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

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About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory body established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

Reporting to the Minister for Health and engaging with the Minister for Children, Equality, Disability, Integration and Youth, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.

- **Regulating social care services** — The Chief Inspector of Social Services within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.

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- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health and social care services, with the Department of Health and the HSE.

Acknowledgements

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HIQA notes that membership of the EAG involves review of evidence synthesis documents; it does not necessarily imply agreement with all aspects of the evidence synthesis report.

The membership of the EAG was as follows:

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Organisations that assisted HIQA in providing information, in writing or through meetings, included:

Merrion Fertility Clinic

The following members of the HTA directorate contributed to the management, technical writing or dissemination of this report:

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Conflicts of Interest

None reported.

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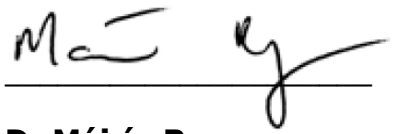
Foreword

Fertility preservation involves freezing a person's reproductive cells and can be used to help a person to have their own biological children, at a later point. Fertility preservation services may be used by people at risk of infertility for either non-medical or medical reasons. Medical reasons include the presence of a medical condition that may impact fertility and or receiving treatments that may impact fertility. Medical reasons may also include a shared decision between a healthcare professional and a person to delay and or avoid conception due to the risk of pregnancy worsening a pre-existing medical condition, or to allow urgent treatment to occur.

In Ireland, the enactment of the Health (Assisted Human Reproduction) Act 2024 in July 2024 has marked a significant legislative development relating to fertility preservation services in Ireland. When commenced, this Act will regulate the provision of any treatment or procedure that involves the handling of gametes, embryos and or tissues for the purposes of establishing, or preserving the possibility of establishing, a pregnancy. The Act also makes provisions relating to fertility preservation services for children. With the legal basis now established for fertility preservation services for medical reasons, there is a need for national policy to provide direction on the use of public funding to support the provision of such services. This report contains a scoping review of publicly-funded fertility preservation services for medical reasons in selected countries, and was conducted at the request of the Department of Health.

An Evaluation Team from the Health Technology Assessment Directorate in HIQA undertook this review. An Expert Advisory Group was convened to advise the Evaluation Team during the course of the review. HIQA would like to thank its Evaluation Team, the members of the Expert Advisory Group and all who contributed to the preparation of this report.



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Key points

- This report provides a summary of publicly-funded services for fertility preservation for medical reasons in selected countries. The findings of this review will support the Department of Health in developing a national fertility preservation policy in Ireland.
- Grey literature and academic publications were identified for 10 selected countries: Australia, Denmark, England, France, Germany, Northern Ireland, Portugal, Scotland, Sweden and Wales.
- A descriptive analysis of information on publicly-funded services for fertility preservation was undertaken. Information examined included methods available and eligible populations, funding, organisational aspects, storage, governance, ethical considerations, and legislation.
- Cryopreservation of gametes (sperm and oocytes) was identified as being publicly funded in all 10 selected countries. In countries with maximum age limits to access services, they range from:
  - 50 years (Germany) to 60 years (Australia and France) for sperm cryopreservation, and
  - 40 years (Germany and Portugal) to 43 years (France) for oocyte cryopreservation.
- Embryo cryopreservation was identified as being funded in seven of the 10 selected countries. It is not funded in France or Germany for the purposes of fertility preservation, and its funding in Northern Ireland was unclear. Portugal and Sweden have a maximum age limit of 40 years in place to access embryo cryopreservation services.
- Ovarian tissue cryopreservation (OTC) is publicly funded in six countries, with broad funding identified in five of these countries (Denmark, France, Germany, Portugal and Sweden) and limited funding in England. Five countries publicly fund testicular tissue cryopreservation (TTC), with broad funding arrangements in Denmark, France and Portugal, and limited funding in England and Sweden. In Australia, Northern Ireland and Wales, OTC and TTC may be available free to limited populations through programmes funded by charitable donations.
- Of the six countries that offer publicly-funded OTC and or TTC, no age limits for access to these services are specified in Denmark and France, and age limits

were unclear in England. In Sweden, access to OTC is funded from puberty up to 32 years, and both OTC and TTC are funded for prepubertal patients if carried out as part of a research study. In Portugal, access to OTC is funded up to 40 years, no upper age limited is specified for TTC, and lower age limits for both are unclear. In Germany, OTC is funded for pubertal and postpubertal patients only.

- In terms of indications for fertility preservation, in all 10 selected countries, people are offered publicly-funded fertility preservation services if they are about to commence cancer treatment that poses a risk to their fertility. A number of the selected countries offer access more broadly to people due to undergo any treatment that will likely affect their fertility. A limited number of countries offer services to people with medical conditions that are likely to impair their fertility.
- The majority of fertility preservation services identified in the selected countries are fully funded through public healthcare or a statutory health insurance system. However, in some countries the person availing of these services may need to pay certain costs (for example, the person pays partial costs for oocyte retrieval in Australia, and pays for the medications used for ovarian stimulation in Portugal).
- General practitioner or consultant referral is required for access to publicly-funded fertility preservation services in eight countries (Australia, England, Germany, Northern Ireland, Portugal, Scotland, Sweden and Wales). Germany noted that preservation treatment undertaken should not worsen a patient's prognosis, or delay the start of curative treatment.
- Storage of cryopreserved gametes or embryos is publicly funded for varying durations in each of the selected countries, with the exception of France, where those availing of services must pay an annual storage fee. In five countries (England, Northern Ireland, Portugal, Scotland and Sweden), storage is funded for a defined period initially (ranging from 3-5 years in Portugal to 10 years in Wales) and may be extended for additional time subject to eligibility. Limited information was identified on the publicly-funded storage periods for ovarian or testicular tissue.
- Information from included resources indicated that in four countries (Denmark, England, France and Scotland), those who wish to use stored gametes or embryos for publicly-funded fertility treatment are required to meet separate

access criteria for such services. Transplantation of cryopreserved ovarian tissue is publicly funded in Denmark and Sweden.

- Arrangements for the disposal of unused materials varied across the selected countries, and included:
  - removal of gametes or embryos from storage and disposal of them, where consent for ongoing storage is not renewed (for example, in UK countries)
  - offering patients the option to donate stored materials for use in research or training (for example, in Australia and Denmark)
  - offering patients the option to donate stored gametes to another individual for the purposes of fertility treatment, subject to meeting relevant donor criteria (for example, in Sweden).
- Governing bodies accountable for the delivery of publicly-funded fertility preservation services include national governments, Ministers or Ministries for Health, and national state agencies. In Australia, Portugal and the UK, regulatory bodies are responsible for the facilities providing fertility preservation services.
- Raising awareness of fertility preservation services among those who are eligible, and or providing detailed information on fertility preservation procedures, were identified as key information requirements of legislation in a number of countries.
- Ethical considerations around fertility preservation were identified for all 10 selected countries. These include obtaining informed consent from children and adolescents, and the provision of fertility preservation procedures in which there is uncertainty regarding the potential success of future fertility and or pregnancy outcomes.
- Legislation governing, or related to, publicly-funded preservation services for medical reasons was identified for all 10 selected countries. In the last five years, Denmark and Sweden amended legislation to increase publicly-funded storage periods for cryopreserved materials. In the UK, legislative change increased the maximum storage period to 55 years for gametes and or embryos; however, public funding for that duration is not guaranteed.
- Public funding for fertility preservation services removes or limits the associated financial burden that may be placed on those wishing to access these services.

However, a number of factors including the availability of resources, the funding available and any underpinning legislation may impact how, and what, services are provided.

Plain language summary

Some medical treatments, such as chemotherapy (for example, cancer medicine), may affect someone's ability to have a child later in their life. Also, if someone is very ill it may be dangerous for their health, or the health of their baby, to become pregnant at that time. In these cases (that is, for medical reasons), 'fertility preservation' can be used to help a person to be able to have their own biological children at a later point. Fertility preservation involves freezing a person's reproductive cells. In this summary, female reproductive cells are called eggs, male reproductive cells are called sperm, and an egg fertilised with sperm is called an embryo.

In some countries, if you need fertility preservation for medical reasons, this is provided free of charge by the government (publicly funded). This report describes publicly-funded fertility preservation services in 10 countries: Australia, Denmark, England, France, Germany, Northern Ireland, Portugal, Scotland, Sweden and Wales. These countries have a similar population size as Ireland, and or provide healthcare in a similar way as Ireland.

This report found that freezing of sperm and eggs is often publicly funded in the selected countries, with freezing of embryos less frequently funded. Freezing of ovarian tissue (groups of cells in the ovary which produce eggs) and testicular tissue (groups of cells in the testicle which produce sperm) is also possible. However, freezing of these tissues is a newer approach that is less often publicly funded, and may be offered to limited groups of people. The groups of people who are offered fertility preservation services, and how long frozen cells (such as eggs and sperm) and tissues are stored, are different across countries.

People undergoing cancer treatment are offered fertility preservation in all of the selected countries. Some countries offer services more broadly to people undergoing any medical treatment that is likely to affect their ability to have children. Services may also be offered to people with an illness that might affect their ability to have children in the future. In terms of age, adults (aged 18 years and older), and young people who have started going through the physical changes of puberty, are typically offered publicly-funded freezing of sperm and eggs in the selected countries.

Public funding to store frozen cells or tissues can last for a different amount of time in different countries. In some countries, storage costs might be covered for a limited amount of time at first, but can be covered for longer if needed. In a number of countries, people who want to use their stored sperm or eggs later to help them

have children will need to meet separate criteria to access publicly-funded treatment. Different countries have different ways of managing stored cells or tissues that are not used. The options include disposing of them, donating them for use in research or training, or donating to other people who might need cells to help them have children.

In eight of the 10 countries, access to fertility preservation services is through the person's family doctor or consultant. A number of the countries note that fertility preservation should not be done if it would make someone more unwell, or set back their medical treatment. In most of the countries, the national government's department of health has overall responsibility for fertility preservation services. In some countries, laws state the ages up to which people can be offered fertility preservation and the medical reasons why they are offered fertility preservation. In some cases, the law also states that people working in healthcare need to provide clear information about fertility preservation.

Many countries considered the principles that guide decision-making and behaviour around fertility preservation for medical reasons. These include making sure the person has enough information to understand and agree to the procedure, particularly children and young adults, and explaining that fertilisation preservation does not guarantee the ability to get pregnant or have children in the future.

This report describes publicly-funded fertility preservation services for medical reasons in 10 selected countries. The findings of this report will help the Department of Health to develop a national fertility preservation policy in Ireland.

List of abbreviations used in this report

AHR	assisted human reproduction
ART	assisted reproductive technology
BMG	*Bundesministerium für Gesundheit* Federal Ministry of Health (Germany)
BMI	body mass index
CAYA	children, adolescents and young adults
CCG	Clinical Commissioning Groups (in context of the NHS)
CNPMA	*Conselho Nacional de Procriação Medicamente Assistida* National Council for Medically Assisted Reproduction (Portugal)
DH	Designated Hospitals (UK)
EAG	expert advisory group
EIM	European IVF-Monitoring Consortium
ESHRE	European Society of Human Reproduction and Embryology
EU	European Union
G-BA	*Gemeinsamer Bundesausschuss* Federal Joint Committee (Germany)
GP	general practitioner
HIQA	Health Information and Quality Authority
HFEA	Human Fertilisation and Embryology Authority (UK)

HSCT	haematopoietic stem cell transplantation
HTA	health technology assessment
HSE	Health Service Executive (Ireland)
ICB	Integrated Care Board (England)
ICS	Integrated Care System (England)
IVF	in vitro fertilisation
MSAC	Medical Services Advisory Committee (Australia)
NHS	National Health Service (UK)
NCCP	National Cancer Control Programme (Ireland)
NICE	National Institute for Health and Care Excellence
NOTTCS	National Ovarian and Testicular Tissue Transport and Cryopreservation Service (Australia)
OTC	ovarian tissue cryopreservation
PGT	pre-implantation genetic testing
PTC	Primary Treatment Centre (UK)
SNS	*Serviço Nacional de Saúde* National Health Service (Portugal)
TESE	testicular sperm extraction
TTC	testicular tissue cryopreservation
TYA	teenage and young adults

UK	United Kingdom
WFI	Wales Fertility Institute

1 Background

Fertility preservation is "the process of freezing eggs (oocytes), sperm, embryos or reproductive tissue so that a person can use them to hopefully have their own biological children in the future".[1] Fertility preservation services may be used by people at risk of infertility for either non-medical or medical reasons. Non-medical reasons include delayed childbearing due to personal, financial or other social factors.[2] Medical reasons include the presence of a medical condition which may impact fertility (for example, endometriosis, or genetic conditions such as Turner Syndrome)[3] and or the receipt of treatments which may impact fertility (for example, chemotherapy or radiotherapy).[2] Medical reasons may also include a shared decision between a healthcare professional and a person to delay and or avoid conception due to the risk of pregnancy worsening a pre-existing medical condition, or to allow urgent treatment to occur.

Advances in the field of fertility preservation have led to the development of a variety of approaches for males and females, and for adults and children.[4-6] These approaches include cryopreservation of gametes (sperm or eggs), embryos, or gonadal tissues (testicular tissue or ovarian tissue). Cryopreservation involves freezing and storing the material so that it can be preserved for an extended time period. For pubertal and postpubertal males, sperm cryopreservation is an established method of preserving fertility, and is relatively non-invasive, depending on the sample collection method used.[7, 8] Testicular tissue cryopreservation (TTC) is invasive and considered an experimental technique. However, as the only fertility preservation approach available to prepubertal males, it is the subject of considerable research and development.[5-7] In postpubertal females, cryopreservation of eggs and embryos are established approaches.[8-10] Both approaches are considered to be moderately invasive, and require a period of ovarian stimulation (that is, treatment with hormones to stimulate the release of eggs) of approximately two weeks' duration prior to egg retrieval. In prepubertal females, for whom egg or embryo cryopreservation is not yet possible, ovarian tissue cryopreservation (OTC) may be an appropriate alternative approach. It may also be appropriate for postpubertal females for whom egg or embryo cryopreservation is unsuitable — for example, where delaying treatment to facilitate egg retrieval would have a significant negative impact on patient outcomes. Ovarian tissue retrieval is invasive and research on long-term outcomes is limited.[8-10] Other approaches to fertility preservation include ovarian transposition (a surgical intervention used to prevent damage to the ovaries during radiotherapy) for pre- and postpubertal females, and also hormonal therapies in early pubertal and postpubertal males and females.[8]

Clinical guidelines have been developed to promote best practice with respect to fertility preservation for medical reasons in specific populations, including females[9] and people with cancer,[8] particularly children, adolescents and young adults (CAYAs) with cancer.[7, 10] The development of healthcare systems and networks in this field has been largely driven by the fertility preservation needs of people with cancer, in response to increases over time in both cancer incidence and survival rates.[11] However, inequitable access to fertility preservation services remains a challenge, particularly among CAYAs,[12] and in populations with or receiving treatment for non-cancer conditions.[13]

The financial burden on patients and a lack of access to funding have been identified as barriers to accessing fertility preservation services.[12] Public funding may help overcome these barriers, with surveys in a number of countries indicating strong support for public funding of fertility preservation services for medical reasons.[14-16] Many countries in Europe (including Denmark,[17] England[18] and Germany[19]) have arrangements in place to publicly fund such services, although access to services and to funding may be dependent on patients meeting certain eligibility criteria.

In Ireland, a fertility preservation service for men commenced in 1998, with funding from the Department of Health. A service for women was introduced in 2006. As of 2024, fertility preservation services are funded by the Health Service Executive (HSE) for people with cancer whose treatment is expected to impact their fertility.[20, 21] Cryopreservation of eggs or embryos (in the case of female patients) or sperm (in the case of male patients) is available to adults with cancer (that is, those aged 18 years or older). The service incorporates supportive care, including tests and counselling, and, in the case of male patients, provides for the surgical retrieval of sperm via testicular sperm extraction (TESE) where clinically indicated. The service is delivered by a private sector Assisted Human Reproduction (AHR) provider based on a service arrangement with funding from the HSE, and is delivered in three locations — two in Dublin, and one in Cork. Storage of the cryopreserved material is funded by the HSE for a period of ten years.[22] The service is accessed on the basis of a referral from the person's oncology team to the relevant HSE-approved private AHR provider.[22] Fertility preservation services (specifically, egg and sperm cryopreservation) have also been made available to adolescents (that is, postpubertal individuals aged under 18 years) through the Childhood Cancer Fertility Project, a partnership between the Irish Cancer Society and Merrion Fertility Clinic, funded through a fixed-term research grant.[23] This project also invites female survivors of childhood cancers aged 17-26 years to have their fertility needs assessed and to be referred for further investigation or treatment where appropriate. The National Cancer Control Programme (NCCP) in the HSE has highlighted the impact of cancer treatment on people under the age of 18 and the need for fertility

preservation services to be developed for this cohort of patients.[24, 25] At present in Ireland there are no publicly-funded fertility preservation services for non-cancer patient groups, such as those whose medical conditions or treatment are likely to impact on their fertility, and those who are advised to delay conception for medical reasons.

The enactment of the Health (Assisted Human Reproduction) Act 2024 in July 2024 marked a significant legislative development relating to fertility preservation services in Ireland.[26] When commenced, this Act will regulate the provision of any treatment or procedure that involves the handling of gametes, embryos and or tissues for the purposes of establishing, or preserving the possibility of establishing, a pregnancy. The Act also makes provisions relating to fertility preservation services for children, including the conditions on which such services may be provided and arrangements for parent(s) or guardian(s) to provide consent. With the legal basis now established for fertility preservation services for medical reasons, there is a need for national policy to provide direction on the use of public funding to support the provision of such services.

This report summarises publicly-funded services for fertility preservation for medical reasons in selected countries. The information contained in the report will inform the development of a national fertility preservation policy in Ireland, which is being led by the Department of Health.

2 Methods

A detailed summary of the methods used to conduct this review is provided in the *Protocol for a summary of publicly-funded services for fertility preservation for medical reasons in selected countries*. In brief, this report presents the findings of a scoping review conducted to identify and summarise available information on publicly-funded services for fertility preservation for medical reasons in 10 selected countries.

Five EU countries were included (Denmark, France, Germany, Portugal and Sweden) as well as the UK (England, Northern Ireland, Scotland, and Wales) and Australia. The countries included were selected to include a combination of EU and non-EU countries, combined with other factors such as geographical proximity to Ireland, similar population size and or organisation of health services, and availability of published information on national fertility preservation policies.

Information was included from peer-reviewed publications, reports and evaluations, as well as grey literature sources such as policies and procedures, press releases,

legislation and other legal documents. Within the identified documents, relevant information included, but was not limited to, the following elements:

- eligibility and or criteria for access (for example, information on age thresholds)
- interventions provided (for example, cryopreservation of gametes, tissues and or embryos)
- organisational aspects
    - referral pathway(s)
    - timelines to access services
    - service provider characteristics (for example, public, private and or voluntary sector providers)
- storage (for example, storage arrangements and durations)
- governance (for example, organisational structures and governance arrangements)
- funding (for example, funding sources)
- communication and information (for example, availability of appropriate information on fertility preservation options for relevant populations)
- ethical considerations (for example, equity)
- supporting legislation (for example, relevant primary and or secondary legislation that provides a legal basis for the provision and or funding of fertility preservation services).

When identifying relevant documents, the following were considered out of scope:

- information on fertility preservation services within private healthcare, not in receipt of public funding
- documents and resources solely focused on publicly-funded fertility preservation services for non-medical reasons
- documents and resources solely focused on publicly-funded fertility treatments which occur following storage of reproductive materials
- for Australia, information on publicly-funded fertility preservation services that are specific to an individual state or territory only.

Representatives from national-level organisations were contacted for confirmation of key documents and additional resources, as appropriate. Information identified up until 21 August 2024 was included for analysis within this scoping review. Any additional relevant information identified up until 26 September 2024 was noted in the discussion.

3 Findings

The findings of the scoping review are presented in two main sections, as follows:

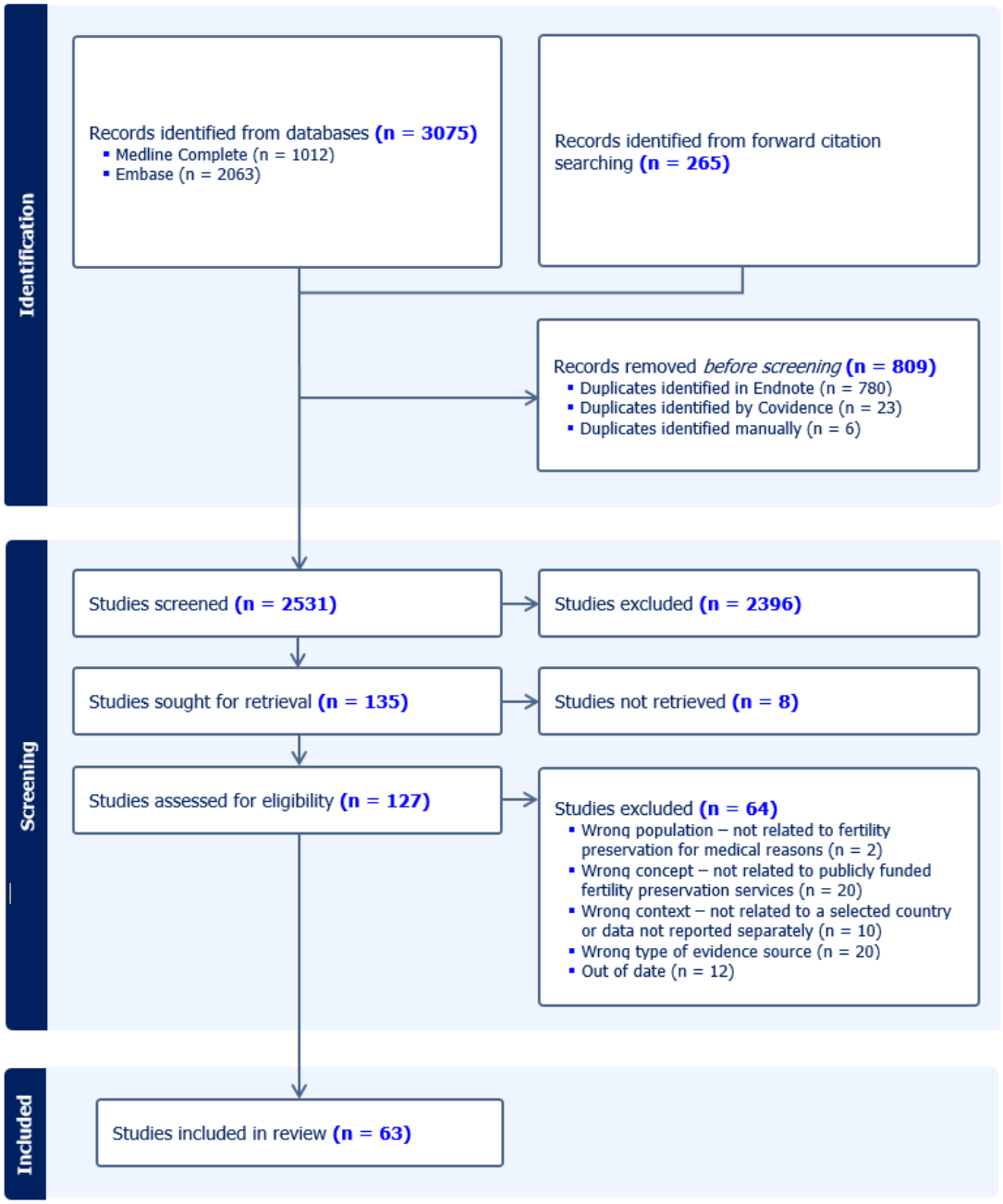
- **Section 3.1 Identified resources:** presents a descriptive summary of the relevant identified published and grey literature.
- **Section 3.2 Summary of resource contents:** presents a summary of the information identified for the selected countries with respect to their publicly-funded fertility preservation services, including preservation methods offered and eligible populations, organisational aspects of the services, storage arrangements, governance, funding, information provision, ethical considerations and relevant legislation.

3.1 Identified resources

3.1.1 Published literature

A total of 3,075 records were identified from database searches. Following the initial study selection process, a further 265 records were identified from forward citation searching of included studies. After removal of duplicates, 2,531 records were assessed for eligibility through title and abstract screening. A total of 135 studies required full-text review. In total, 63 studies fulfilled the inclusion criteria for the review. Figure 3.1 presents an overview of the study selection process.

Figure 3.1 PRISMA flow diagram of the study selection process



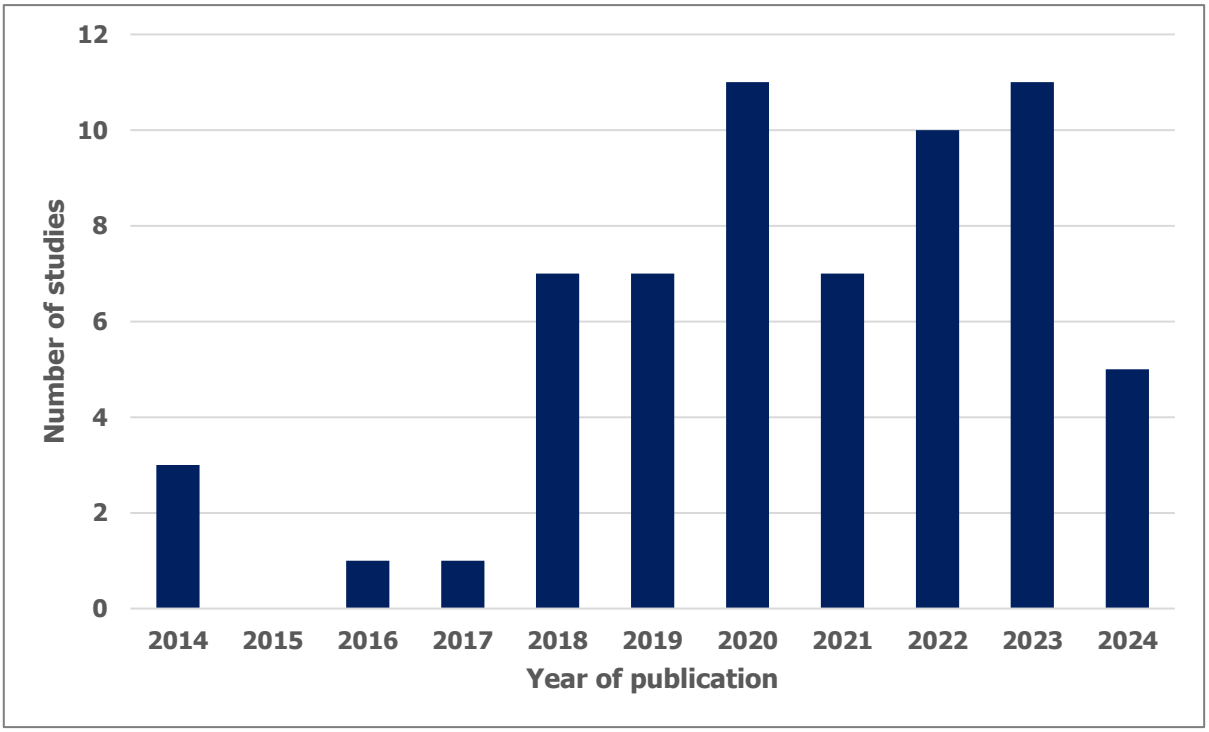
Characteristics of included documents

Sixty-three reports of published studies were included in the review. Table A.1 provides a summary of the characteristics of the included studies. Studies excluded during full-text review and the reasons for their exclusion are presented in Appendix B, Table B.1.

Of the 63 included studies, 48 were journal articles,[15, 16, 27-72] seven were conference abstracts,[54, 73-78] two were book chapters,[79, 80] and the remaining six were other document types,[81-86] including editorial or commentary pieces, and

correspondence to a journal editor. Thirteen studies included information related to publicly-funded fertility preservation services in each of Australia[16, 30, 41, 57, 58, 63, 69, 70, 75, 76, 78, 83, 85] and France,[15, 29, 32, 35, 36, 39, 42, 48, 52, 61, 72, 77, 84] 11 studies related to Sweden,[49, 54, 60, 64-67, 79, 80, 86, 87] 11 studies to the UK[27, 34, 38, 43, 45, 49, 53, 68, 73, 74, 81] (predominantly focused on England), five to Denmark,[31, 44, 46, 47, 71] four to Germany[37, 40, 62, 82] and one study related to Portugal.[51] The remaining five studies included information relevant to multiple countries.[15, 33, 55, 56, 59] The included studies were published between 2014 and 2024 (see Figure 3.2).

Figure 3.2 Included published literature by year of publication



3.1.2 Grey literature

Multiple documents and or website resources were identified for all of the included countries (see Table 3.1). These included government websites or the websites of government-mandated bodies, information leaflets, legislation, and policy documents.

This resulted in information for an individual country identified from either:

- multiple resources published by a single government or a government mandated body, such as the Tissue Council policies identified for Sweden[88, 89]
- multiple resources published by a mixture of government, and or government-mandated bodies, such as for France and Portugal.

Additionally, documents containing information related to publicly-funded fertility preservation services at UK level (while not specific to any individual UK country) were also included. As outlined in the *Protocol for a summary of publicly-funded services for fertility preservation for medical reasons in selected countries*, in countries such as Australia that operate regionally, information on publicly-funded fertility preservation services specific to an individual state or territory was excluded. In England, National Health Service (NHS) fertility preservation policies can vary across the seven NHS regions:

- East of England
- London
- Midlands
- North East and Yorkshire
- North West
- South East
- South West.

Within each region, a number of Integrated Care Systems (ICS) are in place, which act as partnerships between organisations to meet the health and care needs of those in the area. In the absence of a single national policy in England, a sample policy from one ICS was selected at random from each of the seven NHS regions. Where a consolidated policy was not identified for the randomly selected ICS (that is, previous NHS Clinical Commissioning Group (CCG) policies were still in place), an alternative ICS in the same region was selected. If a consolidated policy was not identified for any ICS in a region, the relevant CCG policies applicable in that region were included.

To confirm the identified information, and to identify any additional relevant resources, contact was made with key representatives in Denmark, Portugal and Wales. Key representatives from both Denmark and Wales responded and did not identify further resources. Contact was attempted, but was not made, with representatives for the remaining seven countries (Australia, England, France, Germany, Northern Ireland, Sweden and Scotland).

Table 3.1 Identified grey literature documents or resources related to publicly-funded fertility preservation services for the selected countries.

