Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

A scoping review of publicly-funded services for donor-assisted human reproduction in selected countries

Appendix E: Extracted grey literature

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Table E.1 Extracted data for Australia (Multiple resources)

Australia		
Author(s) **Title [year]**	Australian Government Medicare Benefits Schedule Book Operating from 1 March 2024 and Services Australia[1, 2] [2025] Understanding Medicare Provider Handbook[3] [2024] Assisted Reproductive Technology Storage Funding Program Guidelines[4] [2025] (‘***Storage of donated gametes or embryos’ section***) Assisted reproductive technology services[5] [2026]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**Who is entitled to Medicare benefits?[3] (p.17)** Generally, to be eligible for Medicare a patient must permanently reside in Australia and be one of the following: ▪ an Australian citizen ▪ a permanent visa holder ▪ a New Zealand citizen. In certain circumstances, an applicant for a permanent residence visa. In some circumstances, persons who are not permanent Australian residents may be able to access some Medicare benefits. This may apply to: ▪ temporary residents covered by a relevant ministerial order ▪ temporary visitors whose home country has a reciprocal healthcare agreement with Australia. Medicare benefits Schedule (MBS) provide assisted reproduction technology (ART) involving donates ova are eligible for Medicare when there is an identified infertile recipient. Medical services performed on the donor must be billed under donor’s Medicare and cannot be billed to the recipient. This is because under Medicare an infertile recipient is a precondition for getting ART services. Medicare benefit apply only to services that are considered clinically relevant and medically necessary therefore elective fertility is not covered.[2] Medicare benefits are not payable for assisted reproductive services rendered in conjunction with surrogacy arrangements where surrogacy is defined as 'an arrangement whereby a woman agrees to become pregnant and to bear a child for another person or persons to whom she will transfer guardianship and custodial rights at or shortly after birth'.[1]
DAHR intervention(s) provided		Medicare Benefits Schedule (MBS) - The preparation of frozen or donor embryos, or donor eggs (oocytes), for placement in the female reproductive organs (uterus/womb or fallopian tubes). The treatment also includes pathology tests and counselling. This is for one treatment cycle. This item is used to provide fertility treatments, for example, IVF. **(pp. 579 – 578)** **All costs in Australian Dollars ($)** **Fee 13200** Assisted reproductive technologies super ovulated treatment cycle proceeding to oocyte retrieval, involving the use of drugs to induce superovulation and including quantitative estimation of hormones, ultrasound examinations, all treatment counselling and embryology laboratory services but

		excluding artificial insemination, transfer of frozen embryos or donated embryos or ova or a service to which item 13201, 13202, 13203 or 13218 applies, being services rendered during one treatment cycle—initial cycle in a single calendar year. Fee: $3,543.85 Benefit: 75% = $2657.90 85% = $3445.15 Extended Medicare Safety Net Cap: $1,996.80 **Fee 1202** Assisted reproductive technologies super ovulated 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. Fee: $530.35 Benefit: 75% = $397.80 85% = $450.80 Extended Medicare Safety Net Cap: $77.30 **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 preimplantation 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: $98.75 Benefit: 75% = $74.10 85% = $83.95 Extended Medicare Safety Net Cap: $13.60 **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 13215** Transfer of embryos or both ova and sperm to the uterus or fallopian tubes, excluding artificial insemination—only if rendered in connection with a service to which item 13200, 13201 or 13218 applies, being services rendered in one treatment cycle. Fee: $129.70 Benefit: 75% = $97.30 85% = $110.25 Extended Medicare Safety Net Cap: $61.40 **Fee 13218** Preparation of frozen or donated embryos or donated oocytes for transfer to the uterus or fallopian tubes, by any means and including quantitative estimation of hormones and all treatment counselling but excluding artificial insemination services rendered in one treatment cycle and excluding a service to which item 13200, 13201, 13202, 13203 or 13212 applies. Fee: $925.70 Benefit: 75% = $694.30 85% = $821.20 Extended Medicare Safety Net Cap: $888.30

