or 13218 applies, being services rendered during one treatment cycle—initial cycle in a single calendar year. Fee: $3,543.85; Benefit: 75% = $2657.90; 85% = $3445.15 EMSN Cap: $1,996.80 **Fee 13201:** Assisted reproductive technologies superovulated treatment cycle proceeding to oocyte retrieval, involving the use of drugs to induce superovulation and including quantitative estimation of hormones, ultrasound examinations, all treatment counselling and embryology laboratory services but excluding artificial insemination, transfer of frozen embryos or donated embryos or ova or a service to which item 13200, 13202,

		13203 or 13218 applies, being services rendered during one treatment cycle—each cycle after the first in a single calendar year. Fee: $3,314.90; Benefit: 75% = $2486.20; 85% = $3216.20 EMSN Cap: $2,898.50 **Fee 13202:** Assisted reproductive technologies superovulated treatment cycle that is cancelled before oocyte retrieval, involving the use of drugs to induce superovulation and including quantitative estimation of hormones and ultrasound examinations, but excluding artificial insemination, transfer of frozen embryos or donated embryos or ova or a service to which item 13200, 13201, 13203 or 13218 applies, being services rendered during one treatment cycle. Fee: $530.35; Benefit: 75% = $397.80; 85% = $450.80 EMSN Cap: $77.30 **Fee 13203:** Ovulation monitoring services for artificial insemination or gonadotrophin, stimulated ovulation induction, including quantitative estimation of hormones and ultrasound examinations, being services rendered during one treatment cycle but excluding a service to which item 13200, 13201, 13202, 13212, 13215 or 13218 applies. Fee: $554.45; Benefit: 75% = $415.85; 85% = $471.30 EMSN Cap: $128.70 **Fee 13207:** Biopsy of an embryo, from a patient who is eligible for a service described in item 73384 under clause 2.7.3A of the pathology services table (see PR.7.1), for the purpose of providing a sample for pre-implantation genetic testing—applicable to one or more tests performed in one assisted reproductive treatment cycle. Fee: $125.90; Benefit: 75% = $94.45; 85% = $107.05 **Fee: 13209:** Planning and management of a referred patient by a specialist for the purpose of treatment by assisted reproductive technologies or for artificial insemination—applicable once during a treatment cycle. Fee: $96.45; Benefit: 75% = $72.35; 85% = $82.00 EMSN Cap: $12.90 **Fee 13212:** Oocyte retrieval for the purpose of assisted reproductive technologies—only if rendered in connection with a service to which item 13200 or 13201 applies (Anaes.). Fee: $403.80; Benefit: 75% = $302.85; 85% = $343.25 EMSN Cap: $83.70

		Fee 13241: Open surgical testicular sperm retrieval, unilateral, using operating microscope, including the exploration of scrotal contents, with biopsy, for the purposes of intracytoplasmic sperm injection, for male factor infertility, not being a service associated with a service to which item 13218 or 37604 applies (H) (Anaes.) Fee: $968.35; Benefit: 75% = $726.30 **Fee 13251:** Intracytoplasmic sperm injection for the purpose of assisted reproductive technologies, for male factor infertility, excluding a service to which item 13203 or 13218 applies. Fee: $476.15; Benefit: 75% = $357.15; 85% = $404.75 EMSN Cap: $128.70 **Fee 13260:** Processing and cryopreservation of semen for fertility preservation treatment before or after completion of gonadotoxic treatment for malignant or non-malignant conditions, in a post-pubertal male in Tanner stages II-V, up to 60 years old, if the patient is referred by a specialist or consultant physician, initial cryopreservation of semen (not including storage) – one of a maximum of two semen collection cycles per patient in a lifetime. **A semen cycle collection process involves obtaining up to 3 semen samples on alternate days producing up to 50 cryopreserved straws of frozen sperm.** **Maximum of two semen collection cycles, one cycle collected prior to a patient undergoing the first cytotoxic/radiation treatment and the second cycle to be collected if the patient has relapsed and requires treatment.** Fee: $472.75; Benefit: 75% = $354.60; 85% = $401.85 EMSN Cap: $307.30 *Fee 13260 was included within Medicare following the MSAC recommendation on Application No. 1435 Processing and cryopreservation of male and female gonadal tissue and gametes prior to or after gonadotoxic treatment to preserve fertility for the future (Part A). Processing and cryopreservation in pre-pubertal children undergoing gonadotoxic treatment in the hope that future technology may allow the re-implantation of the tissue or spermatogonial stem cells was considered experimental in this application and therefore was not recommended by MSAC. MSAC agreed that a resubmission for these populations should be considered by ESC and MSAC once evidence becomes available.*[8] **Fee 13290:** Semen, collection of, from a patient with spinal injuries or medically induced impotence, for the purposes of analysis, storage or assisted reproduction, by a medical practitioner using a vibrator or electro-ejaculation device including catheterisation and drainage of bladder where required. Fee: $232.60; Benefit: 75% = $174.45; 85% = $197.75

		Fee 37605: Transcutaneous sperm retrieval, unilateral, from either the testis or the epididymis, for the purposes of intracytoplasmic sperm injection, for male factor infertility, excluding a service to which item 13218 applies. (Anaes.) Fee: $425.45; Benefit: 75% = $319.10; 85% = $361.65 **Fee 37606:** Open surgical sperm retrieval, unilateral, including the exploration of scrotal contents, with our without biopsy, for the purposes of intracytoplasmic sperm injection, for male factor infertility, performed in a hospital, excluding a service to which item 13218 or 37604 applies. (Anaes.) Fee: $631.75; Benefit: 75% = $473.85; 85% = $537.00 ***Important to note*** *In 2018, after considering the strength of the available evidence in relation to comparative safety, clinical effectiveness and cost-effectiveness, MSAC did not support MBS funding for the processing, analysis and cryopreservation of ovarian tissue (ovarian tissue cryopreservation [OTC]) to preserve fertility in females undergoing potentially gonadotoxic treatment. While MSAC acknowledged the merit of such a service, as it is the only option for fertility preservation in pre-pubertal women, it did not support MBS funding due to uncertain clinical effectiveness and unresolved safety concerns, particularly risk of malignancy. [Further information can be found within the application, although it was not included for reimbursement on the initial application in 2018[8] or re-application in 2019][9]*
Organisation	***Referral pathways***	The GP is the gatekeeper for referred services, in recognition that GPs play a major role in the primary care of their patients and should generally be the first point of contact in determining the treatment a patient receives. The referral system was introduced to allow medical practitioners to refer patients to specialists where their specific skills and expertise are required to assist with the diagnosis and treatment of the patient. It is not intended to allow medical practitioners to refer patients to themselves. For a valid referral, a referring practitioner must: ▪ consider the need for the referral ▪ identify themselves as the referring practitioner ▪ explain the reason for the referral, including providing relevant clinical information about the patient's condition for investigation, opinion, treatment and or management, and ▪ sign and date the referral. Below is the pathway which was included in Application No. 1435 to MSAC - Processing and cryopreservation of male and female gonadal tissue and gametes prior to or after gonadotoxic treatment to preserve fertility for the future (Part A).[8] (Which later became Fee 13260)

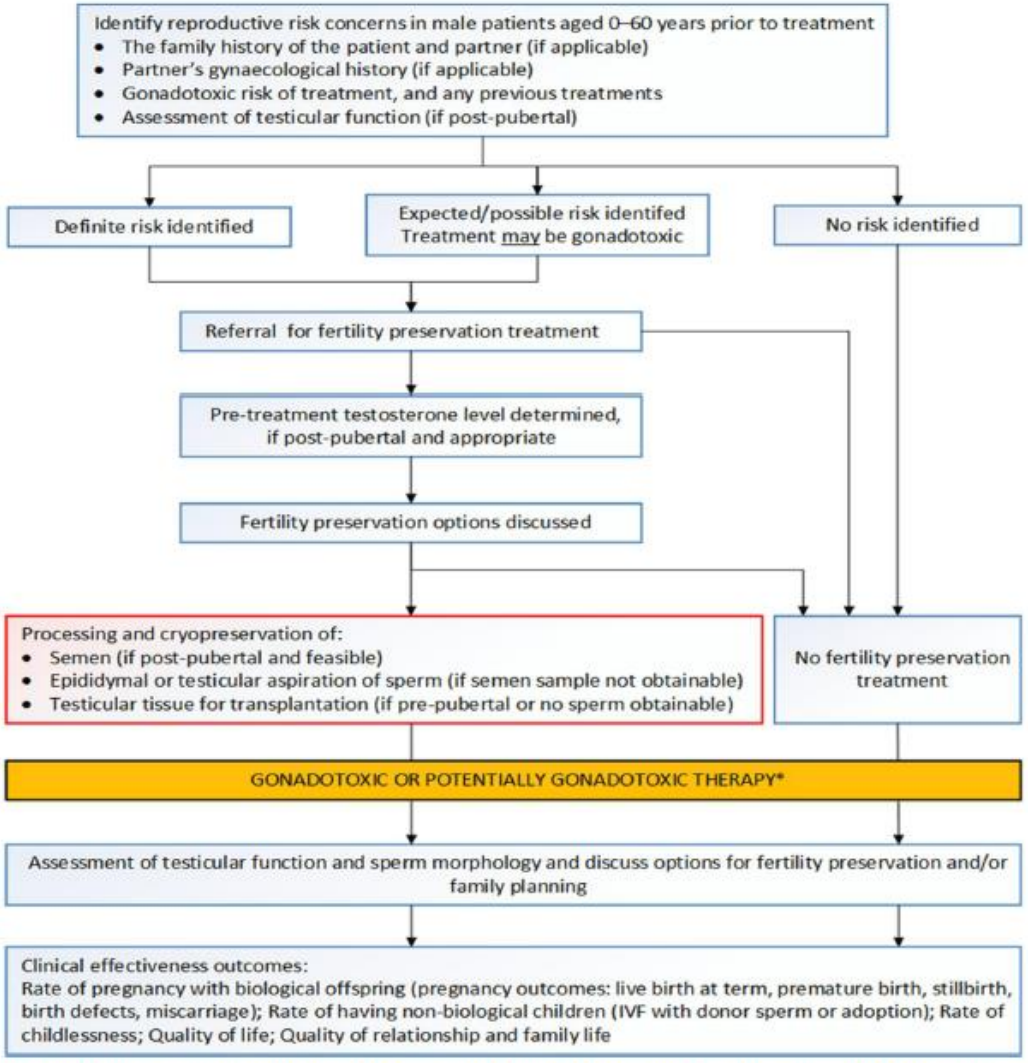


Figure 1 Clinical management algorithm for processing and cryopreservation of semen or testicular tissue prior to gonadotoxic treatment (red box for proposed MBS items)

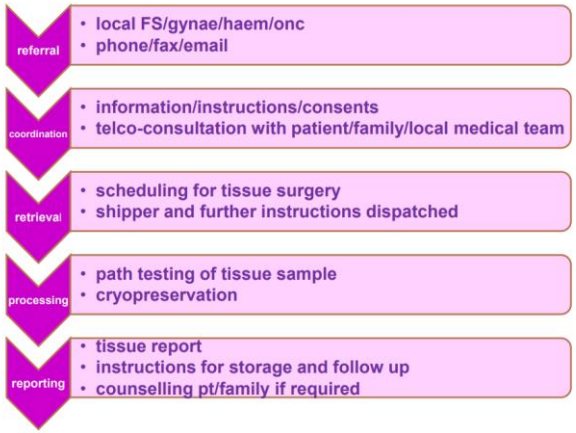
	Service provider characteristics	The major elements of Medicare are contained in the Health Insurance Act 1973, as amended, and include the following: a. Free treatment for public patients in public hospitals. b. The payment of 'benefits', or rebates, for professional services listed in the Medicare Benefits Schedule (MBS). The relevant benefit rates are: i. 100% of the Schedule fee for services provided by a general practitioner to non-referred, non-admitted patients, or for general practitioner attendances specified as not being hospital treatments ii. 100% of the Schedule fee for services provided on behalf of a general practitioner by a practice nurse or Aboriginal and Torres Strait Islander health practitioner*; iii. 75% of the Schedule fee for professional services rendered to a patient as part of an episode of hospital treatment (other than services provided to public patients), including services provided in hospital outpatient settings. iv. 75% of the Schedule fee for professional services rendered as part of a privately insured episode of hospital-substitute treatment such as 'hospital in the home', but generally not including certain services listed below. v. 85% of the Schedule fee for all other services. **GN.2.4 Provider eligibility for Medicare** To be eligible to provide medical service which will attract Medicare benefits, or to provide services for or on behalf of another practitioner, practitioners must meet one of the following criteria: (a) be a recognised specialist, consultant physician or general practitioner; or (b) be in an approved placement under section 3GA of the *Health Insurance Act 1973*; or (c) be a temporary resident doctor with an exemption under section 19AB of the *Health Insurance Act 1973*, and working in accord with that exemption. Any practitioner who does not satisfy the requirements outlined above may still practice medicine but their services will not be eligible for Medicare benefits.
	Timelines to access services	No information identified.
	Any other organisational aspects	[In relation to the fees outlined under 'Preservation method(s) available'] Embryology laboratory services for items 13200 and 13201 include any of the following: ▪ egg recovery from aspirated follicular fluid ▪ semen preparation ▪ monitoring of fertilisation and embryo development ▪ insemination ▪ preparation of gametes or embryos for transfer or freezing.
Storage	***Arrangements and duration(s)***	No storage provided with Medicare. This is now covered in the *ART Storage Funding Programme*.

	Access to stored materials	No information identified.
	Disposal of stored materials	No information identified.
	Any other storage information	No information identified.
Governance		No information identified.
Funding		Fees outlined for each procedure, along with the associated Medicare reimbursement are outlined in *Preservation method(s) available*. The Medicare Safety Net entitlement does not include hospital/day surgery related services, such as egg collection and or embryo transfer. It should be noted that Medicare reimbursement can be following patient payment or bulk billing. The quickest way to claim your Medicare benefit is at your doctor's office straight after you pay. To do this you need to both: be enrolled in Medicare and show your Medicare card. If your doctor bulk bills, you don't need to pay.[10] When you pay at the doctor's office, ask if they can make an electronic claim for you. If they can, they'll do it on the spot. We'll process the claim as soon as possible and pay your Medicare benefit into either the account for the EFTPOS card you used to pay or the bank account you've registered with us. You can also claim Medicare benefits online, in the post, at a service centre or for someone else. Bulk billing means you don't have to pay for your medical service from a health professional.[11] They bill us instead and they accept the Medicare benefit as full payment for the service. You assign the benefit to them by either: signing a form or pressing OK on the EFTPOS terminal after your appointment.
Communication and information provision		No information identified.
Ethical considerations		No information identified.
Relevant legislation (list)		The major elements of Medicare are contained in the Health Insurance Act 1973.
Miscellaneous		Medicare benefits applicable to reproductive treatment post storage: **Fee 13215:** Transfer of embryos or both ova and sperm to the uterus or fallopian tubes, excluding artificial insemination—only if rendered in connection with a service to which item 13200, 13201 or 13218 applies, being services rendered in one treatment cycle (Anaes.) Fee: $126.65 Benefit: 75% = $95.00 85% = $107.70 EMSN Cap: $57.90

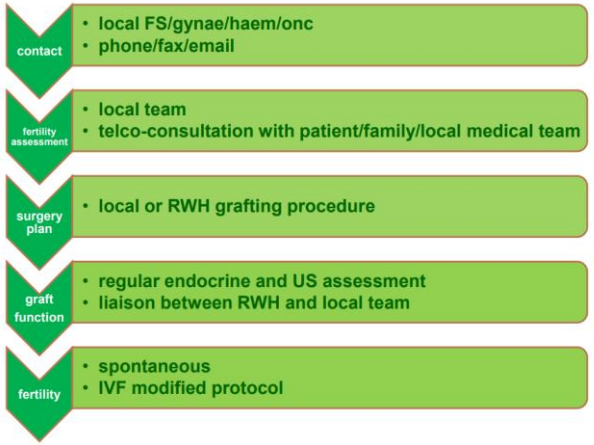
		Fee 13218: Preparation of frozen or donated embryos or donated oocytes for transfer to the uterus or fallopian tubes, by any means and including quantitative estimation of hormones and all treatment counselling but excluding artificial insemination services rendered in one treatment cycle and excluding a service to which item 13200, 13201, 13202, 13203 or 13212 applies (Anaes.) Fee: $904.00 Benefit: 75% = $678.00 85% = $805.30 EMSN Cap: $837.40 **Fee 13321:** Preparation of semen for the purpose of artificial insemination—only if rendered in connection with a service to which item 13203 applies Fee: $57.85 Benefit: 75% = $43.40 85% = $49.20 EMSN Cap: $25.80

Table D.4 Extracted data for Australia (Transport and Cryopreservation Service).

Australia		
Author(s) **Title [year]**	The Royal Women's Hospital, Victoria Australia National Ovarian and Testicular Tissue Transport and Cryopreservation Service (NOTTCS)[12] [2024]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		Patients who are at risk of losing fertility because of their cancer or other serious disease or its treatment and who would otherwise not have access because of where they live. **Clinical inclusion** is defined as: ▪ Patients planning medical treatment that puts their fertility at risk and for whom gonadal tissue freezing is indicated. **Clinical exclusion** is defined as: ▪ Patients not deemed suitable for this service by an oncologist or health care provider or where the patient does not wish to be referred. **This service was made possible, and free of charge to those patients 13–30 year old with a cancer diagnosis, through a generous donation by Sony Foundation.[13]**
Preservation method(s) available		Ovarian and testicular tissue cryopreservation.
Organisation	***Referral pathways***	Referral to the service is required by a referring/treating doctor/hospital/clinic. A referral form can be found online. For general fertility preservation services at Melbourne IVF and the Royal Women's Hospital referrals are accepted from:[14] ▪ oncologist ▪ surgeon ▪ general practitioner (GP) ▪ nurse coordinator ▪ fertility specialist Urgent referral can also be provided by calling the NOTTCS contact phone number.
	Service provider characteristics	The service pathway for tissue extraction, cryopreservation and storage is as follows:[15]



The service pathway for use of the cryopreserved tissue is as follows:[15]



Local gynaecologists, urologists and fertility specialists will undertake surgeries for ovarian tissue harvest and testicular tissue extraction, at their centres. Following tissue extraction the tissue is then transported for processing and cryopreservation at The Royal Women's Hospital and then stored at the Women's and Royal Melbourne Hospital IVF laboratory. Following the multidisciplinary decision to graft the tissue in future, the tissue may be transported back to the local unit. Alternatively, the grafting surgery can be performed at the Women's.

	Timelines to access services	Referrals are fast tracked to eliminate any delay in treatment.
	Any other organisational aspects	This is primarily a transport and storage service for gonadal tissue prior to grafting.
Storage	***Arrangements and duration(s)***	Service for retrieval and transport of ovarian and testicular tissue to centralised centre (Women's and Royal Melbourne Hospital IVF laboratory) with expertise in processing and storage
	Access to stored materials	Following the multidisciplinary decision to graft the tissue in future, the tissue may be transported back to the local unit.
	Disposal of stored materials	No information identified.
	Any other storage information	No information identified.
Governance		No information identified.
Funding		The service is partially funded by Sony Foundation Australia. Sony Foundation Australia is the charitable arm of the Sony Group of Companies in Australia. Sony Foundation Australia funding has made the transport and storage initiative free of charge and available nationally.
Communication and information provision		The service provides: ▪ Specialised fertility preservation counselling for patients ▪ Specialised fertility preservation advisory support for health professionals ▪ Provision of education resources for health professionals and for patients This includes patient information (hard copy and electronic), information on referral pathways, and telephone or video calling with the team. In addition, fertility preservation co-ordination will be available for advice, consultations, to organise the transportation process and arrange follow-up.
Ethical considerations		No information identified.
Relevant legislation (list)		No information identified.
Miscellaneous		The RWH/MIVF fertility preservation service has been preserving ovarian tissue since 1995. This service has been available to children, adolescent young adults (AYA) and adults about to receive gonadotoxic treatment for malignant and non-malignant conditions. In 2013, this service was extended to freezing testicular tissue for pre-pubertal and peri-pubertal males. Until 2019 these fertility preservation options have only been available to those undergoing procedures at Melbourne metropolitan hospitals.[13]

Table D.5 Extracted data for Denmark (Council of Ethics – Storage)

Denmark		
Author(s) **Title [year]**	The Council of Ethics Storage of fertilised eggs and unfertilised egg cells[16] [2020]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		No information identified.
Preservation method(s) available		Cryopreservation of fertilised eggs and unfertilised egg cells
Organisation	***Referral pathways***	No information identified.
	Service provider characteristics	No information identified.
	Timelines to access services	No information identified.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	A majority of the council's members…[15 members]…recommend that the storage time for fertilised eggs as well as unfertilised egg cells be extended to the applicable age limit for receiving reproductive assistance. With the current age limit of 46 years, this means that it is recommended that both fertilised eggs and unfertilised egg cells can be stored until the woman is 46 years old.
	Access to stored materials	**The legal background** While the Assisted Reproduction Act establishes the framework for assisted reproduction, it is professional judgments and political decisions that determine which treatments are offered in the public health system within this framework…While the Act on Assisted Reproduction allows egg freezing for non-medical indications, fertility treatment is offered in the public sector only for medical indications. And while the law allows assisted reproduction to take place until the woman is 46 years old, fertility treatment at public hospital clinics only for women who are referred before they are 40 years old, just as no fertility treatment is given after the woman is 41 years old. As regards IVF and possibly egg freezing, it also applies that such treatment may only be offered if a single woman does not already have a child or a couple does not have children together. If a single woman or a couple has frozen eggs left over after treatment, it can be offered to deposit the eggs so that the single woman or the couple can have more children. However, a maximum of 3 treatment trials are offered under public auspices. If you want more treatment trials, it must therefore take place privately.
	Disposal of stored materials	No information identified.
	Any other storage information	No information identified.

Governance		Finally, all council members also consider it essential that an extension of the storage period is followed up by studies which can confirm that there are actually no significant late consequences associated with such an extension.
Funding		Whether they recommend a retention period of 10 years or until the age of 46, all councilors are aware that this is a significant extension of the current retention period of 5 years, and that such an extension raises the question of whether the extent to which the new storage options should be offered publicly or left to the private market. In this opinion, however, the Council has deliberately chosen not to take a position on this issue. As the council sees it, it should be left to the general political prioritisation, which for example is also behind the fact that today no reproductive assistance is offered in the public health system if the woman is 41 years old, even though the law allows reproductive assistance until the woman is full 46 years.
Communication and information provision		All council members also consider it crucial that an extension of the storage time for fertilised eggs and unfertilised egg cells does not stand alone, but is accompanied by initiatives which partly ensure that all citisens of reproductive age are fully informed about the dependence of fertility on age and lifestyle, and partly that infertility is prevented as far as possible.
Ethical considerations		**The Council's recommendations** As a basis for their recommendation, the members put particular emphasis on 3 considerations. Firstly, they have emphasised the consideration of the person's self-determination. The basic point of view here is that it should initially be up to the person to decide how long they wish to store their fertilised eggs or unfertilised egg cells. Secondly, they have emphasised a consideration of equality. The basic point of view here is that men and women should initially be treated equally as regards the right to control their reproductive cells, and since there is no upper limit to how long sperm cells can be frozen, this speaks in favor of extending the storage time for unfertilised egg cells. Finally, the council members have emphasised the positive consequences that an extension of the storage period can be expected to lead to for the parties involved. In their opinion, existing knowledge thus points to the fact that there are no significant risks associated with storing fertilised eggs or unfertilised egg cells for a longer period of time. And since an extended storage period will not only save some from the discomfort that can be associated with hormone stimulation and egg retrieval, but must also be expected to lead to the birth of children who would otherwise not have been born, according to the council members, it speaks for a extension of the storage period. Although they agree with the described recommendation, 3 council members…want to express some concern that an extension of the storage time for both fertilised eggs and unfertilised eggs egg cells until the age of 46 opens up for freezing of especially unfertilised egg cells on a non-medical indication (so-called 'social freezing'), which the previous limit of 5 years has limited in practice. The council members are particularly concerned about how it will affect the position of women on the labour market and the development of offers that make it easy to be a family with children…[two members]…as well as the general attitude towards having children [one member]. They are aware that figures from, for example, Great Britain, where it has long been possible to freeze unfertilised egg cells

		for non-medical indications, do not indicate that the phenomenon will become particularly widespread. For the stated reasons, however, they consider it important to follow the development closely, and therefore recommend that an extension of the storage period be accompanied by a separate registration of the number of frozen unfertilised egg cells in the Danish Health Data Agency's annual report on assisted reproduction. A minority of the council members…[two members]…recommend that fertilised and unfertilised eggs should be able to be stored for 10 years, with the possibility of extension in case of serious illness, as long as the age limit of 46 years is not exceeded. In connection with their recommendation, the council members have placed particular emphasis on the precautionary principle. They recognise that self-determination and equality have great value, but also believe that special caution must be exercised in connection with interventions that can potentially affect the human genetic makeup. They are aware that there are many indications that there are no particular risks associated with the storage period itself. Since there are not many studies of the possible late consequences in connection with the freezing of unfertilised egg cells and fertilised eggs that have been frozen for a long time, they believe that the limit for both fertilised eggs and unfertilised egg cells should be 10 as a precaution year. They are of the conviction that an extension to 10 years will meet most people, and for those who may have to postpone a possible use of the eggs within the 10 years due to serious illness, the possibility of exemption means that they do not need to destroy the eggs after 10 years. **Ethical aspects** **Five Overall Perspectives** In one of the council's early reports on artificial insemination (from 1995), an overview of 5 different basic perspectives in the public debate regarding assisted reproduction is presented, which will subsequently form the basis for the presentation of the most relevant ethical considerations in connection with a possible extension of the storage time for fertilised eggs and unfertilised egg cells. The 5 basic perspectives are: 1. An autonomy-based perspective 2. A humanistic and 'Samaritan' perspective 3. An individual-oriented consequence-ethical perspective 4. A community-oriented consequence-ethical perspective 5. A religious conservative perspective Briefly described, the autonomy-based perspective primarily emphasises the individual's self-determination, while the humanistic and 'Samaritan' perspective focuses on helping the weak and vulnerable. The individual-oriented consequence-ethical perspective focuses on the good and bad consequences for the parties immediately involved (the childless and future children), while the community-oriented consequence-ethical perspective emphasises the consequences for the community and culture. Finally, the religiously conservative perspective emphasises the moral status of the fertilised egg, while at the same time it will often regard certain reproductive relationships as more natural than others.

Relevant legislation (list)		Freezing of fertilized and unfertilized eggs is regulated by the Assisted Reproduction Act, which regulates a number of matters regarding assisted reproduction including the sale, donation and storage of human eggs, surrogacy and what must happen if the woman or her partner dies or cohabitation ends. While the Assisted Reproduction Act establishes the framework for assisted reproduction, it is professional judgments and political decisions that determine which treatments are offered in the public health system within this framework. The starting point here is that a woman or a couple is offered a fertility assessment after a year of unacknowledged pregnancy wish, if the woman is under 30-35 years of age, and there are no immediately obvious reasons for the infertility in the medical history. If the woman is over 35, a fertility assessment can be offered after half a year of unpaid pregnancy wishes. While the Act on Assisted Reproduction allows egg freezing for non-medical indications, fertility treatment is offered in the public sector only for medical indications. And while the law allows assisted reproduction to take place until the woman is 46 years old, fertility treatment at public hospital clinics only for women who are referred before they are 40 years old, just as no fertility treatment is given after the woman is 41 years old As regards IVF and possibly egg freezing, it also applies that such treatment may only be offered if a single woman does not already have a child or a couple does not have children together. If a single woman or a couple has frozen eggs left over after treatment, it can be offered to deposit the eggs so that the single woman or the couple can have more children. However, a maximum of 3 treatment trials are offered under public auspices. If you want more treatment trials, it must therefore take place privately.
Miscellaneous		You can read more about the 5 overall perspectives in "Artificial insemination - an account" (1995): https://etiskraad.dk/Media/638352133951248229/1995%20kunstig%20befrugtning.pdf

Table D.6 Extracted data for Denmark (Act on Assisted Reproduction 2019)

Denmark		
Author(s) **Title [year]**	Ministry of the Interior and Health LBK no. 902 of 23/08/2019: Executive Order on the Act on Assisted Reproduction in Connection with Treatment, Diagnostics and Research, etc.[17] [2019]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**§ 6.** Assisted reproduction may not take place in cases where the woman who is to give birth to the child is older than 45 years of age. 1) Female: a person with uterine or ovarian tissue. 2) Male: a person with at least one testicle.
Preservation method(s) available		No information identified.
Organisation	***Referral pathways***	No information identified.
	Service provider characteristics	[See 'Funding' for Chapter 1a Offer of treatment with assisted reproduction at the regional hospitals]
	Timelines to access services	No information identified.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	**Chapter 3** **Sale, donation and storage of human eggs** **§ 15.** Fertilized and unfertilized human eggs can be stored for up to 5 years, after which the eggs must be destroyed. The doctor in charge may decide to extend the retention period beyond 5 years and until the time when the woman is older than 45 years if the single woman or one of the parties to the marriage, registered partnership or relationship suffers from a serious illness. The doctor in charge may revoke a decision pursuant to subsection 2 where conditions pursuant to subsection 2 are no longer met. [See 'Disposal of stored materials for subsection 2]
	Access to stored materials	See 'Governance'.
	Disposal of stored materials	**§ 15.** (2) In the event of the woman's death or in the event of the couple's separation or divorce or the termination of cohabitation, the treating healthcare professional must ensure that the stored fertilised eggs are destroyed.

		(3) In the event of the man's death, the treating healthcare professional must ensure that stored fertilised eggs are destroyed, unless there is written consent from the man pursuant to section 23(3), 2nd sentence. [See 'Ethical considerations for section 23(3)] (4) The treating healthcare professional must ensure that the unfertilised eggs stored by the spouse or cohabitant are destroyed in the event of the woman's death. **Chapter 4** **Donation, use and storage of sperm** **Section 18 a.** The treating healthcare professional must ensure that the woman's spouse's or partner's stored sperm is destroyed in the event of the woman's death, unless there is written consent from the man pursuant to section 23(3), 2nd sentence. [See 'Ethical considerations for section 23(3)]
	Any other storage information	**§ 26.** Fertilised eggs may only be kept alive outside a woman's uterus for 14 days from the date of fertilisation. The time during which the fertilised human eggs have been frozen is not taken into account.
Governance		**§ 17.** The Minister of Health may lay down detailed rules on donation, including anonymity and conditions for compensation, on storage, on use, including the number of pregnancies per donor, and on the transfer of human eggs. (2) The Danish Patient Safety Authority is authorised to lay down health professional rules for the donation, use, transfer and storage of human eggs. **§ 20.** The Minister of Health may lay down detailed rules for donation, including anonymity and conditions for compensation, and the use of donor sperm, including the number of pregnancies per donor, as well as the purposes for which donor sperm may be stored. (2) The Danish Patient Safety Authority is authorised to lay down health professional rules for the donation, use and storage of sperm, including with a view to preventing the transmission of diseases.
Funding		**Chapter 1 a** **Offer of treatment with assisted reproduction at the regional hospitals** **§ 1 a.** At their hospitals, the regional councils may only provide treatment with assisted reproduction to single women who do not have children and couples who do not have children together, cf. however, subsection (2) and section 7(1) and (3). (2) To a single woman or a couple who have had a child through assisted reproduction and who, after the end of treatment, still have frozen eggs, the regional councils at their hospitals may, within the time limit mentioned in section 15(1), offer to transfer eggs in order for the single woman or the couple to have more children.
Communication and information provision		**Chapter 6** **Information and consent** [See 'Ethical considerations' for **section 23**.]

		§ 24. The treating healthcare professional must ensure that information is provided on the civil law consequences of a woman or couple receiving donated gametes in connection with assisted reproduction treatment. (2) The treating healthcare professional must ensure that, prior to giving consent pursuant to section 23(3), 2nd sentence, information is provided about the civil law consequences of the man's sperm or eggs fertilised with his sperm being used in assisted reproduction treatment after his death.
Ethical considerations		**Chapter 6** **Information and consent** **§ 23.** Before treatment with assisted reproduction is initiated, written consent for the treatment must be obtained from the woman and from her spouse, registered partner or partner, if any. (2) Consent pursuant to subsection (1) may only be given on the basis of written and oral information about the effects and side effects of the treatment, including the risks associated with the treatment. (3) Before the treatment begins, the treating healthcare professional must also inform that the man can give his written consent for the woman to use his sperm or eggs fertilised with his sperm for assisted reproduction treatment after the man's death, and of the consequences of not giving consent to this. At the request of the man, the healthcare professional must obtain consent pursuant to subsection 1, which may be made conditional. (4) The treating healthcare professional must ensure that consent pursuant to subsection (1) and subsection (3), second sentence, is still valid, subject to subsection (5). (5) If the treatment is to take place after the man's death using his sperm or eggs fertilised with his sperm, the treating healthcare professional must first ensure that there is written consent from the man and that any conditions for the consent are met, cf. subsection 3, 2nd sentence.
Relevant legislation (list)		Act on Assisted Reproduction in Connection with Treatment, Diagnostics and Research, etc., cf. Consolidated Act no. 514 of 12 April 2019, with the amendment resulting from section 1 of Act no. 1688 of 26 December 2017,
Miscellaneous		No information identified.

Table D.7 Extracted data for Denmark (5-year limit on egg freezing lifted)

Denmark		
Author(s) **Title [year]**	Ministry of the Interior and Health New political agreement lifts 5-year limit for freezing eggs[18] [2020]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		Women…[whose]…eggs…[are]…stored frozen…if they have been removed in connection with fertility treatment or illness
Preservation method(s) available		Cryopreservation of fertilized and unfertilized eggs
Organisation	***Referral pathways***	No information identified.
	Service provider characteristics	No information identified.
	Timelines to access services	No information identified.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	Under current legislation, fertilised and unfertilised eggs may be stored for up to 5 years, after which the eggs must be destroyed. This means that women and couples undergoing fertility treatment have their healthy eggs destroyed just because they have reached the 5-year age limit for egg storage. However, a doctor can extend the storage period in case of serious illness of the woman or partner. With the political agreement, women's eggs will be able to be stored until the woman turns 46, which is also the age limit for receiving fertility treatment in Denmark. The parties to the agreement have been prepared to quickly enter into an agreement to lift the 5-year limit for freezing eggs, so that a change in the law can be adopted soon. The new agreement also states that women who have been affected by illness should not be limited by a storage period of 5 years, but should have the opportunity to decide for themselves when they want to use their frozen eggs until the woman turns 46.
	Access to stored materials	The new agreement also states that women who have been affected by illness should not be limited by a storage period of 5 years, but should have the opportunity to decide for themselves when they want to use their frozen eggs until the woman turns 46.
	Disposal of stored materials	See 'Arrangements and duration(s)'
	Any other storage information	No information identified.

Governance		All parties in the Danish Parliament have agreed to abolish the current 5-year limit for freezing eggs in connection with fertility treatment and illness. The government, together with the Liberal Party, the Social Liberal Party, the Danish People's Party, the Socialist People's Party, the Red-Green Alliance, the Conservative People's Party, the New Conservative Party, the Liberal Alliance, the Alternative and Susanne Zimmer (UFG), have entered into an agreement to lift the 5-year ceiling for freezing eggs in connection with fertility treatment and illness.
Funding		The Ministry of Health estimates that the annual costs associated with the abolition of the 5-year limit amount to DKK 2.6 million. The government and the parties to the agreement agree that the agreement will be financed via reprioritisation of non-allocated rate pool funds set aside under § 16.11.79.30. Sub-agreement on implementation of the rate pool for 2017-2020: Action plan for the prevention of violence in housing.
Communication and information provision		No information identified.
Ethical considerations		The parties do not want women and couples to go through an unnecessary and demanding process of hormone stimulation and egg retrieval if there are already frozen eggs that can be used in the attempt to achieve pregnancy. **Statement from the Danish Council of Ethics** The decision to lift the 5-year storage ceiling for freezing eggs in connection with fertility treatment or illness follows a statement from the Danish Council of Ethics. On the basis of a citizens' proposal, the Minister for Health Magnus Heunicke urged the Council of Ethics to assess the ethical aspects in connection with an extension of the storage period for freezing eggs. On 29 September, the Council of Ethics issued a statement stating that it is recommended to extend the storage period for frozen eggs.
Relevant legislation (list)		No information identified.
Miscellaneous		No information identified.

Table D.8 Extracted data for Denmark (Executive Order on Assisted Reproduction 2015)

Denmark		
Author(s) **Title [year]**	Ministry of the Interior and Health BEK no. 672 of 08/05/2015: Executive Order on Assisted Reproduction[19] [2015]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		Woman: For the purposes of this Executive Order, a woman is defined as a person with a uterus or ovarian tissue. Man: For the purposes of this Executive Order, a man is defined as a person with a person with at least one testicle.
Preservation method(s) available		Storage and donation of unfertilized and fertilized human eggs Sperm storage and donation
Organisation	***Referral pathways***	No information identified.
	Service provider characteristics	No information identified.
	Timelines to access services	No information identified.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	**§ 2.** Human eggs retrieved from a woman may not be stored for more than 5 years, subject to subsection (2). No later than after the expiry of the 5 years, the eggs must be destroyed. *(2)* The doctor in charge may decide to extend the storage period beyond 5 years and until the time when the woman is older than 45 years if the single woman or one of the partners in the marriage, registered partnership or relationship suffers from serious illness. *(3)* The doctor responsible may revoke a decision made pursuant to subsection (2) where the conditions under subsection (2) are no longer met.
	Access to stored materials	No information identified.
	Disposal of stored materials	**§ 6.** Stored, unfertilised human eggs must be destroyed if the woman who has donated the eggs dies before 5 years have passed from the beginning of the storage period, cf. however, section 2(2), unless the eggs have been donated for the purposes mentioned in section 3(1)(2) and (3). **§ 7.** Stored, fertilised human eggs must be destroyed in the event of the woman's death and in the event of the couple's separation or divorce or at the end of cohabitation within 5 years of the start of the storage period.

		(2) Fertilised human eggs may only be used if the woman or couple gives written consent before each treatment cycle.
	Any other storage information	**§ 3.** The storage of human eggs may only be for the purposes of: 1) subsequent return to the woman who donated the egg, 2) donation for research purposes, or 3) donation with a view to inducing a pregnancy in another woman, cf. however, section 8. *(2)* Human eggs may only be stored for the purpose of treatment and research. **§ 8.** The donation of fertilised human eggs is only permitted for research purposes. **§ 14.** Storage of sperm may only take place for the purpose of: 1) to obtain a pregnancy either from the man's own partner or from another woman, or 2) research. **§ 25.** Unless a higher penalty is due under other legislation, a fine shall be imposed on a person who violates section 2(1), sections 3, 6, section 7(1), sections 8, 9, 11, section 12(1), sections 13, 14, 16, section 17(1), sections 18, 20, section 21(1) and section 24. (2) Criminal liability may be imposed on companies, etc. (legal persons) in accordance with the rules in Chapter 5 of the Danish Criminal Code.
Governance		**§ 21.** It is not permitted to use new treatment and diagnostic methods, etc., in connection with assisted reproduction until the Minister for Health and Prevention has approved these on the basis of ethical and health considerations. (2) In this context, a new form of treatment or diagnostic method is understood to be a form of treatment or diagnostic method that represents something significant and fundamentally new in relation to previous clinical use in Denmark. (3) The healthcare professional's application is sent to the Danish Health Authority. The notification is sent at the same time to the Danish Council of Ethics, which submits a statement on the method to the Danish Health and Medicines Authority. (4) A new form of treatment or diagnostic method that is used as part of a research project approved by the research ethics committee system is not subject to the notification and approval obligation until a decision is made, on the basis of the results obtained, to apply for the method to be used outside the framework of the research project. (5) In case of doubt, a healthcare professional may consult the Danish Health and Medicines Authority as to whether a given form of treatment or diagnostic method is to be considered to be covered by the notification and approval obligation. **§ 22.** The Danish Health Authority conducts a health professional assessment of applications pursuant to section 21 and, on the basis of this, and on the basis of the opinion of the Danish Council of Ethics, prepares a report and recommendation to the Minister for Health and Prevention.

		(2) The notifier receives a copy of the Danish Health Authority's recommendation to the Minister for Health and Prevention and of the Ethics Council's statement to the Danish Health Authority. **§ 23.** The Danish Health Authority informs the country's healthcare professionals of the Minister for Health and Prevention's decision regarding the notified new form of treatment or diagnosis.
Funding		No information identified.
Communication and information provision		No information identified.
Ethical considerations		**§ 4.** Before the storage of retrieved, unfertilised human eggs takes place, the woman must give written consent for storage. The woman in question must be informed orally and in writing beforehand of the consequences of the storage. *(2)* At the same time, the woman concerned must declare that she has been made aware of the terms and conditions of storage laid down in the Assisted Reproduction Act and in this Order. **§ 5.** Before storage of retrieved, fertilised human eggs takes place, the single woman or the couple must give written consent for storage. The woman or the couple in question must be informed orally and in writing beforehand about the consequences of the storage. *(2)* The woman or the couple concerned must at the same time declare that they have been made aware of the terms and conditions of storage laid down in the Assisted Reproduction Act and in this Order. **§ 15.** The sperm donor must give written consent to the donation. Prior to this, the donor must be informed orally and in writing about the consequences of the sperm donation. (2) The donor must also agree to the terms and conditions laid down for donation in the Act on Assisted Reproduction and in this Executive Order.
Relevant legislation (list)		Act on Assisted Reproduction in Connection with Treatment, Diagnostics and Research, etc., cf. Consolidated Act no. 93 of 19 January 2015,
Miscellaneous		No information identified.

Table D.9 Extracted data for Denmark (AR Guidance – 2020 Update)

Denmark		
Author(s) **Title [year]**	Ministry of the Interior and Health VEJ no. 9351 of 26/05/2015: Guidance on the activities and obligations of healthcare professionals and tissue establishments in the field of assisted reproduction [2020][20]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**8.1. Cryopreservation of ovum/embryos and ovarian tissue for the treatment of ovarian failure after disease or radiotherapy** As a general rule, freezing of embryos reflects the fact that in connection with an infertility treatment there are "surplus" embryos, that is that more eggs have been retrieved and fertilised than the maximum of 2 embryos that can be safely transferred in a treatment cycle. Freezing may also be considered – or may have already taken place with a prior infertility treatment – in situations where a woman is affected by a serious illness that requires chemotherapy with a cell-killing/cell-damaging effect, or radiation therapy to the small pelvic region with a risk of ovarian damage as a result. It can also be considered in the case of hormone therapy that is incompatible with establishing/carrying out a pregnancy. Examples include early breast cancer requiring tamoxifen treatment, aplastic anaemia requiring bone marrow transplantation, or rare cases of severe rheumatoid disorder requiring chemotherapy. **8.2. Cryopreservation of sperm and testicular tissue for the treatment of male fertility deficiency after illness or radiotherapy** Cryopreservation of sperm/testicular tissue may be considered for boys and men affected by a serious illness whose effective and safest treatment requires chemotherapy with a cell-killing/cell-damaging effect, or radiotherapy that carries a risk of permanent damage to the ability to form sperm. It may also be possible to cryopreserve testicular tissue in boys with the aim of preserving fertility in boys, who in adulthood are at risk of becoming sterile because all their spematogonias have disappeared, either because they have undergone cancer treatment or because they have a congenital disorder/condition (for example bilateral cryptorchidism). **8.3. Cryopreservation to compensate for accelerated ovarian failure due to disease or age** Egg freezing as described in section 8.1 may also be used according to medical criteria for conditions that may lead to ovarian failure significantly earlier than normal (for example galactosemia and Turner syndrome). It follows from Section 15(1) of the Act on Assisted Reproduction and Sections 2-3 of the Executive Order on Assisted Reproduction that a woman can freeze (store) her eggs in connection with either disease treatment or in connection with fertility treatment, and that the freezing (storage) is generally limited to 5 years in Denmark. According to information from the Danish Health Authority, the treatment of freezing eggs is not offered under public auspices if the purpose is to seek to cover oneself in relation

		to having children later in life (social egg freezing). It is possible to freeze your eggs in the private sector for any reason. However, the woman must cover the expense herself.
Preservation method(s) available		**8. Cryopreservation, storage and destruction of gametes/embryos and ovarian and testicular tissues, including fertility-preserving treatment** **8.1. Cryopreservation of ovum/embryos and ovarian tissue for the treatment of ovarian failure after disease or radiotherapy** Today, there are 2 approaches that can increase the likelihood that the woman will later have children after iatrogenic ovarian failure. One consists of the removal and freezing of ovarian tissue prior to the potentially ovarian-damaging treatment. Freezing requires special expertise and experience. After curative treatment, the ovarian tissue may be thawed and re-transplanted in order to re-establish the menstrual cycle and fertility. This approach has proved successful in a small number of cases. Although Section 15 of the Act on Assisted Reproduction sets limits on how long unfertilised and fertilised eggs may be stored, it does not restrict the freezing and storage of ovarian tissue or the entire ovary. The second method is based on the retrieval and freezing of eggs (unfertilised or fertilised) for use when the woman is considered to be permanently healed and she wishes to become pregnant. This is a gentler and potentially more effective procedure than the ovarian biopsy. The time limit on stored eggs under section 15 of the Act on Assisted Reproduction should be taken into account (see section 8.4.1.). **8.2. Cryopreservation of sperm and testicular tissue for the treatment of male fertility deficiency after illness or radiotherapy** Cryopreservation of sperm/testicular tissue may be considered for boys and men affected by a serious illness… It may also be possible to cryopreserve testicular tissue in boys with the aim of preserving fertility in boys…However, the specific method for the use of cryopreserved spermatogonia has not yet been clarified. There are no restrictions on how long sperm (and testicular tissue) can be frozen before use or reinserted via transplantation. **8.3. Cryopreservation to compensate for accelerated ovarian failure due to disease or age (egg freezing)**
Organisation	***Referral pathways***	No information identified.
	Service provider characteristics	No information identified.
	Timelines to access services	No information identified.
	Any other organisational aspects	**Reporting of serious adverse events** According to Section 3(5) of the Tissue Act, a serious adverse event is defined as any unintentional incident in connection with the procurement, testing, processing, preservation, storage and distribution of tissues and cells that may result in the transmission of communicable diseases, death, a life-

		threatening or disabling condition or incapacity for work in patients, or which may trigger or prolong hospital stays or illness. According to our practice, the following are considered to be covered by the definition of serious undesirable incident that must be reported: Criteria for reporting serious adverse events ▪ Unsuitable germ cells, embryos, reproductive tissue released for clinical use, whether or not it has been used ▪ The incident could have an impact on other patients or donors due to shared practices, services, supplies, critical equipment or donors ▪ The incident has resulted in a mix-up of gametes or embryos ▪ The incident has resulted in a lack of traceability to gametes or embryos ▪ Contamination or cross-contamination ▪ Accidental loss of gametes, embryos, reproductive tissue (that is, breakdown of incubators, accidental destruction, handling errors) that has led to a complete loss of opportunity for pregnancy in a pregnancy cycle.
Storage	***Arrangements and duration(s)***	**8.2. Cryopreservation of sperm and testicular tissue for the treatment of male fertility deficiency after illness or radiotherapy** There are no restrictions on how long sperm (and testicular tissue) can be frozen before use or reinserted via transplantation. **8.4. Storage time of eggs and sperm** **8.4.1. Destruction of eggs/embryos** The maximum storage period for retrieved, cryopreserved human unfertilised or fertilised eggs is 5 years (Section 15 of the Act on Assisted Reproduction). However, the doctor responsible for assisted reproduction treatment may decide to extend the retention period beyond 5 years and until the time the woman reaches the age of 46 if the single woman or one of the partners in the marriage, registered partnership or relationship suffers from a serious illness. The doctor responsible may revoke a decision made if the conditions are no longer met. Typically, such an extension will apply in the case of serious illness that results in the woman not being able to carry the pregnancy to term, but the proposed provision also provides for the possibility of extending the storage period in the case of serious illness that does not necessarily directly affect the chances of achieving pregnancy. For example, where a couple has had their first child through test-tube treatment at a public fertility clinic with the help of assisted reproduction, and where frozen fertilised eggs have been stored from this treatment. After this, the man in the couple has been diagnosed with a serious illness, for example cancer, which is why the couple wants to wait to use the frozen fertilized eggs. The provision makes it possible – following a specific medical assessment – to extend the storage period for unfertilised or fertilised eggs. The doctor responsible shall decide whether to set a temporal period for the extension of the storage period. If such a period is not stipulated, the stored unfertilised or fertilised egg may be stored until the time when the woman reaches the age of 46.

		In a possible situation where the woman in the couple may have had unfertilised eggs/embryos frozen, and the period of freezing has been extended due to the husband's illness, and where the couple separates along the way, the starting point for the doctor's decision on the exemption lapses. Therefore, the decision is revoked where the conditions are no longer met. If the doctor revokes the decision, the woman's stored, unfertilised eggs/embryos must be used as soon as possible or destroyed. Stored unfertilised and fertilised eggs must be destroyed in the event of the death of the woman. Fertilised eggs must also be destroyed in the event of the couple's separation, divorce or termination of cohabitation. This does not apply where the fertilised egg has been fertilised with donor sperm. The above includes all couples regardless of gender. Fertilized eggs can be used for the purpose of establishing pregnancy after the death of the man. The Danish Health and Medicines Authority recommends that a written agreement be entered into between the couple and the tissue centre that stores the fertilised egg(s) on whether and, if so, under what conditions the fertilised eggs can be used after the man's death. Stored unfertilised eggs must be destroyed in the event of the woman's death.
	Access to stored materials	**8.1. Cryopreservation of ovum/embryos and ovarian tissue for the treatment of ovarian failure after disease or radiotherapy** The woman's/couple's possible wish to achieve pregnancy must be put on hold until the woman can be considered permanently cured and she can tolerate the establishment and completion of a pregnancy. **8.4.1. Destruction of eggs/embryos** Fertilised eggs can be used for the purpose of establishing pregnancy after the death of the man. The Danish Health and Medicines Authority recommends that a written agreement be entered into between the couple and the tissue centre that stores the fertilised egg(s) on whether and, if so, under what conditions the fertilised eggs can be used after the man's death.
	Disposal of stored materials	**8.4.1. Destruction of eggs/embryos** Stored unfertilised and fertilised eggs must be destroyed in the event of the death of the woman. Fertilised eggs must also be destroyed in the event of the couple's separation, divorce or termination of cohabitation. This does not apply where the fertilised egg has been fertilised with donor sperm. The above includes all couples regardless of gender. Stored unfertilised eggs must be destroyed in the event of the woman's death. **8.4.2. Destruction of semen** There are no rules on the destruction of donor sperm. The previous requirement for the destruction of the spouse's or cohabitant's stored sperm in the event of death has been repealed by an amendment to the Act on Assisted Reproduction. Whether stored sperm is to be destroyed in the event of the death of the spouse or cohabitant in the future can be regulated by agreement between the man and the tissue centre (fertility clinic or sperm bank) where the sperm/embryos are deposited. For example, between the man and the fertility clinic/sperm bank, the delivery of sperm to the deceased donor's partner for treatment with assisted reproduction or delivery to others can be agreed.

	Any other storage information	No information identified.
Governance		No information identified.
Funding		**8.3. Cryopreservation to compensate for accelerated ovarian failure due to disease or age** According to information from the Danish Health Authority, the treatment of freezing eggs is not offered under public auspices if the purpose is to seek to cover oneself in relation to having children later in life (social egg freezing). It is possible to freeze your eggs in the private sector for any reason. However, the woman must cover the expense herself.
Communication and information provision		**3.1. Information requirements** **3.1.1. Form** The following information must be given by the fertility clinic both in writing and orally to the woman/couple. The written information must also be available on the clinic's website. **3.1.2. Treatment effectiveness** Information about the prospect of successful treatment results with assisted reproduction will, among other things, shed light on the probability of achieving a viable pregnancy of a child with the treatment in question, calculated per treatment cycle initiated. The information must include conditions in the woman/man that are important for the individual prognosis, for example the woman's age or a combination of several fertility-reducing factors in the couple. It is not sufficient to provide information on average success rates for a larger patient population. The information must be based as far as possible on the individual clinic's own achieved, documentable treatment results. **3.1.3. Treatment complications** The fertility clinic must inform about possible complications and risks of the treatment, such as the risk of overstimulation, infection, extrauterine pregnancy, or multiple pregnancies. If there is no consensus in the relevant professional circles on the magnitude of the possible risks, this should also be mentioned.
Ethical considerations		**1. Introduction** For the purposes of this guide, a "woman" means a person with uterus or ovarian tissue. For the purposes of this guide, a "man" means a person with at least one testicle. **3. Information and consent** Treatment with assisted reproduction requires written consent from the woman for the treatment. Written consent for the use of frozen, thawed fertilised human eggs must be obtained before each treatment cycle. Furthermore, consent must be obtained before allogeneic donation of gametes, and consent must be obtained before storage of unfertilised and fertilised eggs. It will often be sufficient documentation for consent that it appears from the medical record that the treating physician has seen the written consent. For example, it could be a single donation and

		withdrawal from another place in the same hospital or abroad. This may also be the case in connection with autologous transplantation of ovarian and testicular tissue, where the patient will later have the tissue transplanted back.
Relevant legislation (list)		[Applicable as of 22 July 2024: ▪ LAW No 129 of 30/01/2021 Act amending the Act on Assisted Reproduction in Connection with Treatment, Diagnostics and Research, etc. ▪ LBK nr 902 of 23/08/2019 Executive Order on the Act on Assisted Reproduction in Connection with Treatment, Diagnostics and Research, etc.] **1. Introduction** This guide is related to: ▪ The Act on Assisted Reproduction in connection with treatment, diagnostics and research, etc. ▪ Executive Order on Assisted Reproduction. ▪ Act on requirements for quality and safety in the handling of human tissues and cells (the Tissue Act). ▪ Executive Order on Human Tissues and Cells (the Executive Order on Tissues). The guidelines provide detailed information on the rules on assisted reproduction and the Danish Tissue Act with regard to matters relating to assisted reproduction.
Miscellaneous		**5. Treatment** **5.2. Prohibition of processing** The Act on Assisted Reproduction lays down the following other prohibitions: 5. Transplantation of ovaries to a woman for the purpose of alleviating infertility may not take place (Section 11). This prohibition is not considered to prevent ovaries or parts of the ovaries from being removed and stored and subsequently returned to the same woman – (autologous transplantation). It is also permitted to extract and store testicular tissue for subsequent autologous transplantation (see section 8.2) **6. Hormone therapy to stimulate ovulation and mature follicles** Hormonal induction of follicular maturation and ovulation carries a risk of overstimulation (ovarian hyperstimulation syndrome (OHSS)) and or multiple pregnancies. The risk can be reduced by preventive measures. This must be included in the doctor's indication position, examination and treatment, including check-ups during the course of the treatment, and must therefore be organised with a view to minimising (preventing) this risk to the extent possible. Women with certain types of ovulation defects (especially polycystic ovary syndrome, PCOS) may be particularly sensitive to gonadotropins, with associated increased risk. Therefore, particular care should be taken in the choice of stimulation protocol, dose and frequency of monitoring. Anovulatory infertility must be investigated in more detail before treatment is initiated. The majority of this group of women have PCOS. Other treatment strategies (exercise, weight loss, metformin) and other methods of ovarian stimulation (clomifene citrate) should first be tried before gonadotropins are used. Only physicians with special experience in gonadotropic hormone therapy, except synthetic ovarian stimulants with a low risk of hyperstimulation, may perform the treatment.