Country	Policy	Guideline	Other
Australia	1. Medicare Benefits Schedule Book[90] 2. Assisted reproductive technology (ART) services[90] (Services Australia)[91]	1. National Health and Medical Research Council: Ethical guidelines on the use of assisted reproductive technology in clinical practice and research[92] 2. ART Storage Funding Program[93] and Guidelines[94]	1. Medical Services Advisory Committee Public Summary documents on the applications for funding (along with application status): ▪ Males[95] (accepted in 2017) ▪ Females[96] (rejected in 2018) ▪ Females[97] (re-application) (rejected in 2019) 2. National Ovarian and Testicular Tissue Transport and Cryopreservation Service[98]
Denmark	N/A	N/A	1. Guidance on the activities and obligations of healthcare professionals and tissue establishments in the field of assisted reproduction[17] 2. Executive Order on the Act on Assisted Reproduction in Connection with Treatment, Diagnostics and Research, etc. (LBK no. 902 of 23/08/2019)[99] as amended by LOV no. 129 of 30/01/2021[100] and LOV no. 1780 of 28/12/2023[101] 3. Executive Order on Assisted Reproduction (BEK no. 672 of 08/05/2015)[17] 4. New political agreement lifts 5-year limit for freezing eggs (Press Release)[102] 5. Council of Ethics: Storage of fertilised eggs and unfertilised egg cells[103]
France	N/A	N/A	1. Biomedicine Agency: Self-preservation of gametes[104, 105] 2. Biomedicine Agency: What does the law say[106] 3. Public Health Code: Title IV: Medically assisted procreation (Articles L2141-1 to L2143-9)[107] 4. Public Health Code: Title IV: Medically assisted procreation (Articles R2141-1 to R2143-20)[108]

Country	Policy	Guideline	Other
			5. Decree No. 2021-1243 of 28 September 2021 setting the conditions for the organisation and coverage of medically assisted reproduction pathways[109] 6. Funding for medically assisted genetic procreation 2023[110]
Germany	Federal Joint Committee (G-BA). Directive 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)[19]	German Medical Association (BAK). Directive for the removal and transfer of human germ cells or germ cell tissue in the context of assisted reproduction, detailed update[111]	1. G-BA: Cryopreservation[112] 2. Federal Ministry of Health (BMG): Support for young cancer patients: cryopreservation becomes a health insurance benefit[113] 3. G-BA: Cryopreservation of ovarian tissue becomes a health insurance benefit[114] 4. Reasons for the decision of the Federal Joint Committee to amend the guidelines on cryopreservation: Cryopreservation of germ cell tissue[115] 5. Examination according to § 94 SGB V by the BMG[116] 6. Federal Law Gazette: Law for faster appointments and better care[117] 7. Fertility preservation: German Medical Association (BAK) presents revised guideline[118]
Portugal	Joint Normative Circular No. 4/2022/ACSS/DGS: Access to Medically Assisted Procreation Treatments – Exceptional regime for access to medically assisted procreation techniques in the National Health Service, in cases of preservation of reproductive potential due to serious illness[119]	N/A	1. Medically assisted procreation: Law No.32/2006 (Consolidated Legislation)[120] 2. Medically assisted procreation: Law No.17/2016 (Amendment)[121] 3. CNPMA (National Council for Medically Assisted Reproduction)[122] 4. Regulatory Decree No. 06/2016[123] 5. Portuguese Society for Reproductive Medicine: Preservation of fertility in oncological patients[124] 6. ACSS Review of Exemption Categories and Update Values of Moderator Fees[125]

Country	Policy	Guideline	Other
			7. CNPMA: Requirement and parameters- Operation of the medically assisted procreation techniques centres[126]
Sweden	1. Measures to preserve the reproductive capacity of the young: promotion of equal care for young people who are at risk of treatment-induced infertility[88] 2. Measures to preserve reproductive capacity in adults: promotion of equal care for patients at risk of treatment-induced infertility[89]	N/A	N/A
UK	N/A	1. NICE (CG156) Fertility problems: assessment and treatment[127] 2. NICE (NG73) Endometriosis: diagnosis and management[128] 3. NICE Quality Standard (QS73): Fertility problems[129] 4. NICE Interventional procedures guidance: Removal, preservation and reimplantation of ovarian tissue for restoring fertility after gonadotoxic treatment[130]	N/A
England	1. National Health Service (NHS) England. Service specifications: fertility preservation and restoration[131] Service specification and equality and health inequalities impact assessment documents for: ○ Fertility preservation for service users with ovarian tissue who are at high/very high risk of infertility and cannot store mature eggs[132, 133]	N/A	Sample NHS England Integrated Care System policies included: 1. East of England: ▪ NHS Bedfordshire, Luton and Milton Keynes Integrated Care Board (ICB). Gamete (sperm/egg) storage for those undergoing fertility-threatening treatment[139] 2. London: ▪ NHS South West London ICB. Evidence-based interventions policy[140]

Country	Policy	Guideline	Other
	○ Fertility preservation for service users with testicular tissue who are at high/very high risk of infertility and cannot store sperm[134, 135] 2. NHS England: Teenage and young adult cancer clinical network specification[136] ▪ Specialist cancer services for children and young people: Teenage and Young Adults Principal Treatment Centre services[137] ▪ Specialist cancer services for children and young people: TYA Designated Hospitals[138]		3. Midlands: ▪ NHS Coventry and Warwickshire ICB. NHS Funded Cryopreservation of Gametes and Embryos Policy[141] 4. North East and Yorkshire: ▪ NHS West Yorkshire ICB. Cryopreservation for both men and women where the usual fertility policy does not apply[142] 5. North West: ▪ NHS Cheshire and Merseyside. NHS funded treatment for subfertility Clinical Commissioning Group policies[143-152] 6. South East: ▪ NHS Kent and Medway ICB. Policies on fertility treatments[153] ▪ South Central and West Commissioning Support Unit. Schedule of policy statements for ART for Kent and Medway Integrated Care Board[154] 7. South West: ▪ NHS Somerset ICB. Fertility assessment and treatment prior approval policy[155] ▪ NHS Somerset ICB. Evidence Based Interventions Programme for Interventions Not Normally Funded[156]
Northern Ireland	N/A	Department of Health (DoH) Northern Ireland relevant endorsed National Institute for Health and Care Excellence (NICE) guidelines, according to Circular Health and Social Care (HSC) (SQSD) 3/13:[157] 1. Fertility problems: assessment and treatment (CG156)[127] ▪ DoH endorsement[158] ▪ Additional Caveats for CG156[159]	Belfast HSC Trust. Regional Fertility Centre[161]

Country	Policy	Guideline	Other
		2. Endometriosis: diagnosis and management[128] ▪ DoH endorsement[160]	
Scotland	N/A	NHS Scotland: Endocrine and Fertility Preservation Guidance[162]	1. Fertility Scotland (NHS Scotland National Strategic Network)[163] and Annual Report 2021/2022[164] 2. NHS Inform: Fertility and Cancer[165] 3. NHS Lothian: Edinburgh Fertility Centre – Fertility Preservation Referral Form[166] 4. NHS Tayside: Information for patients wishing to freeze eggs or embryos for fertility preservation[167]
Wales	Policies that mention/link to specialist fertility services: ▪ Specialised Services Service Specification: CP79 Haematopoietic stem cell transplantation (HSCT) for adults[168] ▪ Specialised Services Policy Position PP142 HSCT for Adults[169] ▪ Specialised Services Service Specification: Services for Children with Cancer (CP86)[170]	N/A	1. Wales Fertility Institute[171] 2. Wales Fertility Institute: Sperm Freezing[172] 3. Wales Fertility Institute: Fertility Preservation for Trans and Gender Diverse People - Information for patients[173]

Key: ART – assisted reproductive technology; BMG – Federal Ministry of Health (Germany); DoH – Department of Health; EU – European Union; G-BA – Federal Joint Committee (Germany); HSC – Health and Social Care (Northern Ireland); ICB – Integrated Care Board; NHS – National Health Service; NICE – National Institute for Health and Care Excellence; TYA – Teenage and Young Adult; UK – United Kingdom.

3.2 Summary of resource contents

The data extracted from both published and grey literature for each of the selected countries is summarised in the following sections:

- fertility preservation methods available and eligible populations
- funding
- organisational aspects
- storage
- governance
- communication and information provision
- ethical considerations
- legislation.

Due to the variability observed across the countries selected, in the fertility preservation methods available and the eligible populations, this information is outlined for each country individually in Section 3.2.1. However, for the remaining sections (3.2.2, Funding to 3.2.8, Legislation) a high-level summary approach is taken.

3.2.1 Fertility preservation methods available and eligible populations

As outlined in Table 3.2, the fertility preservation methods most frequently identified as being publicly funded across the selected countries are, for males, cryopreservation of sperm (funded in all 10 selected countries) and, for females, cryopreservation of oocytes (funded in all 10 selected countries) or embryos (funded in seven of the 10 selected countries). Embryo cryopreservation for the purposes of fertility preservation is not funded in France or Germany, and its funding in Northern Ireland is unclear from the information identified. Ovarian tissue cryopreservation (OTC) is publicly funded in six countries, with broad funding identified in five of these countries (Denmark, France, Germany, Portugal and Sweden) and limited funding in one country (England). In three further countries (Australia, Northern Ireland and Wales), OTC may be available free of charge to specific populations through programmes funded by charitable donations (see Table 3.2). Public funding for testicular tissue cryopreservation (TTC) was identified for five countries, with broad funding arrangements in three countries (Denmark, France and Portugal) and limited funding in two countries (England and Sweden). TTC may also be available free of charge in three further countries to specific populations through charity funded programmes (Australia, Northern Ireland and Wales).

An overview of the identified age-based eligibility criteria for access to each fertility preservation method in the selected countries is provided in Table 3.3. For sperm cryopreservation, defined age limits were identified in four countries (Australia,

France, Germany and Portugal), ranging from 50 years in Germany to 60 years in Australia and France. For oocyte cryopreservation, age limits were identified in four countries, with a maximum age limit of 40 years in Germany, Portugal and Sweden, and 43 years in France. A maximum age limit of 40 years for embryo cryopreservation was identified in Portugal and Sweden. Local variations in age-based criteria for access to sperm, oocyte or embryo cryopreservation were identified in two further countries (England and Scotland). Where publicly-funded OTC and or TTC is available, information on whether or not these methods are offered to prepubertal populations is included in Table 3.3, as well as any limitations or conditions required for access, where relevant.

A summary of the available fertility preservation methods and the populations eligible to access them in each selected country is provided in the following subsections, with further information provided in Appendix C, Table C.1.

Table 3.2 Fertility preservation methods that are publicly-funded for medical reasons in selected countries.

Country	Sperm cryopreservation	Oocyte cryopreservation	Embryo cryopreservation	Ovarian tissue cryopreservation	Testicular tissue cryopreservation
Australia	Yes	Yes	Yes	Charity funded[a]	Charity funded[a]
Denmark	Yes	Yes	Yes	Yes	Yes
France	Yes	Yes	No	Yes	Yes
Germany	Yes	Yes	No	Yes[b]	No[b]
Portugal	Yes	Yes	Yes	Yes	Yes
Sweden	Yes	Yes	Yes	Yes[c]	For research only[d]
UK					
England	Yes[e]	Yes[e]	Yes[e]	Limited[f]	Limited[f]
Northern Ireland	Yes	Yes	Unclear[g]	Charity funded[h]	Charity funded[h]
Scotland	Yes[e]	Yes[e]	Yes[e]	Unclear[g]	Unclear[g]
Wales	Yes	Yes	Yes	Charity funded[h]	Charity funded[h]

[a] Not publicly funded but available free of charge to limited populations through a programme funded by charitable donation.
[b] As of September 2024, ovarian tissue cryopreservation is only funded for pubertal and postpubertal females; testicular tissue cryopreservation is not funded. However, the Federal Joint Committee (G-BA) has stated that it will review the scientific data in relation to tissue cryopreservation in prepubertal populations in 2024.
[c] Can be offered to women and girls post-menarche when other options are not appropriate. Prior to menarche, the procedure should only be carried out as part of a scientific research study and in conjunction with a necessary surgery.
[d] For prepubertal males only. The procedure should also only be carried out as part of a scientific research study and should preferably be performed in conjunction with a necessary surgery.
[e] Access criteria for publicly-funded services vary at regional and local levels.
[f] As of 2024, publicly-funded tissue preservation services are not available in all regions. In certain locations, services may be available free of charge to specific populations due to funding from charitable sources.
[g] Based on the identified information, as of 2024, the availability of publicly-funded services is unclear. Funding was unclear in the information identified in grey literature. However, a peer-reviewed study indicated that publicly-funded services were available as of May 2021.
[h] Access to tissue preservation services may be available to children at high risk of infertility in Northern Ireland and Wales through a service based in England that is supported by charitable funding.

Table 3.3 Summary of age-based eligibility criteria for access to publicly-funded fertility preservation services in selected countries.

Country	Sperm cryopreservation	Oocyte cryopreservation	Embryo cryopreservation	Ovarian tissue cryopreservation	Testicular tissue cryopreservation
Australia *Prepubertal populations*	From puberty to 60 years *N/A*	No age limits specified *N/A*	No age limits specified *N/A*	Aged 13 to 30 years[a] *No*	Aged 13 to 30 years[a] *No*
Denmark *Prepubertal populations*	No age limits specified *N/A*	No age limits specified *N/A*	No age limits specified *N/A*	No age limits specified	No age limits specified
France *Prepubertal populations*	Up to 60 years *N/A*	Up to 43 years *N/A*	Not funded *N/A*	No age limits specified	No age limits specified
Germany *Prepubertal populations*	From puberty to 50 years *N/A*	Up to 40 years *N/A*	Not funded *N/A*	From puberty to 40 years[b] *No*	Not funded *N/A*
Portugal *Prepubertal populations*	No age limit specified[c] *N/A*	Up to 40 years[c] *N/A*	Up to 40 years[c] *N/A*	Up to 40 years[c] *Unclear*	No age limit specified[c] *Unclear*
Sweden *Prepubertal populations*	From puberty to 56 years *N/A*	From puberty to 40 years *N/A*	From 18 to 40 years *N/A*	Up to 32 years[d] *Experimental*[d]	Prepubertal only *Experimental*[e]
UK NICE [CG156]	Adolescents and adults	Adolescents and adults, as appropriate	Adolescents and adults, as appropriate	N/A	N/A
England Sample ICB policies *Prepubertal populations*	Varied[f] Up to 55 years[g] *N/A*	Varied[f] Up to 43 years[h] *N/A*	Varied[f] Up to 43 years[h] *N/A*	No age limits specified[i] 'Of reproductive age' [j] *Limited* [k]	No age limits specified[i] Not identified *Limited* [k]
Northern Ireland *Prepubertal populations*	Not identified *N/A*	Not identified *N/A*	Not identified *N/A*	'Children and young adults' *Limited* [k]	'Children and young adults' *Limited* [k]
Scotland *Prepubertal populations*	Varied[f] *N/A*	Varied[f] *N/A*	Varied[f] *N/A*	Not identified	Not identified
Wales *Prepubertal populations*	Not identified *N/A*	Not identified *N/A*	Not identified *N/A*	'Children and young adults' *Limited* [k]	'Children and young adults' *Limited* [k]

Key: CG156 – Clinical guidelines 156; ICB – Integrate Care Board; N/A – not applicable; NICE – National Institute for Health and Care Excellence.

Note: Green – publicly-funded services available; Orange – publicly-funded services with limited availability; Yellow – charity funded services only.

[a] OTC and TTC are available free of charge to patients aged 13 to 30 years with a cancer diagnosis through the National Ovarian and Testicular Tissue Transport and Cryopreservation Service, which is funded by charitable donation.

[b] As of September 2024, ovarian tissue cryopreservation is only funded for pubertal and postpubertal females. The Federal Joint Committee (G-BA) has stated that it will review the scientific data in relation to tissue cryopreservation in prepubertal populations in 2024.

[c] The minimum age limit for access to ART services in Portugal is 18 years. It is unclear if this limit applies to fertility preservation for medical reasons.

[d] Can be offered to women and girls post-menarche when other options are not appropriate. Prior to menarche, the procedure should only be carried out as part of a scientific research study and in conjunction with a necessary surgery.

[e] For prepubertal males only. The procedure should also only be carried out as part of a scientific research study and should preferably be performed in conjunction with a necessary surgery.
[f] Access criteria for publicly-funded services vary at regional and local levels.
[g] Somerset ICB.
[h] Bedfordshire, Luton and Milton Keynes ICB and South West London ICB.
[i] As of 2024, publicly-funded tissue preservation services are not available in all regions. In certain locations, services may be available free of charge to specific populations due to funding from charitable sources.
[j] Coventry and Warwickshire ICB.
[k] Separate to NHS funded services, access to tissue preservation services may be available to children and young adults at high risk of infertility in England, Northern Ireland and Wales through a service based in England that is supported by charitable funding.

Australia

Medicare (Australia's universal public healthcare funding system) provides funding for fertility preservation along with a range of other assisted reproduction services.[90] Only 'clinically relevant' services provided by an appropriate health practitioner are eligible for funding. Assisted reproduction services are considered to be 'clinically relevant' when accepted by the medical profession as necessary to appropriately treat a patient's medical infertility.[91] In this way, the patient's general practitioner (GP) and or specialist acts as the gatekeeper in terms of deciding if the patient is eligible for publicly-funded treatment.

Medicare funding is available for retrieval and cryopreservation of oocytes, embryos and sperm. For female patients, partial reimbursement is available for cryopreservation of oocytes or embryos.[16, 41, 70] The services partially funded include planning and management by a specialist, ultrasound examinations, oocyte retrieval and embryology laboratory services. Medicines for ovarian stimulation are subsidised through the publicly-funded Pharmaceutical Benefits Scheme, which can be accessed by those with a current Medicare card.[174] No age limits are specified for these services.[90]

For male patients, Medicare funding is available for processing and initial cryopreservation of semen for fertility preservation before or after completion of gonadotoxic treatment for malignant or non-malignant conditions.[90] Eligible patients are postpubertal males in Tanner stages II-V,[1] aged up to 60 years, and referred by a specialist or consultant physician. A maximum of two semen collection cycles are funded per person in a lifetime. Funding is also available for specific semen collection or sperm retrieval methods, where appropriate. For example, semen collection using a vibrator or electro-ejaculation device for people with spinal injuries or medically induced impotence, or surgical sperm retrieval for the purposes of intracytoplasmic sperm injection for male infertility.

Storage of retrieved and cryopreserved materials is funded separately through the Assisted Reproductive Technology (ART) Storage Funding Program.[93] Each eligible patient can access cryostorage services for up to two different material types (that is, egg or sperm, and embryo). Eligible patients are those who either:

- have a cancer diagnosis and the cancer treatment will affect their fertility or

[1] Tanner staging is defined as is "an objective classification system that providers use to document and track the development and sequence of secondary sex characteristics of children during puberty". Staging is based on a five-point scale, from stage I (prepubertal) to stage V (adult). Stage II refers to the developmental changes observed at the onset of puberty.[175]

- are at risk of passing on a genetic condition and have had pre-implantation genetic testing (PGT) funded through Medicare.

For embryo cryostorage, only one member of the couple needs to meet the eligibility requirements.

Neither ovarian tissue cryopreservation nor the cryopreservation of testicular tissue or spermatogonial stem cells are eligible for Medicare funding. The Medical Services Advisory Committee has acknowledged the potential merits of such methods for fertility preservation in prepubertal populations, but has not supported funding due to uncertain clinical effectiveness and safety concerns in the case of OTC, and the experimental nature of such methods in males.[95, 97] However, OTC and TTC are available free of charge to patients aged 13 to 30 years with a cancer diagnosis through the National Ovarian and Testicular Tissue Transport and Cryopreservation Service (NOTTCS),[98] which is funded by charitable donations.[176] Eligible patients are those whose medical treatment puts their fertility at risk and who are deemed suitable for the service by an oncologist or healthcare provider.

Denmark

In Denmark, cryopreservation of oocytes, embryos or ovarian tissue is available through the publicly-funded healthcare system to female patients at risk of ovarian failure due to disease or medical treatment. This includes medical conditions that may lead to premature ovarian failure (for example, Turner syndrome) and medical treatments such as chemotherapy, radiotherapy, or hormone therapy that is incompatible with establishing and or carrying out a pregnancy.[17, 177] Publicly-funded oocyte cryopreservation is also available if undertaken in connection with fertility treatment. However, public funding does not cover what is termed 'social egg freezing' (that is, oocyte cryopreservation not for medical or fertility treatment purposes, but rather to maintain the potential option to have children later in life).[17] Although no age limits are specified for access to fertility preservation services, in effect, the maximum limit for oocyte and embryo cryopreservation is 46 years, as this is the maximum age limit for both publicly-funded oocyte storage and fertility treatment in Denmark.[102] No age limit exists for cryopreservation of ovarian tissue, which has been available within the public healthcare system in Denmark since 1999.[17, 46, 71]

Cryopreservation of sperm or testicular tissue is publicly funded in Denmark for male patients whose medical treatment carries a risk of infertility, such as chemotherapy or radiotherapy. Testicular tissue cryopreservation may also be offered with the aim of preserving fertility in boys with congenital conditions that may lead to infertility in adulthood, for example, bilateral cryptorchidism. No age limits were identified for access to such services.[17]

France

In France, Article L2141-11 of the Public Health Code states that '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.'[107] Under this legislation, public funding is available for cryopreservation of sperm, oocytes, testicular tissue and ovarian tissue in the context of a medical condition, after multidisciplinary consultation.[110] For people aged less than 18 years, access to services is subject to the consent of a parent or guardian; however, the consent of the patient must be sought if they are capable of expressing their wishes and participating in the decision. The Public Health Code also specifically states that 'modification of the designation of sex in the civil registry shall not prevent the application of this article'; that is, fertility preservation services are available to transgender people.[107]

Certain fertility preservation services are subject to age conditions:

- oocyte retrieval may be carried out up to the age of 43 years
- collection of sperm may be carried out up to the age of 60 years.[108]

In France, fertility preservation for medical reasons is distinct from preservation services offered as part of assisted reproductive technology (ART) treatments or preservation of gametes for non-medical reasons, both of which are also eligible for public funding subject to separate criteria.[104-106, 110]

Germany

Since an updated directive was issued by the Federal Joint Committee (G-BA, *Gemeinsamer Bundesausschuss)* in 2022, statutory health insurance companies in Germany are required to cover cryopreservation of germ cells or germ cell tissue for insured people undergoing germ cell damaging therapy.[19] The scope of this funding includes the preparation, removal, processing, transport, freezing, storage and subsequent thawing of oocytes, ovarian tissue, or sperm cells, including testicular sperm extraction, if necessary.

Cryopreservation will be eligible for funding if it appears medically necessary due to an illness and its treatment with a therapy that damages germ cells.[115] Treatments that are currently recognised as being potentially harmful to germ cells include:

- surgical removal of the gonads (that is, ovaries or testes)
- radiotherapy with expected damage to the gonads or

- the use of potentially fertility-damaging medicines.[112]

In each individual case, the attending physician must assess if treatment may result in damage to the germ cells and, therefore, if a claim for funding of cryopreservation may be warranted.[19, 112]

Age limits are also applicable, as follows:

- Cryopreservation of oocytes or sperm is funded for insured females up to the age of 40 and for insured males up to the age of 50.
- Cryopreservation of ovarian tissue is funded for female children and adolescents from puberty — after the first menstrual period at the earliest — and women up to the age of 40.[19, 112]

In addition, OTC is only funded under the following conditions: if comprehensive advice has been given in consultation with a specialist in reproductive medicine; if reproductive medicine counselling is carried out taking into account the underlying disease, the age of the person and the prognosis; and if OTC is provided with the aim of enabling the insured person to become pregnant at a later date.[115] Testicular tissue cryopreservation is not funded, as of September 2024. However, the G-BA has stated that it will review the scientific data in relation to tissue cryopreservation, particularly in prepubertal populations, in 2024 to determine whether or not an update to the guideline is appropriate.[115]

The appropriate cryopreservation procedure must also be selected by authorised service providers in accordance with the German Medical Association's guideline on assisted reproduction.[19, 111]

Portugal

In Portugal, fertility preservation for medical reasons is publicly funded through the national health service (SNS, *Serviço Nacional de Saúde*).[119-121, 123] This includes fertility preservation procedures for people with cancer, which have been offered since the late 1990s for males and since 2010 for females.[51]

A broad range of ART treatments are funded by the SNS, which include the collection or retrieval and cryopreservation of sperm, oocytes, embryos, ovarian tissue or testicular tissue.[119-121, 123] Although it is publicly funded for fertility treatment purposes, the National Council for Medically Assisted Reproduction (CNPMA, *Conselho Nacional de Procriação Medicamente Assistida*) has advised against the use of embryo cryopreservation for the purposes of fertility preservation.[178]

The minimum age for accessing ART services is 18 years.[120] No maximum age limit is specified for males.[179] For women who access fertility preservation services due

to serious illness, preservation techniques may be performed up to the age of 40 years.[119] A definition of what constitutes a 'serious illness' was not identified. This age limit corresponds with the age limit for access to certain publicly-funded fertility treatments, specifically in vitro fertilisation (IVF) and intracytoplasmic sperm injection (ICSI).[119] Certain other fertility treatments (namely, ovulation induction and intrauterine insemination) are funded up to the age of 42 years.[119] Publicly-funded fertility treatments are available to all women regardless of whether or not they have a diagnosis of infertility.[123]

Sweden

In Sweden, fertility preservation for medical reasons is offered free of charge through the publicly-funded healthcare system.[54, 64, 80, 86] Populations eligible for fertility preservation services include people undergoing medical or surgical treatment that is associated with a risk of infertility or where the risk of infertility is unknown.[88, 89] This includes people with cancer or non-cancer conditions, as well as people with gender dysphoria undergoing gender-affirming treatment.[49, 88, 89] A publicly-funded fertility preservation programme is also offered to women and girls with Turner syndrome.[65, 67]

The Council for Organs, Tissues, Cells and Blood (Tissue Council, *Vävnadsrådet*), has issued guidance for healthcare professionals and decision-makers on fertility preservation for children[88] (in 2021) and adults[89] (in 2023) at risk of treatment-induced infertility. This guidance does not apply where the risk of infertility is congenital or directly caused by disease or injury.[88, 89] The guidance aims to support decision-making in relation to fertility preservation, including the selection of appropriate preservation methods for certain populations.

Established fertility preservation methods that are widely offered to postpubertal patients in Sweden include cryopreservation of sperm, mature oocytes or embryos. OTC may be offered to women or postpubertal girls for whom retrieval and preservation of oocytes or embryos is not appropriate.[88, 89] For prepubertal girls, OTC may only be offered as part of a scientific research study and in conjunction with a necessary surgery.[86, 88] For men and pubertal or postpubertal boys, cryopreservation of sperm retrieved following ejaculation or through TESE may be offered.[88, 89] For prepubertal boys, TTC may only be offered as part of a research study and should preferably be performed in conjunction with a necessary surgery.[88]

In terms of access to fertility preservation services, the Tissue Council has outlined the following age limits for specific fertility preservation methods:

- Oocyte vitrification: aged less than 40 years
- Embryo freezing: aged less than 40 years

- Ovarian tissue freezing: aged less than 32 years
- Sperm freezing: aged less than 56 years.[89]

The age limits for oocyte, embryo and sperm cryopreservation align with the age limits for access to publicly-funded ART treatments in Sweden. A lower age limit is applied for access to OTC due to the loss of a significant number of eggs following retransplantation of ovarian tissue.[89] In addition, to be eligible for publicly-funded fertility preservation services, a person may be the legal parent of a maximum of two children.[89]

UK

Guidance developed by the National Institute for Health and Care Excellence (NICE) is primarily applicable in England and Wales, but may be endorsed elsewhere in the UK, such as in Northern Ireland. The NICE clinical guideline in relation to fertility problems [CG156] includes recommendations regarding fertility preservation for people with cancer.[127] In brief, the guideline recommends offering the following services to individuals who are preparing for treatment that is likely to lead to infertility:

- sperm cryopreservation to men and adolescent boys
- oocyte or embryo cryopreservation, as appropriate, to women of reproductive age including adolescent girls.

The guideline also recommends that, for cancer-related fertility preservation, a lower age limit should not be applied nor should the eligibility criteria for accessing conventional infertility treatment.[127]

OTC is not addressed in the guideline. However, NICE interventional procedures guidance published in 2023 [IPG772] recommends that removal, preservation and reimplantation of ovarian tissue may be used for restoring fertility after gonadotoxic treatment if standard arrangements are in place for clinical governance, consent and audit.[130] This recommendation was made with recognition that egg or embryo cryopreservation may be unsuitable for certain populations, such as those who have not yet reached puberty.[130]

In addition, the NICE guideline for endometriosis [NG73] includes recommendations regarding management if fertility is a priority.[128] This guideline notes that its recommendations should be interpreted within the context of the NICE guideline on fertility problems [CG156]. However, the recommendations are focused on fertility sparing surgical approaches to the management of endometriosis, with no specific reference to other fertility preservation methods in this population.[128]

England

As outlined previously, within each NHS region in England, a number of Integrated Care Systems (ICS) are in place, which act as partnerships between organisations to meet the health and care needs of those in the area. For this scoping review, as there is no single national policy in England regarding fertility preservation for medical reasons, a sample policy from one ICS was selected at random from each of the seven NHS regions. Cryopreservation of oocytes and sperm are routinely funded by the relevant Integrated Care Board (ICB) in all seven regions (that is, Bedfordshire, Luton and Milton Keynes;[139] Coventry and Warwickshire;[141] Cheshire and Merseyside;[180] Kent and Medway;[153] Somerset;[155] South West London;[140] and West Yorkshire[142]). Embryo cryopreservation is routinely funded in six of the seven regions (all except Bedfordshire, Luton and Milton Keynes[139]), although in one region (Somerset[155]) it is only funded for couples in a stable relationship prior to cancer treatment to allow future IVF treatment in line with the relevant policy requirements.[155]

Neither OTC nor TTC is routinely funded in any of the seven sample ICS policies, although in one region (Coventry and Warwickshire[141]) an exception to this is noted for cases where gamete and embryo cryopreservation cannot be achieved.[141] As noted in the identified policy for one region (Bedfordshire, Luton and Milton Keynes[139]), commissioning for OTC and TTC is the responsibility of NHS England. NHS England service specifications are in place to support commissioning of services for those who are at high or very high risk of infertility and cannot store mature eggs or sperm,[132, 134] although no information was identified to indicate the extent to which such services have been commissioned as of September 2024. In a study by Latif et al.[45] that examined NHS CCG fertility preservation policies in place as of May 2021, the authors found that ovarian tissue cryopreservation was funded in 7% of policies at that time.[45] A further identified study described an OTC and TTC service available to children and young adults at high risk of infertility in England, Wales and Northern Ireland.[38] This service is not publicly funded but services are provided free of charge to patients through charitable funding.[181]

In terms of eligibility, the identified information indicates that publicly-funded fertility preservation services are widely available in England to those who are due to commence treatment that is likely to lead to infertility. Sample policies in all seven NHS regions included in this review outline that such individuals are eligible to access services. Populations undergoing treatment for certain conditions are specifically highlighted as being eligible in a number of policies — for example, people with cancer (six regions: Bedfordshire, Luton and Milton Keynes;[139] Coventry and Warwickshire;[141] Cheshire and Merseyside;[180] Somerset;[155] South West London;[140] West Yorkshire[144]) and people with gender dysphoria (five regions: Bedfordshire, Luton and Milton Keynes;[139] Coventry and Warwickshire;[141] Kent and Medway;[153] Somerset;[155] and South West London[140]). In two regions (Kent and

Medway[153]; and South West London[140]), eligible populations include people with a medical condition that is likely to lead to infertility. In addition, people at risk of premature ovarian insufficiency are noted to be eligible in a further two regions (Coventry and Warwickshire;[141] Cheshire and Merseyside,[180] except Cheshire East and Cheshire West). In one region (South West London[140]), access to publicly-funded services is also provided for people whose medical treatment has possible teratogenic effects and stopping treatment for a prolonged period to enable conception is not possible. These findings are consistent with those of Latif et al.[45] who found that cryopreservation was funded for those undergoing treatment for cancer in all CCGs for which policies were available as of May 2021.[45] Additionally, the authors identified that most CCGs (115 out of 129, 89%) also funded fertility preservation for non-cancer conditions that may impair fertility.[45]

At national level, commissioning responsibility for services for teenagers and young adults (that is, people aged 16 to 24 years) with suspected or confirmed cancer lies with NHS England.[136] NHS England Teenage and Young Adult (TYA) cancer clinical network specifications do not include detailed specifications regarding fertility preservation services. However, they outline that Principal Treatment Centres (PTC) and Designated Hospitals (DH) must offer fertility preservation to each individual preparing to have treatment for cancer that is likely to result in fertility problems. Furthermore, PTCs must have a policy defining the male and female fertility preservation methods available.[136-138]

Certain eligibility criteria for access to publicly-funded fertility preservation services vary between regions in England. In particular, in sample policies identified for seven NHS regions, maximum age limits for access to services vary in terms of whether or not they are specified and, if specified, the age limits in place. For example, a maximum age limit for males was outlined in the policy of one of the seven regions (Somerset), with males being considered eligible if aged less than 55 years and females eligible if aged less than 41 years.[155] In two further regions (Bedfordshire, Luton and Milton Keynes;[139] South West London[140]), females are eligible if aged less than 43 years. In one region (Coventry and Warwickshire[141]), a maximum age limit for females is not specified, but female patients 'must be of reproductive age' to be eligible for cryopreservation services. In terms of exclusion criteria, individuals are ineligible to access fertility preservation services in three of the seven policies from the regions if they have previously undergone sterilisation (Bedfordshire, Luton and Milton Keynes;[139] Coventry and Warwickshire;[141] and South West London[140]) or, in one region (Somerset[155]), if the individual wishes to preserve fertility prior to undergoing sterilisation. In addition, in Somerset, a patient is ineligible for fertility preservation services if they already have living offspring from their current relationship or previous relationships, including adopted children, or if the patient has previously received an NHS-funded cycle of fertility treatment.

Northern Ireland

Although guidance developed by NICE is intended for use in England and Wales, the Department of Health in Northern Ireland has established a process for endorsing, implementing and monitoring NICE guidance within health and social care services in Northern Ireland (see Section 3.2.5 Governance for further details). In relation to fertility preservation services, the Department of Health endorsed NICE Clinical Guideline CG156 in November 2013, which includes recommendations regarding people with cancer who wish to preserve fertility. Included recommendations relate to cryopreservation of sperm, oocytes and embryos.[127] NICE Clinical Guideline NG73 regarding treatment and management of endometriosis was also endorsed in October 2017.[160]

Publicly-funded fertility preservation services are offered through Belfast Health and Social Care Trust's Regional Fertility Centre.[161] Specifically, cryopreservation of sperm or oocytes is offered when fertility preservation is required for medical reasons. Services are offered to female patients prior to commencing chemotherapy or a procedure that will affect fertility, and to male patients who are due to commence a treatment or procedure that will affect fertility.[161] A study that examined fertility preservation policies across the UK reported that, as of 2021, cryopreservation of embryos was also funded in Northern Ireland for those undergoing medical or surgical treatment likely to impact their fertility.[45] The authors reported that OTC was not funded at that time.