		Fee 13221 Preparation of semen for the purpose of artificial insemination—only if rendered in connection with a service to which item 13203 applies. Fee: $57.85 Benefit: 75% = $43.40 85% = $49.20 Extended Medicare Safety Net Cap: $25.80 **Note TN.1.4:** Refers to ART list items 13200 – 13221. The treatment cycle for art including donor-assisted reproduction is define in terms of timing - "A treatment cycle that is a series of treatments for the purposes of ART services is defined as beginning either on the day on which treatment by superovulatory drugs is commenced or on the first day of the patient's menstrual cycle, and ending either; not more than 30 days later, or if a service mentioned in item 13212, 13215 or 13221 is provided in connection with the series of treatments-on the day after the day on which the last of those services is provided. The date of service in respect of treatment covered by Items 13200, 13201, 13203, 13209 and **13218 i**s DEEMED to be the FIRST DAY of the treatment cycle." **(p. 465)**
Organisation	***Referral pathways***	The GP is the gatekeeper for referred services, in recognition that GPs play a major role in the primary care of their patients and should generally be the first point of contact in determining the treatment a patient receives. The referral system was introduced to allow medical practitioners to refer patients to specialists where their specific skills and expertise are required to assist with the diagnosis and treatment of the patient. It is not intended to allow medical practitioners to refer patients to themselves. For a valid referral, a referring practitioner must: ▪ consider the need for the referral ▪ identify themselves as the referring practitioner ▪ explain the reason for the referral, including providing relevant clinical information about the patient's condition for investigation, opinion, treatment ▪ and or management, and ▪ sign and date the referral. **(p.24 of the Medicare book)** To claim Medicare for fertility treatment, including assisted reproductive technology (ART) procedures and donor-assisted reproduction, patients must follow the same process as for ART. A referral from a general practitioner (GP) or a specialist gynaecologist or obstetrician is required to initiate Medicare claims for ART consultations and services. GP referrals are generally valid for 12 months, while specialist referrals are typically valid for 3 months to a fertility clinic. All referrals must include the patient details outlined above to be accepted for Medicare payment.
	Service provider characteristic	The major elements of Medicare are contained in the Health Insurance Act 1973, as amended, and include the following: a. Free treatment for public patients in public hospitals. b. The payment of 'benefits', or rebates, for professional services listed in the Medicare Benefits Schedule (MBS). The relevant benefit rates are: i. 100% of the Schedule fee for services provided by a general practitioner to non-referred, non-admitted patients, or for general practitioner attendances specified as not being hospital treatments.

		ii. 100% of the Schedule fee for services provided on behalf of a general practitioner by a practice nurse or Aboriginal and Torres Strait Islander health practitioner. iii. 75% of the Schedule fee for professional services rendered to a patient as part of an episode of hospital treatment (other than services provided to public patients), including services provided in hospital outpatient settings. iv. 75% of the Schedule fee for professional services rendered as part of a privately insured episode of hospital-substitute treatment such as 'hospital in the home', but generally not including certain services listed below. v. 85% of the Schedule fee for all other services. **GN.2.4 Provider eligibility for Medicare** To be eligible to provide medical service which will attract Medicare benefits, or to provide services for or on behalf of another practitioner, practitioners must meet one of the following criteria: (a) be a recognised specialist, consultant physician or general practitioner; or (b) be in an approved placement under section 3GA of the *Health Insurance Act 1973*; or (c) be a temporary resident doctor with an exemption under section 19AB of the *Health Insurance Act 1973*, and working in accord with that exemption. Any practitioner who does not satisfy the requirements outlined above may still practice medicine but their services will not be eligible for Medicare benefits.

	Timelines to access services	**A treatment cycle is a series of treatments for ART services.**
		An ART treatment cycle starts on either:
		▪ the day the patient starts treatment with superovulatory drugs.
		▪ the first day of the patient's menstrual cycle.
		▪ An ART treatment cycle ends no more than 30 days after the treatment cycle starts, or the day after the last:
		  ○ oocyte retrieval
		  ○ transfer of embryos or both ova and sperm
		  ○ preparation of sperm for artificial insemination.
		
		Associated service already paid' or 'maximum number of services already paid'.
		Applies to items 13200, 13201, 13202, 13203, and 13218. The date of service should be the first day of the treatment cycle, which lasts up to 30 days. If a subsequent service occurs within 26 days of the previous one, note 'short cycle' on the account.

	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	**The Assisted Reproductive Technology (ART) Storage Funding Program (p. 4)** (hereafter referred to as the 'programme') aims to reduce eligible patient's costs for preserving eggs, sperm, or embryos through cryostorage (freezing).

