



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Protocol for 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 (HIQA)

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.
- **Regulating health services** — Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of permanent international protection accommodation service centres, health services and children’s social services against the national standards. Where necessary, HIQA investigates serious concerns about the health and welfare of people who use health services and children’s social services.
- **Health technology assessment** — Evaluating the clinical and cost effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland’s health and social care services.
- **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.

Visit www.hiqa.ie for more information.

1. Purpose and Aim

The purpose of this protocol is to outline the process by which the Health Information and Quality Authority (HIQA) will conduct a scoping review of publicly-funded services for fertility preservation for medical reasons in selected countries. The information contained in the review will inform the development of national fertility preservation policy in Ireland, through supporting the work of the Department of Health.

2. Process outline

It is important that a standardised approach to the process is developed and documented, to allow for transparency, aid project management and to mitigate risks.

Four distinct steps in the process have been identified and will be completed. These are listed below and described in more detail in sections 2.1-2.4:

1. Defining the scope
2. Searching for and selecting relevant international sources
3. Extracting relevant information on publicly-funded services for fertility preservation
4. Summarising findings.

2.2. Defining the scope

Fertility preservation is “the process of saving or protecting eggs, sperm, or reproductive tissue so that a person can use them to have biological children in the future”.⁽¹⁾ People may elect to undergo fertility preservation if they are at risk of infertility for either non-medical or medical reasons. Non-medical reasons include delayed childbearing due to personal reasons.⁽²⁾ Medical reasons include the presence of a medical condition, such as Turner syndrome, or undergoing medical or surgical treatment, such as chemotherapy treatment for cancer.⁽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. In Europe, fertility preservation for non-medical reasons is generally conducted within the private healthcare system, with the cost incurred by the patient. However, many countries in Europe (including Ireland,⁽³⁾ England⁽⁴⁾ and Germany⁽⁵⁾) provide some form of publicly-funded services for fertility preservation for medical reasons,^(6, 7) although

access to these services is restricted. This review will focus on publicly-funded fertility preservation services for medical reasons. As medical technologies and research within the field of fertility preservation continue to advance,⁽⁸⁻¹⁰⁾ all identified methods of fertility preservation provided by public funding will be included in this review, including cryopreservation of gametes (sperm or eggs), tissues (testicular or ovarian tissue) and or embryos.

2.3. Searching for and selecting relevant international sources

A scoping review will be conducted to identify information on publicly-funded services for fertility preservation in a selected group of countries. The following research question will be addressed by this review:

- *Within a selected group of countries, what current national policies and practices are in place with respect to publicly-funded fertility preservation services for medical reasons?*

A scoping review can be defined as 'a form of knowledge synthesis that addresses an exploratory research question aimed at mapping key concepts, types of evidence, and gaps in research related to a defined area or field by systematically searching, selecting, and synthesizing existing knowledge'.⁽¹¹⁾ The review will be conducted in line with the methodological approach to scoping reviews described in the JBI Manual for Evidence Synthesis.⁽¹²⁾ A scoping review methodology was chosen to address the research question as this enables a systematic yet flexible and iterative approach to exploring themes and concepts across heterogeneous literature.^(13, 14)

A literature search will be conducted in Medline Complete via EBSCOhost and Embase via Ovid. The search strategies are presented in Appendix 1. Grey literature sources will also be searched, with a particular emphasis on government resources (such as websites, reports and press releases) for the chosen countries. The grey literature sources that will be searched are detailed in Appendix 2. This list is not exhaustive and will be expanded as necessary, should information on publicly-funded fertility preservation services be available elsewhere. Additional search methods used will include forward citation searching of eligible studies and searching reference lists of identified systematic reviews and included studies. Preliminary scoping showed that the majority of national fertility preservation policies and services were developed or updated within the last 10 years. As such, searches will be limited to a 10-year period from January 2014 to July 2024, to reflect this and advances in fertility preservation research and technologies in the last decade.

The population, concept, context (PCC) and types of evidence sources for this review are summarised in Table 2.1.