Scotland

Publicly-funded fertility preservation methods offered through NHS Scotland are cryopreservation of sperm, oocytes and embryos.[165, 166] This may include retrieval of sperm through methods such as TESE, where appropriate.[165] A study that examined fertility preservation policies across the UK reported that, as of 2021, a uniform policy was in place across all 14 NHS Scotland Boards providing funding for cryopreservation of ovarian and testicular tissue.[45] However, no such policy was identified in the current scoping review; therefore, it is unclear if tissue preservation services are publicly funded as of 2024.

In general, publicly-funded services are offered to people who require fertility preservation for medical reasons; for example, people with cancer or other conditions who are undergoing treatments that may affect their fertility,[163] or transgender, non-binary and gender diverse people undergoing gender-affirming treatment.[162] As outlined in Appendix C, Table C.1, the overarching principles of access to NHS funded fertility preservation services include a significant identified risk to the patient's fertility that may be addressed through medical intervention, and

the expectation of long-term survival of the patient, with the ability to be able to use their stored materials in the future.[162]

Access criteria for fertility preservation services for transgender, non-binary and gender diverse people aim to broadly align with national access criteria for NHS-funded ART treatment, with certain differences included for practical reasons.[162] For example, guidance from the National Gender Identity Clinical Network for Scotland outlines that access should be precluded for those who have undergone previous sterilisation or who already have children, either biological or legal. However, criteria relating to smoking cessation or relationship status are not deemed relevant to fertility preservation. Furthermore, for those storing eggs or embryos, a maximum Body Mass Index (BMI) limit of 35 is proposed (as opposed to the maximum limit of 30 for access to NHS-funded IVF services) to account for the time constraints involved in providing fertility preservation services.[162]

Specific access criteria for publicly-funded services for fertility preservation for medical reasons also apply at regional level, and may vary across the 14 regional NHS Scotland Boards. For example, in NHS Tayside, patients must be aged less than 38 years and have a BMI of less than 35,[167] whereas in NHS Lothian, patients storing sperm must be aged less than 56 years and no BMI limits for referral are specified.[166] In both regions, patients are ineligible if they already have children, or if they or their partner have previously been sterilised.[166, 167]

Wales

Publicly-funded sperm, egg and embryo cryopreservation services are provided by NHS Wales through the Wales Fertility Institute (WFI). These services are offered to patients:

- who are due to undergo treatment that could cause infertility, such as surgery, radiotherapy and or chemotherapy
- who plan on taking gender-affirming hormones and or having a surgical intervention to remove the testes or womb/ovaries, which can lead to the loss of fertility.[171, 173]

NHS Wales policies also outline that advice and information regarding fertility preservation should be provided to certain populations prior to the commencement of treatment that presents a risk to fertility, specifically children with cancer and adults undergoing haematopoietic stem cell transplantation.[170, 182, 183] A study that examined fertility preservation policies across the UK reported that OTC was not funded in Wales, as of 2021.[45] However, children at high risk of infertility who are living in Wales may have access to cryopreservation of ovarian tissue or testicular tissue through a service based in England that is supported by charitable funding.[38]

3.2.2 Funding

Subject to the eligibility criteria outlined in Section 3.2.1, fertility preservation services for medical reasons are publicly funded in all 10 of the selected countries. Access is provided through the publicly-funded healthcare systems in eight countries (Australia, Denmark, England, Northern Ireland, Portugal, Scotland, Sweden and Wales), and through statutory health insurance systems in the remaining two countries (France and Germany). In England,[139, 141, 153, 155, 180] Northern Ireland[184] and Wales,[185] those who do not meet the specified access criteria may be eligible to receive publicly-funded fertility preservation services through the Individual Funding Request (IFR) process. An IFR enables a healthcare professional to seek funding on behalf of a single identified patient for a specific intervention on the basis of 'clinically exceptional circumstances' (that is, circumstances that differentiate a patient from other similar patients, making them more likely to benefit from the intervention).[141]

As outlined in Appendix C, Table C.2, in some countries, the patient may be required to pay certain costs associated with fertility preservation procedures. For example, in Portugal, a patient accessing oocyte or embryo cryopreservation services must pay the cost of medications used for ovarian stimulation. These costs may vary between approximately €200 and €500, depending on the stimulation protocol used.[124] In Australia, where service providers claim Medicare benefits directly (known as 'bulk billing'), no payment is required by the patient. However, where a service provider uses the 'patient payment' billing method, the patient will need to pay the cost of a consultation or procedure at the time of receiving the service and be reimbursed through Medicare.[90] Reimbursement rates through Medicare vary from 75% reimbursement (for example, for professional services rendered to a patient as part of hospital treatment) to 100% reimbursement (for example, GP services); therefore, the full costs of fertility preservation services may not be covered. In addition, the extent of reimbursement will depend on whether or not the procedure(s) carried out align with specific Medicare fees; for example, a distinct fee for oocyte cryopreservation is not included in the Medicare Benefits Schedule, therefore approximately 50% of the total costs are reimbursed.[16, 41, 70]

From the patient's perspective, costs associated with collecting or retrieving materials and storage costs may be funded as one, within specified age or time limits (as in Denmark, England, Germany, Northern Ireland, Portugal, Scotland, Sweden and Wales), or separate payment or funding arrangements may be in place (as in Australia and France). For example, in France, the costs of procedures for the collection or retrieval of gametes for preservation are fully covered by statutory health insurance. However, storage costs are not covered and must be paid by the patient at a cost of €40.50 per year.[104, 105] In Australia, the ART Storage Funding Program is distinct from Medicare and separately funds the storage of cryopreserved

materials up to a value of AU$600 annually per patient and per eligible cryostorage service. Payments are made directly to the relevant clinic, with no payments required by patients. In addition, clinics cannot charge additional fees to patients.[94, 186] Separate funding arrangements for the future use of stored gametes, embryos or tissues as part of ART treatment are also highlighted in England,[139] Northern Ireland, Scotland and Wales, where funding for ART treatment is subject to distinct access criteria.[45]

Information on how service providers are funded for the provision of fertility preservation services was also identified for France, where health insurance funding is allocated using an activity-based pricing system. Funding allocations consist of two components: a billable component (which provides funding based on the volume and nature of activities — for example, the number and type of consultations and procedures carried out) and a non-billable component (which is not linked to activity levels and is intended to fund organisational costs, such as personnel and equipment).[110]

Where public funding is not provided, or not consistently provided, identified information indicated that funding from charities may be used to support access to certain preservation methods for certain populations. Specifically, this included sperm cryopreservation and tissue cryopreservation for adolescents and young adults with cancer in Australia,[57, 76, 85] and tissue cryopreservation in England, Northern Ireland and Wales.[38, 181]

3.2.3 Organisational aspects

Referral pathways

Information related to referral pathways for publicly-funded fertility preservation services for medical reasons was identified for Australia, England (ICB policies for Bedfordshire, Luton and Milton Keynes;[139] Kent and Medway;[153] and Somerset[155]), Germany, Northern Ireland, Portugal, Scotland, Sweden and Wales (see Appendix C, Table C.3). General practitioner (GP) or consultant referral is required for all of the referral pathways identified, except for the ART Storage Funding programme in Australia,[94, 186] in which the ART clinic contacts the patient, once they are deemed eligible. Details regarding information which must be provided by the referring healthcare professional were identified for Australia,[187] Germany[19] and Northern Ireland[161] and include the patient's:

- reason for referral, including relevant clinical information about the patient's condition for investigation and or opinion and or treatment
- age and parity
- likelihood of infertility

- date of commencement for treatment and or surgery
- known comorbidities
- time frame available for fertility preservation services
- information as to whether menarche has already occurred (for female patients).

Specific referral pathways for transgender, non-binary and gender diverse people were identified for Scotland and Wales. In Scotland, only those who have been assessed and referred by a local Gender Identity Clinic (GIC) as suitable for gender reassignment, are considered for fertility preservation services.[188] The GIC provides an initial discussion of fertility preservation prior to referral, where early information is provided about the effect of gender reassignment on fertility and fertility options. It is also advised that local referral templates are developed to ensure timely receipt of referral from relevant clinical services.[188] In Wales, GP referral to the Welsh Gender Team is required to access fertility preservation services at the Wales Fertility Institute.[173]

In England, teenagers and young adults with suspected or confirmed cancer are referred to Teenage and Young Adult (TYA) Principal Treatment Centres (PTC) and Designated Hospitals. The TYA PTC must include access to fertility services in accordance with the NICE Quality Standard for fertility problems.[138]

It was outlined in Sweden that referral pathways are drawn up locally within the regions,[88, 89] while no referral pathway information was identified for Denmark or France.

Service provider characteristics

Information related to the characteristics of service providers was identified for all of the 10 selected countries, except Northern Ireland (see Appendix C, Table C.3). The composition of the healthcare team responsible for assisted reproduction and or specifically fertility preservation services was identified for Australia (specifically the NOTTCS[98]), England, France, Germany, Portugal, and Sweden. For example, in France, it is outlined in the Public Health Code that the multidisciplinary team responsible for the clinical activities of assisted reproduction must include, at a minimum:[107, 108]

- 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
- a doctor qualified in urology or general surgery or in gynaecology and obstetrics for sperm retrieval.

Similar requirements are in place in both Germany and Portugal, where it is specified that in institutions conducting services related to assisted reproduction, the heads or directors of these institutes must specialise in gynaecology and or obstetrics;[19, 126] or genetics, endocrinology or urology.[126] In Portugal, the centre director is also required to have at least three years' experience in medically assisted procreation.[126]

In England, a Hub and Spoke model of services is outlined for OTC and TTC.[132, 134] In this model, specialist fertility expertise and coordination of service provision is centralised within a hospital-based clinical service (the Hub), and the ovarian or testicular tissue surgery is undertaken in the service user's local surgical treatment centre (the Spoke). Essential staff for 'the Hub' include a specialist fertility expert, a paediatric and young adult oncology and or haematology consultant, and a consultant in reproductive medicine or fertility or gynaecology. Essential staff for 'the Spoke' include a lead consultant responsible for the fertility preservation treatment activities undertaken, a paediatric or adult surgeon or gynaecologist with an interest in fertility preservation (as appropriate), and a clinical nurse specialist or key worker.[132, 134] A similar model is seen in the NOTTCS in Australia,[76, 98, 176] in which local gynaecologists, urologists and fertility specialists undertake surgeries for ovarian and testicular tissue extraction, at their centres. However, within NOTTCS the tissue is transported for processing and cryopreservation at one centralised location (The Royal Women's Hospital, Melbourne).

Information on the location of specific fertility preservation services, or services for specific sub-groups, was identified for Denmark, Scotland and Sweden. In Denmark,[31] cryopreservation and storage of ovarian tissue is centralised to one laboratory (Laboratory of Reproductive Biology, Copenhagen), whereas three different centres in Copenhagen, Odense and Aarhus offer the initial fertility-preservation counselling and tissue harvesting. In Sweden, at all university hospitals, there are multidisciplinary teams for girls and women with Turner syndrome (located at Turner centres),[65] and multidisciplinary gender identity teams for transgender individuals.[79] These teams provide information to service users on fertility preservation; however, the composition of these teams is not outlined. In Scotland, four NHS Fertility Centres (Aberdeen, Dundee, Edinburgh and Glasgow)[189] provide fertility preservation services to transgender, non-binary and gender diverse people who require treatment.[162]

Timelines to access services

Limited information related to timelines in accessing publicly-funded fertility preservation services was identified for the 10 selected countries (see Appendix C, Table C.3). England (Bedfordshire, Luton and Milton Keynes;[139] and Somerset[155]) and Sweden[88, 89] outlined that fertility preservation should be undertaken in a

timely manner, and where possible, prior to beginning of medical treatment which may impact fertility. In Germany, it is stated that any fertility preservation treatment undertaken should not worsen a patient's prognosis, or delay the start of curative treatment,[111] while in Sweden it is noted that in young people undergoing cancer treatment, this treatment was prioritised over fertility preservation.[88] In Portugal, any waiting time applied to assisted reproductive technologies, including fertility preservation services, should be based on objective criteria of clinical severity.[123]

Specific timelines regarding people receiving cancer treatment were identified for Denmark and France. In Denmark, the Danish Health Authority provide clinically recommended and justified time frames from diagnosis of cancer to primary treatment, and these recommendations may impact any fertility preservation treatment undertaken prior to cancer treatment commencement. For example, for leukaemia and lymphomas in which the primary treatment in most cases is chemotherapy, it is recommended that treatment is initiated within three days of diagnosis.[44] It is also recommended that ovarian tissue cryopreservation is performed in people with leukaemia once they are in complete remission. In France, doctors treating people with cancer should refer the person to the fertility preservation team as soon as possible, which in emergency cases may be within 48 hours.[59]

In Scotland it was outlined that while it was preferable for transgender, non-binary and gender diverse 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.[162] 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 further consideration of gamete storage in the future. This is as gamete storage can be considered any time up until surgical removal of the gonads.[162] Additionally, in the Karolinska University Hospital in Sweden, if patients wish to cryopreserve eggs and have already initiated hormonal gender-affirming treatment, it is the policy to suspend the treatment and await for normalisation of testosterone levels before starting gonadotropin stimulation.[80]

Further timelines to access fertility preservation services were also identified for Sweden, in which it is recommended that:

- adolescent girls with Turner Syndrome who present with spontaneous start of puberty should be referred for appropriate counselling on fertility preservation, and if possible, individualised fertility preservation[67]
- referrals for specialist doctors in reproductive medicine and or andrological (the branch of reproductive science focusing on male sexual health) counselling should be provided after completing gonad-damaging treatment for both adults and young people, as appropriate.[88, 89]

3.2.4 Storage

Arrangements and duration

Information relating to storage arrangements and durations for publicly-funded fertility preservation services for medical reasons was identified for all 10 selected countries. A brief summary of the publicly-funded storage periods for each country is presented in Table 3.4, with further details in Appendix C, Table C.4.

Storage of gametes

Defined storage periods were identified for oocytes in seven countries (Australia, Denmark, England, Germany, Portugal, Scotland and Wales) and for sperm in six countries (Australia, England, Germany, Portugal, Scotland and Wales). In one country (Northern Ireland), the duration of publicly-funded gamete storage was unclear, based on the identified information. In one further country (France), storage of gametes is not publicly funded.[104, 105] The shortest period for which storage of sperm and oocytes is funded in the selected countries is five years, identified in two countries (Portugal and Scotland). No limit on the duration of publicly-funded storage was identified for sperm in two countries (Denmark and Sweden) and oocytes in one country (Sweden). However, in Sweden, storage time may be regulated at regional level.[88, 89] In Germany, rather than providing funding for a defined number of years, the funded storage period is based on the age of the patient. Storage of eggs, sperm or germ cell tissue is publicly funded for insured males aged under 50 years and insured females aged under 40 years.[19] Similarly, in Denmark, storage of oocytes or embryos is funded as long as the woman who is to give birth is aged less than 46 years, in line with the age limit to receive publicly-funded fertility treatment.[100, 101]

Storage of embryos

For embryo cryopreservation, information regarding defined publicly-funded storage periods was identified for eight countries (Australia, Denmark, England, Northern Ireland, Portugal, Scotland, Sweden and Wales). The shortest period for which embryo storage is funded was observed in Portugal, where storage is funded for three years. However, this period may be extended by an additional three years at the request of the couple.[120] In contrast, embryo storage is funded in Denmark for women up to the age of 46 years.[17] The longest publicly-funded storage period for embryos across the selected countries was unclear, as a number of countries do not have a defined maximum storage duration. For example, the maximum storage duration was unclear based on identified information for Northern Ireland and Wales, funded storage periods vary at the local level in England,[45, 53, 73] and storage periods may be extended beyond the initially funded periods in Sweden[88, 89] and Scotland.[163]

Extension of storage periods for gametes or embryos

Other countries in which the duration of storage for sperm, oocytes or embryos may be extended under certain conditions are England (subject to local Integrated Care Board (ICB) policy), Northern Ireland, Portugal, Scotland and Sweden. For example, in Portugal, the director of the fertility centre may extend the five-year period for storage of sperm, eggs, testicular tissue or ovarian tissue for another five years by request from the patient and where justified. Equally, the storage period will be shortened to three years following the death of the patient.[120] In Sweden, embryos may be stored for up to 10 years with public funding; however, the Judicial Council of the National Board of Health and Welfare may grant an exemption for extended storage.[89]

Ovarian and testicular tissue storage

Information on publicly-funded storage periods for ovarian tissue was identified for three countries (Denmark, Germany and Portugal) and for testicular tissue in two countries (Germany and Portugal). As outlined in Table 3.4, ovarian tissue storage is funded up to the age of 40 years in Germany,[19] and ovarian or testicular tissue storage is funded for five years in Portugal, in the first instance.[120] In Denmark, storage of ovarian tissue is centralised to one laboratory in Copenhagen,[31] and there is no defined storage period; the tissue is stored until it is used or until the patient decides otherwise.[71] There is also no restriction on the duration of testicular tissue storage in Denmark.[17]

Storage in the UK – national and local arrangements

Across the UK, the maximum storage period for gametes and or embryos is 55 years, with consent for storage to be renewed every 10 years (see section 3.2.8 for further details).[190] This legally allowable storage period is distinct from the storage periods funded through the public health system in each jurisdiction of the UK. In Scotland, eligible patients receive NHS funded storage for five years in the first instance. Patients should then be reviewed every five years by the relevant fertility clinic to assess whether it is appropriate to continue NHS-funded storage. Further storage will only be provided if the patient continues to meet certain eligibility criteria; for example, if the patient now has children, storage will no longer be funded by the NHS.[163] The information identified for Northern Ireland and Wales was less clear. In Northern Ireland, publicly-funded fertility treatment includes the storage of embryos for two years, with the costs of further storage to be paid for by the patient. Similarly, the costs of storing sperm for future fertility treatment must be paid for by the patient. However, exceptions apply when stored for oncology or other specific medical reasons, but information on the nature and extent of such exceptions was not identified.[161] In Wales, as of 2019, the Welsh Health Specialised

Services Committee funded fertility preservation for people undergoing gender-affirming medication or surgeries for 10 years.[173] Those who wished for eggs, sperm or embryos to remain in storage after that period would be required to pay an annual fee (£275 per year at that time).[173] It is unclear if this storage period and or fee still apply as of 2024.

In England, NHS-funded storage periods vary at local level, depending on ICB policy. Published research examining previous Clinical Commissioning Group policies reported typical storage periods of five to 10 years.[45, 53, 73] Of the seven samples from regions selected for this review, storage is generally funded for up to 10 years in five regions (Bedfordshire, Luton and Milton Keynes;[139] Coventry and Warwickshire;[141] Cheshire and Merseyside;[180] Kent and Medway;[153] West Yorkshire[142]). Certain ICBs outline that this period may be extended subject to meeting specific eligibility criteria (Bedfordshire, Luton and Milton Keynes[139]), or subject to an Individual Funding Request (Coventry and Warwickshire;[141] West Yorkshire[142]). Two ICBs' policies outline a shorter funded storage period of up to five years (Somerset;[155] South West London[140]), but with exceptions allowing longer storage periods for young people. For example, South West London ICB funds storage for up to five years for patients aged 23 years or older or for up to five years after the 23rd birthday for patients aged less than 23 years at the time of preservation. The treating clinician can also apply for an extension if the patient is undergoing treatment that results in them being unable to start a family at the time the funded storage period expires.[140]

Ongoing storage at the expense of the individual

For five countries (Australia,[94, 186] England (Bedfordshire, Luton and Milton Keynes;[139] Coventry and Warwickshire;[141] Kent and Medway;[153] Somerset;[155] South West London[140]), Northern Ireland, Scotland and Wales), information was identified stating that the individual may continue to store materials at their own expense at the end of the publicly-funded storage period. An example from Wales is outlined above in *Storage in the UK – national and local arrangements*; as of 2019, an annual storage fee of £275 must be paid by people undergoing gender-affirming medication or surgeries and who wish to store their eggs, sperm or embryos after the publicly-funded 10-year period.[173] It is unclear if this storage fee still applies as of 2024. Where individuals continue to store material at their own expense, the legal allowable maximum storage periods at national[190] or regional[69, 92] levels apply.

Table 3.4 Publicly-funded storage periods for cryopreserved gametes, embryos and tissues in selected countries.

Country	Sperm	Oocytes	Embryos	Ovarian tissue	Testicular tissue
Australia	For up to 10 years	For up to 10 years	For up to 10 years	Not identified	Not identified
Denmark	No limit specified	Age <46 years	Age <46 years	No limit specified	No limit specified
France	Not funded	Not funded	Not funded	Not funded	Not funded
Germany	Age <50 years	Age <40 years	Not funded	Age <40 years	Not funded
Portugal	5 years[a]	5 years[a]	3 years[b]	5 years[a]	5 years[a]
Sweden	No limit specified	No limit specified	Up to 10 years[c]	Not identified	Not identified
UK					
England	Depends on ICB policy	Depends on ICB policy	Depends on ICB policy	Not identified	Not identified
Northern Ireland	Unclear[d]	Unclear[d]	At least 2 years; unclear thereafter[d]	Not identified	Not identified
Scotland	For up to 5 years initially; subject to eligibility reviews every 5 years thereafter	For up to 5 years initially; subject to eligibility reviews every 5 years thereafter	For up to 5 years initially; subject to eligibility reviews every 5 years thereafter	Not identified	Not identified
Wales	For up to 10 years; unclear thereafter	For up to 10 years; unclear thereafter	For up to 10 years; unclear thereafter	Not identified	Not identified

Key: ICB – Integrated Care Board.

[a] At the request of the beneficiaries, in duly justified situations, the director of the fertility centre may extend the storage period for sperm, oocytes, testicular tissue and ovarian tissue for a new five-year period.

[b] May be extended for a further three-year period, at the request of the couple.

[c] Extended storage can be permitted by the Judicial Council of the National Board of Health and Welfare.

[d] Exceptions to the publicly-funded storage period for fertility treatments apply when stored for specific medical reasons, but information on the nature and extent of these exceptions was not identified.

Access to stored materials

As outlined in Section 2, documents and resources focused solely on publicly-funded fertility treatments (that is, without inclusion of approaches to fertility preservation) were deemed to be outside the scope of the current review. However, within the resources that were eligible for inclusion, certain information was identified regarding the potential use of stored gametes, embryos or tissues for subsequent fertility treatment.

In four countries (Denmark, England, France and Scotland), the identified resources highlight that patients who wish to use stored gametes or embryos for publicly-funded fertility treatment will need to meet separate access criteria for such services. In three of these countries (Denmark,[103] France[106-108] and Scotland[162, 163]), there are clear national access criteria for publicly-funded fertility treatment. For example, age-based criteria are applied in Denmark, where such services may be accessed by women aged less than 40 years at referral and couples who do not already have children.[103] Similarly, in France, ART treatments are funded for women aged less than 45 years and men aged less than 60 years.[106-108] In France, ART treatments are also funded specifically for couples composed of a man and a woman, female couples, and single women. In certain cases, these access criteria may limit possibilities for the use of stored gametes by transgender men and women.[29, 32] In Scotland, national IVF access criteria apply where stored materials are to be used for publicly-funded treatment, and separate screening requirements must be met if third party reproduction is required (that is, donation and or surrogacy).[162]

In England, to use stored materials as part of publicly-funded fertility treatment, the patient will need to meet the access criteria outlined in local policy at the time of seeking referral for treatment.[45] This requirement is highlighted in six of the seven sample ICB policies included in this review (Bedfordshire, Luton and Milton Keynes;[139] Coventry and Warwickshire;[141] Kent and Medway;[153] Somerset;[155] South West London[140]; West Yorkshire). Certain exceptions are outlined for patients who have undergone fertility preservation for medical reasons. For example, Kent and Medway ICB[153] and South West London ICB[140] note that such patients do not need to fulfil usual IVF access criteria relating to ovarian reserve in order to access IVF using their cryopreserved eggs or embryos. South West London ICB's policy also outlines that patients who have gametes stored due to medical reasons will be eligible for two frozen embryo transfer cycles when accessing IVF, since a fresh cycle (that is, unfrozen) is not possible for them.[140]

Compared with access to and use of gametes or embryos, relatively little information was identified regarding the use of cryopreserved ovarian or testicular tissue. Transplantation of cryopreserved ovarian tissue is publicly funded in Denmark.[31, 71]

It is also publicly funded in Sweden, where it is carried out at a single institution as part of a clinical research study.[67] In Germany, the removal, preparation, storage and thawing of ovarian tissue is funded, but its transplantation is not currently funded as the procedure is considered to be experimental.[115] In England, the single centre that offers a tissue preservation service through charitable funding has reportedly performed a small number of successful ovarian tissue transplantation procedures, but not testicular tissue transplantation.[38]

Disposal of stored materials

Information regarding the disposal of stored materials was identified for eight of the 10 selected countries (Australia, Denmark, England, France, Northern Ireland, Portugal, Sweden and Wales). Clear information on the disposal of stored materials was not identified for Germany. For Scotland, although information on disposal was not explicitly included in the identified resources, the provisions of the Human Fertilisation and Embryology Act 1990 apply, as in other jurisdictions in the UK (that is, England, Northern Ireland and Wales). Specifically, gametes or embryos will be removed from storage and disposed of where consent for their storage is not renewed by the patient.[190]

Aside from disposal, the identified information indicated that a number of the selected countries offer patients the option to donate materials for use in research or training. Information regarding such donation was identified for the following countries in relation to:

- gametes – Australia,[41] Denmark,[99] France,[106] Northern Ireland,[161] Portugal,[120] and Sweden[88, 89]
- embryos – Australia[41] and Northern Ireland[161]
- gonadal tissues – Denmark (ovarian tissue),[46] Portugal,[120] and Sweden.[88, 89]

In Portugal, donation for research purposes must be confirmed via written informed consent from the patient, as per the CNPMA's informed consent models.[120] Furthermore, gametes or tissues donated to research may be disposed of if not used in a research project within 10 years of cryopreservation.[120]

For four of the selected countries, the identified information indicated that the patient has the option to donate stored gametes to another individual for the purposes of fertility treatment (Australia,[41] Denmark,[99] France[106] and Sweden).[88, 89] In Australia, stored embryos may also be donated for this purpose.[41] Where such donations are made, distinct requirements for gamete and or embryo donors may need to be met. For example, in Sweden, the National Board of Health and Welfare's regulations on donation and procurement of organs, tissues and cells

(SOSFS 2009:30) specify the relevant national requirements for gamete donors.[88, 89, 191]

Information regarding arrangements for the disposal or use of stored materials following the death of the patient was identified for all 10 selected countries. In England, Northern Ireland, Scotland and Wales, consent to the storage of gametes or embryos must state what is to be done with the gametes or embryos if the patient dies or lacks capacity to vary or withdraw their consent, as per the Human Fertilisation and Embryology Act 1990.[190] If consent is provided by the patient prior to their death, posthumous use of gametes or embryos by a specified partner is possible.[161] In Australia, publicly-funded storage of embryos may be continued by the surviving reproductive partner after the death of the patient, whereas for gametes, ongoing storage beyond the initially funded ten-year period may only be made where legal arrangements for the transfer of their ownership to another person have been made.[94, 186] In Sweden, stored gametes or gonadal tissues may not be used for fertility treatment by another individual in the event of the patient's death. However, if the patient consented to their materials being used for research or other medical purposes, they may continue to be stored and used for that purpose.[88, 89] In Denmark, cryopreserved oocytes or embryos must be destroyed in the event of the woman's death, and embryos must also be destroyed if the couple separates or divorces.[99] Posthumous use of cryopreserved gametes is not permitted in France.[106]

3.2.5 Governance

Limited information related to the overall governance of publicly-funded fertility preservation services for medical reasons was identified for the 10 selected countries (see Appendix C, Table C.5). In Denmark, Northern Ireland and France the Minister of Health, Ministry or Department of Health (as appropriate), or a national state agency under the supervision of the Ministry of Health were outlined as the overall governing authority for publicly-funded fertility preservation services. For example, in Denmark, the Minister of Health may set detailed rules on donation, including anonymity and conditions for compensation, on storage, and on use, including the number of pregnancies per donor, on human eggs and sperm.[99] In France, the Biomedicine Agency is the reference authority on medical, scientific and ethical aspects of harvesting and transplantation of organs, tissues and cells, and human procreation, embryology and genetics.[104, 105] Specifically within the area of medically assisted procreation, their role includes managing authorisations for medical techniques and ensuring the implementation of vigilance systems.[104, 105] In Northern Ireland, where NICE guidelines are endorsed by the Department of Health at a national level, these guidelines are issued directly to Health and Social Care (HSC) Trusts and Boards (and other relevant public health agencies as appropriate) for implementation.[157] The HSC Trusts are then granted 12 months to implement

the endorsed clinical guidelines, after which the Regulation and Quality Improvement Authority (RQIA) assess implementation. The relevant HSC Board must also formally report annually to the Department of Health on the progress made generally in commissioning services in accordance with endorsed NICE guidance.[157]

In Scotland, while the specific department or ministry responsible for publicly-funded fertility preservation services was not outlined, Fertility Scotland is funded by the Scottish Government and ultimately responsible to the Scottish Government and the NHS Board Chief Executives.[163] A number of further governance structures were also identified for the network of NHS Fertility Services in Scotland including the:[163]

- Oversight Board: which provides overall strategic leadership, endorses recommendations from the Core Steering Group and ensures the network remains focussed on delivery
- Core Steering Group: which provides a forum for interchange between working groups, the Programme Management Team and relevant stakeholders. The group makes recommendations to the Oversight Board
- Programme Management Team: which oversees the day to day running of the Network, monitors progress and reports to the Core Steering Group and the Oversight Board
- Working Groups: which are established for each specific Project or Programme of work.

Information related to the governance or regulation of the facilities delivering fertility preservation services was identified for all of the 10 selected countries. More specifically, a number of regulatory bodies, or agencies with regulatory functions in their remit, were outlined, including in:

- Australia, the Reproductive Technology Accreditation Committee, which is responsible for setting the Code of Practice for ART performance and the granting of licences to practice ART[94, 186]
- Portugal, the CNPMA, which has overall governance in relation to the regulation of medically assisted procreation centres. Their functions include receiving annual reports from ART centres, auditing and inspecting ART centres (in collaboration with the General Inspection of Health Activities) and training ART centre auditors[120, 123, 192]
- the UK, the Human Fertilisation and Embryo Authority (HFEA), which is the independent regulator of fertility treatment and research using human embryos.[190] Additionally, the Human Tissue Authority regulates storage of ovarian tissue (which falls outside the remit of the HFEA)[193] and the Information Commissioner regulates patient data[194]
- Northern Ireland, the RQIA, which assesses the implementation of endorsed NICE clinical guidelines.[157]

3.2.6 Communication and information provision

Communication and information provision related to publicly-funded fertility preservation services for medical reasons was identified for all 10 of the selected countries. This includes both raising awareness of fertility preservation services (and the possible requirement for their use) in those who are eligible, and following this, providing comprehensive information around fertility preservation interventions. In Denmark,[99] France,[72] Germany,[111] Portugal[120] and the UK,[195] there is a legal requirement to provide information on fertility preservation services to eligible patients. For instance, in France, healthcare professionals are legally required to provide information on fertility risk, and gamete or germinal tissue preservation, to those whose fertility is likely to be impaired due to a pathology or medical treatment.[72] For example, during a consultation prior to cancer treatment, the oncologist must inform the patient about the gonadotoxicity of chemotherapies and propose a consultation in a specialised centre to discuss fertility preservation feasibility. This information must be fair, clear and appropriate.

In Denmark,[99] Germany,[19, 115] Portugal[120] and the UK,[127] it is a legal requirement for healthcare professionals to provide detailed information on any fertility preservation intervention being undertaken or considered. This includes the purpose and type of intervention; the benefits and risks associated with the intervention; the probability of success associated with the intervention (for example, the probability of pregnancy and live birth following the transplantation of germinal tissue); and any legal, social, ethical, medical, psychosocial or scientific implications of their decision.

While not legally enforced, in Australia, the National Health and Medical Research Council ethical guidelines outline a number of information provision and counselling requirements that ART clinics must comply with.[92] These include, for those considering storing gametes or embryos, the live-birth rate following the use of the thawed gametes, tissues and embryos for the particular clinic. For those considering fertility preservation, ART clinics must provide access to counselling by a professional with appropriate training, skills, experience and competency to support decision-making.[92]

Germany[19, 115] and Sweden[88, 89] specify that information about alternative pathways to parenting should also be given to all patients. This includes information around spontaneous conception, egg and sperm donation, adoption, and fostering. In Sweden, this information is provided when patients are informed that measures to preserve reproductive capacity do not guarantee the ability to have biological children in the future, but that they represent an opportunity.[88, 89]

Providing specific information on fertility preservation, dependent on personal characteristics was also outlined and this included:

- sex-specific information (for example, in Germany and Sweden, information on sex-specific requirements for specific fertility preservation interventions must be provided. Sweden provides separate information brochures for men and women[196]).
- age-specific information (for example, Sweden provides separate information brochures for younger and older men and women;[196] and in the UK, specific, appropriate information on fertility preservation must be provided to minors[195])
- information for those undergoing gender-affirmative treatment (for example, in Wales an information brochure for fertility preservation for transgender, non-binary and gender diverse people is available[173]).