		The purpose of this programme is to support patients from two population groups who face extra costs associated with fertility preservation: ▪ hold a valid Medicare card, and ▪ seek cryostorage of: up to two cryostorage services of different material types that is, eggs, or sperm and embryos for fertility preservation due to a cancer diagnosis as evidenced by medical documentation, or o embryos for fertility preservation when there is a risk of passing on genetic conditions, and they have undergone pre-implantation genetic testing funded by the Medicare Benefit Schedule (MBS), as described in MBS items 13207, 73384, 73385, 73386 or 73387 (further information here), and ▪ consent to their ART clinic sharing their relevant personal information with the Department of Health and Aged Care and Services Australia in order to facilitate their participation in the programme. Under this programme, the federal Government will make a payment to subsidise the cost of cryostorage of eggs, sperm, and embryos for eligible patients for a maximum of ten years per patient and per material stored. This payment will be made directly to eligible ART clinics using a payment system managed by Services Australia. Patients will not receive any payment directly. Patients may not be charged out of pocket costs for cryostorage subsidised by the programme. The programme has been established through an authority via the Financial Framework (Supplementary Powers) Regulations 1997 and will be administered as a demand-driven grant. **NOTE:** If an eligible patient's eggs, sperm, or embryos are donated to another individual, reproductive partnership or organisation, then from the date of transfer the cryostorage service is no longer eligible for subsidies under this programme and cannot be claimed by the ART clinic unless the other individual is also eligible for the programme **(p. 14)** **However:** 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: ▪ ownership has been transferred, or ▪ for a grace period of up to 2 years, or ▪ until the material is donated or destroyed at the person's request, or ▪ until the original ten-year limit that applied to the deceased patient's cryostorage service is reached.
	Access to and or disposal of stored donated gametes or embryos	Donation or Destruction of Genetic Material If an eligible cryostorage service ceases due to the destruction of eggs, sperm, or embryos, the ART clinic's claim must reflect this (that is, they may only lodge a claim for the portion of the 6-month storage period that passed before the material was destroyed). If an eligible patient's eggs, sperm, or embryos are donated to another individual, reproductive partnership or organisation, then from the date of transfer the cryostorage service is no longer eligible for subsidies under this programme and cannot be claimed by the ART clinic; unless the other individual is also eligible for the programme.
	Any other management information	N/A

Governance		Medicare is Australia's universal health insurance scheme. Through Medicare, the Australian Government subsidises all or part of the costs of many health services, including general practice, specialist services, surgical procedures, pathology tests, diagnostic imaging scans and allied health services. **Australian Government – Department of Health and Aged Care** The **Commonwealth Government**, through the Department of Health, is the primary body responsible for **national health policy** and the **administration of Medicare**. The Department also manages: ▪ policy design for Medicare Benefits Schedule (MBS) ▪ subsidy structures for medical services ▪ primary care reform initiatives.
Funding		**Key information on Medicare benefits and billing practices (pp. 15 &16)** The *Health Insurance Act 1973* stipulates that Medicare benefits are payable for professional services. A professional service is a clinically relevant service which is listed in the MBS. A medical service is clinically relevant if it is generally accepted in the medical profession as necessary for the appropriate treatment of the patient. Medical practitioners are free to set their fees for their professional service. However, the amount specified in the patient's account must be the amount charged for the service specified. The fee may not include a cost of goods or services which are not part of the MBS service specified on the account. **Billing practices contrary to the Act** A *non-clinically relevant service* must not be included in the charge for a Medicare item. The non-clinically relevant service must be separately listed on the account and not billed to Medicare. Goods supplied for the patient's home use (such as wheelchairs, oxygen tanks, continence pads) must not be included in the consultation charge. Medicare benefits are limited to services which the medical practitioner provides at the time of the consultation - any other services must be separately listed on the account and must not be billed to Medicare. Charging part of all of an episode of hospital treatment or a hospital substitute treatment to a non-admitted consultation is prohibited. This would constitute a false or misleading statement on behalf of the medical practitioner and no Medicare benefits would be payable. An account may not be re-issued to include charges and out-of-pocket expenses excluded in the original account. The account can only be reissued to correct a genuine error. **Potential consequence of improperly issuing an account** The potential consequences for improperly issuing an account are (a) No Medicare benefits will be paid for the service (b) The medical practitioner who issued the account, or authorised its issue, may face charges under sections 128A or 128B of the *Health Insurance Act 1973*. (c) Medicare benefits paid as a result of a false or misleading statement will be recoverable from the doctor under section 129AC of the *Health Insurance Act 1973*. Providers should be aware that Services Australia is legally obliged to investigate doctors suspected of making false or misleading statements and may refer them for prosecution if the evidence indicates