Table 2.1 Population, concept, context and types of evidence sources for scoping review of fertility preservation services for medical reasons in selected countries

Population	People undergoing fertility preservation for medical reasons, including children, adolescents and adults.
Concept	Fertility preservation services, including cryopreservation of gametes, tissues and or embryos, available through public sector providers, or through private or voluntary sector providers that are in receipt of public funding.
Context	<p>The following countries have been selected for inclusion:</p> <p>EU</p> <ul style="list-style-type: none"> ▪ Denmark ▪ France ▪ Germany ▪ Portugal ▪ Sweden <p>Non-EU</p> <ul style="list-style-type: none"> ▪ Australia ▪ England ▪ Northern Ireland ▪ Scotland ▪ Wales.
Types of evidence sources	<p>Empirical evidence (all study designs) from the following document types:</p> <ul style="list-style-type: none"> ▪ reports ▪ evaluations ▪ peer-reviewed publications. <p>Grey literature sources will include the following document types:</p> <ul style="list-style-type: none"> ▪ policies and procedures ▪ press releases ▪ legislation and other legal documents.

Guidelines endorsed or developed by government agencies, and implemented as part of national policy.

Key: EU – European Union.

The countries outlined in Table 2.1 were selected to include a combination of EU and non-EU countries, and on the basis of 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 policy.

For data management purposes, the results of the search will be exported to Covidence (www.covidence.org). Two reviewers will independently review the titles and abstracts, and subsequently the full texts, of the identified records. Those that meet the inclusion criteria for this scoping review (as per Table 2.2) will be included. Inclusion will be limited to current policies and practices in relation to fertility preservation services for medical reasons; recommendations for alternative policies and practices will be excluded. Any disagreement regarding the eligibility of documents will be resolved through discussion, and using a third reviewer where necessary.

Table 2.2 Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> ▪ Information pertaining to current policy and practice in relation to publicly-funded services for fertility preservation for medical reasons. ▪ Any method of fertility preservation available to males and females, and children, adolescents and adults. 	<ul style="list-style-type: none"> ▪ 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, such as <i>Getting IVF and other specialist treatment through the HSE⁽¹⁵⁾</i> and the NHS <i>Fertility and endocrine restoration using cryopreserved ovarian tissue.⁽¹⁶⁾</i> However, if information on publicly-funded fertility treatments, such as in vitro fertilisation (IVF) or

	<p>intrauterine insemination (IUI), is provided within fertility preservation documents, this is considered in scope.</p> <ul style="list-style-type: none">▪ For countries that operate regionally, such as Australia, information on publicly-funded fertility preservation services that are specific to an individual state or territory only, for example, Western Australia.⁽¹⁷⁾▪ Guidelines not implemented as part of national policy.
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2.4. Extracting relevant information on publicly-funded services for fertility preservation for medical reasons in selected countries

The review will extract relevant information on publicly-funded services for fertility preservation from both academic and grey literature sources, as outlined in Section 2.3. Within the identified documents, relevant information may include, but is not limited to:

- eligibility and or criteria for access (for example, information on age thresholds, medical conditions and or treatments included, and referral requirements)
- 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, subsequent access to and or disposal of stored materials)
- governance (for example, organisational structures and governance arrangements, clinical governance, and relevant regulatory bodies)
- funding (for example, funding sources, aspects of services that are fully or partially funded, and information on any payments or co-payments required by individuals)

- communication and information (for example, availability of appropriate information on fertility preservation options for relevant populations, and supports to access and understand information, where required)
- ethical considerations (for example, equity, potential benefits and harms of fertility preservation interventions in certain populations, and supports to promote informed decision-making and consent)
- 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). Relevant information will be extracted from legislation that is currently in force only; aspects of legislation that have been repealed or amended will not be included.

Data extraction will be performed by one reviewer and cross checked by another. A data extraction tool will be developed and piloted before implementing. A sample data extraction template is outlined in Appendix 3.

As this is a scoping review aiming to provide an overview of current policy and practice, no quality appraisal will be undertaken. Google Translate, DeepL Pro or similar will be used to obtain translations of non-English language documents, where appropriate. When screening grey literature documents, particular attention will be given to the reliability of the source of the document to minimise the risk that the included data do not accurately represent implemented pathways. Where sources are considered less reliable, this will be noted, and confirmation of the information may be sought from additional sources. For example, information regarding a national policy in a blog post may be confirmed from a government resource. Representatives from the selected countries will be contacted for confirmation of included key documents and to identify additional resources, as appropriate.

Any changes to the approach outlined in this document will be noted in the report as a protocol deviation.