Of note, it was identified that all of the information provision requirements outlined within the 10 selected countries are in place to enable patients to make an informed choice around any fertility preservation intervention undertaken. Further detail regarding informed consent is outlined in Section 3.2.7.

3.2.7 Ethical considerations

Information regarding ethical considerations relating to publicly-funded fertility preservation services was identified for all 10 of the selected countries (see Appendix C, Table C.7). For three countries, specific resources were identified that focus on ethical considerations, as follows:

- Australia:
  - National Health and Medical Research Council — Ethical guidelines on the use of assisted reproductive technology in clinical practice and research[92]
- Denmark:
  - Council of Ethics — Storage of fertilised eggs and unfertilised egg cells[103]
- England:
  - NHS England — Fertility preservation for service users with ovarian tissue who are at high/very high risk of infertility and cannot store mature eggs: equality and health inequalities impact assessment[133]
  - NHS England — Fertility preservation for service users with testicular tissue who are at high/very high risk of infertility and cannot store sperm: equality and health inequalities impact assessment.[135]

These resources include considerations relating to specific fertility preservation methods and or to assisted reproduction in general. For example, the NHS England impact assessment documents outline the potential positive and negative impacts of NHS commissioned tissue preservation services on people with certain protected characteristics (such as age, gender, sex, disability, religion and belief) and people

who experience health inequalities (such as carers, homeless people, and people with poor literacy or health literacy).[133, 135] The report from the Danish Council of Ethics includes recommendations to inform national policy based on consideration of the ethical aspects of the proposed policy decision (specifically, to extend the publicly-funded storage period for fertilised and unfertilised eggs).[103] The recommendations broadly centre on considerations of the benefits and risks of the policy change, as well as considerations relating to equity and respect for autonomy. The Australian NHMRC guidelines include guiding principles that are applicable to all fertility clinics and their practices, such as maximising benefits and minimising harms to individuals, couples and children, and supporting decision-making processes that respect the relevant social and cultural contexts, as well as the autonomy of all relevant parties.[92]

Considerations of the benefits and risks associated with specific fertility preservation methods and or in certain populations were outlined in identified information across a number of the selected countries; for example, the detailed guidance in relation to adults and young people in Sweden.[88, 89] The importance of such considerations are particularly emphasised, as noted in Section 3.2.6, in Denmark, Germany, Portugal and the UK, where healthcare professionals are legally required to discuss the benefits and risks of fertility preservation interventions with patients.[88, 89]

In terms of justice and equity, equality impact assessments were also identified in two of the seven sample ICB policies included for England (Coventry and Warwickshire[141] and South West London[140]). These assessments also considered potential impacts of the policy on people with certain protected characteristics, similar to the NHS England impact assessment documents identified.[133, 135] However, inequity was highlighted in published literature relating to the UK, and particularly to England, in light of the local variations that exist in fertility preservation policy.[45, 53, 73] Geographical inequity was also highlighted in Australia, where those who reside in rural and remote areas may be unable to access specialist services, such as tissue cryopreservation services.[85] Some countries also highlighted considerations to promote equitable access to appropriate fertility preservation services for people with gender dysphoria (for example, Sweden[88, 89]) and transgender people (for example, France[107]), including the need for cultural competence among staff (as noted in England[133, 135] and Wales[173]).

A major ethical consideration identified in resources across the selected countries was consent. This includes the provision of informed consent in relation to fertility preservation procedures, as noted in Section 3.2.6, and consent to storage and use or disposal of materials, as noted in Section 3.2.4. Challenges to clear decision-making, and therefore, to providing informed consent, that are relevant to many populations offered fertility preservation for medical reasons are outlined by the Swedish Tissue Council,[88, 89] including:

- the anxiety associated with receiving a diagnosis of serious illness
- the time pressure under which decisions must often be made
- the uncertainty and complexity of the procedures involved and
- the resulting difficulty in understanding the situation and weighing up the options.

In addition, further ethical challenges were highlighted in published literature in relation to ovarian or testicular tissue cryopreservation. The potential impacts of the tissue retrieval procedure on the individual and the uncertainty regarding the potential success of future transplantation of cryopreserved tissue may lead to difficulties in decision-making, particularly for children.[34, 82]

As outlined in Section 3.2.4, legislation regarding consent to ART treatment is in place in a number of the selected countries, including Denmark,[99] France[107] and Portugal,[120] and specifically in relation to storage, use and disposal of stored materials across the UK (England, Northern Ireland, Scotland and Wales).[190] This includes arrangements for providing consent to the use or disposal of stored materials in cases where an individual becomes unable to provide or renew consent, for example, if an individual loses their capacity to make decisions, or in the event of their death.[99, 120, 190]

A number of the selected countries outline specific guidance or requirements in relation to consent to fertility preservation in children and adolescents (that is, those aged less than 18 years), such as Australia,[92] France,[107] Germany[111] and Sweden.[88] For example, in France, the Public Health Code details specific arrangements for the storage of gametes or germ cell tissue from a minor (in France, a 'minor' refers to a person aged less than 18 years).[107] Informed consent to any procedure and to storage are required from a parent or guardian, but the consent of the minor must be systematically sought if they are capable of expressing their wishes and participating in the decision. Parents or guardians must also be contacted each year in writing to collect information useful for storage — for example, any change in contact details. The stored gametes or tissues of a minor can only be destroyed in the event of their death. In such cases, the parents or guardians may alternatively consent to the donation of the stored materials for research.[107]

Further ethical considerations are the implications of the chosen fertility preservation method for the person's future reproductive autonomy. This is particularly relevant to embryo cryopreservation, as future use in fertility treatment is dependent on the relationship remaining stable and both parties providing consent (as highlighted in Denmark,[99] Sweden,[64, 86] and across the UK[27, 50, 190]). For this reason, published literature has noted a preference among women in Sweden to choose oocyte cryopreservation, rather than embryo storage,[64, 86] and, in Portugal, clinical

recommendations advise against the storage of embryos for the purposes of fertility preservation.[178]

In Portugal, for healthcare professionals, legislation on medically assisted procreation makes provision for them to exercise autonomy in relation to their practices, specifically in relation to conscientious objection (that is, the refusal of a healthcare professional to provide or participate in providing certain care on the basis of personal beliefs).[120]

3.2.8 Legislation

Legislation governing, and or related to, publicly-funded preservation services for medical reasons was identified for all 10 selected countries (see Appendix C, Table C.8). In Denmark, France, Germany and Portugal, specific legislation governing the populations eligible for publicly-funded fertility preservation services was identified. These documents include:

- Denmark — the Assisted Reproduction Act[177]
- France — the Bioethics Law and Public Health Code[107, 108]
- Germany — the German Social Code (SGB) Fifth Book (V) – Statutory Health Insurance, amended with the TSVG (Appointment Service and Supply Act)
- Portugal — Medically assisted procreation: Law No.32/2006 (Consolidated Legislation).[120]

Within these countries, the legislation specifies, where applicable, the age criteria and or medical reasons that confer eligibility for publicly-funded fertility preservation services (see Section 3.2.1). In the UK, the Human Fertilisation and Embryology Act (1990) established the legal framework governing fertility treatment; however, for fertility preservation services, the methods offered and eligibility criteria are not included within this Act.[190] In Australia, the major elements of Medicare, the universal health insurance scheme, are contained within the Health Insurance Act 1973.[197]

Legislation governing publicly-funded storage periods for eggs or embryos has been amended, within the last five years, in both Denmark (2021[100] and 2023[101]) and Sweden (2019[89]). In Denmark, an amendment to the Assisted Reproduction Act increased egg and embryo storage periods for women from five years to until the woman reaches 46 years old.[100, 101] In Sweden, an amendment to the Act on Genetic Integrity increased the storage period for embryos from five of 10 years.[89] In 2022, the UK amended the Human Fertilisation and Embryology Act 1990 to allow for a maximum storage period of 55 years for gametes and or embryos; however, public funding is not included within the legislation, or guaranteed for this length of time.[190, 198]

In Sweden, in 2013, an amendment to legislation resulted in the removal of sterilisation as a compulsory part of gender affirmation treatment.[49, 60, 79, 80] This change enables transgender individuals seeking gender-affirming treatment to undergo fertility preservation within the publicly-funded healthcare system.

Further legislation was also identified, that, while not directly governing the provision of fertility preservation services, may impact service delivery, including legislation related to:

- the handling of human tissues and cells (for example, the Danish Tissue Act in Denmark,[17] the Human Tissue Act 2004 in the UK,[193] and the Law on the Quality and Safety of Human Tissues and Cells in Germany[111])
- the provision of broader healthcare services (for example, the Health and Care Act 2022 in the UK[199])
- medicinal products (for example, the Medicines Act and the Medicinal Products and Active Substances Manufacturing Ordinance in Germany[19, 111]).

4 Discussion

Over the last two decades, the field of fertility preservation has experienced immense growth.[9] This is primarily due to the increased recognition of medical reasons which may impact fertility or result in advice to delay or avoid conception, and due to advances in fertility preservation technology.[9] There is now widespread availability of certain fertility preservation methods; a survey conducted by the European IVF-Monitoring (EIM) Consortium for the European Society of Human Reproduction and Embryology (ESHRE) stated that, as of 2022, cryopreservation of gametes for medical conditions was allowed in 43 European countries.[200] However, this survey also noted that public funding for this service, and more broadly ART services, varied considerably across European countries.[200] An understanding of what fertility preservation services are publicly funded, and who is eligible to access such services, will support the development of national fertility preservation policy in Ireland. An international scoping review of 10 countries was therefore undertaken; these countries were selected based on a combination of factors, including having a similar health service structure, population size and geographical proximity to Ireland.

4.1 Fertility preservation methods

In terms of fertility preservation methods available, cryopreservation of sperm and oocytes are publicly funded for medical reasons in all 10 selected countries. Embryo cryopreservation is also widely funded, with acknowledgements in some countries that it may be unsuitable for certain people (for example, those without a partner) and may restrict a persons' future reproductive choices (for example, in the event of

a change in relationship status). Notably, these methods are only possible in pubertal and postpubertal individuals. The only methods possible in prepubertal individuals — ovarian tissue cryopreservation (OTC) and testicular tissue cryopreservation (TTC) — are less widely funded in the selected countries or their status is unclear. Furthermore, even in the selected countries where public funding is provided for tissue preservation services, the majority have limited funding and service provision arrangements in place. For example, prepubertal populations may be ineligible to access services or limited to accessing services through research studies only. This restricted availability of publicly-funded OTC and TTC may be due to these methods being viewed as experimental in many European countries. While TTC is still considered an experimental approach,[201] since 2019 OTC has been considered an acceptable option for fertility preservation in carefully selected individuals by the American Society of Reproductive Medicine, with acknowledgement of the limited available data on its efficacy, safety and long-term outcomes.[202] Additionally, in 2020, ESHRE provided a strong recommendation to offer OTC in people undergoing moderate or high risk gonadotoxic treatment where oocyte or embryo cryopreservation is not feasible, or at patient preference.[9] Factors that may influence patient preference were not outlined, but may include preferences to avoid undergoing ovarian stimulation, or to avoid delaying treatment to undergo stimulation and oocyte retrieval. The ESHRE guideline development group noted that OTC should still be considered an innovative method for postpubertal women, with further data on its effectiveness and long-term safety required before OTC can be considered an established procedure.[9] These relatively recent developments in relation to OTC are reflected in Germany, where funding for OTC is provided for postpubertal females only, following a change in national policy in 2022.[111]

Of the selected countries in the current review, Denmark is a notable exception in terms of the availability of tissue preservation and structures in place to support its provision. OTC has been provided within the Danish public healthcare system since 1999, and a number of successful transplantations of stored ovarian tissue have been carried out.[31, 71] This service is provided through the Danish Network, which offers services to patients across Denmark and the south of Sweden,[71] an area with a similar total population to that of Ireland. Within this network, patients access fertility services at a small number of publicly-funded university hospitals, and storage is largely centralised, enabling the required specialist expertise and facilities to be concentrated in certain locations.[71] On a larger multinational scale, an example may be found in the FertiPROTEKT® network, which is an association of fertility centres in Germany, Austria and Switzerland; this network supports centralisation of ovarian tissue storage, as well as data collection and professional development across the three countries.[71] The data collection opportunities made possible through such networks may be of great value to the developing field of

tissue preservation. While meta-analyses examining obstetric outcomes of patients who underwent OTC for both cancer and non-cancer indications have reported promising results, the current research in this field has a number of limitations.[203-205] These include small sample sizes, a relative lack of data on long-term outcomes, and challenges in comparing OTC with established methods, such as embryo and oocyte cryopreservation, due to differences in the populations which may avail of each method (for example, in terms of age and clinical circumstances).[203-205]

4.2 Eligibility – access to services and storage

In Ireland, HSE-funded sperm, oocyte and embryo preservation services are currently available for adults, aged 18 years and older, with cancer whose treatment is expected to impact fertility. This service is provided in three locations through one HSE-approved AHR provider, with storage funded for ten years.[20, 21] Egg and sperm cryopreservation is also available to postpubertal individuals aged under 18 years, through the Childhood Cancer Fertility Project.[23] Fertility preservation services for prepubertal children are not currently provided in Ireland. Of the selected countries, publicly-funded fertility preservation services are also not offered to prepubertal populations in Australia and Germany, with agencies in both countries stating that this is due to the lack of satisfactory evidence for the clinical effectiveness and safety of OTC and TTC in this population. A more flexible approach is in place in Sweden, where OTC and TTC may be carried out in appropriate prepubertal populations as part of a research study. This practice is in line with recommendations from the PanCareLIFE Consortium and the International Late Effects of Childhood Cancer Guideline Harmonization Group (a collaboration formed to facilitate global consensus on fertility preservation in childhood, adolescent, and young adult cancer patients).[10]

In all selected countries, people are offered publicly-funded fertility preservation services if they are about to commence treatment for cancer that poses a risk to their fertility. A number of the selected countries extend access more broadly to people due to undergo any treatment that will likely affect their fertility, regardless of the condition being treated. A limited number of the selected countries (Denmark, France, Sweden, and certain regions in England) specify that fertility preservation services are offered to people with conditions that are likely to impair their fertility. Publicly-funded fertility preservation services are not currently provided in Ireland for non-cancer patient groups, such as those whose medical conditions or treatment are likely to impact on their fertility, and those who are advised to delay conception for medical reasons. Notably, only one identified policy (South West London ICB[140]) specifically provided for access to publicly-funded services for people advised to delay conception due to the possible teratogenic effects of their medical treatment,

and in this case, access is provided only 'where stopping treatment for a prolonged period to enable conception is not possible'.

Variations in access criteria are evident between the selected countries, and also within certain countries, such as in England, where the variation in access criteria for publicly-funded fertility preservation services has been referred to as a 'postcode lottery'.[27, 68, 73] However, in the absence of clearly defined eligibility criteria, the potential size of the population that could be under consideration for fertility preservation may be substantial. Equally, it is challenging from a practical perspective to develop criteria that provide the appropriate breadth and specificity to include all populations who are intended to be included. This issue was addressed in a number of the selected countries by establishing processes for consideration of cases on an individual basis; for example, processes for assessment and determination of eligibility by the patient's GP or specialist in Australia, and the attending physician in Germany. Similarly, the use of Individual Funding Requests in England, Northern Ireland and Wales enables consideration of the specific clinical circumstances involved when determining eligibility.

The majority of the selected countries included storage arrangements for cryopreserved materials as part of publicly-funded fertility preservation services. Overall, variation and flexibility in storage periods was observed across the selected countries. A number of countries, including Portugal, Scotland, Sweden, Wales and parts of England, offer defined periods of publicly-funded storage in the first instance, with opportunities to extend for longer durations if deemed necessary and or appropriate. Such an approach allows fertility preservation services to meet the varying needs of patients and accommodate their changing circumstances over time. This opportunity to extend storage periods is particularly useful for services provided to different population sub-groups, for example, different age groups or groups with particular clinical needs. An alternative approach to storage was observed in Denmark, where the publicly-funded storage period for gametes and embryos aligns with national age-based access criteria for publicly-funded fertility treatment.[100, 101] This creates a coherent care pathway for patients who avail of fertility preservation services for medical reasons and ultimately wish to use their stored materials as part of fertility treatment. The disposal of stored material was also identified as a consideration in eight countries. In Ireland, the disposal of gametes, embryos and tissue is included within the Health (Assisted Human Reproduction) Act 2024, which outlines the legal requirements which AHR centres (or AHR storage facilities) must undertake prior to material disposal.[26] This includes contacting, or making a notable effort to contact, the relevant eligible person six months prior to the expiration of any stored material.

While documents focused on publicly-funded fertility treatment (such as IVF and ICSI) were considered out of scope within the current review, information that linked

fertility preservation and fertility treatment access criteria was identified for a number of countries. For example, in Sweden, the age-based access criteria for publicly-funded fertility preservation (of oocytes, sperm and embryos) and fertility treatment are aligned; and in Denmark the same maximum age limit for both publicly-funded oocyte storage and fertility treatment for women is used. In 2014, the ESHRE Task Force on Ethics and Law outlined that professionals should try to use access criteria to medically assisted reproduction that have been proven to predict the welfare of children and applicants, and that this should be evaluated in regards to the scientific evidence.[206] Currently, in Ireland the access criteria to confer eligibility for publicly-funded fertility treatment include criteria around residency, age and children the couple have together.[207] Alignment of the criteria to access fertility preservation with these criteria may be dependent on a number of factors including available resources, budget allocation and the eligible population size. However, regardless of alignment or not, patients who are undergoing fertility preservation should be informed that they will be required to meet the access criteria for publicly-funded fertility treatments in place at the time of use, should they wish to do so. This is outlined in six ICB policies included for England,[139-142, 153, 155] and while some exceptions may apply, for those who do not meet their local NHS fertility treatment access criteria they may be required to pay privately for fertility treatments.

4.3 Funding

In regards to funding, this scoping review focused only on publicly-funded fertility preservation services, with the majority of services available through public healthcare or a statutory health insurance system. A 2008 recommendation from the ESHRE Task Force on Ethics and Law stated that countries should provide at least partial reimbursement for reproductive care treatment to ensure equitable access for all citizens.[208] This is similar to what was identified for Portugal and Australia, where the patient may incur costs. The ESHRE Task Force outlined that access to partial reimbursement may limit the amount of people partaking in cross-border reproductive care.[208] This may be of particular relevance to countries that lack publicly-funded fertility preservation services, and where it is cheaper to travel to nearby countries than undergo private treatment at home.[209] While charitable funding sources were also identified in Australia,[57, 76, 85] England, Northern Ireland and Wales,[38, 181] this funding may be allocated for specified time periods, with no guarantee of long-term service provision. In Ireland, this is similar to the Childhood Cancer Fertility Project, a partnership between the Irish Cancer Society and Merrion Fertility Clinic, funded through a fixed-term three-year research grant.[23]

4.4 Legislation, and information and communication

Legislation related to publicly-funded preservation services for medical reasons was identified for all of the selected countries. This is in line with the results of the 2022 survey on ART legislation, regulation and funding, which outlined that 39 of the 43 European countries providing results had specific legislation on ART.[200] Within the legislation identified, a number of areas are regulated, including the age criteria and or medical conditions which confer eligibility for publicly-funded fertility preservation services, storage periods, and the provision of information around fertility preservation services. The legal requirement to provide information is supported by a number of clinical guidelines related to fertility preservation for medical reasons, including those published by NICE,[127] the ESHRE (which provides a checklist for clinicians to cover the information needs of patients undergoing fertility preservation counselling),[9] and the American Society of Clinical Oncology.[8] The information provided should be accessible and appropriate, and allow people to make an informed decision regarding their care and treatment.[127] It may also include counselling around any potential social and psychological implications of their decision to undertake fertility preservation. The Health (Assisted Human Reproduction (AHR)) Act 2024 in Ireland stipulates that appropriate AHR counselling must be undertaken by those undergoing AHR treatment involving the making or use of embryo or gamete donation, surrogacy or posthumous AHR, and that such counselling must be received before the treatment is conducted.[26] However, AHR counselling is not mandatory for individuals undergoing fertility preservation within this legislation.

4.5 Ethical considerations

Informed consent was identified as a recurring ethical consideration for all of the selected countries. This was in relation to both fertility preservation procedures, and consent to store, use and or dispose of cryopreserved materials. Specific guidance or requirements in relation to consent for fertility preservation in children and adolescents was regularly highlighted within the selected countries. In Ireland, while a child is defined by law as a person under the age of 18 years, a person over the age of 16 years can give consent to surgical, medical or dental treatment (and any associated procedures).[210] It is also outlined as good practice to involve those under 16 years of age in decision-making and to seek their permission for the proposed care.[210] Additionally, although not yet commenced as of October 2024, the Health (Assisted Human Reproduction) Act 2024 specifies the conditions under which a child's gametes or tissues may be obtained and stored for the purposes of fertility preservation, as well as the associated consent requirements.[26] A 2021 systematic review, conducted by the PanCareLIFE Consortium and the International Late Effects of Childhood Cancer Guideline Harmonization Group, resulted in a number of recommendations and ethical considerations for fertility preservation in children, adolescents, and young adults (aged 25 years or younger) diagnosed with

cancer.[211] While it was stated that the national legal regulations for informed consent with minors should be met, it was also recommended that healthcare providers assess a patient's emotional, psychological, and intellectual status as part of the process for informed consent. Additionally, it was recommended that any decision regarding fertility preservation in a child, adolescent or young adult should be made in the patient's best interests, with the informed consent documents disclosing any risks and or benefits associated with the procedure.[211] Consideration of the child's best interests will also be required under Irish legislation, once commenced.[26]

The provision of information around the risks and or benefits of OTC or TTC in particular, was also identified as a key ethical consideration. This is due to the invasive nature of these procedures, and the uncertainty regarding the potential success of future transplantation of cryopreserved tissue (as outlined in Section 4.1). This may lead to difficulties in decision-making, particularly for children.[34, 82] This is supported, in part, by a 2024 critical interpretive review of 162 studies, which outlined that in those with childhood cancer, it firstly may be difficult to consider future reproductive capabilities.[28] Following this, it was noted that the provision of OTC may create false hope about the likelihood of pregnancy in adulthood.[28] The provision of family support in decision-making, and appropriate, accessible information (as outlined in Section 4.4) may help overcome this.

4.6 Limitations

While this scoping review presents a comprehensive descriptive analysis of publicly-funded fertility preservation services for medical reasons in 10 selected countries, there are notable limitations. Firstly, this review is a descriptive analysis and does not include an evaluation of the effectiveness or delivery of fertility preservation services. Additionally, while efforts were made to ensure that the services outlined are currently in place (through triangulation of grey and published literature, and contacting key representatives in selected countries), some of the outlined services may represent what is intended or recommended to be provided, rather than those that are actually being delivered. Lastly, the fertility preservation landscape is complex, spanning multiple clinical specialties and impacting many patient sub-groups. The literature search conducted within this review focused on the identification of national policy documents and information related to fertility preservation for medical reasons. While an inclusive search strategy and a broad definition of "medical reasons" were adopted in this review, it is possible that some policy documents and information that focused on specific sub-groups (such as those with specific rare diseases or disorders, or those receiving surgical treatment for gender dysphoria) may have been missed.

5 Conclusion

This scoping review of publicly-funded fertility preservation services for medical reasons identified that cryopreservation of sperm and oocytes is typically publicly funded for adults and postpubertal adolescents in the selected countries. However, ovarian and testicular tissue cryopreservation are less frequently publicly funded. Funding for these services may vary depending on location, the population sub-group, or funding available. Eligibility to access fertility preservation services and the storage period for cryopreserved materials varied across the selected countries. In terms of the medical reasons for fertility preservation identified, those undergoing cancer treatment that poses a risk to their fertility are offered fertility preservation in all of the selected countries. The referral pathway to access services is regularly through a general practitioner or treating consultant, and it was noted that any fertility preservation treatment undertaken should not worsen a patient's prognosis, or delay the start of curative treatment.

Governing bodies accountable for publicly-funded fertility preservation services included national ministries for health, or equivalent, and state agencies under their supervision. Legislation in certain countries specifies the age criteria and or medical reasons that confer eligibility for publicly-funded fertility preservation services, and in some cases refers to the need for clear information provision to those considering or undertaking fertility preservation. Ethical considerations around fertility preservation for medical reasons were also highlighted. These included obtaining informed consent, particularly from children and adolescents, and caution surrounding the provision of fertility preservation procedures for which there is uncertainty regarding potential successful outcomes.

This review provides insights into what fertility preservation methods countries offer, how services are delivered, how materials are stored, and the governance and funding structures used to support service delivery, and will support the development of a national fertility preservation policy in Ireland.

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Appendices

Appendix A – Included published literature

Table A.1 Characteristics of included published literature.

No.	Author(s) [Reference] (Year)	Title	Type of evidence source	Country
1.	Abdallah et al.[27] (2018)	A nationwide UK survey of female fertility preservation prior to cancer treatment	Journal article	UK
2.	Affdal et al.[212] (2020)	Impact of legislation and public funding on oncofertility: a survey of Canadian, French and Moroccan pediatric hematologists/oncologists	Journal article	France
3.	Affdal et al.[28] (2024)	Ethical, legal, social, and policy issues of ovarian tissue cryopreservation in prepubertal girls: a critical interpretive review	Journal article	Numerous
4.	Agopiantz et al.[29] (2023)	Assisted reproductive technology in France: The reproductive rights of LGBT people	Journal article	France
5.	Allan et al.[30] (2018)	The Impact of the Law in Helping or Hindering Fertility Preservation for Children with Cancer Facing Gonadotoxic Therapies	Journal article	Australia
6.	Anderson and Davies[81] (2016)	Preserving fertility in girls and young women with cancer	Editorial	UK
7.	Bach et al.[31] (2020)	Futures and fears in the freezer: Danish women's experiences with ovarian tissue cryopreservation and transplantation	Journal article	Denmark
8.	Barry et al.[32] (2022)	What issues, changes and adaptations for French ART centers in the context of the new bioethics law?	Journal article	France
9.	Baston-Bust and Bielfeld[82] (2022)	Fertility preservation in the pediatric population-experience from a German Cryobank for ovarian tissue	Perspective	Germany
10.	Blecher et al.[83] (2022)	AUTHOR REPLY	Author reply	Australia
11.	Calhaz-Jorge et al.[33] (2020)	Survey on ART and IUI: legislation, regulation, funding, and registries in European countries-an update	Journal article	Numerous
12.	Courbière et al.[72] (2023)	[Restatement. Cancer and fertility preservation]	Journal article	France
13.	Dash et al.[73] (2019)	Fertility preservation provision for breast cancer patients in England - a postcode lottery	Conference abstract	England
14.	De Proost and Johnston[84] (2022)	The revision of the French bioethics law and the questions it raises for the future of funding for egg freezing	Commentary	France

No.	Author(s) [Reference] (Year)	Title	Type of evidence source	Country
15.	Elmusharaf et al.[74] (2017)	Review of existing fertility preservation options and advice given to teenagers and young adults with haematological malignancies in the United Kingdom	Conference abstract	UK
16.	Eustache[35] (2018)	[Missions and organization of the CECOS]	Journal article	France
17.	Fearon[34] (2023)	What do families affected by Turner Syndrome think of ovarian tissue freezing in childhood?	Journal article	UK
18.	Geoffron et al.[36] (2021)	Fertility preservation in women with malignant and borderline ovarian tumors: Experience of the French ESGO-certified center and pregnancy-associated cancer network (CALG)	Journal article	France
19.	Germeyer and Nawroth[37] (2023)	Indication and implementation of fertility preservation measures in female cancer patients	Journal article	Germany
20.	Ghattaura et al.[38] (2024)	Fertility preservation service for children and young adults at high risk of infertility; the hub and spoke model	Journal article	UK (England, Wales and NI)
21.	Gosset et al.[39] (2019)	État des lieux régional de l'accès à une consultation d'oncofertilité chez les femmes jeunes ayant un cancer du sein [Regional overview of access to oncofertility consultation among young women with breast cancer]	Journal article	France
22.	Hoffmann et al.[40] (2023)	Fertility and fertility preservation in men	Journal article	Germany
23.	Johnston et al.[16] (2022)	Financing future fertility: Women's views on funding egg freezing	Journal article	Australia
24.	Johnston et al.[41] (2024)	Storage trends, usage and disposition outcomes following egg freezing	Journal article	Australia
25.	Jourdain et al.[42] (2021)	Evaluation of physicians' practice patterns in France concerning fertility preservation in women with endometriosis	Journal article	France
26.	Kasaven et al.[43] (2024)	A Cross-Sectional Survey of Healthcare Professionals' Knowledge, Attitude and Current Behaviours towards Female Fertility Preservation Services within the UK	Journal article	UK
27.	Kristensen et al.[44] (2019)	Time from referral to ovarian tissue cryopreservation in a cohort of Danish women	Journal article	Denmark
28.	Latif et al.[45] (2023)	Fertility preservation provision in the NHS: a national assessment of care policies	Journal article	UK
29.	Macklon et al.[46] (2014)	Cryobanking of human ovarian tissue: Do women still want their tissue stored beyond 5 years?	Journal article	Denmark
30.	Macklon et al.[47] (2020)	Fertility counselling of younger women after cancer treatment	Journal article	Denmark

No.	Author(s) [Reference] (Year)	Title	Type of evidence source	Country
31.	Martin et al.[75] (2022)	A FERTILE FUTURE for CANCER patients: and update on improvements on options in Australia	Conference abstract	Australia
32.	Martin et al.[76] (2021)	Breaking down the barriers to fertility preservation in the oncology patient via a National Ovarian and Testicular Tissue Transportation and Cryopreservation Service (NOTTCS)	Conference abstract	Australia
33.	Martinet-Kosinski et al.[48] (2023)	Access to information and oncofertility consultation for young women with breast cancer: a population-based study	Journal article	France
34.	Mattelin et al.[49] (2022)	Fertility preservation and fertility treatment in transgender adolescents and adults in a Swedish region, 2013-2018	Journal article	Sweden
35.	McDougall et al.[50] (2020)	Outcomes of delivering a fertility preservation service for women with cancer over a 12-year period at a UK assisted conception unit	Journal article	UK
36.	Melo et al.[51] (2018)	Portuguese oncologists' practices regarding female fertility preservation: Which barriers most relate to these practices?	Journal article	Portugal
37.	Merlet and Hoog-Labouret[52] (2014)	Integrate fertility preservation in cancer management (in part II: A personalized and integrated treatment programme to better meet the needs of patients)	Journal article	France
38.	Mertes and De Proost[77] (2023)	Is access to egg freezing equitable and fair? A comparison between policies in Belgium and France	Conference abstract	France
39.	Mittal and Schubert[78] (2018)	Cost-Effectiveness of Cryopreserving Sperm in Males Undergoing Gonadotoxic Therapy	Conference abstract	Australia
40.	Newton et al.[53] (2021)	Inconsistencies in fertility preservation for young people with cancer in the UK	Journal article	UK
41.	Olofsson et al.[54] (2018)	Fertility preservation procedures for female and male patients facing gonadotoxic treatment-a micro-costing and diagnostic related group payment comparison analysis	Conference abstract	Sweden
42.	Ozimek et al.[55] (2023)	National oncofertility registries around the globe: a pilot survey	Journal article	Australia and Germany
43.	Pasten González et al.[56] (2024)	Current Status of Fertility Preservation in Pediatric Oncology Patients	Journal article	Numerous
44.	Patterson et al.[57] (2021)	The Australian youth cancer service: developing and monitoring the activity of nationally coordinated adolescent and young adult cancer care	Journal article	Australia
45.	Patterson et al.[57] (2023)	Beyond Medical Care: How Different National Models of Care Impact the Experience of Adolescent and Young Adult Cancer Patients	Journal article	Australia

No.	Author(s) [Reference] (Year)	Title	Type of evidence source	Country
46.	Pawłowski et al.[59] (2023)	Fertility Preservation in Children and Adolescents during Oncological Treatment-A Review of Healthcare System Factors and Attitudes of Patients and Their Caregivers	Journal article	Numerous
47.	Payne and Erbenius[60] (2018)	Conceptions of transgender parenthood in fertility care and family planning in Sweden: from reproductive rights to concrete practices	Journal article	Sweden
48.	Puy et al.[61] (2022)	Fertility preservation in transgender people	Journal article	France
49.	Rimon-Zarfaty et al.[62] (2021)	Between "Medical" and "Social" Egg Freezing : A Comparative Analysis of Regulatory Frameworks in Austria, Germany, Israel, and the Netherlands	Journal article	Germany
50.	Robson et al.[63] (2020)	Fertility preservation in oncology patients: A literature review examining current fertility preservation techniques and access to oncofertility services in Australia	Journal article	Australia
51.	Rodriguez-Wallberg et al.[64] (2020)	Fertility preservation for young adults, adolescents, and children with cancer	Journal article	Sweden
52.	Rodriguez-Wallberg et al.[86] (2019)	National guidelines and multilingual age-adapted patient brochures and videos as decision aids for fertility preservation (FP) of children and teenagers with cancer-A multidisciplinary effort to improve children's information and access to FP in Sweden	Letter to the editor	Sweden
53.	Rodriguez-Wallberg et al.[66] (2019b)	A prospective study of women and girls undergoing fertility preservation due to oncologic and non-oncologic indications in Sweden-Trends in patients' choices and benefit of the chosen methods after long-term follow up	Journal article	Sweden
54.	Rodriguez-Wallberg[79] (2020)	Fertility preservation for transgender individuals	Book chapter	Sweden
55.	Rodriguez-Wallberg[80] (2020b)	Fertility Preservation in Transgender Males	Book chapter	Sweden
56.	Rodriguez-Wallberg and Wilhelmsen[65] (2020)	The complexity of fertility preservation for women with Turner syndrome and the potential risks of pregnancy and cardiovascular complications	Journal article	Sweden
57.	Rodriguez-Wallberg et al.[67] (2020b)	Trends and outcomes of fertility preservation for girls, adolescents and young adults with Turner syndrome: A prospective cohort study	Journal article	Sweden
58.	Rogers et al.[68] (2020)	A retrospective study of positive and negative determinants of gamete storage in transgender and gender-diverse patients	Journal article	UK
59.	Rozen et al.[85] (2020)	Breaking down the barriers: a new collaborative model providing fertility care for young cancer patients	Perspective	Australia
60.	Stuhmcke and Chandler[69] (2014)	Storage limits of gametes and embryos: regulation in search of policy justification	Journal article	Australia
61.	Takae et al.[70] (2019)	Fertility Preservation for Child and Adolescent Cancer Patients in Asian Countries	Journal article	Australia

No.	Author(s) [Reference] (Year)	Title	Type of evidence source	Country
62.	von Wolff et al.[71] (2019)	Ferti PROTEKT, Oncofertility Consortium and the Danish Fertility-Preservation Networks - What Can We Learn From Their Experiences?	Journal article	Denmark
63.	Wikander et al.[87] (2021)	A Prospective Study on Fertility Preservation in Prepubertal and Adolescent Girls Undergoing Hematological Stem Cell Transplantation	Journal article	Sweden

Key: ART – assisted reproductive technology; CALG – Expert Breast Cancer and Pregnancy Centre (France); CECOS – Centre for the study and conservation of human eggs and sperm (France); ESGO – European Society of Gynaecological Oncology; FP – fertility preservation; IUI – intrauterine insemination; LGBT – lesbian, gay, bisexual & transgender; NHS – National Health Service; UK – United Kingdom.