		fraudulent charging to Medicare. If Medicare benefits have been paid inappropriately or incorrectly, Services Australia will take recovery action.
Counselling, communication and information provision		N/A
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		Medicare are contained in the Health Insurance Act 1973.
Miscellaneous		**Fee 13241** Open surgical testicular sperm retrieval, unilateral, using operating microscope, including the exploration of scrotal contents, with biopsy, for the purposes of intracytoplasmic sperm injection, for male factor infertility, not being a service associated with a service to which item 13218 or 37604 applies (H) (Anaes.) Fee: $968.35 Benefit: 75% = $726.30 **(p. 578)** **Fee 13251** Intracytoplasmic sperm injection for the purpose of assisted reproductive technologies, for male factor infertility, excluding a service to which item 13203 or 13218 applies. Fee: $476.15 Benefit: 75% = $357.15 85% = $404.75 Extended Medicare Safety Net Cap: $128.70 **(p. 578)** **Note TN.1.5** Intracytoplasmic Sperm Injection. Item 13251 provides for intracytoplasmic sperm injection for male factor infertility under the following circumstances: ▪ where fertilisation with standard IVF is highly unlikely to be successful or ▪ where in a previous cycle of IVF, the fertilisation rate has failed due to low or no fertilisation. Item 13251 excludes a service to which item 13218 applies. Sperm retrieval procedures associated with intracytoplasmic sperm injection are covered under items 37605 and 37606. Items 13251, 37605, 37606 do not include services provided in relation to artificial insemination using the husband's or donated sperm. **(p. 465)** **Fee 13260** Processing and cryopreservation of semen for fertility preservation treatment before or after completion of gonadotoxic treatment for malignant or non-malignant conditions, in a post-pubertal male in Tanner stages II-V, up to 60 years old, if the patient is referred by a specialist or consultant physician, initial cryopreservation of semen (not including storage) - one of a maximum of two semen collection cycles per patient in a lifetime. Fee: $472.75 Benefit: 75% = $354.60 85% = $401.85 Extended Medicare Safety Net Cap: $307.30 **(p. 578)** Note: TN.1.22 of semen (Item 13260) A semen cycle collection process involves obtaining up to three semen samples on alternate days producing up to 50 cryopreserved straws of frozen sperm. Maximum of

		two semen collection cycles, one cycle collected prior to a patient undergoing the first cytotoxic/radiation treatment and the second cycle to be collected if the patient has relapsed and requires treatment. **Fee 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 **(p. 578)** **Fee 37605** Transcutaneous sperm retrieval, unilateral, from either the testis or the epididymis, for the purposes of intracytoplasmic sperm injection, for male factor infertility, excluding a service to which item 13218 applies. (Anaes.) (See para TN.1.5, TN.8.58 of explanatory notes to this Category) Fee: $411.05 Benefit: 75% = $308.30 85% = $349.40 **(p. 744)** **Fee 37606** Open surgical sperm retrieval, unilateral, including the exploration of scrotal contents, with or without biopsy, for the purposes of intracytoplasmic sperm injection, for male factor infertility, performed in a hospital, excluding a service to which item 13218 or 37604 applies. (Anaes.) Fee: $610.40 Benefit: 75% = $457.80 85% = $518.85 **(p. 744)** **Note: TN.8.59 Surgical Sperm Retrieval, by Open Approach - (Item 37606)** Item 37606 covers open sperm retrieval for the purposes of intracytoplasmic sperm injection (item 13251) for male factor infertility, in association with assisted reproductive technologies. Item 37606 provides for the procedure to be performed unilaterally. Where it is clinically necessary to perform the service bilaterally, the multiple operation rule would apply. Benefits for item 37606 may be claimed in conjunction with a service or services provided under item 37605, where an open approach is clinically necessary following an unsuccessful percutaneous approach. Likewise, such services would be subject to the multiple operation rule. Benefit is not payable for item 37606 in conjunction with item 37604. **(p. 511)**