		In the case of hormonal induction of follicular maturation with injections containing gonadotropic hormones, the ovarian response should always be checked by ultrasound scan before ovulating hormone is administered. **6.2. Induction of follicular maturation and ovulation for self-treatment of ova** Hormone stimulation with a view to retrieval of eggs for self-treatment may continue to take place only as appropriate stimulation based on recognised protocols, so that risks and side effects for the woman are minimised. In the event that the patient has a demonstrably high risk of hyperstimulation syndrome (for example high AMH and a large number of antral follicles), the doctor may choose to treat with a so-called short protocol, where a GnRH agonist can be given instead of hCG. If an unexpectedly large number of follicles develops in a woman who is treated with a long protocol, the doctor may choose to discontinue FSH stimulation for a few days while monitoring oestradiol levels (coasting) or to freeze all eggs/embryos or cancel the cycle. The risk of side effects (overstimulation) is particularly linked to the fact that an hCG preparation is given prior to egg retrieval, which induces the maturation and ovulation of the developed follicles (follicles). The effect of hCG does not diminish until after 10-12 days, which is a disadvantage compared to an egg donor, where it is preferable that the hormonal effect disappears immediately when the eggs have been retrieved. Ovulatory treatment with hCG can therefore be advantageously replaced with a GnRH agonist protocol, which is just as effective at maturing/releasing the eggs, but since the substance has a very short half-life in the blood, so the hormonal effect decreases within a day, the risk of overstimulation is practically eliminated. Any surplus eggs from the treatment can be donated to others in compliance with the rules on consent, etc.

Table D.10 Extracted data for England (Gamete Storage Policy; Bedfordshire, Luton, MK)

England		
Author(s) **Title [year]**	NHS England – Bedfordshire, Luton and Milton Keynes Integrated Care Board Gamete (sperm/egg) Storage for those undergoing fertility-threatening treatment V2.0 [2021][21]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		This policy covers cryopreservation of gametes (sperms/eggs) for individuals about to commence a treatment that is likely to lead to permanent infertility and would like to have their gametes preserved for future use. BLMK ICB fund gamete storage and cryopreservation under the following circumstances: Patients are about to commence treatment deemed likely to cause permanent infertility. This treatment should be carried out in a recognised NHS pathway or advised by a specialist. It should be noted that following some treatments fertility may recur, in which case ongoing gamete preservation will be reassessed. Conditions considered appropriate for gamete cryopreservation are: ▪ Medical conditions requiring treatment with cytotoxic drugs (including malignancies). OR ▪ Conditions requiring total body irradiation or radiotherapy that may affect an individual's reproductive organs. OR ▪ Conditions requiring male urological or female gynaecological surgery, which are likely to lead to permanent infertility (including gender reassignment surgery). When requested under gender reassignment surgery, the patient should be undergoing treatment at a nationally accredited clinic. OR ▪ Hormone therapy causing permanent infertility secondary to the inability to produce gametes. The following conditions must also be met: ▪ After thorough counselling and a discussion regarding risks and implications of the procedure the patient would like to have gamete storage (shared decision-making). AND ▪ The patient is aware that funding for gamete retrieval and cryopreservation of material does not guarantee future funding of assisted conception or fertility treatment. AND ▪ Female patients must be referred for gamete storage before their 43rd birthday. AND ▪ The patient has not undergone a previous sterilisation and or reversal of sterilisation procedure. Gamete retrieval and cryopreservation will not be funded where the patient has previously undergone elective sterilisation (vasectomy or where fallopian tubes are blocked or sealed to prevent the eggs from becoming fertilised)

		AND ▪ The patient is registered with a BLMK ICB GP Females of reproductive age should be offered oocyte cryopreservation if they meet all of the following criteria: ▪ They are well enough to undergo ovarian stimulation and egg collection ▪ The procedure will not worsen their condition ▪ Enough time is available before the start of their treatment Offer sperm cryopreservation to males of reproductive age who are preparing for the treatments outlined above that are likely to make them permanently infertile. ***Where a patient does not meet the policy criteria or the intervention is not normally funded by the NHS, an application for clinical exceptionality can be considered via the ICB's Individual Funding Request (IFR) Policy and Process.***
Preservation method(s) available		Cryopreservation of gametes (sperms/eggs). **Number of attempts at gamete extraction** For patients eligible for gamete extraction, up to 2 attempts from an accredited provider are funded. **Exclusion Criteria** The following circumstances will not be eligible for ICB funding: ▪ Gamete harvesting and cryopreservation in pre-pubertal patients. ▪ Cryopreservation of gametes requested for social reasons. ▪ Cryopreservation of ovarian and testicular tissue. Note that ovarian and testicular cryopreservation for patients receiving gonadotoxic treatment who are at high risk of infertility and cannot store mature eggs or sperm is the commissioning responsibility of NHS England (All ages).
Organisation	***Referral pathways***	Referal by GP is required.
	Service provider characteristics	NHS.
	Timelines to access services	Females of reproductive age should be offered oocyte cryopreservation if there is enough time available before the start of their treatment.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	**Storage Duration:** The initial storage period funded will be up to 10 years, in accordance with the Human Fertilisation and Embryology Authority (HFEA) regulations and guidance and the agreed period of patient consent. Storage could continue if the following criteria is met:

		1. The provider has gained continued consent from the patient every 10 years in line with HFEA guidelines 2. The provider must confirm with the patient that they understand eligibility for IVF treatment funded by the NHS means they must have started treatment before the age of 43, as well as meeting other eligibility criteria. 3. At the time of reconsent (every 10 years), individuals, regardless of gender, remain aged below 43 years and demonstrate compliance with all other aspects of the patient eligibility criteria within this policy at the time of renewal. 4. For all patients, if fertility returns as demonstrated by conception, funding for ongoing storage of remaining stored material will cease. Patients who have undergone NHS-funded cryopreservation but no longer meet eligibility criteria may choose to self-fund ongoing cryopreservation of their stored material.
	Access to stored materials	No information identified.
	Disposal of stored materials	No information identified.
	Any other storage information	No information identified.
Governance		All patients, including those aged under 16 years, must be able to understand the procedure being carried out and considered competent to give informed consent. The provider must ensure appropriate consent to storage is in place and that the patient understands the need for ongoing consent.
Funding		The funding of gamete retrieval and cryopreservation does not commit the ICB to funding for Assisted Conception services. Patients who have undergone NHS-funded cryopreservation but no longer meet eligibility criteria may choose to self-fund ongoing cryopreservation of their stored material. Where a patient does not meet the policy criteria or the intervention is not normally funded by the NHS, an application for clinical exceptionality can be considered via the ICB's IFR Policy and Process.
Communication and information provision		The provider of the service must ensure the patient receives appropriate counselling and provides full consent. The provider of the service must ensure patients are aware of legal issues on posthumous use of gametes should they wish a partner to be able to use these should their treatment not be successful. Patients will need to provide consent for continued storage in line with HFEA Guidelines.
Ethical considerations		No information identified.
Relevant legislation (list)		**Human Fertilisation and Embryology Act 1990 and Health & Social Care Act 2022** Cryopreservation of gametes must meet the current legislative standards. The provider of the service must ensure the patient receives appropriate counselling and

		provides full consent. The provider of the service must ensure patients are aware of legal issues on posthumous use of gametes should they wish a partner to be able to use these should their treatment not be successful. Patients will need to provide consent for continued storage in line with HFEA Guidelines. The patient will be responsible for ensuring the storage provider has up to date contact details. Failure to provide ongoing consent may result in the destruction of stored materials.
Miscellaneous		No information identified.

Table D.11 Extracted data for England (Gamete Storage Policy; Coventry & Warwickshire)

England		
Author(s) **Title [year]**	NHS England – Coventry and Warwickshire Integrated Care Board (Joint ICB Clinical Commissioning Policy Development Group) NHS Funded Cryopreservation of Gametes and Embryos Policy[22] [2022]	
Focus Area	**Sub-focus area**	**Information extracted**

Population(s) and eligibility criteria		The policy specifically relates to cryopreservation of gametes and embryos in patient groups who are at risk of infertility due to medical or surgical NHS funded treatment including patients with gender dysphoria or for patients at risk of premature ovarian insufficiency (POI).
		
		The following patient groups are covered in this policy:
		▪ Patients who will be having medical or surgical treatment for cancer.
		▪ Patients who will be having NHS funded medical or surgical treatment for other conditions and as a result infertility is potential risk.
		▪ Patients who are at high risk of POI. Most common genetic cause of POI is Turner syndrome.
		
		Cryopreservation is not available for any other patient group, that is, for patients embarking on a private pathway of care likely to cause infertility or patients who wish to delay conception for non-medical reasons.
		
		Eligibility criteria for cryopreservation
		▪ The patient must be permanently registered with a Coventry and Warwickshire GP practice.
		▪ The patient, if female, must be of reproductive age.
		▪ The patient, if male, must have reached or else undergone adolescence.
		▪ The patient must meet one of the following clinical criteria:
		  ○ The patient must be undergoing NHS funded medical or surgical treatment which is likely to lead to infertility.
		  ○ Patient is at high risk of POI. For the purposes of this policy, POI is defined as:
		  – Amenorrhea of at least 12 months;
		  – Hormonal profile in the menopausal range;
		  – Under the age of 40.
		▪ In females preparing to undergo medical treatment for cancer that is likely to render them infertile, the following should be considered:
		  ○ The patient is well enough to undergo ovarian stimulation and egg collection; AND
		  ○ This will not worsen their condition; AND
		  ○ Enough time is available before the start of their cancer treatment.

Preservation method(s) available		Cryopreservation of gametes (sperm and oocytes) and embryos. The ICB does not routinely fund cryopreservation of ovarian and testicular tissues except in cases where gamete and embryo cryopreservation cannot be achieved.
Organisation	***Referral pathways***	No information identified.
	Service provider characteristics	This policy applies to Coventry and Warwickshire ICB and the principle providers of these services, NHS and private providers, irrespective of where the patient is being treated.
	Timelines to access services	No information identified.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	NHS funding for storage of gametes and embryos conditions ▪ Cryopreservation for fertility for adults may be funded for up to 10 years. ▪ If fertility is found to have returned, either through fertility testing or through conception and pregnancy, or the patient dies with no written consent regarding posthumous use, then continued storage will not be funded. ▪ The patient is able to self-fund for a further period providing that the appropriate length of storage set out by Human Fertilisation and Embryology Authority (HFEA) regulations is not exceeded. ▪ If storage is desired for longer than 10 years, then an application for exceptional funding could be made to the Individual Funding Request Panel and each request will be considered on its own merit and in line with HFEA legislation. ▪ The preferred provider for services is the Centre of Reproductive Medicine, University Hospitals of Coventry and Warwickshire NHS Trust. However, other clinics will be considered upon application to the ICB.
	Access to stored materials	Approval for cryopreservation does not guarantee future funding of assisted conception treatment. For this the patient will be required to meet the criteria set out in the Assisted Conception Treatment policy at time of application.
	Disposal of stored materials	No information identified.
	Any other storage information	No information identified.
Governance		**Quality and Equality Impact Assessment** [Outcome assessment (Positive, Negative or Neutral) applied to each domain] ***NHS Outcomes Framework*** ▪ Enhancing qualty of life – Positive (Policy will offer patients opportunity to preserve their fertility) ▪ Ensuring people have a postiive experience of care – Neutral ▪ Preventing people from dying prematurely – Neutral ▪ Helping people recover from episodes of ill health or following injury – Neutral ▪ Treating and caring for people in a safe environment and protecting them from avoidable harm – Neutral

		Compliance with NHS Constitution ▪ Quality of care and environment – Neutral ▪ Nationally approved treatment/drugs – Neutral ▪ Respect, consent and confidentiality – Neutral ▪ Informed choice and involvement – Neutral ▪ Complain and redress – Neutral
Funding		Patients will be offered one NHS funded treatment to recover and preserve gametes subject to the patient meeting the eligibility criteria. For patients who do not fall within the scope of this policy but where there is demonstratable evidence that the patient has clinically exceptional circumstances*, an Individual Funding Request (IFR)† may be considered. * Exceptional clinical circumstances are the clinical circumstances pertaining to a particular patient, which can properly be described as exceptional when compared to the clinical circumstances of other patients with the same clinical condition and at the same stage of development of that condition (that is, similar patients). A patient with exceptional clinical circumstances will have clinical features or characteristics which differentiate that patient from other patients in that cohort and result in that patient being likely to obtain significantly greater clinical benefit (than those other patients) from the intervention for which funding is sought. † IFR is a request received from a provider or a patient with explicit support from a clinician, which seeks exceptional funding for a single identified patient for a specific treatment – on the basis of their clinical individuality. NHS funded cryopreservation treatment will not be available if the infertility is the result of a sterilisation procedure. The ICB does not fund cryopreservation for those who wish to delay conception for non-medical reasons. The ICB does not routinely fund cryopreservation of ovarian and testicular tissues except in cases where gamete and embryo cryopreservation cannot be achieved.
Communication and information provision		All patients about to embark on a treatment within an NHS pathway of care that might cause infertility should be offered an opportunity to discuss their circumstances with a fertility specialist, regardless of potential eligibility for cryopreservation. The provider of the service must ensure that the patient receives appropriate counselling.
Ethical considerations		There must be written consent for treatment and gamete storage. **Quality and Equality Impact Assessment** [Outcome assessment (Positive, Negative or Neutral) applied to each domain]

		Could the scheme impact positively or negatively on any of the following: ***Duty of Quality*** ▪ Effectiveness: clinical outcome – Positive (References from public health research support effectiveness) ▪ Patient experience – Positive (Extent of policy will impact on patient experience) ▪ Patient safety – Neutral ▪ Parity of esteem – Neutral ▪ Safeguarding children or adults – Neutral ***Patient Services*** ▪ A modern model of integrated care, with key focus on multiple long-term conditions and clinical risk factors – Neutral ▪ Access to the highest quality urgent and emergency care – Neutral ▪ Convenient access for everyone – Neutral ▪ Ensuring that citizens are fully included in all aspects of service design and change – Neutral ▪ Patient choice – Neutral ▪ Patients are fully empowered in their own care – Neutral ▪ Wider primary care, provided at scale – Neutral ***Access*** ▪ Patient choice – Neutral ▪ Access – Neutral ▪ Integration – Neutral ***Equality Questions*** Is there likely to be a differential impact? [for protected groups listed] ▪ Gender – No ▪ Race – No ▪ Disability – No ▪ Religion/belief – No ▪ Sexual orientation – No ▪ Age – Yes ▪ Social deprivation – No ▪ Carers – No ▪ Human rights – No ▪ Pregnancy and maternity – No The impact of this policy has been discussed at length by the Coventry and Warwickshire Joint Policy Development group and all protected characteristics and Human Rights values given due regard and only patient demographic issues that could impact on individual risk and or clinical effectiveness were taken into account when reaching a decision. The evidence used to inform this policy consists of: Advice and guidance from the Department of Health, current relevant regional policies and guidance, NHS England commissioning policies. In summary, any negative impact on equality is unlikely and the policy is concordant with current advice and guidance from NICE, Department of Health and NHS England.

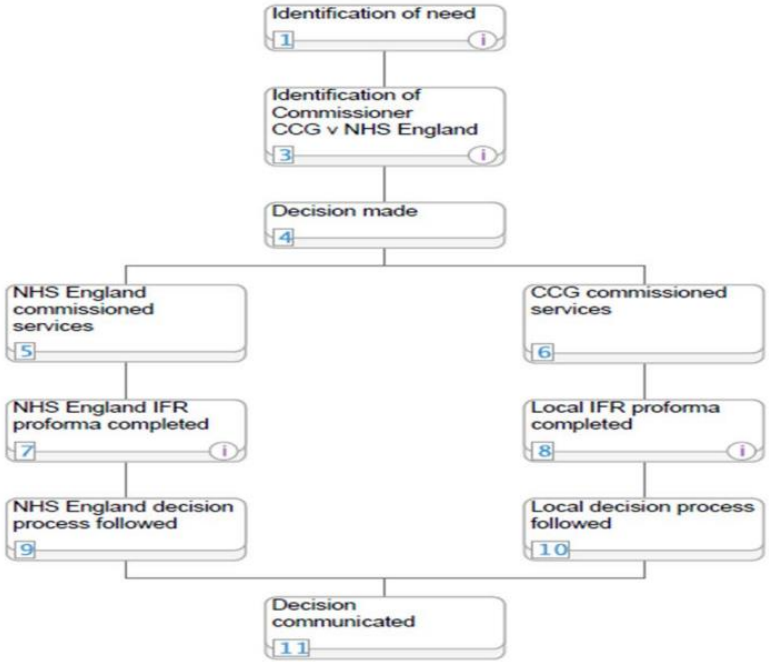
Relevant legislation (list)		**Relevant National Guidelines and Facts** ***Human embryo and fertility act 1990*** Cryopreservation of gametes or embryos must meet the current legislative standards. The provider of the service must ensure that the patient receives appropriate counselling and provides full consent. Both partners must be aware of the legal position regarding embryos which have been cryopreserved, should one partner remove consent to their ongoing storage or use. The provider of the service should contact patients annually to confirm that they wish to continue storage. The patient will be responsible for ensuring the storage provider has up to date contact details. The provider must ensure that material is only stored where there is a valid consent in place.
Miscellaneous		**Relevant National Guidelines and Facts** ***NICE Guidance CG 156 Fertility: Assessment and treatment for people with fertility problems*** The impact of the medical/surgical intervention on the patient's fertility should be discussed by the relevant medical/surgical team. When deciding to offer fertility preservation to people diagnosed with cancer, the following should be taken into account: ▪ Diagnosis ▪ Treatment plan ▪ Expected outcome of subsequent fertility treatment ▪ Prognosis of the cancer treatment ▪ Viability of stored/post-thawed material A lower age limit for cryopreservation fertility preservation will not be used. Patients must be informed that even though they may meet criteria for cryopreservation, it does not automatically mean they will meet criteria for using the stored material for assisted conception in an NHS setting. ***Royal College of Physicians, Royal College of Radiologists and Royal College of Obstetricians and Gynecologists (2007) – Joint Guidance "The effects of cancer treatment on reproductive functions"*** This guidance makes recommendations specifically around cancer diagnosis and treatment of induced infertility. It recommends the use of cryopreservation of material prior to commencing a treatment pathway that could potentially make a patient infertile. Possible future effects of chemotherapy or radiotherapy on fertility should be discussed with all patients with reproductive potential. It should be recognised that the prospect of infertility can be psychologically and socially damaging for both men and women by that such an outcome can, to some extent, be mitigated by gamete and embryo storage. Gametes can only be stored and used in a centre licensed by the HFEA. ***Human Fertilisation and Embryology Authority (HFEA) Code of Practice*** The HFEA is the UK's independent regulator overseeing use of gametes and embryos in fertility treatment. Its Code of Practice sets out both mandatory requirements and recommended guidance (incorporating an interpretation of mandatory guidance) for organisations involved in this area of health care.

		British Fertility Society Policy and Practice Guideline: Fertility preservation for medical reasons in girls and women. January 2018. The policy has made certain recommendations regarding cryopreservation. For instance, the risk of infertility, diminished ovarian reserve, and POI should be assessed based on age, type and dose of chemotherapy. Women/couples should be advised that embryo cryopreservation is an established technique, with success rates for the transfer of frozen-thawed embryos comparable to those for the transfer of fresh embryo. Furthermore, women/couples should be advised of the length of time their oocytes/embryos can be stored and that this limit is statutory. ***NHS England*** ***Gender Identity Dysphoria*** NHS England commissions the gender identity dysphoria pathway. Cryopreservation is advised in the service specification of NHS England to be the responsibility of the patient's ICB and is not commissioned by NHS England.

Table D.12 Extracted data for England (Treatment for Subfertility Policy: Merseyside)

England		
Author(s) **Title [year]**	NHS Cheshire and Merseyside NHS Funded Treatment for Subfertility Policy[23] [policies from Clinical Commissioning Groups still in place, some with interim ICB updates] ▪ Liverpool CCG[24]; Knowsley CCG[25]; Warrington CCG[26]; Halton CCG[27] (same docs) ▪ St Helens CCG (same as above plus appendix)[28] [2015] ▪ Wirral CCG[29] [2019; updated 2023] ▪ NHS South Sefton CCG; NHS Southport and Formby CCG (same docs)[30, 31] [2014] ▪ NHS West Cheshire[32] [2017; udpated 2023] ▪ NHS Eastern Cheshire CCG, NHS South Cheshire CCG, NHS Vale Royal CCG[33] [updated 2023 – Cheshire and Mersyside ICB interim policy updates]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		*[For all policies:]* The eligibility criteria does not apply to the use of assisted conception techniques for reasons other than subfertility, for example in families with serious inherited diseases where in-vitro fertilization (IVF) is used to screen out embryos carrying the disease or to preserve fertility, for example for patients about to undergo chemotherapy, radiotherapy or other invasive treatments. *[For policies for all areas covered by NHS Cheshire and Merseyside ICB, except Cheshire East and Cheshire West:]* Cryopreservation services in line with the relevant principals outlined in NICE IPG 156 Section 1.16 will be offered to: Women with premature ovarian failure under the age of 40 (see previous definition - see section 17). Men and women with cancer, or other illnesses which may impact on fertility, may access tertiary care services to discuss fertility preservation (egg, embryo or sperm storage). Other illnesses are not defined in this policy but will be considered on an individual basis via an Individual Funding Request. *[For policies covering Cheshire West (NHS West Cheshire) and Cheshire East (NHS Eastern Cheshire CCG, NHS South Cheshire CCG and NHS Vale Royal CCG):]* Cryopreservation services in line with the relevant principles outlined in NICE IPG 156 Section 1.16 will be offered to: Men and women with cancer, or other treatments which may impact on fertility, may access tertiary care services to discuss fertility preservation (egg, embryo or sperm storage). Other treatments are not defined in this policy but will be considered on an individual basis via an Individual Funding Request.

Preservation method(s) available		Egg, embryo or sperm storage. Storage of ovarian tissue will not be funded.
Organisation	***Referral pathways***	Cryopreservation services in line with the relevant principals outlined in NICE IPG 156 Section 1.16 will be offered…
	Service provider characteristics	The criteria set out in this policy apply irrespective of where the residents of the CCG have their treatment (local NHS hospitals, tertiary care centres or independent sector providers). A patient is defined as someone registered with a GP practice within the CCG boundary.
	Timelines to access services	No information identified.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	*[For all policies:]* Storage will be in-line with section 19. *[For all areas covered by NHS Cheshire and Merseyside ICB, except Cheshire East and Cheshire West:]* 19. Embryo, egg and sperm storage will be funded for patients who are undergoing NHS subfertility treatment in line with The Human Fertilisation and Embryology Authority (HFEA) guidance. The storage standard period for sperm, egg and embryo storage is normally 10 years. *[For Cheshire West (NHS West Cheshire) and Cheshire East (NHS Eastern Cheshire CCG, NHS South Cheshire CCG and NHS Vale Royal CCG):]* 19. Embryo, egg and sperm storage will be funded for patients who are undergoing NHS subfertility treatment or may wish to do so in the future as a result of medical treatment for cancer or other relevant treatments which may affect their fertility. Storage will be in line with The HFEA guidance. The storage standard period for sperm, egg and embryo storage is normally 10 years (subject to 4.3). *4.3 Once a patient is accepted for subfertility treatment they will no longer be eligible for further treatment if a pregnancy leading to a live birth occurs or the patient adopts a child.
	Access to stored materials	The eligibility criteria set out in this policy do not apply to cryopreservation but do apply to the use of the stored material.
	Disposal of stored materials	No information identified.
	Any other storage information	No information identified.
Governance		Previously CCG areas made local decisions around their clinical commissioning policies, which has resulted in some differences across Cheshire and Merseyside. To address these differences, we have been reviewing these policies to look at how they can be made the same for all former CCG areas, now known as 'places' (Cheshire East, Cheshire West, Halton, Knowsley, Liverpool, Sefton, St. Helens, Warrington and Wirral).

		The review is happening in stages and aims to 'harmonise' these separate policies for each of the treatments they cover into single, up to date Cheshire and Merseyside versions. Where policies are yet to be harmonised, patients continue to be treated under the existing policy of the CCG that covered the area they live in[23]...
Funding		This policy describes circumstances in which the Clinical Commissioning Group (CCG) will fund treatment for subfertility as defined in section 3. [See 'Population(s) and eligiibility criteria' for details] Other illnesses [`other treatments' for East and West Cheshire] are not defined in this policy but will be considered on an individual basis via an Individual Funding Request. The eligibility criteria set out in this policy do not apply to cryopreservation but do apply to the use of the stored material. *[From St Helens CCG policy:]* **Appendix 1 IFR Process** 

Communication and information provision		Cryopreservation services in line with the relevant principals outlined in NICE IPG 156 Section 1.16 will be offered.
Ethical considerations		No information identified.
Relevant legislation (list)		No information identified.
Miscellaneous		No information identified.

Table D.13 Extracted data for England (Fertility Preservation Service – Ovarian tissue)

England		
Author(s) **Title [year]**	NHS England – Women and Children's Specialised Services Service specification: Fertility preservation service for services users with ovarian tissue who are at high/very high risk of infertility and cannot store mature eggs[34] [2023] Equality and Health Inequalities Impact Assessment: Fertility preservation service for services users with ovarian tissue who are at high/very high risk of infertility and cannot store mature eggs[35] [2023]	
Focus Area	**Sub-focus area**	
Population(s) and eligibility criteria		This service specification covers the provision of fertility preservation services for service users with ovarian tissue who are at high/very high risk of infertility and endocrine failure and cannot store mature eggs. There are no lower and upper age limit criteria contained in this specification and the eligibility criteria is based on physiological potential of the ovarian tissue. **Eligibility criteria** ▪ service users who cannot store mature eggs 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 oophorectomy AND ▪ who must be medically fit for fertility preservation surgery under general anaesthesia AND ▪ not in premature ovarian insufficiency (POI) and whose ovarian 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 mature eggs ▪ who are at low** or medium** risk of infertility as defined by international guidelines and peer reviewed tools. ○ low risk** (<10%: that is, 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 POI with ovarian tissue that lacks the physiological potential to ensure sufficient reserve for future use

		▪ where ovarian tissue cryopreservation (OTC) could delay their primary treatment and cause detrimental harm ▪ where surgery or a general anaesthetic would carry undue risk.
Preservation method(s) available		Ovarian tissue cryopreservation.
Organisation	***Referral pathways***	**Referring centre/patient/person with parental responsibility (PPR):** 1. Primary diagnosis is confirmed by the patient's treatment centre. Treatment discussion to include risk to fertliity and fertility preservation options. 2. Patient/PPR wants to proceed with fertility preservation treatment. 3. Refer to Hub. **Hub:** 4. Referral accepted by Hub as within eligibility criteria. 5. Patient/PPR receives information and the consent form from the Hub. A consent consultation with the patient/PPR is carried out. 6. Patient/PPR wishes to proceed and completes consent -> Collection of tissue at designated Spoke Centre. OR Patient/PPR declines to proceed -> Primary treatment continues. OR 4. Referral outside eligibility criteria 5. Referred to National Expert Group (NEG) 6. Hub feeds back NEG decision to referrer: Patient to proceed with tissue storage OR Hub feeds back NEG decision to referrer: Patient should not to proceed to tissue storage.
	Service provider characteristics	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 ovarian 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.
	Timelines to access services	No information identified.
	Any other organisational aspects	The aims of the service are to: ▪ Provide fertility preservation treatment for service users with ovarian tissue who are at high or very high risk of reproductive and endocrine failure and who cannot store mature eggs. ▪ Provide specialist fertility expertise and advice. ▪ Provide surgery to remove ovarian tissue. ▪ Provide a Tissue Establishment (TE) that can store and cryopreserve ovarian tissue. ▪ Ensure compliance with the Human Tissue Authority (HTA) Regulations.

		▪ Ensure that service delivery is in line with national and international guidelines and established best practice. **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. ▪ Onco- and specialist 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 **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 ovarian 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 ovarian tissue and, other treatment related surgery such as insertion of a central venous line or gastrostomy ▪ IT and data management support
Storage	***Arrangements and duration(s)***	[From referral pathway] ▪ Collection of tissue at designated Spoke Centre ▪ Tissue transported from Spoke Centre for processing and storage at Tissue Establishment ▪ Patient/PPR isssed with contact details, unique sample identifier, conditions of storage and copy of consent [No further information on storage identified]
	Access to stored materials	See 'Fertility and endocrine restoration using cryopreserved ovarian tissue: service specification' (https://www.england.nhs.uk/wp-content/uploads/2023/09/1867-fertility-and-endocrine-restoration-using-cryopreserved-ovarian-tissue-service-spec.pdf)

	Disposal of stored materials	…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. 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 ovarian tissue.
	Any other storage information	**Service Model** ***The Tissues Establishment (Cryopreservation services)*** The tissue establishment (TE): ▪ 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 ovarian 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.
Governance		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/

		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 ovarian 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. **Service model** ***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 ovarian 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 ovarian tissue if ovarian 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 (see 'Fertility and endocrine restoration using cryopreserved ovarian tissue service specification'). ***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, where OTC 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 ovarian 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 ovarian 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 ovarian 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 ovarian 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 ovarian tissue in theatre, packaging of the tissue, completion of all essential paperwork and the return of the ovarian 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 ovarian 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.
Funding		Relates to service provided by the NHS (that is, funded by taxation). [From Equality and Health Inequalities Assessment:] Surgical removal of reproductive tissue will occur as close to home as possible. Patients and their families can access financial assistance to support their treatment. Staff should be familiar with the travel costs under the Healthcare Travel Costs Scheme (HTCS) and be able to advise families about accommodation in or near the hospital.
Communication and information provision		The Hub will: ▪ 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. ▪ Ensure all service users, parents and PPR have adequate information to give informed consent for the storage of ovarian tissue. ▪ Have in place arrangements to enable the reconsenting of service users at the age of 18 years for ongoing storage of ovarian tissue if ovarian 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. The Spoke Centre: ▪ 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 mature eggs is not appropriate,…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.
Ethical considerations		**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 ovarian 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 ovarian tissue. [From Equality and Health Inequalities Assessment:] **Main potential impact (positive or negative) on people with the nine protected characteristics:** ▪ **Age**: There are no identified potential positive or adverse impacts. o There are no lower and upper age criteria limits contained in the service specification. Eligibility is based on physiological potential of the ovarian tissue. o Providers will need to ensure that people with this protected characteristic have timely access to this service. ▪ **Disability**: There are no identified potential positive or adverse impacts. o Patients eligible for treatment within this service specification will be treated in NHS Childrens and Young Adult Facilities, all which are designed to be able to support access to all available treatments for all children and young adults irrespective of disability. o Staff must ensure that information is available in ways that meet the needs of patients and carers, particularly those with learning disabilities. ▪ **Gender Reassignment and or people who identify as Transgender**: There are no identified potential positive or adverse impacts. o Staff will need to be culturally competent to meet the needs of people who identify as transgender. This can be addressed by equality and diversity training which is part of statutory and mandatory training for all staff involved with children and young adult services. ▪ **Marriage & Civil Partnership**: There are no identified potential positive or adverse impacts. ▪ **Pregnancy and Maternity**: Fertlity preservation treatment would not be required in pregnancy and maternity settings. ▪ **Race and ethnicity**: There are no identified potential positive or adverse impacts. o Staff will need to be culturally competent. This can be addressed by equality and diversity training which is part of statutory and mandatory training for all staff involved with children and young adult services. o Staff will need to be able to communicate effectively with people and must have access to interpreters and or information in easy read formats and in different languages.

		▪ **Religion and belief**: There are many arguments for and against the preservation of fertility/storage of fertility tissue. People with different beliefs or none, may agree or disagree with these arguments. People with different beliefs or none are eligible for the service if they wish to consent for the procedure. ○ Staff will need to be culturally competent. This can be addressed by equality and diversity training which is part of statutory and mandatory training for all staff involved with children and young adult services. ▪ **Sex**: Ovarian tissue storage is available to all patients who have ovarian tissue and meet the eligibility criteria for the service. ▪ **Sexual orientation**: There are no identified potential positive or adverse impacts. ○ Staff will need to be culturally competent. This can be addressed by equality and diversity training which is part statutory and mandatory training for all staff involved with children and young adult services. **Main potential positive or adverse impact for people who experience health inequalities:** ▪ **Looked after children and young people**: This service is for all children and young adults at risk of infertility who cannot store mature eggs, irrespective of whether they are looked after or not. ○ Staff will need to ensure that they are clear about who is supporting the child and who has parental responsibility and able to consent if the child is not Fraser competent. ▪ **Carers of patients**: There are no identified potential positive or adverse impacts. ○ Staff will need to ensure that the needs of people requiring care from this patient group have been discussed with the relevant agencies as part of the overall treatment and care planning process. ▪ **Homeless people**: All people who are eligible for ovarian tissue cryopreservation (OTC) will be able to access the service irrespective of their living arrangements. ○ Staff should be familiar with the NICE guideline (https://www.nice.org.uk/guidance/NG214) that covers providing integrated health and social care services for people. It aims to improve access to and engagement with health and social care, and ensure care is coordinated across different services. ▪ **People invovled in the criminal justice system**: All people who are eligible for OTC will be able to access the service irrespective of their personal situation with regards to the criminal justice system. ○ Staff should be familiar with the 'principle of equivalence' which means that the health needs of a population constrained by their circumstances are not compromised and that they receive an equal level of service as that offered to the rest of the population. ▪ **People with addictions and or substance misuse issues**: The NHS advises that tobacco, alcohol and recreational drugs can negatively impact on fertility and thus impact the success of fertility preservation treatment. However, all people who are eligible for OTC will be able to access the service if they are medically fit to undergo treatment. ▪ **People or families on a low income**: There are no identified potential positive or adverse impacts. ○ Surgical removal of reproductive tissue will occur as close to home as possible. Patients and their families can access financial assistance to support their treatment. Staff should be familiar with the

		travel costs under the Healthcare Travel Costs Scheme (HTCS) and be able to advise families about accommodation in or near the hospital. ▪ **People with poor literacy or health literacy**: There are no identified potential positive or adverse impacts. ○ Staff should consider the needs of people with poor literacy or health literacy when providing information about treatment, options, and consent. ▪ **People living in deprived areas**: All people who are eligible for OTC will be able to access the service irrespective of their deprivation status. ○ Staff should be familiar with the travel costs under the Healthcare Travel Costs Scheme (HTCS) and be able to advise families about accommodation in or near the hospital. ▪ **People living in remote, rural and island locations**: All people who are eligible for this service will be able to receive treatment in at least a regionally based hospital which may benefit people living in remote areas. ○ Staff should be familiar with the travel costs under the Healthcare Travel Costs Scheme (HTCS) and be able to advise families about accommodation in or near the hospital. ▪ **Refugess, asylum seekers or those experiencing modern slavery**: All people who are eligible for OTC will be able to access the service irrespective of their status. ○ Staff should be familiar with the guidance on providing NHS treatment to asylum seekers (https://www.gov.uk/government/news/guidance-on-providing-nhs-treatment-for-asylum-seekers-and-refugees).
Relevant legislation (list)		▪ Human Tissue Authority Regulations ▪ United Kingdom Data Protection Action (UKDPA) regulations ▪ General Medical Council (GMC) regulations
Miscellaneous		**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 (https://www.england.nhs.uk/publication/childrens-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 (https://www.england.nhs.uk/publication/childrens-cancer-services-paediatric-oncology-shared-care-unit-service-specification/) ▪ NHS England » Teenage and young adult cancer clinical network specification (https://www.england.nhs.uk/publication/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 testicular tissue who are at high/very high risk of infertility and cannot store sperm: service specification (https://www.england.nhs.uk/wp-content/uploads/2023/09/1867-testicular-tissue-cryo-serv-users-high-risk-infertility-cannot-store-sperm-service-spec.pdf) Fertility and endocrine restoration using cryopreserved ovarian tissue: service specification (https://www.england.nhs.uk/wp-content/uploads/2023/09/1867-fertility-and-endocrine-restoration-using-cryopreserved-ovarian-tissue-service-spec.pdf)

Table D.14 Extracted data for England (Fertility Preservation Service – Testicular tissue)

England		
Author(s) **Title [year]**	NHS England – Women and Children's Specialised Services Service specification: Fertility preservation service for service users with testicular tissue who are at high/very high risk of infertility and cannot store sperm[36] [2023] Equality and Health Inequalities Impact Assessment: Fertility preservation service for service users with testicular tissue who are at high/very high risk of infertility and cannot store sperm[37] [2023]	
Focus Area	**Sub-focus area**	
Population(s) and eligibility criteria		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. 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. **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%: that is, 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 testicular tissue cryopreservation (TTC) could delay their primary treatment and cause detrimental harm ▪ where surgery or a general anaesthetic would carry undue risk.
Preservation method(s) available		Testicular tissue cryopreservation.
Organisation	***Referral pathways***	**Referring centre/patient/person with parental responsibility (PPR):** 7. Primary diagnosis is confirmed by the patient's treatment centre. Treatment discussion to include risk to fertliity and fertility preservation options. 8. Patient/PPR wants to proceed with fertility preservation treatment. 9. Refer to Hub. **Hub:** 10. Referral accepted by Hub as within eligibility criteria. 11. Patient/PPR receives information and the consent form from the Hub. A consent consultation with the patient/PPR is carried out. 12. Patient/PPR wishes to proceed and completes consent -> Collection of tissue at designated Spoke Centre. OR Patient/PPR declines to proceed -> Primary treatment continues. OR 7. Referral outside eligibility criteria 8. Referred to National Expert Group (NEG) 9. Hub feeds back NEG decision to referrer: Patient to proceed with tissue storage OR Hub feeds back NEG decision to referrer: Patient should not to proceed to tissue storage
	Service provider characteristics	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.
	Timelines to access services	No information identified.
	Any other organisational aspects	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 (HTA) Regulations. ▪ Ensure that service delivery is in line with national and international guidelines and established best practice. **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 **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.
Storage	***Arrangements and duration(s)***	[From referral pathway] ▪ Collection of tissue at designated Spoke Centre ▪ Tissue transported from Spoke Centre for processing and storage at Tissue Establishment ▪ Patient/PPR isssed with contact details, unique sample identifier, conditions of storage and copy of consent. [No further information on storage identified]
	Access to stored materials	The fertility and endocrine restoration service specification does not include the restoration of testicular tissue as…it is not currently clinically available for males.

	Disposal of stored materials	…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. 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.
	Any other storage information	**Service Model** ***The Tissues Establishment (Cryopreservation services)*** The tissue establishment (TE): ▪ 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.
Governance		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/

		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. **Service model** ***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. ***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, 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.
Funding		Relates to service provided by the NHS (that is, funded by taxation). Surgical removal of reproductive tissue will occur as close to home as possible. Patients and their families can access financial assistance to support their treatment. Staff should be familiar with the travel costs under the Healthcare Travel Costs Scheme (HTCS) and be able to advise families about accommodation in or near the hospital.
Communication and information provision		The Hub will: ▪ 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. ▪ Ensure all service users, parents and PPR have adequate information to give informed consent for the storage of testicular tissue. ▪ 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. The Spoke Centre: ▪ 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,…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.
Ethical considerations		**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. [From Equality and Health Inequalities Assessment:] **Main potential impact (positive or negative) on people with the nine protected characteristics:** ▪ **Age**: There are no identified potential positive or adverse impacts. ○ There are no lower and upper age criteria limits contained in the service specification. ○ Eligibility is based on physiological potential of the testicular tissue. ○ The majority of service users will be children, young people and young adults. ○ Providers will need to ensure that people with this protected characteristic have timely access to this service. ▪ **Disability**: There are no identified potential positive or adverse impacts. ○ Patients eligible for treatment within this service specification will be treated in NHS Childrens and Young Adult Facilities, all which are designed to be able to support access to all available treatments for all children and young adults irrespective of disability. ○ Staff must ensure that information is available in ways that meet the needs of patients and carers, particularly those with learning disabilities. ▪ **Gender Reassignment and or people who identify as Transgender**: There are no identified potential positive or adverse impacts. ○ Staff will need to be culturally competent to meet the needs of people who identify as transgender. This can be addressed by equality and diversity training which is part of statutory and mandatory training for all staff involved with children and young adult services. ▪ **Marriage & Civil Partnership**: There are no identified potential positive or adverse impacts. ▪ **Pregnancy and Maternity**: N/A ▪ **Race and ethnicity**: There are no identified potential positive or adverse impacts. ○ Staff will need to be culturally competent. This can be addressed by equality and diversity training which is part of statutory and mandatory training for all staff involved with children and young adult services. ○ Staff will need to be able to communicate effectively with people and must have access to interpreters and /or information in easy read formats and in different languages. ▪ **Religion and belief**: There are many arguments for and against the preservation of fertility/storage of fertility tissue. People with different beliefs or none, may agree or disagree with these arguments.

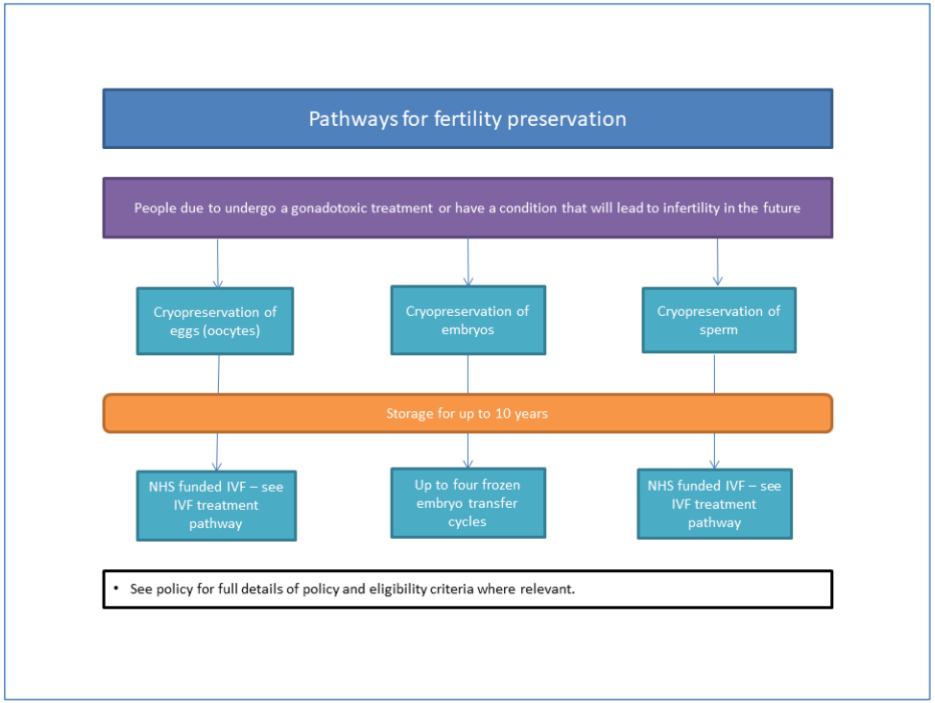
		People with different beliefs or none are eligible for the service if they wish to consent for the procedure. ○ Staff will need to be culturally competent. This can be addressed by equality and diversity training which is part of statutory and mandatory training for all staff involved with children and young adult services. ▪ **Sex**: Testicular tissue storage is available to all patients who have testes and meet the eligibility criteria for the service. ▪ **Sexual orientation**: There are no identified potential positive or adverse impacts. ○ Staff will need to be culturally competent. This can be addressed by equality and diversity training which is part statutory and mandatory training for all staff involved with children and young adult services. **Main potential positive or adverse impact for people who experience health inequalities:** ▪ **Looked after children and young people**: This service is for all children and young adults at risk of infertility who cannot store sperm, irrespective of whether they are looked after or not. ○ Staff will need to ensure that they are clear about who is supporting the child and who has parental responsibility and able to consent if the child is not Fraser competent. ▪ **Carers of patients**: There are no identified potential positive or adverse impacts. ○ Staff will need to ensure that the needs of people requiring care from this patient group have been discussed with the relevant agencies as part of the overall treatment and care planning process. ▪ **Homeless people**: All people who are eligible for testicular tissue cryopreservation will be able to access the service irrespective of their living arrangements. ○ Staff should be familiar with the NICE guideline (https://www.nice.org.uk/guidance/NG214) that covers providing integrated health and social care services for people. It aims to improve access to and engagement with health and social care, and ensure care is coordinated across different services. ▪ **People invovled in the criminal justice system**: All people who are eligible for testicular tissue cryopreservation will be able to access the service irrespective of their personal situation with regards to the criminal justice system. ○ Staff should be familiar with the 'principle of equivalence' which means that the health needs of a population constrained by their circumstances are not compromised and that they receive an equal level of service as that offered to the rest of the population. ▪ **People with addictions and or substance misuse issues**: The NHS advises that tobacco, alcohol and recreational drugs can negatively impact on fertility and thus impact the success of fertility preservation treatment. However, all people who are eligible for testicular tissue cryopreservation will be able to access the service if they are medically fit to undergo treatment. ▪ **People or families on a low income**: There are no identified potential positive or adverse impacts. ○ Surgical removal of reproductive tissue will occur as close to home as possible. Patients and their families can access financial assistance to support their treatment. Staff should be familiar

		with the travel costs under the Healthcare Travel Costs Scheme (HTCS) and be able to advise families about accommodation in or near the hospital. ▪ **People with poor literacy or health literacy**: There are no identified potential positive or adverse impacts. ○ Staff should consider the needs of people with poor literacy or health literacy when providing information about treatment, options, and consent. ▪ **People living in deprived areas**: All people who are eligible for testicular tissue cryopreservation will be able to access the service irrespective of their deprivation status. ○ Staff should be familiar with the travel costs under the Healthcare Travel Costs Scheme (HTCS) and be able to advise families about accommodation in or near the hospital. ▪ **People living in remote, rural and island locations**: All people who are eligible for this service will be able to receive treatment in at least a regionally based hospital which may benefit people living in remote areas. ○ Staff should be familiar with the travel costs under the Healthcare Travel Costs Scheme (HTCS) and be able to advise families about accommodation in or near the hospital. ▪ **Refugess, asylum seekers or those experiencing modern slavery**: All people who are eligible for testicular tissue cryopreservation will be able to access the service irrespective of their status. ○ Staff should be familiar with the guidance on providing NHS treatment to asylum seekers (https://www.gov.uk/government/news/guidance-on-providing-nhs-treatment-for-asylum-seekers-and-refugees).
Relevant legislation (list)		▪ Human Tissue Authority Regulations ▪ United Kingdom Data Protection Action (UKDPA) regulations ▪ General Medical Council (GMC) regulations
Miscellaneous		**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 (https://www.england.nhs.uk/publication/childrens-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 (https://www.england.nhs.uk/publication/childrens-cancer-services-paediatric-oncology-shared-care-unit-service-specification/) ▪ NHS England » Teenage and young adult cancer clinical network specification (https://www.england.nhs.uk/publication/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 (https://www.england.nhs.uk/wp-content/uploads/2023/09/1867-fertility-preservation-serv-users-ovarian-tissue-high-risk-infertility-and-cannot-store-mature-eggs-servi.pdf) Fertility and endocrine restoration using cryopreserved ovarian tissue; service specification(https://www.england.nhs.uk/wp-content/uploads/2023/09/1867-fertility-and-endocrine-restoration-using-cryopreserved-ovarian-tissue-service-spec.pdf)

Table D.15 Extracted data for England (Fertility Treatment Policy; Kent & Medway)

England		
Author(s) **Title [year]**	NHS Kent and Medway Integrated Care Board Policies on fertility treatments[38] [2024] Schedule of policy statements for assisted reproductive technologies (ART) for Kent and Medway Integrated Care Board[39] [2024]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		People who have a possible pathological problem (physical or psychological) to explain their infertility. Kent and Medway ICB will fund treatment for eligible individuals and couples provided there is evidence of subfertility. Policies listed only apply to couples, and where appropriate individuals, who are registered with a Kent and Medway GP. For patients not meeting the eligibility criteria, the ICB will only fund the treatment if an IFR application is successful. Cryopreservation (freezing) of eggs, embryos or sperm will be funded for eligible patients who are under the care of a specialist clinician who has confirmed one of the following: ▪ they are due to undergo a gonadotoxic treatment; this may include patients undergoing interventions for gender affirmation (Fertility preservation will be funded for patients who have started hormone therapy only if all hormone treatment is paused until either the person's normal menstrual cycle has resumed and testosterone has returned to a normal female range, or sperm production has returned and sperm parameters have returned to a normal range) ▪ they currently do not have fertility problems but they have a medical condition that, in their case, is likely to progress such that it will lead to infertility in the future. Up to 2 egg collection procedures will be funded for eligible patients when deemed clinically appropriate by the treating clinician. To access cryopreservation and storage of sperm, eggs or embryos, fertility preservation patients do not need to meet the eligibility criteria outlined for ART. However, fertility preservation patients who require cryopreservation of eggs or embryos must: ▪ be well enough to undergo ovarian stimulation and egg collection, and this will not worsen their condition, and ▪ enough time is available before the start of their gonadotoxic treatment, where applicable.
Preservation method(s) available		Cryopreservation (freezing) of eggs, embryos or sperm.

		
Organisation	***Referral pathways***	The treating consultant must complete and submit The Assisted Conception Prior Approval and Fertility Preservation Form (PA).
	Service provider characteristics	No information identified.
	Timelines to access services	No information identified.
	Any other organisational aspects	Women undergoing gonadotoxic treatment should have access to a consultation with an NHS fertility specialist before and after undergoing gonadotoxic treatment.

Storage	***Arrangements and duration(s)***	Storage of sperm, embryos and eggs will be funded for 10 years duration after cryopreservation. NHS funding of storage will end sooner where: ▪ following treatment, fertility has been established through tests or conception, or ▪ the patient dies and no written consent has been left permitting posthumous use. Patients will have the opportunity to fund continued cryopreservation of any unused sperm, embryos or eggs for future self-funded assisted conception treatment after the NHS funded storage period concludes.
	Access to stored materials	To access assisted conception treatments using cryopreserved sperm, eggs or embryos, fertility preservation patients must meet the same eligibility criteria as other patients with fertility problems. An exception to this is that fertility preservation patients do not need to fulfil the criterion for ovarian reserve criteria to access IVF using their cryopreserved eggs or embryos. **Transportation of genetic materials (cryopreserved eggs, embryos or sperm)** Kent and Medway ICB will fund 1 transportation of genetic materials and ongoing storage for patients who have undergone NHS funded assisted conception treatments, but only where the receiving provider is undertaking NHS funded assisted conception treatments using these materials.
	Disposal of stored materials	No information identified.
	Any other storage information	No information identified.
Governance		No information identified.
Funding		Treatment is funded by NHS Kent and Medway ICB but only where a patient meets the eligibility criteria set out in the relevant policy and their consultant has obtained funding approval before the treatment is performed; this is called 'prior approval'. Hospitals and other health care providers should be aware that payment may be withheld if prior approval was not given prior to the procedure being carried out. If you do not meet the eligibility criteria for a particular treatment or the treatment is not normally funded, your doctor can make an individual funding request (IFR) if they think that you meet the criteria for 'exceptionality' or 'rarity'. For patients not meeting the eligibility criteria, the ICB will only fund the treatment if an IFR application is successful.
Communication and information provision		No information identified.
Ethical considerations		No information identified.
Relevant legislation (list)		No information identified.
Miscellaneous		No information identified.

Table D.16 Extracted data for England (Fertility Assessment & Treatment policy – Somerset)

England		
Author(s) **Title [year]**	NHS Somerset Integrated Care Board Evidence Based Interventions (EBI) Programme for Interventions Not Normally Funded (INNF)[40] [2024] Fertility assessment and treatemnt prior approval (PA) policy[41] [2022]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		Patients receiving oncology and other medical interventions that may compromise fertility or the management of post-treatment fertility problems. - Patients who will receive treatments which are likely to compromise their fertility, are eligible for fertility preservation treatment including: ▪ For single individuals or those not in a stable relationship: spermcollection and storage, or oocyte harvesting and storage, or ▪ Storage for couples in a stable relationship: oocyte harvesting, fertilisation and embryo cryopreservation prior to any oncology treatment to allow subsequent IVF treatment in line with this policy as long as they meet the requirements for funding below. - Patients must have commenced puberty (presently there is insufficient evidence to support the clinical effectiveness of ovarian or testicular tissue collection for pre-pubescent people). - Female patient must not be older than 40 years of age. - Male patients must not be older than 54 years of age. - For those patients who are undergoing gonad toxic treatment, taking into consideration cancer incidence and survival among this age group. - A patient who is to receive oncology and other medical treatments that are likely to compromise their fertility, should be offered cryopreservation appropriate to their status. - At the time of fertility preservation treatment, patients do not need to demonstrate they comply with the criteria below as NHS Somerset ICB recognises this would be unfair and delaying treatment until a patient could comply would be dangerous: ▪ Of a non-smoker ▪ A BMI between >19 and <30 ▪ Have documented history of unexplained infertility. - Transgender individuals preparing for gender reassignment should be offered cryopreservation prior to commencing hormone replacement therapy and or transgender re-assignment surgery as appropriate to their status. **Fertility preservation for the following patient(s) is not commissioned and will not be funded where:** ▪ The patient wishes to undergo a vasectomy or female sterilisation and wishes to preserve fertility, or

		▪ The patient wishes to delay conception, or ▪ The patient has living offspring from their current relationship or previous relationships, including adopted children but excluding fostered children. ▪ The patient has previously received an NHS funded cycle of fertility treatment. **Please note:** To qualify for funding for fertility preservation treatment, there should be no living children from the current relationship or previous relationships for either partner, including adopted children but excluding fostered children.
Preservation method(s) available		Patients would be eligible for fertility preservation treatment including: ▪ Sperm collection and storage or ▪ Egg harvesting and storage for single individuals or those not in a stable relationship or ▪ Egg harvesting, fertilisation and embryo storage for couples in a stable relationship prior to any oncology treatment to allow subsequent IVF treatment in line with this policy as long as they meet the requirements for funding.
Organisation	***Referral pathways***	The treating NHS provider is required to forward a completed Fertility Preservation form (this can be accessed on the website) to an appropriate NHS service who provides the treatment requested. A copy of the completed Fertility Preservation form to be forwarded to the EBI (Evidence Based Interventions) Service to advise of the referral for treatment.
	Service provider characteristics	NHS hospital within the Somerset ICB.
	Timelines to access services	Where cryostorage of gametes and or embryos is to be undertaken,because of a medical treatment that is likely to make people infertile, cryostorage should occur before such treatment begins.
	Any other organisational aspects	Local protocols should exist to ensure that health professionals are aware of the value of semen cryostorage in these circumstances, so that they deal with the situation sensitively and effectively. Sperm, Egg, Embryo storage will be handled in line with the provider Cryopreservation Policy which is in place at the time of collection. The treating NHS provider is required to forward a completed Fertility Preservation form (this can be accessed on the website) to an appropriate NHS service who provides the treatment requested. A copy of the completed Fertility Preservation form to be forwarded to the EBI Service to advise of the referral for treatment.
Storage	***Arrangements and duration(s)***	The funding time period for patients who fulfil the criteria: ▪ Up to 5 years or up to 25 years of age, if age is less than 20 years at the time of preservation ▪ Funding for storage will cease 6 months following the death of the patient or if the patient or their partner reaches the upper age limit ▪ If continued funding is required a funding application should be made to the NHS Somerset ICB Evidence Based Interventions Panel.