Appendix B – Excluded published literature

Table B.1 Excluded studies and reasons for exclusion

Author(s) [Reference] (Year)	Title	Reason for exclusion
Abdallah et al.[213] (2017)	Better referrals and funding are needed for preserving fertility	Wrong type of evidence source - abstract only
Agresta et al.[214] (2019)	Australian oncofertility, a changing landscape	Wrong type of evidence source - abstract only. Further information: Excluding as this information is the same as what is extracted in the grey literature.
Alexandroni et al.[215] (2019)	Fertility preservation from the point of view of hematopoietic cell transplant specialists-a worldwide-web-based survey analysis	Wrong context - not related to a selected country, or data on a selected country not reported separately. Further information: Results not disaggregated by country.
Anazodo et al.[216] (2019)	How can we improve oncofertility care for patients? A systematic scoping review of current international practice and models of care	Wrong concept - not related to publicly-funded FP services.
Audibert and Glass[217] (2015)	A global perspective on assisted reproductive technology fertility treatment: An 8-country fertility specialist survey	Wrong concept - not related to publicly-funded FP services.
Baram and Myers[218] (2019)	Fertility preservation for transgender adolescents and young adults: a systematic review	Wrong context - not related to a selected country, or data on a selected country not reported separately.
Benard et al.[219] (2016)	Fertility preservation in women of the childbearing age: Indications and strategies	Other - justify in note. Further information: Useful overview of FP, but sections on Bioethics Law are out of date.
Borgmann-Staudt et al.[220] (2021)	Fertility preservation in children and adolescents with cancer	Other - justify in note. Further information: Out of date - published after G-BA guideline but before statutory health insurance coverage was confirmed.
Campo-Engelstein et al.[221] (2023)	Ethical Considerations for Transgender and Non-Binary Reproduction	Wrong concept - not related to publicly-funded FP services.
Catherine and Jean-Christophe (2020)	Ovarian tissue cryopreservation in France: Data from the grecot (Research And Study Group For Ovarian And Testicular Cryopreservation) register	Wrong type of evidence source - abstract only. Further information: No information on funding.

Author(s) [Reference] (Year)	Title	Reason for exclusion
Chen et al.[222] (2022)	How fertility preservation guidelines have progressed worldwide: Potential implications and inspiration	Wrong concept - not related to publicly-funded FP services.
Collinet et al.[223] (2018)	Management of endometriosis: CNGOF/HAS clinical practice guidelines - Short version	Wrong concept - not related to publicly-funded FP services. Further information: Limited info on FP in relation to ovarian endometriomas only.
Connolly et al.[224] (2022)	Adolescent and young adult (AYA) needs, services, and recent developments within NSW	Wrong type of evidence source - abstract only.
Cooper et al.[225] (2020)	North of England paediatric oncology fertility preservation audit	Wrong type of evidence source - abstract only. Further information: Examined referral patterns. Costs/funding not reported.
Courbiere et al.[226] (2022)	French clinical practice guidelines developed by a modified Delphi consensus process for oocyte vitrification in women with benign gynecologic disease	Other - justify in note. Further information: Good practice advice, not national policy.
Croitoru and Irwin[227] (2021)	Addressing fertility preservation in patients under the age of 35 diagnosed with breast cancer. A ten-year audit in a regional unit	Wrong type of evidence source - abstract only.
Dalla et al.[228] (2023)	"An Analysis of the Legal Gaps and Jurisprudential Paradigms Surrounding Supernumerary Embryos in Italy: A Comparative Law Approach to Propose Practical Solutions"	Wrong type of evidence source - abstract only.
Daudin et al.[229] (2015)	Sperm cryopreservation in adolescents and young adults with cancer: Results of the French national sperm banking network (CECOS)	Other - justify in note. Further information: Covers a 34-year period up to 2007 therefore out of date.
Degraeve et al.[230] (2024)	The habits of European urologists in the field of cryopreservation before the urological cancers treatment	Wrong concept - not related to publicly-funded FP services.
Diedrich et al.[231] (2020)	Forty years of in vitro fertilization-past achievements and future perspectives	Wrong concept - not related to publicly-funded FP services.

Author(s) [Reference] (Year)	Title	Reason for exclusion
Dittrich et al.[232] (2018)	Fertility Preservation for Patients with Malignant DiseaseGuideline of the DGGG, DGU and DGRM (S2k-Level, AWMF Registry No. 015/082, November 2017) - Recommendations and Statements for Girls and Women	Wrong concept - not related to publicly-funded FP services. Further information: No indication that these guidelines are the basis for policy. Currently under revision (update due 30.09.2024).
Dolmans[2] (2018)	Recent advances in fertility preservation and counseling for female cancer patients	Wrong context - not related to a selected country, or data on a selected country not reported separately.
Duffin et al.[233] (2024)	A 20-year overview of fertility preservation in boys: new insights gained through a comprehensive international survey	Wrong context - not related to a selected country, or data on a selected country not reported separately.
Duffin et al.[234] (2023)	FERTILITY DISCUSSIONS with CHILDHOOD CANCER PATIENTS: INITIAL RESULTS from A CCLG NATIONAL AUDIT	Wrong type of evidence source - abstract only. Further information: Audit of practices, but no data on funding.
El Alaoui-Lasmaili et al.[235] (2022)	Fertility discussions and concerns in childhood cancer survivors, a systematic review for updated practice	Other - justify in note. Further information: No new information added.
Eustache et al.[236] (2021)	Fertility preservation and sperm donation in transgender individuals: The current situation within the French CECOS network	Other - justify in note. Further information: The Bioethics law has been revised since this was published.
Fauser and Levy-Toledano[237] (2017)	Public perception of In-Vitro Fertilization (IVF) and fertility preservation: Assessed by the listening IVF and fertility in europe (LIFE) survey	Wrong type of evidence source - abstract only. Further information: Abstracts reports pooled data across 6 countries (not all selected countries). No data on current funding status reported.
Findeklee[238] (2021)	Desire for children and cancer	Other - justify in note. Further information: Can't access.
Freund et al.[239] (2020)	Financial and social consequences of cancer in adolescent and young adult (AYA) patients: How statutory health insurances have dealt with assumption of costs for fertility protection	Other - justify in note. Further information: out of date; describes time prior to the G-BA guidelines being published/taking effect.
Hangan et al.[240] (2016)	Assisted reproductive technology in Europe: Research, legal and ethical aspects	Wrong concept - not related to publicly-funded FP services.

Author(s) [Reference] (Year)	Title	Reason for exclusion
Hilgendorf (2019)	Management of AYA cancer patients in Germany	Wrong type of evidence source - abstract only.
Johnston et al.[241] (2019)	Freezing for future fertility: does the Australian public support oocyte cryopreservation?	Wrong type of evidence source - abstract only. Further information: No data on current funding policy included.
Kanthabalan et al.[242] (2024)	An international survey of contemporary practices towards fertility assessment and preservation in patients undergoing radical inguinal orchidectomy for testicular cancer	Wrong concept - not related to publicly-funded FP services.
Kliesch[243] (2020)	Cryopreservation of germ cells in German law and guidelines - The right to preserve fertility?	Other - justify in note. Further information: Published prior to G-BA guidelines taking effect - reports on what is planned, rather than current services that are in place.
Labrosse and Grynberg[244] (2022)	Fertility of tomorrow: Are there any restrictions left?	Wrong population - not related to FP for medical reasons.
Latif et al.[245] (2021)	Fertility preservation in the NHS: A national assessment of care policies for cryopreservation of oocytes, sperm and embryos	Wrong type of evidence source - abstract only. Further information: full paper (Latif 2023) includes this information in greater detail.
Latif et al.[246] (2021)	Fertility preservation for medical reasons-the gap between guidance and access	Wrong type of evidence source - abstract only.
Lotz et al.[247] (2019)	Ovarian Tissue Transplantation: Experience From Germany and Worldwide Efficacy	Wrong concept - not related to publicly-funded FP services.
Lotz et al.[248] (2016)	Ovarian tissue cryopreservation and retransplantation what do patients think about it?	Other - justify in note. Further information: out of date due to change in German law.
Marinho and Coimbra[249] (2020)	Parenthood Intentions, Pathways to Parenthood, and Experiences in the Health Services of Trans People: an Exploratory Study in Portugal	Other - justify in note. Further information: The Portuguese experience of fertility preservation is very limited - "Only one participant carried out fertility preservation, and he did it outside of Portugal."
McDougall et al.[250] (2018)	Ethics of fertility preservation for prepubertal children: should clinicians offer procedures where efficacy is largely unproven?	Other - justify in note; Further information: Describes a sample ethics framework used in one public hospital in Melbourne. Not national policy.

Author(s) [Reference] (Year)	Title	Reason for exclusion
Melan et al.[11] (2018)	Fertility preservation healthcare circuit and networks in cancer patients worldwide: what are the issues?	Wrong concept - not related to publicly-funded FP services;
Melo et al.[251] (2014)	Oncologist-patient discussion about the reproductive future: What are the practices of the Portuguese oncologists and what do they want to know about oncofertility?	Wrong type of evidence source - abstract only.
Mendes et al.[252] (2020)	Transgender and Fertility preservation: how to assist young adults and adolescents transgender pathway	Other - justify in note. Further information: Agree. Results re: legal challenges to using stored materials are somewhat out of date given 2021 amendments to bioethics law.
Moravek et al.[253] (2022)	Psychosocial and Ethical Aspects of Ovarian Tissue Cryopreservation in Children and Adults	Other - justify in note. Further information: no new information is added.
Nadon et al.[254] (2021)	LEGAL BASIS FOR THE USE OF ASSISTED REPRODUCTIVE TECHNOLOGIES: A COMPARATIVE ANALYSIS OF THE LEGISLATION OF UKRAINE AND EUROPEAN STATES	Wrong concept - not related to publicly-funded FP services.
Nawroth and von Wolff (2020)	Networks for Fertility Preservation	Other - justify in note. Further information: No access.
Nieder et al.[255] (2022)	RepronormativitÃ¤t und reproduktive Gerechtigkeit eine interdisziplinÃ¤re Analyse zur Fortpflanzung im Kontext von Trans	Other - justify in note. Further information: No access.
Nunes et al.[256] (2015)	Breast cancer in young women: Fertility preservation as a component of treatment planning and discussion	Wrong type of evidence source - abstract only. Further information: Abstract describing a case study of two centres only.
Ojo et al.[257] (2022)	Global uptake of fertility preservation by women undergoing cancer treatment: An unmet need in low to high-income countries	Other - justify in note. Further information: Information on funding included is out of date (2008; 2010) or relates to the US.
Pacey et al.[258] (2014)	How do men in the United Kingdom decide to dispose of banked sperm following cancer treatment?	Other - justify in note. Further information: Focused on long-term outcomes rather than providing details on policy/funding.

Author(s) [Reference] (Year)	Title	Reason for exclusion
Pereira et al.[259] (2015)	Patients' views on the embryo storage time limits	Wrong population - not related to FP for medical reasons.
Poirot[260] (2022)	Ovarian Cryopreservation for Transplantation With Prepubertal and Adolescent Girls	Other - justify in note. Further information: access limitations and no new information.
Preaubert et al.[261] (2016)	Can we improve referrals for fertility preservation? Evolution of practices after the creation of a fertility network	Other - justify in note. Further information: Evaluating the impact of a local network.
Rahman et al. (2022)	Optimising model of care for female oncology patients needing urgent fertility preservation	Wrong type of evidence source - abstract only.
Rives et al.[262] (2022)	What should be done in terms of fertility preservation for patients with cancer? The French 2021 guidelines	Other - justify in note. Further information: Unclear if publicly-funded services are required to implement these guidelines; accredited by the French National Cancer Institute.
Rives et al. (2018)	[Fertility preservation]	Other - justify in note. Further information: The information is out of date due to the update in the bioethics law.
Rivet-Danon et al.[263] (2024)	[The revision of the Bioethics Act, two years on: major principles and consequences for practice in the reproductive biology laboratory]	Other - justify in note. Further information: Can't access.
Rodriguez-Wallberg et al.[264] (2014)	Follow-up of 1,001 adults and children after fertility preservation for oncologic conditions within a publicly financed health care program	Wrong type of evidence source - abstract only. Further information: Abstract only. Reports outcomes of patients in publicly-funded system.
Rodriguez-Wallberg et al.[265] (2014)	Preserving eggs for men's fertility. A pilot experience with fertility preservation for female-to-male transsexuals in Sweden	Wrong type of evidence source - abstract only. Further information: Only useful info is statement that FP is available to transgender people in Sweden (already extracted from grey literature).
Rodriguez-Wallberg[266] (2022)	Regulatory Aspects of Ovarian Tissue Cryopreservation and Transplantation: How to Set Up a Program in Your Center	Exclusion reason: Other - justify in note. Further information: No access.
Rousset-Jablonski et al.[267] (2018)	Fertility preservation, contraception and menopause hormone therapy in women treated for rare ovarian tumors: Guidelines from the French national network dedicated to rare gynaecological cancer	Wrong concept - not related to publicly-funded FP services.

Author(s) [Reference] (Year)	Title	Reason for exclusion
Sanger et al.[268] (2018)	Fertility Preservation in Prepubertal und Pubertal Children and Adolescents	Other - justify in note. Further information: References to funding are out of date - funding introduced in 2021.
Schallmoser et al.[269] (2023)	Cryostorage of human ovarian tissue: evaluating the storage and disposal pattern over a 22-year period in 2475 patients	Wrong concept - not related to publicly-funded FP services. Further information: Study period was 2019-2021, before OTC was covered under statutory insurance.
Schneider et al.[270] (2019)	Options for fertility treatments for trans women in Germany	Other - justify in note. Further information: Legislation has been updated since.
Seido et al.[271] (2020)	Current status of fertility preservation for child and adolescent cancer patients in asian countries	Wrong type of evidence source - abstract only. Further information: Full text is record number #3192 (Takae 2019).
Smajdor[272] (2015)	Perimortem gamete retrieval: should we worry about consent?	Other - justify in note. Further information: Out of date. The HFEA provides clear information now on requirements for written informed consent, and what happens to gametes after death/in the event of losing capacity.
Wise[273] (2016)	Frozen tissue service offers fertility hope to young people with cancer	Other - justify in note. Further information: Describes ongoing research in one unit only.
Wurfel[274] (2018)	Reproductive medicine: The current situation in Germany	Other - justify in note. Further information: Can't access.
Yasmin et al.[275] (2018)	Fertility preservation for medical reasons in girls and women: British fertility society policy and practice guideline	Other - justify in note. Further information: Guidelines which present no new information, only what "should" happen.
Yasmin et al.[276] (2021)	Fertility preservation for medical reasons: International and intra-national variation in provision and the gap between guideline and practice	Wrong type of evidence source - abstract only.

Appendix C – Summary tables

Table C.1 Summary of populations eligible for publicly-funded fertility preservation methods offered in selected countries

Country Relevant documents	Fertility preservation methods offered and eligible populations
Australia ▪ ART Storage Funding Program[93] and Guidelines[94] ▪ Medicare Benefits Schedule Book[90] ▪ National Ovarian and Testicular Tissue Transport and Cryopreservation Service[98] ▪ Johnston et al.[16] ▪ Martin et al.[75]	**Assisted Reproductive Technology Storage Funding Programme:** Each eligible patient can access up to 2 cryostorage services of different material type (as in egg or sperm, and embryo). 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 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 program. 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 pre-implantation genetic testing (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 program 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, general practitioner (GP), oncologist, endocrinologist, haematologist) may act as evidence of eligibility. **Fertility preservation and related services covered by Medicare:** **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. A person is eligible if they have received Medicare benefits for one of the relevant Medicare Benefits Schedule (MBS) items. Evidence of the patient being billed for MBS items 13207, 73385, 73384, 73386 or 73387 may act as evidence of eligibility. **Exclusions (based on the patient) to the program include:** ▪ For the purposes of this program, 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

Country Relevant documents	Fertility preservation methods offered and eligible populations
	▪ Patients who undertake pre-implantation genetic testing, who are not known carriers of genetic conditions, are ineligible for this program. These patients will not satisfy eligibility requirements for claiming MBS items 13207, 73385, 73384, 73386 or 73387**.** **Preservation methods offered through Medicare and eligibility:** The MBS provides a rebate for out-of-pocket costs for out-of-hospital services (including GP and specialist attendances). The Extended Medicare Safety Net 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.[91] No stand-alone items for oocyte or embryo cryopreservation; benefits are claimed under items used for in-vitro fertilisation.[16] **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 postpubertal 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 2 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 2 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 13260 was included within Medicare following the Medical Services Advisory Committee (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 prepubertal 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 evaluation sub-committee and MSAC once evidence becomes available.*[95] **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.

Country Relevant documents	Fertility preservation methods offered and eligible populations
	Fee 37605: Transcutaneous sperm retrieval, unilateral, from either the testis or the epididymis, for the purposes of intracytoplasmic sperm injection, for male infertility, excluding a service to which item 13218 applies. (Anaes.) **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 infertility, performed in a hospital, excluding a service to which item 13218 or 37604 applies. (Anaes.) ***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) 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 prepubertal 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[95] or re-application in 2019][97]* **National Ovarian and Testicular Tissue Transport and Cryopreservation Services (NOTTCS):** **Preservation methods offered:** Ovarian and testicular tissue cryopreservation. **Eligible populations:** 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. NOTTCS provides services to children, adolescents and adults. **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.
Denmark ▪ Council of Ethics: Storage of fertilised eggs and unfertilised egg cells[103] ▪ Executive Order on the Act on Assisted Reproduction in Connection with Treatment, Diagnostics and Research, etc. (LBK no. 902 of 23/08/2019)[99] ▪ Executive Order on Assisted Reproduction	**Fertility preservation methods offered and eligible populations:** Overall, storage and donation of unfertilized and fertilized human eggs, sperm storage and donation, and storage of ovarian and testicular tissue. Specifically what is offered is: ▪ **Cryopreservation of ovum/embryos and ovarian tissue for the treatment of ovarian failure after disease or radiotherapy:** Freezing may 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. ▪ **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).

Country Relevant documents	Fertility preservation methods offered and eligible populations
(BEK no. 672 of 08/05/2015)[17] ▪ Guidance on the activities and obligations of healthcare professionals and tissue establishments in the field of assisted reproduction[17] ▪ Bach et al.[31]	▪ **Cryopreservation to compensate for accelerated ovarian failure due to disease or age:** Egg freezing 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). 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. ▪ **Cryopreservation, storage and destruction of gametes/embryos and ovarian and testicular tissues, including fertility-preserving treatment.** ▪ **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. 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. ▪ **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. ▪ **Cryopreservation to compensate for accelerated ovarian failure due to disease or age (egg freezing)** Age conditions are only applicable to females, where it is stated that 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.
France ▪ Funding for medically assisted genetic procreation 2023[110] ▪ Biomedicine Agency: Self-preservation of gametes[104, 105] ▪ Biomedicine Agency: What does the law say[106] ▪ Public Health Code: Title IV: Medically assisted procreation (Articles L2141-1 to L2143-9)[107] ▪ Public Health Code: Title IV: Medically assisted	**Fertility preservation methods offered:** ▪ sperm cryopreservation ▪ oocyte cryopreservation ▪ ovarian tissue cryopreservation ▪ testicular tissue cryopreservation. **Eligible populations:** 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. ▪ 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. Since 2021, the 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, age conditions have to be met to be able to self-preserve gametes: ▪ For women from the 29th birthday to the 37th birthday*

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procreation (Articles R2141-1 to R2143-20)[108] ▪ Decree No. 2021-1243 of 28 September 2021 setting the conditions for the organisation and coverage of medically assisted reproduction pathways[109]	▪ 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. The collection, sampling and storage of materials 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. The modification of the designation of sex in the civil registry shall not prevent the application of this article.
Germany ▪ Federal Ministry of Health (BMG): Support for young cancer patients: cryopreservation becomes a health insurance benefit[113] ▪ G-BA: Cryopreservation of ovarian tissue becomes a health insurance benefit[114] ▪ G-BA: Cryopreservation[112] ▪ Federal Joint Committee (G-BA). Directive 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)[19] ▪ Reasons for the decision of the Federal Joint Committee to amend the guidelines on cryopreservation:	**Fertility preservation methods offered:** 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. **Eligible populations:** ▪ 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. **Age conditions are then applied:** ▪ Female insured persons up to the age of 40. ▪ Male insured persons up to the age of 50. Furthermore, the preservation of ovarian tissue is currently only possible for girls and women from the first menstrual period. 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.

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Cryopreservation of germ cell tissue[115]	
Portugal ▪ Regulatory Decree No. 06/2016[123] ▪ CNPMA: Requirement and parameters- Operation of the medically assisted procreation techniques centres[126] ▪ CNPMA: FAQs[179] ▪ 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[119] ▪ Portuguese Society for Reproductive Medicine: Preservation of fertility in oncological patients[124] ▪ Melo et al.[51]	**Fertility preservation methods offered:** ▪ sperm cryopreservation ▪ oocyte cryopreservation ▪ ovarian tissue cryopreservation ▪ testicular tissue cryopreservation **Eligible populations (for ART in general):** ▪ Couples of different sexes or couples of women, respectively married or married or living in conditions similar to those of their spouses, can use medically assisted procreation (PMA) techniques, as well as all women regardless of their marital status and their sexual orientation. ▪ 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 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.[179] **In general:**[119] ▪ 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 second-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. ▪ Female couples are not allowed on the SNS to simultaneously undergo ART treatments. **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]
Sweden ▪ Measures to preserve the reproductive capacity of the young: promotion of	**Fertility preservation methods offered:** *Women:* ▪ save and vitrify (freeze) mature oocytes (eggs) after hormone stimulation ▪ preserve and freeze embryos (fertilised eggs) after hormone stimulation

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equal care for young people who are at risk of treatment induced infertility[88] ▪ Measures to preserve reproductive capacity in adults: promotion of equal care for patients at risk of treatment induced infertility[89] ▪ Rodriguez-Wallberg et al.[67] ▪ Rodriguez-Wallberg et al.[65]	▪ preserve and freeze ovarian tissue (ovary tissue). This method has showed good results in 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. *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). *Girls – before menarche:* preserve and freeze ovarian tissue (invasive procedure). This method has proven results in 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. *Girls – after menarche:* ▪ 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. *Boys – prepubertal:* 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. The procedure should preferably be performed in conjunction with other necessary surgery. *Boys – pubertal and postpubertal:* ▪ preserve and freeze ejaculated sperm (non-invasive procedure) ▪ freeze sperm extracted from open testicular biopsy or aspiration from epididymis and/ or testicle (invasive procedure). **A number of considerations are outlined when selecting the fertility preservation method:** *Women:* ▪ Treatment that entails a low risk of infertility: No reproductive preservation method recommended ▪ 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. 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

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	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, the woman must also receive an assessment of her fertility potential. The forecast for the future ovarian function can be assessed by measuring anti-müllerian hormone, FSH, estradiol and by ultrasound of ovaries with assessment of the number antral follicles ▪ Transposition of ovaries: Rarely used. 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 gonadotropin releasing hormone (GnRH) agonist: For forms of cancer other than breast cancer, there is no evidence that simultaneous treatment with GnRH 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:* ▪ Treatment that entails a low risk of infertility: For this group, sperm freezing should only be offered exceptionally ▪ 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, invasive procedures by aspiration from epididymis/testis or open biopsy from testis is considered. *People with gender dysphoria:* *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 6 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 by 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. *Young people who are at risk of treatment-induced infertility:* **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 during adolescence, to

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	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 ethics review board, 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/postpubertal 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:*

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	▪ 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 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 ethics review board, with the aim of enabling future re-transplantation or maturation of sperm in vitro. **Eligible populations:** Patients at risk of treatment-induced infertility, where treatment with chemotherapy, radiation or surgery can lead 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. 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. The following age limits have therefore been set: ▪ oocyte vitrification: age <40 years ▪ embryo freezing: age <40 years ▪ ovarian tissue freezing: age <32 years ▪ sperm freezing: age <56 years 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. For all measures, the person who is to undergo publicly-funded fertility preservation measures may previously have a maximum of 2 children of whom he is the legal parent. This is regardless of whether a possible partner is also a parent of the children, a new partner exists without a joint child or if the person is single. A publicly-funded fertility preservation programme is available to female patients (children, adolescents and adults) with Turner syndrome. This includes cardiac assessments to inform fertility preservation discussions.
UK ▪ NICE (CG156) Fertility problems: assessment and treatment[127]	**Fertility preservation methods:** ▪ egg, sperm or embryo cryopreservation ▪ since 2023, 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.

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▪ NICE (NG73) Endometriosis: diagnosis and management[128] ▪ NICE Quality Standard (QS73): Fertility problems[129] ▪ NICE Interventional procedures guidance: Removal, preservation and reimplantation of ovarian tissue for restoring fertility after gonadotoxic treatment[130]	**Eligible populations:** ▪ Men and adolescent boys who are preparing for medical treatment for cancer that is likely to impact their fertility – offer sperm cryopreservation. 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. ▪ Women of reproductive age (including adolescent girls) who are preparing for medical treatment for cancer that is likely to impact their fertility – offer oocyte or embryo cryopreservation as appropriate if: ○ they are 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. ▪ Girls before puberty or people with oestrogen-sensitive malignancies – offer ovarian tissue cryopreservation. NICE recommend a lower age limit is not imposed for cryopreservation for fertility preservation in people diagnosed with cancer. **There are specific NICE guidelines in regards to those with endometriosis which outline:**[128] *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.*
England ▪ NHS Bedfordshire, Luton and Milton Keynes ICB: Gamete (sperm/egg) storage for those undergoing fertility-threatening treatment[139] ▪ NHS South West London ICB: Evidence-based interventions policy[140] ▪ NHS Coventry and Warwickshire ICB: NHS Funded Cryopreservation of Gametes and Embryos Policy[141] ▪ NHS West Yorkshire ICB: Cryopreservation for both men and women	**Fertility preservation methods offered:** ▪ egg, sperm or embryo cryopreservation ▪ ovarian tissue cryopreservation or testicular tissue cryopreservation (limited access in certain locations only) **Eligible populations (local level):** Access criteria are defined at local level by Integrated Care Board (ICB) policy and therefore may vary by region. Of the 7 sample ICBs selected for the current review, the following are examples of populations identified as being eligible for NHS funded egg, sperm or embryo cryopreservation: ▪ people who are due to commence treatment that is likely to lead to infertility (7 ICBs) ▪ people with a medical condition that is likely to lead to infertility (2 ICBs) ▪ people at risk of premature ovarian insufficiency (2 ICBs) ▪ people whose medical treatment has possible teratogenic effects and stopping treatment for a prolonged period to enable conception is not possible (1 ICB). <u>Example of eligible populations for one sample ICB (South West London ICB):</u> ▪ 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.