2.5. Summarising findings

Information on publicly-funded services for fertility preservation, where available for the included countries, will be documented and presented. Information extracted from documents identified, as outlined in Section 2.3, will be compared across the selected countries, and similar and contrasting elements will be presented descriptively. This scoping review will be reported in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist.⁽¹⁸⁾

3. Quality assurance process

The review question will be undertaken in accordance with HIQA's HTA Directorate Quality Assurance Framework and led by an experienced member of the team. Data extraction for each country will be carried out by one reviewer and checked by a second reviewer for inaccuracies. The report will be reviewed by at least two members of the senior management team to ensure processes are followed and quality is maintained. To further ensure quality and accurate interpretation of the information included, an Expert Advisory Group of relevant national and, where possible, international experts in the field of fertility preservation will be constituted. Input from this group will be sought as appropriate, and a draft of the protocol and report will be circulated to them for review.

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Appendix 1. Search strategies: Information on publicly-funded services for fertility preservation for medical reasons in selected countries

Database: Medline Complete			
#	Query	Limiters/Expanders	Results
S17	S10 OR S15	Limiters - Publication Date: 20140101-20241231 Expanders - Apply equivalent subjects Search modes - Proximity	1,012
S16	S10 OR S15	Expanders - Apply equivalent subjects Search modes - Proximity	2,123
S15	S6 AND S14	Expanders - Apply equivalent subjects Search modes - Proximity	2,074
S14	S11 OR S12 OR S13	Expanders - Apply equivalent subjects Search modes - Proximity	1,440,267
S13	AB (britain OR (British NOT "British Columbia") OR "UK" OR "U.K." OR "United Kingdom" OR (England* NOT "New England") OR "northern ireland" OR "northern irish" OR scotland OR scottish OR welsh OR wales) OR TI (britain OR (British NOT "British Columbia") OR "UK" OR "U.K." OR "United Kingdom" OR (England* NOT "New England") OR "northern ireland" OR "northern irish" OR scotland OR scottish OR welsh OR wales)	Expanders - Apply equivalent subjects Search modes - Proximity	332,007
S12	AB (denmark OR danish OR france OR french OR german OR germany OR portugal OR portuguese OR Sweden OR Swedish OR Australia*) OR TI (denmark OR danish OR france OR french OR german OR germany OR portugal OR portuguese OR Sweden OR Swedish OR Australia*)	Expanders - Apply equivalent subjects Search modes - Proximity	661,690

S11	(MH "Australia+") OR (MH "Denmark+") OR (MH "Germany+") OR (MH "France+") OR (MH "Sweden") OR (MH "Portugal") OR (MH "United Kingdom+")	Expanders - Apply equivalent subjects Search modes - Proximity	953,286
S10	S6 AND S9	Expanders - Apply equivalent subjects Search modes - Proximity	81
S9	S7 OR S8	Expanders - Apply equivalent subjects Search modes - Proximity	150,305
S8	AB (public OR publicly) N3 (fund* OR reimbursement* OR service* OR system*) OR TI (public OR publicly) N3 (fund* OR reimbursement* OR service* OR system*))	Expanders - Apply equivalent subjects Search modes - Proximity	54,278
S7	(MH "National Health Programs+")	Expanders - Apply equivalent subjects Search modes - Proximity	98,218
S6	S1 OR S2 OR S3 OR S4 OR S5	Expanders - Apply equivalent subjects Search modes - Proximity	63,233
S5	AB ((freez* OR cyropreserv* OR preserv*) N2 (egg OR sperm)) OR TI ((freez* OR cyropreserv* OR preserv*) N2 (egg OR sperm))	Expanders - Apply equivalent subjects Search modes - Proximity	2,676
S4	AB (cryopreserv* OR cryoconserv*) OR TI (cryopreserv* OR cryoconserv*)	Expanders - Apply equivalent subjects Search modes - Proximity	29,995
S3	AB fertility N2 preserv* OR TI "fertility N2 preserv*	Expanders - Apply equivalent subjects Search modes - Proximity	8,235
S2	(MH "Cryopreservation+")	Expanders - Apply equivalent subjects Search modes - Proximity	43,026
S1	(MH "Fertility Preservation")	Expanders - Apply equivalent subjects Search modes - Proximity	4,180