		Once the period of NHS funding ceases, patients or their family can elect to self-fund for a further period, not to exceed appropriate HFEA regulations on length of storage.
	Access to stored materials	Patients who have completed oncology or other medical treatments and been advised by clinicians that they may safely commence fertility treatment, must meet all the requirements of the NHS Somerset ICB Fertility Assessment and Treatment policy to be eligible for NHS funded fertility treatment. Patients who wish to use cryopreserved sperm, oocytes or embryos following the death of their partner, may only do so where appropriate consents have been obtained prior to the death of their partner, as set down in HFEA guidelines.
	Disposal of stored materials	No information identified.
	Any other storage information	No information identified.
Governance		No information identified.
Funding		NHS funded. Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or Consultant believes clinical exceptional circumstances exist that warrant deviation from the rule of this policy. Completion of a Generic EBI Application Form by a patient's GP or Consultant is required.
Communication and information provision		Females preparing for medical treatment that is likely to make them infertile should be informed that oocyte cryostorage has very limited success, and that cryopreservation of ovarian tissue is still in an early stage of development and is NOT CURRENTLY FUNDED. People preparing for medical treatment that is likely to make them infertile should be offered counselling from someone who is independent of the treatment unit to help them cope with the stress and the potential physical and psychological implications for themselves, their partners and any potential children resulting from cryostorage of gametes and or embryos.
Ethical considerations		No information identified.
Relevant legislation (list)		No information identified.
Miscellaneous		No information identified.

Table D.17 Extracted data for England (Evidence Based Interventions - SW London)

England		
Author(s) **Title [year]**	NHS South West London Evidence Based Interventions Policy V4.1 [2023] [Fertility Preservation Section][42]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		- Patients in receipt of a clinically appropriate diagnosis, usually in line with NHS Guidance, who are preparing to undergo medical, non-medical and surgical treatment that is likely to have a permanent harmful effect on subsequent sperm or egg production. Such treatment may include but is not limited to: ▪ Surgery, radiotherapy or chemotherapy for malignant disease, ▪ Treatment for gender dysphoria. - Patients whose ongoing medical condition or treatment causes harmful effects on sperm or egg production or has possible teratogenic effects and when stopping treatment for a prolonged period, to enable conception is not possible. **<u>The SWL ICB does not routinely fund the following:</u>** ▪ Pre-pubertal individuals, as treatment is regarded as experimental ▪ Fertility preservation (including egg (oocyte) or embryo cryo-storage) in women of over 42 years of age ▪ Patients who choose to undergo medical or surgical treatment whose primary purpose is infertility, such as sterilisation ▪ Patients who have previously undergone sterilisation, even if it has been reversed ▪ Cryopreservation of ovarian or testicular tissue, as this is regarded as experimental ▪ 'Elective freezing': where a man or woman requests this for non-medical reasons ▪ Patients who are already infertile for any reasons ▪ An extension of the 12-month cryopreservation period (related to embryos stored for IVF/ICSI).
Preservation method(s) available		Fertility preservation may entail the harvesting and freezing of eggs or sperm that may then be thawed for use in future assisted conception treatment (ACT). Alternatively, it may entail the creation of embryos for freezing that may be implanted in the womb later. One cycle of fertility preservation, including sperm, egg and embryo cryo-storage.
Organisation	***Referral pathways***	No information identified.

	Service provider characteristics	NHS hospital within the SWL ICB.
	Timelines to access services	No information identified.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	**<u>Patients under 23 years of age</u>** The SWL ICB will fund fertility preservation for patients under 23 years of age until they reach their 23rd birthday. At the point when the patient reaches their 23rd birthday funding will be available for up to an additional 5 years from this date, similarly to those aged 23 years or over. The combined funded storage period up to age 28 years (23 + 5) gives those youngest patients entering the cryopreservation pathway the opportunity to reach an age of maturity approaching the UK averages at which men and women have children. In 2012, the most recent data at the time of writing, for first births the standardised average age of mothers was 28.1 years. Example: a young person entering the cryopreservation pathway at 15 years of age would be eligible for seven years funded storage up to age 23, then an additional 5 years funded storage up to age 28. Giving them a total potential funded storage period of 12 years. **<u>Patients aged 23 years or over</u>** The SWL ICB funds fertility preservation for patients aged 23 years or over for up to 5 years, and will only be terminated sooner in the following circumstances: ▪ Following a live birth, OR ▪ The period of cryo-storage reaches 5 years, OR ▪ The woman's 43rd birthday for eggs or embryos. If either partner dies after the freezing of gametes, the requirements of the Human Fertilisation and Embryology Act 1990 consent process must be followed. **<u>Funding of additional years</u>** Patients may choose to self-fund cryo-storage for a further period in accordance with HFEA guidelines. Retrieval and storage of sperm, eggs or embryos should also be in accordance with HFEA guidelines. In the case where patients continue to undergo active medical treatments that result in them being unable to start their families at the time their NHS-funded fertility preservation expires, the patient's treating clinician can apply on behalf of the patient for an extension to the period of storage.
	Access to stored materials	**<u>Access to assisted conception following fertility preservation</u>** Eligibility for fertility preservation is assessed separately from eligibility for ACT, and commencement of NHS-funded fertility preservation does not automatically entitle patients to access NHS-funded ACT.

		Therefore, there is the potential for patients to meet the eligibility criteria for fertility preservation and not to meet the eligibility criteria for ACT at a later date. If a patient who has undergone fertility preservation wishes to access ACT, they will be assessed against the ACT criteria as detailed within the ACT Policy, however the FSH and AMH ovarian reserve criteria will not apply in the assessment. Patients who had eggs or sperm frozen due to medical reasons, funded by the NHS, will be eligible for 2 Frozen Embryo Transfer (FET) cycles, as in these circumstances a fresh cycle is not available for them.
	Disposal of stored materials	No information identified.
	Any other storage information	**<u>Patients moving into the SWL ICB</u>** Patients moving into SWL ICB who have used NHS-funded fertility preservation services elsewhere will continue to be funded as per their previous CCG/ICB's funding arrangements. This is the same as any other treatment commenced whilst registered to another CCG/ICB's GP practice. Once the original policy agreement has elapsed (or is about to), then an application for continuing storage in accordance with the local policy would need to be made. At this time the applicant will need to demonstrate compliance with the SWL ICB policy for further storage to be supported. Fertility preservation services will continue to be funded at the same provider. When the sperm or egg requires transfer for an NHS-funded IUI/IVF/ICSI treatment the patient is responsible for all costs including transportation cost to the ACU. **<u>Patients leaving the SWL ICB</u>** Patients leaving the SWL ICB, who have used NHS-funded fertility preservation services, will no longer be the responsibility of the SWL ICB for ongoing funding of storage. In England the new CCG/ICB will need to honour and apply the SWL ICB's original policy until it expires that is, the end of the currently agreed period of storage. After this time the new CCG/ICB's policy will apply.
Governance		No information identified.
Funding		The SWL ICB will fund one cycle of fertility preservation, including sperm, egg and embryo cryo-storage.
Communication and information provision		No information identified.
Ethical considerations		Policy document includes Equality Impact Assessment based on the following protected characteristics: ▪ Race ▪ Religion/Spirituality ▪ Sex ▪ Disability ▪ Sexual orientation ▪ Age ▪ Pregnancy/Maternity ▪ Gender reassignment ▪ Marriage and Civil Partnership ▪ Carers

		▪ Overseas status
Relevant legislation (list)		Human Fertilisation and Embryology Act 1990
Miscellaneous		No information identified.

Table D.18 Extracted data for England (Services for teenagers & young adults)

England		
Author(s) **Title [year]**	NHS England Specialist cancer services for children and young people: Teenage and Young Adults Designated Hospitals[43] (2023) and Specialist cancer services for children and young people: Teenage and Young Adults Principal Treatment Centre Services[44] (2023) Teenage and Young Adult Cancer Clinical Network Specification[45] (2023)	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		The population covered by the Teenage and Young Adult (TYA) Principal Treatment Centre Service (the 'Service') is people aged 16 years up to 25th birthday who are within the commissioning responsibility of NHS England and who have a suspected or confirmed cancer. Within the Specification, the following definitions apply: ▪ Teenager refers to people aged 16 to 18 years, up to the 19th birthday; ▪ Young Adult refers to people aged 19 to 24 years, up to the 25th birthday; and ▪ Teenager and Young Adult refers to people aged 16 to 24 years, up to 25th birthday. It is acknowledged that, in some networks, age criteria may vary and there may be some flexibility in age boundaries of services to enable service users to access optimum disease and age-appropriate services. Under agreed network arrangements, and in conjunction with Children's Cancer Services, it may be appropriate for a TYA Principal Treatment Centre (PTC) Service to treat people aged 13 years and above; similarly, for some Children's Cancer PTCs to treat people aged 18 years and younger.
Preservation method(s) available		No information identified.
Organisation	***Referral pathways***	Teenagers and young adults must be referred to Principal Treatment Centres and Designated Hospitals with suspected or confirmed cancer. The TYA PTC must ensure that there are clear referral and management pathways in place for the following services (if not delivered on-site): Onco-fertility/reproductive medicine. Onco-fertility/reproductive medicine do not need to be delivered on-site, however, the TYA DH must have clear referral and management pathways in place for the following services, if not delivered on-site.
	Service provider characteristics	No information identified.

	Timelines to access services	No information identified.
	Any other organisational aspects	The Teenage and Young Adult (TYA) Cancer Network, (the 'Network') is designed to bring the key teams and personnel together that comprise the clinical and holistic components of the pathway of care for teenagers and young adults with cancer. The Network should…Agree, and ensure adherence to, Network-wide referral pathways, disease-specific treatment pathways (including diagnostic pathways, access to critical care, linkages with the TYA MDT, site-specific MDTs and adult cancer services), treatment and supportive care protocols and follow-up pathways. This must include…access to fertility services in accordance with the NICE Quality Standard 'Fertility Problems' (QS73). The TYA PTC is responsible for hosting the Network TYA MDT, which must make a recommendation to the managing clinician about how the holistic needs may influence the pragmatic aspects of different treatment options. This must include the consideration and comment upon fertility preservation services for the young person. An outcome must be provided within 7 working days of its team discussion to all relevant clinicians, including a new service user discussion for all clinicians within the diagnostic pathway.
Storage	***Arrangements and duration(s)***	No information identified.
	Access to stored materials	No information identified.
	Disposal of stored materials	No information identified.
	Any other storage information	No information identified.
Governance		Clinical Networks are a vehicle for specialty level collaboration between patients, providers and commissioners. They should have a clear line of accountability to Integrated Care Boards (ICBs), and NHS England (NHSE) Regional Teams, to ensure local ownership, alignment and a local mandate. …the…scope for the work of TYA Cancer Network…will inform the development of the annual work plans developed in conjunction with network commissioners. Indicators of outcomes, quality of care and patient experience for TYA PTCs and TYA DHs include provider-submitted data on the proportion of TYA service users offered fertility preservation where their treatment may impact on fertility. The Chair of the TYA MDT must ensure…fertility preserving measures are offered where appropriate.
Funding		No information identified.
Communication and information provision		Principal treatment centres (PTC) and Designated Hospitals (DH) must offer fertility preservation to each teenager and young adult preparing to have treatment for cancer that is likely to result in fertility problems. Consideration should be given to the diagnosis, treatment plan and associated risk of infertility, urgency of treatment initiation, prognosis and

		likelihood of success of possible fertility preservation methods. The TYA PTC must have a policy defining male and female fertility preservation options available and this must be supported by Network protocols and guidelines.
Ethical considerations		No information identified.
Relevant legislation (list)		No information identified.
Miscellaneous		No information identified.

Table D.19 Extracted data for England (Cryopreservation Policy – W Yorkshire)

England		
Author(s) **Title [year]**	NHS England – West Yorkshire Integrated Care Board Cryopreservation for both men and women where the usual fertility policy does not apply[46] [2021]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**Patients requesting cryopreservation must satisfy all of the following criteria:** ▪ Patient is due to commence chemotherapy, radiotherapy or other medical or surgical treatment which the treating clinician believes is likely to affect their future fertility ▪ The impact of the treatment on the patient's fertility has been discussed between the patient and the treating clinician as soon as clinically possible, including any impact of the process of gamete harvesting on the patient's health ▪ The patient is able to make an informed choice to undertake gamete harvesting and cryopreservation of semen, oocytes or embryos for an initial period of 10 years ▪ The patient is aware that funding for gamete harvesting and cryopreservation of material does not guarantee future funding of assisted conception or fertility treatment. If the patient requests an estimate of the current costs of privately funded fertility treatment then details of how to find a clinic should be given, along with information on the current local commissioning position for NHS fertility treatment, recognising this may be subject to change. ▪ In line with the NICE guidelines, the usual local eligibility criteria for fertility treatment will NOT apply at the time of gamete harvesting and cryopreservation. Approval of cryopreservation does NOT guarantee future funding of assisted conception or fertility treatment at which time the local eligibility criteria for fertility treatment will apply. **Age** ▪ There are no specific age limits to this policy for males or females. The decision to attempt to preserve fertility is a clinical decision.
Preservation method(s) available		**Cryopreservation in Males** The ICS will align to clinical evidence and clinical guidance at the time as to the number of semen samples to be collected over the recommended period of time and stored before treatment for cancer. The ICS will commission the number of samples of semen that is considered sufficient to provide future fertility. **Cryopreservation in Females** (Enhancement for people in Bradford District and Craven as current policy in that area is for Males only)

		The ICS will align to clinical evidence and clinical guidance at the time as to the number of recommended cycles of egg retrieval, with or without fertilisation. If insufficient eggs are retrieved following this first cycle of egg retrieval, then one further cycle can be offered. **Policy exclusions** ▪ Testicular tissue freezing is considered experimental and will not be funded. ▪ Ovarian tissue storage is considered experimental and will not be funded.
Organisation	***Referral pathways***	No information identified.
	Service provider characteristics	NHS hospitals within the West Yorkshire ICB
	Timelines to access services	No information identified.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	**Duration of Storage** ▪ People who preserve their fertility should be offered follow up after an appropriate interval following treatment for their medical condition, this would generally be around one year following conclusion of treatment. A discussion with a clinician should take place at this follow up regarding the need to continue storage based on whether their fertility has been affected, or could reasonably be expected to be affected in the future. NHS funded storage should only be continued if fertility has been affected by the medical treatment or if the medical treatment is likely to cause future fertility problems. ▪ The legal duration of storage is governed by statutory HFEA legislation and regulations; the ICB will routinely fund storage of gametes or embryos for an initial 10 year period. If storage is desired for longer than 10 years then an application should be made as an exceptional request to the Individual Funding Request panel, and each case will be considered on its own merit andin line with the HFEA legislation. (Note that statutory storage periods for gametes and embryos permit patients to store for a maximum of 10 years, and regulations for extending storage periods up to a maximum of 55 years). *[This has been updated to 55 years]*
	Access to stored materials	▪ Approval of cryopreservation does NOT guarantee future funding of assisted conception or fertility treatment at which time the local eligibility criteria for fertility treatment will apply.
	Disposal of stored materials	No information identified.
	Any other storage information	No information identified.
Governance		No information identified.
Funding		NHS funded procedures.

Communication and information provision		A discussion with a clinician should take place at this follow up regarding the need to continue storage based on whether their fertility has been affected, or could reasonably be expected to be affected in the future. If the patient requests an estimate of the current costs of privately funded fertility treatment then details of how to find a clinic should be given, along with information on the current local commissioning position for NHS fertility treatment, recognising this may be subject to change.
Ethical considerations		No information identified.
Relevant legislation (list)		The legal duration of storage is governed by statutory HFEA legislation and regulations.
Miscellaneous		No information identified.

Table D.20 Extracted data for France (Funding for AR)

France		
Author(s) **Title [year]**	Biomedicine Agency (*Agence de la biomédecine*) Funding for medically assisted genetic procreation 2023[47] [2024]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**2.6. Medical preservation of fertility** The medical preservation of fertility referred to here is the preservation of gametes carried out after multidisciplinary consultation, in the context of an oncological or non-oncological condition, with the aim of guaranteeing the possibility of subsequent treatment in medically assisted procreation, after the patient has recovered. The following are therefore not covered by this mission of general interest (MIG) compartment: ▪ gamete preservation as part of exclusive medically assisted procreation, ▪ preservation as part of a "societal" request (self-preservation authorised since the new law on bioethics 2021). … people whose medical care is likely to alter fertility, or whose fertility is at risk of being prematurely altered, who can benefit from the collection and preservation of their gametes or germinal tissues, or sometimes their embryos, with a view to subsequently carrying out, for their benefit, medically assisted procreation, or with a view to preserving and restoring their fertility. People benefiting from self-preservation during medically assisted procreation are not included.
Preservation method(s) available		[Summarised from section 2.6. Medical preservation of fertility] ▪ Sperm cryopreservation ▪ Oocyte or embryo cryopreservation ▪ Testicular tissue cryopreservation ▪ Ovarian tissue cryopreservation
Organisation	***Referral pathways***	No information identified.
	Service provider characteristics	The financing of an ART centre (whatever its status; the ART MIG one of the rare MIG awarded to both the public ("ex-DG") and private ("ex-OQN") sectors according to strictly identical rules)…
	Timelines to access services	No information identified.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	No information identified.

	Access to stored materials	No information identified.
	Disposal of stored materials	No information identified.
	Any other storage information	No information identified.
Governance		The Biomedicine Agency supports and sustains the financing of care activities whose supervision and supervision fall within its field of competence (bioethics law of July 7, 2011), in particular activities of medically assisted procreation, diagnosis prenatal and preimplantation, and human genetics. In order to take into account the specificity of these activities and the need to remunerate establishments as closely as possible for the various public health missions and obligations, the financing methods in these areas have been improved since 2011, with the creation and or modelling of missions of general interest (MIG), thanks to the collective work carried out between the Biomedicine Agency, professionals (learned societies, federation), and the General Directorate of Care Offering (DGOS). This information leaflet aims to inform the clinical and biological teams as well as all the stakeholders concerned (in particular the management of establishments and the Regional Health Agency), on the methods of financing assisted reproductive technology (ART) activities in public health establishments and private, and on the financing of additional costs attributable to the activities of multidisciplinary prenatal diagnosis centres (CPDPN), and preimplantation diagnosis centres (CDPI). Concerning the ART MIG, the year of activity taken into account for the calculation of the allocation is now, and since 2022, the year N-1 (and no longer N-2), which makes the MIG allocation more responsive in relation to reality and the evolution of care. In 2023, the year of activity taken into account for the MIG DPI has also been modified (N-1 instead of N-2). Major renovation work on the ART MIG compartments continued in 2023. Following on from 2022 where the allocation for SPERMATOZOID DONATION was modified, this year all the other MIG compartments were reviewed, in the context of the new revision of the EBL and the evolution of practices. Finally, in 2023, and similarly to last year, all funding levels in the Additional Costs in ART compartment have been revalued in order to integrate the revision of the salaries of health professionals granted within the framework of Ségur de la santé. This compartment of the MIG was favoured because it concerns all the ART centres.
Funding		**What is a MIG?** Activity pricing, known as T2A, since its origin, has had 2 complementary components: ▪ Financing the diagnostic, treatment and care activity through service rates and national packages (for example homogeneous group of stays (GHS rate) packages allocated to hospital stays):

		resources are thus allocated to establishments according to the volume and nature of their activity (described by the medicalisation of information systems programme). ▪ Compensation for expenses linked to the accomplishment of missions of general interest, through specific grants called MIG or MIGAC (missions of general interest and assistance with contracting). The national MIG/MIGAC funding allocation finances missions and actions which the legislator has deemed should not be subject solely to variations in activity. Indeed, the activities of health establishments are not limited to activities quantifiable through data from the medicalisation of information systems programme and billable to Health Insurance. This notion of a mission of general interest is not specific to the French system and most foreign activity-based pricing systems provide for such additional financing arrangements. The MIG/MIGAC allocations aim to compensate for observed additional costs, which are potentially different depending on the establishment given the disparities in activities and results. Thus, activity data (activity measured in "levels" and not by stay or by act) must necessarily be integrated into the calibration of allocations and ultimately allow a re-evaluation of these in the light of the results observed. The diversity of missions of general interest explains why the legislator wanted to delimit and order them. Finally, remember that, like all T2A financing, only health establishments can receive MIG grants. **Illustration: the MIG allocation dedicated to ART activities** The MIG grant aims to compensate for the additional costs of care activities…Concerning ART, additional costs have been identified for ART activity in general and for certain specific treatments. These missions are therefore compensated - subject to valid authorisation of the activities - by structural and annual funding of the MIG type based on quantitative indicators, and allocated by establishment. The financing of an ART centre (whatever its status; the ART MIG is one of the rare MIG awarded to both the public ("ex-DG") and private ("ex-OQN") sectors according to strictly identical rules) is thus made up of 2 complementary components: a billable part (clinical, biological, imaging procedures, consultations, hospitalisation stays) and a non-billable part (linked to the execution of different missions). The non-billable component, or MIG allocation, is intended to finance personnel and equipment costs. In the case of gamete and embryo donation, it also guarantees the principle of financial neutrality for donors. Under this principle, the establishment in charge of collecting for gamete donation reimburses all of the donor's non-medical expenses and exempts him from the co-payment and the daily rate. Concerning biology, laboratory procedures not registered with the Nomenclature of Medical Biology Procedures (NABM; acts outside the nomenclature) are not financed by the ART MIG but by an ad hoc MIG concerning all acts outside the nomenclature (invoicing within the Reference Framework for Innovative Acts Outside the Nomenclature of Biology and Anatomopathology, RIHN).

		The "historic" ART MIG envelope, initially dedicated to financing gamete donation activities, was redefined in several stages by integrating new scopes of activity and new distribution rules (2013 – 2014), and more recently by integrating the new practices included in the Bioethics Law of August 2, 2021. In 2023, the ART MIG allocation amounts to more than €33 million in total and includes 7 compartments: 1. Additional costs of the MPA (§ 2.1) 2. ART in viral context (§ 2.2) 3. Egg donation (§ 2.3) 4. Sperm donation (§ 2.4) 5. Embryo reception (§ 2.5) 6. Fertility preservation (§ 2.6) 7. Non-medical self-preservation of gametes (§ 2.7) For centres starting an activity or in a situation of economic deployment, the financing prospects will be integrated into a contractualisation process with the Regional Health Agency on the basis of a start-up package provided for all compartments. **2.6. Medical preservation of fertility** The MIG allocation attributable to the fertility preservation activity is calculated based on the number of patients* with tissues or cells collected in year "N-1" and cryopreserved in the same year (stock level as of December 31 of the same year). *These are people whose medical care is likely to alter fertility, or whose fertility is at risk of being prematurely altered, who can benefit from the collection and preservation of their gametes or germinal tissues, or sometimes their embryos, with a view to subsequently carrying out, for their benefit, medically assisted procreation, or with a view to preserving and restoring their fertility. People benefiting from self-preservation during medically assisted procreation are not included. The work carried out in 2023 with the "Law on Bioethics Financing" working group made it possible to include indicators related to the use of gametes in the existing indicators for cryopreservation and to modify the weighting coefficients. This also made it possible to dissociate use in an oncological and non-oncological context. The annual activity indicator is defined by adding these six items: 1. the number of patients with frozen sperm straws in the year 2. + the number of patients with cryopreserved sperm straws on December 31 3. + 4.6 times the number of patients with frozen oocytes (or embryos) in the year 4. + the number of patients with cryopreserved oocytes (or embryos) on December 31 5. + 4.4 times the number of patients with frozen testicular tissues in the year 6. + 5 times the number of patients with frozen ovarian tissues in the year

7. + the number of patients with cryopreserved germinal tissues on December 31
Establishments that start the activity benefit from level 1.

The coefficients have been integrated in order to weight upwards the activities of preservation of oocytes and germinal tissues, activities less widespread and requiring greater investment from teams. This increase aims to support centres offering a variety of techniques allowing women and young people to access fertility preservation. The minimum level of activity is set at the indicator value 100.

In 2023, the revaluation linked to the integration of a portion of the envelope corresponding to the AC paid to ART centres, allowed the creation of a 6th flat-rate level, as well as the upward revision of the levels.

The funding levels become:

	Indicator		**Prices 2023**
	≥0	**99**	**€**
Level 1	100	250	€55,000
Level 2	251	850	€90,000
Level 3	851	1450	€125,000
Level 4	1451	3600	€160,000
Level 5	3601	7500	€195,000
Level 6	7501	++	€230,000

Furthermore, it was decided to also take into account fertility restoration activities, distinguishing this treatment according to the context, oncological or non-oncological.

The new indicators linked to the restoration of fertility are:

Indicators	**Prices 2023**
Number of patients who used frozen oocytes in an oncological context	€454
Number of patients who used oocytes for non-oncological medical reasons	€334
Number of patients who received an ovarian tissue transplant	€1,062
Number of patients who used frozen spermatozoa in an oncological context	€206
Number of patients who used sperm for non-oncological medical reasons	€170

Expenses falling within the scope of the "PF" compartment of the "ART" MIG:
The expenses covered concern the preparation of files, programming, interviews, opinions and expertise of examination results, multidisciplinary staff, file management and annual reminders to people with cryopreserved samples.
The depreciation (set at 10 years) of cryopreservation equipment such as the oximetry control extraction systems of the dedicated room and the cryopreservation tanks is also included in the MIG.

<table>
<tr><td></td><td></td><td>Expenses outside the MIG scope:
Clinician consultations, NABM or non-nomenclature biology procedures and CCAM tissue/cell sampling procedures are not financed by the MIG allocation.

Summary and evolution of the ART MIG 2022-2023 (with geographical coefficient)*
* The geographical coefficient is a regional increase correction which applies to hospital rates and MIG amounts: Corsica +11% / Île-de-France +7% / Martinique and Guadeloupe +27% / Guyana +29% / Reunion +31%.

[Extracted for ‘Fertility preservation’ for medical reasons only]
<table>
<tr><th></th><th>ART MIG 2022 (activity 2021) with Ségur revaluation</th><th>ART MIG 2023 (activity 2022) with Ségur revaluation</th><th>Share of the compartment in the total MIG envelope</th></tr>
<tr><td>Number of centres funded</td><td>53</td><td>55</td><td rowspan="3">24%</td></tr>
<tr><td>Amounts</td><td>€5,500,000</td><td>€7,880,564</td></tr>
<tr><td>Evolution of the allocation</td><td>7%</td><td>43%</td></tr>
</table>
</td></tr>
<tr><td>Communication and information provision</td><td></td><td>No information identified.</td></tr>
<tr><td>Ethical considerations</td><td></td><td>No information identified.</td></tr>
<tr><td>Relevant legislation (list)</td><td></td><td>▪ Bioethics Law of August 2, 2021
▪ Bioethics Law of July 7, 2011
▪ Social Security Code</td></tr>
<tr><td>Miscellaneous</td><td></td><td>No information identified.</td></tr>
</table>

Table D.21 Extracted data for France (Self-Preservation of Gametes)

France		
Author(s) **Title [year]**	Biomedicine Agency (*Agence de la biomédecine*) Self-preservation of gametes [webpage and brochure][48, 49] [2024]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		[From brochure:] NB: Before treatment likely to alter the functioning of the ovaries or testicles, a gamete conservation must be offered to the patient. This is called fertility preservation. ▪ For women, egg collection as part of fertility preservation can be done until the 43rd birthday ▪ For men, sperm collection in this context can be done up to the 60th birthday. [From webpage and brochure:] The 2021 bioethics law provides for the possibility of self-preservation of one's gametes without medical conditions and without the condition of donating part of the gametes to others. However, you will have to meet age conditions to be able to self-preserve your gametes: ▪ For women from the 29th birthday to the 37th birthday* ▪ For men from the 29th birthday to the 45th birthday* *Age at the time of gamete collection. Preserved gametes can then be used up until the 45th birthday for women, and the 60th birthday for men. [From brochure:] Self-preservation without prior donation conditions and without the need to carry out an infertility assessment is therefore now possible.) [From webpage and brochure:] **How is the gamete collection done?** If the age conditions set by decree of the Council of State are respected, after medical care by the clinicobiological team and with written consent after information on "the conditions, risks and limits of the procedure and its consequences", the procedures may begin…
Preservation method(s) available		**What is gamete self-preservation?** It is the preservation of one's own gametes, by freezing spermatozoa or vitrification for oocytes, to possibly use them later, for IVF for example. **How is the gamete collection done?**

		For women: egg retrieval is done by puncture of the ovaries* after about 10 days of injections for their stimulation. The process is long and restrictive, but oocyte activation makes it possible to obtain sufficient oocytes in number and quality for future IVF. *Female reproductive organs, 2 in number, located on each side of the uterus. Also called "female gonads", the ovaries produce female reproductive cells (oocytes) and female hormones (mainly oestradiol and progesterone). For men: several masturbation collections are carried out in the laboratory.
Organisation	***Referral pathways***	**Where can I find out more about gamete self-preservation?** In medically assisted reproduction centres approved by the regional health agencies. The list of approved medically assisted reproduction centres can be consulted on this link. You can also talk about it with your GP, gynaecologist or midwife.
	Service provider characteristics	[See 'Referral pathways']
	Timelines to access services	No information identified.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	After you have self-preserved your gametes, you will have to pay the annual storage fee. These costs relating to the storage of gametes may not be borne or compensated, directly or indirectly, by the employer or by any natural person or any person on whom the person concerned is in a situation of economic dependence. Each year, you will also need to indicate whether you want to: ▪ store them ▪ use them for ART ▪ donate it to people waiting for gamete donation ▪ donate it to scientific research ▪ end their retention. It is important to note that for self-preservation of spermatozoa, the person can at any time consent to a part of the spermatozoa collected being dedicated to donation. If you don't respond to reminders for 10 consecutive years, your gametes will be destroyed. It should be noted that in the event of death, conservation is stopped, unless you have consented to donation or medical research during your lifetime.
	Access to stored materials	The gametes self-preserved by freezing or vitrification can then be used: ▪ Until the 45th birthday for women ▪ Until the 60th birthday for men
	Disposal of stored materials	[See 'Arrangements and duration(s)]

	Any other storage information	After collection, the gametes are packaged in straws* and then stored in liquid nitrogen at a temperature of – 196 °C after freezing or vitrification. *Packaging for small-volume biological samples to store small doses of frozen sperm. The straws are resistant to very low temperatures and thus guarantee the safety of the samples.
Governance		[From brochure] The Biomedicine Agency is a national state agency placed under the supervision of the Ministry of Health. It was created by the bioethics law of 2004. It carries out its missions in the areas of harvesting and transplantation of organs, tissues and cells, as well as in the fields of human procreation, embryology and genetics. The Biomedicine Agency does everything possible to ensure that each patient receives the care they need, while respecting the rules of health safety, ethics and equity. Through its expertise, it is the reference authority on the medical, scientific and ethical aspects relating to these questions. In terms of medically assisted procreation, the Agency: ▪ manages the register of gamete and embryo donors ▪ manages authorisations for medically assisted procreation techniques ▪ aims to improve access to medically assisted procreation ▪ evaluates practices ▪ ensures the implementation of medically assisted procreation vigilance systems ▪ promotes egg donation and sperm donation. Finally, it is responsible for informing the general public in close collaboration with health professionals.
Funding		After you have self-preserved your gametes, you will have to pay the annual storage fee. These costs relating to the storage of gametes may not be borne or compensated, directly or indirectly, by the employer or by any natural person or any person on whom the person concerned is in a situation of economic dependence. **What is the cost of self-preservation of gametes?** Acts related to the collection or removal of gametes as part of self-preservation will be covered by the Health Insurance. However, the cost of storing the gametes is not covered by the Health Insurance and remains the responsibility of the insured at €40.50/year.
Communication and information provision		No information identified,
Ethical considerations		**What is the 2021 bioethics law that governs ART?** The law of 2 August 2021 amends the legal provisions of ART, also known as MAP (Medically Assisted Procreation): ▪ It expands access to ART to all women, whether they are in a relationship with a man, a woman or single. ▪ It authorises the self-preservation of gametes without medical indication, and without prior donation conditions. ▪ It gives new rights to people born from ART with a 3rd -party donor.

Relevant legislation (list)		Law No. 2021-1017 of 2 August 2021 on bioethics (1) The law of August 2, 2021 modifies the legal provisions of medically assisted procreation (AMP, also called PMA): It expands access to AMP to all women, whether they are in a relationship with a man, a woman or single. It authorizes the self-preservation of gametes without medical indication, and without prior donation conditions. It confers new rights to people born from ART with a third party donor.
Miscellaneous		**Self-preservation of gametes in practice** ***Why self-preserve your gametes?*** The objective of the self-preservation of gametes, spermatozoa and oocytes is to have them available if, later, a planned child should require ART. With age, the chances of procreation decrease, the quality of the gametes also decreases and the risks to children's health increase. This physiological phenomenon is earlier and more marked in women because the decrease in ovarian reserve automatically reduces the chances of motherhood. Self-preservation of one's gametes does not guarantee the success and birth of a child by artificial insemination or IVF. The indication is not of a medical nature but is the result of a choice of the person. This is the novelty introduced by the 2021 bioethics law.

Table D.22 Extracted data for France (Self-Preservation Laws)

France		
Author(s) **Title [year]**	Biomedicine Agency (*Agence de la biomédecine*) What does the law say[50] [2024]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**Self-preservation: the framework** The bioethics law introduces the possibility of self-preservation of one's gametes: ▪ for women from the 29th birthday to the 37th birthday and for men from the 29th birthday to the 45th birthday with a view to carrying out subsequent medically assisted reproduction; ▪ without condition of infertility; ▪ without any condition of donating part of the gametes to others; ▪ in the context of medical care by the clinicobiological team and with written consent after information on the conditions, risks and limits of the approach and its consequences. **Self-preservation without a medical indication is different from fertility preservation for medical reasons** Before treatment that may impair the functioning of the ovaries* or testicles±, a freezing of the gametes must be proposed: ▪ For the woman, egg retrieval as part of the preservation of the fertility¥ can be done until the 43rd birthday. ▪ For men, sperm collection in this context can be done until the age of 60. This is referred to as the preservation of the fertility. The framework was already defined by previous bioethics laws. *Female reproductive organs, 2 in number, located on each side of the uterus. Also called "female gonads", the ovaries produce female reproductive cells (oocytes) and female hormones (mainly oestradiol and progesterone). ±Male organs of reproduction, 2 in number, located in the bursa. Also called male "gonads", the testicles produce spermatozoa and male hormones (mainly testosterone). ¥Ability for a couple to conceive, that is to start a pregnancy.
Preservation method(s) available		…freezing of the gametes...
Organisation	***Referral pathways***	No information identified.

	Service provider characteristics	Medically assisted reproduction is practiced in licensed facilities and by practitioners who are competent in these activities.
	Timelines to access services	No information identified.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	**The continuation of gamete conservation, year after year** Each year, people who have carried out a self-preservation will have to let us know if they wish to: ▪ keep them ▪ use them for medically assisted reproduction ▪ donate it to people waiting for gamete donation ▪ donate it to scientific research ▪ to put an end to their retention. It is possible to specify one's choice on the fate of one's gametes in the event of death. When you choose to stop storing your gametes, you will be asked for confirmation after a period of 3 months. If you do not respond to reminders for 10 years, your stored gametes may be destroyed.
	Access to stored materials	The implementation of medically assisted reproduction is indicated for: ▪ couples composed of a man and a woman, ▪ single women and female couples. Individuals using medically assisted reproduction must be of childbearing age.
	Disposal of stored materials	[See 'Arrangements and duration(s)']
	Any other storage information	No information identified.
Governance		No information identified.
Funding		**What are the costs of gamete self-preservation?** The costs associated with the collection or removal of gametes for self-preservation are covered by the Health Insurance. However, the expenses related to the conservation of gametes are not covered by the Health Insurance and remain the responsibility of the insured, amounting to €40.50 per year.
Communication and information provision		No information identified.

Ethical considerations		**The three main principles of gamete donation and embryo reception** Anonymity, free of charge and voluntary are the main principles on which gamete donation and embryo reception are based. These 3 main principles remain unchanged following the revision of the bioethics law in 2021.
Relevant legislation (list)		Bioethics Law No. 2004-800 of 6 August 2004 amended in 2011 and 2021
Miscellaneous		**Embryo conservation** The preservation of one's gametes does not guarantee the success of ART or the birth of a child, especially the self-preservation of oocytes. (Consult the figures and results of the GPA in 2020) It should also be noted that the health of children born of ART is the subject of scientific studies. An information sheet on the health of children born of ART is available on this link as well as on this page.

Table D.23 Extracted data for France (Decree No. 2021-1243 – AR Pathways)

France		
Author(s) **Title [year]**	France Decree No. 2021-1243 of 28 September 2021 setting the conditions for the organisation and coverage of medically assisted reproduction pathways[51] [2021]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		Notice: the text specifies the age conditions for benefiting from medically assisted procreation and self-preservation of their gametes for subsequent purposes of medically assisted procreation for their benefit. **Article 1** Section 8 is created, within Chapter I of Title IV of Book I of Part Two of the Public Health Code, which reads as follows: "Section 8 "Age requirements for medically assisted procreation and self-preservation of one's gametes…" [See data extraction of Regulatory part of Public Health Code for details]
Preservation method(s) available		[See data extraction of Regulatory part of Public Health Code for details]
Organisation	***Referral pathways***	No information identified.
	Service provider characteristics	Notice: the text specifies the age conditions for benefiting from medically assisted procreation and self-preservation of their gametes for subsequent purposes of medically assisted procreation for their benefit. It also sets out the composition of the clinico-biological medical team with regard to clinical activities of medically assisted procreation, which will be responsible in particular for carrying out individual interviews with applicants prior to the implementation of medically assisted procreation. [See data extraction of Regulatory part of Public Health Code for details]
	Timelines to access services	No information identified.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	[See data extraction of Regulatory part of Public Health Code for details]

	Access to stored materials	[See data extraction of Regulatory part of Public Health Code for details]
	Disposal of stored materials	[See data extraction of Regulatory part of Public Health Code for details]
	Any other storage information	[See data extraction of Regulatory part of Public Health Code for details]
Governance		[See data extraction of Regulatory part of Public Health Code for details]
Funding		…the decree provides for the abolition of the contribution to the costs relating to medically assisted procreation. **Article 3** Article R. 160-17 of the Social Security Code is amended as follows: 1° In 2° of I, the first sentence is replaced by the following provisions: "For the investigations necessary for the diagnosis and treatment of infertility."; 2° After 8° of I, a 9° is inserted as follows: "9° For medically assisted procreation carried out under the conditions provided for in Chapter I of Title IV of Book I of Part Two of the Public Health Code. The decision of the health insurance fund to cancel the contribution shall be taken on the advice of the medical board on the care protocol provided for in Article L. 324-1 of this Code. The fund's decision sets the duration of the exemption period. Challenges to the said decision shall give rise, when they relate to the assessment made by the medical control service, to a medical expert opinion under the conditions laid down in Chapter I of Title IV of Book I. "When an insured person changes managing body during the exemption period, this change has no impact on the period during which he or she benefits from this exemption."
Communication and information provision		No information identified.
Ethical considerations		[See data extraction of Legislative parts of the Public Health Code]
Relevant legislation (list)		▪ Social Security Code ▪ Public Health Code ▪ Law No. 2021-1017 of 2 August 2021 on bioethics
Miscellaneous		No information identified.

Table D.24 Extracted data for France (Public Health Code: Articles L2141-1 to L2141-13)

France		
Author(s) **Title [year]**	France Public Health Code, Chapter I: General provisions. (Articles L2141-1 to L2141-13)[52] [version in force as of 2024 July 30]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**Article L2141-11** I. Any person whose medical care is likely to impair fertility or whose fertility is at risk of being prematurely altered may benefit from the collection or removal and conservation of his or her gametes or germinal tissues with a view to the subsequent realisation, for his or her benefit, of medically assisted procreation, with a view to the preservation or restoration of his or her fertility or with a view to the restoration of hormonal function. The collection, collection and storage referred to in the first paragraph shall be subject to the consent of the person concerned and, where applicable, that of one of the parents vested with parental authority or of the guardian when the person concerned is a minor, after information on the conditions, risks and limits of the procedure and its consequences. The consent of the minor must be systematically sought if he or she is capable of expressing his or her wishes and participating in the decision. With regard to adults who are the subject of a legal protection measure with representation relating to the person, Article 458 of the Civil Code applies. The modification of the designation of sex in the civil registry shall not prevent the application of this article. [Note: See Regulatory part (Article R2141-36 for age conditions that apply when fertility preservation is carried out with a view to subsequent assisted reproduction.]
Preservation method(s) available		**Article L2141-11** The biological processes used for the conservation of gametes and germinal tissues are included in the list provided for in Article L. 2141-1 of this Code, under the conditions determined in the same Article L. 2141-1. [Note: This list is available on the Biomedicine Agency's website (link). It includes the following relevant processes: ▪ Freezing of gametes ▪ Freezing of germinal tissues

		▪ Freezing of embryos, zygotes. In addition, the following are included on the list of techniques that aim to improve the processes above: ▪ Gamete vitrification (technique for improving the gamete freezing process) ▪ Vitrification of embryos and zygotes (technique for improving the embryo freezing process). The linked document contains technical details on these processes and techniques, supporting literature, and data on their safety and effectiveness.]
Organisation	***Referral pathways***	No information identified.
	Service provider characteristics	No information identified.
	Timelines to access services	No information identified.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	**Article L2141-11** I. In the year in which he or she reaches the age of majority [Note: 18 years in France], the person whose gametes or germinal tissues are stored pursuant to this I shall receive information from the multidisciplinary team of the centre where his or her gametes or germinal tissues are stored on the conditions for such storage and the follow-up to the procedure. II. Parents vested with parental authority of a minor whose gametes or germinal tissues are preserved pursuant to this article shall be contacted each year in writing to collect information useful for storage, including a possible change of contact details. The preservation of the gametes or germinal tissues of a minor, even an emancipated person, can only be terminated in the event of death. In the event of the death of a minor whose gametes or germinal tissues are preserved, the parents with parental authority may consent in writing: 1° That its gametes or germinal tissues are the subject of research under the conditions provided for in Articles L. 1243-3 and L. 1243-4 ; 2° That the conservation of his gametes or germinal tissues be terminated. Consent may be revoked until the gametes or germinal tissues are used or until their storage is terminated. The period mentioned in IV of this article shall apply to minors, even if emancipated, only from the date of majority [Note: that is, the date the person reaches 18 years of age]. III. The adult whose gametes or germinal tissues are preserved pursuant to this article shall be consulted each year. He or she consents in writing to the continuation of this retention.

		If he or she no longer wishes to continue this retention or if he or she wishes to specify the conditions of conservation in the event of death, he or she agrees in writing: 1° That his gametes be donated pursuant to Chapter IV of Title IV of Book II of Part One; 2° That his or her gametes or germinal tissues are the subject of research under the conditions provided for in Articles L. 1243-3 and L. 1243-4; 3° That the conservation of his gametes or germinal tissues be terminated. In all cases, this consent is confirmed in writing at the end of a 3-month reflection period from the date of the first consent. Consent may be revoked until the gametes or germinal tissues are used or until their storage is terminated.
	Access to stored materials	**Article L2141-2** Medically assisted procreation is intended to respond to a parental project. Any couple consisting of a man and a woman or two women or any unmarried woman shall have access to medically assisted procreation after the individual interviews of the applicants with the members of the multidisciplinary clinicobiological medical team carried out in accordance with the procedures provided for in Article L. 2141-10. This access may not be subject to any difference in treatment, in particular with regard to the applicants' marital status or sexual orientation. Both members of the couple or the unmarried woman must give their prior consent to artificial insemination or embryo transfer. In the case of a couple, the following are obstacles to insemination or embryo transfer: 1° The death of one of the members of the couple; 2° The filing of a divorce petition; 3° The submission of an application for legal separation; 4° The signing of a divorce or legal separation agreement by mutual consent in accordance with the procedures provided for in Article 229-1 of the Civil Code; 5° The termination of cohabitation; 6° The written revocation of the consent provided for in the third paragraph of this article by one or other of the members of the couple to the doctor responsible for implementing medically assisted procreation. A follow-up study is offered to the recipient couple or the recipient woman, who consents in writing.

		The age conditions required to benefit from medically assisted procreation are set by decree of the Council of State, adopted after consultation with the Biomedicine Agency. They take into account the age-related medical risks of procreation as well as the interest of the unborn child. [Note: The age conditions to access publicly-funded ART are (link): ▪ Until the person's 45th birthday in the case of the woman, unmarried or in a couple, who intends to carry the child ▪ Until their 60th birthday for the member of the couple who will not be carrying the child.] **Article L2141-11-1** The import and export of gametes or germinal tissues from the human body are subject to an authorisation issued by the Biomedicine Agency. They are exclusively intended to enable the pursuit of a parental project by means of medically assisted procreation or the restoration of the applicant's fertility or hormonal function, to the exclusion of any commercial purpose. Only an establishment, an organisation, a health cooperation group or a laboratory holding the authorisation provided for in Article L. 2142-1 to carry out a biological activity of medically assisted procreation may obtain the authorisation provided for in this article. Only gametes and germinal tissues collected and intended to be used in accordance with the quality and safety standards in force, as well as the principles mentioned in Articles L. 1244-3, L. 1244-4, L. 2141-2, L. 2141-3, L. 2141-11 and L. 2141-12 of this Code and Articles 16 to 16-8 of the Civil Code, may be the subject of an import or export authorisation. Any violation of the requirements set out in the authorisation for the import or export of gametes or germinal tissues shall result in the suspension or withdrawal of this authorisation by the Biomedicine Agency.
	Disposal of stored materials	**Article L2141-11** [Note: See sections II. And II. under 'Arrangements and duration(s)'] IV. In the absence of a response from the adult for 10 consecutive years, the storage of his gametes or germinal tissues shall be terminated. The period of 10 consecutive years runs from the age of majority of the person. When the person reaches an age that no longer justifies the interest of retention and in the absence of the consent provided for in 1° or 2° of III, this retention shall be terminated. This age limit is set by an order of the Minister for Health, issued after consultation with the Biomedicine Agency. In the event of the death of the person and in the absence of the consent provided for in the same 1° or 2°, the storage of gametes or germinal tissues shall be terminated.

	Any other storage information	**Article L2141-1** The implementation of medically assisted procreation favours practices and procedures that make it possible to limit the number of embryos stored. The Biomedicine Agency shall report in its annual report on the methods used and the results obtained.
Governance		**Article L2141-1** The list of biological processes used in medically assisted procreation is set by order of the Minister for Health after consultation with the Biomedicine Agency. A decree of the Council of State specifies the procedures and criteria for the inclusion of processes on this list. Any technique aimed at improving the efficiency, reproducibility and safety of the processes appearing on the list…shall, before its implementation, be the subject of an authorisation issued by the Director-General of the Biomedicine Agency after a reasoned opinion from his or her Advisory Board. Where the Steering Committee considers that the proposed amendment is likely to constitute a new procedure, its implementation shall be subject to its inclusion on the list... An order of the Minister for Health, adopted on the proposal of the Biomedicine Agency, defines the rules of good practice applicable to medically assisted procreation.
Funding		**Article L2141-11** I. Any person whose medical care is likely to impair fertility or whose fertility is at risk of being prematurely altered may benefit from the collection or removal and conservation of his or her gametes or germinal tissues with a view to the subsequent realisation, for his or her benefit, of medically assisted procreation, with a view to the preservation or restoration of his or her fertility or with a view to the restoration of hormonal function. **Article L2141-12** I. An adult who meets the age conditions set by a decree of the Council of State, adopted after consultation with the Biomedicine Agency, may benefit, after medical care by the multidisciplinary clinicobiological team, from the collection, removal and storage of his or her gametes with a view to subsequent realisation, for his or her benefit, medically assisted procreation under the conditions provided for in this chapter. The costs relating to the storage of gametes carried out pursuant to this I may not be borne or compensated, directly or indirectly, by the employer or by any natural person or any legal person governed by public or private law on whom the person concerned is in a situation of economic dependence. Only public health establishments or private non-profit health establishments authorised to provide the public hospital service may, when they have been authorised to do so, collect, collect and store the gametes referred to in this I. These activities may not be carried out within the framework of the liberal activity provided for in Article L. 6154-1. By way of derogation, if no public or private non-profit health

		body or establishment carries out these activities in a department, the director-general of the regional health agency may authorise a private for-profit health establishment to carry them out, subject to the latter's guarantee that there is no invoicing of overruns of the rates set by the administrative authority and the rates of fees provided for in 1° of I of Article L. 162-14-1 of the Social Security Code.
Communication and information provision		No information identified.
Ethical considerations		**Article L2141-1** The list of biological processes used in medically assisted procreation is set by order of the Minister for Health after consultation with the Biomedicine Agency. A decree of the Council of State specifies the procedures and criteria for the inclusion of processes on this list. The criteria relate in particular to compliance with the fundamental principles of bioethics provided for in particular in Articles 16 to 16-8 of the Civil Code, the efficacy, the reproducibility of the process and the safety of its use for the woman and the unborn child. **Article L2141-11** I. The collection, collection and storage referred to in the first paragraph shall be subject to the consent of the person concerned and, where applicable, that of one of the parents vested with parental authority or of the guardian when the person concerned is a minor, after information on the conditions, risks and limits of the procedure and its consequences. The consent of the minor must be systematically sought if he or she is capable of expressing his or her wishes and participating in the decision. With regard to adults who are the subject of a legal protection measure with representation relating to the person, Article 458 of the Civil Code applies. The modification of the designation of sex in the civil registry shall not prevent the application of this article.
Relevant legislation (list)		These sections of the Public Health Code were most recently amended by Law No. 2021-1017 of 2 August 2021.
Miscellaneous		No information identified.

Table D.25 Extracted data for France (Public Health Code: Articles R2141-1 to R2143-20)

France		
Author(s) **Title [year]**	France Public Health Code, Title IV: Medically assisted reproduction (Articles R2141-1 to R2143-20).[53] [version in force as of 2024 July 30]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**Article R2141-36** The age conditions required by Article L. 2141-2 to benefit from the removal or collection of one's gametes, with a view to medically assisted procreation, are set as follows: 1° Oocyte retrieval may be carried out from a person up to his or her forty-third birthday; 2° The collection of spermatozoa may be carried out in a person up to his or her sixtieth birthday. These provisions shall apply to the removal or collection of gametes or germinal tissues carried out pursuant to Article L. 2141-11, when this is carried out with a view to medically assisted subsequent procreation.
Preservation method(s) available		See data extraction of Legislative parts of the Public Health Code
Organisation	***Referral pathways***	No information identified.
	Service provider characteristics	**Article R2142-18** The multidisciplinary clinicobiological medical team referred to in Article L. 2141-2 is composed, for clinical activities of medically assisted procreation, of at least: 1° A doctor qualified in gynaecology-obstetrics or medical gynaecology or endocrinology, diabetes, metabolic diseases for clinical activities of oocyte retrieval for the purpose of medically assisted procreation or donation, transfer and implementation of embryo reception; 2° A doctor qualified in urology or general surgery or in gynaecology and obstetrics for sperm retrieval. These practitioners meet the conditions mentioned in Article R. 2142-10. II. It also includes, for the conduct of private interviews of both members of the couple or of the unmarried woman: 1° In addition to the doctors mentioned in I, at least one psychiatrist, psychologist or nurse with training or experience in psychiatry; 2° Where necessary, a social service assistant. III. It also includes, for biological activities of medically assisted procreation, at least one medical biologist and one laboratory technician, meeting the conditions mentioned in Article R. 2142-11. **Article R2142-10**

		I. Practitioners who meet the following conditions of cumulative training and experience are deemed to be able to prove their competence to carry out the clinical activities of medically assisted procreation mentioned in 1° of Article R. 2142-1: 1° Be a qualified doctor specialising in gynaecology and obstetrics, medical gynaecology, urology, general surgery or endocrinology, diabetes, metabolic diseases or qualified competent in gynaecology and obstetrics or obstetrics or in medical gynaecology or endocrinology depending on the type of activity carried out and under the conditions specified by order of the Minister for Health; 2° Possess a diploma of additional specialised studies or, failing that, a right to practise in the specialties allowing the clinical activities of medically assisted procreation to be carried out and under the conditions set by the same decree; 3° Justify the conditions of duration and nature of experience in these activities under the conditions defined by the same decree. II. Doctors who meet the conditions mentioned in 1° of I and who are registered with a view to obtaining a diploma of additional specialised studies mentioned in 2° of I are also deemed to be able to prove their competence to carry out clinical activities of medically assisted procreation for a period of one year, renewable once, provided that they are able to appeal in their practice, as necessary, to a doctor who can prove that he meets all the conditions mentioned in I and who practices within the same structure. **Article R2142-11** I. Practitioners who meet the following cumulative training and experience conditions are deemed to be able to prove specific skills to carry out the biological activities of medically assisted procreation mentioned in 2° of Article R. 2142-1: 1° Be a medical biologist within the meaning of Articles L. 6213-1, L. 6213-2 or L. 6213-2-1 and possess one or more university diplomas in reproductive biology totalling a period of practical training of at least one year; 2° Justify the conditions of duration and nature of the experiment allowing the biological activities of medically assisted procreation to be carried out under the conditions defined by order of the Minister for Health. II. Medical biologists registered with a view to obtaining the university degree(s) in reproductive biology mentioned in 1° of I who do not meet the conditions of experience mentioned in 2° are also deemed to be able to prove their competence to carry out the biological activities of medically assisted procreation for a period of one year, renewable once, provided that they can call upon a medical biologist who can justify all the conditions mentioned in I and who practices within the same structure.
	Timelines to access services	No information identified.