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where the usual fertility policy does not apply[142] ▪ NHS Cheshire and Merseyside: NHS funded treatment for subfertility Clinical Commissioning Group policies[143-152] ▪ NHS Kent and Medway ICB: Policies on fertility treatments[153] and Schedule of policy statements for ART for Kent and Medway Integrated Care Board[154] ▪ NHS Somerset ICB: Fertility assessment and treatment prior approval policy[155] and Evidence Based Interventions Programme for Interventions Not Normally Funded[156] ▪ NHS England. Service specification: Fertility preservation for service users with ovarian tissue who are at high/very high risk of infertility and cannot store mature eggs[132] ○ NHS England. Service specification: Fertility preservation for service users with testicular tissue who are at high/very high risk of infertility and cannot store sperm[134]	▪ 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. The South West London ICB does not routinely fund the following: ▪ prepubertal 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) **Specific populations (national level):** NHS England is responsible for commissioning services for teenagers and young adults (that is, people aged 16 to 24 years) with suspected or confirmed cancer. Service specifications state that principal treatment centres and designated hospitals must offer fertility preservation to each individual preparing to have treatment for cancer that is likely to result in fertility problems. Principal treatment centres must also have a policy defining the male and female fertility preservation methods available. **Ovarian and testicular tissue cryopreservation**: NHS England service specifications cover the provision of fertility preservation services for service users with ovarian tissue or testicular tissue who are at high or very high risk of infertility and endocrine failure and cannot store mature eggs, or who cannot store sperm. There are no lower and upper age limit criteria and the eligibility criteria are based on the physiological potential of the relevant tissue. **Eligible populations:** service users who cannot store mature eggs or 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 oophorectomy or total orchidectomy AND ▪ who must be medically fit for fertility preservation surgery under general anaesthesia AND ▪ for those with ovarian tissue, not in premature ovarian insufficiency (POI) and whose ovarian tissue has a physiological potential to ensure sufficient reserve for future use or, for those with testicular tissue, 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:

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▪ NHS England: Teenage and young adult cancer clinical network specification[136] ▪ NHS England: Specialist cancer services for children and young people: teenage and young adults principal treatment centre services[137] ▪ NHS England: Specialist cancer services for children and young people: teenage and young adults designated hospitals[138] ▪ Latif et al.[45] ▪ Ghattaura et al. [38]	▪ who can successfully store mature eggs or 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 POI with ovarian tissue that lacks the physiological potential to ensure sufficient reserve for future use, or who are in reproductive failure with testicular tissue that lacks the physiological potential to ensure sufficient reserve for future use ▪ where ovarian tissue cryopreservation or testicular tissue cryopreservation could delay their primary treatment and cause detrimental harm ▪ where surgery or a general anaesthetic would carry undue risk.
Northern Ireland ▪ Belfast HSC Trust. Regional Fertility Centre[161] ▪ Department of Health (DoH) Northern Ireland relevant endorsed National Institute for Health and Care Excellence (NICE) guidelines, according to Circular Health and Social Care (HSC) (SQSD) 3/13:[157] ▪ Fertility problems: assessment and treatment (CG156)[127] ▪ DoH endorsement[158] ▪ Additional Caveats for CG156[159]	**Fertility preservation methods offered for medically required fertility preservation:** Cryopreservation of: ▪ egg ▪ sperm ▪ embryos (unclear – published literature indicates that this is publicly funded, but grey literature confirming this was not identified) ▪ ovarian tissue (access for children and young adults at high risk of infertility through charity funded service based in England)[38] ▪ testicular tissue (access for children and young adults at high risk of infertility through charity funded service based in England).[38] **Eligible populations:** ▪ 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. The Department of Health Northern Ireland also endorse the following NICE guidelines (see UK for further info): ▪ NICE Clinical Guideline CG 156 - Fertility: assessment and treatment for people with fertility problems. ▪ NICE Clinical Guideline NG73 – Endometriosis: diagnosis and management. A service based in England may provide access to cryopreservation of ovarian tissue or testicular tissue for children at high risk of infertility who are living in Northern Ireland. This service is supported by charitable funding.[38]

Country Relevant documents	Fertility preservation methods offered and eligible populations
▪ Endometriosis: diagnosis and management[128] ▪ DoH endorsement[160] ▪ Ghattaura et al.[38]	
Scotland ▪ NHS Inform: Fertility and Cancer[165] ▪ Fertility Scotland (NHS Scotland National Strategic Network)[163] and Annual Report 2021/2022[164] ▪ NHS Lothian: Edinburgh Fertility Centre – Fertility Preservation Referral Form[166] ▪ NHS Tayside: Information for patients wishing to freeze eggs or embryos for fertility preservation[167] ▪ NHS Scotland: Endocrine and Fertility Preservation Guidance[162] ▪ Latif et al.[45]	**Fertility preservation methods offered:** Cryopreservation of: ▪ eggs ▪ sperm ▪ embryos ▪ ovarian tissue (unclear – published literature indicates that this is publicly funded, but grey literature confirming this was not identified)[45] ▪ testicular tissue (unclear – published literature indicates that this is publicly funded, but grey literature confirming this was not identified).[45] **Eligible populations:** 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 an NHS Tayside leaflet titled "Information for patients wishing to freeze eggs or embryos for fertility preservation" it outlined the following criteria for NHS funded fertility preservation treatment:[167] ▪ 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:][166] 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. *Overarching principles to access fertility preservation include:*[162] ▪ 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%), fertility preservation 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

Country Relevant documents	Fertility preservation methods offered and eligible populations
	For transgender, non binary and gender diverse people, eligibility is line with nationally agreed access criteria for assisted reproduction and includes: ▪ for those storing eggs/embryos, BMI needs to be under 35. This differs from IVF criteria (due to time constraints) ▪ upper cut off age for oocyte/embryo/ovarian tissue fertility preservation should be 41 ▪ 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 ▪ the individual proposing to store gametes will have no biological children, or not be a legal parent ▪ previous sterilisation will preclude access ▪ smoking would not preclude access to storage; however where there is time, patients should be strongly encouraged to stop smoking ▪ being in a stable relationship is not a relevant criterion for access (or ongoing storage) ▪ if they are in a relationship, whether the partner meets IVF access criteria (for example, BMI) is not relevant. All guidance are directed at those who have completed puberty.
Wales ▪ Wales Fertility Institute[171] ▪ Wales Fertility Institute: Sperm Freezing[172] ▪ Wales Fertility Institute: Fertility Preservation for Trans and Gender Diverse People - Information for patients[173] ▪ Ghattaura et al.[38]	**Fertility preservation methods offered:** Sperm, egg and embryo freezing. **Eligible populations:** Wales Fertility Institute (WFI) currently provides storage for patients who are due to undergo surgery, radiotherapy, chemotherapy or whose future potential fertility may be compromised. 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: ▪ 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. 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 (HSCT) for adults [2020][183] ▪ Specialised Services Policy Position PP142 HSCT for Adults [2020][182] ▪ Specialised Services Service Specification: Services for Children with Cancer (CP86) [2024].[170] A service based in England may provide access to cryopreservation of ovarian tissue or testicular tissue for children at high risk of infertility who are living in Wales. This service is supported by charitable funding.[38]

Key: ART – assisted reproductive technology; BMI – body mass index; GnRH – gonadotropin releasing hormone; GP – general practitioner; HSCT – haematopoietic stem cell transplantation; ICB – integrated care board; MBS – Medicare Benefits Schedule (Australia); MSAC – Medical Services Advisory Committee (Australia); NOTTCS – National Ovarian and Testicular Tissue Transport and Cryopreservation Service (Australia); PGT – pre-implantation genetic testing; PMA – medically assisted procreation (Portugal); POI – premature ovarian insufficiency; UHW – University Hospital Wales; WFI – Wales Fertility Institute.

Table C.2 Summary of funding information identified for publicly-funded fertility preservation services for medical reasons in selected countries

Country Relevant documents	Funding
Australia ▪ Medicare Benefits Schedule Book[90] ▪ ART Storage Funding Program[93] and Guidelines[94] ▪ National Ovarian and Testicular Tissue Transport and Cryopreservation Service[98] ▪ Johnston et al.[16] ▪ Johnston et al.[16] ▪ Martin et al.[75]	A number of fertility preservation procedures are covered by Medicare reimbursement. You can enrol in Medicare if you live in Australia and are any of the following: ▪ an Australian citizen ▪ a New Zealand citizen ▪ an Australian permanent resident ▪ applying for permanent residency ▪ a temporary resident covered by a ministerial order. You can also enrol if you are a citizen or permanent resident of any of the following: ▪ Norfolk Island ▪ Cocos (Keeling) Islands ▪ Christmas Island ▪ Lord Howe Island. You may be able to enrol if you are visiting from a Reciprocal Health Care Agreement country. 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. 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. **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 lab 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 Extended Medicare Safety Net Cap: $1,996.80

Country Relevant documents	Funding
	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 lab 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 Extended Medicare Safety Net 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 Extended Medicare Safety Net 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 Extended Medicare Safety Net 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 Extended Medicare Safety Net 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 Extended Medicare Safety Net 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 infertility, not being a service associated with a service to which item 13218 or 37604 applies (H) (Anaes.)

Country Relevant documents	Funding
	Fee: $968.35; Benefit: 75% = $726.30 **Fee 13251:** Intracytoplasmic sperm injection for the purpose of assisted reproductive technologies, for male infertility, excluding a service to which item 13203 or 13218 applies. Fee: $476.15; Benefit: 75% = $357.15; 85% = $404.75 Extended Medicare Safety Net 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 postpubertal 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 2 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 2 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 Extended Medicare Safety Net 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 prepubertal 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.*[95] **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 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 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***

Country Relevant documents	Funding
	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 prepubertal 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[96] *or re-application in 2019]*[97] The Medicare Safety Net entitlement does not include hospital/day surgery related services, such as egg collection and or embryo transfer. Oocyte cryopreservation is not a stand-alone item for rebate in the Australian Medicare system; it is claimed under item numbers that are used for standard in vitro fertilisation cycles. The cost of oocyte cryopreservation varies between patients and providers in Australia. Usually, one cycle costs approximately AUD$10,000, including costs for medication. Patients who have a medical indication for oocyte cryopreservation are eligible for Medicare reimbursement (approximately 50% of treatment costs).[16, 41] It should be noted that Medicare reimbursement can be following patient payment or bulk billing. ▪ **Patient payment:** The quickest way to claim Medicare benefit is at the doctor's office straight after the patient pays. To do this the patient and doctor need to both be enrolled in Medicare and you must show your Medicare card. The doctor's office can make an electronic claim for you on the spot. Services Australia will process the claim as soon as possible and pay the Medicare benefit into either the account for the EFTPOS card used to pay or the registered bank account registered. Medicare benefits can be claimed online, in the post, at a service centre or for someone else. ▪ **Bulk billing:** Bulk billing means you don't have to pay for your medical service from a health professional.[277] They bill Services Australia instead and accept the Medicare benefit as full payment for the service. **ART Storage Funding Program Subsidy Amount** The ART storage funding programme provides a subsidy amount up to AUD$600 per year per patient and per eligible cryostorage service. Payments of up to $300 are made in arrears on a 6 monthly basis. The payment amount is calculated on a monthly pro-rata basis: as in, 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 program. The National Ovarian and Testicular Tissue Transport and Cryopreservation 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.
Denmark ▪ New political agreement lifts 5-year limit for	All fertility preservation methods are provided, for medical reasons, free of charge within the public healthcare system. For tissue cryopreservation, this includes extraction of tissue, freezing, storage, and transplantation. Furthermore, if ART is needed after transplantation, this will also be covered by the public health care system.

Country Relevant documents	Funding
freezing eggs (Press Release)[102] ▪ Von Wolff et al.[71]	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. The Ministry of Health estimates that the annual costs associated with the abolition of the 5-year limit for storage of cryopreserved eggs amounts to DKK 2.6 million.
France ▪ Funding for medically assisted genetic procreation 2023[110] ▪ Biomedicine Agency: Self-preservation of gametes[104, 105] ▪ Biomedicine Agency: What does the law say[106] ▪ Public Health Code: Title IV: Medically assisted procreation (Articles R2141-1 to R2143-20)[108]	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. **Funding for providers of fertility preservation services (and ART services in general):** An activity-based pricing system is used that has 2 complementary components: ▪ Financing the diagnostic, treatment and care activity through service rates and national packages: resources are allocated to establishments according to the volume and nature of their activity. ▪ 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. 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. Only health establishments can receive MIG grants. For 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 ART MIG is one of the rare MIG allocations awarded to both the public and private sectors according to identical rules. It is 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.
Germany ▪ German Medical Association (BAK). Directive for the removal and transfer of human germ cells or germ cell tissue in the context of assisted reproduction, detailed update[111] ▪ Fertility preservation: German Medical Association (BAK) presents revised guideline[118]	The Appointment Service and Care Act (TSVG), 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. It included the cryopreservation of egg and sperm cells as well as germ cell tissue, as well as the associated medical measures, in the catalogue of services provided by statutory health insurance. 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 the G-BA's Cryopreservation Directive. (See fertility preservation methods available and eligibility for further information on what is covered and for who). **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.

Country Relevant documents	Funding
▪ Federal Ministry of Health (BMG): Support for young cancer patients: cryopreservation becomes a health insurance benefit[113] ▪ G-BA: Cryopreservation[112]	
Portugal ▪ Medically assisted procreation: Law No.32/2006 (Consolidated Legislation)[120] ▪ Medically assisted procreation: Law No.17/2016 (Amendment)[121] ▪ CNPMA (National Council for Medically Assisted Reproduction)[122] ▪ Regulatory Decree No. 06/2016[123] ▪ Portuguese Society for Reproductive Medicine: Preservation of fertility in oncological patients[124] ▪ ACSS Review of Exemption Categories and Update Values of Moderator Fees[125] ▪ CNPMA: Requirement and parameters-Operation of the medically assisted procreation techniques centers[126]	Medically assisted procreation services, including fertility preservation services, are funded through the National Health Service (SNS, *Serviço Nacional de Saúde*) For cancer patients specifically, this includes: ▪ **Conservation of cryopreserved sperm:** Within the scope of the SNS, in general, procedures that do not involve costs for the patient. ▪ **Cryopreservation of testicular tissue:** Within the scope of the SNS, in general, procedures that do not involve costs for the patient. ▪ **Embryo cryopreservation:** Within the scope of the SNS, 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 SNS, 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 SNS, 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:[125] ▪ 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 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.
Sweden	Fertility preservation in Sweden is publicly funded through the tax-funded healthcare system.

Country Relevant documents	Funding
▪ Rodriguez-Wallberg et al.[79] ▪ Rodriguez-Wallberg et al.[64] ▪ Rodriguez-Wallberg et al.[66] ▪ Olofsson et al.[54]	From a service provider's perspective, a study that measured the costs of fertility preservation procedures carried out in a single centre (using 2015 as the reference year) found that total costs per patient were as follows: ▪ oocyte cryopreservation: €2,227 ▪ oocyte-embryo cryopreservation: €3,077 ▪ ovarian tissue cryopreservation: €5,990 ▪ semen banking: €1,356 ▪ cryopreservation of sperm obtained by testicular biopsy: €1,981. The tariffs allocated (that is, the payments that the hospital received) were lower for all procedures evaluated (-14.4%, -38.0%, -8.7%, -32.1% and -27.8%, respectively). This translated into a budget deficit of -27.1% for the year 2015 for fertility preservation services.
UK ▪ Newton et al.[53] ▪ Latif et al.[45] ▪ Rogers et al.[68]	There is currently no UK-wide funding policy for fertility preservation. Although sperm banking is widely available (though not necessarily funded), provision of the other techniques is patchy or absent. It is noted that sperm banking is usually available on the NHS and 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.
England ▪ NHS Bedfordshire, Luton and Milton Keynes Integrated Care Board (ICB). Gamete (sperm/egg) storage for those undergoing fertility-threatening treatment[139] ▪ NHS Coventry and Warwickshire ICB. NHS Funded Cryopreservation of Gametes and Embryos Policy[141] ▪ NHS Kent and Medway ICB. Policies on fertility treatments[153] ▪ NHS South West London ICB. Evidence-based interventions policy[140] ▪ National Health Service (NHS) England. Service specifications: fertility preservation and restoration[131]	NHS funding varies considerably depending on the area. Examples include: ▪ **NHS England – Bedfordshire, Luton and Milton Keynes Integrated Care Board:**[139] 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 Individual Funding Request (IFR) Policy and Process. ▪ **NHS England – Coventry and Warwickshire Integrated Care Board:**[141] 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. ▪ **NHS Kent and Medway Integrated Care Board:**[153] 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. ▪ **NHS South West London:**[140] The SWL ICB will fund one cycle of fertility preservation, including sperm, egg and embryo cryo-storage. * 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 (i.e., 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.

Country Relevant documents	Funding
Service specification and equality and health inequalities impact assessment documents for: ○ Fertility preservation for service users with ovarian tissue who are at high/very high risk of infertility and cannot store mature eggs[132] ○ Fertility preservation for service users with testicular tissue who are at high/very high risk of infertility and cannot store sperm[134]	† Individual funding request (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. From the 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.
Northern Ireland ▪ Belfast HSC Trust. Regional Fertility Centre[161] ▪ Latif et al.[45]	There is public funding for the cryopreservation of oocytes, sperm and embryos is funded for those undergoing medical or surgical treatment likely to impact their infertility. **Storage of embryos or sperm for use in treatment:** This 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. 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.
Scotland ▪ Fertility Scotland (NHS Scotland National Strategic Network)[163] and Annual Report 2021/2022[164] ▪ NHS Inform: Fertility and Cancer[165] ▪ NHS Scotland: Endocrine and Fertility Preservation Guidance[162] ▪ Latif et al.[45]	Funding is availble for cryopreservation of oocytes, sperm, embryos, and ovarian and testicular tissue. One cycle of ovarian stimulation is offered. If it is considered that the ovarian stimulation regimen did not result in an optimal response for that patient, a second stimulation may be considered.[45] [From NHS Lothian Fertility Preservation Referral Form:][166] 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 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. **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

Country Relevant documents	Funding
	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. **Endocrine and Fertility Preservation Guidance:**(162) Travel costs for patients where required will be met. 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. The Fertility Scotland Strategic Plan has been approved by NHS National Services Division. Fertility Preservation is included in this plan.
Wales ▪ Wales Fertility Institute(171) ▪ Wales Fertility Institute: Sperm Freezing(172) ▪ Wales Fertility Institute: Fertility Preservation for Trans and Gender Diverse People - Information for patients(173) ▪ Latif et al.(45)	Cryopreservation of oocytes, sperm and embryos is funded for those undergoing medical or surgical treatment likely to impact their fertility.(45) 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. A key representative from Wales also outlined that fertility preservation for those aged 18 years and older is via the Individual Patient Funding Request (IPFR) route.(185)

Key: ART – assisted reproductive technology; BAK – Medical Association (Germany); BMG – Federal Ministry of Health (Germany); EBI – Evidence Based Intervention; G-BA – Federal Joint Committee (Germany); GP – General Practice; ICB – Integrated Care Board; IFR – Individual Funding Request; MBS – Medicare Benefit Schedule; MIG – Municipal Infrastructure Grant; MSAC – Medical Services Advisory Committee; NABM – Nomenclature of medical Biology Acts (France); NHS – National Health Service; PMA – Medically Assisted Procreation (Portugal); SGB – Code of Social Law (Germany); SNS – National Health Service (Portugal); SWL – South West London; TSVG – The Appointment Service and Care Act (Germany); UK – United Kingdom.

Table C.3 Summary of organisational aspects identified for publicly-funded fertility preservation services for medical reasons in selected countries

Country Relevant documents	Organisational aspects
Australia ▪ ART Storage Funding Program[93] and Guidelines[94] ▪ Medicare Benefits Schedule Book[90] ▪ Assisted reproductive technology (ART) services[90] (Services Australia)[91] ▪ National Ovarian and Testicular Tissue Transport and Cryopreservation Service[98] ▪ Martin et al.[75]	**Referral pathway for ART (assisted reproductive technology) Storage Funding Program:** No referral required: If the patient is eligible the clinic will invite the patient to take part in the program. **Service provider characteristics:** A cryostorage service is eligible for subsidy under the program 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 program, 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 (for example, multiple storage of eggs from multiple cycles stored together would comprise one claim for one yearly payment under the program, and so forth). A cryostorage service is not eligible for subsidy under this program 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 ▪ program, or ▪ the cryostorage subsidy limit of 10 years has been exceeded, 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 program, or ▪ it is a duplicate cryostorage service. Subsidy under this program is only available for eligible patients for up to 2 different types of cryostorage service. **An ART clinic is eligible for the program 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 program guidelines.

Country Relevant documents	Organisational aspects
	ART clinics must be able to provide evidence: ▪ that their clinic holds a current RTAC licence ▪ that the patients for whom the clinic is seeking a subsidy are eligible for the program ▪ that the cryostorage services for which the clinic is seeking a subsidy are eligible for the program ▪ that the clinic has not charged the patient any out-of-pocket costs for cryostorage services being subsidised under this program, and ▪ that the clinic has received consent from all eligible patients to seek a subsidy under this program. **Exclusions (based on the service) to the program 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 program ▪ Where a patient's cryostorage service is partly or fully subsided under any other Commonwealth, state or territory funded cryostorage service or program, it is not eligible for this program ▪ 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 program. **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 program subsidy. 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. **Referral pathways for Medicare:** The general practitioner (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.

Country Relevant documents	Organisational aspects
	Provider eligibility for Medicare: To be eligible to provide a 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. **Referral pathway for NOTTCS**: Referral to the NOTTCS is required by a referring/treating doctor/hospital/clinic. For general fertility preservation services at Melbourne IVF and the Royal Women's Hospital referrals are accepted from:(278) ▪ oncologist ▪ surgeon ▪ general practitioner (GP) ▪ nurse coordinator ▪ fertility specialist Urgent referral can also be provided by calling the NOTTCS contact phone number. **Service pathway for NOTTCS:** 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. Referrals are fast tracked to eliminate any delay in treatment. **Service provider characteristics:** The service provides education, consultation, logistic support, and a robust tissue transport protocol to ensure optimal tissue viability prior to cryopreservation. The service operates with a centralised dedicated nurse coordinator and lab staff, providing 24 hour support to rural oncology centres. Follow up is provided to the referring centres and the patients.(75)
Denmark ▪ Guidance on the activities and obligations of healthcare professionals and tissue establishments in the field of assisted reproduction(17) ▪ Bach et al.(31) ▪ Kristensen et al.(44) ▪ Macklon et al.(47) ▪ von Wolff et al.(71)	**Referral pathway:** Patients potentially requiring fertility preservation identified in the oncological, haematological, or other departments in which patients are exposed to potential gonadotoxic treatment are referred to the consultants of the fertility clinic where they immediately get a consultation. Depending on the clinical evaluation and the patient's wishes, a plan for fertility preservation is agreed upon.(71) Information on the reporting of servious adverse events (defined within the Tissue Act) is outlined (see Appendix D, Table D.9). **Service provider characteristics:** Cryopreservation and storage of ovarian tissue is centralised to one lab in Denmark (Laboratory of Reproductive Biology in Copenhagen), whereas 3 different centres in Copenhagen, Odense and Aarhus offer the initial fertility-preservation counselling and tissue harvesting. Data from the local units are merged into a register, which is relatively easy to create due to its limited size. Follow up consultation after the end of cancer treatment differs between centres. Some patients are offered regular follow-up visits at the fertility clinic, which carried out the initial counselling, whereas others are not and are seen by their own general practitioner or gynaecologist. At Rigshospitalet's fertility clinic, a new outpatient clinic has therefore been established, where the women are offered an appointment for a follow-up assessment of their ovarian function and fertility after the end of their treatment in connection

Country Relevant documents	Organisational aspects
	with their first visit prior to chemotherapy and/or radiotherapy. The concept of fertility counselling has long existed at Rigshospitalet's fertility clinic, which is the first of now many fertility clinics to offer counselling to young women and men without a history of cancer, but with a desire to have their fertility assessed. The follow-up programme for patients with a previous cancer diagnosis is structured at Rigshospitalet so that each woman is offered a total of 3 visits after completing treatment [at 6 months, 12 months and 24 months], and it is expected to see 120 women in the outpatient clinic per year. At the follow-up visits, you can plan how and when to best use the cryopreserved tissue/egg. **Timelines to access services:** In Denmark, the Danish Health Authority provide clinically recommended and justified time frames from diagnosis of cancer to primary treatment is initiated. In the group of hematological conditions, including leukemia and lymphomas, the choice of primary treatment in the clear majority of cases is chemotherapy with the recommendation that treatment is initiated within 3 days. For sarcomas, breast cancer, and pelvic cancers the recommended time frames are approximately 10 - 13 days, when the primary treatment is chemotherapy or neoadjuvant chemotherapy. The recommended time frames for initiation of cancer treatment in most cancers highlight the urgency of treatment and the fact that these women have very little time in which to commence fertility-preserving strategies without affecting their cancer treatment. In Denmark, OTC is only performed in patients with leukemia once they are in complete remission, which allows more time for FP.
France ▪ Funding for medically assisted genetic procreation 2023[110] ▪ Biomedicine Agency: Self-preservation of gametes[104, 105] ▪ Public Health Code: Title IV: Medically assisted procreation (Articles R2141-1 to R2143-20)[108] ▪ Courbière et al.[279] ▪ Eustache[35] ▪ Merlet et al.[52] ▪ Puy et al.[61] ▪ Pawlowski et al.[59]	**Service provider characteristics:** Within the Public Health Code it stipulated that: The multidisciplinary clinicobiological medical team 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. 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 above, at least one psychiatrist, psychologist or nurse with training or experience in psychiatry **2.** Where necessary, a social service assistant. It also includes, for biological activities of medically assisted procreation, at least one medical biologist and one lab technician. 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: **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. 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:

Country Relevant documents	Organisational aspects
	1. Be a medical biologist 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. The interruption or cessation of activity of an establishment, a health cooperation group or a lab 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 lab authorised to store gametes, germinal tissues or embryos must enter into an agreement with another establishment, group or lab 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. 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. With the exception of the gamete donor, 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. 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. If fertility preservation (preservation of sperm and or testicular tissue) has been carried out in a minor, a follow-up consultation at the age of 18 is a legal obligation. The Centres for the Study and Conservation of Human Eggs and Sperm (CECOS) are spread over French territory and are units integrated into the university hospitals. They are associated with a reproductive medicine service or a medically assisted reproduction centre which can implement the exploration of infertility and the care of couples for procreation (inseminations, in vitro fertilisation, etc.). These are multidisciplinary teams mainly comprising biologists, clinicians, midwives, psychologists and staff competent in the care developed in these centres. For more than thirty years, thanks to the links established between CECOS and cancer specialists, sperm conservation has made it possible to preserve the fertility of many men. More recently, germinal tissue preservation techniques have been developed. The use of these tissues to restore fertility requires continued research. Thus, the preservation of testicular tissue is reserved for prepubescent children and in cases where it is impossible to collect sperm. CECOS has been involved in the management of FP in transgender people. In France, the care of transgender people has been organized at the national level for the past 10 years, with the establishment of multidisciplinary networks that have made it possible to target questions and better manage information, by creating a link between the different medical specialties involved in the trans identity process. **Timeline to access services:** The doctors in charge of cancer treatment refer the patient to the fertility preservation team as soon as possible (in emergency cases, within 48 hours throughout the year).
Germany ▪ G-BA: Cryopreservation[112]	**Referral pathway:** 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

Country Relevant documents	Organisational aspects
▪ German Medical Association (BAK). Directive for the removal and transfer of human germ cells or germ cell tissue in the context of assisted reproduction, detailed update[111] ▪ Federal Joint Committee (G-BA). Directive 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)[19] ▪ G-BA: Cryopreservation of ovarian tissue becomes a health insurance benefit[114]	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, 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 timeframe 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 and b) in the case of male insured persons, also specialist doctors who offer the necessary measures in connection with the collection of sperm cells and the removal of germ cell tissue and who fulfil the relevant requirements. 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, 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. **3.** The cryopreservation procedure suitable for the insured person, including the associated measures, must be selected by the service providers authorised in accordance with the provisions of the German Medical Association's guideline on assisted reproduction.

Country Relevant documents	Organisational aspects
	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 lab tests required for the extraction requires a permit from the responsible authority in accordance with the Medicines Act. A separate permit for the tissue extraction and for the necessary lab 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 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 Tissue Ordinance. Measures for the collection of germ cells may only be carried out by: 1. licensed physicians, authorised physicians or authorised medically managed institutions who fulfil the following requirements: ▪ 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." ▪ The practice or institution must have the following knowledge and experience (hospitals must also have this): ○ Endocrinology of reproduction ○ Gynecological sonography ○ Operative gynecology ○ Reproductive biology ○ when treating male insured persons, additional andrology. ▪ Of these areas, only 2 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. ▪ In the case of male insured persons, measures 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. This applies accordingly to hospitals. **Timelines for access to services:** 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.
Portugal ▪ CNPMA (National Council for Medically Assisted Reproduction): Requirement and parameters – Operation of the medically assisted procreation techniques centres[126] ▪ Medically assisted procreation: Law No.32/2006 (Consolidated Legislation)[120] ▪ Medically assisted procreation: Law No.17/2016 (Amendment)[121]	**Referral pathway:** 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:** 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 CNPMA (National Council for Medically Assisted Reproduction). A number of requirements are outlined for authorised PMA (medically assisted procreation) Centres in Portugal (that is, centres that provide medically assisted procreation services, including fertility preservation services). These are outlined in the following categories: **Organisation and quality management** Organisation: The Centre 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 (further examples outlined in Appendix D, Table D.36).

Country Relevant documents	Organisational aspects
▪ Portuguese Society for Reproductive Medicine: Preservation of fertility in oncological patients[124] ▪ CNPMA[122] ▪ ACSS Review of Exemption Categories and Update Values of Moderator Fees[125] ▪ Regulatory Decree No. 06/2016[123]	Quality management system: A person responsible for quality management at the PMA Centre must be designated, this may be the director (further examples outlined Appendix D, Table D.36). **Human resources** The Centre must have staff in sufficient numbers and with adequate competence for the tasks assigned to them (further examples outlined in Appendix D, Table D.36). Medical team: The director of the Centre is a doctor specializing in Gynaecology/Obstetrics, Genetics, Endocrinology or Urology, recognised by the Medical Association, with minimum experience of 3 years in the PMA area (further examples outlined in Appendix D, Table D.36). Clinical embryology team: 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. Centres dedicated exclusively to donor selection and gamete preservation must have at least one technician with a degree, experience and competence in the area to handle gametes and their cryopreservation (further examples outlined in Appendix D, Table D.36). 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 Centre. 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 Centre director (further examples outlined in Appendix D, Table D.36). **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 (further examples outlined in Appendix D, Table D.36). **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. **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.
Sweden ▪ Measures to preserve reproductive capacity in	**Referral pathway and service provider characteristics:** 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. In addition, the Swedish Turner Academy, established in 1994, provides a National Healthcare Program for Turner syndrome. In

Country Relevant documents	Organisational aspects
adults: promotion of equal care for patients at risk of treatment induced infertility[89] ▪ Measures to preserve the reproductive capacity of the young: promotion of equal care for young people who are at risk of treatment induced infertility[88] ▪ Rodriguez-Wallberg et al.[64] ▪ Rodriguez-Wallberg et al.[66] ▪ Rodriquez-Wallberg et al.[67] ▪ Payne et al.[60] ▪ Rodriquez-Wallberg[79]	the program, girls and women with Turner syndrome are followed up throughout life by the multidisciplinary teams at Turner centres established at all university hospitals. *For transgender patients:* multidisciplinary gender identity teams have been also organised at the Swedish university hospitals. **Timelines:** *Adults:* 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. *Young people:* Cancer treatment and prognosis must always be prioritised. *Adolescent girls with Turner Syndrome:* According to the recommendation of the Swedish Turner multidisciplinary program, adolescent girls who present with spontaneous start of puberty should be referred for appropriate counselling on fertility preservation, and if possible, individualised fertility preservation. *Transgender people:* Individuals that are referred for fertility preservation may have already initiated hormonal gender-affirming treatment. If these patients aim to cryopreserve eggs, it is the policy to suspend the treatment and await for normalisation of testosterone levels before starting gonadotropin stimulation. Waiting times for fertility preservation in general are long. *In Karolinska University Hospital (which provides FP healthcare to the Stockholm region (population 2.2 million)):* Referrals for fertility preservation are received daily and evaluated by the senior medical staff. Patients obtain an appointment within a few days. Personnel resources have been allocated to enable scheduling and immediate access to consultations, including on-call clinicians and embryologists during holiday periods. When patients are referred from oncology clinics, information is requested on the disease stage and planned date of initiation of treatment. As a rule, fertility preservation should not cause any delay in starting a planned cancer treatment. The fertility preservation consultation and the patients' decisions are documented in the medical records. **Follow-up:** *Adults:* 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. *Young people:* 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 programs 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

Country Relevant documents	Organisational aspects
	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 program 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.
UK ▪ NICE (CG156) Fertility problems: assessment and treatment[127] ▪ NICE (NG73) Endometriosis: diagnosis and management[128] ▪ NICE Quality Standard (QS73): Fertility problems[129] ▪ NICE Interventional procedures guidance: Removal, preservation and reimplantation of ovarian tissue for restoring fertility after gonadotoxic treatment[130]	**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. In relation to the preservation and reimplantation of ovarian tissue, 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. **Timeline:** 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.[195]
England ▪ NHS Bedfordshire, Luton and Milton Keynes Integrated Care Board (ICB). Gamete (sperm/egg) storage for those undergoing fertility-threatening treatment[139] ▪ NHS Kent and Medway ICB. Policies on fertility treatments[153] ▪ NHS Somerset ICB. Fertility assessment and treatment prior approval policy[155] ▪ Specialist cancer services for children and young people: teenage and young adults designated hospitals[138]	**Referral pathway:** A number of ICB policies outline that GP or consultant referral is required for a consultation with an NHS fertility specialist including Bedfordshire, Luton and Milton Keynes;[139] Kent and Medway,[153] and Somerset.[155] For Kent and Medway the treating consultant must complete and submit The Assisted Conception Prior Approval and Fertility Preservation Form,[153] while for Somerset a Fertility Preseravation Form must be completed and forwarded to the Evidence Based Interventions Service to advise of the referral for treatment.[155] **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. **Referral pathway for teenagers and young adults:** Teenagers and young adults must be referred to Principal Treatment Centres (TYA PTC) and Designated Hospitals with suspected or confirmed cancer. The TYA PTC must include access to fertility services in accordance with the National Institute for Health and Care Excellence (NICE) Quality Standard 'Fertility Problems' (QS73). The TYA PTC 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. **Timelines to access services:** An outcome must be provided within 7 working days of team discussion to all relevant clinicians, including a new service user discussion for all clinicians within the diagnostic pathway.