Table E.2 Extracted data for Australia (Ethical guidelines)

Australia		
Author(s) **Title [year]**	National Health and Medical Research Council Ethical guidelines on the use of assisted reproductive technology in clinical practice and research[6] [2017]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		Individuals or couples seeking donor conception programmes: This includes both donors and recipients of gametes or embryos. **(p. 23)**
DAHR intervention(s) provided		N/A
Organisation	***Referral pathways***	N/A
	Service provider characteristic	N/A
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	**Use of imported gametes (p. 32)** 5.5.1 Treatment in Australia using gametes donated by persons living in another country must not take place unless it can be established that the gametes were obtained in a manner consistent with any Commonwealth legislation and any relevant state or territory legislation, accreditation body guidelines and these Ethical Guidelines. ▪ Where a recipient has had a child born before the introduction of these Ethical Guidelines [2017] and gametes or embryos are in storage, within Australia, for the recipient's future use, the gametes or embryos may be used in the treatment of the recipient provided that the relevant requirements are satisfied. **Embryo (p. 37)** 6.1.3 Where a donated embryo (including one created using donated gametes) is no longer required by the individual or couple to whom the embryo was donated, the embryo may be reallocated to another individual or couple, subject to any directions or limitations expressed as part of the consent from the embryo donor(s), or imposed by law. **Accepting and allocating gamete donations** **Respect the donor's wishes (p. 30)** 5.1.1 If the donor specifies recipients they know personally (known donation), clinics must respect the wishes of the donor unless the donation is prohibited by law or is contrary to these Ethical Guidelines. 5.1.2 Clinics must not accept donations from any donor who wishes to place conditions on the donation that the gametes are for the use only by individuals or couples from particular ethnic or social groups, or not to be used by particular ethnic or social groups. This type of donation

		('unknown directed donation') is considered unethical on the basis that it is discriminatory and inequitable. 5.1.3 Donors wishing to direct their donations to individuals or couples from particular ethnic or social groups can only do so through known donation. This also applies to gametes and embryos in storage that were not allocated to a specific individual or couple prior to the introduction of these Ethical Guidelines [2017]. **Consider the physical, psychological and social wellbeing of each party when accepting or allocating gamete donations (p. 30)** 5.2.1 **Clinics must not accept** donations from children and young people (who are defined as 'minors' in each jurisdiction) for use by others in a reproductive procedure. **Donation from a relative (p. 31)**: The donation of gametes between relatives (for example, between sisters, from daughter to mother) may offer benefits to all parties involved, including the person who may be born. However, due to the possible influence the relationship, or the family, could have on the potential donor's decision to donate and the impact of potentially confusing family relationships, this practice requires special consideration. 5.2.2 Clinics must not create embryos from gametes derived from close genetic relatives, as defined by relevant legislation. **Older donors** 5.2.3 Clinics must not create embryos from gametes derived from close genetic relatives, as defined by relevant legislation. The risk of an abnormality occurring in the person who would be born increases with the advancing age of the gamete donor. Therefore, clinics should not use gametes provided by older donors unless the potential recipient understands and accepts the implications and risks of proceeding with such an arrangement for the person who would be born. **Donors with an increased risk of infectious disease (p. 31)** 5.2.4 Clinics must meet regulatory requirements and have policies and procedures in place to minimise transmission of infectious diseases from the donor to the recipient or the person who would be born. These policies and procedures must be reviewed in light of new evidence. **Limit the number of families created from a single donor** 5.3.1 Clinics must take all reasonable steps to minimise the number of families created through donated gamete treatment programmes. Gametes from a single donor must be used to create only a limited number of families. in the absence of specific state or territory legislation, clinics must take account of the following factors when deciding on an appropriate number of families to be created: ▪ the number of persons already born from the donor's gametes