	Any other organisational aspects	**Article R2142-26** The collection, preparation, storage and provision of gametes or germinal tissues as well as the preparation, storage and provision of embryos shall be carried out, in accordance with the rules of good practice for medically assisted procreation referred to in Articles R. 2142-24 and R. 2142-27, in each health establishment, body, health cooperation group or medical biology laboratory in which the activities defined in 2° of Article R. 2142-1. **Article R2142-30** The interruption or cessation of activity of an establishment, a health cooperation group or a laboratory authorised to store gametes, germinal tissues or embryos must not lead to the cessation of their storage. To this end, any health establishment, body, health cooperation group or laboratory authorised to store gametes, germinal tissues or embryos must enter into an agreement with another establishment, group or laboratory authorised to carry out the same activity, with a view to the possible movement of these gametes, germinal tissues or embryos. This agreement must be sent to the regional health agency prior to the compliance visit provided for in Article L. 6122-4. In this case, the displacement of gametes, germinal tissues or embryos must be reported in advance to the competent regional health agencies and to the Biomedicine Agency. If this travel is not carried out within the framework of the agreement provided for in the previous paragraph, it must be authorised by the regional health agency, after consultation with the Biomedicine Agency. When circumstances so require, the regional health agency may designate a centre authorised to carry out the same activity to receive gametes, germinal tissues or embryos. It shall inform the Biomedicine Agency thereof. **Article R2142-31** With the exception of the gamete donor mentioned in Article L. 1244-2, any person who has consented to the storage of gametes, germinal tissues or embryos must be informed in advance of their removal and of the new place of their storage.
Storage	***Arrangements and duration(s)***	[See data extraction of Legislative parts of the Public Health Code] **Article R2141-19** I. Any person whose gametes or germinal tissues are stored pursuant to Article L. 2141-11 shall be informed in advance of the age limits set, on the one hand, by the decree provided for in IV of the same article, and on the other hand, in Article R. 2141-38, as well as of the impossibility of storing germinal tissues for procreation purposes for his or her own benefit beyond these limits. It is also informed that it will be consulted each year to find out whether it wishes to maintain this method of retention. This information shall specify in particular the conditions under which this annual consultation will be carried out.

		The person referred to in the first paragraph shall also be informed that he or she may consent to a gamete donation, to research on his or her gametes or germinal tissues, as well as to the end of the storage of his or her gametes or germinal tissues, under the conditions specified in III of Article L. 2141-11, provided that he or she is of legal age. II. The holders of parental authority shall receive the information provided for in I when the person whose gametes or germinal tissues are to be stored pursuant to Article L. 2141-11 is a minor. III. An order of the Minister for Health issued after consultation with the Director General of the Biomedicine Agency shall set the model for the annual consultation referred to in I and specify the terms and conditions.
	Access to stored materials	**Article R2141-38** Artificial insemination, the use of gametes or germinal tissues collected, removed or stored for the purpose of medically assisted procreation pursuant to Articles L. 2141-2, L. 2141-11 and L. 2141-12, as well as the embryo transfer referred to in Article L. 2141-1, may be carried out: 1° Until the 45th birthday in the case of an unmarried woman or within the couple, who is intended to carry the child; 2° Until the 60th birthday in the case of the member of the couple who is not intended to carry the child. *Note:* *Refer to the conditions of application provided for in Article 4 of Decree No. 2021-1243 of 28 September 2021.*
	Disposal of stored materials	[See data extraction of Legislative parts of the Public Health Code]
	Any other storage information	[See data extraction of Legislative parts of the Public Health Code] **Article R2141-23** As soon as the gametes, initially stored for the purpose of medically assisted procreation on the basis of Article L. 2141-2, or pursuant to Articles L. 2141-11 and L. 2141-12, are the subject of a donation, the provisions of Chapter IV of Title IV of Book II of Part One of the Code as well as the health safety rules relating to gametes for donation, apply. **Article R2142-29** The health establishment, the body, the health cooperation group or the laboratory authorised for the activities mentioned in e of 2° of Article R. 2142-1 shall keep, in compliance with confidentiality, for each person whose gametes or germinal tissues it keeps, pursuant to the provisions of Article L. 2141-11: 1° The written consent of the person and, where applicable, that of the holder of parental authority in the case of a minor; 2° The reason and indication for the preservation of gametes or germinal tissues made jointly with the doctor who is treating the pathology likely to alter the person's fertility.

Governance		[See data extraction of Legislative parts of the Public Health Code] **Article R2142-42** The actors of the vigilance system relating to medically assisted procreation are: 1° The Biomedicine Agency; 2° Health establishments, medical biology laboratories and bodies authorised to carry out the activities mentioned in Article L. 2142-1; 3° The following professionals: a) Practitioners working in health establishments, medical biology laboratories or organisations mentioned in 2°; b) Any other health professional who is aware of an adverse reaction which, in view of the information in his or her possession, appears to be related to the activities mentioned in Article R. 2142-1. [Further details on the national vigilance system are outlined in Articles R2142-42 to R2142-44. Local vigilance systems are outlined in Articles R2142-45 to R2142-49.]
Funding		**Article R2141-36** The age conditions required by Article L. 2141-2 to benefit from the removal or collection of one's gametes, with a view to medically assisted procreation, are set as follows: 1° Oocyte retrieval may be carried out from a person up to his or her forty-third birthday; 2° The collection of spermatozoa may be carried out in a person up to his or her sixtieth birthday. These provisions shall apply to the removal or collection of gametes or germinal tissues carried out pursuant to Article L. 2141-11, when this is carried out with a view to medically assisted subsequent procreation. **Article R2141-37** The age conditions required by Article L. 2141-12 to benefit from the self-preservation of one's gametes with a view to the subsequent provision of medically assisted procreation are set as follows: 1° The removal of oocytes may be carried out from a person from his or her 29th birthday until his or her 37th birthday; 2° The collection of spermatozoa may be carried out in a person from his 29th birthday until his 45th birthday.
Communication and information provision		**Article R2142-33** The registers of gametes or germinal tissues that must be kept by any health establishment, body, health cooperation group or laboratory authorised to store these gametes or tissues must mention: 1° The identity of the person whose gametes were collected or removed in the case of medically assisted procreation without the use of a 3rd-party donor, or the identity of the person whose gametes or germinal tissues are stored pursuant to Article L. 2141-11; 2° The Single European Donation Code or the code for the anonymisation of the gamete donor in the case of medically assisted procreation with the use of a 3rd-party donor;

		3° The place and dates of freezing of the gametes or tissues; 4° Their dates and methods of use; 5° Precise indications of the place of their conservation in the room assigned for this purpose; 6° In the case of gamete donation, the elements allowing the identification of the recipient couple or the unmarried recipient woman. **Article R2142-34** The embryo register that must be kept by any health establishment, body, health cooperation group or laboratory authorised to store embryos must mention: 1° The identity of the couple or unmarried woman who originated the embryo and, where applicable, the single European donation code or the gamete donor anonymisation code in the case of an embryo conceived with the use of a 3rd-party donor; 2° The number of embryos stored for each couple or each unmarried woman; 3° The place and dates of fertilization and freezing; 4° Precise indications of the place where the embryos are stored in the containers in the room assigned for this purpose; 5° Where applicable, the places of previous conservation; 6° Information relating to the fate of each embryo, in particular the dates and results of the annual consultation of the members of the couple on the maintenance of their parental project and the date of thawing of each embryo; 7° In the case of embryo reception, the Single European Donation Code. **Article R2142-35** Practitioners meeting the criteria mentioned in Article R. 2142-11 for the conservation of gametes, germinal tissues or embryos are responsible for keeping the registers mentioned in Articles R. 2142-33 and R. 2142-34 and for ensuring the accuracy of the information they record therein. **Article R2142-36** These registers must be kept in premises located close to those where gametes, germinal tissues or embryos are stored, under conditions guaranteeing confidentiality.
Ethical considerations		See data extraction of Legislative parts of the Public Health Code.
Relevant legislation (list)		Articles R2141-36 and R2141-37: ▪ Amended by Decree No. 2022-1187 of 25 August 2022 Article R2141-38: ▪ Created by Decree No. 2021-1243 of 28 September 2021 Articles R2142-10 and R2142-11: ▪ Amended by Decree No. 2015-150 of 10 February 2015 Article R2142-18: ▪ Amended by Decree No. 2021-1243 of 28 September 2021

		Article R2142-26 ▪ Amended by Decree No. 2017-631 of 25 April 2017
Miscellaneous		No information identified.

Table D.26 Extracted data for Germany (German Medical Association Guidelines)

Germany		
Author(s) **Title [year]**	German Medical Association (BÄK, *Bundesärztekammer*) Guideline for the removal and transfer of human germ cells or germ cell tissue in the context of assisted reproduction, detailed update.[54] [2022]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		…there is a right to cryopreservation…if cryopreservation appears medically necessary due to an illness and its treatment with a therapy that damages germ cells in order to be able to carry out subsequent medical measures to bring about a pregnancy. *2.3.1 Additional information before the removal and cryopreservation of human germ cells or germ cell tissue due to germ cell-damaging therapy or in the case of genetic abnormalities with a germ cell deficiency* The medical background of the interventions are both malignant diseases (approx. 90% of cases), such as breast cancer, lymphomas, testicular or ovarian tumors, and non-malignant diseases (approx. 10% of cases), such as rheumatoid arthritis, glomerulonephritis, thalassemia or endometriosis, for which germ cell-damaging therapy is indicated, or unchangeable influencing factors of a genetic nature, for example microdeletion of the Y chromosome, genetic diseases such as cystic fibrosis, or variants of the sex chromosomes such as Klinefelter syndrome or Turner syndrome.
Preservation method(s) available		The removal and transfer of human germ cells or germ cell tissue in the context of assisted reproduction. [Note: Methods outlined in section 2.3: Cryopreservation of ▪ sperm ▪ unfertilised or impregnated egg cells ▪ embryos ▪ testicular tissue ▪ ovarian tissue] [Note: References are made throughout document to "impregnated egg cells". This refers to "human egg cells from the moment of…introduction of the human sperm cell until the moment of nuclear fusion." This includes cells after the formation of two pronuclei, but before the fusion of the two pronuclei. In German legislation, an embryo is defined as a fertilised egg cell from the moment of fusion of the nuclei.] **3. Collection and transfer of human germ cells or germ cell tissue**

		3.1 Germ cell or germ cell tissue collection [Note: Document contains subsections with the headings below that outline detailed procedural requirements to ensure compliance with the relevant legislation] ▪ *3.1.1 Sperm collection and examination* ▪ *3.1.2 Egg collection and examination* ▪ *3.1.3 Obtaining ovarian tissue for fertility preservation due to germ cell damaging therapy or in case of genetic abnormalities with a germ cell deficiency*
Organisation	***Referral pathways***	*2.3.1 Additional information before the removal and cryopreservation of human germ cells or germ cell tissue due to germ cell damaging therapy or in the case of genetic abnormalities with a germ cell deficiency* Whether a fertility-protective measure is useful and which measures can be recommended should be based on the following criteria for [female] patients: ▪ The risk of a failure of the endocrine and reproductive ovarian function due to the therapy or due to a corresponding genetic abnormality should be estimated as medium to high for the later desire to have children. This risk depends on both the type and dose of the planned therapy, or the dose and location of the planned radiation, as well as on the ovarian reserve at the time of the consultation and should be estimated on an individual basis. ▪ The illness and the age of the patient when the fertility-protective measures are carried out should make it sufficiently likely that the desire to have children can still be fulfilled later. ▪ A later pregnancy should be compatible with the underlying illness and the therapy carried out in terms of the course of the pregnancy and birth as well as the child's health. ▪ The fertility-protective therapy should be feasible without a significant deterioration in the patient's prognosis. The main factor here is the delay in the start of curative treatment caused by fertility-protective therapy. ▪ When considering whether ovarian tissue removal can be recommended, the expected risk of metastasis involving the ovary and the corresponding risk of metastasis transmission must also be taken into account. If tissue removal is carried out without complications, further therapy can be initiated promptly, ideally the following day. Whether fertility-protective measures are useful and which measures can be recommended should be based on the following criteria for [male] patients: ▪ The risk of disruption of sperm production, potential failure of endocrine testicular function or disruption of sperm deposition depends on the type and dose of the planned surgical or medicinal therapy, or the dose and location of the planned radiation. In patients, the extent of potentially permanent damage to sperm cell production cannot be reliably estimated, as an individual sensitivity of spermatogenesis as well as a certain dependence on existing pre-existing damage to testicular function can be observed. An assessment of fertility and possible pre-existing damage can be carried out by an ejaculate examination according to the guidelines of the World Health Organization (WHO 2021), if necessary additionally confirmed by hormone levels (at least FSH [follicle stimulating hormone], LH [luteinising hormone], testosterone) and an examination of the testicles.

		▪ Fertility-protective therapy should be feasible without a significant deterioration in the patient's prognosis. The primary factor here is the delay in the start of curative treatment caused by fertility-protective therapy. ▪ Sperm cells are obtained through masturbation and cryopreservation can in most cases be combined with ejaculate diagnostics. Several semen samples may have to be obtained in order to create a sufficient cryodeposit. The normally recommended waiting period of 2-7 days can be ignored in order to avoid delays in treatment. ▪ In the case of azoospermia or a disorder of semen deposition (for example anejaculation, retrograde ejaculation), surgical removal of testicular tissue can be offered and carried out as a microsurgically assisted or multiple standard TESE [testicular sperm extraction]. In the case of a testicular tissue removal for TESE without complications, further treatment can be started promptly.
	Service provider characteristics	An institution that wants to obtain human germ cells or germ cell tissue for use in humans as part of assisted reproduction or to carry out the laboratory tests required for the extraction requires a permit from the responsible authority in accordance with…the AMG [the Medicines Act]…a separate permit for the tissue extraction and for the necessary laboratory tests is not required for extraction facilities and laboratories that cooperate contractually with a manufacturer or processor to carry out these activities who has a permit... In this case, the corresponding permit is granted to the manufacturer or processor. These facilities are tissue facilities within the meaning of the TPG [the Transplantation Act]. The requirements for the extraction and examination of germ cells or germ cell tissue are set out in Section 8d TPG and in the TPG-GewV [the TPG Tissue Ordinance]. An establishment that processes, preserves, tests, stores or markets human germ cells or germ cell tissue as part of assisted reproduction requires a permit in accordance with…the AMG from the competent state authority in consultation with the Paul Ehrlich Institute. Under [certain] conditions of…[the] AMG, a permit requirement…may be waived. This applies to human germ cells or germ cell tissue that remain with the same doctor from the time of collection to the time of use. This means that the doctor collects, processes and treats these himself and then uses the germ cells or germ cell tissue on the patient himself. The doctor may, for example, seek help from staff in his area of responsibility during processing or testing, but the application must be carried out personally. The activities in question must be reported to the responsible state authority...
	Timelines to access services	[Section 2.3.1. Repeated for both female and male patients:] Fertility-protective therapy should be feasible without significantly worsening the patient's prognosis. The main factor here is the delay in the start of curative treatment caused by fertility-protective therapy.
	Any other organisational aspects	**2.7 Medical assessment of the medical suitability of the donors** ***2.7.1 Examination of the woman*** *2.7.1.1 Special features prior to cryopreservation of egg cells and ovarian tissue for autologous use due to germ cell damaging therapy or genetic abnormalities with a germ cell deficiency* The patient must be examined by a suitably qualified doctor before a planned fertility protection procedure. In addition to the medical history, the necessary measures include a physical examination,

		supplemented by sonography of the genital organs and age-appropriate basic hormonal diagnostics. In postpubertal women, serum AMH [Anti-Müllerian hormone] should also be measured to assess the individual ovarian reserve, if necessary supplemented by a determination of the antral follicle population. The treatment measures for fertility protection covered by this guideline are the removal of eggs and the subsequent cryopreservation of unfertilised or impregnated eggs (see 3.1.2) and the removal, preparation and cryopreservation of ovarian cortex (see 3.1.3). A combination of both procedures is possible; in this case, laparoscopic removal should be carried out first and hormonal stimulation treatment for egg retrieval should begin immediately afterwards. Unfertilised eggs are just as capable of surviving cryopreservation through vitrification as impregnated eggs and of leading to a pregnancy with an unremarkable course. The cryopreservation of unfertilised eggs leaves questions about partner choice open. ***2.7.2 Examination of the man*** *2.7.2.1 Special features prior to cryopreservation of sperm cells or testicular tissue due to germ cell damaging therapy or genetic abnormalities with a germ cell deficiency* The patient must be examined by a suitably qualified doctor before a planned fertility protection procedure. In addition to the medical history, the necessary measures include a physical examination, supplemented by an examination of the testicles using sonography and a blood sample for hormone analysis. As basic diagnostics, at least LH, FSH and testosterone are required, which may be supplemented by additional parameters (prolactin, estradiol, free testosterone, SHBG [Sex hormone-binding globulin] and inhibin-B). The required serology according to TPG and TPG-GewV must be carried out before cryopreservation. In order not to lose any sperm cells for cryopreservation through diagnostics, the measure of cryopreservation of sperm cells from the ejaculate should, if possible, be combined with diagnostic ejaculate analysis. The ejaculate analysis as part of the cryopreservation of ejaculate sperm is carried out in accordance with the WHO specifications in their currently valid version (WHO 2021). Depending on the urgency of the desired cryopreservation measure, the findings obtained from the diagnostics are only partially applicable for immediate therapy to improve fertility, but are included in the consultation on the application of the measures. In addition, they represent an important starting point for assessing the fertility reserve after completion of germ cell-damaging therapy or in the case of a genetic abnormality with germ cell deficiency. The collection of germ cell tissue from a patient is indicated if one of the following constellations of findings is found in the ejaculate analysis required for cryopreservation: ▪ azoospermia (absence of sperm in the ejaculate), ▪ severe cryptozoospermia with a very low concentration (<0.1 million sperm/ml or <0.1 million sperm/ejaculate), ▪ an ejaculate quality that is insufficient for cryopreservation, for example a lack of vital sperm before cryopreservation or after thawing an aliquot, ▪ an ejaculation disorder that does not allow the collection of an ejaculate suitable for cryopreservation, or if an ejaculate analysis is not possible due to a prepubertal situation.

		The germ cell tissue is obtained either conventionally by taking multiple testicular biopsies or by microsurgically assisted testicular tissue sampling, each in combination with cryopreservation of the tissue for later TESE for an assisted fertilisation procedure, if possible from both testicles. In rare cases, in patients with an uncorrectable obstruction of the ejaculatory ducts, microsurgical aspiration of sperm from the epididymis (microsurgical epididymal sperm aspiration, MESA) can also be considered and carried out. The aim of cryopreservation as a fertility-preserving measure is to preserve sufficient sperm, which is sufficient for at least 10 or more treatment cycles if possible.
Storage	***Arrangements and duration(s)***	Both ejaculate sperm and testicular tissue for TESE are cryopreserved…and can be stored in the liquid or gas phase (from -196°C to -160°C) of nitrogen for the patient's lifetime, unless the patient specifies otherwise. **3.4 Cryopreservation of germ cells, impregnated oocytes or germ cell tissue** Cryopreservation and storage of cells or tissues is ensured in tissue facilities. The vitrification process should be used for cryopreservation of nonimpregnated egg cells. For cryopreservation of impregnated egg cells, the vitrification process or the programmed slow freezing process (so-called slow freezing) can be used. According to current knowledge, the cryopreservation of sperm, testicular tissue or ovarian tissue should be carried out using the method of programmed slow freezing. [Note: Further details on storage procedures, temperatures, and transport arrangements are outlined in section 3.4]
	Access to stored materials	**3.3 Transfer of human germ cells or germ cell tissue** ***3.3.1 Release of germ cells or germ cell tissue for transfer*** [Note: This section outlines the requirements according to the relevant legislation.] *3.3.2 Use and application of human germ cells and other measures* The transfer of germ cells refers to various measures of assisted reproduction, for example: 3.3.2.1 Use of sperm cells for insemination 3.3.2.2 Use of egg and sperm cells 3.3.2.3 Further measures ▪ Examination of the eggs for fertilisation ▪ Handling impregnated eggs ▪ Polar body diagnostics [Note: this refers to a method for the genetic analysis of oocytes before the end of fertilisation] *3.3.3 Autologous transfer of ovarian cortex tissue to preserve fertility after germ cell-damaging therapy or in the case of genetic abnormalities with a germ cell deficiency*
	Disposal of stored materials	**8.10 Documentation of activities and annual report of tissue establishments** …the tissue establishment maintains documentation of its activities, including information on the type and quantity of human germ cells or germ cell tissue removed, examined, prepared, treated or processed, preserved, stored, given away or otherwise used, imported and exported, as well as the

		origin and destination of the germ cells or germ cell tissue, and makes a description of its activities publicly available. It submits an annual report to the responsible higher federal authority with information on the type and quantity of tissue removed, prepared, treated or processed, preserved, given away or otherwise used, imported and exported.
	Any other storage information	***2.7.2 Examination of the man*** *2.7.2.1 Special features prior to cryopreservation of sperm cells or testicular tissue due to germ cell damaging therapy or genetic abnormalities with a germ cell deficiency* When cryopreserving sperm, cell survival after freezing and thawing depends on minimising intracellular ice crystal formation, which can be achieved by using suitable cryoprotectants (usually glycerol-based) and adjusted cooling and warming rates. In the case of severely reduced sperm quality, it is recommended to determine sperm motility before cryopreservation and after thawing. Storage and the duration of storage of ejaculate (and TESE and MESA material) under suitable conditions does not lead to any further deterioration in sperm quality. Since a single vital sperm is used per egg cell for ICSI [intra-cytoplasmic speerm injection] treatment, cryopreservation of significantly reduced semen samples with individual sperm is also useful. Germ cell tissue is obtained from prepubertal boys by biopsy of a testicle to preserve immature testicular stem cells in the testicular tissue. The procedure for refertilisation of the donor (here: retransfer of testicular tissue) is currently experimental. The methods of tissue sampling, tissue preparation of the tissue pieces and cryopreservation based on dimethyl sulfoxide are established published protocols, while the possible procedures and the timing of refertilisation of the donors are not yet clinically established. ***2.7.3 Testing for infection parameters*** *2.7.3.1 Testing for infection parameters when using autologous germ cell tissue* To protect the personnel involved in the collection, processing, storage, transport and transfer and to assess the need for any additional measures required in connection with the storage of the tissue, the person must be tested for infection parameters in accordance with [relevant Annexes of the TPGGewV]. [Note: Detailed requirements are also outlined under the following section headings:] **4. Requirements for medical care facilities, tissue establishments and testing laboratories** 4.1 Requirements for establishments that obtain and or process, preserve, test, store or market human germ cells or germ cell tissue for assisted reproduction *4.1.1 Spatial requirements* *4.1.2 Personnel requirements* *4.1.3 Technical requirements* 4.2 Requirements for testing laboratories **5. Quality management, quality assurance and data protection** 5.1 Quality management and quality assurance 5.2 Data protection **6. Activities on behalf of tissue establishments** **7. Reporting of serious adverse reactions and serious incidents as well as recalls** **8. Documentation**

		8.1 General obligation to document reproductive medical procedures 8.2 Creating and maintaining a donor file 8.3 Documentation of information, consent and advice 8.4 Collection report 8.5 Documentation of removed, donated and transferred tissues 8.6 Further documentation requirements according to AMWHV 8.7 Documentation in the context of cryopreservation of germ cells or germ cell tissue due to germ cell-damaging therapy or in the case of genetic abnormalities with a germ cell deficiency 8.8 Documentation within the framework of quality management and quality assurance 8.9 Documentation of notifications 8.10 Documentation of activities and annual report of tissue establishments 8.11 Retention and deletion periods
Governance		**Foreword** According to Section 16b of the…TPG, the German Medical Association, in agreement with the Paul Ehrlich Institute, can, in addition to the requirements of the TPG Tissue Ordinance, establish the generally accepted state of knowledge in medical science on the requirements for the medical assessment of medical suitability as a tissue donor, the examination of tissue donors and the removal, transfer and use of human tissue in guidelines and specify the various regulations at the statutory and sub-legal level. Accordingly, the "Guideline for the removal and transfer of human germ cells in the context of assisted reproduction" adopted by the Board of the German Medical Association on the recommendation of the Scientific Advisory Board sets out the medical and scientific issues while clearly separating them from the socio-political aspects. The guideline published in May 2018 created practical and uniform framework conditions with regard to the quality of the tissue and the care of those affected, which give those involved the necessary legal certainty and guarantee a high level of treatment safety. According to the decision of the Board of the German Medical Association in January 2014, the "Guideline for the removal and transfer of human germ cells in the context of assisted reproduction" will be reviewed at least every two years by the Scientific Advisory Board of the German Medical Association under the leadership of the Chairman of the Advisory Board to determine whether they are up to date. This regular procedure ensures that any application problems are identified at an early stage and that the guideline can be further developed on the basis of the current state of knowledge in medical science in the sense of a "learning system". The Appointment Service and Care Act (TSVG), which came into force in May 2019, standardised the entitlement of those with statutory insurance to reimbursement of the costs of cryopreservation of germ cells or germ cell tissue prior to germ cell-damaging therapy in Section 27a Paragraph 4 of the Social Security Code (SGB V). In view of this, the Executive Board of the German Medical Association, on the recommendation of the Advisory Board, decided to update the guideline in a specific manner as part of the regular review of the current status carried out in 2019. In accordance with this mandate, the Standing Working Group "Guidelines for the removal and transfer of human germ cells in the context of assisted reproduction" under the leadership of Prof. Dr. Jan-Steffen Krüssel has supplemented the current state of knowledge in medical science regarding the cryopreservation of germ cells and germ cell tissue and

		has made editorial adjustments to the guideline. In the interest of procedural transparency, the appendix to the guideline now contains the consultation process for the described update. Human germ cells (egg and sperm cells) are tissues within the meaning of…[the] TPG. **1.3 Legal basis for the removal and transfer of human germ cells or germ cell tissue in the context of assisted reproduction** The removal and transfer as well as the treatment and processing of tissue in the context of assisted reproduction is governed in particular by the provisions of the AMG…the TPG and the respective associated legal regulations... In addition, the ESchG, the Sperm Donor Register Act (SaRegG), the Genetic Diagnostics Act (GenDG), the provisions of §§ 630a ff. of the German Civil Code (BGB), provisions of the SGB V…including the guidelines issued by the Federal Joint Committee (G-BA) in the area of statutory health insurance…as well as the professional and continuing education regulations of the (state) medical associations must be observed.
Funding		The Appointment Service and Care Act (TSVG), which came into force in May 2019, standardised the entitlement of those with statutory insurance to reimbursement of the costs of cryopreservation of germ cells or germ cell tissue prior to germ cell-damaging therapy in Section 27a Paragraph 4 of the Social Security Code (SGB V). *2.1.5 Further information-related obligations to provide information* The economic information obligation in accordance with Section 630c Paragraph 3 of the German Civil Code must be observed in particular with regard to the partial or full assumption of treatment costs. As part of the economic information, it should also be pointed out that according to Section 27a Paragraph 4 of the Social Code Book V, there is a right to cryopreservation of egg or sperm cells or germ cell tissue as well as to the associated medical measures if cryopreservation appears medically necessary due to an illness and its treatment with a therapy that damages germ cells in order to be able to carry out subsequent medical measures to bring about a pregnancy. The patient should be informed about the possibility of a separate contractual agreement on the storage period of cryopreserved tissue, possibly beyond the age limits specified in Section 2 Paragraph 3 of the Cryopreservation Directive.
Communication and information provision		**2. Requirements for the collection and transfer of human germ cells or germ cell tissue** ***2.1 Legal requirements for information and education prior to the removal and transfer of human germ cells or germ cell tissue*** *2.1.1 Requirements according to Section 8b in conjunction with Section 8 Paragraph 2 TPG* Germ cells or germ cell tissue are subject to the scope of the TPG, with the exception of tissues that are removed from a person during one and the same surgical procedure in order to be transferred back to that person without changing their material properties…Accordingly…the "donor must be informed by a doctor in an understandable form about: 1. the purpose and type of intervention, 2. the examinations and the right to be informed about the results of the examinations,

		3. the measures that serve to protect the donor, as well as the extent and possible, including indirect, consequences and long-term consequences of the intended organ or tissue removal for his health, 4. the doctor's duty of confidentiality, 5. the expected prospects of success of the […] tissue transfer and the consequences for the recipient as well as other circumstances to which he clearly attaches importance for the donation, as well as 6. the collection and use of personal data. The donor must be informed that his consent is a prerequisite for the […] tissue removal." *2.1.2 Supplementary application of § 630c and § 630e BGB* In addition, the provisions on the treatment contract…also apply to treatment within the framework of assisted reproduction…for example…the obligation to explain to the patient all the circumstances essential to the treatment, in particular the diagnosis, the expected health development, the therapy and the measures to be taken during and after the therapy. The doctor is also obliged…to inform the patient of all the circumstances essential to the consent. This includes in particular the type, extent, implementation, expected consequences and risks of the measure as well as its necessity, urgency, suitability and prospects of success with regard to the diagnosis or therapy. Alternatives to the measure must also be indicated if several medically equally indicated and usual methods can lead to significantly different burdens, risks or chances of recovery. *2.1.3 Further requirements for the information in accordance with Section 630e Paragraph 2 Clause 1 Numbers 1 - 3 BGB* The information is provided verbally. In addition, reference can be made to documents that the patient receives in text form. The information must be provided in good time so that the patient can make a well-considered decision about consent. It must be provided in an understandable form and by a person who has the training necessary to carry out the measure. *2.1.4 Expendability of information* The information may be expendable [non-essential] under the strict conditions set out in Section 630e Paragraph 3 of the German Civil Code. According to case law, expendability is also recognized if the patient is already aware of certain circumstances due to the information provided by the referring doctor and could have included them in his or her decision without further information. *2.1.5 Further information-related obligations to provide information* Further information-related obligations to provide information arise in the context of statutory health insurance benefits for measures within the framework of assisted reproduction in accordance with Section 27a of the Social Code Book V. In this case, as far as the scope of application is open, the advisory and information obligations under the G-BA guideline on medical measures for artificial insemination and the G-BA guideline on the cryopreservation of egg or sperm cells or germ cell tissue (Cryo-RL) in the respective adopted version must also be observed.

		The economic information obligation in accordance with Section 630c Paragraph 3 of the German Civil Code must be observed in particular with regard to the partial or full assumption of treatment costs. As part of the economic information, it should also be pointed out that according to Section 27a Paragraph 4 of the Social Code Book V, there is a right to cryopreservation of egg or sperm cells or germ cell tissue as well as to the associated medical measures if cryopreservation appears medically necessary due to an illness and its treatment with a therapy that damages germ cells in order to be able to carry out subsequent medical measures to bring about a pregnancy. The patient should be informed about the possibility of a separate contractual agreement on the storage period of cryopreserved tissue, possibly beyond the age limits specified in Section 2 Paragraph 3 of the Cryo Directive. ***2.2 Findings on the content of information and explanation required from a medical point of view*** *2.2.2 Content of the information in general* Within the framework of the legal requirements outlined, the following medical aspects must be included when informing women and, if applicable, men before an assisted reproduction procedure: Regarding the "purpose and type of procedure": ▪ Causes of infertility, ▪ Procedure of the respective procedure, ▪ Possibility of becoming pregnant without assisted reproduction measures, ▪ Determination of the maximum number of embryos to be transferred at one time, ▪ Possibility of cryopreservation of sperm cells, egg cells, testicular tissue and impregnated egg cells, ▪ Cryopreservation of embryos in the event that these cannot be transferred for unforeseen reasons. Regarding the "necessity, urgency and suitability" of the procedure: ▪ Duration of the desire to have children, ▪ Age of the woman and man, ▪ Indication for the procedure. When determining the indication for certain procedures, the age of the person concerned, the duration of the unfulfilled desire to have children, the condition of the fallopian tubes, the presence of risk factors such as endometriosis, the ovarian reserve, previous treatment cycles and the quality of the ejaculate must be taken into account. Regarding the "scope" of the procedure: ▪ Pre-treatment with hormone stimulation, ▪ Egg retrieval, ▪ Sedation/anesthesia during egg retrieval, ▪ Embryo transfer, ▪ Hormonal support of the luteal phase.

		Regarding the "implementation" of the procedure: ▪ Monitoring of hormonal stimulation using ultrasound/hormone analysis, ▪ Ultrasound-guided or, if necessary, laparoscopic egg retrieval, ▪ Further handling of eggs/sperm cells/embryos, ▪ Embryo transfer. Regarding "measures to protect the donor, as well as the extent and possible, including indirect and long-term consequences" of the intended removal of germ cells or germ cell tissue for health: ▪ cyst formation after stimulation treatment, ▪ overstimulation reactions, ▪ side effects of medication, ▪ surgical complications during follicle punctures or during the removal of germ cell tissue. Regarding the expected "probability of success" of the transfer of human germ cells or germ cell tissue and the "consequences for the recipient and other circumstances" that are clearly considered to be important for the donation: ▪ Expected probability of success of the respective procedure (probability of pregnancy and live birth) depending on the woman's age and possibly other risk factors when carrying out one or more treatment cycles, ▪ Risk of miscarriage depending on the woman's age, ▪ Ectopic pregnancy and other complications during pregnancy, ▪ The increased probability of multiple births caused by stimulation and the one-time transfer of several embryos and the associated maternal and child risks (including as a result of premature birth), ▪ Risk of psychological and physical abnormalities in children in the context of fertility treatment, ▪ Risks of new procedures whose final risk assessment has not been clarified. The aim of egg retrieval is to remove mature eggs in order to be able to transfer embryos after they have been processed later. These should then lead to a pregnancy and the birth of a child. Before the procedure begins, those affected must be informed of the following facts: ▪ Not every egg cell obtained is suitable, as some of the eggs obtained are non-viable, their meiotic division or cytoplasmic maturation has not yet progressed to the point where the egg cell is in the stage of fertilization (metaphase II). ▪ Not every suitable egg cell can be fertilized by IVF or ICSI. ▪ Not every fertilized egg cell is capable of development and will regularly go through preimplantation development up to the blastocyst stage. ▪ Not every blastocyst and not every embryo capable of development will implant after the transfer. ▪ Not every pregnancy leads to the birth of a child. Regarding "expected consequences and risks": ▪ Pregnancy risks depending on the woman's age and state of health,

		▪ Regarding the removal of germ cell tissue: risk of a reduction in endocrine and reproductive ovarian function. Regarding "alternatives to the measure": ▪ Attempt at spontaneous conception, ▪ Adoption, ▪ Foster child, ▪ Heterologous use of sperm cells, ▪ Forgoing having a child. Other "circumstances essential to treatment": From a psychosocial perspective, information, explanation and advice must be given in particular about: ▪ reducing feelings of guilt and shame (before giving detailed explanations, the treating doctor should also get an overview of the affected person's existing knowledge of biological relationships), ▪ psychological stress during therapy (the psychological stress caused by the medical treatment can be experienced as more stressful than the medical treatment), ▪ possible influence of psychosocial factors in the sense of a behavior-related fertility disorder (for example disordered eating behavior, high-performance sport, abuse of stimulants and drugs, no sexual intercourse on fertile days, non-organic sexual dysfunction), ▪ possible effects on the couple's relationship and on sexuality, ▪ possible increase in the suffering of childlessness if treatment is unsuccessful (possible depressive reaction if it fails), ▪ development of alternative perspectives (for example adoption, foster child, not undergoing therapy). ***2.3 Special features of information and explanation before cryopreservation of germ cells or germ cell tissue due to germ cell-damaging therapy or in the case of genetic abnormalities with a germ cell deficiency*** *2.3.1 Additional information before the removal and cryopreservation of human germ cells or germ cell tissue due to germ cell-damaging therapy or in the case of genetic abnormalities with a germ cell deficiency* Concepts of fertility preservation in the case of germ cell-damaging therapy or in the case of genetic abnormalities with a germ cell deficiency must be an integral part of the information. In the case of oncological diseases in particular, the exceptional situation of those affected in the face of a life-threatening situation must be taken into account. (Potential) therapy-related infertility can be perceived as an additional existential limitation and challenge, with the associated intense emotional stress and a double threat from the disease and possible later childlessness. The information should point out that fertility protection in the case of serious illnesses has been a standardized medical procedure in postpubertal patients for over 30 years and in postpubertal female patients for the last 10-15 years. While, due to the anatomical requirements, the extraction of sperm from the ejaculate and, in rarer cases, from the testicular tissue for cryopreservation are standard

		procedures that can in principle be carried out in postpubertal boys and adult men within a few hours of diagnosis and before further therapy, the cryopreservation of germ cells or germ cell tissue in female patients requires significantly more complex preparatory measures. Information must be provided about these gender-specific requirements and measures in each case. To provide information on opportunities and risks, the age of the patient in particular and, for all genders, the type of underlying disease, the prognosis and the type of germ cell-damaging therapy or the genetic abnormality with a germ cell deficiency must be taken into account. Furthermore, knowledge of the type and extent of the provisionally planned germ cell-damaging therapy enables an assessment of the extent of the gonadal damage that is likely to be expected. *2.3.2 Additional information before the removal, cryopreservation and transfer of human germ cells or germ cell tissue due to germ cell-damaging therapy or in the case of genetic abnormailities with a germ cell deficiency* When providing information regarding germ cell-damaging therapy or in the case of genetic abnormalities with a germ cell deficiency, aspects relating to the type, extent and prognosis of the underlying disease or genetic abnormality, as well as the type and extent of the planned chemotherapy, or the dose and location of the planned radiation or other germ cell-damaging therapy must be included. Part of the information session is also a detailed discussion of the established cryopreservation measures possible within the specified time frame, the risks of the measure itself and the prospects of success with regard to the extraction of germ cells or germ cell tissue. In the case of female patients, contraindications to treatment measures within the framework of assisted reproduction or to pregnancy may need to be mentioned. When removing and autologously transplanting premature ovarian tissue, reference must be made to the experimental study basis of the procedure and the unpredictable prospects of success. The risks of the respective surgical procedure must be explained in accordance with established principles. The content of the explanation should in particular be: ▪ Loss of germ cell tissue, which is missing for the later restoration of endocrine ovarian activity and fertility, ▪ Need for a further operation for autologous transplantation in the future, ▪ Risk of autologous transplantation of malignant cells that cannot be ruled out. By collecting anamnestic parameters (including current or future desire to have children, previous pregnancies and births, cycle history and contraception, underlying disease and planned therapy, concomitant diseases, previous operations, medication intake, allergies, exposure to noxious substances, family history, recent stays abroad), the benefits, burdens and risks of the planned procedure should be assessed and discussed with the patient. With regard to the course of pregnancy and birth, risks and burdens resulting from the underlying disease and therapy should be taken into particular consideration when informing the patient and planning the procedure.

		When informing patients, it is important not only to refer to the therapy that damages germ cells or to the genetic abnormality with a germ cell deficiency, but also to discuss surgical procedures that reduce the number of germ cells (for example through organ-preserving tumor enucleation) or remove them (unilateral or bilateral orchiectomy), compromise sperm transport by blocking the sperm ducts or sperm deposition by damaging nerves. This damage is irreversible in almost all cases. Both ejaculate sperm and testicular tissue for TESE are cryopreserved according to standard protocols…and can be stored…for the patient's lifetime, unless the patient specifies otherwise. However, it should be noted that due to existing damage to the ejaculate sperm caused by the underlying disease or accompanying previous illnesses, the sensitivity of the sperm cells to cryopreservation is increased and up to 50% of the sperm cells can die during the cryopreservation process and the subsequent thawing for assisted fertilisation. Before cryopreserving sperm cells from the ejaculate, the patient should therefore be informed about: ▪ a significantly limited suitability of cryopreserved sperm cells from donors with previous illnesses that limit fertility or already existing limitations in sperm quality for intrauterine insemination or IVF, ▪ the probable need for extracorporeal fertilisation using ICSI. If surgical removal of germ cells or germ cell tissue is necessary, the risks and limitations of the treatment options should be explained. When surgically removing testicular tissue for cryopreservation of testicular sperm, this includes in particular information about: ▪ a very low risk of bleeding and local inflammation as well as the very low risk of possible subsequent damage to testicular function due to complications, ▪ the failure of the operation if the germinal epithelium already shows a severe disruption of spermatogenesis, ▪ the need for extracorporeal fertilisation using ICSI when using testicular sperm, ▪ the risk of not having a sufficient number of functional sperm after later thawing of the tissue samples for extracorporeal fertilization, ▪ the predominant immotility of testicular sperm and the need for additional vitality tests for the selection of vital immotile sperm in the context of assisted fertilisation (for example laser technology). When surgically removing testicular tissue for cryopreservation of immature germ cell tissue, this includes in particular information about: ▪ the experimental stage of the donor refertilisation procedure (here: retransfer of testicular tissue), for which no standardized methods have been established in clinical use at present, ▪ completely different, established laboratory protocols for cryopreservation, which differ from the cryopreservation of mature sperm or mature germ cell tissue, ▪ a very low risk of bleeding and local inflammation despite the tissue removal preferably only being done on one side, as well as the very low risk of possible subsequent damage to testicular function due to complications, ▪ the failure of the operation if the immature germ cell tissue already shows a severe disorder of the stem cells. By collecting anamnestic parameters (including previous damage to the testicles, underlying disease and planned therapy, concomitant diseases, previous operations, medication intake, allergies, exposure to noxious substances, family history) and through clinical and laboratory examinations (testicles,

		hormones, ejaculate), the benefits, burdens and risks of the planned procedure are to be assessed and discussed with the patient.
Ethical considerations		**Foreword** The regulations on the removal of germ cells or germ cell tissue from underage patients who are unable to give their consent were discussed in detail in the Standing Working Group; however, the existing incongruence could not be resolved at the level of the guideline. ***2.2 Findings on the content of information and explanation required from a medical point of view*** *2.2.2 Content of the information in general* It has been scientifically documented that those at risk of mental disorders are more likely to develop depression, anxiety and or a manifest mental illness during treatment. In these cases in particular, those affected should be informed of the possibility of treatment-independent medical advice (that is outside of medically assisted reproduction) and the possibility of treatment-independent psychosocial advice in the sense of emotional support and help in dealing with problems, regardless of the stage of assisted reproduction and especially if they have had previous negative experiences with infertility or several unsuccessful treatment cycles. If a mental illness develops, those affected should be informed of the possibility of psychotherapeutic treatment. **2.6 Consent** A mandatory requirement for the removal of germ cells or germ cell tissue is the consent of: ▪ the woman whose egg cell is to be removed for later fertilisation or whose ovarian tissue is to be removed for later retransfer, and ▪ the man whose sperm cells are to be obtained for later fertilisation or whose testicular tissue is to be removed for later retransfer (…TPG). The removal of germ cells or germ cell tissue from a living person and their transfer is only permitted…if the person is capable of giving consent. Only the removal of egg cells and ovarian or testicular tissue for retransfer is permissible even in the case of a person who is not capable of giving consent…if the legal representative or an authorised representative has been informed…and has consented to the removal and retransfer. In this case…the regulations on exercising parental responsibility and care in accordance with…[the German Civil Code] BGB must be observed…the parents exercise parental responsibility for the child's well-being. However, the parents' right of custody is limited where the planned measure is contrary to the child's well-being. [The] BGB stipulates that the carer is bound to comply with the wishes and the subjectively determined well-being of the person being cared for. …consent can be "revoked in writing, electronically or verbally".

Relevant legislation (list)		▪ Transplantation Act (TPG) ▪ TPG Tissue Ordinance (TPG-GewV) ▪ Medicines Act (AMG) ▪ Medicinal Products and Active Substances Manufacturing Ordinance (AMWHV) ▪ Appointment Service and Care Act (TSVG) ▪ Law on the Quality and Safety of Human Tissues and Cells (Tissue Law) of July 20, 2007, which implemented: ○ Directive 2004/23/EC of the European Parliament and of the Council of March 31, 2004 setting quality and safety standards for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells ▪ Law implementing directives (EU) 2015/566 and (EU) 2015/565 on the import and coding of human tissues and tissue preparations (GewEinfRÄndG).
Miscellaneous		The guideline…does not apply to egg donation for heterologous use, as this is prohibited under Section 1 Paragraph 1 No. 1 and No. 2 of the Embryo Protection Act (ESchG). The transfer and donation of embryos (Section 8 Paragraph 1 ESchG) is also not covered, as according to the legislator's intent, these are not tissues within the meaning of Section 1a No. 4 TPG (BTDrs. 16/3146, p. 23) and are also not tissue preparations (Section 4 Paragraph 30 Sentence 2 AMG).

Table D.27 Extracted data for Germany (German Medical Association Guidelines Press Release)

Germany		
Author(s) **Title [year]**	German Medical Association (BÄK, *Bundesärztekammer*) Fertility preservation: German Medical Association presents revised guideline[55] [2022]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		The guideline…establishes the state of medical science findings on the prerequisites, type and extent of cryopreservation of female and male germ cells or germ cell tissue due to germ cell damage therapy or in the case of congenital (genetic) diseases with a high risk of fertility restriction.
Preservation method(s) available		Cryopreservation of female and male germ cells or germ cell tissue.
Organisation	***Referral pathways***	No information identified.
	Service provider characteristics	No information identified.
	Timelines to access services	No information identified.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	No information identified.
	Access to stored materials	No information identified.
	Disposal of stored materials	No information identified.
	Any other storage information	No information identified.
Governance		The Appointment Service and Supply Act, which came into force in May 2019, introduced the right of legally insured persons to have the costs of cryopreservation of germ cells or germ cell tissue covered before a germ cell-damaging therapy. In view of this, the Executive Board of the German Medical Association, on the recommendation of the Scientific Advisory Board of the BÄK, has decided on a circumscribed update of the guideline as part of the up-to-dateness review carried out on a regular basis in 2019. In accordance with this mandate, the Permanent Working Group "Guidelines for the Removal and Transfer of Human Germ Cells in the Context of Assisted Reproduction" has supplemented the state of medical science findings regarding the cryopreservation of germ cells and germ cell tissue. As part of the update, editorial adjustments to the guideline were also made. For example, in the interest of procedural transparency, the consultation process of the circumscribed update is presented in the annex to the Directive.

Funding		The Appointment Service and Supply Act, which came into force in May 2019, introduced the right of legally insured persons to have the costs of cryopreservation of germ cells or germ cell tissue covered before a germ cell-damaging therapy.
Communication and information provision		A special focus is on information and education. "Due to their pre-existing conditions, those affected are already in a difficult situation, in which it can be particularly sensitive to address the topic of fertility protection," explains Prof. Dr. Jan-Steffen Krüssel, head of the working group responsible for the directive.
Ethical considerations		In addition to medical issues, such as age-appropriate examinations, genetic dispositions, differentiated biological characteristics, possible risks and psychological stress, complex legal requirements must also be observed.
Relevant legislation (list)		The Appointment Service and Supply Act
Miscellaneous		With the rewritten guideline now available, the medical profession continues to assume responsibility in an area that requires a particularly differentiated consideration due to different concerns, resulting from many integrated medical disciplines, heterogeneous socio-cultural backgrounds and enormous medical progress. Thus, medical action in reproductive medicine goes hand in hand with many regulations, which are shaped by constitutional law, social law, transplantation law, family law and medical professional law, among other things. "In view of this initial situation, the Directive is intended to concretise the various regulations at statutory and sub-legislative level and thus give the parties involved the necessary legal certainty," said Krüssel.

Table D.28 Extracted data for Germany (Cryopreservation Guidelines – BMG Examination)

Germany		
Author(s) **Title [year]**	Federal Ministry of Health (BMG, *Bundesministeriums für Gesundheit*) Examination according to § 94 SGB V by the BMG[56] [2022]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		No information identified.
Preservation method(s) available		No information identified.
Organisation	***Referral pathways***	No information identified.
	Service provider characteristics	No information identified.
	Timelines to access services	No information identified.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	No information identified.
	Access to stored materials	No information identified
	Disposal of stored materials	No information identified.
	Any other storage information	No information identified.
Governance		The above-mentioned resolution of 18 August 2022, submitted by you in accordance with Section 94 SGB V, on an amendment to the cryopreservation guideline is not objected to.
Funding		The above-mentioned resolution of 18 August 2022, submitted by you in accordance with Section 94 SGB V, on an amendment to the cryopreservation guideline is not objected to.
Communication and information provision		No information identified.
Ethical considerations		The entitlement to benefits in Section 27a Paragraph 4 of the Social Code Book V for cryopreservation of germ cell tissue in the case of treatment that is potentially damaging to germ cells does not explicitly stipulate a lower age limit. The Federal Ministry of Health (BMG) therefore welcomes the fact that Section 8 of the resolution explicitly provides for a renewed review of the scientific data on cryopreservation of germ cell tissue, particularly in prepubertal children and adolescents. It seems appropriate that the G-BA should exercise particular care in fulfilling its duty to monitor the regulations it has made and resume its deliberations before the expiry of the 2-year period specified in the resolution as soon as the relevant findings are available. This is particularly important in light of the assessments of

		the current state of knowledge already presented by relevant professional associations as part of the statement procedure.
Relevant legislation (list)		The Fifth Book of the Social Code Book (SGB V)
Miscellaneous		No information identified.

Table D.29 Extracted data for Germany (Cryopreservation in Young Cancer Patients)

Germany		
Author(s) **Title [year]**	Federal Ministry of Health (BMG, *Bundesministeriums für Gesundheit*) Support for young cancer patients: cryopreservation becomes a health insurance benefit[57] [last updated 2019]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		Young people with cancer.
Preservation method(s) available		With a new law, we are ensuring that the freezing of their sperm and egg cells is paid for by the health insurance companies.
Organisation	***Referral pathways***	No information identified.
	Service provider characteristics	No information identified.
	Timelines to access services	No information identified.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	No information identified.
	Access to stored materials	No information identified.
	Disposal of stored materials	No information identified.
	Any other storage information	No information identified.
Governance		With the TSVG the new health insurance benefit was decided in the Bundestag on 12 April 2019. What's next? The Federal Joint Committee must now issue a guideline for the implementation of the law.
Funding		With a new law, we are ensuring that the freezing of their sperm and egg cells is paid for by the health insurance companies. The Appointment Service and Supply Act (TSVG), we are ensuring that health insurance companies will pay for the freezing of eggs and sperm cells of young cancer patients in the future.
Communication and information provision		No information identified.

Ethical considerations		Young people with cancer should also be able to have children. With a new law, we are ensuring that the freezing of their sperm and egg cells is paid for by the health insurance companies. In this way, the young patients should draw strength and hope in a difficult time.
Relevant legislation (list)		The Appointment Service and Supply Act (TSVG)
Miscellaneous		Federal Health Minister Jens Spahn has campaigned for this legal change after hearing about the fate of colorectal cancer patient Claudia Neumann at the Felix Burda Award. He promised her to take up the issue - and kept his word.

Table D.30 Extracted data for Germany (Cryopreservation Directive – 2022)

Germany		
Author(s) **Title [year]**	Federal Joint Committee (G-BA, *Gemeinsamer Bundesausschuss*) Directive of the Federal Joint Committee for the cryopreservation of egg or sperm cells or germ cell tissue as well as corresponding medical measures for germ cell damaging therapy – Cryo-RL[58] [2022]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**§ 2 Conditions of performance** (1) Insured persons are entitled to cryopreservation of egg or sperm cells or germ cell tissue as well as to the associated medical measures under the conditions set out below. (2) The prerequisite for the claim under paragraph 1 is that: 1. cryopreservation of the insured person appears medically necessary due to an illness (underlying illness) and its treatment with germ cell-damaging therapy within the meaning of Section 3 in order to be able to carry out subsequent medical measures to bring about a pregnancy in accordance with the Directive on artificial insemination, 2. the specialist who diagnosed or treated the underlying disease provided a medical consultation in accordance with Section 4 Paragraph 2 Number 1 and issued a certificate in accordance with Section 4 Paragraph 2 Number 1 upon presentation by a specialist who is qualified in reproductive medicine or andrology, 3. after presentation of the medical certificate pursuant to Section 4 Paragraph 2 Number 1, the patient was given a reproductive medical and, where necessary, andrological consultation and information pursuant to Section 4 Paragraph 2 Number 2 and 4. the requirements of the Transplantation Act (TPG) for consent are observed. According to the provisions set out therein, the patient must be capable of giving consent at the time of the removal of germ cells or germ cell tissue and must have consented to the implementation of these measures. (3) the claim under paragraph 1 does not exist or no longer exists: 1. for male insured persons aged 50 and over and for female insured persons aged 40 and over. 2. with the death of the insured person. **§ 3 Medical indications** (1) For the medical indication for cryopreservation and for the associated medical measures under this Directive, in addition to the general requirements for carrying out cryopreservation for a disease, treatments must be planned which, according to the current state of scientific knowledge, may be damaging to germ cells; these include in particular: ▪ surgical removal of the gonads, ▪ radiotherapy with expected damage to the gonads or ▪ medication that may potentially damage fertility.

		The determination of whether this requirement is met is made by the specialist who diagnoses or treats the underlying disease. (2) The indication for the cryopreservation of egg or sperm cells or germ cell tissue due to a therapy damaging to germ cells and for the associated medical measures is made by specialist physicians who are qualified to provide the consultation in accordance with Section 4 Paragraph 2 Number 2.
Preservation method(s) available		**§ 5 Scope of medical measures** (1) The medical measures associated with cryopreservation are preparation, removal, processing, transport, freezing, storage and subsequent thawing of egg or sperm cells as well as germ cell tissue. (2) Preparation for cryopreservation shall include the following medical measures recorded: 1. Required laboratory tests according to Section 6 Paragraph 1 Sentence 2 in conjunction with Annex 4 Numbers 1 and 3 of the TPG Tissue Ordinance (Anti-HIV-1,2, HBsAg, Anti-HBc, Anti-HCV-Ab; in individual cases, if necessary, further tests according to Annex 4 Number 1 Letters d and e of the TPG Tissue Ordinance) within 3 months prior to germ cell collection. The results of the tests should be available when the germ cells or germ cell tissue are obtained, processed, used and stored. Otherwise, storage under quarantine conditions is required until the infection parameters are available. 2. Measures related to the collection of eggs: Implementation of hormonal stimulation treatment in compliance with the limits of the drug approval (for example ovarian stimulation for egg collection), laboratory medical determinations of luteinizing hormone, estradiol and progesterone; sonographic examinations and transvaginal or laparoscopic egg collection (follicular puncture). 3. Measures relating to the collection of ovarian tissue for female children and adolescents from puberty, at the earliest after menarche, and women up to the age of 40: a) Surgical removal (laparoscopy, in exceptional cases laparotomy) of ovarian tissue, as well as preparation of the ovarian tissue before cryopreservation, in compliance with the guideline of the German Medical Association "Guideline for the removal and transfer of human germ cells and germ cell tissue in the context of assisted reproduction" of January 14, 2022. b) The benefit requires a comprehensive consultation for the insured person from the treating specialist in gynecology and obstetrics with a specialisation in "gynecological endocrinology and reproductive medicine" in accordance with Section 4, Paragraph 2, Number 2 a). 4. Measures related to the collection, examination and preparation of sperm cells in male persons from puberty onwards, including spermiogram, and if necessary testicular sperm extraction (TESE). (3) The cryopreservation procedure suitable for the insured person, including the associated measures, must be selected by the service providers authorised under Section 6 in accordance with the provisions of the German Medical Association's guideline on assisted reproduction pursuant to Section 16b TPG.
Organisation	***Referral pathways***	**§ 4 Consultation** In order to provide a comprehensive consultation to those affected and to integrate cryopreservation and the associated medical measures into the treatment of the underlying disease, close cooperation

		between the specialist disciplines involved must be ensured, taking into account the individual disease situation. In order to benefit from the cryopreservation of egg or sperm cells or germ cell tissue and the associated medical measures in accordance with Section 5, the following must be done in advance: 1. consultation with the specialist who diagnoses or treats the underlying disease, taking into account the individual prognosis regarding the risks of germ cell damage associated with the treatment of the underlying disease and initial information about the possibility of reproductive medical treatment. This consultation also includes a medical assessment and certificate with the following information: a) Indication of the underlying disease for which a therapy potentially damaging to germ cells is planned according to the current state of scientific knowledge, b) any previous therapy of the underlying disease, c) planned germ cell damaging therapy, d) known comorbidities, e) for female insured persons, information as to whether a hormone-dependent tumor is present, f) recommendation for the consultation referred to in point 2, g) a recommendation on the time frame available for the measures to cryopreservation, h) for female insured persons, information as to whether menarche has already occurred and j) that the consultation referred to in point 1 has been given. As part of the consultation pursuant to point 1, a recommendation is made for reproductive medical and, where necessary, andrological consultation on cryopreservation and the associated medical measures pursuant to point 2. 2. reproductive medical and, where necessary, andrological consultation and information on cryopreservation and the associated medical measures after presentation of the medical certificate in accordance with point 1. The following are authorised to provide this consultation: a) Specialists in gynecology and obstetrics with a focus on gynecological endocrinology and reproductive medicine of a practice or facility that meets the requirements of Section 6 Paragraphs 1 and 2 and b) in the case of male insured persons, also specialist doctors who offer the necessary measures pursuant to Section 5 in connection with the collection of sperm cells and the removal of germ cell tissue and who fulfil the relevant requirements pursuant to Section 6. The consultation according to number 2 is carried out taking into account the underlying disease itself, the age of the patient and the prognosis. The consultation must take into account the advantages and disadvantages of the available options for fertility protection, the discussion of the prospects of success and risks of the possible measures and the associated, possibly also psychosocial stresses. At the end of the consultation regarding germ cell-damaging therapy, the specialist will check whether there is a medical indication for cryopreservation in accordance with Section 3 Paragraph 2, including the associated medical measures, taking all relevant aspects into account. If there is an indication, the insured person or the legal representative or the authorised person will determine together with the specialist whether egg or sperm cells or germ cell tissue should be removed and cryopreserved.