Database: Embase		
#	Searches	Results
1	exp fertility preservation/	8,674
2	exp cryopreservation/	54,316
3	(fertility adj2 preserv*).ab,ti.	13,869
4	(cryopreserv* or cryoconserv*).ab,ti.	46,113
5	((freen* or cryopreserv* or preserv*) adj2 (egg or sperm)).ab,ti.	2,561
6	1 or 2 or 3 or 4 or 5	80,379
7	((public or publicly) adj3 (fund* or reimburse* or service* or system)).ab,ti.	50,232
8	6 and 7	84
9	exp Australia/	206,349
10	exp Denmark/	59,857
11	exp Germany/	214,131
12	exp France/	141,234
13	Sweden/	93,498
14	exp Portugal/	26,284
15	exp United Kingdom/	479,735
16	(denmark or danish or france or french or german or germany or portugal or portuguese or sweden or swedish or australia*).ab,ti.	898,415
17	(britain or (British not "British Columbia") or "UK" or "U.K." or "United Kingdom" or (England* not "New England") or "northern ireland" or "northern irish" or scotland or scottish or wales).ab,ti.	570,842
18	9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17	1,860,041
19	6 and 18	3,661
20	8 or 19	3,727
21	limit 20 to yr="2014 -Current"	2,063

Appendix 2. List of countries and associated grey literature sources

The sources listed below will be searched for relevant data relating to publicly-funded services for fertility preservation (this list is not exhaustive and will be added to as necessary):

EU

- Denmark
 - [Ministry of the Interior and Health](#)
 - [Danish Health Authority](#)
 - [Danish Patient Safety Authority](#)
 - [Rigshospitalet](#) (hospital group providing specialised care)
- France
 - [Ministry of Labour, Health and Solidarity](#)
 - [Haute Autorité de Santé](#)
 - [Biomedicine Agency](#) (including related thematic site regarding [assisted human reproduction](#))
 - [L'Assurance Maladie](#) (health insurance information website)
 - [Service Public](#) (official website of the French administration)
- Germany
 - [Federal Ministry of Health](#)
 - [Federal Joint Committee](#) (G-BA, *Gemeinsame Bundesausschuss*)
 - [FertiPROTECKT Network](#) (network of clinical and research centres in Germany-speaking countries)
- Portugal
 - [Directorate-General of Health](#)
 - [National Health Service](#) (SNS, *Serviço Nacional de Saúde*)
 - [National Council for Medically Assisted Reproduction](#) (CNPMA, *Conselho Nacional de Procriação Medicamente Assistida*)
 - [Official Gazette](#) (*Diário da República*)
- Sweden
 - [Ministry of Health and Social Affairs](#)
 - [National Board of Health and Welfare](#)
 - [Swedish Tissue Council](#)
 - [Swedish Agency for Health and Care Services Analysis](#)

Non-EU

- Australia
 - [Australian Government Department of Health and Aged Care](#)
 - [National Health and Medical Research Council](#)
 - [Medicare Benefits Schedule](#)
 - [Medical Services Advisory Committee](#)
- England
 - [NHS England](#)
- Northern Ireland
 - [Department of Health](#)
 - [Health and Social Care \(HSC\)](#)
- Scotland
 - [Scottish Government – Health and Social Care](#)
 - [NHS Scotland](#)
 - [Fertility Scotland](#)
- Wales
 - [Welsh Government – Health and Social Care](#)
 - [NHS Wales](#)
- UK
 - [Department of Health and Social Care](#)
 - [National Institute for Health and Care Excellence](#)
 - [Human Fertilisation and Embryology Authority](#)

Appendix 3. Sample data extraction template

Country (Reference)		
Author(s) Title [year]		
Focus Area	Sub-focus area	Information extracted
Population(s) and eligibility criteria		
Preservation method(s) available		
Organisation	<i>Referral pathways</i>	
	<i>Service provider characteristic</i>	
	<i>Timelines to access services</i>	
	<i>Any other organisational aspects</i>	
Storage	<i>Arrangements and duration(s)</i>	

	<i>Access to stored materials</i>	
	<i>Disposal of stored materials</i>	
	<i>Any other storage information</i>	
Governance		
Funding		
Communication and information provision		
Ethical considerations		
Relevant legislation (list)		
Miscellaneous		

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For further information please contact:

Health Information and Quality Authority

George's Court

George's Lane

Smithfield

Dublin 7

D07 E98Y

+353 (0)1 8147400

info@hiqa.ie

www.hiqa.ie

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