		▪ the risk of a person born from donor gametes inadvertently having a sexual relationship with a close genetic relative (with particular reference to the population and ethnic group in which the donation will be used) ▪ any limitations on the number of families expressed as part of the consent of the donor ▪ whether the donor has already donated gametes at another clinic. 5.3.3. in the absence of a national registry for gamete donation, to encourage disclosure of multiple donations at multiple clinics, potential gamete donors should be reminded of the importance of limiting the number of families created from a single donor. Prior to donation, clinics must: ▪ ask potential donors whether they have donated at other clinics ▪ obtain consent from potential donors to contact other clinics about any previous donations.
	Storage of donated gametes or embryos	**Responsibilities of the clinic for stored gametes and embryos (p. 39)** <u>Maintain the safe storage and accurate identification of all gametes and embryos</u>. 7.1.1 Clinics must have procedures in place to ensure all reasonable efforts are taken to maintain the safe storage and accurate identification of all gametes and embryos. All procedures should be consistent with current best practice. 7.1.2. Clinics must ensure that all reasonable efforts are made to keep gametes and embryos in safe storage for the period of storage specified in the consent form. After this time, if the individual or couple responsible for the stored gametes and embryos cannot be contacted to provide further direction and consent, clinics may discard the gametes or embryos, in accordance with the clinic's policy. **Assess the suitability for continued (long term) storage of gametes and embryos.** 7.2.1 Clinics should have policies that guide the clinical determination for continued storage of gametes and embryos. **Stored gametes or embryos following the death (p.40)** 7.5.1 Clinics must have clear policies for managing disputes that may arise between individuals for whom an embryo is stored. 5.5.2 Unless prohibited by law, if a clinic receives confirmation that a gamete provider has died, the gametes or embryos should remain stored and made available for use, or be discarded, in accordance with the wishes of the deceased expressed in the consent for storage**.**
	Access to and or disposal of stored donated gametes or embryos	**Responsibility for use, storage and discard of donated gametes (p. 35)** Recipients of donated gametes need to know who is responsible for the gametes and resulting embryos used in their treatment. At the same time, the right of the gamete donor to withdraw their consent for donation also needs to be protected. 5.11.1 Clinics must maintain clear procedures for the transfer of responsibility for gametes and the resulting embryos at each stage.

		▪ When the gamete donor has not specified a recipient for their gametes (unknown donation), the clinic has responsibility for decision-making about the allocation, storage and discard of the gametes, subject to any directions or limitations expressed in the consent of the donor. Once allocated, the responsibility for decision-making is transferred to the recipient. ▪ When the gamete donor has specified a recipient for their gametes (known donation), and consent for treatment has been given by the recipient, the recipient has responsibility for decision-making about the use, storage and discard of the gametes or resulting embryos, subject to any directions or limitations expressed in the consent of the donor. ▪ The clinic is responsible for maintaining the appropriate storage of donated gametes. **Responsibility for donated embryos (pp. 37 & 38)** Recipients of donated embryos need to know who is responsible for decision-making about the embryos used in their treatment. At the same time, the rights of the embryo donor(s) to place limitations on the use, storage and discard of the donated embryos and to withdraw their consent for donation also need to be protected. Clinics must have clear procedures for the transfer of responsibility for embryos at each stage. ▪ The embryo donors are responsible for decision-making about the use, storage and discard of an embryo whilst it is in storage awaiting donation to an identified individual or couple (known donation), or to another individual or couple (unknown donation). ▪ The clinic is responsible for maintaining the appropriate storage of an embryo. ▪ in circumstances involving unknown donation, the clinic is also responsible for the allocation of an embryo to an individual or couple. ▪ Once a recipient individual or couple has accepted a donated embryo, they are responsible for decision-making about its use, storage and discard, including decisions about the reallocation of an embryo, subject to any directions or limitations expressed in the consent of the donor(s) or imposed by law. ▪ When an embryo is reallocated to a subsequent individual or couple, and they have accepted an embryo, that individual or couple is responsible for decision-making about its use, storage and discard, including decisions about the reallocation of embryos, subject to any directions or limitations expressed in the consent of the embryo donor(s) or imposed by law. **Manage the discard of stored gametes and embryos (p. 41)** 7.6.1 Clinics must have policies and procedures in place for discarding stored gametes and embryos. These policies should provide for the responsible party(ies) to determine the means of removal or discard of the embryos from the clinic, including those which are legal, but are not available at the particular clinic. 7.6.2. Clinics may, in limited circumstances, and in line with the clinic's policy, discard stored gametes or embryos without the consent of the individual or couple for whom the gametes or embryos are stored.