		§ 5 Scope of medical measures (3) The cryopreservation procedure suitable for the insured person, including the associated measures, must be selected by the service providers authorised under Section 6 in accordance with the provisions of the German Medical Association's guideline on assisted reproduction pursuant to Section 16b TPG.
	Service provider characteristics	**§ 6 Authorised service providers** (1) Measures pursuant to Section 5 may only be carried out by service providers who, in addition to the requirements of paragraphs 2, 3 or 4 applicable to the insured person, also fulfil the requirements of the German Medical Association's Guideline on the removal and transfer of human germ cells or germ cell tissue in the context of assisted reproduction applicable to the measures required pursuant to Section 5. When providing the service components of transport, processing, cryopreservation and storage, the service providers can also ensure compliance with the requirements under sentence 1 by means of cooperation agreements with institutions which meet the relevant requirements of the directive of the German Medical Association referred to in sentence 1 for the respective necessary measures and which have the respective necessary approval under Section 20b or Section 20c of the Medicines Act (AMG). (2) Measures for the collection of germ cells pursuant to Section 5 may only be carried out by: 1. licensed physicians, authorised physicians or authorised medically managed institutions who fulfil the following requirements: a) The head of the practice or facility must be a specialist in gynecology and obstetrics and have the Specialization in "Gynecological Endocrinology and Reproductive Medicine." (b) The practice or institution must have the following knowledge and experience: ▪ Endocrinology of reproduction ▪ Gynecological sonography ▪ Operative gynecology ▪ Reproductive biology ▪ when treating male insured persons, additional andrology. Of these areas, only two can be managed simultaneously by a doctor or scientist from the practice or institution. Regular cooperation with a human geneticist and a psychotherapist must be guaranteed. 2. Hospitals which fulfil the requirements of point 1(b). (3) The surgical removal of ovarian tissue in accordance with Section 5 Paragraph 2 Number 3 may be carried out 1. in female children and adolescents from puberty onwards, but at the earliest after menarche, depending on physical development, either by specialists in gynecology and obstetrics or by specialists in paediatric surgery and 2. for women up to the age of 40 by specialists in gynecology and obstetrics. (4) In the case of male insured persons, measures pursuant to Section 5 in connection with the collection of sperm cells and the removal of germ cell tissue may also be carried out by specialist doctors

		with additional training in andrology who offer all of the measures specified in Section 5 Paragraph 2 Number 4. This applies accordingly to hospitals. (5) The specialist, specialty and additional designations used in the guideline are based on the (model) continuing education regulations of the German Medical Association and include doctors who hold a corresponding designation under the old law. (6) The relevant requirements for the measures pursuant to the Directive of the The provisions of the German Medical Association regarding assisted reproduction pursuant to Section 16b TPG must be observed.
	Timelines to access services	No information identified.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	**§ 2 Conditions of performance** (3) the claim under paragraph 1 does not exist or no longer exists: 1. for male insured persons aged 50 and over and for female insured persons aged 40 and over. 2. with the death of the insured person. **§ 5 Scope of medical measures** (1) The medical measures associated with cryopreservation are preparation, removal, processing, transport, freezing, storage and subsequent thawing of egg or sperm cells as well as germ cell tissue.
	Access to stored materials	**§ 5 Scope of medical measures** (1) The medical measures associated with cryopreservation are preparation, removal, processing, transport, freezing, storage and subsequent thawing of egg or sperm cells as well as germ cell tissue.
	Disposal of stored materials	**§ 2 Conditions of performance** (3) the claim under paragraph 1 does not exist or no longer exists: 1. for male insured persons aged 50 and over and for female insured persons aged 40 and over. 2. with the death of the insured person.
	Any other storage information	**§ 6 Authorised service providers** (1) When providing the service components of transport, processing, cryopreservation and storage, the service providers can also ensure compliance with the requirements under sentence 1 by means of cooperation agreements with institutions which meet the relevant requirements of the directive of the German Medical Association referred to in sentence 1 [*Note: this refers to the German Medical Association's directive on the removal and transfer of human germ cells or germ cell tissue in the context of assisted reproduction*] for the respective necessary measures and which have the respective necessary approval under Section 20b or Section 20c of the Medicines Act (AMG). **§ 7 Transitional cases**

		In cases where insured persons have already had their egg, sperm or germ cell tissue cryopreserved due to an illness and its treatment with a therapy that damages germ cells, or have already started with the cryopreservation measures within the meaning of these guidelines, there is a right to cryopreservation and the associated medical measures in accordance with these guidelines from the day on which the implementation of this guideline in the uniform assessment standard comes into force to the extent required in the specific individual case from that point onwards. Corresponding benefits are granted upon application by the insured person. A medical certificate in accordance with Section 4, Sentence 2, Number 1 must be attached to the application.
Governance		No information identified.
Funding		**§ 1 Subject matter** This Directive determines the prerequisites as well as the type and extent of the entitlement of insured persons to benefits regulated in Section 27a Paragraph 4 of the Fifth Book of the Social Code (SGB V) for cryopreservation of female and male germ cells and germ cell tissue due to germ cell-damaging therapy as well as for the associated medical measures. [Note: Extract from relevant section of the **SGB V § 27a Artificial Insemination** (3) Entitlement to benefits in kind pursuant to subsection (1) shall exist only for insured persons who have reached the age of 25; the entitlement does not apply to female insured persons who have reached the age of 40 and to male insured persons who have reached the age of 50. (4) Insured persons shall be entitled to cryopreservation of egg or sperm cells or germ cell tissue, as well as to the associated medical measures, if cryopreservation appears medically necessary due to a disease and its treatment with germ cell-damaging therapy in order to be able to take subsequent medical measures to induce pregnancy in accordance with subsection (1). Subsection 3 sentence 1 second half-sentence shall apply mutatis mutandis. (5) In the guidelines pursuant to Section 92, the Federal Joint Committee shall determine the medical details of the prerequisites, nature and scope of the measures pursuant to subsections (1) and (4).]
Communication and information provision		**§ 4 Consultation** The consultation according to number 2 [*See 'Referrral pathways' above*] is carried out taking into account the underlying disease itself, the age of the patient and the prognosis. The consultation must take into account the advantages and disadvantages of the available options for fertility protection, the discussion of the prospects of success and risks of the possible measures and the associated, possibly also psychosocial stresses. At the end of the consultation regarding germ cell-damaging therapy, the specialist will check whether there is a medical indication for cryopreservation in accordance with Section 3 Paragraph 2, including the associated medical measures, taking all relevant aspects into account. If there is an indication, the insured person or the legal representative or the authorised person will determine together with the specialist whether egg or sperm cells or germ cell tissue should be removed and cryopreserved.

Ethical considerations		**§ 2 (2) 4.** In the case of female insured persons, in the event of incapacity to consent, a legal representative or an authorised representative can give consent.
Relevant legislation (list)		▪ Social Code (SGB) Fifth Book (V) – Statutory Health Insurance ▪ Act on the Donation, Removal and Transfer of Organs and Tissues (Transplantation Act – TPG) ▪ Ordinance on the Requirements for Quality and Safety of the Removal of Tissue and its Transfer under the Transplantation Act (TPG Tissue Ordinance – TPG-GewV ▪ Act on the Circulation of Medicinal Products (Medicines Act – AMG)
Miscellaneous		**§ 8 Review** The Federal Joint Committee will review the scientific data on the cryopreservation of germ cell tissue, particularly in prepubertal children and adolescents, 2 years after this change in the directive comes into force and, on the basis of the results, will advise on the need to adapt the regulations.

Table D.31 Extracted data for Germany (Cryopreservation of Ovarian Tissue)

Germany		
Author(s) **Title [year]**	Federal Joint Committee (G-BA, *Gemeinsamer Bundesausschuss*) Cryopreservation of ovarian tissue becomes a health insurance benefit[59] [2022]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**Requirements for eligibility for cryopreservation** If medical treatment is accompanied by the risk of germ cell damage… The surgical removal of ovarian tissue is an option for young women from the first menstrual period and for older women up to the age of 40. The G-BA requires comprehensive advice from specialists in gynaecology and obstetrics with a focus on "gynaecological endocrinology and reproductive medicine". In addition, the qualification requirements of the specialists who are authorised to take samples are tailored to different patient groups. A distinction is made according to physical development and age. The G-BA has not made a decision for very young girls who have not yet started their menstrual period. Due to the study situation, which is to be classified as experimental, it is currently unclear whether the associated medical-scientific concept for cryopreservation of ovarian tissue and subsequent pregnancy can be transferred to this group and what special requirements would have to be placed on the service providers.
Preservation method(s) available		Cryopreservation of ovarian tissue.
Organisation	***Referral pathways***	The G-BA requires comprehensive advice from specialists in gynaecology and obstetrics with a focus on "gynaecological endocrinology and reproductive medicine". In addition, the qualification requirements of the specialists who are authorised to take samples are tailored to different patient groups. A distinction is made according to physical development and age.
	Service provider characteristics	No information identified.
	Timelines to access services	No information identified.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	No information identified.
	Access to stored materials	No information identified.
	Disposal of stored materials	No information identified.

	Any other storage information	No information identified.
Governance		No information identified.
Funding		**Utilisation expected from spring 2023** The following steps are still necessary before the services for the cryopreservation of ovarian tissue can be provided and billed by specialists: The decision of the G-BA can only be published in the Federal Gazette and enter into force after no objection by the Federal Ministry of Health. Subsequently, the so-called evaluation committee of doctors and health insurance companies (*Bewertungsausschuss der Ärzte und Krankenkassen*) – a body in which the G-BA is not involved – still has to decide on the amount of medical remuneration. It has a maximum of six months to do so. **Background: Cryopreservation** On behalf of the legislator, the G-BA defines the conditions under which egg or sperm cells or germ cell tissue can be removed, processed and stored, which accompanying medical measures are part of the scope of services and which quality assurance requirements must be observed: Guideline on cryopreservation The legislator introduced the entitlement of people with statutory health insurance to cryopreservation in the case of a therapy that potentially damages germ cells into the Social Code in 2019 (§ 27a (4) SGB V). It had already specified that this claim includes germ cells or germ cell tissue.
Communication and information provision		**Requirements for eligibility for cryopreservation** If medical treatment is accompanied by the risk of germ cell damage, the patients are informed about this. In addition, the attending physician informs that cryopreservation of egg or sperm cells or ovarian tissue could be used against this background. If this is an option in principle, the patient will be informed and advised in detail about the various options for cryopreservation of germ cells and germ cell tissue in their specific case, as well as about the risks, prospects of success and contraindications. The G-BA requires comprehensive advice from specialists in gynaecology and obstetrics with a focus on "gynaecological endocrinology and reproductive medicine".
Ethical considerations		**Requirements for eligibility for cryopreservation** The G-BA has not made a decision for very young girls who have not yet started their menstrual period. Due to the study situation, which is to be classified as experimental, it is currently unclear whether the associated medical-scientific concept for cryopreservation of ovarian tissue and subsequent pregnancy can be transferred to this group and what special requirements would have to be placed on the service providers.
Relevant legislation (list)		▪ Social Code (§ 27a (4) SGB V)

Miscellaneous		**Data on cryopreservation of testicular and ovarian tissue will be reviewed in two years at the latest** The G-BA also discussed the extent to which cryopreservation of testicular tissue can be regulated as a benefit of statutory health insurance. As a result, the G-BA does not yet see any possibility for this, with the exception of testicular spermatozoan extraction (TESE), because cryopreserved testicular tissue is currently only transferred back in individual cases as experimental experiments. Since the scientific data situation on fertility treatment and thus also on cryopreservation of germ cells and germ cell tissue is developing very rapidly, the G-BA will review and advise again in 2 years at the latest. **Background: Cryopreservation** In contrast to the regulations for the cryopreservation of egg and sperm cells, there are still no established procedures with a reliable state of knowledge for the cryopreservation of ovarian and testicular tissue apart from TESE. The current decision on the cryopreservation of ovarian tissue is based on the available literature for the group of adult women, case reports and expert surveys conducted by the G-BA. The relevant guideline of the German Medical Association and indications from the comment procedure were also taken into account. Information on the currently applicable regulations for cryopreservation can be found on the website of the G-BA: Cryopreservation of egg and sperm cells

Table D.32 Extracted data for Germany (Cryopreservation Webpage)

Germany		
Author(s) **Title [year]**	Federal Joint Committee (G-BA, *Gemeinsamer Bundesausschuss*) Cryopreservation [webpage][60] [2024]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		People with statutory health insurance…who require a potentially germ cell-damaging therapy **What are germ cell damaging treatments?** During the treatment of cancer, for example, damage to the gonads (ovary or testicles) or the egg and sperm cells can occur, thus impairing the patient's ability to reproduce. The treatments of diseases which, according to the current state of scientific knowledge, can be harmful to germ cells include, in particular: • the surgical removal of the gonads, • radiotherapy with expected damage to the gonads, or • the use of potentially fertility-damaging drugs. Whether the medically indicated therapy can be accompanied by damage to the germ cells in the individual case and thus whether there is a claim to benefits for the cryopreservation of egg or sperm cells or ovarian tissue is assessed by the attending physician. **What services are currently covered?** Cryopreservation and the associated medical measures can be carried out at the expense of statutory health insurance for female insured persons up to the age of 40 and for male insured persons up to the age of 50. The preservation of ovarian tissue is currently only possible for girls and women from the first menstrual period.
Preservation method(s) available		Cryopreservation of germ cells (egg and sperm cells) or germ cell tissue (ovarian and testicular tissue) The current scope of benefits of statutory health insurance includes the preparation, removal, preparation, transport, freezing, storage and subsequent thawing of • Eggs or ovarian tissue • Sperm cells and testicular tissue for testicular spermatozoan extraction (TESE)
Organisation	***Referral pathways***	Whether the medically indicated therapy can be accompanied by damage to the germ cells in the individual case and thus whether there is a claim to benefits for the cryopreservation of egg or sperm cells or ovarian tissue is assessed by the attending physician.
	Service provider characteristics	No information identified.

	Timelines to access services	No information identified.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	No information identified.
	Access to stored materials	The medical measures that can later be used for pregnancy with the help of the preserved egg or sperm cells are regulated in a separate guideline on artificial insemination of the G-BA: Artificial insemination.
	Disposal of stored materials	No information identified.
	Any other storage information	No information identified.
Governance		Since 1 July 2021, the G-BA guideline has been regulating the details of the entitlement to benefits as well as the requirements for doctors and reproductive medicine facilities on behalf of the legislator.
Funding		In 2019, the legislator introduced the entitlement of people with statutory health insurance to cryopreservation who require a potentially germ cell-damaging therapy into the Social Security Code. Since 1 July 2021, the G-BA guideline has been regulating the details of the entitlement to benefits as well as the requirements for doctors and reproductive medicine facilities on behalf of the legislator. **Assumption of costs in individual cases before the cut-off date of 1 July 2021** The following applies to patients who have already started cryopreservation within the meaning of this guideline before the cut-off date of 1 July 2021 due to a treatment that potentially damages germ cells: Since this cut-off date, there has been an entitlement to cryopreservation and the associated medical measures in the specific individual case for those partial services that accrue after this date (for example for further storage costs, if cryopreservation has already been performed). The health insurance funds grant the corresponding benefits at the request of the insured. The entitlement to benefits does not apply retroactively.
Communication and information provision		**Medical consultation** The patient receives comprehensive advice from the attending physician before a therapy that may damage germ cells: in particular, on the risk of germ cell damage and on possible fertility-preserving measures. If cryopreservation is an option in principle, the patient is informed and advised in detail about the various options in his or her specific case, risks, prospects of success and contraindications by particularly qualified specialists. This also includes the medical measures associated with cryopreservation, such as hormonal stimulation treatment before egg retrieval.
Ethical considerations		**Data on cryopreservation of germ cell tissue will be reviewed by 2024 at the latest** The G-BA also discussed the extent to which cryopreservation of testicular tissue can be regulated as a benefit of statutory health insurance. As a result, the G-BA does not yet see any possibility for this – with the exception of testicular spermatozoan extraction (TESE) – because cryopreserved testicular tissue can currently only be retransferred as an experimental experiment in individual cases.

		The cryopreservation of germ cell tissue in very young girls who have not yet started their menstrual period is also not yet a service. Due to the study situation that can be classified as experimental, it is currently still unclear whether the associated medical-scientific concept for the cryopreservation of ovarian tissue, which can demonstrably enable a later pregnancy in adult women, can be transferred to this group and what special requirements would have to be placed on the service providers who treat such young people. Since the scientific data situation on fertility treatment and thus also on cryopreservation of germ cells and germ cell tissue is developing very rapidly, the G-BA will review it by 2024 at the latest – 2 years after the decision of 18 August 2022 came into force.
Relevant legislation (list)		▪ Social Security Code (SGB V)
Miscellaneous		No information identified.

Table D.33 Extracted data for Germany (Reasons for Amendment of Cryopreservation Directive)

Germany		
Author(s) **Title [year]**	Federal Joint Committee (G-BA, *Gemeinsamer Bundesausschuss*) Reasons for the decision of the Federal Joint Committee to amend the guidelines on cryopreservation: Cryopreservation of germ cell tissue[61] [2022]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**1. Legal basis** This entitlement exists within the age limits of Section 27a Paragraph 3 Clause 1 2nd half of the Social Code Book V if cryopreservation appears medically necessary due to an illness and its treatment with a therapy that damages germ cells in order to be able to carry out later medical measures to bring about a pregnancy. **2.3 Section 5 paragraph 2 number 3 Scope of medical measures** Measures related to the collection of ovarian tissue for female children and adolescents from puberty and adults: The benefit applies to female children and adolescents from puberty – after menarche at the earliest – and women up to the age of 40. There is only an entitlement to the legally introduced benefit if comprehensive advice has been given in accordance with Section 4 Paragraph 2 Number 2 of the Cryo-RL. Reproductive medicine counseling is carried out taking into account the underlying disease itself, the age of the patient and the prognosis. The benefit is provided with the aim of enabling the insured person to become pregnant at a later date.
Preservation method(s) available		**1. Legal basis** Cryopreservation of germ cells and germ cell tissue as well as the associated medical measures **2. Key points of the decision** …the cryopreservation of germ cell tissue, including the associated medical measures, with the sole aim of subsequent artificial insemination is covered by Section 27a Paragraph 4 of the Social Code Book V, as is the cryopreservation, including the associated medical measures, with the aim of restoring fertility or conception with, if necessary, subsequent artificial insemination.
Organisation	***Referral pathways***	**2.1 Section 4 paragraph 2 number 1 h) Consultation** Since the measures relating to the collection of ovarian tissue apply to female children and adolescents from puberty onwards – after menarche at the earliest – and to adults, as part of the consultation by the specialist doctor diagnosing or treating the underlying disease, information must be provided on the certificate for female insured persons stating whether menarche has already occurred.
	Service provider characteristics	**2.5 § 6 Authorised service providers** Accordingly, Section 6 Service Providers defines relevant requirements for service providers in paragraphs 2, 3 or 4:

		▪ Section 6 paragraph 2 addresses service providers for the collection of germ cells from male or female insured persons by reproductive medicine facilities (outpatient or inpatient), ▪ Section 6 paragraph 3 addresses service providers for the removal of germ cell tissue from female insured persons, ▪ Section 6 paragraph 4 addresses service providers for the collection of germ cells or germ cell tissue from male insured persons by specialists with additional training in andrology (without connection to reproductive medicine facilities) (outpatient or inpatient). Different service providers are responsible for obtaining the different germ cells and germ cell tissue, each of whom has acquired their respective qualifications in accordance with their specialist, specialty and additional designations. **1. Service providers for the collection of germ cells from female insured persons by reproductive medicine facilities (outpatient or inpatient)** The specialist in gynecology and obstetrics with a focus on gynecological endocrinology and reproductive medicine has, in addition to being authorized to collect ovarian germ cell tissue (due to his or her specialist designation), additionally acquired knowledge, experience and skills in assisted fertilization methods including hormonal stimulation, inseminations, in vitro fertilization (IVF), intracytoplasmic sperm injection (ICSI) and cryopreservation procedures as part of obtaining the 36-month specialist designation. Although the collection of germ cells takes place according to Section 27a Paragraph 4 of the Social Code Book V due to a different indication, the medical procedures for egg collection are identical to those of the "Guidelines on artificial insemination". In accordance with the congruence in the G-BA guidelines, the requirements for the same method are identical. **2. Service providers for the removal of germ cell tissue from female insured persons** Once the German specialist title of "specialist in gynecology and obstetrics" has been obtained, laparoscopies may be performed. Laparoscopic surgery on the ovary is a standard operation. This was also confirmed by the experts in the "further expert hearing on the cryopreservation of germ cell tissue": around 10 laparoscopic procedures on the ovary are carried out per week by appropriate surgeons. No additional qualifications are required for the surgeon removing ovarian germ cell tissue, in particular no AMG approval (see final report Chapter A-7.2, verbatim transcript p. 16/17). Equivalent statements apply to pediatric surgeons. The specialist title for pediatric surgery provides the corresponding qualification for the service provider. The corresponding further processing of the ovarian germ cell tissue must be initiated by the institution or the surgeon carrying out the removal, taking into account the BÄK directive "Directive on the removal and transfer of human germ cells or germ cell tissue in the context of assisted reproduction". The addition in paragraph 4 is intended to clarify that the specialists mentioned there with additional training in andrology, who offer all of the measures mentioned in Section 5 paragraph 2 number 4, can also work in hospitals to provide the service. This applies regardless of paragraph 2, that is a connection to a reproductive medicine facility is not necessary.

	Timelines to access services	No information identified.
	Any other organisational aspects	**1. Service providers for the collection of germ cells from female insured persons by reproductive medicine facilities (outpatient or inpatient)** For subsequent successful fertilization, it is essential that the oocyte is freed from the surrounding somatic cells. The unfertilized oocyte - intended for cryopreservation - has the corresponding cumulus cells removed (so-called denudation). Since native egg cells are not very stable during transport over long distances, the egg cells should be prepared on site. According to the BÄK guideline "Guideline for the removal and transfer of human germ cells or germ cell tissue in the context of assisted reproduction" of January 14, 2022, from a medical point of view, the laboratory should be located in the immediate vicinity of the rooms for egg collection in order to minimize the spatial distances during the individual work steps and not to impair the functionality of the germ cells through transport. The measures for obtaining germ cells may therefore only be carried out if the knowledge required in Section 6 Paragraph 2 Number 1 b is available in the facility. **2. Service providers for the removal of germ cell tissue from female insured persons** In order for the ovarian germ cell tissue to remain functional after later thawing, the step of preparing the ovarian tissue before cryopreservation is particularly crucial. Ovarian germ cell tissue is stable during transport in appropriate media. As can be seen from the BÄK guideline "Guideline for the removal and transfer of human germ cells or germ cell tissue in the context of assisted reproduction" dated January 14, 2022, if the quality assurance specified there is observed, transport or shipment to the destination of the processing can take up to 24 hours without any loss of quality (see BÄK guideline "Guideline for the removal and transfer of human germ cells or germ cell tissue in the context of assisted reproduction" dated January 14, 2022: Number 3.2 Labeling, storage and transport in the tissue facility). This can also be seen from the S2k guideline on fertility preservation in oncological diseases.
Storage	***Arrangements and duration(s)***	**2.6 § 7 Transitional cases** From the date on which the implementation of this Directive amendment in the Uniform Assessment Standard comes into force, the provision shall also apply to female germ cell tissue in transitional cases. In transitional cases for the storage of germ cell tissue, the time of the germ cell tissue sampling is decisive in relation to the puberty status. Storage costs of immature germ cell tissue are not reimbursable by the statutory health insurance.
	Access to stored materials	The retransplantation of ovarian tissue is currently classified as experimental. This step is not addressed in the current cryo-guideline, since according to the legal justification of Section 27a Paragraph 4 SGB V, only the services related to cryopreservation are included, in particular removal, preparation, storage and subsequent thawing.
	Disposal of stored materials	No information identified.

	Any other storage information	No information identified.
Governance		**1. Legal basis** Pursuant to Section 27a Paragraph 5 of the Fifth Book of the Social Code (SGB V) in conjunction with Section 92 Paragraph 1 Sentence 2 Number 10 of the SGB V, the Federal Joint Committee (G-BA) is empowered to issue a guideline in which it determines the medical details regarding the prerequisites, type and extent of the measures for the cryopreservation of egg or sperm cells or germ cell tissue and the associated medical measures.
Funding		**1. Legal basis** With the entry into force of the Appointment Service and Care Act (TSVG) on May 11, 2019 (Federal Law Gazette I, p. 646), Section 27a Paragraph 4 of the Social Code Book V regulated the entitlement to cryopreservation of germ cells and germ cell tissue as well as the associated medical measures. **2. Key points of the decision** With Section 27a Paragraph 4 of the Social Code Book V, the legislature has included the cryopreservation of egg and sperm cells as well as germ cell tissue, including the associated medical measures, in the catalogue of services provided by statutory health insurance. **4. Bureaucracy cost assessment** The proposed resolution will not give rise to any new or amended information obligations for service providers within the meaning of Annex II to Chapter 1 of the Rules of Procedure and will therefore not result in any bureaucratic costs.
Communication and information provision		**2.2 Section 4 paragraph 2 number 2 reproductive medical or andrological counselling** Reproductive medical and, where necessary, andrological counseling should be carried out taking into account the individual disease situation. If family planning is not yet complete, counseling is provided. The patient should be informed about the basics of possible measures for later inducing a pregnancy. It should also be discussed how such measures could possibly be incorporated into the individual therapy concept. Patients should be counseled about later family planning as soon as possible after diagnosis or before treatment of the disease in order to be able to provide individual counseling and a patient-specific option for measures for later inducing a pregnancy. The consulting doctor should discuss the available options for fertility protection with the person concerned. This includes weighing up the advantages and disadvantages of germ cell collection compared to germ tissue collection in order to then decide together whether egg cells, sperm cells or germ cell tissue should be collected and cryopreserved. The discussion of the prospects of success and risks of the possible measures as well as the associated, possibly psychosocial stresses must also be taken into account. In the case of underlying genetic diseases or the presence of high-risk genes (for example BRCA mutation) that can be passed on to offspring when tissue is preserved as in a natural pregnancy, appropriate information is necessary.

		If cryopreservation of germ cell tissue is offered as a fertility-preserving method in individual cases in which patients have already received or have started treatment that damages germ cells (see Section 4 Paragraph 2 Number 1 Letter b), the unclear data on this procedure must be pointed out (ESHRE guideline: female fertility preservation 2020).
Ethical considerations		**2.2 Section 4 paragraph 2 number 2 reproductive medical or andrological counselling** Despite the importance of the topic of fertility for educating the patient before the start of therapy and its significance for the future, fertility counseling and any associated measures to bring about a pregnancy at a later date - including the cryopreservation of ovarian tissue - should not lead to a relevant postponement of the start of therapy and possibly associated worsening of the prognosis. The aim of the consultation should be to enable patients to make their own decisions regarding family planning that has not yet been completed. The following aspects in particular should be taken into account as individual influencing factors in the consultation: ▪ underlying disease and comorbidities, ▪ age of the patient, ▪ prognosis, the planned therapy, ▪ gonadotoxicity (taking into account the current guidelines), ▪ time window for measures to induce pregnancy at a later date, ▪ in the case of oncological diseases, additionally: - possible progression of the disease due to a later start/suspension of therapy, - metastasis, - general condition and - psyche. **Evidence in prepubertal children** The G-BA assesses the overall evidence for this service for prepubertal children as poor. Against this background, germinal tissue sampling within the meaning of Section 27a Paragraph 4 SGB V cannot be generally recommended for certain groups of insured persons. The indication for cryopreservation of ovarian tissue in pre- and peripubertal girls is currently unclear. If ovarian tissue cryopreservation (OTC) should take place as part of a port implantation, for example, this is not, from a medical point of view, a simple extension of a procedure that is taking place "anyway". For an OTC, an intubation anesthesia is required, and the peritoneum is opened. In the pre-pubertal phase, especially in small children, an entire ovary is removed and cryopreserved. Unilateral oophorectomy involves a reduction in the ovarian reserve, and a fertility-damaging effect from the procedure itself cannot be ruled out. It is currently not possible to make any statement regarding the complication rates associated with the removal of ovaries or ovarian tissue in children.

		A benefit-harm assessment for prepubertal girls is not possible on the basis of the available data. A rational weighing up of the harm caused by oophorectomy or removal of large parts of the ovary against a potential benefit in terms of preserving fertility is not possible. Cryopreservation of immature testicular tissue before puberty, which is removed by biopsy, is still an experimental approach. The procedure for refertilising the donor is still in an experimental stage. There is currently no proof of principle in humans for prepubertal boys. The procedure has so far only been carried out successfully in rhesus monkeys. This assessment was also confirmed by those who submitted comments during the comment procedure and the hearing. An experimental procedure involving children who are unable to give their consent – outside of study conditions – should not be introduced at the expense of the statutory health insurance (SHI).
Relevant legislation (list)		▪ The Fifth Book of the Social Code (SGB V) ▪ The Appointment Service and Care Act (TSVG)
Miscellaneous		**2. Key points of the decision** The current "ESMO Clinical Practice Guidelines" (2020) (see final report, Appendix 2) also provide only recommendations for fertility preservation in postpubertal girls and women. There are currently no guidelines in Europe that recommend the collection of germinal tissue from prepubertal girls. The evaluation of the data situation (national and international) and the recommendations derived from it regarding the importance of cryopreservation of prepubertal/immature testicular tissue are classified as in no way established and experimental at the time of the decision, especially since the tissue removed to date has not yet been used on humans. Thus, the cryopreservation of immature testicular tissue is not included in this guideline for the time being. However, since this is an active and dynamic field of research, 2 years after this change in the guideline comes into force, the G-BA will review the scientific data on the cryopreservation of germ cell tissue in male children and adolescents before spermarche and, on the basis of the results, will advise on the need to adapt the regulations (see No. 2.7 Section 8 Review). **2.7 § 8 Review** The G-BA will review the scientific data on the cryopreservation of germ cell tissue, particularly in children and adolescents before menarche or before spermarche, 2 years after its entry into force and, on the basis of the results, will advise on the need to adapt the regulations.

Table D.34 Extracted data for Northern Ireland (Belfast Health & Social Care Trust)

Northern Ireland		
Author(s) **Title [year]**	Belfast Health and Social Care Trust (Health and Social Care in Northern Ireland) Regional Fertility Centre[62] [2024] Patient Information: New Storage Laws[63] [2024]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		Female patients – prior to commencing chemotherapy treatment or a procedure which will affect her fertility. Male patients – where he is to commence a treatment or procedure which will affect his fertility.
Preservation method(s) available		For medically required fertility preservation: Egg or sperm storage
Organisation	***Referral pathways***	**Referral for Medically Required Fertility Preservation – Female[64]** Information to be provided: ▪ Clinical reason for referral (We do not accept referrals for social reasons) ▪ Age and parity ▪ Likelihood of infertility ▪ Date of commencement of treatment/surgery. If the patient has a long term partner, they should also attend the appointment. Please provide Partner details (if applicable). **Sperm storage referral** If referring a patient for sperm storage where he is to commence a treatment or procedure which will affect his fertility you must undertake HIV, hepatitis B surface antigen (HBsAG), hepatitis B core antigen antibody (anti-HBc) & hepatitis C screening tests on the patient and submit copies of the results with the referral. To avoid any unnecessary delay, distress or discomfort to the patient we are unable to process any referral if the results of the screening blood tests are not submitted with the referral. You should provide the patients full details, including a contact number for the patient so we can arrange the appointment in a timely manner. Where the referral is routine and storage is not urgent, a referral should be submitted in writing by post to the Regional Fertility Centre. **For fertility treatment:** You need to be referred by a GP or hospital consultant to access NHS services in the Regional Fertility Centre. There are four stages of fertility treatment (generally): ▪ Consultation – when we receive a referral from your GP or consultant, we will contact you to arrange an initial consultation.

		▪ Investigations – after your consultation, some further investigations may be arranged to give us more information. ▪ Review – when we have the results of these investigations, we will meet with you to discuss the results and possible treatment options. ▪ Treatment – if treatment is right for you, your name will then be placed on a waiting list.
	Service provider characteristics	Information applicable to Belfast Health and Social Care Trust.
	Timelines to access services	No information identified.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	UK law permits you to store your eggs, embryos, sperm, ovarian or testicular tissue for use in treatment for up to 55 years from the date they are first placed in storage, but you must renew your consent every 10 years. **From 1 July 2022, a new law means that:** 1. All patients can store their eggs, sperm and embryos for their own treatment for up to 55 years, as long as they reconsent every 10 years. 3. As long as patients consent to their sperm, eggs or embryos being used in the event of their death, they can remain in storage up to 10 years from they pass away. **Renewing your consent:** The RFC will attempt to contact you at least 12 months before the expiry of each consent period to ask whether you wish to continue storage or not. When contacted, it is very important that you reply to us and let us know your wishes. The renewal period begins 12 months prior to the expiry of your consent and ends 6 months afterwards (a total of 18 months). **Consenting to storage for less than 10 years** [from Patient Information] You can choose to store your gametes or embryos for a period less than 10 years. You should consider carefully your reasons for consenting to a short period and be aware of the requirements of renewal of consent (renewal period) and the consequences if consent is not renewed in the renewal period (that is that consent is taken to be withdrawn). Importantly, there is no grace period when extending consent to storage for periods less than 10 years. Material will be removed from storage the day the consent expires. This could happen if you have not contacted the clinic and extended your consent to storage or we have been unable to get in contact with you.
	Access to stored materials	**Consent to treatment** You will be asked to provide your consent to the use of your sperm or eggs in treatment (IVF or ICSI). If you have a partner, you may also wish to consider storing your sperm for your partner's future treatment with IUI.

		Consent for use of your gametes or embryos in training or research The new consents allow you to consent for other uses of your gametes or embryos in the future, including for use in someone else's treatment, training, or research. Training activities or research can only be carried out in accordance with relevant standard or research licence conditions. At present the RFC does not hold a research license or have an agreement with a research centre. The RFC cannot therefore accept gametes or embryos for research. Please be aware that if you consent to donate your gametes or embryos and they have already been used in training or transferred to training, they cannot then be used in treatment should your circumstances change. When consenting to training, you can specify any period of storage of gametes for use in training up to 55 years and you will not need to periodically renew consent for training. For embryos, you can specify any period of storage of embryos for use in training up to 10 years from the date that you give consent. **Posthumous (after death) use of gametes and embryos** Gametes or embryos can only be used posthumously (after death) by a partner if you have provided written consent to posthumous storage and use, and named your partner on your consent form. If at the time of storage, you do not have a partner but you later meet a partner and want them to be able to use your gametes or embryos in the event of your death, you must inform the RFC and update your consent form(s) as soon as possible. Unless your partner is named on your consent form(s), they would not be legally able to your gametes or embryos even if you have provided effective consent to posthumous use. If treatment after death would involve a surrogate, then additional consent forms and screening must be completed to allow surrogacy treatment to take place. You must be screened in line with requirements for gamete donors. If this is something that you wish to consider, you should contact the RFC for more information on screening and associated costs. **Storage and use of gametes or embryos after death** The new consent forms allow you to state what you wish to happen in the event of your death. They also allow you to consent to being registered as the legal parent of any child born as a result of your partner's treatment, if treatment occurs after your death. You can consent to use and storage of your gametes or embryos for up to 10 years in these circumstances. If you consent for a period less than 10 years, you will not be able to benefit from the full amount of time (10 years) permitted in law. The consent of both patients (gamete providers) is needed to store embryos. If the living patient withdraws their consent to storage at any point in the posthumous 10-year storage period, embryos must be removed from storage and disposed of. **Use of gametes or embryos in the event of mental incapacity**

		The new consent forms allow you to state what you wish to happen in the event of mental incapacity. Your gametes or embryos can only be used by your partner if you have provided written consent to their storage and use in these circumstances, and your partner is named on your consent form. It is unlawful to store a patient's gametes for any longer than 10 years from the date on which they lose mental capacity, as certified by a medical practitioner, unless the patient has regained mental capacity and renewed their consent to a longer storage period in the intervening time.
	Disposal of stored materials	If at the end of the renewal period, you have not replied and provided written renewed consent, the law states that this will be taken as proof of lack of consent and your gametes (sperm or eggs) will be removed from storage and disposed of. By law, embryo(s) may continue to be stored for a further period of 6 months after the end of this 18 month renewal period after which, they must be removed from storage and allowed to perish. However, it is crucial to note that you will no longer be able to renew your consent to storage or use your embryo(s) in this time (that is after the 18 month renewal period).
	Any other storage information	**Withdrawal of Consent** At any point during storage you may decide to withdraw your consent to storage. If you withdraw your consent to storage for treatment purposes, we may ask you to consider whether you would like to consider giving consent to the use of your gametes or embryos for someone else's treatment (if appropriate), in training or whether they would like them to be removed from storage and disposed of. You will then be required to complete the relevant withdrawal of consent form. If you give consent for storage for use in training then this also means it is possible that gametes or embryos may be used in training even after death or mental incapacity. If you do not wish for this to happen, you should not give consent to storage for use in training. **Withdrawal of consent to embryo storage or use by one partner** You can withdraw consent to the storage of embryos created with your own gametes and a partner. If this happens, the RFC will take several actions: ▪ Your partner/ex-partner will be notified by the RFC of your wishes. ▪ You will enter what is called a 12-month cooling off period where embryos are kept in storage but cannot be used and both parties will be offered counselling (together or separate). ▪ During this period the embryos will not be able to be used unless with consent withdrawal is removed by the person initiating it. ▪ After 12 months if you still wish to withdraw consent, the embryos will be discarded even if the other partner does not wish to do so. ▪ If you withdraw consent to use embryos, they can remain in storage as long as you wish without being used.
Governance		No information identified.

Funding		**Publicly-funded treatment** ***Storage of embryos or sperm for use in treatment*** Your publicly-funded treatment includes the storage of embryos for 2 years from the date of your treatment. If you wish to store embryos for longer, you will need to meet the storage costs – see Private fertility treatments. If you wish to store sperm for use in further treatment, the same costs must be met. Exceptions apply when stored for oncology or other specific medical reasons. **Making the decision to renew my consent** …things you may wish to consider and discuss when making such a decision: ▪ The costs associated with use of this material in the future. **Posthumous (after death) use of gametes and embryos/Use of gametes or embryos in the event of mental incapacity** If treatment after death would involve a surrogate, then additional consent forms and screening must be completed to allow surrogacy treatment to take place. You must be screened in line with requirements for gamete donors. If this is something that you wish to consider, you should contact the RFC for more information on screening and associated costs.
Communication and information provision		No information identified.
Ethical considerations		**Making the decision to renew my consent** [from Patient Information] The decision whether to renew your consent and keep sperm, eggs or embryos in storage can be a challenging one. It is vital that you think carefully about this decision every time your consent is renewed or extended and consider whether it is likely you would use these in your own treatment or the treatment of your partner, including treatment with a surrogate in the future. It is also important to consider whether you may wish to donate these for the treatment of others in the future or for training. It is important to carefully consider and discuss with your partner, if appropriate, the implications of future treatment for yourself and others including factors such as age, general health and the risks of such a pregnancy in the future as well as the implications for any future children. Although the law permits a maximum storage period of 55 years few women would seek to carry a pregnancy beyond the age of 50 and this may not be possible. Other examples of things you may wish to consider and discuss when making such a decision ▪ The chances of a livebirth using the material in the future ▪ The costs associated with use of this material in the future ▪ What your wishes would be if you became sick or died ▪ The implications of using gametes or embryos after either partner dies ▪ The welfare of any children born in the future ▪ The implications for you and any children if material is donated and used many years in the future. **Counselling**

		This is a complex area and we offer you the opportunity to receive counselling about the implications of renewing your consent with our fertility counselling service. This can be really useful when balancing all the complicated implications around storage and potential use into the future or how you feel about allowing material to perish. If you would like to have counselling, you can arrange this independently or through the RFC. **Change of Circumstances** It is important that you make the RFC aware of any changes in your circumstances which may affect your consent decision (for example, if you have separated from your partner or have a new partner). This is important so that your wishes can be carried out in the unlikely event of death or mental incapacity. We also ask you to provide contact details for your next of kin and it is important that you make us aware of any changes to these details also. The RFC complies with all relevant confidentiality (including section 33 of the HFE Act 1990 (as amended).
Relevant legislation (list)		▪ Health and Care Act 2022 ▪ Human Fertilisation and Embryology Act 1990
Miscellaneous		No information identified.

Table D.35 Extracted data for Northern Ireland (DOH/NICE Guidelines)

Northern Ireland		
Author(s) **Title [year]**	Department of Health (Northern Ireland) Circular HSC (SQSD) 3/13. Subject: NICE Clinical Guidelines Endorsement, Implementation, Assurance in Northern Ireland[65] [2013] NICE – Endorsed Clinical Guidelines 2013/2014 (NICE Clinical Guideline CG 156 - Fertility: assessment and treatment for people with fertility problems)[66] [2013] Additional Caveats for CG 156 - Fertility: assessment and treatment for people with fertility problems[67] [2013] Circular HSC (SQSD) (NICE NG73) 35/17, Subject: NICE Clinical Guideline NG73 – Endometriosis: diagnosis and management[68] [2017]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		In November 2013, the Department of Health (DoH) in Northern Ireland endorsed NICE Clinical Guideline CG 156 - Fertility: assessment and treatment for people with fertility problems. This guideline includes a recommendation regarding people with cancer who wish to preserve fertility [see CG 156 data extraction]. In October 2017, the DoH reviewed and endorsed NICE Clinical Guideline NG73 – Endometriosis: diagnosis and management [see NG73 data extraction].
Preservation method(s) available		As per CG 156, recommendation 1.16.1 Cryopreservation of semen, oocytes and embryos.
Organisation	***Referral pathways***	No information identified.
	Service provider characteristics	No information identified.
	Timelines to access services	No information identified.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	No information identified.
	Access to stored materials	No information identified.
	Disposal of stored materials	No information identified.
	Any other storage information	No information identified.
Governance		**National Institute for Health and Care Excellence (NICE) Clinical Guidelines – Process for Endorsement, Implementation, Monitoring and Assurance in Northern Ireland** NICE guidance to promote clinical excellence and the effective use of resources for people using the NHS is designed for use in England and, as such, does not automatically apply in NI.

		The Department established formal links with NICE on 1 July 2006 whereby guidance published by the Institute from that date would be locally reviewed for applicability to Northern Ireland and, where appropriate, endorsed for implementation in Health and Social Care (HSC). This circular sets out the new NI process for NICE Clinical Guidelines, which relate to specific diseases and or groups of patients/clients. The new arrangements will be effective from 18th December 2013 and will apply to all HSC organisations, including Family Practitioners. It should also be noted by independent health and social care providers. It will be the responsibility of HSC organisations, under the statutory duty of quality as specified in Article 34 of the HPSS (Quality, Improvement and Regulation) (NI) Order 2003, to put in place the necessary systems, which should include adequate and comprehensive dissemination, as part of their clinical and social care governance arrangements, for implementing NICE guidance. NICE guidance will be proofed by the Department only to check for legal, policy and financial consequences related to its implementation in NI. As a result, the guidance may be endorsed with caveats to advise local HSC organisations of any equivalent legislation/policy or any specific instructions/requirements. Following endorsement, the Department will issue a circular directly to the HSC Trusts and other relevant providers and stakeholders at the same time as the HSC Board/Public Health Agency (PHA). The HSC Board will ensure that relevant guidance is sent to the appropriate Family Practitioners. The Regulation and Quality Improvement Authority (RQIA) will disseminate guidance to the independent sector as appropriate. The working assumption is that HSC Trusts will implement Clinical Guidelines within a further 9 months following the initial 3 month planning period after the DHSSPS issued the guideline. The HSC Board will seek positive assurance that implementation has been achieved at bi-monthly director level meetings with HSC Trusts. It is recognised that the implementation of aspects of a Clinical Guideline may be beyond an individual HSC Trust. This might arise through cost or wider strategic implications. In such cases, HSC Trusts will raise these with the HSC Board at the bi-monthly director level meetings. The HSC Board will be responsible for monitoring implementation of NICE guidance within the HSC…RQIA will lead on assessing the implementation of Clinical Guidelines. The Department will require the HSC Board to formally report annually on the progress made generally in commissioning services in accordance with NICE guidance endorsed by the Department.
Funding		No information identified.
Communication and information provision		No information identified.

Ethical considerations		**Additional Caveats for CG 156 - Fertility: assessment and treatment for people with fertility problems** Where the guidance indicates that informed consent should be obtained and documented, the DHSSPS guidance 'Reference Guide to Consent for Examination, Treatment or Care (2003)', which is available on the DHSSPS website, gives advice on the law concerning consent to intervention.
Relevant legislation (list)		▪ HPSS (Quality, Improvement and Regulation) (NI) Order 2003
Miscellaneous		No information identified.

Table D.36 Extracted data for Portugal (Parameters for operation of AR centres)

Portugal		
Author(s) **Title [year]**	National Council for Medically Assited Procreation (CNPMA, *Conselho Nacional de Procriação Medicamente Assistida*) Requirements and parameters for the operation of PMA centres[69] [2021]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		No information identified.
Preservation method(s) available		***II.3.1. Clinical standards*** The Center must have action protocols covering at least the following procedures/situations, when applicable: ▪ controlled stimulation of the ovaries ▪ ultrasound-guided puncture of the ovaries ▪ sedation/anesthesia ▪ surgical obtaining of sperm or male gonadal tissue [Not preservation methods, but protocols also required for: ▪ cardiopulmonary resuscitation ▪ artificial insemination ▪ intrauterine embryo transfer ▪ follow-up after treatment ▪ ovarian hyperstimulation syndrome]
Organisation	***Referral pathways***	No information identified.
	Service provider characteristics	Document applies to authorised PMA Centres in Portugal (that is, centres that provide medically assisted procreation services, including fertility preservation services.
	Timelines to access services	No information identified.
	Any other organisational aspects	**<u>Part I – Requirements</u>** **I.1 ORGANISATION AND QUALITY MANAGEMENT** ***I.1.1 Organisation*** ▪ The Center must have the necessary resources for the activities it carries out, in terms of personnel, facilities, equipment and materials, registration and information systems, and security. ▪ The Center must ensure an organizational structure and operational procedures appropriate to the activities carried out. ▪ The organizational structure of the Center must create an environment in which all personnel are fully involved in ensuring that the quality management system functions properly and the stated requirements are met. ▪ The health structure in which the Center is part or the Center itself must appoint a person responsible, from here on referred to as director.

		The Center director's responsibilities are: ▪ ensure the authorisation conditions for the operation of the Centre; ▪ ensure compliance with requirements regarding staff training, quality management system, documentation, record keeping, traceability, notification of incidents or serious adverse reactions, data protection and confidentiality; ▪ ensure that appropriate procedures are carried out in the Center's activities, namely that the obtaining, processing, preservation, storage and distribution of gametes, gonadal tissue and embryos are in accordance with the legal standards in force and the determinations contained in this document; ▪ provide the CNPMA with data relating to the Center's activity, in accordance with the standards established for this purpose; ▪ communicate to the member of the Government responsible for health the closure of the Center's activity, six months in advance, and take the necessary measures to ensure the transfer of gametes, gonadal tissue and cryopreserved embryos, as well as clinical and laboratory data relating to the PMA, to the recipient entity previously defined by that authority. ***I.1.2 Quality management system*** The Center must implement a Quality Management System certified by an entity accredited in the Portuguese Quality System, in accordance with the standard NP EN ISO 9001:2015, or another that may succeed it. ▪ A person responsible for quality management at the PMA Center must be designated, who may be the director. **I.2 HUMAN RESOURCES** ▪ The Center must have staff in sufficient numbers and with adequate competence for the tasks assigned to them. ▪ Professionals directly involved in the activities of obtaining, processing, preserving, storing and distributing gametes, gonadal tissue and embryos must have specific qualifications for such functions. ***I.2.1 Medical team*** The director of the Center is a doctor specializing in Gynecology/Obstetrics, Genetics, in Endocrinology or Urology, recognized by the Medical Association, with minimum experience of 3 years in the PMA area. ▪ In Centers dedicated to the practice of in vitro fertilization/intracytoplasmic sperm microinjection techniques, the medical team must consist of at least 2 doctors specialized in Gynecology/Obstetrics, preferably with the subspecialty of reproductive medicine, one of whom may be the director. ▪ In Centers dedicated exclusively to the practice of artificial insemination, the medical team must consist of at least one gynecologist/obstetrician. ▪ In Centers dedicated exclusively to the selection of donors and the preservation of gametes, the medical team must consist of, at a minimum, a doctor specialized in Gynecology/Obstetrics, Medical Genetics, Endocrinology or Urology, with experience and competence in this area.

		▪ The Centers must ensure the support of specialist doctor(s) from other specialties whenever the standards of good clinical practice require it, namely as a specialist with expertise in andrology. ▪ Centers authorized to practice PMA must ensure the support of a doctor specializing in Psychiatry or a clinical psychologist. ***I.2.2 Clinical embryology team*** ▪ In Centers dedicated to the practice of in vitro fertilization/intracytoplasmic sperm microinjection techniques, the clinical embryology team must consist of at least 2 technicians with a degree or higher in the areas of medicine, biology, biochemistry or pharmacy, with specific training and sufficient time of practical experience in PMA techniques. ▪ Among the team members, one must be designated as responsible for the laboratory, with supervisory duties assigned to him. ▪ Centers dedicated exclusively to donor selection and gamete preservation must have at least one technician with a degree, with experience and competence in the area to handle gametes and their cryopreservation. ***I.2.3. Remaining staff*** The number and qualifications of nursing, administrative and auxiliary staff must be appropriate to the type and quantity of activities carried out at the Center. ***I.2.4 Personnel in training*** ▪ Training personnel must follow structured training programmes under appropriate supervision in accordance with the Quality Management System. Compliance with training objectives must be confirmed by the Center director. ▪ The assessment of the competence of a new clinical embryologist must be carried out by the person in charge of the laboratory and approved by the director of the Center, in accordance with the Quality Management System. **I.3 FACILITIES** ▪ Facilities and environmental conditions must be appropriate to the specificities and volume of activity. Its characteristics are fundamental elements for maintaining the quality and safety of gametes, gonadal tissue and embryos and must meet the health and safety requirements of all staff and users involved. ▪ The Centers must ensure that the facilities are adequate to guarantee the privacy and comfort of patients, including those with reduced mobility. [Further detailed requirements in relation to Physical Spaces and Environmental Conditions not extracted as not deemed relevant] **I.4 EQUIPMENT**

		The equipment and number of workstations must be appropriate to the characteristics and volume of activity and its continuity must be ensured in the event of operating anomalies or sudden breakdowns. [Detailed lists of euqipment and its specifications not extracted as not deemed relevant]
Storage	***Arrangements and duration(s)***	No information identified.
	Access to stored materials	No information identified.
	Disposal of stored materials	No information identified.
	Any other storage information	In beneficiaries applying for IVF/ICSI techniques, it is mandatory to search for biological markers of infection for: ▪ HIV (Anti-HIV1 and HIV2 Ac.) ▪ hepatitis C (Anti-HCV Ac.) ▪ hepatitis B (Ag Hbs, Ac. anti-HBc) ▪ syphilis ▪ testing for anti-Human T-Cell Lymphotropic Virus Types I and II antibodies (in beneficiaries who live in or come from regions with high prevalence or where sexual partners or parents come from these regions). Specific studies are sometimes necessary depending on patients' travel history or particular exposures, such as rhesus disease, malaria, cytomegalovirus, Trypanosoma cruzi. In situations of self-preservation of gametes or gonadal tissue, the tests listed above should be carried out routinely. In the case of urgent self-preservation, everything must be done to know the serological status before processing and storing gametes or gonadal tissue in the laboratory. Beneficiaries with positive viral markers may be treated if the standards set out in *Specific Provisions for Beneficiaries with Viral Infections* are met. [Other procedures detailed in document but not extracted in full:] **II.4. LABORATORY PROCEDURES** There must be detailed and updated manuals with all procedures relating to the techniques carried out at the Centre. **II.5. RECORDS** It is mandatory to record data regarding all PMA techniques. **II.6. TRACEABILITY** Centers must ensure that all gametes, gonadal tissue and embryos are traceable from acquisition to use. **II.7. THIRD PARTY DONORS** **II.8. INCIDENTS AND ADVERSE REACTIONS**

Governance		Law no. 32/2006, of July 26th (which had its seventh amendment with Law no. 48/2019, of July 8th), established the National Council for Medically Assisted Procreation (CNPMA) and committed it a wide range of functions which include the definition of the necessary quality and safety requirements to be met by the Centres in which these techniques are carried out, Centres which are obliged to provide adequate advice and treatment to patients, to record and provide data to the CNPMA relative to these treatments. The extracted document is presented in two parts: ▪ Part I (Requirements) – contains a set of general specifications on relevant aspects that Centers that are candidates or authorised to carry out PMA techniques must comply with, with regard to organisation, personnel, facilities and equipment; Compliance with these requirements will be an essential condition for granting or renewing authorisation to the Centers to practice these techniques. ▪ Part II (Procedures) – contains a set of mandatory procedural rules and additional information on how the activities of the Centers are expected to be carried out and the exercise, in practice, of their functions and responsibilities; its objective is to contribute to the promotion of good clinical and laboratory practices in the implementation of therapeutic techniques, with proof of compliance being a fundamental element in the decision on whether the operating authorisation of a PMA Center should be renewed.
Funding		[Document applies to authorised PMA Centres in Portugal. PMA services, including fertility preservation services, are funded through the National Health Service (SNS, *Serviço Nacional de Saúde*)]
Communication and information provision		**II.2. INFORMATION AND CONSENT** ▪ Centers must ensure that before any treatment, donation or cryopreservation of gametes, gonadal tissue or embryos is initiated, or consent is given to such techniques, patients receive adequate oral and written information explaining the medical implications of their decision. Centers must take into account that consent can only be considered if it is given voluntarily (without pressure that constitutes an unacceptable influence on the acceptance of treatment) and by people with the capacity to consent to the execution of such treatment. ▪ Written consent must be obtained from each person receiving PMA treatments or providing gametes or gonadal tissue for use in treatment or preservation. To this end, models approved by the CNPMA must be used. ▪ Gametes, gonadal tissue or embryos cannot be used without the express written consent of their originators. Specifically, in the case of preserving sperm or testicular tissue from the male partner of a couple candidate for PMA, preserved gametes can only be used when the partner confirms this through signed informed consent. ▪ When transferring cryopreserved embryos, the respective informed consent must be signed by the beneficiaries at the time of each transfer.
Ethical considerations		No information identified.
Relevant legislation (list)		▪ Law no. 32/2006, of July 26th [established the CNPMA] ▪ Law no. 12/2009, of March 26 [procedures for verifying the equivalence of quality standards and safety of imported tissues and cells, including gametes, gonadal tissue and embryos]
Miscellaneous		No information identified.