Country Relevant documents	Organisational aspects
▪ NHS England: Teenage and young adult cancer clinical network specification[136] ▪ Specialist cancer services for children and young people: teenage and young adults principal treatment centre services[137] ▪ National Health Service (NHS) England. Service specifications: fertility preservation and restoration[131] ▪ Service specification and equality and health inequalities impact assessment documents for: ○ Fertility preservation for service users with ovarian tissue who are at high/very high risk of infertility and cannot store mature eggs[132] ○ Fertility preservation for service users with testicular tissue who are at high/very high risk of infertility and cannot store sperm[134]	*Specific to service users with ovarian tissue who are at high/very high risk of infertility and cannot store mature eggs and service users with testicular tissue who are at high/very high risk of infertility and cannot store sperm:* **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 or testicular tissue 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 (HTA). **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 6. Hub feeds back NEG decision to referrer: Patient to proceed with tissue storage **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

Country Relevant documents	Organisational aspects
	▪ 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:***

Country Relevant documents	Organisational aspects
	▪ 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.
Northern Ireland Belfast HSC Trust. Regional Fertility Centre[161]	**Referral pathway 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 4 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. Referral for Medically Required Fertility Preservation (Female): 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, hepatitis B core antigen antibody & 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.
Scotland	**Referral pathway** (Sample referral pathway information from NHS Lothian):

Country Relevant documents	Organisational aspects
▪ Fertility Scotland[163] [2024] Annual Report 2021/22[164] [2022] ▪ NHS Inform: Fertility and Cancer[165] ▪ NHS Lothian: Edinburgh Fertility Centre – Fertility Preservation Referral Form[166] ▪ NHS Scotland: Endocrine and Fertility Preservation Guidance[162]	▪ *Referral Guidelines:* For transgender patients requesting fertility preservation, the Edinburgh Fertility Centre (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 X and email the completed referral form and direct the referral as follows [email and telephone details provided]. **Service provider characteristics:** Fertility services in NHS Scotland 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 and intra-cytoplasmic sperm injection 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). **Referral pathways and timelines for access to services for men and women undergoing cancer treatment:** Before your treatment starts, talk to your doctor or nurse about how your fertility may be affected. You may be able to visit a fertility expert/clinic (with referral) 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 **Referral pathway for transgender, non binary and gender diverse (TGD) people:** 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. **Service provider characteristics:** There are 4 NHS Fertility Centres in Scotland that provide fertility preservation for those patients that require this treatment. ***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. **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.

Country Relevant documents	Organisational aspects
	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. **Timelines for 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.
Wales ▪ Wales Fertility Institute[171] ▪ Wales Fertility Institute: Sperm Freezing[172] ▪ Wales Fertility Institute: Fertility Preservation for Trans and Gender Diverse People - Information for patients[173] ▪ Specialised Services Service Specification: CP79 Haematopoietic stem cell transplantation (HSCT) for adults[168] ▪ Specialised Services Policy Position PP142 HSCT for Adults[169] ▪ Specialised Services Service Specification: Services for Children with Cancer (CP86)[170]	**Referral pathway (trans and gender diverse people):** 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. **Referral pathway for others:** A referral is required from a clinician involved in the patient's treatment. **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. They provide specialist fertility consultations and treatments including fertility preservation. All 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.

Country Relevant documents	Organisational aspects
	Timeline: As soon as the lab has received the screening test results, they will contact the patient to arrange a convenient time to attend for storage.

Key: ART – assisted reproductive technology; CNMPA – National Council for Medically Assisted Procreation (Portugal); EFC – Edinburgh Fertility Centre; GIC – gender identity clinic; GP – general practitioner; HTA – Human Tissue Authority (UK); ICB – integrated care board; NOTTCS – National Ovarian and Testicular Tissue Transport and Cryopreservation Service (Australia); RTAC – Reproductive Technology Accreditation Committee (Australia); TGD – trans gender, non binary and diverse; TYA PTC – Teenager and Young Adult Primary Treatment Centre; WFI – Wales Fertility Institute.

Table C.4 Summary of storage information identified for publicly-funded fertility preservation services for medical reasons in selected countries

Country Relevant documents	Storage
Australia ▪ ART Storage Funding Program[93] and Guidelines[94] ▪ Assisted reproductive technology (ART) services[90] (Services Australia)[91] ▪ National Health and Medical Research Council: Ethical guidelines on the use of assisted reproductive technology in clinical practice and research[92] ▪ National Ovarian and Testicular Tissue Transport and Cryopreservation Service[98] ▪ Johnston et al.[41] ▪ Stuhmcke and Chandler[69]	**Duration:** In Australia, storage duration for gametes vary between states and territories. In the state of Victoria, legislation allows gametes to be kept in storage for up to 10 years, unless it is deemed that there is a medical risk to fertility (for example, iatrogenic threats or a medical condition that affects egg quality); in those cases, gametes can be stored for 20 years. Storage beyond these limits is only possible if an extension is granted by the Patient Review Panel, the independent body responsible for granting certain permissions related to access to assisted reproduction or management of gametes or embryos. Patients approaching the storage limits, or who no longer require their frozen eggs, must decide from 3 options as to how they manage their unused or 'surplus' eggs: donate for reproductive purposes; donate to research; or disposal. Where no decision is made or contact is lost, once the storage limit has been reached, the gametes must be removed from storage and disposed.[41] **Duration by region:[69]** Jurisdiction: Australian Capital Territory Storage limitation periods for Gametes: Subject to NHMRC Ethical Guidelines Storage limitation periods for embryos: Subject to NHMRC Ethical Guidelines Jurisdiction: New South Wales Storage limitation periods for Gametes: Donated gametes: 10 years. Own gametes: subject to gamete provider's consent and individual clinic policies. Storage limitation periods for embryos: Donated embryos and embryos formed with donated gametes: 10 years. Patients' own gametes used to form embryo: subject to gamete provider's consent and individual clinic policies. Jurisdiction: Northern Territory Storage limitation periods for Gametes: Subject to NHMRC Ethical Guidelines Storage limitation periods for embryos: Subject to NHMRC Ethical Guidelines Jurisdiction: Queensland Storage limitation periods for Gametes: Subject to NHMRC Ethical Guidelines Storage limitation periods for embryos: Subject to NHMRC Ethical Guidelines Jurisdiction: Victoria Storage limitation periods for Gametes: 10 years Storage limitation periods for embryos: 5 years with the option to consent for a further 5-year period Jurisdiction: South Australia Storage limitation periods for Gametes: Subject to NHMRC Ethical Guidelines Storage limitation periods for embryos: Subject to NHMRC Ethical Guidelines

Country Relevant documents	Storage
	Jurisdiction: Tasmania Storage limitation periods for Gametes: Subject to NHMRC Ethical Guidelines Storage limitation periods for embryos: Subject to NHMRC Ethical Guidelines Jurisdiction: Western Australia Storage limitation periods for Gametes: 15 years Storage limitation periods for embryos: 10 years Arrangements and duration for the ART Storage Programme **Claim Process:** Every 6 months, assisted reproductive technology (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 program subsidy. Each 'cryostorage service' would include all storage samples of the same type of genetic material that are saved in one container (for example, multiple eggs from multiple cycles stored together would comprise one claim for one yearly payment of $600, and so forth). 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. 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 and 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 program and cannot be claimed by the ART clinic; unless the other individual is also eligible for the program. **Disposal of stored material:** **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 program 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:

Country Relevant documents	Storage
	a. gain consent from the surviving reproductive partner to enter the program, and to share their personal information with Services Australia and the Department of Health and Aged Care, then ART Storage Funding Program Guidelines 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 program 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. The National Health and Medical Research Council also outlines a number of ethical guidelines related storage of gametes and embryos including: ▪ **Maintain the safe storage and accurate identification of all gametes and embryos** ▪ **Assess the suitability for continued (long term) storage of gametes and embryos** ▪ **Manage the collection and storage of gonadal tissue or gametes for fertility preservation:** *Specific to 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. ▪ **Manage embryos no longer needed by an individual or couple for their own reproductive purposes** ▪ **Manage stored gametes or embryos following the death of a gamete provider** ▪ **Manage the discard of stored gametes and embryos** ▪ **Manage disputes between members of a couple for whom an embryo is stored.** **Arrangement and durations for the National Ovarian and Testicular Tissue Transport and Cryopreservation Service (NOTTCS):** retrieval and transport of ovarian and testicular tissue is brought to a centralised centre (Women's and Royal Melbourne Hospital IVF laboratory) with expertise in processing and storage. Following the multidisciplinary decision to graft the tissue in future, the tissue may be transported back to the local unit.
Denmark ▪ Guidance on the activities and obligations of healthcare professionals and tissue	**Arrangement and duration:** Under current legislation, fertilised and unfertilized human eggs can be stored until the applicable age limit for receiving publicly-funded 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. The relevant legislation was amended from the previous 5-year limit on storage following a political agreement. The agreement also stated that women who have been affected by

Country Relevant documents	Storage
establishments in the field of assisted reproduction[17] ▪ Executive Order on the Act on Assisted Reproduction in Connection with Treatment, Diagnostics and Research, etc. (LBK no. 902 of 23/08/2019)[99] as amended by LOV no. 129 of 30/01/2021[100] and LOV no. 1780 of 28/12/2023[101] ▪ Executive Order on Assisted Reproduction (BEK no. 672 of 08/05/2015)[17] ▪ New political agreement lifts 5-year limit for freezing eggs (Press Release)[102] ▪ Council of Ethics: Storage of fertilised eggs and unfertilised egg cells[103]	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. Of note, there are no restrictions on how long sperm (and testicular tissue) can be frozen before use or reinserted via transplantation. **Access to stored material:** 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. 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. 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. **Disposal of stored material:** ▪ 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. ▪ 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. 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. ▪ 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. **Other storage information:** 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. 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.

Country Relevant documents	Storage
France ▪ Biomedicine Agency: Self-preservation of gametes[104, 105] ▪ Biomedicine Agency: What does the law say[106] ▪ Public Health Code: Title IV: Medically assisted procreation (Articles L2141-1 to L2143-9)[107] ▪ Public Health Code: Title IV: Medically assisted procreation (Articles R2141-1 to R2143-20)[108]	**Arrangements and durations:** 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. **Access to stored materials:** 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. The gametes self-preserved by freezing or vitrification can then be used: ▪ Until the 45th birthday for women ▪ Until the 60th birthday for men. 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. Additionally, the implementation of medically assisted reproduction is indicated for couples composed of a man and a woman, single women and female couples. 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 procedures 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. **Disposal of stored material:** The adult whose gametes or germinal tissues are preserved shall be consulted each year. He or she consents in writing to the continuation of this retention. 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. When you choose to stop storing your gametes, you will be asked for confirmation after a period of 3 months. Additionally, when the person reaches an age that no longer justifies the interest of retention and in the absence of the consent storage shall be terminated. This age limit is set by an order of the Minister for Health, issued after consultation with the Biomedicine Agency. **Specific to the stored materials of minors:**

Country Relevant documents	Storage
	▪ 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 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. ▪ 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 2. That the conservation of his gametes or germinal tissues be terminated. Information is also provided around the import and export of gametes or germinal tissues from the human body (see Appendix D, Table D.24).
Germany ▪ German Medical Association (BAK). Directive for the removal and transfer of human germ cells or germ cell tissue in the context of assisted reproduction, detailed update[111] ▪ Federal Joint Committee (G-BA). Directive 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)[19]	**Arrangements and durations:** 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: These no longer exist with male insured persons aged 50 and over and for female insured persons aged 40 and over, and or with the death of the insured person. 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 under suitable conditions does not lead to any further deterioration in sperm quality. Since a single vital sperm is used per egg cell for 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. **Testing for infection parameters:** 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 the law. **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 G-BA guideline on artificial insemination.

Country Relevant documents	Storage
Portugal ▪ CNPMA: Requirement and parameters- Operation of the medically assisted procreation techniques centers[126] ▪ Medically assisted procreation: Law No.32/2006 (Consolidated Legislation)[120] ▪ Medically assisted procreation: Law No.17/2016 (Amendment)[121] ▪ Portuguese Society for Reproductive Medicine: Preservation of fertility in oncological patients[124] ▪ ACSS Review of Exemption Categories and Update Values of Moderator Fees[125] ▪ CNPMA: Requirement and parameters- Operation of the medically assisted procreation techniques centers[126]	**Arrangements and durations:** ▪ Spermatozoa, oocytes, testicular tissue and ovarian tissue, which are collected and not used, are cryopreserved for a maximum period of 5 years. In the event of death this period will be shortened to a maximum period of 3 years after death. ▪ 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 ▪ Without prejudice to the extension of the period provided for in the previous paragraph, after the 5-year period 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 ▪ The destination of spermatozoa, oocytes, testicular tissue and ovarian tissue for the purposes of scientific research, 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 ▪ Once the donation has been consented to, 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 ▪ 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. **Disposal of stored material:** ▪ At the end of any specified period, in the absence of a signed statement requesting a new period of cryopreservation, the sperm/testicular/oocyte/ovarian tissue and or embyro will be thawed and disposed of ▪ If donation is not consented to, as soon as any of the periods have elapsed, spermatozoa, oocytes, testicular tissue and ovarian tissue may be thawed and eliminated, as determined by the director of the ART centre.
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[88] ▪ Measures to preserve reproductive capacity in adults: promotion of equal care for patients at risk of treatment induced infertility[89]	**Arrangements and durations:** 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. **Access to stored materials:** 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. **Disposal of stored materials:** If the patient dies, harvested cells/tissues may not be used for fertilisation 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. For younger patients in particular, 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

Country Relevant documents	Storage
	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]
UK ▪ NICE (CG156) Fertility problems: assessment and treatment[127] ▪ NICE (NG73) Endometriosis: diagnosis and management[128] ▪ NICE Quality Standard (QS73): Fertility problems[129] ▪ NICE Interventional procedures guidance: Removal, preservation and reimplantation of ovarian tissue for restoring fertility after gonadotoxic treatment[130]	**Arrangements and durations:** As of July 01 2022 the statutory storage limits for gametes and embryos (for everyone regardless of medical need) is 10-year renewable periods, with a maximum limit of 55 years. 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. **Access:** 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). 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 HFEA form must be completed. **Disposal:** The centre will need to keep in contact with the patient, particularly towards the end of the statutory 10-year renewable period, to see whether samples should be destroyed or whether storage for a further period of years is necessary.
England ▪ NHS Bedfordshire, Luton and Milton Keynes Integrated Care Board (ICB). Gamete (sperm/egg) storage for those undergoing fertility-threatening treatment[139] ▪ NHS South West London ICB. Evidence-based interventions policy[140] ▪ NHS Coventry and Warwickshire ICB. NHS Funded Cryopreservation of Gametes and Embryos Policy[141] ▪ NHS Cheshire and Merseyside. NHS funded treatment for subfertility Clinical Commissioning Group policies[143-152]	**Arrangements and storage durations:** Generally, across the ICB policies selected, for adults 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 may continue if certain criteria are met. For example, *Bedforshire, Luton and Milton Keynes ICB* specify:[139] ▪ the provider has gained continued consent from the patient every 10 years in line with HFEA guidelines ▪ 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 ▪ 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 ▪ for all patients, if fertility returns as demonstrated by conception, funding for ongoing storage of remaining stored material will cease. In addition, *Coventry and Warwickshire ICB* specify:[141] ▪ 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. *Somerset ICB specify:*[155] 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.

Country Relevant documents	Storage
▪ NHS Kent and Medway ICB. Policies on fertility treatments[153] ▪ NHS Somerset ICB. Fertility assessment and treatment prior approval policy[155] ▪ NHS Somerset ICB. Evidence Based Interventions Programme for Interventions Not Normally Funded[156] ▪ NHS West Yorkshire ICB. Cryopreservation for both men and women where the usual fertility policy does not apply[142] ▪ Dash et al.[73]	*South West London ICB specify:*[140] 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. 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. 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. If a patient who has undergone fertility preservation wishes to access assisted conception treatment (ACT), they will be assessed against the ACT criteria as detailed within the ACT Policy, however the 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 cycles, as in these circumstances a fresh cycle is not available for them. **Access to stored materials:** Generally, across the ICB policies selected, for adults: ▪ 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. 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. ▪ 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:** Generally, across the ICB policies selected, for adults: ▪ for all patients, if fertility returns as demonstrated by conception, funding for ongoing storage of remaining stored material will cease ▪ if the patient dies with no written consent regarding posthumous use, then continued storage will not be funded ▪ patients who have undergone NHS-funded cryopreservation but no longer meet eligibility criteria may choose to self-fund ongoing cryopreservation of their stored material. A 2019 study identified that 97 CCGs offered 10 years' storage. 36 offered 5 years only, 17 offered 3 years and 4 only offered 1 year's worth of storage.[73]

Country Relevant documents	Storage
Northern Ireland Belfast HSC Trust. Regional Fertility Centre[161]	**Arrangements and durations:** Publicly-funded fertility treatment includes the storage of embryos for 2 years from the date of treatment. To store embryos for longer, the patient will need to meet the storage costs. 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. 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 consent must be renewed every 10 years. In Northern Ireland the Regional Fertility Centre 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. The renewal period begins 12 months prior to the expiry of your consent and ends 6 months afterwards (a total of 18 months). From 1 July 2022, a new law means that: ▪ 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. ▪ 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. *Consenting to storage for less than 10 years:* 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 (i.e. that consent is taken to be withdrawn). Importantly, there is no grace period when extending consent to storage for periods less than 10 years. **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 (in vitro fertilisation or intracytoplasmic sperm injection. If you have a partner, you may also wish to consider storing your sperm for your partner's future treatment with intrauterine insemination. *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.

Country Relevant documents	Storage
	▪ 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 use 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. *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. *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. **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 (for example, after the 18 month renewal period).
Scotland ▪ Fertility Scotland (NHS Scotland National Strategic Network)[163] and Annual Report 2021/2022[164] ▪ NHS Scotland: Endocrine and Fertility Preservation Guidance[162]	**Arrangements and durations:** 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. 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. ▪ 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 (fertility preservation treatment to be initiated before 42nd/54th birthday) ▪ 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 ▪ not being in a stable relationship is not a relevant criterion for either initiating storage, or for ongoing storage

Country Relevant documents	Storage
	▪ young patients may need to store gametes for a very long time ▪ 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, i.e 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 ▪ 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. ▪ 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. ▪ 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 material:** 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. *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).
Wales ▪ Wales Fertility Institute[171] ▪ Wales Fertility Institute: Sperm Freezing[172] ▪ Wales Fertility Institute: Fertility Preservation for Trans	**Arrangements and durations:** In line with HFEA regulation, eggs, sperm and embryos can be stored for up to 55 years, in 10 year renewable periods. 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. In Wales, previously 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 there was a wish for the eggs, sperm or embryos to remain in storage, there would be an annual fee (currently £275 per year). Given the change in the legislation period to 55 years, with 10-year renewable periods, it is unclear if this fee still applies. For oncology

Country Relevant documents	Storage
and Gender Diverse People - Information for patients[173]	patients and those undergoing treatment which has the potential to reduce fertility, the sample will be split between 2 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. WFI will contact patients 12 months before their consent is due to expire.

Key: ACT – assisted conception treatment; ART – assisted reproductive technology; HFEA – Human Fertilisation and Embryology Authority (UK); ICB – integrated care board; NOTTCS – National Ovarian and Testicular Tissue Transport and Cryopreservation Service (Australia).

Table C.5 Summary of governance information identified for publicly-funded fertility preservation services for medical reasons in selected countries

Country Relevant documents	Governance
Australia ▪ National Health and Medical Research Council: Ethical guidelines on the use of assisted reproductive technology in clinical practice and research[92] ▪ ART Storage Funding Program[93] and Guidelines[94] ▪ Robson et al.[63] (2020)	Assisted reproductive technology (ART) clinics are required to register their details with the Services Australia Organisation. Once they have registered, ART clinics will enter into a Grant Agreement with the Department of Health and Aged Care. In regards to the Storage Funding Programme, the Department of Health and Aged Care will evaluate the program as part of the quality assurance process to ensure it is achieving its intended purpose. All ART clinics registered to receive funding through the program must: ▪ ensure their information in the Organisation Register remains up to date ▪ maintain a Reproductive Technology Accreditation Committee (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 ▪ 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 program requirements for a minimum of 7 years. **Programme compliance** The Department may undertake post-payment compliance activities at any time to ensure that ART clinics comply with these program guidelines. Program compliance activities may include a post-payment review of practice documents. **Further governance** Additionally, ART clinics must provide evidence of compliance with the NHMRC Ethical Guidelines (unless alternate policies have been directed by a registered and affiliated Human Research Ethics Committee). The retrieval and use of gonadal tissue for fertility preservation continues to be subject to institutional governance. This may include a combination of human research ethics committee review, clinical ethics governance and or executive oversight as a new technology. Research on the tissue itself is also be subject to human research ethics committee review. The Australian government has also established the National Service Delivery Framework for Adolescents and Young Adults with Cancer which seeks to uphold the recommendations established in the Oncofertility Consortium Charter, specifically focusing on fertility preservation and sexual health of adolescents and young adults.
Denmark ▪ Executive Order on the Act on Assisted Reproduction in Connection with Treatment, Diagnostics and Research, etc. (LBK no. 902 of 23/08/2019)[99] ▪ Executive Order on Assisted Reproduction (BEK no. 672 of 08/05/2015)[17]	In Denmark, 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, on human eggs and sperm. The Danish Patient Safety Authority is authorised to lay down health professional rules for the donation, use, transfer and storage of human eggs and sperm. It is not permitted to use new treatment and diagnostic methods in connection with assisted reproduction until the Minister for Health and Prevention has approved these on the basis of ethical and health considerations. The healthcare professional's application is sent to the Danish Health Authority. The Danish Health Authority: ▪ conducts a health professional assessment of applications for new treatments. The notification of a new treatment assessment 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

Country Relevant documents	Governance
	▪ based on their assessment 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 ▪ informs the country's healthcare professionals of the Minister for Health and Prevention's decision regarding the notified new form of treatment or diagnosis. 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.
France ▪ Biomedicine Agency: Self-preservation of gametes[104, 105] ▪ Public Health Code, Title IV: Medically assisted reproduction (Articles R2141-1 to R2143-20)[108] ▪ Eustache[35] (2018)	The Biomedicine Agency is a national state agency placed under the supervision of the Ministry of Health. 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 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. Additionally, the Public Health Code outlines that the actors of the vigilance system relating to medically assisted procreation are: ▪ the Biomedicine Agency ▪ health establishments, medical biology laboratories and bodies authorised to carry out the relevant activities ▪ practitioners working in health establishments, medical biology laboratories and relevant organisations and ▪ any other relevant health professionals. The CECOS (Centres for the Study and Conservation of human Eggs and Sperm) Federation is aimed at harmonising the practices of gamete and embryo donation as well as those of fertility preservation at the national level. Several commissions make it possible to provide support to the various CECOS: ▪ The genetics commission: to discuss difficult clinical cases, thus being a tool for case-by-case decision-making in the centres ▪ the psychologists' commission: brings together the psychologists and psychiatrists involved in the centres and may call on external specialists. It participates in the general reflection on issues specific to the donation or preservation of fertility, more particularly on the psychological level ▪ the ethics commission: brings together all volunteer staff of the CECOS, regardless of their specialty, as well as members from outside the CECOS by invitation. It is asked to deal with general ethical issues. ▪ the scientific, technical and administrative commission: the development of procedures for the management of donation and the preservation of fertility. It has a role in particular in the training of staff by developing training programmes ▪ the commission for the dissemination of information: communicates with the public, public authorities or bodies on its activities and on the major issues related to these activities

Country Relevant documents	Governance
	A board of directors represents the decision-making body of the CECOS Federation. The board of directors includes a representative of each CECOS, 2 personalities competent in reproductive medicine (a clinician and a biologist) and representatives of patient associations.
Germany ▪ German Medical Association. Directive for the removal and transfer of human germ cells or germ cell tissue in the context of assisted reproduction, detailed update(111) ▪ Federal Joint Committee (G-BA). Directive 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)(19) ▪ Reasons for the decision of the Federal Joint Committee to amend the guidelines on cryopreservation: Cryopreservation of germ cell tissue(115)	The Appointment Service and Care Act (TSVG) 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. The Federal Joint Committee (G-BA) is then empowered to issue a guideline that regulates the details of the entitlement to benefits as well as the requirements for doctors and reproductive medicine facilities on behalf of the legislator. The German Medical Association, in addition to the requirements of the TPG Tissue Ordinance, can establish the 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. 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 will be reviewed at least every 2 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.
Portugal ▪ CNPMA: Requirement and parameters- Operation of the medically assisted procreation techniques centres(126) ▪ Medically assisted procreation: Law No.32/2006 (Consolidated Legislation)(120) ▪ Medically assisted procreation: Law No.17/2016 (Amendment)(121) ▪ Regulatory Decree No. 06/2016(123)	The National Council for Medically Assisted Procreation (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 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. The CNPMA having overall governance in relation to the regulation of these centres including: ▪ receiving annual reports from ART centres ▪ auditing and inspecting ART centres (in collaboration with the General Inspection of Health Activities (IGAS)) ▪ training ART centre auditors. A request for authorisation of a centre to administer ART techniques is made by submitting an application addressed to the member of the Government responsible for the health area and delivered to the regional health administration with territorial competence depending on the location of the centre. 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. In conjunction with the CNPMA, the General Inspectorate of Health Activities (IGAS) carries out audits, inspections and monitoring of public and private centres that provide ART techniques.

Country Relevant documents	Governance
Sweden ▪ Pawłowski et al.[59] (2023) ▪ Rodriguez-Wallberg et al.[66] (2019)	Guidelines on oncofertility are published by the Swedish Human Tissue Authority, as requested by the Swedish Association of Local Authorities and Regions. Individual institutes such as the Karolinska University Hospital have also developed standardised protocols, in line with national guidelines, which encompasses a summary of recognized and approved FP practice, and defines duties and responsibilities among the staff.
UK ▪ NICE Fertility problems: assessment and treatment[127]	All fertility facilities within the UK are independently regulated by the HFEA. Sperm, eggs or embryos can only be stored and used in a centre licensed by the HFEA. 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 and or 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. 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. 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. Storage of such tissue is subject to tissue banking regulations and its availability is therefore very restricted. Only ovarian tissue that has been stored under Human Tissue Authority regulations can be reimplanted.
England ▪ NHS Cheshire and Merseyside. NHS funded treatment for subfertility Clinical Commissioning Group policies[143-152] ▪ NHS England. Service specifications: fertility preservation and restoration[131] Service specification and equality and health inequalities impact assessment documents for: ○ Fertility preservation for service users with ovarian tissue who are at high/very high risk of	Previously, Clinical Commissioning Group (CCG) areas made local decisions around their clinical commissioning policies. Since the establishment of Integrated Care Systems, Integrated Care Boards (ICBs) have been reviewing these policies to look at how they can be harmonised for all former CCG areas within their respective regions. However, where policies are yet to be harmonised, patients may continue to be treated under the existing policy of the CCG that covered the area they live in (for example, in Cheshire and Merseyside). Services for ovarian and testicular tissue cryopreservation are commissioned by NHS England and delivered through a Hub and Spoke model. Within this model, the Hub will: ▪ have a named Programme Lead responsible for ensuring compliance of the service across the Hub/Spoke/Tissue Establishment (TE) services in accordance with the service specification standards ▪ put in place Service Level Agreements/Third Party Agreements with the Spoke site and TE and agree and monitor quality assurance measures across the Hub/Spoke services. ▪ have a Hub panel which oversees the fertility preservation programme and monitor quality assurance between Hub/Spoke and Hub/TE services ▪ 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 ▪ store data on all referrals and tissue procurement episodes and report data as required to NHS England 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.

Country Relevant documents	Governance
infertility and cannot store mature eggs[132] ○ Fertility preservation for service users with testicular tissue who are at high/very high risk of infertility and cannot store sperm[134] ▪ NHS England: Teenage and young adult cancer clinical network specification[136] ○ Specialist cancer services for children and young people: teenage and young adults principal treatment centre services[137] ○ Specialist cancer services for children and young people: teenage and young adults designated hospitals[138]	▪ collect data on deceased service users and pass this information onto the TE ▪ 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 ▪ ensure that all patient data complies with the United Kingdom Data Protection Action (UKDPA) regulations. 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 ▪ 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 In relation to NHS England specialist cancer services for children and young people, Clinical Networks are a vehicle for specialty level collaboration between patients, providers and commissioners. They should have a clear line of accountability to ICBs, and NHS England Regional Teams, to ensure local ownership, alignment and a local mandate.
Northern Ireland ▪ Circular Health and Social Care (HSC) (SQSD) 3/13:[157] ▪ Fertility problems: assessment and treatment (CG156)[127] ▪ Additional Caveats for CG156[159] ▪ Circular HSC (SQSD) (NICE NG73) 35/17, Subject: NICE Clinical Guideline NG73 – Endometriosis: diagnosis and management[128]	The Department of Health established formal links with NICE in 2006, whereby guidance published by NICE from that date would be locally reviewed for applicability to Northern Ireland and, where appropriate, endorsed for implementation in Health and Social Care (HSC). It is 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 is proofed by the Department of Health 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. 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. RQIA will lead on assessing the

Country Relevant documents	Governance
	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. Additionally, as Northern Ireland is located within the UK, fertility centres are subject to regulation by the HFEA (see UK governance for more information).
Scotland ▪ Fertility Scotland (NHS Scotland National Strategic Network)[163] ▪ NHS Scotland: Endocrine and Fertility Preservation Guidance[162]	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: 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 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. For complex cases, discussion by a review group with multi-disciplinary expertise from all 4 Scottish Fertility Centres has 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. In regards to data collection, Information Services Division (Scotland) 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. This includes the: ▪ number and source of referrals ▪ number of patients proceeding to fertility preservation and their characteristics ▪ data on usage/other outcomes. As Scotland is in the UK it is also subject to HFEA regulations (see UK governance information).
Wales ▪ Wales Fertility Institute[171] ▪ Wales Fertility Institute: Sperm Freezing[172] ▪ Wales Fertility Institute: Fertility Preservation for Trans and Gender Diverse People - Information for patients[173]	The Wales Fertility Institute (WFI) is a NHS facility managed by Swansea Bay University Health Board. All facilities providing fertility treatments in the UK, including the WFI, are within the remit of the UK fertility regulator, the HFEA. Therefore patients will be required to complete HFEA consent forms covering the storage and use of stored samples (See UK governance information for more detail). Within the WFI, patients will also be required to complete the Cardiff Cryopreservation of Sperm Consent.

Key: ART – assisted reproductive technology; CCG – Clinical Commissioning Group; CECOS – Centres for the Study and Conservation of human Eggs and Sperm (France); CNPMA – National Council for Medically Assisted Procreation (Portugal); DHSSPS – Department of Health, Social Services and Public Safety (Northern Ireland); FP – Fertility Preservation; G-BA – Federal Joint Committee (Germany); HFEA – Human Fertilisation and Embryology Authority (UK); HPSS – Health and Personal Social Services; HSC –

Health and Social Care; HTA – Health Technology Assessment; ICB – Integrated Care Board (England); IGAS - General Inspectorate of Health Activities (Portugal); NHS – National Health Service; NICE – National Institute for Health and Care Excellence; PPR – Person with Parental Responsibility; RQIA – Regulation and Quality Improvement Authority; RTAC - Reproductive Technology Accreditation Committee; SLA – Service Level Agreements; TE – Tissue Establishment; TPA – Third Party Agreements; TPG – The Transplantation Act (Germany); UK – United Kingdom; UKDPA – United Kingdom Data Protection Action; WFI – The Wales Fertility Institute.

Table C.6 Summary of communication and information provision identified for publicly-funded fertility preservation services for medical reasons in selected countries.

Country Relevant documents	Communication and information
Australia ▪ ART Storage Funding Program[93] and Guidelines[94] ▪ National Ovarian and Testicular Tissue Transport and Cryopreservation Service[98] ▪ National Health and Medical Research Council: Ethical guidelines on the use of assisted reproductive technology in clinical practice and research[92]	There is a fact sheet available for patients on the ART Storage Funding Program. 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. 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. ART clinics must provide a statement to the patient every 6 months once they have received the program 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 (i.e., may be a portion of the 6 month period) ▪ which material/s storage was subsidised (i.e., eggs, sperm, embryo/s), and ▪ instructions for the patient regarding how to proceed if they no longer require the storage service/s. Within the NHMRC ethical guidelines a number of information provision and counselling requirements are also outlined, including: *Information giving (general requirements): Information should be provided:* ▪ verbally, supported by written information in plain language ▪ with sensitivity to cultural diversity, religious beliefs and personal circumstances. *Individuals and couples seeking to store gametes or embryos: in addition to general requirements the following should be discussed:* ▪ 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. *Specific to fertility preservation:* ▪ 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. Further detail is provided in Appendix D, Table D.2. The National Ovarian and Testicular Tissue Transport and Cryopreservation Service 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.