Table D.37 Extracted data for Portugal (AR Law and associated AR resources)

Portugal		
Author(s) **Title [year]**	The Portuguese Government Medically assisted reproduction: Law No.32/2006 (Consolidated Legislation)[70] and amendment due to Law No. 17/2016[71] and the Joint Normative Circular (2002)[72] Further supporting information included by the Portuguese Society of Reproductive Medicine[73], the National Council for Medically Assisted Procreation (CNPMA)[74] and the ACSS Review of Exemption Categories and Update Values of Moderator Fees.[75] Further legal documents which support include Law No. 12/2009.[76]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		1. The use of PMA techniques can only be carried out upon diagnosis of infertility or, where applicable, to treat a serious illness or the risk of transmission of diseases of genetic, infectious or other origin. 2. PMA techniques can still be used by all women regardless of the diagnosis of infertility [this was added in June 2016] The beneficiaries are outlined as: 1 - Couples of different sexes or couples of women, respectively married or married or living in conditions similar to those of their spouses, can use PMA techniques, as well as all women regardless of their marital status and their sexual orientation. 2 - The techniques can only be used for the benefit of those who are at least 18 years of age and provided that there is no accompanying sentence prohibiting the use of such techniques. In 2022 amendment to the law was made, with the following age criteria implemented:[72] ▪ Admission for fertility support consultation: no limit on the woman's age, as long as it is referred by the Family Doctor or by the Doctor who monitors the woman in a situation of illness. ▪ Admission for first-line PMA techniques (ovulation induction and intrauterine insemination): women who do not exceed 42 years of age (41 years and 365 days or 366 in the case of a leap year). Admission is understood as the moment in which the technique is performed. ▪ Admission to 2nd line PMA techniques (in vitro fertilization and intracytoplasmic sperm injection): women who do not exceed 40 years of age (39 years and 365 days or 366 in the case of a leap year). Admission is understood as the moment in which the technique is performed. **In cases of preservation of reproductive potential due to serious illness of the woman.** This regime only considers the "Age of the woman" criterion for accessibility to PMA techniques. ▪ Admission for treatments to preserve reproductive potential: women in situations of serious illness, who do not exceed 40 years of age (39 years and 365 days or 366 in the case of a leap year). Admission is understood as the moment in which the technique is performed.

		▪ Admission for Medically Assisted Procreation (PMA) treatments, in situations where cryopreserved material is available, in the context of preserving reproductive potential due to serious illness: women who do not exceed 50 years of age (49 years and 365 days or 366 in the case of a leap year). Admission is understood as the moment in which the technique is performed. Minimum age limit of 18 years for ART. There is no maximum limit for the male partner. [CNPMA FAQs].(77)
Preservation method(s) available		1. This law applies to the following PMA techniques: a) Artificial insemination; b) In vitro fertilisation; c) Intracytoplasmic sperm injection; d) Transfer of embryos, gametes or zygotes; e) Pre-implantation genetic diagnosis; f) Other equivalent or subsidiary gametic or embryonic manipulation laboratory techniques. 2. This law also applies to situations of surrogacy.
Organisation	***Referral pathways***	Referral to the Fertility Support Consultation is usually carried out by the family doctor or by the doctor who accompanies the woman in a situation of illness. There is also the possibility for a patient's private doctor to make a request for a specialised consultation to an NHS hospital by filling out a "Consultation on time" form. [CNPMA FAQs](77)
	Service provider characteristics	1. ART techniques, including those carried out in the context of surrogacy situations…, may only be administered in public or private centres expressly authorised for this purpose by the Minister of Health. 2. The following are defined in a specific law, namely: a) The qualifications required of medical teams and other health personnel; b) The method and criteria for periodic evaluation of technical quality; c) Situations in which the operating authorisation can be revoked. See the list of authorised centres: here [CNPMA FAQs](77)
	Timelines to access services	No information identified.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	All viable embryos that are not transferred will be cryopreserved for a maximum period of 3 years, extendable for another 3 years, at the request of the couples. [CNPMA FAQs](77) Storage periods are controlled for in Law No.32/2006: 1 - Spermatozoa, oocytes, testicular tissue and ovarian tissue, which are collected and not used, are cryopreserved for a maximum period of 5 years. 2 - At the request of beneficiaries, in duly justified situations, the director of the medically assisted procreation centre (PMA) may assume responsibility for extending the cryopreservation period for

		sperm, oocytes, testicular tissue and ovarian tissue for a new period of 5 years, successively renewable for the same period. 3 - Without prejudice to the extension of the period provided for in the previous paragraph, after the 5-year period referred to in paragraph 1 has elapsed, spermatozoa, oocytes, testicular tissue and ovarian tissue may be destroyed or donated for scientific research if another destination is not is given to them. 4 - The destination of spermatozoa, oocytes, testicular tissue and ovarian tissue for the purposes of scientific research, under the terms set out in the previous paragraph, can only be verified with the free, informed consent, expressly and in writing, of the original beneficiaries, through informed consent models prepared by the National Council for Medically Assisted Procreation, presented to the responsible doctor. 5 - Once the donation has been consented to, under the terms provided for in paragraph 3, without the spermatozoa, oocytes, testicular tissue and ovarian tissue having been used in a research project within 10 years of cryopreservation, they may be thawed and eliminated, as determined by the director of the ART centre. 6 - If donation is not consented to, under the terms of paragraph 4, as soon as any of the periods indicated in paragraph 1 or paragraph 2 have elapsed, spermatozoa, oocytes, testicular tissue and ovarian tissue may be thawed and eliminated, as determined by the director of the ART centre. <u>Storage periods as outlined in CNPMA informed consent forms:</u> In regards to **sperm cryopreservation**:[78] I understand and accept that the sperm will be cryopreserved for a maximum period of 5 years and that, during this period, this authorisation may be revoked by me at any time. Furthermore, I understand that in the event of my death and once the post-mortem insemination procedure has been consented/authorised, this period will be shortened to a maximum period of 3 years after my death. **Maintenance of cryopreservation of spermatozoa and or testicular tissue:[79]** Following the Informed Consent text signed by me previously, and because the 5-year period stipulated therein has elapsed, I declare that I wish for the conservation of my sperm and or testicular tissue to be maintained for an additional period of 5 years. – I further understand that in the event of my death and once the post-mortem insemination procedure has been consented/authorised, this period will be shortened to a maximum period of 3 years from my death. – I understand that, in accordance with current regulations, at the end of this additional period of 5 years I will have to go to the centre again to sign a consent to maintain this freeze. In the absence of a signed statement requesting a new period of cryopreservation, – I declare that I have been clearly informed that the sperm and or testicular tissue will be thawed and disposed of, unless I express authorisation for their use for donation or for scientific purposes. In regards **to cryopreservation of oocytes and or ovarian tissue**:[80] I understand and accept that the oocytes and or ovarian tissue will be cryopreserved for a maximum period of 5 years AND understand that, according to current regulations, at the end of this 5-year period I will have to go to

		the centre to sign a consent to maintain this freeze. In the absence of a signed statement requesting a new period of cryopreservation, I declare that I have been clearly informed that the oocytes and or ovarian tissue will be thawed and eliminated, unless I express authorisation for their use for donation or for scientific purposes. **Maintenance of cryopreservation of oocytes and or ovarian tissue:**[81] Following the Informed Consent text signed by me previously, and because the 5-year period stipulated therein has elapsed, I declare that I wish for the conservation of my oocytes and or ovarian tissue to be maintained for an additional period of 5 years – I understand that, in accordance with current regulations, at the end of this additional period of 5 years I will have to go to the centre again to sign a consent to maintain this freeze. In the absence of a signed statement requesting a new period of cryopreservation, I declare that I have been clearly informed that the oocytes and or ovarian tissue will be thawed and eliminated, unless I express authorization for their use for donation or for scientific purposes. In regards to **embryo cryopreservation**:[82] I understand that, in accordance with current legislation, embryos will be preserved for a period of 3 years (or, in duly justified situations, for a maximum period of six years) and that, after this period, if the embryos have not been used by me/us or have not been given another use by me/us, they will be thawed and deleted. **Maintenance of cryopreservation of embryos (or pre-zygotes):**[83] Following the Informed Consent text signed by me/us previously, and because the 3-year period stipulated therein has elapsed, I/we declare that I/we wish that the conservation of my/our embryos (or pre-zygotes) be maintained by an additional period of 3 years – I understand that, in accordance with the regulations in force, at the end of this additional period of 3 years, if the embryos (or pre-zygotes) have not been used by me/us or have not been given any other use by me /we consent, will be thawed and eliminated.
	Access to stored materials	No information identified.
	Disposal of stored materials	All viable embryos that are not transferred will be cryopreserved for a maximum period of 3 years, extendable for another 3 years, at the request of the couples. According to the choice of the beneficiary (ies), the cryopreserved embryos can be used later, or donated to other beneficiaries and or for scientific research. In the absence of any of these options and after the period provided for by law, the embryos are thawed and disposed of. [CNPMA FAQs][77]
	Any other storage information	No information identified.
Governance		The CNPMA is the competent, independent and specialised authority, legitimised to regulate, discipline and monitor the practice of PMA in Portugal, following the scientific and technical evolution and its ethical, social and legal implications.

		The CNPMA, as a competent entity, is responsible for ensuring quality and safety in relation to the donation, collection, analysis, processing, storage and distribution of reproductive cells and human embryonic stem cells.[76] Law No 12/2009[76] comprehensively outlines what is required of ART centres, with CNPMA having overall governance in relation to the regulation of these centres.
Funding		Information from produced by the Portuguese Society of Reproductive Medicine indicates, for cancer patients:[73] **Conservation of cryopreserved sperm:** Within the scope of the National Health Service (SNS), the cryopreservation of sperm from cancer patients and their maintenance are, in general, procedures that do not involve costs for the patient. **Cryopreservation of testicular tissue:** Within the scope of the National Health Service (SNS), the cryopreservation of testicular tissue from cancer patients and its maintenance are, in general, procedures that do not involve costs for the patient. **Embryo cryopreservation:** Within the scope of the National Health Service, the cancer patient will only have to bear the costs of the medicines used to stimulate ovulation, which can vary between approximately €200 and €500. These costs depend on the stimulation protocol used. **Oocyte cryopreservation:** Within the scope of the National Health Service, the cancer patient will only have to bear the costs of the medicines used to stimulate ovulation, which can vary between approximately €200 and €500. These costs depend on the stimulation protocol used. **Cryopreservation of ovarian tissue:** Within the scope of the National Health Service (SNS), the cryopreservation of ovarian tissue from Oncological tests and their maintenance are, in general, procedures that do not involve costs for the patient. Overall costs indicated are: In the case of embryo cryopreservation and oocyte cryopreservation techniques, the patient will have to bear the costs of medication for ovarian stimulation. These costs vary between approximately €200 and €500, depending on the stimulation protocol used. **Cryopreservation techniques for ovarian tissue, sperm and testicular tissue generally do not involve any costs for cancer patients.** The ACSS Review of Exemption Categories and update values of Moderator Fees in the public health system (SNS) also indicates:[75] ▪ Family planning requires genetic and marital counselling actions, information on methods and provision of means of contraception, treatment of infertility and prevention of sexually transmitted diseases, with, accordingly, free consultations on family planning and contraceptive means provided by public entities. ▪ A family planning consultation corresponds to a consultation, within the scope of the General and Family Medicine specialty or another specialty, in which there is a response from the health professional to a request about contraception, preconception, infertility or fertility. These consultations, whether carried out in a primary health care environment or in a hospital environment, are exempt from payment of moderating fees, as are the additional acts prescribed during these consultations.

		▪ Consultations and complementary acts prescribed within the scope of Medically Assisted Procreation (PMA) are considered acts provided within the scope of family planning. ▪ Within the scope of Primary Health Care, consultations and all complementary diagnostic and therapeutic exams prescribed during these are exempt from payment of moderating fees. **Article 17 (Charges) of Law No.32/2006:** 1 - Centres authorised to provide ART techniques may not, in calculating the remuneration required, attribute any value to the donated genetic material or to the donated embryos. 2 - The use of PMA techniques within the scope of the National Health Service is supported under the conditions that may be defined in a specific statute, taking into account the opinion of the National Council for Medically Assisted Procreation.
Communication and information provision		**Consent is outlined in Law No.32/2006 (Article 14):** 1 - Beneficiaries must give their free, informed consent, expressly and in writing, to the responsible doctor. 2 - For the purposes of the provisions of the previous paragraph, beneficiaries must be informed in advance, in writing, of all known benefits and risks resulting from the use of PMA techniques, as well as their ethical, social and legal implications. 3 - The information contained in the previous number must be contained in a document, to be approved by the National Council for Medically Assisted Procreation, through which the beneficiaries provide their consent. 4 - The consent of the beneficiaries is freely revocable by any of them until the beginning of the PMA therapeutic processes. 5 - The provisions of paragraphs 1, 2 and 3 are applicable to the surrogate mother in the situations provided for in article 8, and, in these cases, her consent is freely revocable until the moment of registration of the born child, established in paragraph 10 of article 8. 6 – In the situations provided for in article 8, the beneficiaries and the surrogate mother must also be informed, in writing, of the significance of the surrogate mother's influence on embryonic and foetal development. **Informed Consent Models[(84)]** Before starting the therapeutic processes of ART, the beneficiary person(s) must give their consent expressly and in writing. For free and informed consent, the beneficiary person(s) must be duly informed about the known benefits and risks resulting from the use of these techniques, as well as their ethical, social and legal implications (Article 14 of Law No. 32/2006, of 26 July, as amended by Law No. 17/2016, of 20 June). The consent models were approved in 2008 and revised in 2012, 2015, 2016, 2017, 2020 and 2021 following the legislative changes and the update of the "Requirements and parameters for the operation of the PMA Centres". The content of the informed consent forms may not, under any circumstances, be altered, and it is at the discretion of each centre to supplement these documents with additional information.

Ethical considerations		**Dignity and non-discrimination** 1. PMA techniques, including those carried out in surrogacy situations, must respect the human dignity of all people involved. 2. Discrimination based on genetic heritage or the fact of being born as a result of the use of PMA techniques is prohibited. **Beneficiary rights are considered in Law No.32/2006 (Article 12):** a) Not be subjected to techniques that do not offer a reasonable chance of success or whose use poses significant risks to the health of the mother or child; b) Be assisted in a suitable medical environment that has all the material and human conditions required for the correct execution of the recommended technique; c) Be correctly informed about the likely medical, social and legal implications of the proposed treatments; d) Know the reasons that motivate the refusal of PMA techniques; e) Be informed of the conditions under which it would be possible for them to resort to adoption and the social relevance of this institute. **Article 11 Medical decision and conscientious objection** 1 - It is the responsibility of the physician in charge to propose to the beneficiaries the ART technique that scientifically appears to be most appropriate when other treatments have not been successful, do not offer prospects of success or are not convenient according to the precepts of medical knowledge. 2 - No health professional may be obliged to supervise or collaborate in the performance of any of the ART techniques if, for medical or ethical reasons, he or she does not consider it necessary. 3 - The professional's refusal must specify the clinical or other reasons that motivate it, namely conscientious objection. **Article 13 Duties of beneficiaries** 1 - The duties of the beneficiaries are: a) Provide all the information requested by the medical team or that they deem relevant for the correct diagnosis of their clinical situation and for the success of the technique to which they are going to be submitted; b) Strictly observe all the prescriptions of the medical team, both during the diagnosis phase and during the different stages of the ART process. 2 - In order to assess the medical, health and psychosociological results of the ART processes as a whole, the beneficiaries shall provide all information related to the health and development of children born using these techniques.
Relevant legislation (list)		Medically assisted reproduction: Law No.32/2006 (Consolidated Legislation)[70] and amendment due to Law No. 17/2016[71] and the Joint Normative Circular (2002)[72] Lei n.º 12/2009:[76] Establishes the legal regime for quality and safety relating to the donation, collection, analysis, processing, preservation, storage , distribution and application of tissues and cells of

		human origin, transposing Directives No. 2004/23/ into the domestic legal system. EC, of the European Parliament and of the Council, of 31 March, 2006/17/EC, of the Commission, of 8 February, and 2006/86/EC, of the Commission, of 24 October.
Miscellaneous		No information identified.

Table D.38 Extracted data for Portugal (Regulatory Decree)

Portugal		
Author(s) **Title [year]**	Diario de Republica Regulatory Decree No. 06/2016[85]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		Access for all couples and all women to ART, regardless of their marital status, sexual orientation and diagnosis of infertility, thus proceeding with the second amendment to Law no. 32/2006, of 26 of July, which regulates ART techniques. In this sense, the change introduced aims to eliminate the restriction currently in force, according to which access to ART techniques was reserved for married people or people of different sex who have lived in conditions similar to those of their spouses for at least 2 years, thus ensuring respect for the principle of equal access to ART techniques and rejecting the exclusion of any woman from access to them. Access to ART techniques within the scope of the National Health Service (SNS) by couples of women or by women, regardless of a diagnosis of infertility, marital status and sexual orientation, who meet the requirements set out in no. 2 of article 6 of Law no. 32/2006, of 26 July, amended by Laws no. August 22nd, must comply with the same criteria that are applied to different-sex couples with access to ART techniques under Law No. 32/2006, of July 26th, in its original version. Female couples are not allowed on the SNS to simultaneously undergo ART treatments.
Preservation method(s) available		No information identified.
Organisation	***Referral pathways***	Referral to the SNS of different-sex couples, couples of women or women without a partner, is carried out by primary health care or SNS hospital entities to the ART Centres that are part of the referral network.
	Service provider characteristics	A centre authorised to provide ART techniques is the set of human, material and organisational resources that allow ART to be carried out. The centres can be public or private and must be expressly authorised for this purpose by the member of the Government responsible for the health area, after consulting the National Council for Medically Assisted Procreation (CNPMA). The centres referred to in the previous paragraph may be authorised to carry out all the ART techniques provided for in article 2 of Law no. 32/2006, of 26 July, amended by Law no. 59/2007, of September 4, 17/2016, June 20, and 25/2016, August 22, for the exclusive execution of the artificial insemination technique or for the selection of donors and preservation of gametes.

		The application of ART techniques provided for in article 2 of Law no. 32/2006, of 26 July, amended by Law no. 59/2007, of 4 September, 17/2016, of June 20 , and 25/2016, August 22, to female couples and women regardless of a diagnosis of infertility, marital status and sexual orientation, who meet the requirements set out in paragraph 2 of article 6. the of referred to Law, can only be administered in ART Centres, public or private, duly authorised by the Ministry of Health, after consulting the National Council for Medically Assisted Procreation, under the terms of this regulatory decree.
	Timelines to access services	Different waiting times for ART treatments are prohibited, depending on whether the beneficiary is a couple of different sex, a couple of women or women without a partner, without prejudice to the priorities established based on objective criteria of clinical severity.
	Any other organisational aspects	The psychological assessment is always carried out by a doctor specialising in psychiatry or a clinical psychologist. **From Articles 8 and 9:** [Applicable to authorised ART centres] The director of the ART centre is a doctor specialising in gynaecology/obstetrics, medical genetics, endocrinology or urology, recognised by the Medical Association, with a minimum of 3 years' experience in the ART area. ART centres have at least 2 doctors specialising in gynaecology/obstetrics, preferably with the subspecialty of reproductive medicine, one of whom may be the director. The experience of the director of the ART centre is proven through the curriculum and assessed by the CNPMA. The ART centres have staff with experience and skills compatible with the ART, including at least 2 technicians with a degree or higher degree in the areas of medicine, biology, biochemistry or pharmacy. **Article 11: Staff assigned to centres exclusively dedicated to donor selection and gamete preservation** Centres dedicated exclusively to the selection of donors and the preservation of gametes must have a team consisting of, at least, a doctor specialised in gynaecology/ obstetrics, medical genetics, endocrinology or urology, with experience and competence in this area. These centres must have at least one technician with a degree, with experience and competence in the area to handle gametes and their cryopreservation.
Storage	***Arrangements and duration(s)***	No information identified.

	Access to stored materials	No information identified.
	Disposal of stored materials	No information identified.
	Any other storage information	No information identified.
Governance		The request for authorisation of a centre to administer ART techniques is made by submitting an application, preferably electronically, addressed to the member of the Government responsible for the health area and delivered to the regional health administration territorially competent in function of the centre location. The territorially competent regional health administration is responsible for instructing the authorisation process for public or private centres that intend to provide ART techniques. The director is responsible for the centre authorised to provide ART techniques, hereinafter referred to as the ART centre. ART centres send annual activity reports to the CNPMA, which cannot contain personal data that would directly or indirectly allow any of the people involved to be identified. ART centres are audited every 2 years, without prejudice to interim visits. **Audit, inspection and supervision** In conjunction with the CNPMA, the General Inspection of Health Activities (IGAS) carries out audits, inspections and inspections of public and private centres that provide ART techniques. For the purposes of the provisions of the previous paragraph, IGAS must conclude a protocol with the CNPMA to regulate the form and means of articulation between the two entities, as well as define the terms of articulation with other public entities, namely the General Directorate of Health. The specific, initial and ongoing training of auditors is the responsibility of the CNPMA. IGAS must communicate to the territorially competent regional health administration the initiation of processes relating to public and private centres that provide ART techniques. **Article 14:** The operating authorisation granted to the ART centre may be revoked in situations of malpractice resulting from the violation of Law No. 32/2006, of 26 July, [as] amended…as well as the lack of technical and safety conditions, defined by the CNPMA under the terms of Article 30(2)(b) of Law No. 32/2006, of 26 July, as amended…

Funding		Consultations and complementary acts prescribed in the SNS within the scope of the ART for couples of different sex, couples of women or women without a partner are considered acts provided within the scope of family planning for the purposes of applying user fees. Authorised public centres are financed through contracts with the Central Administration of the Health System, IP. The Ministry of Health may agree with authorised private centres to finance the use of PMA techniques.
Communication and information provision		No information identified.
Ethical considerations		The application of ART techniques in the absence of infertility further highlights the general requirement, for good medical practice and safety of care to be provided to beneficiaries of PMA techniques and provided there is a reasonable probability of success, to favour insemination artificial in relation to other ART techniques, given its lower intervention and invasiveness. It is also important to ensure that the use of ART techniques does not pose significant risks to the health of the mother and child, thus safeguarding their health and physical integrity. With the expansion of access to medically assisted procreation techniques, it is urgent to ensure the principle of equal treatment between new beneficiaries and beneficiaries who meet the requirements set out in articles 4 and 6 of Law no. 32/2006, of July 26, in its original version, favouring equity in access to ART techniques. It is therefore intended, through this regulatory decree, to achieve this access without exclusion, ensuring an adequate, safe and non-discriminatory provision of services, as set out in Law no. 17/2016, of 20 June. Regardless of whether the beneficiary is a couple of different sex, a couple of women or women without a partner, if the director of the ART centre understands that it is necessary to carry out a psychological assessment prior to the application of ART techniques, he must declare it to the beneficiary, and this assessment cannot be carried out without the latter's prior consent. It is lawful for the director of the ART centre not to authorise the application of ART techniques if the beneficiary refuses to carry out the prior psychological assessment provided for in the previous paragraph.
Relevant legislation (list)		Article 5 and paragraph 2 of article 16 of Law no. 32/2006, of 26 July, which regulates the use of medically assisted procreation (ART) techniques; Law no. 17/2016, of June 20, guaranteeing the access for all women to ART.
Miscellaneous		No information identified.

Table D.39 Extracted data for Scotland (Fertility Scotland)

Scotland		
Author(s) **Title [year]**	Fertility Scotland – NHS Scotland National Strategic Network Fertility Scotland[86] [2024] Annual Report 2021/22[87] [2022]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		Patients requiring preservation for medical purposes, for example when undergoing cancer or other treatments that may affect their fertility. [Note: eligibility criteria may vary for each of the 14 NHS Scotland regional health boards] In a leaflet titled "Information for patients wishing to freeze eggs or embryos for fertility preservation" it outlined:[88] In Scotland to be eligible for NHS funded fertility preservation treatment you must meet the following criteria: ▪ you must be less than 38 years of age ▪ your Body Mass Index (BMI) must be less than 35 ▪ you must have not have children ▪ Neither you nor your partner should have been sterilised. There may be other criteria that apply when you come to use your stored eggs or embryos, such as being a non-smoker. [Additional eligibility criteria from NHS Lothian Fertility Preservation Referral Form:][89] For NHS funded treatment, please confirm that patient meets <u>all</u> eligibility criteria shown: ▪ Patient is resident in Lothian or Borders (Patients from other health boards require funding approval from board of residence before treatment can commence.) ▪ Patient storing sperm is ≤55 years old ▪ Patient has no existing biological children / not the legal parent ▪ Estimated >30% chance of loss of fertility. The unit you have been referred to will be able to confirm if your treatment to freeze eggs or embryos, ongoing storage and the future transfer of embryos will be NHS funded. If not they will be able to confirm if you could pay for your own treatment and tell you the cost of this.
Preservation method(s) available		Cryopreservation of:[89] ▪ eggs ▪ sperm ▪ embryos.

Organisation	***Referral pathways***	[Note: Sample referral pathway information from NHS Lothian outlined below. Referral pathways may vary for each of the 14 NHS Scotland regional health boards.][90] **Referral Guidelines** For transgender patients requesting fertility preservation, the EFC only accepts referrals from the Chalmers Gender Identity Clinic. Please direct these patients there in the first instance. ***Who not to refer:*** Please do not refer if the female partner is >44 years of age, as there are no treatment options available in EFC. Patients can consider self-funded/private egg donation treatment: please refer them to the HFEA website. ***Secondary care (emergency) referrals*** For patients who want to discuss emergency fertility preservation please phone 0131 242 2450 and email the completed referral form and direct the referral as follows… [Email and telephone details provided].
	Service provider characteristics	… fertility services in NHSScotland in primary care (GP), secondary care (hospital or community setting) or tertiary care (specialised services) depending on the type and complexity of treatment required… Tertiary Centres perform a variety of specialised treatments ranging from in vitro fertilisation (IVF) and intra-cytoplasmic sperm injection (ICSI) to donor treatment and fertility preservation (for patients requiring preservation for medical purposes, for example when undergoing cancer or other treatments that may affect their fertility).
	Timelines to access services	No information identified
	Any other organisational aspects	No information identified
Storage	***Arrangements and duration(s)***	If you are eligible, the NHS will provide storage for 5 years in the first instance. After that time, storage will continue if you still meet the eligibility criteria. You may not, for example if you have had a child in the meantime: in this case, you may need to pay if you want your eggs or embryos to remain in storage.
	Access to stored materials	No information identified
	Disposal of stored materials	No information identified
	Any other storage information	Before eggs, embryos or ovarian tissue can be stored a blood sample must be taken. This will be done at your first visit the assisted conception service. The test screens for hepatitis B, hepatitis C and HIV. [Below information extracted Annual Report 2021/22, linked on website: Fertility Scotland National Network. Annual Report 2021/22 [Internet]. 2022. Available from: https://fertility.scot/wp-content/uploads/2022/08/2021-22-Fertility-Scotland-Annual-Report-v1.0.pdf]

		Progress in 2021/22 ***Fertility Preservation - Storage*** Deliverable: Establish common "Once for Scotland" paperwork for Fertility Preservation Storage. Progress: This work will commence in 2022. Benefits: i) Streamlined and consistent praactice. ii) Minimising duplication of effort across fertlity centres. **Work Plan 2022/23** ***Fertility Preservation - Storage*** Standardise national paperwork to comply with new UK storage regulation.
Governance		**About Fertility Scotland** In 2010, the Scottish Government established the National Infertility Group (NIG) to "… bring together fertility service representatives, key national bodies and stakeholder representatives to actively provide expert knowledge and advice to the development of existing and evolving Scottish Government policy on infertility and its implementation within NHS Boards." (NIG report 2013) Launched in 2021, Fertility Scotland is commissioned via NHS National Services Scotland on behalf of Scottish Government and will support NHS fertility services to learn from best practice, adopting a "Once for Scotland" approach and identify areas of improvement and develop work streams to address these areas. The network is led by a clinician Abha Maheshwari and scientist Joanne Leitch and brings together representatives across the fertility care sector including patient groups, doctors, nurses, scientists, managers and Scottish Government policy leads. Fertility Scotland includes senior managers, clinicians, nurses, scientists and patient representatives. **How is Fertility Scotland Governed?** Fertility Scotland is funded by the Scottish Government and ultimately responsible to the Scottish Government and the NHS Board Chief Executives to ensure delivery of improved care to patients and users of NHS Fertility Services in Scotland. The network consists of the Oversight Board, the Core Steering Group, Programme Management Team and Working Groups. In summary: ▪ The Oversight Board provides overall strategic leadership, endorses recommendations from the Core Steering Group and ensures the network remains focussed on delivery. ▪ The Core Steering Group provides a forum for interchange between working groups, the Programme Management Team and relevant stakeholders. The group makes recommendations to the Oversight Board. ▪ The Programme Management Team oversees the the day to day running of the Network, monitors progress and reports to the Core Steering Group and the Oversight Board. ▪ The Working Groups are established for each specific Project or Programme of work. [Below information extracted Annual Report 2021/22, linked on website:

		Fertility Scotland National Network. Annual Report 2021/22 [Internet]. 2022. Available from: https://fertility.scot/wp-content/uploads/2022/08/2021-22-Fertility-Scotland-Annual-Report-v1.0.pdf] The Network is funded by an allocation from Scottish Government.
Funding		[From NHS Lothian Fertility Preservation Referral Form:] For NHS funded treatment, please confirm that patient meets all eligibility criteria shown: ▪ Patient is resident in Lothian or Borders (Patients from other health boards require funding approval from board of residence before treatment can commence.) ▪ Patient storing eggs/embryos has BMI under 35 ▪ Patient storing eggs/embryos is ≤37 years old or Patient storing sperm is ≤55 years old ▪ Patient has no existing biological children / not the legal parent ▪ Patient has not previously undergone sterilisation ▪ Estimated >30% chance of loss of fertility.
Communication and information provision		No information identified
Ethical considerations		No information identified
Relevant legislation (list)		No information identified
Miscellaneous		No information identified

Table D.40 Extracted data for Scotland (Fertility & Cancer)

Scotland		
Author(s) **Title [year]**	NHS Inform Fertility and cancer[91] [2024]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		Fertility and cancer [no information on eligibility criteria identified]
Preservation method(s) available		**Fertility in Women** ***Preserving your fertility*** There are different ways of preserving your fertility: ▪ freezing eggs – your ovaries are stimulated to produce more eggs, these eggs are collected and then frozen ▪ freezing embryos – the collected eggs can be fertilised with sperm in a sterile dish – the sperm can be from a partner or donor; if the fertilised egg develops into embryos, these are frozen and stored ▪ if you later decide to try to get pregnant, the frozen eggs or embryos can be thawed and put into your womb. Scientists are researching a technique which involves removing and freezing ovarian tissue that may contain eggs. But very few babies have been born from this technique. **Fertility in men** ***Preserving your fertility*** It's sometimes difficult to know whether cancer treatment will affect your fertility. Your doctors may advise you to store some sperm, even if you have a low chance of becoming infertile. Your sperm can be used after cancer treatment to help you and a partner have a child. If you can't provide a sample of sperm, there are still options for storing sperm. It may be possible to take fluid or tissue straight from the testicle. Doctors may be able to collect sperm from your urine if you have retrograde ejaculation. Researchers are looking into other ways of preserving fertility. Speak to your doctors about these options, as they can tell you if they are suitable for you.
Organisation	***Referral pathways***	**Fertility in women** ***Talking about fertility before treatment starts*** Before your treatment starts, talk to your doctor or nurse about how your fertility may be affected. It's not always possible for doctors to predict what will happen. You may be able to visit a fertility expert before you start treatment to look at ways to increase your chances of having a baby later on. This depends on when your treatment has to start. ***Preserving your fertility***

		You may be referred to a fertility clinic for advice before you start cancer treatment. This depends on your age and type of cancer. Doctors will talk about options that may allow you to have a baby in the future. **Fertility in men** ***Talking about fertility before treatment starts*** Your cancer doctor can refer you to a fertility clinic straight away. This means that having your sperm stored won't cause too much delay to your treatment. But in some situations treatment has to start immediately, so sperm banking may not always be possible.
	Service provider characteristics	No information identified
	Timelines to access services	**Fertility in women** ***Talking about fertility before treatment starts*** You may be able to visit a fertility expert before you start treatment to look at ways to increase your chances of having a baby later on. This depends on when your treatment has to start. ***Using donated eggs, sperm or embryos*** Women without a partner who want to freeze embryos rather than eggs before their cancer treatment may choose to use donor sperm. It can take a while to find a suitable donor and this may cause too long a delay to cancer treatment. **Fertility in men** ***Talking about fertility before treatment starts*** Your cancer doctor can refer you to a fertility clinic straight away. This means that having your sperm stored won't cause too much delay to your treatment. But in some situations treatment has to start immediately, so sperm banking may not always be possible.
	Any other organisational aspects	No information identified
Storage	***Arrangements and duration(s)***	No information identified
	Access to stored materials	**Fertility in Women** ***Preserving your fertility*** ▪ if you later decide to try to get pregnant, the frozen eggs or embryos can be thawed and put into your womb.
	Disposal of stored materials	No information identified
	Any other storage information	No information identified
Governance		No information identified

Funding		**Fertility in Women** ***Using donated eggs, sperm or embryos*** Some women or couples who have been affected by cancer may choose to use donated eggs or sperm. This isn't funded by the NHS in all areas and there's also a shortage of donors, so it may not be an easy option. Women without a partner who want to freeze embryos rather than eggs before their cancer treatment may choose to use donor sperm. It can take a while to find a suitable donor and this may cause too long a delay to cancer treatment. **Fertility in men** ***Talking about fertility before treatment starts*** If you decide to have fertility treatment later, it is important to remember that NHS rules will apply to your partner as well as to you. Fertility treatment rules and funding vary across the UK. Talk to your fertility specialist about this.
Communication and information provision		**Fertility in women** ***Talking about fertility before treatment starts*** Before your treatment starts, talk to your doctor or nurse about how your fertility may be affected. It's not always possible for doctors to predict what will happen. Your age and planned treatment can help give an idea of your individual risk. Try to think about the questions you want to ask your doctor or nurse so you can get all the information you need. If you have a partner, it's usually a good idea to include them too. **Fertility in men** ***Talking about fertility before treatment starts*** Being told you have cancer and that treatment may make you infertile can be very difficult. For some men, the possibility of losing their fertility may be as difficult to accept as the cancer diagnosis. It's important to talk to your cancer doctor or specialist nurse about fertility before starting treatment. Think about the questions you want to ask so you can get all the information you need. If you have a partner it's usually a good idea to include them too. If treatment can make you infertile, your doctor should talk to you about having your sperm stored before treatment starts. This is sometimes called sperm banking. It means you and a partner may be able to have a child later on, even if treatment makes you infertile. ***Getting support*** Infertility can be distressing to live with. Having children is an important part of many people's lives or their future plans. It may seem especially hard when you're already coping with cancer. Not knowing whether your fertility will come back or not can be hard to cope with. Some people find it helpful to talk things over with their partner, family or friends. Others might prefer to talk to a trained counsellor. Your GP or cancer specialist can arrange this for you. Many hospitals also have specialist nurses who can offer support, and fertility clinics usually have a counsellor you can talk to.

		Talking to other people in a similar position may help you feel less isolated. Some organisations can arrange this for you as well as providing specialist advice and counselling. Or you can talk to people online. The Macmillan online community [cancer support charity] is a good place to talk to other women or men who may be in a similar situation.
Ethical considerations		**Fertility in Women** ***Using donated eggs, sperm or embryos*** Choosing to use donated eggs, sperm or embryos is a difficult decision and it isn't going to suit everyone. Some religions are against any type of fertility treatment; others are against using donors. Talk to your partner, family or religious advisor about any concerns you have. You can also talk to the staff at the fertility clinic about this. **Fertility in Men** ***Preserving your fertility*** If you decide to store sperm, you will have to sign a consent form.
Relevant legislation (list)		No information identified.
Miscellaneous		No information identified.

Table D.41 Extracted data for Scotland (Endocrine & Fertility Preservation)

Scotland		
Author(s) **Title [year]**	NHS Scotland – National Gender Identity Clinical Network for Scotland Endocrine and fertility preservation guidance[92] [2022]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		This guidance relates to people…who are over the age of 16 and who have completed puberty. …the principles of provision and criteria for accessing NHS funded fertility preservation (FP) for transgender, non binary and gender diverse (TGD) people… The over-riding principles of access to NHS funded fertility preservation are that: ▪ A specific, imminent and significant risk to the patient's fertility is identified. Quantifying that risk is difficult and may be uncertain at the time of referral, but where it is clinically judged to be low (estimated on available evidence to be <30%), FP will not be offered. ▪ A pathway of medical intervention exists that has the potential to successfully address the risk to the patient's fertility. ▪ There is a route to achieving a successful pregnancy and birth of a child for that patient in the future. ▪ Any clinical risks to the patient from the required intervention (and where relevant, of subsequent pregnancy) are identified. ▪ Long-term survival of the patient is expected, with the ability to be able to use their stored gametes. ***3.6.Access criteria*** The principle for these is that they should largely be in line with nationally agreed access criteria for assisted reproduction, while recognising the special circumstances surrounding fertility preservation. All NHS patients will be assessed using the same equitable criteria for treatment and storage. 1. For those storing eggs/embryos, BMI needs to be under 35. This differs from IVF criteria (due to time constraints). 2. Upper cut off age for oocyte/embryo/ovarian tissue fertility preservation should be 41. 3. There is a need for an upper age limit for those storing sperm, although this is based on less clear grounds. The group considered that 53 years is an appropriate age limit for those storing sperm because of increasing risk to offspring with paternal age. 4. The individual proposing to store gametes will have no biological children, or not be a legal parent. 5. Previous sterilisation will preclude access. 6. Smoking would not preclude access to storage; however where there is time, patients should be strongly encouraged to stop smoking. 7. Being in a stable relationship is not a relevant criterion for access (or ongoing storage) 8. If they are in a relationship, whether the partner meets IVF access criteria (for example BMI) is not relevant.

Preservation method(s) available		This document considers only fertility preservation through gamete/ovarian tissue cryopreservation for those who are pubertal or adult. Egg/embryo storage: one cycle of ovarian stimulation will be offered. When it is considered that the ovarian stimulation regimen did not result in an optimal response for that patient, a second stimulation may be considered. The number of eggs stored is not the basis for whether a second cycle is offered. Sperm storage: this may involve the storage of sperm obtained from more than one ejaculate or a surgical sperm extraction procedure. Centres may offer storage of up to 3 ejaculates, but this may be limited by the time available and may not be necessary if the sample quality is high.
Organisation	***Referral pathways***	***3.1.Referral pathways and initial assessment considerations*** Pathways for referral need to be developed locally that ensure timely receipt of referral from relevant clinical services. A template referral form should be used by the referring gender identity clinic (GIC) (consultant or specialist nurse) giving an outline of the diagnosis and proposed treatment, other relevant medical issues, and documenting completion of any relevant initial tests. ***3.2.Specific issues regarding TGD individuals*** 1. Referral pathways: only patients who have been assessed and referred by the GIC as suitable for gender reassignment will be considered. Initial discussion of fertility preservation will be provided by the GIC prior to referral, when early information provision about the effect of gender reassignment on fertility and fertility options will be provided. The HFEA has developed specific information related to this (https://www.hfea.gov.uk/treatments/fertility-preservation/information-for-trans-and-non-binary-people-seeking-fertility-treatment/). 2. An appointment with the fertility clinic counsellor should be arranged initially. 3. Discussion will include consideration how the gametes will be used in the future as well as just storage, although it is recognised that there may be considerable uncertainty about potential use when patients are just about to start on hormones or other treatment and options must be kept open. Options may include surrogacy or stopping gender affirming hormone treatment. 4. The effect of trans-endocrine treatment on fertility is considered reversible, however it is likely that many people would not want to stop treatment once initiated for the several months that would be required. Guidance on the appropriate pathway for people already taking gender-affirming hormone treatment is given in the next section. 5. Clinics need to be sensitive to dysphoria and should provide gender-neutral signage whenever possible. Transvaginal egg recovery is a central part of the process of egg storage. Transabdominal egg recovery is only appropriate where the ovaries are physically not accessible transvaginally. 6. Some people may later choose or require surrogacy. This may not be known at the time of gamete storage and has issues for whether subsequent use will count as 'gamete donation' and thus what clinical activities/tests are required. Please see Appendix 2 for details of how to approach this.
	Service provider characteristics	***3.1.Referral pathways and initial assessment considerations*** There are four NHS Fertility Centres in Scotland that provide fertility preservation for those patients that require this treatment.

	Timelines to access services	***3.3.TGD patients already taking gender-affirming hormone treatment*** While it is preferable for TGD people to store eggs or sperm before starting gender-affirming hormone treatment, sometimes this is not possible, and consideration must be given to how best to manage that situation. In some cases, it may be considered more appropriate to defer gamete storage (perhaps for years) despite imminently starting gender affirming hormone treatment, to allow continuing consideration of the wish for such storage. Gamete storage can be considered at any time up until surgical removal of the gonads.
	Any other organisational aspects	No information identified.
Storage	***Arrangements and duration(s)***	***3.10. Ongoing NHS storage of gametes*** Current HFEA regulations use duration of storage rather than age. The main upper age limit for NHS IVF treatment in Scotland is a female age of 40 however Scotland follows the NICE guidance which allows for women aged 40 to 42 to have one cycle of NHS IVF treatment if they meet certain criteria, therefore gametes in storage after that age cannot be used for NHS treatment. 1. The above access criteria specify the cut off age for starting storage of gametes should be 41 for egg/embryo storage and 53 for sperm storage, at time of storage (that is fertility preservation treatment to be initiated before 42nd/ 54th birthday). 2. Patients should have a 5 year follow up initiated by the fertility clinic that provided storage (with further assessment as required) to assess whether it is appropriate to continue NHS funded storage. 3. Not being in a stable relationship is not a relevant criterion for either initiating storage, or for ongoing storage. 4. Young patients may need to store gametes for a very long time. 5. If at follow up review the patient is not eligible (for example now has children, or age >42 for oocyte storage or 55 for sperm storage, that is up to 43rd/56th birthday) then ongoing NHS funded storage will not be provided. A review appointment offers the opportunity for discussion/assessment (potentially also with an appointment with the fertility clinic counsellor) without denying ongoing storage, which may need to be at the patient's own expense. 6. It is considered that a normal semen analysis indicates likely fertility, and certainly shows the presence of sperm which could potentially be used in assisted conception. If at the 5 year appointment or thereafter the patient is shown to have a normal semen analysis, there should be a discussion regarding disposal of stored sperm; or alternatively, ongoing storage will need to be at the patient's expense. If however the sperm count is found to be low then ongoing storage will be provided. If the patient does not provide a semen sample, further storage at NHS expense will not be provided, and the stored samples will be disposed of or with further storage at the patient's expense. 7. Regular menstrual cycles or biochemical tests of ovarian function should not be used as grounds for disposal or charging for ongoing storage of oocytes, where other criteria for access to NHS treatment are still met. 8. A patient contract is considered the best way of combining these aspects of duration of storage, the need to reassess eligibility, and self-funding of further storage. This needs to be completed at the time of storage.

	Access to stored materials	It is essential that patients recognise that full IVF access criteria will apply when it comes to using stored material for assisted conception in an NHS setting.
	Disposal of stored materials	No information identified.
	Any other storage information	**Appendix 5: Gamete storage for use by 3rd party reproduction** Some patients undergoing gamete storage may subsequently require 3rd party reproduction (donation and surrogacy). For this, they are considered to be gamete donors, requiring additional screening tests, as specified in the current HFEA Code of practice that the donor is tested for cystic fibrosis, karyotype, cytomegalovirus, syphilis and gonorrhoea and blood group (in addition to standard viral testing) and completes a questionnaire regarding risk of genetic disease. All individuals undergoing gamete storage should be assessed as to the potential need for 3rd party reproduction, recognising that the individual's situation in the years to come is difficult to predict. This applies equally to those storing sperm and eggs, and it is important to recognise that this possibility should be discussed (and recorded) with all patients proceeding to fertility preservation procedures. If there is considered to be a possibility of needing 3rd party reproduction, the following approach should be taken: ▪ Infection-related tests should be done at the time of gamete storage, with medical/behavioural/social questionnaire ▪ Karyotype, blood group and CF screening should be done at time of gamete use, not at the time of gamete storage. ▪ Genetic questionnaire: to be completed at the time of gamete use. Not doing these tests at time of storage will not preclude later use in donation, except where infection tests are positive at time of potential donation and would have been negative at time of storage (but were not done).
Governance		***3.1.Referral pathways and initial assessment considerations*** In many cases the decision to proceed to fertility preservation can be made simply and quickly. However, for more complex cases, discussion by a review group with multi-disciplinary expertise from all four Scottish Fertility Centres has now been established and should be used to help with decisions to ensure that these are consistent between the centres. Record keeping will allow past decisions to be recalled. Documentation of the key issues raised by the case, the decision made and the outcome will be recorded to allow reference to previous decisions. ***3.11. Data Collection*** It is important that information regarding use of NHS resources is collected, and this will become a valuable and robust data set informing future service development. Information to be collected includes: 1. Number and source of referrals 2. Number of patients proceeding to fertility preservation; their characteristics for example age, diagnosis) and FP results (for example no of eggs) 3. Ultimately, data on usage/other outcomes. ISD have developed a data capture form which has been circulated to all centres to start using immediately, with the opportunity for revision to improve functionality. Centres will send completed

		forms to ISD monthly to align with their IVF returns. ISD will collate data at quarterly intervals. Centralised storage by SNBTS will allow collection of these data with sample storage: this is being developed.
Funding		Travel costs for patients where required will be met. ***3.7.Treatment to be offered*** Egg/embryo storage: one cycle of ovarian stimulation will be offered. When it is considered that the ovarian stimulation regimen did not result in an optimal response for that patient, a second stimulation may be considered. The number of eggs stored is not the basis for whether a second cycle is offered. Sperm storage: this may involve the storage of sperm obtained from more than one ejaculate or a surgical sperm extraction procedure. Centres may offer storage of up to 3 ejaculates, but this may be limited by the time available and may not be necessary if the sample quality is high. ***3.12. Funding options considered*** The Fertility Scotland Strategic Plan has been approved by NHS National Services Division. Fertility Preservation is included in this plan.
Communication and information provision		**1. Masculinising gender affirming hormone treatment** ***1.5.Advice on the impact on fertility, contraception and pregnancy*** *Fertility* People should be made aware that hormonal preparations impair fertility. Prior to starting testosterone, future fertility options need to be explored. Should the person wish to preserve their fertility then referral to the local fertility clinic or fertility preservation team should be made, ideally prior to starting full dose testosterone treatment. **2. Feminising gender affirming hormone treatment** ***2.6.Fertility and contraception*** *Fertility* Prior to the initiation of feminising gender affirming hormone treatment the individual should be made aware that hormonal preparations impair fertility. Prior to starting feminising treatment, future fertility options need to be explored. Should the person wish to preserve their fertility then referral to the local fertility clinic/fertility preservation team should be made, ideally prior to starting full dose hormone treatment. **3. Provision of Fertility Preservation in NHS Scotland** It is important that all relevant patients are offered a consultation with an appropriately trained medical/paramedical member of staff, and that there is provision of information on the full range of methods for fertility preservation that might be appropriate for that individual. In general, this discussion will take place at the referring clinic (that is the gender identity clinic [GIC]) with referral to assisted reproduction only where the patient is keen to proceed to a fertility preservation procedure, and access criteria are met. It is recognised that the details of relevant procedures are likely to be outwith the

		knowledge of staff at the GIC, but such staff should have sufficient knowledge to be able to provide initial information, and signpost patients to further information. ***3.8.Information provision*** Patients should be provided with verbal and written information at all stages, that is both in the referring clinic and in the assisted reproduction clinic. The use of Near Me in conjunction with the "Language Line" telephone interpretation service and "face to face" language or British Sign Language (BSL) interpreters may be appropriate for non-English speaking people. Patient information leaflets in line with this guidance are available (Appendix), for sperm and egg storage. Information is available from the HFEA website (including information specific for TGD people): https://www.hfea.gov.uk/treatments/fertility-preservation/
Ethical considerations		***3.4.For egg cryopreservation*** The procedures required prior to oocyte cryopreservation, such as hormonal ovarian stimulation and transvaginal ultrasound (TVS), have a negative impact on gender dysphoria; successful management requires sensitivity and awareness of these issues, for example offering transabdominal ultrasound monitoring (Armound et al 2017). ***3.5.For sperm cryopreservation*** The procedures for sperm cryopreservation may have a negative impact on gender dysphoria; successful management requires sensitivity and awareness of these issues. ***3.9.Counselling*** Access to a specialist fertility Counsellor will be offered to patients prior to their giving consent to treatment (on, among other things, the implications of taking the proposed steps) and following fertility preservation. The HFEA Code of Practice states that fertility centres should provide a suitable opportunity for counselling after the individual or couple has received oral and written information about the services to be provided and before they consent to treatment, donation, or to the storage or use of gametes or embryos. The HFEA also state that the centre should provide proper counselling throughout the treatment, donation or storage processes, and afterwards if requested.
Relevant legislation (list)		No information identified.
Miscellaneous		**Introduction** The guidance development group convened by National Services Division (listed in an appendix 6) had diverse professional and lived experience. While previous versions of this and other guidelines as well as primary research were used in developing this document, it is recognised that the evidence base remains incomplete and that there is variation in acceptable practice, which will therefore evolve over time. In this document we have aimed to outline what is currently considered best practice for safe and effective care as applicable within NHS Scotland for endocrine management and fertility preservation in this field. **3. Provision of Fertility Preservation in NHS Scotland**

		Fertility preservation is a relatively new speciality with an emerging evidence base. The recommendations…are therefore based largely on national and international guidelines (for example WPATH and the European Society for Human Reproduction and Embryology [ESHRE]), and taking into account the current provision of assisted reproduction services in NHS Scotland.

Table D.42 Extracted data for Sweden (Preserving Reproductive Capacity of Adults)

Sweden		
Author(s) **Title [year]**	The Tissue Council (Sweden) Measures to preserve the reproductive capacity of the adults: promotion of equal care for patients at risk of treatment-induced infertility [2023][93]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		Patients at risk of treatment-induced infertility, where treatment with chemotherapy, radiation or surgery can lead to infertility. It does not apply infertility risk that is congenital or directly caused by disease or injury. It is important to consider these treatment-related injuries as a separate category and create own regulations, which may differ from those that exist for assisted living fertilisation due to infertility. Treatment-induced infertility also includes egg or sperm retrieval for a person with gender dysphoria before the start of treatment with gender-affirming hormones and or removal of gonads. From a resource perspective, it is appropriate with a 40-year limit for freezing eggs or embryos. This age limit is the one that generally applied in assisted fertilisation in Sweden for publicly-funded clinics. When it comes to ovarian tissue, there are different age limits internationally, such as varies between 30 and 35 years. When the tissue is retransplanted, it takes up to one week to revascularise and during this period a significant percentage of eggs are destroyed. Therefore, it is appropriate to have a lower age limit for saving ovarian tissue than for egg freezing. For men, there has long been a limit of 56 years for treatment with assisted reproduction at a publicly-funded clinic. The assessment has then been made that this age limit makes it possible for the man to participate during the child's upbringing. The following age limits have therefore been set: ▪ Oocyte vitrification: <40 years of age ▪ Embryo freezing: <40 years of age ▪ Ovarian tissue freezing: <32 years of age ▪ Sperm freezing: <56 years of age For all the measures, the person who is to undergo them is publicly-funded fertility preservation measure previously have a maximum of 2 children as this is legal parent to. This is regardless of whether any partner is also a parent of the children, a new partner exist without common children or if the person is single. Referral for fertility preservation measure must contain information on the number of children.
Preservation method(s) available		**Measures of preservation** *Women:* - save and vitrify (freeze) mature oocytes (eggs) after hormone stimulation - preserve and freeze embryos (fertilised eggs) after hormone stimulation

		- Preserve and freeze ovarian tissue (ovary tissue). This method has showed good results in adult women, but is still considered inferior development. The method can be offered when other options are not applicable, for example if the patient needs immediate cancer treatment, or if the patient does not wish to/cannot undergo hormonal stimulation and transvaginal egg aspiration. **Decision support for selection of appropriate intervention** Treatment that entails a low risk of infertility (see table below): If it is well known that the effect on the ovaries is not likely, it is generally recommended not any reproductive preservation measure before cancer treatment begins. After completed cancer treatment, in individual cases a follow-up can be done to investigate possible effect on fertility. Treatment that entails an intermediate, high or very high risk of infertility or where the risk of infertility is unknown: Women must - if there is time - be offered hormone stimulation, egg retrieval and oocyte/embryo vitrification. There are many years of experience in freezing embryos while oocyte vitrification is a newer technique. Embryo freezing has previously been considered to be the method where one can with the greatest certainty provide information about the result at a later date use. Nowadays there is a lot of experience with the use of vitrified oocytes, which gives comparable results as when using fresh eggs. There is also psychological and legal advantages of oocyte vitrification that should be considered when choosing method. If for example the couple later separates, frozen embryos cannot by law be used. In addition, embryos have a permitted freezing time of 10 years, while the freezing time for eggs is not limited, which can be an important aspect if the woman is younger at the time of freezing. When immediate start of gonad-damaging treatment is necessary, an offer of freezing of tissue from the ovary is considered, unless there are contraindications. Risk of early menopause: Some of the treatments given to young women do not give an immediate total ovarian failure. Most people regain their reproductive capacity. However, there is a risk of one shortened fertile period, which can vary from quite insignificant to significantly shortened. If threatened ovarian failure is suspected, referral to a reproductive medicine unit should be made issued to assess whether fertility preservation measures can be implemented, as well as to the woman must receive an assessment of her fertility potential. The forecast for the future ovarian function can be assessed by measuring AMH (anti-müllerian hormone), FSH, estradiol and by ultrasound of ovaries with assessment of the number antral follicles (AFC) Transposition of ovaries: This is a surgical method to move the ovaries out of a planned radiation field that can be relevant at for example treatment of cervical cancer, rectal cancer and Hodgkin's lymphoma. The method is now rarely used. Known complications are risk of vascular damage, benign ovarian cysts, chronic pelvic pain and ovarian migration that is that the ovary spontaneously moves back down into the small pelvis. Despite transposition, the ovary may lose its function and therefore parallel freezing of ovarian tissue is recommended as an alternative vitrification of oocytes/embryos.

		Treatment with GnRH agonist: For forms of cancer other than breast cancer, there is no evidence that simultaneous treatment with GnRH (Gonadotropin releasing hormone) agonist provides improved fertility after the cytostatic treatment. Treatment with GnRH agonists for the purpose of fertility preservation in breast cancer should be considered as complementary and should not replace the established methods of freezing of oocytes and embryos. *Men:* - save and freeze ejaculated sperm - freeze spermatozoa after aspiration from epididymis and or testis or extracted from open testicular biopsy. *People with gender dysphoria:* - save and freeze ejaculated sperm - freeze spermatozoa after aspiration from epididymis and or testis or extracted from open testicular biopsy - preserve and vitrify mature oocytes after hormone stimulation - preserve and freeze embryos (fertilised eggs) after hormone stimulation - preserve and freeze ovarian tissue (ovary tissue). **Decision support for selection of appropriate intervention** Treatment that entails a low risk of infertility (see table below): For this group, sperm freezing should only be offered exceptionally. After completion cancer treatment, in individual cases a follow-up can be done to investigate possible fertility impact. Treatment that entails an intermediate, high or very high risk of infertility or where the risk of infertility is unknown: The man must be offered cryopreservation of sperm prior to the start of cytostatic treatment or radiotherapy where the testicles are in the radiation field. If he cannot leave one ejaculate with live sperm, can invasive procedures by aspiration from epididymis/testis or open biopsy from testis is considered. *People with gender dysphoria:* - Since 2013, patients with gender dysphoria can be offered fertility preservation measures such as led to gender correction to perceived gender. - Fertility preservation measures are also offered to patients who feel that they are either as male or female, but desires hormonal treatment that deviates from that congenital sex. - Below, the terms transwoman and transman are mentioned. A trans woman has assigned male gender at birth and corrected to female gender. A transman has assigned female gender at birth and corrected to male gender. *Trans women:* Patients are offered sperm freezing. Age rules apply as at fertility preservation measure for another reason. If the patient is already under hormonal treatment may be interrupted and a semen sample submitted after 2–3 months at the earliest. If no sperm is found, a new sperm sample is given on a few more occasions up

		to six months. Regular ejaculations improve sperm quality, which the patient should be informed about. In case of persistent azoospermia (absence of sperm) after 6 months the patient should be examined according to standard guidelines and aspiration from epididymis or testicular biopsy is considered. *Trans men:* Patients are offered freezing of oocytes after customary hormonal stimulation treatment before the start of planned opposite sex hormonal treatment. Age rules apply as in the case of fertility preservation measures for other reasons. About the patient lives with a biologically born man where the couple otherwise meets conditions for assisted living fertilisation, embryos can also be frozen. The embryos are then the couple's and may only be used of the couple jointly. The same rules for frozen storage time of embryos apply as for other couples. Transmen with remaining fertile capacity, but who are under the gender opposite hormonal treatment, in case of fertility wishes, can end this treatment and then undergo stimulation and oocyte or embryo freezing. Trans men with preserved fertility can undergo treatment with insemination or IVF which single, and this even after changing legal gender. In the legal text, however, the whole is written the time "the single woman" and it may be unclear how this should be interpreted. It is suitable in the long term with gender-neutral legal text. **<u>Assessment of appropriate action</u>** - *Established methods or methods under development* An important question is whether a reproductive conservation measure should be taken before that there is a useful method by which the saved material can be used for future always done individually, depending on the clinical situation and in consultation with fertility treatment. Young adults who today undergo gonad-damaging treatment may not be relevant for parenthood for several years. This is a research-intensive area where new methods in the future may have been developed and established. The assessment is therefore that if it is reasonable based on the clinical situation harvesting tissue from the ovary or testicle can also be considered in those cases there is currently no clinical method for using the material. - *Risk of infertility* Gonad-damaging treatment, such as cytostatics and radiation therapy and surgery for cancer, increases the risk of infertility to varying degrees. Since a treatment usually consists of a combination of several preparations, the risk increases of a specific drug difficult to evaluate. In addition to this, there are probably individual differences between people when it comes to this sensitivity to the gonad-damaging effect of one and the same drug. We don't have today sufficient knowledge of how large these individual differences are and no methods yet to identify particularly sensitive individuals. In recent years, new ones have been developed classes of anti-cancer drugs, such as monoclonal antibodies, tyrosine kinase inhibitors and immunological drugs. What effect these drugs has on fertility is still unknown. Women's and men's fertility can be permanently or temporarily affected by the cancer treatment. [Further information around the impact of cancer available, but not extracted].

		- *Risk groupings* ▪ Cytostatics Below the classification of the infertility risk caused by some different cytostatics and radiation doses, in cases where there is known knowledge of the risk of damage. Those preparations where the facts are insufficient to make such a risk assessment, as well as several combination treatments with different preparations and risk profiles are not included. The classification can be used as a rough estimate of the infertility risk in it individual case, where the total treatment with possible additive negative effects of the different preparations, the number of courses given, the type of disease the patient is being treated for and the patient's age may be factored into the risk assessment.

Table of cancer-treating preparations and associated risk of gonadal damage

	Low risk (<20%)	Intermediate risk	High/very high risk (ÿ80%)
Men	Wine rack Methotrexate Bleomycin Vinblastine 5-FU Etoposide Dacarbazine ABVD x 2-4 BEP x 1–2	Cisplatin <500 mg/m2 Carboplatin CHOP x 6 CHOEP ABVD x 6	Cyclophosphamide (high cumulative doses) Ifosfamide (high cumulative doses) Procarbazine Cisplatin >400 mg/m2 Radiotherapy ÿ2.5 Gy to the testis (possibly reversible damage) BEACOPP esc Autologous SCT Allogeneic SCT
Women	Vincristin Methotrexate Bleomycin Vinblastine 5-FU ABVD x 2–4 CHOP x 3	Cisplatin Carboplatin FEC in women 30–39 years ACx4 in women >40 years Taxanes Bevacizumab	Cyclophosphamide (high cumulative doses) Ifosfamide (high cumulative doses) Procarbazine FECx6 in women >40 years Radiotherapy to ovaries ÿ6 Gyÿ BEACOPP esc >30 years

	CHOEP x 3 FEC x 6 in women <30 years AC x 4 in women <40 years Tamoxifen AML treatment** ALL treatment**	Radiotherapy against ovaries 2 Gyÿ BEACOPP esc <30 years ABVD x 6 CHOP x 6 CHOEP x 6	Autologous SCT Allogeneic SCT	

(SCT: Stem Cell Transplantation, AML: Acute Myeloid Leukemia, ALL: Acute Lymphocytic Leukemia; 5-FU, ABVD, BEP, CHOP, CHOEP, FEC, AC, BEACOPP escalated: short names for cancer-treating preparations or combinations of preparations, Gy: Gray; a unit of measurement for radiation dose)

ÿ2 Gy corresponds roughly to the dose where approx. 50% of the follicles die. However, this dose is dependent on ovarian reserve and the patient's age

** Without subsequent allogeneic SCT

▪ Radiation treatment

The gonads of both men and women are very sensitive to radiotherapy. The damage on ovaries/testicles depends on the fractionation of the radiotherapy, total dose and on the spread of the radiation field. Treatment that produces secondary effects on the gonads, such as high doses of radiation against pituitary gland/hypothalamus, is not included in the above table because external hormone treatment with pituitary hormones can restore fertility in these cases.

[Further information on the impact of radiotherapy on the fertility of men and women is available, but not extracted].

▪ Surgery

In cases where the gonads are surgically removed as part of the cancer treatment the patient obviously has fertility problems. In for example ovarian cancer you can't carry out oocyte vitrification due to the risk of spreading the cancer if you stimulate and aspirate from the ovaries. If the uterus is missing, there is none with today's legislation possibility of treatment either with own or donated oocytes. An opportunity for these patients could be uterus transplant in the future. The children born after uterine transplantation has been the result of research, not regular care and treatment.

- *Risks with the fertility preservation measure*

▪ *Men*

		Production of sperm via masturbation is an action without medical risk and provides a good opportunity to preserve fertility for the future. If the patient's general condition does not allow him to leave the ward, logistics should be arranged for the transport of sperm sample to the responsible tissue establishment. If the general condition is so bad that If masturbation is not possible, other measures such as surgical extraction of sperm can be used discussed with specialist doctors in reproductive medicine, if there is time for this. Cancer treatment and prognosis must always be prioritised. Specific risks for certain procedures: Aspiration of sperm from epididymis/ testis: May cause bleeding and swelling in the scrotum and pain. Testicular tissue extraction (biopsy): May cause bleeding and swelling in the scrotum and pain. There is a theoretical risk that the biopsy from the testicle may cause a disturbance of the normal testicular function and could then be a risk factor in itself for reduced future fertility. ▪ *Women* For women, more invasive measures are required to be able to save eggs or ovarian tissue. A requirement to carry out invasive measures in reproductive conservation purpose is that these interventions should not entail an unreasonably increased risk with regard to the patient's status and to the underlying disease. Such risks rarely exist, however cancer patients are generally ill at diagnosis, which means an increased risk of bleeding, risk of thrombosis, risk of anaesthesia and risk of infection. The patient's general condition must permit the action. If there is a risk of tumour spread in connection with the procedure, reproductive preservation measures not offered. Specific risks in certain interventions: Hormone stimulation and oocyte vitrification: The risk of overstimulation syndrome can be minimised by special stimulation protocol. To undergo the hormone stimulation requires 10–14 days, which is why this treatment is only offered to patients there cancer treatment initiation and planning allows it. It is therefore important to referral to reproductive medicine unit early in the course. For those people who risk early menopause, but where the treatment has not eliminated ovarian function completely, oocyte freezing can be performed even after chemotherapy has been completed, however at the earliest six months after completion of treatment. Ovarian tissue freezing: If there is a very high risk of future infertility, an entire ovary can be saved or ovarian biopsies. Surgery may involve a risk of complications such as bleeding and infection. - *Risks of returning cells/tissue* In for example leukaemia's there is a high risk that the ovarian biopsy may contain tumour cells. Contamination can also occur with some solid tumours. At contamination with tumour cells, the tissue cannot be used for re-transplantation. Methods under development could in the future enable maturation of oocytes or sperm where contamination can be ruled out. Therefore, in some cases it can be suitable for handling even contaminated tissue. It is important to be clear in the information to the patient about this. - *Possibility that fertility can be preserved with the performed measure*

		The possibilities that exist today to use cells or tissue that are taken into use must be considered when deciding on interventions. ▪ There are good conditions for preserved fertility when oocytes are vitrified. A decisive factor for the chance of achieving a full-term pregnancy is the number vitrified oocytes. By doing hormone stimulation with gonadotropins is it possible to get many eggs out at one time. However, there is one individual response to the stimulation. One should aim for as large a number as possible, because there is often only time to do a single stimulation before cancer treatment needs to be initiated. The chance of children through fertilisation thawed oocytes are today comparable to the results when using fresh ones oocytes. ▪ Optimal time for a pregnancy after undergoing cancer treatment varies with tumour type and between different patients. The decision should be based on the patient's age, ovarian reserve and the individual risk of a possible relapse. The decision on the fertility treatment to achieve a pregnancy must be taken in consultation with the treating oncologist ▪ In Hodgkin's and breast cancer patients, it has not been seen that pregnancy itself would mean a risk of relapse. ▪ Retransplantation of frozen ovarian tissue taken from adult women has resulted in several pregnancies both in Sweden and internationally. Birth of more and more children has been reported both after in vitro fertilisation of retrieved eggs from the transplants and after spontaneous pregnancies where ovarian tissue has been retransplanted. The method is still considered under development. There are good conditions for freezing sperm. Sperm survival after freezing varies greatly between different people but can also be affected by freezing method. It is important to aim for a sufficient amount of sperm to be frozen for several future fertility treatments, for example, several ejaculates may be needed be left. ▪ When taking tissue from the testicles, the result depends entirely on whether you can find sperm or not in the material. Methods of sampling, preparation, freezing and thawing of the material are critical. - *Medical risks for future children* There is currently limited knowledge about the outcome for children who are born after fertility preservation measures for parents who have undergone cancer treatment. This one group will increase in the future. An organised careful follow-up of the children which is born should be done for example with coordination of existing registers such as Medical the birth registry and the Cancer Registry and through international cooperation. - *Recovery of germ cells after completion of cancer treatment* If recovery and freezing of gametes could not be carried out before cancer treatment, then for certain patient groups this can be done after completion primary treatment. This applies above all to women where gonadal damage, combined with increasing age, causes her to have a continuous deterioration of ovarian function and risks early menopause. In case of recurrence of cancer, where there is still curative treatment, can recovery and freezing of germ cells be done before starting a

		new cancer treatment? Optimal timing for fertility preservation measures after termination cancer treatment is not established, but the clinical should wait at least six months after finishing treatment. For breast cancer there is one recommendation that because of tamoxifen's teratogenic effects and long half-life, the preparation should be withdrawn at least 2 months before trying to conceive. Regarding trastuzumab, it is considered safe the preparation has been exposed 3 months before pregnancy. In men, any long-term recovery of sperm production depends on which treatment the patient has undergone and there may be reason to check sperm sample several years after completed treatment. During ongoing treatment with testosterone for hypogonadism this must stop for about 3-6 months to sperm production must be able to be evaluated.
Organisation	***Referral pathways***	Fertility preservation measures require specialist knowledge in reproductive medicine and can be performed at the country's university hospitals. Routines for referral flow may be drawn up locally within the regions.
	Service provider characteristics	Fertility preservation measures require specialist knowledge in reproductive medicine and can be performed at the country's university hospitals.
	Timelines to access services	The time aspect is very essential. It is important to initiate any fertility preservation measures early in the course. Referral must reach reproductive medicine unit as soon as the diagnosis is established and a preliminary treatment plan is available. This can be even before the patient arrives at the treating clinic. **Follow-up** Women should 6-12 months after completing gonad-damaging treatment, or at the latest at final visit to a cancer treatment clinic, a referral to a specialist doctor is offered in reproductive medicine for evaluation of the reproductive capacity. Frozen eggs should not be destroyed until the woman has reached the age when fertility is normal strong decline. Men who have undergone gonad-damaging treatment should no later than one year after completion gonad-damaging treatment is offered to provide sperm samples for control and follow-up with specialist doctors in reproductive medicine. One should not destroy frozen samples even if the control samples are of normal quality, then this patient group has a certain risk of relapse and long-term effects are not known in detail either sperm quality.
	Any other organisational aspects	Recovery, preparation and use must be documented to achieve full traceability in accordance with the regulations for tissues and cells for use on person. In addition to this documentation, the following must be documented in the event of measures for preservation of the reproductive capacity of women and men as well as people with gender dysphoria. 1. The information received by the patient about measures for the preservation of the reproductive capacity and the decision on action must be documented and kept as a journal document. The documentation should include descriptions of how risk versus benefit was weighed, how the information and consent process went, what the patient's considerations and stances were and the decision reached. 2. Agreement and Consent to freezer storage of germ cells/gonadal tissue must be documented and signed by the patient. The clinic/tissue facility is responsible for this being done. The document templates *Consent regarding frozen storage of sperm/testicular tissue respectively Consent regarding*

		frozen storage of unfertilised oocytes/ ovarian tissue can be used. The consent documents must be kept in the patient's medical record. 3. After the freezing of the germ cells/gonadal tissue, the patient and referring doctor receive confirmation letter about the results of the freezing. Results and given information must be documented in the patient's medical record.
Storage	***Arrangements and duration(s)***	Patient who dies There are no biological or national regulations for sperm and oocytes time constraints. Freezer storage time may be regulated at regional level for public healthcare but does not normally include private healthcare. For storing fertilised eggs (embryos) there is a maximum frozen storage period of 10 years, but exemption for extended storage can be permitted by the Judicial Council, the National Board of Health and Welfare. Information about these regulations should be included in the patient information that the patient must receive at the freezing time. *[requirements arising from the tissue regulations]* Information and consent to the storage of gametes and tissues Applicable parts of the Biobank Act (2002:297) also apply to tissues and germ cells which must be kept for self-donation, that is for fertility preservation measures. One an important part is the requirement for information and consent. For tissues and cells to get stored, it is required that the patient has received information and given his consent to the storage. **Area for development** The storage of gametes and gonadal tissue: Currently, publicly-funded healthcare providers apply different age limits to some extent for how long gametes and gonadal tissue must be saved and may be used. It is probable not possible or even desirable with fixed concepts of time when people's life situations are various. On the other hand, a consensus and dialogue regarding the time aspect is important in order to obtain equivalents principles for treatment within the country. The material can be transferred to private tissue facilities. According to current regulations, recovered material cannot be passed on to countries with different legislation.
	Access to stored materials	The document does not describe in detail how and when saved germ cells and tissue can be used later in life. The use is expected to take place in accordance with the regulations and the methods that are then applicable.
	Disposal of stored materials	If the patient dies, harvested germ cells/tissues may not be used. The frozen the material cannot be used for fertility treatment by anyone other than the patient self. If the patient previously consented to the germ cells/tissue being saved in a biobank for research and other medical purposes, they may be saved. The tissue facilities it is recommended to make an annual check of frozen material against the population register and destroy germ cells/tissues from deceased persons. *[requirements arising from the tissue regulations]*
	Any other storage information	No information identified.
Governance		No information identified.

Funding		The document does not concern the financing of the measures described. Fertility preservation measures entail a high cost and also displacement effects within publicly-funded healthcare. This makes resource-related limitations must exist. [See 'Population(s) and eligibility criteria' for further of details criteria applied in publicly-funded services]
Communication and information provision		- *Information about alternative ways of parenting should be given to all patients* All patients should be informed about alternative ways of having children, if not their own gametes are available. Alternative treatment methods include sperm or egg donation. They should also be informed about the possibility of adoption, but restrictions may occur based on the underlying disease. For those patients there fertility preservation measures are indicated, but cannot be implemented, for example due to the patient's general condition, this information is extremely important. Patients undergoing fertility preservation measures should also be informed the alternatives, because despite the implementation of fertility preservation measures, one does not can guarantee that use of the saved cells or the saved tissue will result in children. **<u>To inform the patient</u>** ▪ It is important that the patient receives the best available information. The information should describe the risks of infertility that cancer treatment entails and possible measures to be able to have children in the future, and touch both established methods and methods developing. ▪ Women and men and people with gender dysphoria must be given the same opportunities information and reproductive promotion efforts. It has been reported that men in to a much greater extent than women receive information about the risks of infertility as well opportunities for reproductive conservation measures before cancer treatment. ▪ The information about the reproductive capacity should be given by specialist doctors within reproductive medicine and not just the doctor responsible for the patient. Virtually all patients who are exposed to treatment with a high risk of damage to ovaries or testicles have need for informational talks, even if measures for the conservation of reproductive capacity does not become relevant for any reason. The information must be matter-of-fact and sincere regarding both possibilities and limitations in the future. During the calls, the patient must be informed that measures for the preservation of the ability to reproduce does not guarantee that you will be able to have your own biological children in the future, but that the measures may represent an opportunity. ▪ You should also inform about alternatives ways to become a parent, such as sperm/egg donation or adoption. It may be of value that the patient before a decision on fertility preservation measures is offered support from a counsellor or psychologist if desired, and if there is time. Information brochure are provided for both men (Freeze your sperm elderly) https://vavnad.se/wp-content/uploads/2017/11/broschyr-frysa-dina-spermier-aldre-engb.pdf and women (Freeze your eggs younger) https://vavnad.se/wp-content/uploads/2017/11/broschyr-frysa-dina-agg-aldre-engb.pdf .

Ethical considerations		It is often perceived as positive to have a conversation about fertility preservation measures when it gives hope for the future. From an ethical perspective, however, there are several circumstances in this situation which makes it difficult to give informed consent to the preservation of reproductive capacity. The patient may find it difficult to make a decision for several reasons, to example: ▪ The patient has recently received a diagnosis of serious illness. Worry and anxiety affects the situation ▪ The decision often has to be made under great time pressure ▪ The measures/techniques are not always to be considered clinically accepted, but can be under development ▪ The measures/techniques are in many cases also complex, and some even associated with medical risks and psychological stress ▪ Difficulty understanding the situation and weighing the pros and cons.
Relevant legislation (list)		The following laws and regulations are relevant and governing self-donation of germ cells and tissue. This enumeration may be incomplete: ▪ Act (2006:351) on genetic integrity etc. Act on amendments to the law (2006:351) on genetic integrity etc. from 2016 regarding for example single women can be found here: http://rkrattsdb.gov.se/SFSdoc/16/160018.PDF ▪ Act on quality and safety standards in the handling of human tissues and cells (SFS 2008:286) ▪ Act (2002:297) on biobanks in health care, etc. ▪ Ordinance on quality and safety standards in the handling of human tissues and cells (SFS 2008:414) ▪ The National Board of Health and Welfare's regulations on donation and disposal of organs tissues and cells (SOSFS 2009:30) ▪ Regulations on tissue facilities in healthcare (SOSFS 2009:31) ▪ Regulations and general advice on the use of tissues and cells in health and healthcare and clinical research (SOSFS 2009:32) ▪ There is a change in the law regarding sterilisation in case of change of gender from 2013 regulated in the following legal text: https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-constitutional collection/sterilization law-1975580_sfs-1975-580 ▪ The major change in the law that entered into force on 1/1 2019 regarding that is extended frozen storage time for embryos (10 years), donation of embryos and double donation (both egg and sperm) is found in "More modern rules about assisted fertilisation and parenthood" https://www.regeringen.se/contentassets/428b06fbb3384045b13b281228b5216d/modernare-regler-om-assisterad-befruktning-och-foraldraskap-prop.-201718155
Miscellaneous		In connection with the recovery of germ cells and tissue, samples are taken for infection screening: The patient must provide samples to test the presence of HIV 1 and 2, hepatitis B and C, HTLV I/II and presence of syphilis. The analyses must be carried out at accredited laboratory. Positive findings do not exclude harvesting of tissue/gametes. At positive findings require separate storage to prevent cross-contamination. *[requirements arising from the tissue regulations]* A number of development areas are outlined:

		Collaboration between different parts of healthcare: Today, there are not always established routines for how to accommodate the reproductive the health of this patient group. Therefore, clear routines for collaboration and transition between different parts of healthcare is created nationally/regionally. Fertility preservation measures require specialist knowledge in reproductive medicine and can be performed at the country's university hospital. Routines for referral flow may be drawn up locally within the regions. **Method development:** Methods for freezing/vitrification, storage and thawing of tissue from ovary or testis as well as of single spermatozoa should be developed/further developed. There are needs of developing alternative freezing methods adapted to the individual sperm sample to optimise the result. Methods for restoring reproductive capacity after cryopreservation of ovarian tissue should develop. The possibility of undergoing uterus transplantation may also be appropriate in the future some cases. **Follow-up patient group:** The patient group for whom fertility preservation measures are performed should be followed up over time. Therefore, information about treatment performed (for example cytostatics, radiation dose), if any, should reproductive conservation measures as well as the individuals' reproductive health are described in the journal. The documentation can also be advantageously done by expanding existing ones register, such as for example national quality registry for assisted reproduction (Q-IVF) which can be coordinated with the cancer registers.

Table D.43 Extracted data for Sweden (Preserving Reproductive Capacity of the Youth)

Sweden		
Author(s) **Title [year]**	The Tissue Council (Sweden) Measures to preserve the reproductive capacity of the young: promotion of equal care for young people who are at risk of treatment-induced infertility[94] [2021]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		Young people who are at risk of treatment-induced infertility, that is not for infertility risk that is congenital or directly caused by disease or injury.
Preservation method(s) available		Measures that are currently available, or may become available: <u>Girls – before menarche:</u> ▪ preserve and freeze ovarian tissue (invasive procedure). This method has proven results in adult women, but in prepubertal girls it is not considered clinically accepted today. The procedure must therefore take place within the framework of a scientific study and in connection with other necessary surgery. <u>Girls – after menarche:</u> ▪ preserve and vitrify mature oocytes after hormone stimulation (invasive intervention) ▪ preserve and freeze ovarian tissue (invasive procedure). The method can offered when other options are not applicable. <u>Boys – prepubertal:</u> ▪ preserve and freeze testicular tissue (invasive procedure). This method is experimental and should today only be done within the framework of scientific research studies that are approved by the Ethics Review Board (EPN). The procedure should preferably be performed in conjunction with other necessary surgery. <u>Boys – pubertal and postpubertal:</u> ▪ preserve and freeze ejaculated sperm (non-invasive procedure) ▪ freeze sperm extracted from open testicular biopsy or aspiration from epididymis and/ or testicle (invasive procedure). Assessment of the appropriate reproductive preservation measure for an individual patient must always be made individually, depending on the clinical situation. The calculated infertility risk based on planned treatment is central. The patient's clinical status and ethical aspects must be weighed. Decisions on appropriate measures must be taken after multidisciplinary consultation together with the patient and parents. The patient's paediatric oncologist has ultimate responsibility.

		<u>There is also comprehensive discussion on "Assessment of appropriate action"</u> ***Established methods or methods under development:*** important question is whether a reproductive preservation measure should be taken before there is a useful method by which the saved material can be used for future fertility treatment. Children and young people who are undergoing gonadotoxic treatment today will not be eligible for parenthood for many years. This is a research intensive area so in the future new methods may have been developed and established. If it is reasonable based on the clinical situation, harvesting of tissue can be considered. The measure that is not clinically accepted should take place within the framework of scientific studies that are approved by the ethical review board. Participation in such a study can then only be relevant if the patient meets the inclusion and exclusion criteria that the study requires. ***Risk of infertility:*** Gonad-damaging treatment, such as chemotherapy and radiotherapy for cancer, increases the risk of infertility to varying degrees. When a treatment usually consists of a combination of several preparations, the risk increase with a specific drug is difficult to assess. In addition to this, there are probably individual differences between people in terms of sensitivity to the gonad-damaging effect of one and the same drug. Today, we do not have sufficient knowledge of how large these individual differences are and no methods yet to identify particularly sensitive individuals. In recent years, new groups of drugs against cancer have been developed and the effect these drugs have on fertility is still unknown. ***Risk groupings:*** the risk of infertility is classified, including the cytostatics and radiation doses where there is evidence regarding the risk of primary gonadal damage. The preparations where the facts are insufficient to make such a risk assessment, as well as combination treatment with different preparations and risk profiles, are not included in the classification. Treatment that causes secondary effects on the gonads, such as high doses of radiation to the pituitary/hypothalamus, is also not listed because external hormone therapy with pituitary hormones can restore fertility in these cases. The classification can be used as a rough estimate of the infertility risk in the individual case, where the total treatment with possible additive negative effects of the various preparations must be weighed into the risk assessment.

Appendix 1 Classification of risks for infertility

The appendix will be revised after the ongoing work on new international guidelines from *the International Guideline Harmonization Group for Late Effects of Childhood Cancer* (see e.g. www.pancaresurfup.eu) is completed.

	Low risk	Intermediate risk	High risk	Very high risk
Boys	• Vincristine • Methotrexate • Actinomycin D • Bleomycin • Mercaptopurine • Vinblastine • 5-FU	• Cisplatin < 600 mg/m2 • Carboplatin • Cyclophosphamide < 7.5 g/m2 • Ifosfamide < 60 g/m2 • BCNU 1 g/m2 • CCNU < 500 mg/m2	• Cyclophosphamide > 7.5 g/m2 • Ifosfamide > 60 g/m2 • Procarbazine • Cisplatin > 600 mg/m2 • BCNU > 1 g/m2 • CCNU > 500 mg/m2 < 4 Gy to testis •	• Radiation treatment to the gonads > 4 Gy against the testis • Allogeneic HSCT • High dose treatment with autologous stem cell return
Girls	• Vincristine • Methotrexate • Actinomycin D • Bleomycin • Mercaptopurine • Vinblastine • 5-FU	• Cisplatin • Carboplatin • Cyclophosphamide < 9 g/m2 • Ifosfamide < 60 g/m2 • CCNU < 360 mg/m2	Cyclophosphamide > 9 g/m2 • Ifosfamide > 60 g/m2 • Procarbazine • BCNU, no dose information • CCNU > 360 mg/m2 < 10 Gy to ovaries	• Radiation treatment to the gonads > 10 Gy to ovaries • Allogeneic HSCT • High-dose treatment with autologous stem cell transplantation

Risk with action:

Non-invasive procedures: Production of sperm via masturbation is a procedure without medical risk and provides a good opportunity to preserve fertility for the future. However, psychological aspects must be taken into account especially when it comes to very young boys. The attending physician must make sure that the boy is well informed about what he has to do and that the physical conditions for producing a sperm sample exist. If the boy's general condition does not allow him to leave the ward, logistics should be arranged for the transport of the sperm sample to the responsible tissue facility. If the general condition is so bad that masturbation is not possible, other measures can be discussed with specialist doctors in reproduction, if there is time for this.

Invasive interventions: requirement for carrying out invasive measures for the purpose of reproductive preservation is that these interventions must not entail an unreasonably increased risk with

		regard to the patient's status and the underlying disease. Such risks rarely exist, but young cancer patients are generally ill at diagnosis, which means an increased risk of bleeding, risk of anaesthesia and risk of infection. The patient's general condition must allow surgery or a possible extension of an already planned one surgery and the procedure should be coordinated with other procedures to reduce the number of general anaesthesia for the patient. If there is a risk of tumour spread in connection with the procedure, reproductive preservation measures should not be offered *Specific risks in certain interventions:* ▪ Ovarian biopsy: If there is a very high risk of future infertility, an entire ovary can be saved. Small biopsies carry a greater risk of bleeding compared to removing the entire ovary. ▪ Hormonal stimulation and retrieval of oocytes: A known complication of hormone stimulation is overstimulation syndrome. The risk can be minimized by special stimulation protocols (use of antagonist protocol, sometimes called short protocol). To undergo the hormone stimulation can cause a delay in the start of cancer treatment 10 - 14 days, therefore this treatment is only offered to patients where treatment starts and planning allows it. Above all, this method may be suitable after the end of treatment for those women who are at risk of early menopause. ▪ Testicular biopsy: After a testicular biopsy, boys can experience bleeding and swelling in the scrotum, so called scrotal hematoma, which causes severe pain. There is a theoretical risk that biopsy from the testicle may cause a disturbance of normal testicular function and could then be a risk factor in itself for reduced future fertility. ***Risk of return of cells/tissue:*** In the case of haematological diseases, there is a high risk that the biopsy may contain tumour cells. Contamination can also occur with some solid tumours. This tissue cannot then be used for re-transplantation. However, future methods may enable the isolation of identified germ cells where contamination or maturation of oocytes or sperm can be ruled out. It is important to be clear in the information to the patient about this. ***Chance that fertility can be preserved with performed action:*** The possibilities that exist today for using the cells or the tissue that are taken into account must be weighed when deciding on interventions. Below is a brief description of the possibilities available with different cells and tissues. There are good conditions for vitrification of oocytes. A decisive factor for the chance of achieving a full-term pregnancy is the number of vitrified oocytes. The chance of a child by fertilizing thawed oocytes today corresponds to the results when using fresh oocytes. Strong hormone stimulation produces more oocytes, but this must be balanced against the risk of overstimulation syndrome and other complications associated with the procedure. Retransplantation of frozen ovarian tissue taken from adult women has resulted in pregnancies. Birth of children has been reported both after in vitro fertilization of retrieved eggs from the transplants and after spontaneous pregnancies. The method is still to be considered under development. For prepubertal girls, there are no data yet.

		There are good conditions for freezing sperm. Sperm survival after freezing varies greatly between men but can also depend on the freezing method used. It is important that a sufficient amount (if possible) of sperm is frozen for several future treatments. When biopsies are taken from pubertal boys, the result depends entirely on whether sperm can be found in the material or not. The methods of biopsy, preparation, freezing and thawing of the material are critical factors. Testicular biopsy from prepubertal boys can be stored, but there is currently no clinical method for using such tissue. Continued development is therefore important. ***Medical risks for future children:*** Previous studies on children born to parents who were treated for cancer in childhood show no increased risk of cancer or malformation. However, a Danish-Swedish registry study, which included just over 1.8 million newborns, showed a marginally increased risk of congenital malformations in children of men who have been treated for cancer. Only individuals who carry a hereditary cancer have a known increased risk of having children who develop cancer during childhood. Experience in general of risks in children born after various forms of assisted reproduction is limited, but a certain increase in congenital malformations has been observed. Women who have had radiotherapy to the small pelvis have an increased risk of pregnancy complications. Miscarriages, premature births and lower than normal birth weights can occur due to radiation damage to the uterus. ***Information about alternative ways of having children should be given to all patients [also see Communication and Information Provision]:*** All patients should be informed about alternative ways of having children. The information can be given to parents where the patient is too young to understand on their own, and repeated to the patient when he/she reached an appropriate age. Alternative treatment methods include sperm and egg donation. They should also be informed about the possibility of adoption. In addition, this information is very important for those patients in whom fertility preservation measures are indicated but cannot be carried out. Patients undergoing fertility preservation should also be informed of the options, as carrying out fertility preservation opens up future possibilities, but none of the current procedures has a 100% success rate and therefore it cannot be guaranteed that use of the saved cells or tissue will to result in children. If reproductive preservation measures can be performed but the uterus is seriously damaged during the radiation treatment, a surrogate mother could be considered in the future. This happens in other parts

		of the world but is not allowed in Sweden today. A government investigation into a possible change in the law regarding surrogacy has begun in 2015. ***Recovery of gametes after completion of treatment:*** If recovery and freezing of gametes could not be carried out before cancer treatment, so for certain patient groups this can be done after primary treatment has been completed. This may be justified if there is a risk of relapse and for girls if there is a risk of treatment-induced early menopause. The timing of fertility preservation measures after completion of cancer treatment has not been established, but the clinical recommendation is that one should wait at least six months after completion of treatment. If there is a need for renewed cancer treatment, the preservation and freezing of germ cells can be done between treatments. **Choice of reproductive conservation measure** **Girls and young women** ▪ *Risk of menopause* The majority of treatments given during childhood and adolescence to girls do not result in immediate total ovarian failure. Most people regain reproductive function or, if they are prepubertal at the time of treatment, go through puberty normally. However, there is a risk of a shortened fertile period. The fertile period can vary from a very short period, which means menopause already during adolescence, to menopause a few years earlier than normal. Girls are followed with regard to growth and pubertal development at a children's clinic with endocrinological expertise. If threatened ovarian failure is suspected, a referral to a reproductive clinic can be issued. Today, it is possible to freeze eggs even from pubertal girls after hormonal stimulation. Ovarian reserve can be assessed by measuring AMH, anti-müllerian hormone, FSH, estradiol and ultrasound of ovaries. ▪ *Girls after menarche* In the case of treatment that **entails a low or intermediate risk of infertility, no reproductive preservation measures are recommended before gonadotoxic treatment is started.** After completion of treatment, a long-term follow-up of this patient group should be carried out to investigate possible effects on fertility and, if so, decide on possible conservation measures of reproductive capacity, such as vitrification of oocytes. If there is time for treatment that entails **a high or very high risk of infertility**, hormone stimulation, egg retrieval and oocyte vitrification can be performed. However, the time aspect (10-14 days) means that this is rarely relevant when it comes to child cancer patients. The method also requires strong motivation and maturity on the part of the girl, as the treatment can be perceived as stressful. When immediate start of gonadotoxic treatment is necessary, ovarian biopsy can be considered, unless there are contraindications for invasive measures. ▪ *Girls before menarche*

		In the case of treatment that entails **a low, intermediate or high risk of infertility**, no reproductive preservation measure is recommended before gonadotoxic treatment is started. After completion of treatment, a long-term follow-up of this patient group should be carried out to investigate any impact on fertility and, if so, decide on oocyte freezing. In case of treatment that entails **a very high risk of infertility** in girls before menarche, an ovarian biopsy may be performed, within the framework of an ongoing scientific study which is approved by the EPN, and then preferably in connection with another necessary operation. Contraindications for invasive procedures must be considered. Ovarian biopsy may be used in the future if it becomes possible to re-transplant prepubertal ovarian tissue or alternatively it is possible to mature oocytes in vitro. **Boys and young men** ▪ *Pubertal/post-pubertal boys* There are good chances of having sperm in the ejaculate if the testicle size is over 6-8 ml, which usually corresponds to puberty stage Tanner 3. All boys who have reached this physical maturity should therefore be offered cryopreservation of sperm before starting cytostatic treatment or radiotherapy with the testicles in the radiation field. If the boy/young man is unable to produce an ejaculate through masturbation, vibrator stimulation may be considered. However, this procedure should only be relevant if the boy himself is motivated. Electrostimulation via the rectum is not recommended. If the boy **is at high or very high risk** of treatment-induced infertility and is unable to ejaculate with live sperm, invasive procedures by open testicular biopsy or epididymal aspiration may be considered. This procedure is performed under the condition that there are no contraindications such as neutropenia or an increased tendency to bleed. The risk of tumour spread in connection with the procedure has been discussed, but there is no clinical evidence of spread. The responsible paediatric oncologist must be consulted before such a procedure is performed. ▪ *Prepubertal boys* For prepubertal boys, there is currently no clinically accepted routine for reproductive preservation measures. Boys who are to undergo treatment that entails a very high risk of infertility, can nevertheless be offered the collection and cryopreservation of testicular tissue for possible future use, within the framework of a scientific study. Contraindications for invasive procedures must always be taken into account. Today, there are no methods of using testicular tissue for fertility treatment after a prepubertal testicular biopsy. Therefore, the procurement of testicular biopsy and research must be coordinated in scientific studies, approved by the EPN, with the aim of enabling future re-transplantation or maturation of sperm in vitro.
Organisation	***Referral pathways***	No information identified.

	Service provider characteristics	No information identified.
	Timelines to access services	Cancer treatment and prognosis must always be prioritised. **<u>Follow-up</u>** All children should be followed up regularly and the aim is to see if a normal puberty occurs. If this is not the case, puberty must be induced using the supply of sex hormones according to the special programmes available. In addition, a summary assessment of reproductive health must be made to identify any care needs as an adult. If necessary, reproductive medicine or andrological counselling should be considered in adulthood. All boys who have undergone gonadotoxic treatment should be offered a semen sample for control and follow-up at the end of their visit to the children's clinic, or during follow-up in adulthood. Frozen samples should not be destroyed even if the control samples are of normal quality, as this patient group has a certain risk of recurrence and long-term effects on sperm quality are also not known in detail. In today's situation, there is no systematic control of young women over the age of 18 who had cancer as children, which is why there is a risk that a number of women miss the opportunity to preserve their fertility before an early menopause occurs. The girls who received treatment with alkylating cytostatics and or radiotherapy to the abdomen are at risk of early menopause. They should therefore, at the end of the visit to the paediatric oncology centre, be referred to a specialist in reproductive medicine for follow-up and information on measures to preserve reproductive capacity. A national programme for the follow-up of ovarian function in young adult women who had cancer as children should be established. This patient group should be followed up in adult care.
	Any other organisational aspects	The acquisition, preparation and use must be documented to achieve full traceability in accordance with the regulations for tissues and cells for human use. The following must be documented: 1. The information that the patient/parents received about measures for the preservation of the reproducibility and the decision on action must be documented and kept as a journal document. The documentation should include descriptions of how risk was weighed against benefit, how the information and consent process went, what the patients and guardian's considerations and stances were, and the decision reached. 2. Agreement on and consent to frozen storage of germ cells/gonadal tissue must be documented and signed by the patient/guardian. The clinic/tissue facility is responsible for this being done. The document templates *Consent regarding frozen storage of sperm/ testicular tissue and Consent regarding frozen storage of unfertilized oocytes/ ovarian tissue* can be used. The consent documents must be kept in the patient's medical record. As regards the frozen storage of biopsies from testicles or ovaries for prepubertal boys and girls, these are only done within the framework of scientific studies, approved by an EPN, and are documented separately.

		3. After the freezing of the germ cells/gonadal tissue, the patient/guardian and the referring doctor must receive a confirmation letter about the results of the freezing. Results and information given must be documented in the patient's medical record.
Storage	***Arrangements and duration(s)***	For sperm and oocytes, there are no biological or national regulatory time limits. Freezer storage time may be regulated at county council level for public healthcare, but does not normally include private healthcare. This information should be included in the patient information that the patient must receive at the time of freezing. *[requirement arising from tissue regulation]* Currently, healthcare providers apply different age limits for how long germ cells and gonad tissue must be saved and can be used. It is probably not possible or even desirable to have fixed concepts of time as life situations for different people are individual. On the other hand, a consensus and dialogue regarding the time aspect is important in order to obtain equivalent principles and to avoid excessive divergence between different care providers.
	Access to stored materials	The document does not describe how and when saved germ cells and tissue can be used in adulthood. The use is expected to take place in accordance with the regulations and methods that are then applicable.
	Disposal of stored materials	If the patient dies, harvested cells/tissues may not be used for fertilization or insemination. This means that the frozen material cannot be used for fertility treatment by anyone other than the patient himself. If the patient previously consented to that the cells/tissue are saved in a biobank for research and other medical purposes, they may be saved, otherwise they must be destroyed. It is important to make it clear to the family in the information prior to disposal that the cells/tissue will be thrown away if the patient dies, provided that there is no consent for research and other medical purposes. The family is therefore not contacted. The tissue facilities are recommended to make an annual check of frozen material against the population register and to destroy cells/tissues from deceased patients. *[requirement arising from tissue regulation]*
	Any other storage information	No information identified.
Governance		No information identified.
Funding		The document does not concern the financing of the measures described.
Communication and information provision		Applicable parts of the Biobank Act (2002:297) also apply to tissues and cells that must be stored for self-donation, that is in fertility preservation measures. An important part is the requirement for information and consent. In order for tissues and cells to be stored, it is required that the child/guardian has received information and consented to the storage. *[requirement arising from tissue regulation]* *See Any other organisational aspects for information the clinic must store.* ▪ It is important that the patient and their parents receive the best available information. ▪ The information should describe the risks of infertility that the cancer treatment entails and possible measures, both established methods and methods in development, to be able to have children in the future.

		▪ The information for the young patient must be age-appropriate. ▪ It is important that the privacy of the individual is taken into account and that information is provided individually if necessary. Experience shows that most children and parents are grateful that these issues are discussed. ▪ It is important that girls and boys in puberty have the opportunity to talk individually without their parents. ▪ It is important that both girls and boys are given the same opportunities for information and reproductive conservation efforts. This is particularly important because it has been reported that men/boys receive information to a much greater extent than girls/women about the risks of infertility and the possibilities of reproductive preservation measures before cancer treatment. ▪ It is important that the information about the reproductive capacity is given by a paediatric oncologist other than the patient responsible, such as an andrologist, gynaecologist, paediatric endocrinologist or a specialist in reproductive medicine. From an ethical point of view, it is important that the patient and his parents are offered support (possibly by someone other than the attending physician, such as a counsellor or the like) before he/she has to make a decision. ▪ Virtually all patients who are exposed to treatment with a high risk of damage to ovaries or testicles need an informational interview, even if measures to preserve reproductive capacity are not relevant. The information must be factual and honest regarding both opportunities and limitations in the future. During the conversations, the patient should be informed that measures to preserve reproductive capacity do not guarantee that one in the future may have its own biological children, but that they may represent an opportunity. You should also inform about alternative ways to become a parent, such as sperm/egg donation or adoption. **Information specific to girls:** The girls who, after cancer treatment, are expected to have a high/very high risk of infertility must, before the start of treatment, be given information about what measures are available to preserve reproductive capacity, as well as the individual possibility of having the appropriate measure carried out. Girls who received so-called alkylating drugs in their treatment have an increased risk of early menopause. They should therefore be referred to a gynaecologist/reproductive specialist for information on measures to preserve reproductive capacity, such as frozen storage of oocytes after hormone stimulation. The timing of information and possible freezing must be individualized based on the gynaecologist's overall assessment of ovarian reserve. **Information specific to boys:** Boys must be informed about the reproductive conservation options available to them. All boys who can provide a semen sample should be advised to do so before treatment. Those who have undergone treatment that affects fertility must be offered an analysis of sperm sample at the appropriate time after completion of treatment, in order to gain knowledge of their current sperm production. This semen sample must be submitted no earlier than six months after the end of treatment. Fertility can return up to 10 years after the end of treatment. Additional sperm samples may therefore be relevant.

		Information brochures have also been developed: Freeze your eggs (younger) https://vavnad.se/wp-content/uploads/2017/11/broschyr-frysa-dina-agg-yngre-engb.pdf Freeze your sperm (younger) https://vavnad.se/wp-content/uploads/2017/11/broschyr-frysa-dina-spermier-yngre-engb.pdf
Ethical considerations		It is often perceived as positive to have a conversation about fertility preservation measures as it is seen as a signal that the patient can survive. From an ethical perspective, however, there are several circumstances in this situation that make informed consent to the preservation of reproductive capacity difficult. The minor and the parents may find it difficult to make a decision for several reasons, for example: ▪ the minor patient has recently received a diagnosis of serious illness. Anxiety and the anxiety affects the situation ▪ the decision must probably be made under great time pressure, ▪ the measures/techniques are not always to be considered clinically accepted ▪ the approaches involved are in many cases also complex, some are even associated with medical risks and psychological stress ▪ difficulties for the minor (and the parents) to understand the situation and consider disadvantages. Since it concerns a minor patient, there is a difficult balance to be made, which concerns on the one hand the young patient's right to self-determination and privacy, and on the other hand the minor's need for protection and the parents' ability to exercise their obligation to meet the child's needs. The information for small children is initially given to the parents. In line with the child's increasing age and maturity, information should also be provided directly to the patient. At the latest upon reaching the age of majority and transitioning to adult healthcare, full information must be given about the fact that tissue/cells are in frozen storage and what possibilities are available for treatment. The timing of this information can be much later than when the cells/tissue were harvested. The technological development during this time has probably changed the conditions for how the cells/tissue can be used. Information for parents and patients as well as routines for the transition from paediatric to adult healthcare should be drawn up nationally.
Relevant legislation (list)		The following laws and regulations are relevant and governing self-donation of germ cells and tissue: ▪ Act (2006:351) on genetic integrity etc. ▪ Act on quality and safety standards in the handling of human tissues and cells (SFS 2008:286) ▪ Act (2002:297) on biobanks in health care, etc. ▪ Ordinance on quality and safety standards in the handling of human tissues and cells (SFS 2008:414) ▪ The National Board of Health and Welfare's regulations on donation and disposal of organs, tissues and cells (SOSFS 2009:30)

		▪ Regulations on tissue facilities in health care (SOSFS 2009:31) ▪ Regulations and general advice on the use of tissues and cells in healthcare and clinical research (SOSFS 2009:32)
Miscellaneous		The document does not describe how and when saved germ cells and tissue can be used in adulthood. The use is expected to take place in accordance with the regulations and methods that are then applicable. In connection with the recovery of germ cells and tissue, samples are taken for infection screening: The child/patient must provide samples to test the presence of HIV 1 and 2, hepatitis B and C, HTLV I/II and the presence of syphilis. The analyses must be carried out at an accredited laboratory. Positive findings do not exclude harvesting of tissue/gametes. In case of positive findings, separate storage is prescribed to prevent cross-contamination. *[requirement arising from tissue regulation]* <u>A number of development areas are outlined:</u> **Cooperation between children's healthcare and adult healthcare:** There are currently no established routines for how to cater for the reproductive health of this patient group when they reach adulthood. Therefore, clear routines for collaboration and transition between children's healthcare and adult care need to be created nationally/regionally. Girls who received so-called alkylating drugs in their treatment have an increased risk of early menopause. Routines must be developed regionally so that the girls are called to the gynaecologist/specialist in reproduction for information on measures to preserve reproductive capacity, such as cryopreservation of oocytes after hormone stimulation. The timing of information and possible freezing must be individualized based on the gynaecologist's overall assessment of ovarian reserve. Routines must be developed so that boys undergoing cancer treatment and for whom fertility-impairing complications are feared should be offered the opportunity to see a reproductive specialist or andrologist, either at the final visit to the paediatric oncology clinic or at follow-up in young adulthood. They must be offered to provide a semen sample for control and follow-up. **Measures to preserve reproductive capacity in adults [see extracted doc]** **Germ cells and gonad tissue storage length:** Currently, healthcare providers apply different age limits for how long germ cells and gonad tissue must be saved and can be used. It is probably not possible or even desirable to have fixed concepts of time as life situations for different people are individual. On the other hand, a consensus and dialogue regarding the time aspect is important in order to obtain equivalent principles and to avoid excessive divergence between different care providers. **Methods development:** Methods for freezing/vitrification, storage and thawing of tissue from ovary or testicle and of single spermatozoa should be developed/further developed. There is a need to develop alternative freezing methods adapted to the individual sperm sample in order to optimize the results of sperm freezing from boys and men who are at risk of sperm formation being affected after treatment.

		Methods for restoring reproductive capacity after cryopreservation of ovarian tissue well as prepubertal testicular tissue should develop. **Follow-up of patient group:** The patient group for whom fertility preservation measures are performed should be followed up over time. Therefore, information on treatment carried out (radiation dose, medication and strength, etc.), any reproductive preservation measure and the individuals' reproductive health should be documented in registers. The documentation can advantageously be done by expanding existing registers, such as for example national quality register for assisted fertilization (Q-IVF) and cancer register, which can then be coordinated if necessary. A national programme for the follow-up of ovarian function in young adult women who had cancer as children should be established. This patient group should be followed up in adult care.

Table D.44 Extracted data for United Kingdom

United Kingdom		
Author(s) **Title [year]**	National Institute for Health and Care Excellence (NICE) Fertility problems: assessment and treatment[95] (Published 2013, updated in 2017) This is supported by the guidance on management on the effects of cancer treatment on reproductive functions (2007) by the Royal College of Physicians, the Royal College of Radiologists, the Royal College of Obstetricians and Gynaecologists[96], NICE NG73 Endometriosis: diagnosis and management[97] (2017, updated 2024), NICE Quality standard [QS73]: Fertility problems (2014; updated 2016) and NICE Removal, preservation and reimplantation of ovarian tissue for restoring fertility after gonadotoxic treatment: Interventional procedures guidance (2023).	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		This document is in general regarding fertility problems however section 1.16 is for "People with cancer who wish to preserve fertility". ▪ Where treatment is planned that may result in infertility (such as treatment for cancer), early fertility specialist referral should be offered. ▪ For cancer-related fertility preservation, do not apply the eligibility criteria used for conventional infertility treatment. ▪ Do not use a lower age limit for cryopreservation for fertility preservation in people diagnosed with cancer. **There are specific NICE guidelines in regards to those with endometriosis which outline:[97]** *The recommendations in this section should be interpreted within the context of NICE's guideline on fertility problems. The management of endometriosis-related subfertility should have multidisciplinary team involvement with input from a fertility specialist and access to fertility services. Depending on the severity of the endometriosis this may be in a secondary care gynaecology service or a tertiary care specialist endometriosis service.* *This should include the recommended diagnostic fertility tests or preoperative tests, as well as other recommended fertility treatments such as assisted reproduction that are included in the NICE guideline on fertility problems.* The guidance on management on the effects of cancer treatment on reproductive functions (2007):[96] **Sperm storage:** All postpubertal males who may develop gonadal dysfunction, should, whenever relevant, be offered sperm banking. Proxy consent cannot be given for the collection and storage of sperm. For this reason, individuals who are under the age of legal consent for medical intervention (18 years in England, Wales and Northern Ireland, 16 years in Scotland) must be involved in these discussions as they alone can provide legal consent.