Country Relevant documents	Communication and information
	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.
Denmark ▪ Council of Ethics: Storage of fertilised eggs and unfertilised egg cells[103] ▪ Executive Order on the Act on Assisted Reproduction in Connection with Treatment, Diagnostics and Research, etc. (LBK no. 902 of 23/08/2019)[99] ▪ Guidance on the activities and obligations of healthcare professionals and tissue establishments in the field of assisted reproduction[17] ▪ Von Wolff et al.[71] ▪ Macklon et al.[47]	Within the Executive Order on the Act on Assisted Reproduction, the following information provisions (related to fertility preservation) are included: ▪ the treating healthcare professional must ensure that, prior to giving consent, 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. Additionally, the following information must be given by the fertility clinic both in writing and orally to the woman/couple, along with being available on the clinic's website: ▪ information about the prospect of successful treatment results with assisted reproduction ▪ information about 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. ▪ the fertility clinic must also 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. It is noted in the published literature that oncologists, haematologists, paediatricians and other specialists who treat patients with serious, life-threatening diseases are aware of referring their patients to a fertility preservation consultation before starting chemotherapy or other treatment with the risk of inducing egg loss, and if if there is time and the patient wants it, a fertility-preserving treatment can be initiated. At consultation the different options are discussed with the patient including ovarian stimulation with cryopreservation of mature oocytes, excision, and cryopreservation of ovarian tissue or doing nothing.
France ▪ Courbière et al.[72] ▪ Martinet et al.[48] ▪ Public Health Code: Title IV: Medically assisted procreation (Articles L2141-1 to L2143-9)[107]	Under the Public Health Code, the collection and storage of gametes or tissues 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 is provided on the conditions, risks and limits of the procedure and its consequences. The main objectives of the recommendations of the National Cancer Institute (INCa) are to promote the provision of information on fertility risks and fertility preservation possibilities for all patients concerned, in order to enable them to make an informed choice, and to improve the quality of the medical service provided to patients in order to reduce inequalities in care. The decree of 30 June 2017 on the rules of good clinical and biological practice for ART specifies that "any person whose subsequent fertility is likely to be impaired, due to a pathology or its treatments, or whose fertility is likely to be prematurely impaired, has access to information concerning the risks to his or her subsequent fertility and the possibilities of preserving gametes or germinal tissue. Fair, clear and appropriate information allows the patient to become an actor in his or her care." In current clinical practice in France, during a consultation prior to cancer treatment, the oncologist must inform the patient about the gonadotoxicity of chemotherapies and must propose a consultation in a specialised centre to discuss fertility preservation feasibility. During

Country Relevant documents	Communication and information
	this consultation, the gynaecologist assesses the patient's ovarian reserve, explains the impact of the treatments on fertility and presents the diferent possible preservation techniques. Then the gynaecologist registers the patient for a multidisciplinary team meeting where the physicians validate the indication for preservation and then the technique used.
Germany ▪ German Medical Association (BAK). Directive for the removal and transfer of human germ cells or germ cell tissue in the context of assisted reproduction, detailed update(111) ▪ Federal Joint Committee (G-BA). Directive 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)(19) ▪ G-BA: Cryopreservation of ovarian tissue becomes a health insurance benefit(114) ▪ G-BA: Cryopreservation(112) ▪ Reasons for the decision of the Federal Joint Committee to amend the guidelines on cryopreservation: Cryopreservation of germ cell tissue(115)	**Requirements for the collection and transfer of human germ cells or germ cell tissue** ***Legal requirements for information and education prior to the removal and transfer of human germ cells or germ cell tissue*** Germ cells or germ cell tissue are subject to the scope of the Transplantation Act, 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. 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 intervention. *Expendability of information* The information may be expendable [non-essential] under the strict conditions set out in the German Civil Code. According to case law, expendability is also recognised 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. The economic information obligation in 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 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. ***Findings on the content of information and explanation required from a medical point of view*** *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:

Country Relevant documents	Communication and information
	▪ **Regarding the "purpose and type of procedure":** causes of infertility; possibility of becoming pregnant without assisted reproduction measures; determination of the maximum number of embryos to be transferred at one time (further information in Appendix D, Table D.26) ▪ **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 (further information in Appendix D, Table D.26) ▪ **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 (further information in Appendix D, Table D.26) ▪ **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 (further information in Appendix D, Table D.26) ▪ **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 (further information in Appendix D, Table D.26) ▪ **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 (further information in Appendix D, Table D.26) ▪ **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; fostering (further information in Appendix D, Table D.26) ▪ **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 behaviour-related fertility disorder (e.g. disordered eating behavior, high-performance sport, abuse

Country Relevant documents	Communication and information
	of stimulants and drugs, no sexual intercourse on fertile days, non-organic sexual dysfunction) (further information in Appendix D, Table D.26). ***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*** 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 standardised 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 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. 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. 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. 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:

Country Relevant documents	Communication and information
	▪ 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 (further information in Appendix D, Table D.26) 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 standardised methods have been established in clinical use at present, ▪ completely different, established lab protocols for cryopreservation, which differ from the cryopreservation of mature sperm or mature germ cell tissue (further information Appendix D, Table D.26). **Consultation** A consultation 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, 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. **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.
Portugal ▪ CNPMA: Requirement and parameters- Operation of the medically assisted procreation techniques centres[126] ▪ Medically assisted procreation: Law No.32/2006 (Consolidated Legislation)[120] ▪ Medically assisted procreation: Law No.17/2016 (Amendment)[121]	**Information and consent** ▪ Centres 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. **Consent is outlined in Law No.32/2006:**

Country Relevant documents	Communication and information
▪ Portuguese Society for Reproductive Medicine: Preservation of fertility in oncological patients[124] ▪ ACSS Review of Exemption Categories and Update Values of Moderator Fees[125] ▪ Melo et al.[51]	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 CNPMA, 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. Portuguese guidelines recommend that, before the infertility-inducing cancer treatment, all cancer patients of reproductive age should be fully informed about the cancer-related infertility risk and of possible fertility preservation options, and that they should be referred to fertility specialists to make a decision about FP. These are also the recommendations of the Portuguese guidelines for oncologists about fertility preservation in adults with cancer. It is important to note that in Portugal, the fertility specialists that consult female cancer patients regarding their fertility preservation are doctors with the clinical specialty in gynaecology and a subspecialisation in reproductive medicine.
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[88] ▪ Measures to preserve reproductive capacity in adults: promotion of equal care for patients at risk of treatment induced infertility[89]	**Information about alternative pathways to parenthood 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, e.g. 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. **To inform the patient:** ▪ It is important that the patient (and their parent where applicable) 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. *Specific to younger patients:* ▪ The information for the young patient must be age-appropriate.

Country Relevant documents	Communication and information
	▪ 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 brochures are provided for both men (Freeze your sperm elderly) and women (Freeze your eggs younger), and younger boys (Freeze your sperm (younger)) and girls (Freeze your eggs (younger)).[196] **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.
UK ▪ NICE (CG156) Fertility problems: assessment and treatment[127]	**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.

Country Relevant documents	Communication and information
▪ NICE (NG73) Endometriosis: diagnosis and management[128] ▪ NICE Quality Standard (QS73): Fertility problems[129] ▪ NICE Interventional procedures guidance: Removal, preservation and reimplantation of ovarian tissue for restoring fertility after gonadotoxic treatment[130]	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.[195] 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.[195] 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.[195]
England ▪ NHS Bedfordshire, Luton and Milton Keynes Integrated Care Board (ICB). Gamete (sperm/egg) storage for those undergoing fertility-threatening treatment[139] ▪ NHS Coventry and Warwickshire ICB. NHS Funded Cryopreservation of Gametes and Embryos Policy[141] ▪ National Health Service (NHS) England. Service specifications: fertility preservation and restoration[131] Service specification and equality and health inequalities impact assessment documents for:	A number of information provisions are outlined for the selected ICB policies and also within NHS England tissue cryopreservation service specifications, including: ▪ 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 ▪ 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 ▪ females preparing for medical treatment that is likely to impact their fertility 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. Specific to Hubs, they should: ▪ 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 PPR. ▪ 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. Specific to the Spoke Centre, they: ▪ will ensure that all service users have fertility risk discussed and recorded as part of the primary treatment planning MDT.

Country Relevant documents	Communication and information
○ Fertility preservation for service users with ovarian tissue who are at high/very high risk of infertility and cannot store mature eggs[132] ○ Fertility preservation for service users with testicular tissue who are at high/very high risk of infertility and cannot store sperm[134] ▪ NHS Somerset ICB. Fertility assessment and treatment prior approval policy[155] ▪ NHS West Yorkshire ICB. Cryopreservation for both men and women where the usual fertility policy does not apply[142]	▪ 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.
Northern Ireland	See Appendix C, Table C.7 for information regarding fertility counselling.
Scotland ▪ NHS Inform: Fertility and Cancer[165] ▪ NHS Scotland: Endocrine and Fertility Preservation Guidance[162]	**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. **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. 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

Country Relevant documents	Communication and information
	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. **For people accessing gender identity services:** 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) 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 outside the knowledge of staff at the gender identity clinic, but such staff should have sufficient knowledge to be able to provide initial information, and signpost patients to further information. 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. Patient information leaflets in line with this guidance are available for sperm and egg storage. Information is available from the HFEA website including information specific for transgender, non binary and gender diverse people.
Wales ▪ Wales Fertility Institute[171] ▪ Wales Fertility Institute: Fertility Preservation for Trans and Gender Diverse People - Information for patients[173]	Within the Wales Fertility Institute (WFI), 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. In regards to children and young people with cancer, these patients 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.[170] In regards to those undergoing gender affirmative treatments, a brochure from the WFI is provided to those looking for information. Additionally, the offer of counselling forms part of the process of fertility preservation and treatment.

Key: ART – assisted reproductive technology; BAK – Medical Association (Germany); CNPMA – National Council for Medically Assisted Procreation (Portugal); DH – Designated Hospitals; ESHRE – European Society of Human Reproduction and Embryology; G-BA – Federal Joint Committee (Germany); GP – General Practice; HFEA – Human Fertilisation and Embryology Authority; ICB – Integrated Care Board; ICSI – Intracytoplasmic sperm injection; IVF – In Vitro Fertilisation; MDT – Multidisciplanary team; NHS – National Health Service; NICE – National Institute for Health and Care Excellence; PMA – Medically Assisted Procreation (Portugal); PPR – parents/person with parental responsibility; PTC – Principal treatment centres; TESE – Testicular Sperm Extraction; TYA – Teenage and Young Adult.

Table C.7 Summary of ethical considerations identified for publicly-funded fertility preservation services for medical reasons in selected countries

Country Relevant documents	Ethical Considerations
Australia ▪ National Health and Medical Research Council (NHMRC): Ethical guidelines on the use of assisted reproductive technology in clinical practice and research[92] ▪ Allan et al.[30]	The NHMRC National 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. Adherence to the NHMRC Ethical Guidelines is required as a condition for accreditation for fertility clinics across the country. However, if the guidelines are inconsistent with statute or common law ruling, the legislation and or common law rules would prevail. The following guiding principles and their application are outlined (See Appendix D, Table D.2 for further detail): **1.**ART activities must be conducted in a way that shows respect to all involved. **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. **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. **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. **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. **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. **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. **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 **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. *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.

Country Relevant documents	Ethical Considerations
	Specific to children and young people (Until a child reaches 18 years of age in all States/Territories except South Australia which recognises medical decision-making capacity for children above the age of 16 years) **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. Additionally, a child may consent to their own health care/medical procedures and treatment if they demonstrate "Gillick competence". Such competence is not decided upon by the age of the child, but rather by evaluating whether he/she demonstrates sufficient understanding and intelligence to consent to health care treatment themselves. *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 of paragraph 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

Country Relevant documents	Ethical Considerations
	▪ 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 ▪ certain conditions in relation to allowing sufficient time before attempting conception and or pregnancy are satisfied.
Denmark ▪ Council of Ethics: Storage of fertilised eggs and unfertilised egg cells[103] ▪ Executive Order on the Act on Assisted Reproduction in Connection with Treatment, Diagnostics and Research, etc. (LBK no. 902 of 23/08/2019)[99] ▪ New political agreement lifts 5-year limit for freezing eggs (Press Release)[102] ▪ Executive Order on Assisted Reproduction (BEK no. 672 of 08/05/2015)[17] ▪ Guidance on the activities and obligations of healthcare professionals and tissue establishments in the field of assisted reproduction[17]	**The Council's recommendations** As a basis for their recommendation to extend the storage period for fertilised and unfertilised egg cells, the members put particular emphasis on 3 considerations: **1.**They 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. **2.**They 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. **3.**They 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. 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 subsequently formed 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

Country Relevant documents	Ethical Considerations
	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. A number of Danish documents also place an emphasis on the provision of information and gaining informed consent. Examples related specifically to fertility preservation include: ▪ 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 ▪ assisted reproduction 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 ▪ 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 for assisted reproduction treatment, which may be made conditional ▪ 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 ▪ 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. 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.
France ▪ Biomedicine Agency: Self-preservation of gametes[104, 105] ▪ Biomedicine Agency: What does the law say[106] ▪ Public Health Code: Title IV: Medically assisted procreation (Articles R2141-1 to R2143-20)[108]	**What is the 2021 Bioethics Law that governs ART?** The law of 2 August 2021 amends the legal provisions of assisted reproductive technology (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 third-party donor. **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. **A number of ethical considerations are also outlined within the Public Health Code, most notably:** ▪ 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

Country Relevant documents	Ethical Considerations
	inclusion of processes on this list. The criteria relate in particular to compliance with the fundamental principles of bioethics provided for the efficacy, the reproducibility of the process and the safety of its use for the woman and the unborn child. ▪ The collection and storage 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. ▪ The modification of the designation of sex in the civil registry shall not prevent the application of this article.
Germany ▪ German Medical Association. Directive for the removal and transfer of human germ cells or germ cell tissue in the context of assisted reproduction, detailed update(111) ▪ Fertility preservation: German Medical Association (BAK) presents revised guideline(118) ▪ Examination according to § 94 SGB V by the BMG(116) ▪ Federal Joint Committee (G-BA). Directive 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)(19) ▪ G-BA: Cryopreservation of ovarian tissue becomes a health insurance benefit(114) ▪ G-BA: Cryopreservation(112) ▪ Federal Joint Committee (G-BA) Reasons for the decision of the Federal Joint Committee to amend the guidelines on cryopreservation: Cryopreservation of germ cell tissue(115)	***Findings on the content of information and explanation required from a medical point of view*** *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 (i.e. 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. **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. ▪ 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 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 German Civil Code 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". **Requirements for eligibility for cryopreservation and evidence in prepubertal children** The G-BA has not made a decision for very young girls who have not yet started their menstrual period, and therefore the cyropreservation of germ cell tissue in this group is not yet a service. 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. A benefit-harm assessment for prepubertal girls is not possible on the basis of the

Country Relevant documents	Ethical Considerations
	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. 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. **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 - psyche.
Portugal ▪ Medically assisted procreation: Law No.32/2006 (Consolidated Legislation)[120] ▪ Medically assisted procreation: Law No.17/2016 (Amendment)[121] ▪ Regulatory Decree No. 06/2016[123]	**A number of ethical considerations are outlined including:** *Dignity and non-discrimination* ▪ PMA techniques, including those carried out in surrogacy situations, must respect the human dignity of all people involved ▪ Discrimination based on genetic heritage or the fact of being born because of the use of PMA techniques is prohibited. Within Law No.32/2006 a number of ethical considerations are also outlined: *Beneficiary rights (Article 12):* ▪ 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 ▪ be assisted in a suitable medical environment that has all the material and human conditions required for the correct execution of the recommended technique ▪ be correctly informed about the likely medical, social and legal implications of the proposed treatments ▪ know the reasons that motivate the refusal of PMA techniques ▪ be informed of the conditions under which it would be possible for them to resort to adoption and the social relevance of this institute.

Country Relevant documents	Ethical Considerations
	Medical decision and conscientious objection (Article 11): ▪ 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 ▪ 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 ▪ the professional's refusal must specify the clinical or other reasons that motivate it, namely conscientious objection. *Duties of beneficiaries (Article 13):* ▪ The duties of the beneficiaries are: - 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 - strictly observe all the prescriptions of the medical team, both during the diagnosis phase and during the different stages of the ART process - 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. Additionally, 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.
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[88] ▪ Measures to preserve reproductive capacity in adults: promotion of equal care for patients at risk of treatment induced infertility[89] ▪ Rodriguez-Wallberg et al.[64] ▪ Rodriguez-Wallberg[79]	The following ethical considerations apply to both young people and adults: 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. ***Ethical considerations specific to minors*** Since it concerns a minor, 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

Country Relevant documents	Ethical Considerations
	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. It was also noted in the published literature that for transgender patients contextual sensitivity during fertility preservation procedures is important, and health-care providers should have knowledge of transgender patients' vulnerable situation in connection to fertility preservation. With that knowledge, providers can help to reduce distress through their actions, or at least not increase it. It was also noted that an increasing number of women in committed relationships have chosen to cryopreserve unfertilised oocytes, which is important as it provides autonomy to the women.
UK ▪ NICE (CG156) Fertility problems: assessment and treatment[127] ▪ 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[195] ▪ NICE NG73 Endometriosis: diagnosis and management[128] ▪ NICE Quality Standard (QS73): Fertility problems[129] ▪ NICE Interventional procedures guidance: Removal, preservation and reimplantation of ovarian tissue for restoring fertility after gonadotoxic treatment[130] ▪ Netwon et al.[53]	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. Additionally, it was noted that 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][129] It is also noted within the published literature that in the absence of centralised NHS funding, inequality in regards to access to fertility preservation funding may occur.
England ▪ National Health Service (NHS) England. Service specifications: fertility preservation and restoration[131]	ICB policies indicate that consent must be obtained for treatment and gamete storage. Additionally, the Coventry and Warwickshire ICB policy contains a Quality and Equality Impact Assessment. **Quality and Equality Impact Assessment** [Outcome assessment (Positive, Negative or Neutral) applied to each domain]

Country Relevant documents	Ethical Considerations
Equality and health inequalities impact assessment documents for: ○ Fertility preservation for service users with ovarian tissue who are at high/very high risk of infertility and cannot store mature eggs[132] ○ Fertility preservation for service users with testicular tissue who are at high/very high risk of infertility and cannot store sperm[134] ▪ NHS Coventry and Warwickshire ICB. NHS Funded Cryopreservation of Gametes and Embryos Policy[141] ▪ Latif et al.[45] ▪ Newton et al.[53]	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.

Country Relevant documents	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 PPR who will provide consent on behalf of the patient. The consent from the PPR 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. Similar Equality and Health Inequalities Assessments are conducted for fertility preservations service specifications: **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 ovarian tissue. ○ 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**: Fertlity preservation treatment would not be required in pregnancy and maternity settings. ▪ **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.

Country Relevant documents	Ethical Considerations
	▪ **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 will be able to access the service irrespective of their living arrangements. ○ Staff should be familiar with the NICE guideline that covers providing integrated health and social care services for people.[280] 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 ovarian 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 ovarian 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.

Country Relevant documents	Ethical Considerations
	○ 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 ovarian 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 ovarian 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.(281) In August 2018, the Equality and Human Rights Commission initiated a judicial review, challenging NHS England's failure to offer fertility preservation to the transgender population. The case was subsequently dropped when NHS England agreed to issue guidance to all CCGs about their responsibility to commission fertility preservation services, outlining that any refusal would require strong justification and would be challenged in court. Additionally, it is noted within the published literature that in the absence of central NHS funding arrangements, there is the potential for inequality and significant variation in service provision across the UK for young people with cancer who may be at risk of future long-term subfertility. The reliance on charitable sources, particularly for ovarian and testicular tissue cryopreservation, may lead to restrictions in access. Patients may be disadvantaged in the future without robust centralised funding, with the presented data identifying that service users in England may be more susceptible to this than residents of the Devolved Nations of the UK.
Northern Ireland ▪ Belfast HSC Trust. Regional Fertility Centre(161) ▪ Department of Health (DoH) Northern Ireland relevant endorsed National Institute for Health and Care Excellence (NICE) guidelines, according to Circular Health and Social Care (HSC) (SQSD) 3/13:(157) Fertility problems: assessment and treatment (CG156)(127) ▪ DoH endorsement(158) ▪ Additional Caveats for CG156(159) Endometriosis: diagnosis and management(128) DoH endorsement(160)	**A number of ethical considerations are outlined in regards to storage of sperm, eggs or embryos and providing consent:** *Making the decision to renew my consent:* 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

Country Relevant documents	Ethical Considerations
	▪ 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. **Further ethical considerations outlined:** **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 Regional Fertility Centre (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)).
Scotland ▪ NHS Inform: Fertility and Cancer[165]	**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.
Wales ▪ Wales Fertility Institute[171] ▪ Wales Fertility Institute: Fertility Preservation for Trans and Gender Diverse People - Information for patients[173] ▪ Wales Fertility Institute: Sperm Freezing[172] ▪ Specialised Services Service Specification: CP79 Haematopoietic stem cell transplantation for adults[183] ▪ Specialised Services Policy Position PP142 Haematopoietic Stem Cell Transplantation (HSCT) for Adults[182] ▪ Specialised Services Service Specification: Services for Children with Cancer (CP86)[170]	A number of ethical considerations are outlined including: ▪ When banking sperm the patient will find out more about their potential fertility. In the event of the lab finding no sperm in a sample, they will be unable to store. The lab 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 you 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. ▪ 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 lab 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 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.

Country Relevant documents	Ethical Considerations
	Additionally it is outlined that at NHS Wales all staff undertake mandatory training to ensure they are competent in their obligations under equality and human rights law.

Key: ART – assisted reproductive technology; BAK – Medical Association (Germany); BGB – German Civil Code; BMG – Federal Ministry of Health (Germany); DoH – Department of Health; G-BA – Federal Joint Committee (Germany); HFE – Human Fertilisation and Embryology; HTA – Health Technology Assessment; HTCS – Healthcare Travel Costs Scheme; ICB – Integrated Care Board; NHRMC – National Health and Medical Research Council; NHS – National Health Service; NICE – National Institute for Health and Care Excellence; OTC - Ovarian Tissue Cryopreservation; PMA – Medically Assisted Procreation (Portugal); RFC – Regional Fertility Centre; TESE – Testicular Sperm Extraction; TGP – The Transplantation Act (Germany).

Table C.8 Summary of legislation information identified for publicly-funded fertility preservation services for medical reasons in selected countries

Country Relevant documents	Legislation
Australia ▪ National Health and Medical Research Council: Ethical guidelines on the use of assisted reproductive technology in clinical practice and research[92] ▪ Medicare Benefits Schedule Book ▪ Assisted reproductive technology (ART) services[90] (Services Australia)[91] ▪ Stuhmcke and Chandler[69] ▪ Allan and Jayasinghe[30]	The major elements of Medicare are contained in the Health Insurance Act 1973. It is stated that all activities referred to in the Ethical Guidelines must be carried out in compliance with existing laws and regulatory frameworks, such as the Fertility Society of Australia and the Reproductive Technology Accreditation Committee's Code of Practice for Assisted Reproductive Technology Units (RTAC Code). The activities must also comply with relevant professional and accreditation standards. Under the Research Involving Human Embryos Act 2002, embryos can be used or developed only in the course of a woman's reproductive treatment by ART units that have been accredited by the Reproductive Technology Accreditation Committee. It is through the Commonwealth Act that the RTAC Code is given quasi-legislative effect and has become a means of regulating the provision of ART across Australian States and Territories. Only 4 Australian States have legislated on the provision of ART in their jurisdictions: New South Wales, Victoria, South Australia and Western Australia. Of these, just New South Wales, Victoria and Western Australia now impose statutory storage limits on reproductive tissues. In the remaining States and Territories, access to, and the provision of, ART (including how long embryos or gametes may be stored) is regulated by the RTAC accreditation scheme, which mandates adherence to the NHMRC Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (NHMRC Ethical Guidelines). Legislation in governing various aspects of assisted reproduction then varies depending on the State. For example, while provision does exist in the New South Wales and Victorian legislation in relation to obtaining and storing gametes from children, this may not be accounted for in the remaining states.
Denmark ▪ Council of Ethics: Storage of fertilised eggs and unfertilised egg cells[103] ▪ Executive Order on the Act on Assisted Reproduction in Connection with Treatment, Diagnostics and Research, etc. (LBK no. 902 of 23/08/2019)[99] ▪ Executive Order on Assisted Reproduction (BEK no. 672 of 08/05/2015)[17]	Freezing of fertilised and unfertilised 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 trying to conceive without success, if the woman is under 30-35 years of age, and there are no

Country Relevant documents	Legislation
▪ Guidance on the activities and obligations of healthcare professionals and tissue establishments in the field of assisted reproduction[17] ▪ Bach, et al.[31]	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 trying to conceive without success or funded interventions. 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. According to Danish legislation, embryos have to be destoryed if the couple splits up. Further amendments have also been made to the Act on Assisted Reprouction including ▪ LAW No 129 of 30/01/2021 ▪ LBK nr 902 of 23/08/2019 The handling of human tissues and cells is also protected by the Danish Tissue Act.
France ▪ Funding for medically assisted genetic procreation 2023[110] ▪ Biomedicine Agency: Self-preservation of gametes[104, 105] ▪ Biomedicine Agency: What does the law say[106] ▪ Decree No. 2021-1243 of 28 September 2021 setting the conditions for the organisation and coverage of medically assisted reproduction pathways[109] ▪ Public Health Code: Title IV: Medically assisted procreation (Articles L2141-1 to L2143-9)[107] ▪ Public Health Code: Title IV: Medically assisted procreation (Articles R2141-1 to R2143-20)[108] ▪ Agopiantz et al.[29] ▪ Barry et al.[32] ▪ Jourdain et al.[42] ▪ Puy et al.[61]	The latest Bioethics Law, of August 2, 2021 introduces a range of measures affecting different areas of ART, such as the cessation of donor anonymity, access for singles and lesbian couples and allowing egg freezing for non-medical reasons. This included, the law: ▪ set the conditions for the organisation and coverage of medically assisted procreation pathways (specifies the age conditions for carrying out ART and self-preservation of one's gametes) ▪ set the terms and conditions for authorising gamete self-preservation activities for non-medical reasons. The Bioethics law specified that "any couple made up of a man and a woman or 2 women or any unmarried woman have access to medically assisted procreation". It also states that the use of posthumous cryopreserved sperm or embryo transfer is legally banned. It is notable that the new law also limits non-medical egg freezing to the public and not-for-profit hospital sector as well as prohibits companies based in France from offering to subsidise the costs of egg freezing for their employees, a growing trend by companies. Consistent with previous legislation, the principle of non commodification appears to be at the core of the 2021 Bioethics Law. In France, the use of gametes remains limited, but it is very likely that changes in French legislation will make it easier for some transgender people to have recourse to them in the context of medically assisted reproduction in the near future.

Country Relevant documents	Legislation
	This Bioethics Law is supported and or delivered throught the following associated legislation: ▪ Social Security Code ▪ Public Health Code
Germany ▪ German Medical Association. Directive for the removal and transfer of human germ cells or germ cell tissue in the context of assisted reproduction, detailed update[111] ▪ Examination according to § 94 SGB V by the BMG[116] ▪ Federal Joint Committee (G-BA). Directive 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)[19] ▪ G-BA: Cryopreservation of ovarian tissue becomes a health insurance benefit[114] ▪ Reasons for the decision of the Federal Joint Committee to amend the guidelines on cryopreservation: Cryopreservation of germ cell tissue[115] ▪ Rimon-Zarfaty et al.[62] ▪ Hoffmann et al.[40] ▪ Baston-Bust and Bielfeld[82]	In August 2021, the German Social Code (SGB) Fifth Book (V) – Statutory Health Insurance was amended. With the TSVG (Appointment Service and Supply Act), the entitlement of public health insurance funding in case of artifcial insemination was expanded to include the cryopreservation of gamete cells and tissue in cases of threatened fertility due to disease or germ cell damaging treatments. Further legislation associated with fertility preservation include: ▪ Transplantation Act (TPG) ▪ TPG Tissue Ordinance (TPG-GewV) ▪ Medicines Act (AMG): In Germany, approval under the Medicines Act is a mandatory requirement for cryopreserving sperm and testicular tissue ▪ Medicinal Products and Active Substances Manufacturing Ordinance (AMWHV) ▪ Law on the Quality and Safety of Human Tissues and Cells (Tissue Law)
Portugal ▪ Medically assisted procreation: Law No.32/2006 (Consolidated Legislation)[120] ▪ Medically assisted procreation: Law No.17/2016 (Amendment)[121] ▪ Regulatory Decree No. 06/2016[123] ▪ ACSS Review of Exemption Categories and Update Values of Moderator Fees[125] ▪ CNPMA: Requirement and parameters- Operation of the medically assisted procreation techniques centres[126]	The following legislation has been identified as relevant to the area of fertility preservation: ▪ Law no. 32/2006 – regulates the use of medically assisted procreation (ART) techniques and established the CNPMA ▪ Law no. 17/2016 – broadened the scope of the beneficiaries of ART ▪ Law no. 12/2009 – outlines procedures for verifying the equivalence of quality standards and safety of imported tissues and cells, including gametes, gonadal tissue and embryos
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[88] ▪ Measures to preserve reproductive capacity in adults: promotion of equal care for patients at risk of treatment induced infertility[89] ▪ Mattelin et al.[49] ▪ Payne and Erbenius[60] ▪ Rodriguez-Wallberg[80]	The following legislation were identified as relevant to the governing of self-donation of germ cells and tissue. ▪ Act (2006:351) on genetic integrity ▪ 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 ▪ 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)

Country Relevant documents	Legislation
	▪ Regulations and general advice on the use of tissues and cells in health and healthcare and clinical research (SOSFS 2009:32) Of note, in 2013 there was a change in Swedish law (2013:405) with sterilisation no longer a compulsory part of gender affirmation treatment. This change enabled transgender individuals seeking gender-affirming treatment to undergo fertility preservation and preserve their gametes for future reproductive possibilities, under the tax-financed healthcare. In 2019, a change in the law occurred regarding extended frozen storage time for embryos (10 years), and donation of embryos and double donation (both egg and sperm).
UK ▪ NICE (CG156) Fertility problems: assessment and treatment[127] ▪ NICE (NG73) Endometriosis: diagnosis and management[128] ▪ NICE Quality Standard (QS73): Fertility problems[129] ▪ NICE Interventional procedures guidance: Removal, preservation and reimplantation of ovarian tissue for restoring fertility after gonadotoxic treatment[130]	In the UK, the Human Fertilisation and Embryology Act 1990 was amended in July 2022, to increase the statutory storage limits for eggs, sperm, and embryos for everyone, regardless of medical need, to 10-year renewable storage periods, with a maximum limit of 55 years.
England ▪ NHS Bedfordshire, Luton and Milton Keynes Integrated Care Board (ICB). Gamete (sperm/egg) storage for those undergoing fertility-threatening treatment[139] ▪ NHS Coventry and Warwickshire ICB. NHS Funded Cryopreservation of Gametes and Embryos Policy[141] ▪ National Health Service (NHS) England. Service specifications: fertility preservation and restoration[131] Service specification and equality and health inequalities impact assessment documents for: ○ Fertility preservation for service users with ovarian tissue who are at high/very high risk of infertility and cannot store mature eggs[132] ○ Fertility preservation for service users with testicular tissue who are at high/very high risk of infertility and cannot store sperm[134] ▪ NHS South West London ICB. Evidence-based interventions policy[140]	In England, as in all UK countries, cryopreservation of gametes or embryos must meet the current legislative standards as set by the Human Fertilisation and Embryology Act 1990. This includes that both partners must be aware of the legal position regarding embryos that 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. Further legislation also identified as relevant to fertility preservation include: ▪ Human Tissue Authority Regulations ▪ United Kingdom Data Protection Action (UKDPA) regulations ▪ General Medical Council (GMC) regulations ▪ Health & Social Care Act 2022
Northern Ireland Department of Health (DoH) Northern Ireland relevant endorsed National Institute for Health and Care Excellence (NICE) guidelines, according to Circular Health and Social Care (HSC) (SQSD) 3/13:[157] Fertility problems: assessment and treatment (CG156)[127] ▪ DoH endorsement[158]	The following legislation were identified as relevant to fertility preservation: ▪ Health and Care Act 2022 ▪ Human Fertilisation and Embryology Act 1990 ▪ Health, Social Services and Public Safety (Quality, Improvement and Regulation) (NI) Order 2003

Country Relevant documents	Legislation
▪ Additional Caveats for CG156[159] Endometriosis: diagnosis and management[128] ▪ DoH endorsement[160]	
Scotland	While no specific legislation was outlined in the documents identified, as a part of the UK, the following legislation is fully or partially applicable (parts of the legislation may be adapted based on each territory within the UK): ▪ Human Fertilisation and Embryology Act 1990 ▪ Health and Care Act 2022.
Wales	While no specific legislation was outlined in the documents identified, as a part of the UK, the following legislation is fully or partially applicable (parts of the legislation may be adapted based on each territory within the UK): ▪ Human Fertilisation and Embryology Act 1990 ▪ Health and Care Act 2022.

Key: ACSS – Central Health Administration system (Portugal); ART – assisted reproductive technology; CNPMA – National Council for Medically Assisted Procreation (Portugal); DoH – Department of Health; GMC – General Medical Council; ICB – Integrated Care Board; IVF – In Vitro Fertilisation; NHMRC – National Health and Medical Research Council; NHS – National Health Service; NI – Northern Ireland; NICE – National Institute for Health and Care Excellence; UK – United Kingdom; UKDPA – United Kingdom Data Protection Action; SFS – Swedish Code of Statutes; SOSFS – National Board of Health and Welfare Code (Sweden); RTAC – Reproductive Technology Accreditation Committee.

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