Preservation method(s) available		When deciding to offer fertility preservation to people diagnosed with cancer, take into account the following factors: ▪ diagnosis ▪ treatment plan ▪ expected outcome of subsequent fertility treatment ▪ prognosis of the cancer treatment ▪ viability of stored or post-thawed material. When using cryopreservation to preserve fertility in people diagnosed with cancer, use sperm, embryos or oocytes. ▪ Offer sperm cryopreservation to men and adolescent boys who are preparing for medical treatment for cancer that is likely to make them infertile. ▪ Prior to sperm banking all patients must be tested serologically for evidence of HIV, hepatitis B and C and syphilis. In urgent cases sperm banking can take place in a separate vessel while these results are obtained. ▪ Offer oocyte or embryo cryopreservation as appropriate to women of reproductive age (including adolescent girls) who are preparing for medical treatment for cancer that is likely to make them infertile if: o they are well enough to undergo ovarian stimulation and egg collection and o this will not worsen their condition and o enough time is available before the start of their cancer treatment. In most cases, because of timing considerations or absence of a partner, production of embryos will not be realistic and egg or ovarian tissue storage may be considered. It should be emphasised that neither of these techniques is available on a routine basis in the NHS and both should be regarded as at an early stage of use/research.[96] Introduced in 2023:[98] Removal, preservation and reimplantation of ovarian tissue for restoring fertility after gonadotoxic treatment may be used if standard arrangements are in place for clinical governance, consent and audit. It may be the only fertility preservation option suitable before puberty or for people with oestrogen-sensitive malignancies.
Organisation	***Referral pathways***	No information identified.
	Service provider characteristics	Evidence of local arrangements to ensure that people preparing to have treatment for cancer that is likely to result in fertility problems are offered cryopreservation.[Quality standard][99]
	Timelines to access services	In general it is recommended that at least 2 semen samples are collected over a period of one week and stored before treatment for cancer. In patients with advanced cancer, or those where there is an urgent need to start treatment, it may only be possible to store one sample before commencing treatment. In some situations, the individual may be too unwell to provide a semen sample prior to exposure to cytotoxic therapy. If it is decided to attempt sperm storage following exposure to any systemic cytotoxic

		therapy, this exposure must be clearly recorded by the sperm bank. The DNA damaging effects of cytotoxic therapy cannot currently be established and the sample may not be appropriate for subsequent use. Individuals should be warned of this before providing a sample for storage.[96] [See 'Preservation method(s) available' for timing and other considerations for oocyte or embryo cryopreservation]
	Any other organisational aspects	In regards to the preservation and reimplantation of ovarian tissue:[98] Healthcare organisations should: ▪ Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure. ▪ Regularly review data on outcomes and safety for this procedure. ▪ Clinicians should enter details about everyone having removal, preservation and reimplantation of ovarian tissue for restoring fertility after gonadotoxic treatment onto a suitable register, such as the UKSTORE register. ▪ Patient selection should be done by a multidisciplinary team experienced in the procedure, ideally using nationally agreed criteria.
Storage	***Arrangements and duration(s)***	Inform people diagnosed with cancer that the eligibility criteria used in conventional infertility treatment do not apply in the case of fertility cryopreservation provided by the NHS. However, those criteria will apply when it comes to using stored material for assisted conception in an NHS setting. Store cryopreserved material for an initial period of 10 years. Offer continued storage of cryopreserved sperm, beyond 10 years, to men who remain at risk of significant infertility. *This was updated on July 01 2022 and now the storage period is statutory storage limits for gametes and embryos for everyone regardless of medical need to 10-year renewable periods, with a maximum limit of 55 years.*[100] A sperm storage facility together with counselling resources should be available to all cancer centres and units. In the past, arbitrary limits on sperm concentrations suitable for freezing were set, but following advances in IVF and in particular ICSI, any number of sperm (whatever the quality) should be considered for storage.[96]
	Access to stored materials	In order for a woman to use her deceased partner's sperm for treatment, the man must have given consent to the posthumous use of his sperm for that purpose/treatment (HFEA form MT). In the event of the sperm being used after the man is dead, the man is not treated as the father of the child that results from the use of the sperm, except for the purpose of being recorded as the father of the child on the register of births. In order to be recorded on a birth certificate as the father, section 6 of the MT form must be completed.[96]

	Disposal of stored materials	The centre will need to keep in contact with the patient, particularly towards the end of the statutory 10-year period, (*since updated (July 2022) to 10-year renewable periods, with a maximum limit of 55 years*)[100] to see whether samples should be destroyed or whether storage for a further period of years is necessary.[96]
	Any other storage information	Use freezing in liquid nitrogen vapour as the preferred cryopreservation technique for sperm. In cryopreservation of oocytes and embryos, use vitrification instead of controlled-rate freezing if the necessary equipment and expertise is available.
Governance		Sperm, eggs or embryos can only be stored and used in a centre licensed by the HFEA (www.hfea.gov.uk). All patients need to complete HFEA consent forms covering the storage and use of the stored samples and such consent can only be obtained by a member of staff named on the sperm or egg or embryo bank licence. All patients banking sperm or storing eggs or embryos whose fertility is likely to be impaired as a result of chemotherapy/radiotherapy need to complete and sign HFEA form MS, which provides consent for sperm/egg/embryo storage. This form does not cover consent for use of the samples; before the stored sperm/eggs/embryo can be used in treatment services, consent for use must be obtained (HFEA form MT). This form giving consent for use (MT) also details the generation of embryos in vitro and the fate of these embryos if the man dies or is unable because of incapacity to vary the terms of consent or revoke it. The patient may vary their consent at any time, but must inform the centre storing the samples in writing.[96] In order to maintain accurate records the oncologist should provide full medical details about the patient as well as full details of where the details of the sperm count should be sent. It is important also for the semen bank to maintain accurate up-to-date records of the status of the patient as well as to establish whether the sperm should be destroyed should the patient die.[96] Storage of ovarian tissue is not covered by the HFEA as it does not contain mature gametes but it is covered by the Human Tissue Authority (www.hta.gov.uk). Storage of such tissue is subject to tissue banking regulations and its availability is therefore very restricted. As of 2023, preservation of ovarian tissue for this procedure is regulated by the Human Tissue Authority (HTA). Only ovarian tissue that has been stored under HTA regulations can be reimplanted.[98]
Funding		There is currently no national funding policy for any of these techniques. Although sperm banking is widely available (though not necessarily funded), provision of the other techniques is patchy or absent. Sperm banking is usually available on the NHS. NHS funding may be available for embryo storage. However, this is not always the case and so services may only be available in the private sector.
Communication and information provision		Principles of Care **Providing information** ▪ People should have the opportunity to make informed decisions regarding their care and treatment via access to evidence-based information. These choices should be recognised as an integral part of the decision-making process. Verbal information should be supplemented with written information or audio-visual media.

		▪ Information regarding care and treatment options should be provided in a form that is accessible to people who have additional needs, such as people with physical, cognitive or sensory disabilities, and people who do not speak or read English. Adolescent patients have the same rights to privacy as adults and may prefer not to discuss, for example, sperm banking, with their parents present. Capacity to provide written consent will need to be determined by the health professionals caring for the individual. Assessment should be based on Gillick criteria. Involvement of a paediatric psychologist, specialist paediatric nurse or fertility specialist may be useful in cases where the clinical team are uncertain as to the patient's competence/capacity to provide this.(96) It is an HFEA requirement that all males banking sperm and females storing eggs, or either storing embryos, should be offered independent counselling by a suitably qualified individual and receive oral and written explanation about the medical, scientific, legal and psychosocial implications of their decision (with leaflets in an appropriate language level for adolescents). Discussion with a patient should include a description of the process of freezing, storing the samples and the patient's ability to change their consent. It should be made clear that there is no guarantee of intact sperm/egg/embryo function after thawing and that the patient's illness itself may affect sperm/egg quality. It is, however, possible to store sperm/eggs/embryos for many years without the quality being compromised. The patient should be advised, where appropriate, that the recovery of fertility is possible following treatment and that they can be offered further counselling at a later stage if required. Patients should also receive information about options available in the event of death or mental incapacity and the consent required to fulfil these wishes. They should also receive specific information appropriate to minors.(96) At the counselling session the appropriate HFEA factsheet should be provided and a copy of the completed forms (HFEA MS, MT) given to the patient.(96)
Ethical considerations		A number of principles of care are outlined. Those that are relevant are below: **Psychological effects of fertility problems** ▪ People who experience fertility problems should be informed that they may find it helpful to contact a fertility support group. ▪ People who experience fertility problems should be offered counselling because fertility problems themselves, and the investigation and treatment of fertility problems, can cause psychological stress. ▪ Counselling should be offered before, during and after investigation and treatment, irrespective of the outcome of these procedures. ▪ Counselling should be provided by someone who is not directly involved in the management of the individual's and or couple's fertility problems. **Generalist and specialist care** ▪ People who experience fertility problems should be treated by a specialist team because this is likely to improve the effectiveness and efficiency of treatment and is known to improve people's satisfaction with treatment.

		The best validated technique is egg harvesting and fertilisation with sperm of a partner or donor: the resulting embryos can be cryopreserved long-term with good results following embryo transfer. There are, however, a number of drawbacks to this approach. The procedure involves hormonal administration to induce multiple follicular development (superovulation), and oocyte recovery which is generally performed trans-vaginally under local anaesthetic. These manipulations take a minimum of 2–4 weeks (plus additional time for referral) and this may be an unacceptable delay for many patients. Sperm are also required, which may not be available, or may raise ethical or legal issues regarding involvement and level of commitment of the male partner. There are concerns about the very high oestradiol levels attained during superovulation as this may accelerate growth, for example of oestrogen receptor positive breast cancer. Research studies suggest that the use of FSH with tamoxifen or letrozole may result in lower oestrogen levels with satisfactory egg harvests.[96] The existence of living children should not be a factor that precludes the provision of fertility treatment. There should not be a lower age limit for cryopreservation for fertility preservation in people diagnosed with cancer. [Quality Standard][99]
Relevant legislation (list)		Legislation permits the storage of sperm/eggs/embryos for up to 10 years for any patient regardless of age *(updated in July 2022 to 10-year renewable periods, with a maximum limit of 55 years).*[100] This period can be extended for individuals whose fertility has been or is likely to be impaired by treatment for cancer and who are less than 45 years old when the gametes are produced. The continued storage of sperm/eggs/embryos is not permitted beyond the patient's 55th birthday.[96]
Miscellaneous		No information identified.

Table D.45 Extracted data for Wales (Fertility Preservation for Gender Diverse People)

Wales		
Author(s) **Title [year]**	Wales Fertility Institute (WFI) Fertility Preservation for Trans and Gender Diverse People: Information for patients[101] [2019]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		For those that plan on gender affirming hormones and or having a surgical intervention to remove the testes or womb/ovaries, which can lead to the loss of fertility. The WFI accepts referrals for patients living anywhere in Wales.
Preservation method(s) available		▪ Sperm freezing (only carried out at WFI Cardiff in University Hospital of Wales (UHW)) ▪ Egg storage (carried out in WFI Cardiff in UHW or in WFI Neath Port Talbot hospital). ▪ Embryo Storage
Organisation	***Referral pathways***	If you feel that fertility preservation is something that you wish to pursue then your GP will refer you to WFI. GP referral to the Welsh Gender Team is required to access services at the Wales Fertility Institute. If a patient is already under the care of the Gender Identity Clinic in Charing Cross this step is not necessary.
	Service provider characteristics	The Wales Fertility Institute is a two site service based at the University Hospital of Wales, Cardiff and Neath Port Talbot Hospital. We provide specialist fertility consultations and treatments including fertility preservation.
	Timelines to access services	No information identified.
	Any other organisational aspects	Patients will have a consultation with one of the WFI specialists to individualise your treatment options. Specialists will need to take some blood and urine samples. Everyone accessing fertility treatment will undergo screening as a standard procedure. Screening is required to ensure that there is no transmission of infectious disease to other samples that we have in storage or to a partner/surrogate/child if the patient comes through for treatment. Screening is also in place as some of these diseases can have a detrimental effect on the developing babies. We will screen you as a donor which will allow the option of using a surrogate in the future if you needed. This involves you being tested for the following: ▪ HIV (Human Immunodeficiency Virus) ▪ Hepatitis B ▪ Hepatitis C ▪ Syphilis ▪ Chlamydia ▪ Gonorrhoea ▪ HTLV (Human T-Lymphotropic Virus) ▪ CMV (Cytomegalovirus)

		Some people may already know their screening status. If it is all negative, we can accept these results provided we receive copies with your referral and we are able to carry out the storage appointment/s within 3 months of the test date. For tests performed over 3 months ago, we will require repeat screening. If you know you are positive or your results are returned as positive for HIV, Hep B, Hep C or HTLV your referrer could offer you a referral to an alternative centre who are able to offer this service. An individual patient funding request for the transfer of NHS funds will be made to the Welsh Health Specialised Services Committee (WHSSC).
Storage	***Arrangements and duration(s)***	You are in control of how long you wish your eggs, sperm or embryos to be stored for. You can chose to store for 1 year to up to 55 years. The statutory storage period is 10 years but this can be extended for up to 55 years if you are or are likely to become prematurely infertile. This condition would be met if you are going to commence hormone therapy or undergo gender confirmation surgery. However, your case will need to be reviewed every 10 years by a medical practitioner to confirm that you are still eligible that is you are still prematurely infertile or you are still likely to become prematurely infertile or your partner is or the person who has been assigned the gametes is. We will contact you a year in advance of your consent to storage expiring. This gives you time to consider what you would like to do next. Options would include extending your consent to storage, using your gametes or embryos in treatment or you may decide that you no longer wish for them to remain in storage. You are able to book an appointment to discuss all your options. In Wales, the Welsh Health Specialised Services Committee (WHSSC) funds fertility preservation for people embarking on gender confirmation medication or surgeries for 10 years. If after the 10 years you wish for your eggs, sperm or embryos to remain in storage, there would be an annual fee (currently £275 per year). *This is now not applicable given the change in law that the statutory storage period is 55 years, with consent required for storage every 10 years. Unsure how this impacts the storage costs.*
	Access to stored materials	No information identified.
	Disposal of stored materials	Please ensure that you keep us up to date of any address or telephone number changes. If we are unable to get in touch it may result in us having to discard your gametes or embryos as it is against the law for us to keep them in storage without your consent.
	Any other storage information	Unfortunately Wales Fertility Institute does not have storage facilities to store for sero-positive patients. If you were to test positive for syphilis, gonorrhoea or chlamydia then we would be able to delay storage until you've completed a course of treatment. Depending on your ethnic background, whether you grew up in another country or your recent travel history, there may also be additional tests performed.
Governance		During the appointment specialists will discuss the storage process and assist the patient in completing HFEA (Human Fertilisation and Embryology Authority) consent forms and WFI (Wales Fertility Institute) consent forms.

Funding		In Wales, the Welsh Health Specialised Services Committee (WHSSC) funds fertility preservation for people embarking on gender confirmation medication or surgeries for 10 years. If after the 10 years you wish for your eggs, sperm or embryos to remain in storage, there would be an annual fee (currently £275 per year). If…positive for HIV, Hep B, Hep C or HTLV your referrer could offer you a referral to an alternative centre who are able to offer this service. An individual patient funding request for the transfer of NHS funds will be made to the Welsh Health Specialised Services Committee (WHSSC). Unfortunately Wales Fertility Institute does not have storage facilities to store for sero-positive patients.
Communication and information provision		The brochure extracted is provided to those looking for information. The offer of counselling forms part of the process of fertility preservation and treatment. Counselling is available to you before, during and after your treatment.
Ethical considerations		Some people can experience dysphoria about their genitals or the impact of hormones can make producing a sample more difficult. Under these circumstances, the WFI can arrange for the production of a sperm sample at home. This may depend where the patient lives as the laboratory need to receive the sample within a suitable time frame. The offer of counselling forms part of the process of fertility preservation and treatment. Counselling is available to before, during and after treatment. Being able to talk freely in a quiet, confidential, non-judgemental setting can be invaluable with helping make decisions about fertility preservation and future treatment. **Equality statement** The NHS is about people. The people who use the service and the people who provide it. At NHS Wales we have a responsibility towards our patients, the general public and each other to promote equality, eliminate discrimination and harassment, and foster good relations. Everyone counts! All staff undertake mandatory training to ensure they are competent in their obligations under equality and human rights law.
Relevant legislation (list)		No information identified.
Miscellaneous		No information identified.

Table D.46 Extracted data for Wales (Fertility Preservation)

Wales		
Author(s) **Title [year]**	Wales Fertility Institute (WFI) Fertility Preservation[102] Supported by Information for Patients: Sperm Freezing[103], Specialised Services Service Specification: CP79 Haematopoietic stem cell transplantation for adults [2020],[104] Specialised Services Policy Position PP142 Haematopoietic Stem Cell Transplantation (HSCT) for Adults [2020],[105] Specialised Services Service Specification: Services for Children with Cancer (CP86) [2024].[106]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		WFI currently provides storage for patients who are due to undergo surgery, radiotherapy, chemotherapy or whose future potential fertility may be compromised. In addition we back up freeze for a limited number of patients receiving fertility treatment. Both NHS and privately paying patients can use the services of the WFI. The following documents outline that the relevant populations should be provided with advice and information regarding fertility preservation prior to the commencement of treatment which induces infertility (unless urgent): ▪ Specialised Services Service Specification: CP79 Haematopoietic stem cell transplantation for adults [2020][104] ▪ Specialised Services Policy Position PP142 Haematopoietic Stem Cell Transplantation (HSCT) for Adults [2020][105] ▪ Specialised Services Service Specification: Services for Children with Cancer (CP86) [2024].[106]
Preservation method(s) available		Sperm, egg and embryo freezing.
Organisation	***Referral pathways***	You are not able to self-refer to this service, a referral will be sent to us by one of the clinicians involved with your treatment.
	Service provider characteristics	No information identified.
	Timelines to access services	As soon as the laboratory has received the screening test results, they will contact the patient to arrange a convenient time to attend for storage.
	Any other organisational aspects	Patients will be required to be screen for a range of infectious agents. These are HIV, Hepatitis B and C, Syphilis, Chlamydia and Gonorrhoea, in addition we will also require HTLV I&II if you are considered to be at high risk of exposure.
Storage	***Arrangements and duration(s)***	For oncology patients and those undergoing treatment which has the potential to reduce fertility, the sample will be split between two storage vessels to minimise the risks to the samples.

	Access to stored materials	Wales Fertility Institute are happy to give advice on fertility treatments and address any other fertility related concerns patients may have. They will also assist patients with transferring stored sample to another Clinic if they require this.
	Disposal of stored materials	To be able to legally keep your samples in storage, we are required to have up to date contact details for you. If we are unable to contact you, we are unable to keep your samples in storage.
	Any other storage information	WFI will contact patients 12 months before their consent is due to expire.
Governance		The Wales Fertility Institute is a NHS facility managed by Swansea Bay University Health Board. The patient will be required to complete the HFEA GS and CD forms, as well as a Cardiff Cryopreservation of Sperm Consent, if they have a partner they will also be required to complete a MT form. These forms will be given to the patient by their referring clinician, if not they can be completed at the first appointment. A partner will be required to complete a HFEA CD form. The patient and their partner will be required to provide photographic identification
Funding		No information identified.
Communication and information provision		Information is provided around the procedure of obtaining the sperm sample. After storage is completed, we will send you a letter confirming the total number of straws stored and the year that consent expires. Where you have consented to us contacting other healthcare professionals, we will also send a copy of this to the referring clinician. The model should ensure that access to fertility support is available…Children and young people with cancer and their parents or carers should have the risks discussed with them and be advised about their options for fertility preservation before cancer treatment starts. Fertility advice should also be made available to all long-term survivors.(106)
Ethical considerations		When banking sperm the patient will find out more about their potential fertility. One in 10 men has a fertility problem and one in 50 men ejaculate no sperm at all. In the event of the laboratory finding no sperm in a sample, they will be unable to store, the laboratory is able to put the patient in contact with a counsellor if they would like to speak to one. The patient will be asked to decide if they wish to let a named partner/wife have treatment with their sperm even in the event of their death. Alternatively they can decide that if anything happens to them the sperm should be disposed of, this is also the situation if they do not name a partner. The patient can name a partner/wife at a later date; however they will be required to complete the appropriate forms. Consent forms will remain in force until they are changed in writing Patients can withdraw consent at any time
Relevant legislation (list)		No information identified.

Miscellaneous		Note: The Specialised Services Commissioning Policy: CP38 Specialist Fertility Services excludes those who require fertility preservation for medical reasons.

References

1. (Australia) DoHaAC. Assisted Reproductive Technology (ART) Storage Funding Program [Internet]. Australia: Department of Health and Aged Care (Australia); 2023 [cited 2024 July 22]. Available from: https://www.health.gov.au/our-work/assisted-reproductive-technology-art-storage-funding-program.
2. Department of Health and Aged Care (Australia). ART Storage Funding Program Guidelines [Internet]. Australia: Department of Health and Aged Care (Australia); 2023 [cited 2024 July 24]. Available from: https://www.health.gov.au/sites/default/files/2023-10/art-storage-funding-program-guidelines.docx.
3. Department of Health and Aged Care (Australia). ART Storage Funding Program – fact sheet for patients [Internet]. Australia: Department of Health and Aged Care (Australia); 2023 [cited 2024 July 25]. Available from: https://www.health.gov.au/resources/publications/art-storage-funding-program-fact-sheet-for-patients.
4. National Health and Medical Research Council (Australia). Ethical guidelines on the use of assisted reproductive technology in clinical practice and research [Internet]. Canberra: National Health and Medical Research Council (Australia); 2017 [updated 2023; cited 2024 July 22]. Available from: https://www.nhmrc.gov.au/about-us/publications/art.
5. National Health and Medical Research Council (Australian Government). 2023 update to the ART Guidelines [Internet]. Canberra: National Health and Medical Research Council (Australian Government); 2023 [cited 2024 July 26]. Available from: https://www.nhmrc.gov.au/file/18958/download?token=S70euCnC#:~:text=The%20most%20recent%20update%20in,(Maeve's%20Law)%20Act%202022.
6. Department of Health and Aged Care (Australia). Medicare Benefits Schedule Book Operating from 1 July 2024 [Internet]. Australia: Department of Health and Aged Care (Australia); 2024 [cited 2024 July 25]. Available from: https://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/B013E0789A07D708CA258B030013670A/$File/PDF%20Version%20of%20the%20MBSBook%20-%201%20July%202024.pdf.
7. Services Australia. Assisted reproductive technology services [Internet]. Australia: Australian Government; 2024 [cited 2024 July 25]. Available from: https://www.servicesaustralia.gov.au/mbs-billing-for-assisted-reproductive-technology-services?context=20.
8. Medical Services Advisory Committee (Australian Government). Public Summary Document: Application No. 1435 - Processing and cryopreservation of male and female gonadal tissue and gametes prior to or after gonadotoxic treatment to preserve fertility for the future (Part A) [Internet]. Sydney: Medical Services Advisory Committee (Australian Government); 2017 [cited 2024 July 22]. Available from: http://www.msac.gov.au/internet/msac/publishing.nsf/Content/B82B7C383F44B6ACCA25801000123C27/$File/1435-Final-PSD.pdf.
9. Medical Services Advisory Committee (Australian Government). Public Summary Document: Application No. 1435.1 - Processing and cryopreservation (freezing) of ovarian tissue and thawing and preparation of ovarian tissue for ovarian tissue transplantation following gonadotoxic treatment [Internet]. Australia: Medical Services Advisory Committee (Australian Government); 2019 [cited 2024 July 22]. Available from: http://www.msac.gov.au/internet/msac/publishing.nsf/Content/B4C51BB344EDF0E8CA2583CF001BC23A/$File/1435.1%20-%20Final%20PSD.pdf.
10. Services Australia. Medicare claims [Internet]. Australia: Australian Government; 2024 [cited 2024 July 26]. Available from: https://www.servicesaustralia.gov.au/medicare-claims?context=60092.
11. Services Australia. Bulk billing [Internet]. Australian Government: 2024 [cited 2024 July 26]. Available from: https://www.servicesaustralia.gov.au/bulk-billing?context=60092.
12. The Royal Women's Hospital. National Ovarian and Testicular Tissue Transport and Cryopreservation Service (NOTTCS) [Internet]. Australia: The Royal Women's Hospital; 2024 [cited 2024 July 29]. Available from: https://www.thewomens.org.au/health-professionals/womens-health-services/sexual-reproductive-health/reproductive-services-main/nottcs.
13. MARTIN A, TORO M, ROZEN G, AGRESTA F, GOOK D, STERN K. National Ovarian and Testicular Tissue Transport and Cryopreservation Service (NOTTCS). Fertility & Reproduction. 2022;04(03n04):198-.
14. The Royal Women's Hospital and Melbourne IVF. Preserving your fertility for the future [Internet]. Australia: The Royal Women's Hospital and Melbourne IVF; 2020 [cited 2024 July 29]. Available from: https://thewomens.r.worldssl.net/images/uploads/fact-sheets/Preserving-your-fertility-for-the-future.pdf.
15. The Royal Women's Hospital. Fertility preservation for young people [Internet]. Australia: The Royal Women's Hospital; 2019 [cited 2024 July 29]. Available from: https://www.fertilitysociety.com.au/wp-content/uploads/2019-Info-for-NOTTCS.pdf.
16. Council of Ethics (Denmark). Storage of fertilised eggs and unfertilised egg cells [Internet]. Denmark: Council of Ethics (Denmark),; 2020 [cited 2024 July 23]. Available from: https://etiskraad.dk/Media/637834725832136120/2020%20Udtalelse%20om%20opbevaring%20af%20befrugtede%20aeg%20og%20ubefrugtede%20aegceller.pdf.

17. Ministry of the Interior and Health (Denmark). LBK nr 902 af 23/08/2019: Executive Order on the Act on Assisted Reproduction in Connection with Treatment, Diagnostics and Research, etc. [Internet]. Denmark: Ministry of the Interior and Health (Denmark); 2019 [cited 2024 July 22]. Available from: https://www.retsinformation.dk/eli/lta/2019/902.
18. The Danish Ministry of Health. New political agreement lifts 5-year limit for freezing eggs [Internet]. Denmark: The Danish Ministry of Health; 2020 [cited 2024 July 23]. Available from: https://www.ism.dk/nyheder/2020/oktober/ny-politisk-aftale-ophaever-5-aars-graense-for-nedfrysning-af-aeg.
19. Ministry of the Interior and Health (Denmark). BEK no 672 of 08/05/2015: Executive Order on Assisted Reproduction [Internet]. Denmark: Ministry of the Interior and Health (Denmark); 2015 [updated 2015 June 15; cited 2024 July 23]. Available from: https://www.retsinformation.dk/eli/lta/2015/672.
20. Ministry of the Interior and Health (Denmark). VEJ no 9351 of 26/05/2015: Guidance on the activities and obligations of healthcare professionals and tissue establishments in the field of assisted reproduction [Internet]. Denmark: 2020 [updated 2020 July 16; cited 2024 July 22]. Available from: https://www.retsinformation.dk/eli/retsinfo/2015/9351.
21. NHS Bedfordshire Luton and Milton Keynes: Integrated Care Board. Gamete (sperm/egg) storage for those undergoing fertility-threatening treatment V2.0 [Internet]. United Kingdom: NHS Bedfordshire Luton and Milton Keynes: Integrated Care Board,; 2022 [cited 2024 August 14]. Available from: https://bedfordshirelutonandmiltonkeynes.icb.nhs.uk/~documents/policies/evidence-based-clinical-policies/gamete-storage-blmk-policy/?layout=default.
22. NHS Coventry and Warwickshire Integrated Care Board. NHS Funded Cryopreservation of Gametes and Embryos Policy [Internet]. England: NHS Coventry and Warwickshire Integrated Care Board; 2022 [cited 2024 August 12]. Available from: https://www.happyhealthylives.uk/document-library/?keyword_search=preservation&category_id=all&sub_category_id=all&file_date_month=&file_date_year=&file_type=#
23. NHS Cheshire and Merseyside Integrated Care Board. Clinical commissioning policies [Internet]. England: NHS Cheshire and Merseyside; 2024 [cited 2024 September 04]. Available from: https://www.cheshireandmerseyside.nhs.uk/your-health/clinical-policies/.
24. NHS Liverpool Clinical Commissioning Group. NHS Funded Treatment for Subfertility Policy [Internet]. England: NHS Cheshire and Merseyside Integrated Care Board; 2015 [cited 2024 August 9]. Available from: https://www.cheshireandmerseyside.nhs.uk/media/3vqhombp/liv-subfertility-21-10-2015.pdf.
25. NHS Knowsley Clinical Commissioning Group. NHS Funded Treatment for Subfertility Policy [Internet]. England: NHS Cheshire and Merseyside Integrated Care Board; 2015 [cited 2024 August 9]. Available from: https://www.cheshireandmerseyside.nhs.uk/media/laljoeqf/kno-subfertility-21-10-2015.pdf.
26. NHS Warrington Clinical Commissioning Group. NHS Funded Treatment for Subfertility Policy [Internet]. England: NHS Cheshire and Merseyside Integrated Care Board; 2015 [cited 2024 August 9]. Available from: https://www.cheshireandmerseyside.nhs.uk/media/z54gh3in/place-war-subfertility-21-10-2015.pdf.
27. NHS Halton Clinical Commissioning Group. NHS Funded Treatment for Subfertility Policy [Internet]. England: NHS Cheshire and Merseyside Integrated Care Board; 2015 [cited 2024 August 9]. Available from: https://www.cheshireandmerseyside.nhs.uk/media/zywp2psf/hal-subfertility-21-10-2015.pdf.
28. NHS St. Helen's Clinical Commissioning Group. St Helens CCG NHS Funded Treatment for Subfertility Policy [Internet]. England: NHS St. Helen's Clinical Commissioning Group; 2015 [cited 2024 August 9]. Available from: https://www.cheshireandmerseyside.nhs.uk/media/gqvhhloy/subfertility-policy-2015-16-st-helens-may-2015.pdf.
29. NHS Wirral Clinical Commissioning Group. NHS Funded Treatment for Subfertility Policy [Internet]. England: NHS Cheshire and Merseyside ICB; 2023 [cited 2024 August 9]. Available from: https://www.cheshireandmerseyside.nhs.uk/media/f4wmalsk/wirral-sub-fertility-policy-updated-071123.pdf.
30. NHS South Sefton Clinical Commissioning Group. NHS Funded Treatment for Subfertility Policy [Internet]. England: NHS South Sefton Clinical Commissioning Group; 2014 [cited 2024 August 9]. Available from: https://www.cheshireandmerseyside.nhs.uk/media/lwmme4hn/subfertility-policy-2014-15-sefton-21-11-2014.pdf.
31. NHS Southport and Formby Clinical Commissioning Group. NHS Funded Treatment for Subfertility Policy [Internet]. England: NHS Southport and Formby Clinical Commissioning Group; 2014 [cited 2024 August 9]. Available from: https://www.cheshireandmerseyside.nhs.uk/media/ja3mlegd/subfertility-policy-2014-15-southport-and-formby-21-11-2014.pdf.
32. NHS West Cheshire Clinical Commissioning Group. NHS Funded Treatment for Subfertility Policy [Internet]. England: NHS West Cheshire Clinical Commissioning Group; 2017 [updated 2023; cited 2024 August 9]. Available from: https://www.cheshireandmerseyside.nhs.uk/media/fozbs4q4/wc-sub-fertility-policy-updated-071123.pdf.
33. NHS Eastern Cheshire Clinical Commissioning Group, NHS South Cheshire Clinical Commissioning Group, NHS Vale Royal Clinical Commissioning Group. NHS Funded Treatment for Subfertility Policy [Internet]. England: NHS Cheshire and Merseyside Integrated Care Board; 2017 [updated 2023; cited 2024 August

9]. Available from: https://www.cheshireandmerseyside.nhs.uk/media/5q5fk0u5/ec-sc-vr-sub-fertility-policy-updated-071123.pdf.

34. National Health Service (NHS). Fertility preservation for service users with ovarian tissue who are at high/very high risk of infertility and cannot store mature eggs [Internet]. National Health Service (NHS); 2023 [cited 2024 July 22]. Available from: https://www.england.nhs.uk/wp-content/uploads/2023/09/1867-fertility-preservation-serv-users-ovarian-tissue-high-risk-infertility-and-cannot-store-mature-eggs-servi.pdf.
35. NHS England. NHS England and NHS Improvement: Equality and Health Inequalities Impact Assessment (EHIA) template [Internet]. England: NHS England; 2020 [cited 2024 September 04]. Available from: https://www.england.nhs.uk/wp-content/uploads/2023/09/1867-fertility-preservation-serv-users-ovarian-tissue-high-risk-infertility-and-cannot-store-mature-eggs-ehia.pdf.
36. National Health Service (NHS). Fertility preservation for service users with testicular tissue who are at high/very high risk of infertility and cannot store sperm [Internet]. National Health Service (NHS); 2023 [cited 2024 July 22]. Available from: https://www.england.nhs.uk/wp-content/uploads/2023/09/1867-testicular-tissue-cryo-serv-users-high-risk-infertility-cannot-store-sperm-service-spec.pdf.
37. NHS England. NHS England and NHS Improvement: Equality and Health Inequalities Impact Assessment (EHIA) template [Internet]. England: NHS England; 2020 [cited 2024 September 04]. Available from: https://www.england.nhs.uk/wp-content/uploads/2023/09/1867-testicular-tissue-cryo-serv-users-high-risk-infertility-cannot-store-sperm-ehia.pdf.
38. NHS Kent and Medway Integrated Care Board. Policies on fertility treatments [Internet]. United Kingdom: NHS Kent and Medway Integrated Care Board,; 2024 [cited 2024 August 14]. Available from: https://www.kentandmedway.icb.nhs.uk/about-us/strategies-policies-and-frameworks/719.
39. South Central and West Commissioning Support Unit (SCW CSU). Schedule of policy statements for assisted reproductive technologies (ART) for Kent and Medway Integrated Care Board [Internet]. United Kingdom: South Central and West Commissioning Support Unit (SCW CSU); 2024 [cited 2024 August 14]. Available from: https://www.kentandmedway.icb.nhs.uk/application/files/7417/1655/8382/Kent_and_Medway_ART_policy_document_June_2024.pdf.
40. NHS Somerset. Evidence Based Interventions (EBI) Programme for Interventions Not Normally Funded (INNF) [Internet]. United Kingdom: NHS Somerset; 2024 [cited 2024 August 18]. Available from: https://nhssomerset.nhs.uk/my-health/interventions-not-normally-funded/.
41. NHS Somerset. Fertility assessment and treatment prior approval (PA) policy [Internet]. United Kingdom: NHS Somerset; 2022 [cited 2024 August 14]. Available from: https://nhssomerset.nhs.uk/wp-content/uploads/sites/2/Fertility-Assessment-and-Treatment-Policy-22425.v7c-20240625.pdf.
42. NHS South West London. Evidence Based Interventions Policy V4.1 [Internet]. United Kingdom: NHS South West London; 2023 [cited 2024 August 14]. Available from: https://www.southwestlondon.icb.nhs.uk/wp-content/uploads/2022/07/NHS-South-West-London-evidence-based-interventions-policy-4.1.pdf.
43. NHS England. Specialist cancer services for children and young people: Teenage and Young Adults Designated Hospitals [Internet]. England: NHS England; 2023 [cited 2024 August 09]. Available from: https://www.england.nhs.uk/wp-content/uploads/2023/05/service-spec-tya-designated-hospitals.pdf.
44. NHS England. Specialist cancer services for children and young people: Teenage and Young Adults Principal Treatment Centre Services [Internet]. England: NHS England; 2023 [cited 2024 August 09]. Available from: https://www.england.nhs.uk/wp-content/uploads/2023/05/service-spec-tya-ptc.pdf.
45. National Health Service (NHS). Teenage and young adult cancer clinical network specification [Internet]. National Health Service (NHS); 2023 [cited 2024 July 22]. Available from: https://www.england.nhs.uk/publication/teenage-and-young-adult-cancer-clinical-network-specification/.
46. NHS West Yorkshire Integrated Care Board. Cryopreservation for both men and women where the usual fertility policy does not apply [Internet]. United Kingdom: NHS West Yorkshire Integrated Care Board; 2021 [cited 2024 August 14]. Available from: https://www.wypartnership.co.uk/application/files/7916/8907/1280/Cryopreservation_for_fertility_treatment_12.2021.pdf.
47. Biomedicine Agency (France). Funding for medically assisted genetic procreation 2023 [Internet]. France: Biomedicine Agency; 2024 [cited 2024 August 1]. Available from: https://www.agence-biomedecine.fr/IMG/pdf/plaquette_financement_en_pegh_2023_vdef_2805.pdf.
48. Biomedicine Agency (France). Self-preservation of gametes [Internet]. France: Biomedicine Agency (France); 2024 [cited 2024 July 23]. Available from: https://www.procreation-medicale.fr/autoconservation-gametes/.
49. Biomedicine Agency (France). Self-preservation of gametes (Guide) [Internet]. France: Biomedicine Agency (France); 2024 [cited 2024 July 23]. Available from: https://www.procreation-medicale.fr/wp-content/uploads/2024/05/BD_BIOM24-2_MAJ_BROCH_GUIDE_PATIENTS_AUTOCONSERVATION.pdf.
50. Biomedicine Agency (France). What does the law say [Internet]. France: Biomedicine Agency (France); 2024 [cited 2024 July 30]. Available from: https://www.procreation-medicale.fr/ce-que-dit-la-loi/.

51. French Government. Decree No. 2021-1243 of 28 September 2021 setting the conditions for the organisation and coverage of medically assisted reproduction pathways [Internet]. France: French Government; 2021 [cited 2024 July 23]. Available from: https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044111531.
52. French Government. Public Health Code: Title IV: Medically assisted procreation (Articles R2141-1 to R2143-20) [Internet]. France: French Government; 2024 [cited 2024 July 30]. Available from: https://www.legifrance.gouv.fr/codes/section_lc/LEGITEXT000006072665/LEGISCTA000006160967/.
53. French Government. Public Health Code: Title IV: Medically assisted procreation (Articles L2141-1 to L2143-9) [Internet]. France: French Government; 2024 [cited 2024 July 23]. Available from: https://www.legifrance.gouv.fr/codes/section_lc/LEGITEXT000006072665/LEGISCTA000006155015/#LEGISCTA000006155015.
54. Federal Medical Association (Germany). Guideline for the removal and transfer of human germ cells or germ cell tissue in the context of assisted reproduction, detailed update [Internet]. Germany: Federal Medical Association (Germany); 2022 [cited 2024 July 23]. Available from: https://www.wbbaek.de/fileadmin/user_upload/BAEK/Themen/Medizin_und_Ethik/RiLi-ass-Reproduktion.pdf.
55. German Medical Association (BAK). Fertility preservation: German Medical Association presents revised guideline [Internet]. Germany: German Medical Association (BAK); 2022 [cited 2024 September 04]. Available from: https://www.bundesaerztekammer.de/presse/aktuelles/detail/fertilitaetserhalt-bundesaerztekammer-legt-ueberarbeitete-richtlinie-vor.
56. Federal Ministry of Health (Bundesministerium für Gesundheit) (Germany). Examination according to § 94 SGB V by the BMG [Internet]. Berlin: The Federal Joint Committee (Germany) (Gemeinsamer Bundesausschuss); 2022 [cited 2024 July 25]. Available from: https://www.g-ba.de/downloads/40-268-8944/2022-08-18_Kryo-RL_Kryokonservierung-Keimzellgewebe_BMG.pdf.
57. Federal Ministry of Health (Bundesministerium für Gesundheit) (Germany). Support for young cancer patients: cryopreservation becomes a health insurance benefit [Internet]. Germany: Federal Ministry of Health (Bundesministerium für Gesundheit) (Germany); 2019 [cited 2024 July 23]. Available from: https://www.bundesgesundheitsministerium.de/kryokonservierung.
58. The Federal Joint Committee (Germany) (Gemeinsamer Bundesausschuss). Cryopreservation Policy: Guideline for the cryopreservation of egg or sperm cells or germ cell tissue as well as corresponding medical measures for germ cell damaging therapy – Cryo-RL [Internet]. Germany: The Federal Joint Committee (Germany) (Gemeinsamer Bundesausschuss); 2022 [cited 2024 July 23]. Available from: https://www.g-ba.de/richtlinien/119/.
59. The Federal Joint Committee (Germany) (Gemeinsamer Bundesausschuss). Cryopreservation of ovarian tissue becomes a health insurance benefit [Internet]. Berlin: Gemeinsamer Bundesausschuss (G-BA); 2022 [cited 2024 July 24]. Available from: https://www.g-ba.de/presse/pressemitteilungen-meldungen/1066/.
60. The Federal Joint Committee (Germany) (Gemeinsamer Bundesausschuss). Cryopreservation [Internet]. Germany: The Federal Joint Committee (Germany) (Gemeinsamer Bundesausschuss); 2024 [cited 2024 July 23]. Available from: https://www.g-ba.de/themen/methodenbewertung/kryokonservierung-von-ei-und-samenzellen/.
61. The Federal Joint Committee (Germany) (Gemeinsamer Bundesausschuss). Reasons for the decision of the Federal Joint Committee to amend the guidelines on cryopreservation: Cryopreservation of germ cell tissue [Internet]. Germnay: The Federal Joint Committee (Germany) (Gemeinsamer Bundesausschuss); 2022 [cited 2024 July 25]. Available from: https://www.g-ba.de/downloads/40-268-8771/2022-08-18_Kryo-RL_Kryokonservierung-Keimzellgewebe_TrG.pdf.
62. Belfast Health and Social Care Trust. Regional Fertility Centre [Internet]. Northern Ireland: Belfast Health and Social Care Trust; 2024 [cited 2024 July 23]. Available from: https://belfasttrust.hscni.net/services/rfc/.
63. Belfast Health and Social Care Trust. Patient Information: New Storage Laws [Internet]. Northern Ireland: Belfast Health and Social Care Trust; 2024 [cited 2024 September 04]. Available from: https://belfasttrust.hscni.net/download/208/rfc/14337/storage-laws-patient-info.pdf.
64. Belfast Health and Social Care Trust. Referral for Medically Required Fertility Preservation – Female [Internet]. Northern Ireland: Belfast Health and Social Care Trust; 2024 [cited 2024 September 04]. Available from: https://belfasttrust.hscni.net/download/208/rfc/14382/fm203-v4-female-referral.pdf.
65. Department of Health (Northern Ireland). Circular HSC (SQSD) 3/13. Subject: NICE Clinical Guidelines Endorsement, Implementation, Assurance in Northern Ireland [Internet]. Northern Ireland: Department of Health (Northern Ireland); 2013 [cited 2024 August 8]. Available from: https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/hsc-sqsd-3-13.pdf.
66. Department of Health (Northern Ireland). NICE - Endorsed Clinical Guidelines 2013/2014 [Internet]. Northern Ireland: Department of Health (Northern Ireland); 2024 [cited 2024 July 24]. Available from: https://www.health-ni.gov.uk/articles/nice-endorsed-clinical-guidelines-20132014.
67. Department of Health (Northern Ireland). Additional Caveats for CG 156 - Fertility: assessment and treatment for people with fertility problems [Internet]. Northern Ireland: Department of Health

(Northern Ireland); 2013 [cited 2024 July 24]. Available from: https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/cg156-additional-caveats.pdf.

68. Department of Health (Northern Ireland). Subject: NICE Clinical Guideline NG73 – Endometriosis: diagnosis and management [Internet]. Northern Ireland: Department of Health (Northern Ireland); 2017 [cited 2024 July 24]. Available from: https://www.health-ni.gov.uk/sites/default/files/publications/health/hsc-sqsd-nice-ng73-35-17.pdf.
69. CNPMA. Requirement and operating parameters for ART Centres [Internet]. Portugal: CNPMA; 2021 [cited 2024 September 10]. Available from: https://www.cnpma.org.pt/profissionais/Paginas/requisitos-e-parametros.aspx.
70. Diario De Republica (Portugal). Medically assisted reproduction: Law No.32/2006 (Consolidated Legislation) [Internet]. Portugal: Diario De Republica (Portugal),; 2006 [cited 2024 July 23]. Available from: https://diariodarepublica.pt/dr/legislacao-consolidada/lei/2006-34529775.
71. Diario De Republica (Portugal). Law No. 17/2016 [Internet]. Portugal: Diario De Republica (Portugal),; 2016 [cited 2024 July 23]. Available from: https://diariodarepublica.pt/dr/detalhe/lei/17-2016-74738646.
72. Central Administration of the Health System (Portugal), Directorate-General of Health of Portugal. Joint Normative Circular No. 4/2022/ACSS/DGS: Access to Medically Assisted Procreation Treatments – Exceptional regime for access to PMA techniques in the National Health Service, in cases of preservation of reproductive potential due to serious illness [Internet]. Portugal: Central Administration of the Health System (Portugal), Directorate-General of Health of Portugal,; 2022 [cited 2024 July 23]. Available from: https://www.acss.min-saude.pt/wp-content/uploads/2016/11/Normativa-4-2022-Acesso-a-Tratamentos-de-Procria%C3%A7%C3%A3o-Medic_DO_.pdf.
73. Portuguese Society of Reproductive Medicine. Preservation of fertility in oncological patients [Internet]. Portugal: Portuguese Society of Reproductive Medicine; 2015 [cited 2024 July 31]. Available from: https://www.spmr.pt/attachments/brochura_oncofertilidade.pdf.
74. National Council for Medically Assisted Reproduction (CNPMA). National Council for Medically Assisted Reproduction [Internet]. Portugal: National Council for Medically Assisted Reproduction (CNPMA); 2024 [cited 2024 July 23]. Available from: https://www.cnpma.org.pt/.
75. ACSS. Review of Exemption Categories and Update Values of Moderator Fees [Internet]. Portugal: ACSS; 2021 [cited 2024 August 01]. Available from: https://www.acss.min-saude.pt/wp-content/uploads/2016/09/FAQ_taxas_moderadoras_012022.pdf.
76. Assembly of the Republic (Portugal). Law no 12/2009: Establishes the legal regime for quality and safety relating to the donation, collection, analysis, processing, preservation, storage, distribution and application of tissues and cells of human origin, transposing Directives No. 2004/23/ into the domestic legal system. EC, of the European Parliament and of the Council, of 31 March, 2006/17/EC, of the Commission, of 8 February, and 2006/86/EC, of the Commission, of 24 October [Internet]. Portugal: Assembly of the Republic (Portugal); 2009 [cited 2024 August 01]. Available from: https://www.cnpma.org.pt/CNPMA%20Legislacao/Legislacao_Lei_12_2009.pdf.
77. National Council for Medically Assisted Reproduction (CNPMA). FAQs [Internet]. Portugal: National Council for Medically Assisted Reproduction (CNPMA); 2024 [cited 2024 July 31]. Available from: https://www.cnpma.org.pt/cidadaos/Paginas/faqs.aspx.
78. National Council for Medically Assisted Reproduction (CNPMA). CRYOPRESERVATION OF SPERM: Informed Consent [Internet]. Portugal: CRYOPRESERVATION OF SPERM: Informed Consent; 2024 [cited 2024 August 01]. Available from: https://www.cnpma.org.pt/CNPMA%20Modelos%20de%20Consentimento/CI_13.pdf.
79. National Council for Medically Assisted Reproduction (CNPMA). MAINTENANCE OF CRYOPRESERVATION OF SPERMATOZOA AND/OR TESTICULAR TISSUE: Informed Consent [Internet]. Portugal: National Council for Medically Assisted Reproduction (CNPMA); 2022 [cited 2024 August 01]. Available from: https://www.cnpma.org.pt/CNPMA%20Modelos%20de%20Consentimento/CI_17.pdf.
80. National Council for Medically Assisted Reproduction (CNPMA). CRYOPRESERVATION OF OVOCYTES AND/OR OVARIAN TISSUE: Informed Consent [Internet]. Portugal: National Council for Medically Assisted Reproduction (CNPMA); 2024 [cited 2024 August 01]. Available from: https://www.cnpma.org.pt/CNPMA%20Modelos%20de%20Consentimento/CI_14.pdf.
81. National Council for Medically Assisted Reproduction (CNPMA). MAINTENANCE OF CRYOPRESERVATION OF OVOCYTES AND/OR OVARIAN TISSUE: Informed Consent [Internet]. Portugal: National Council for Medically Assisted Reproduction (CNPMA); 2020 [cited 2024 August 01]. Available from: https://www.cnpma.org.pt/CNPMA%20Modelos%20de%20Consentimento/CI_18.pdf.
82. National Council for Medically Assisted Reproduction (CNPMA). EMBRYO CRYOPRESERVATION: Informed Consent [Internet]. Portugal: National Council for Medically Assisted Reproduction (CNPMA); 2022 [cited 2024 August 01]. Available from: https://www.cnpma.org.pt/CNPMA%20Modelos%20de%20Consentimento/CI_15.pdf.
83. National Council for Medically Assisted Reproduction (CNPMA). MAINTENANCE OF CRYOPRESERVATION OF EMBRYOS (OR PRE-ZYGOTES): Informed Consent [Internet]. Portugal: National Council for Medically

Assisted Reproduction (CNPMA); 2020 [cited 2024 August 01]. Available from: https://www.cnpma.org.pt/CNPMA%20Modelos%20de%20Consentimento/CI_19.pdf.

84. National Council for Medically Assisted Reproduction (CNPMA). Informed Consent [Internet]. Portugal: National Council for Medically Assisted Reproduction (CNPMA); 2024 [cited 2024 August 01]. Available from: https://www.cnpma.org.pt/cidadaos/Paginas/modelos-de-consentimento-informado.aspx.
85. Diario De Republica (Portugal). Regulatory Decree No. 6/2016 [Internet]. Portugal: Diario De Republica; 2016 [cited 2024 August 20]. Available from: https://iasaude.pt/attachments/article/1928/decreto_regulamentar_6_2016_%20procriacao_medica_assistida.pdf.
86. Scotland F. Fertility Scotland (NHS Scotland National Strategic Network) [Internet]. Scotland: NHS Scotland; 2024 [cited 2024 July 23]. Available from: https://fertility.scot/.
87. NHS Scotland. Fertility Scotland National Network Annual Report 2021/22 [Internet]. Scotland: NHS Scotland; 2022 [cited 2024 August 20]. Available from: https://fertility.scot/wp-content/uploads/2022/08/2021-22-Fertility-Scotland-Annual-Report-v1.0.pdf.
88. NHS Tayside. Information for patients wishing to freeze eggs or embryos for fertility preservation [Internet]. Scotland: NHS Tayside; 2023 [cited 2024 July 29]. Available from: https://www.nhstaysidecdn.scot.nhs.uk/NHSTaysideWeb/idcplg?IdcService=GET_SECURE_FILE&dDocName=PROD_342153&Rendition=web&RevisionSelectionMethod=LatestReleased&noSaveAs=1.
89. NHS Lothian. Edinburgh Fertility Centre: Fertility Preservation Referral Form [Internet]. Scotland: NHS Lothian; 2021 [cited 2024 August 20]. Available from: https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fapps.nhslothian.scot%2Ffiles%2Fsites%2F2%2FFertility-Preservation-Referral-Form-v4.doc&wdOrigin=BROWSELINK.
90. NHS Lothian. Fertility and Reproductive Endocrinology [Internet]. Scotland: NHS Lothian; 2024 [cited 2024 September 04]. Available from: https://apps.nhslothian.scot/refhelp/guidelines/fertilityreproductive-endocrinology/.
91. NHS Inform. Fertility and cancer [Internet]. Scotland: NHS Inform; 2024 [cited 2024 August 20]. Available from: https://www.nhsinform.scot/illnesses-and-conditions/cancer/practical-issues/fertility-and-cancer/#:~:text=tests%20and%20advice.-,Preserving%20your%20fertility,a%20partner%20have%20a%20child.
92. NHS Scotland. Endocrine and Fertility Preservation guidance [Internet]. Scotland: NHS Scotland,; 2022 [cited 2024 July 29]. Available from: https://www.nn.nhs.scot/ngicns/wp-content/uploads/sites/17/2023/04/NSD_GRP_OG_05-Endocrine-and-fertility-preservation-guidance-2022-v0.8.pdf.
93. The Tissue Council (Sweden). Measures to preserve reproductive capacity in adults: promotion of equal care for patients at risk of treatment induced infertility [Internet]. Sweden: The Tissue Council (Sweden); 2023 [cited 2024 July 23]. Available from: https://vavnad.se/wp-content/uploads/2023/02/atgarder-for-att-bevara-reproduktionsformagan-hos-vuxna-version-10.pdf.
94. The Tissue Council (Sweden). Measures to preserve the reproductive capacity of the young: promotion of equal care for young people who are at risk of treatment induced infertility [Internet]. Sweden: The Tissue Council (Sweden); 2021 [cited 2024 July 23]. Available from: https://vavnad.se/wp-content/uploads/2021/09/atgarder-for-att-beavara-reproduktionsforrmamgan-hos-unga-003.pdf.
95. National Institute for Health and Care Excellence (NICE). Fertility problems: assessment and treatment [Internet]. NICE; 2013 [updated 2017; cited 2024 July 23]. Available from: https://www.nice.org.uk/guidance/cg156/resources/fertility-problems-assessment-and-treatment-pdf-35109634660549.
96. Royal College of Radiologists, Royal College of Obstetricians & Gynaecologists, editors. The Effects of Cancer Treatment on Reproductive Functions: Guidance on Management: Report of a Working Party 2007: Royal College of Physicians.
97. National Institute for Health and Care Excellence (NICE). Endometriosis: diagnosis and management [Internet]. NICE; 2017 [updated 2024; cited 2024 July 23]. Available from: https://www.nice.org.uk/guidance/ng73/resources/endometriosis-diagnosis-and-management-pdf-1837632548293.
98. National Institute for Health and Care Excellence (NICE). Removal, preservation and reimplantation of ovarian tissue for restoring fertility after gonadotoxic treatment [Internet]. United Kingdom: National Institute for Health and Care Excellence (NICE); 2023 [cited 2024 August 07]. Available from: https://www.nice.org.uk/guidance/ipg772/resources/removal-preservation-and-reimplantation-of-ovarian-tissue-for-restoring-fertility-after-gonadotoxic-treatment-pdf-1899876458396869.
99. National Institute for Health and Care Excellence (NICE). Fertility problems: Quality Standatd [QS73] [Internet]. United Kingdom: National Institute for Health and Care Excellence (NICE); 2014 [cited 2024 August 07]. Available from: https://www.nice.org.uk/guidance/qs73.
100. Human Fertilisation & Embryology Authority. Egg freezing [Internet]. United Kingdom: Human Fertilisation & Embryology Authority; 2024 [cited 2024 August 07]. Available from: https://www.hfea.gov.uk/treatments/fertility-preservation/egg-freezing/#:~:text=The%20law%20now%20permits%20you,are%20first%20placed%20in%20storage.

101. Wales Fertility Institute (WFI). Fertility Preservation for Trans and Gender Diverse People: Information for patients [Internet]. Wales: Wales Fertility Institute (WFI); 2019 [cited 2024 August 09]. Available from: https://gpcpd.heiw.wales/assets/Gender-diversity/Fertility-Preservation-Information-for-Gender-Diversity..V1.pdf.

102. Wales Fertility Institute (WFI). Fertility Preservation [Internet]. Wales: Wales Fertility Institute (WFI); 2024 [cited 2024 August 09]. Available from: https://www.thefertilityinstitute.co.uk/en/page/fertility-preservation.

103. Wales Fertility Institute (WFI). Information for patients: Sperm freezing [Internet]. Wales: Wales Fertility Institute (WFI); 2024 [cited 2024 August 09]. Available from: https://www.thefertilityinstitute.co.uk/image/Patient%20information%20-%20Freeze%20[Web].pdf.

104. NHS Wales. Specialised Services Service Specification: CP79: Haematopoietic stem cell transplantation for adults [Internet]. Wales: NHS Wales; 2020 [cited 2024 August 09]. Available from: https://whssc.nhs.wales/commissioning/whssc-policies/cancer/haematopoietic-stem-cell-transplantation-for-adults-service-specification-cp79-january-20201/#:~:text=HSCT%20is%20a%20term%20that,groups%2C%20autologous%20and%20allogeneic%20transplantation.

105. NHS Wales. Specialised Services Policy Position PP142: Haematopoietic Stem Cell Transplantation (HSCT) for Adults [Internet]. Wales: NHS Wales; 2020 [cited 2024 August 09]. Available from: https://whssc.nhs.wales/commissioning/whssc-policies/cancer/haematopoietic-stem-cell-transplantation-policy-position-statement-pp142-january-2020/.

106. NHS Wales. Specialised Services Service Specification: Services for Children with Cancer (CP86) [Internet]. Wales: NHS Wales; 2024 [cited 2024 July 23]. Available from: https://whssc.nhs.wales/commissioning/whssc-policies/all-policy-documents/services-for-children-with-cancer-cp86-december-2024/.

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