<table>
<tr><td></td><td></td><td>7.6.3 Before a clinic may discard stored gametes or embryos without the consent of the responsible party(ies), clinics must make all reasonable efforts, and document all attempts, to notify the responsible party(ies) and allow reasonable time for the responsible party(ies) to take action.</td></tr>
<tr><td></td><td>Any other management information</td><td>N/A</td></tr>
<tr><td>Governance</td><td></td><td>Maintain appropriate records – General requirements (p. 59)
Clinics must have appropriate policies and procedures for the collection, storage and release of data related to ART activities. Clinics must maintain records that are adequate to allow:
▪ monitoring of, and access to, data regarding the creation, storage, use and discard of embryos where applicable, the exchange of information between a gamete donor, recipient and person born as a result of donation.

Maintain appropriate records – Donor conception programmes arrangements (p.60)
9.2.1 Clinics must ensure that all relevant information about parties involved in donor conception programmes or surrogacy arrangements are recorded so that this information is available to potential recipients of the donation, any persons born, and/or the gamete or embryo donors.
9.2.2 Information about all parties involved in a donor conception programme or surrogacy arrangement must be kept indefinitely (or at least for the expected lifetime of any persons born); in a way that is secure but is accessible to any relevant party.</td></tr>
<tr><td>Funding</td><td></td><td>Acquisition of donated human gametes - reimbursement of verifiable out-of-pocket expenses (p. 32)
The current situation in Australia is that gamete donation must be altruistic, and that commercial trading in human gametes or the use of direct or indirect inducements is prohibited by legislation. This position reflects concerns about the potential exploitation of donors (particularly egg donors) and the potential risks to all parties.

5.4.1 While direct or indirect inducements are prohibited, it is reasonable to provide <u>reimbursement of verifiable out-of-pocket expenses directly associated with the donation</u>, including, but not limited to:
▪ medical and counselling costs, both before and after the donation
▪ travel and accommodation costs within Australia
▪ loss of earnings (Donors who access paid leave during the donation process cannot be reimbursed for loss of earnings. Loss of earnings can be demonstrated by the donor providing payslips verifying that unpaid leave was taken.)
▪ insurance
▪ childcare costs when needed to allow for the donor’s attendance at donation related appointments and procedures
▪ legal advice.</td></tr>
<tr><td>Counselling, communication and information provision</td><td></td><td>Provide and discuss all relevant information - Individuals and couples involved in donor conception programmes (pp. 23 & 24)</td></tr>
</table>

		4.2.3 Clinics must consider the information needs of both donors and recipients. in addition to the requirements outlined in paragraph 4.1, clinics should ensure that the following information is discussed: ▪ the possible implications and long-term psychosocial consequences of gamete or embryo donation for the donor(s) and their families, the recipient(s) and their families, and the person who would be born ▪ the arrangements of the clinic for collection, storage and release of identifying information ▪ any difficulties in finding gamete or embryo donors, including those related to specific preferences expressed by recipients ▪ the scope of consent, decision-making responsibilities and the rights of each person involved to withdraw consent including the possibility that there may be unused gametes or embryos at the completion of the recipient's treatment and the possible options for these gametes or embryos ▪ the ongoing responsibilities of each party to all other parties ▪ the rights and responsibilities of the gamete or embryo donor and the intended parent(s) in the jurisdiction in which the clinic is located, or the gametes or embryos are used ▪ the possibility that egg donation may affect the egg donor's own fertility. 4.2.4**.** Potential gamete or embryo recipients need information about the potential gamete donor (or gamete providers in the case of embryos) that is relevant to the care of the person who would be born. Clinics must allow recipients of donated gametes or embryos access, through either a medical practitioner or an appropriately qualified health professional, to at least the following information about gamete donors: ▪ medical history, family history and any existing genetic test results that are relevant to the future health of the person who would be born (or any subsequent offspring of that person) or the recipient of the donation ▪ details of the physical characteristics of the gamete donor ▪ the number, age and sex of persons already born from the gametes provided by the same gamete donor and the number of families involved. 4.2.5 Where a potential gamete donor has a spouse or partner, clinics should encourage the potential donor to include their spouse or partner in the discussions about their gamete donation, acknowledging the benefits of open disclosure and the potential impact of the decision on the spouse or partner, the couple's relationship and/or the family unit. **(p. 24)** **Provide and discuss all relevant information - Individuals and couples seeking to store gametes or embryos (p. 24)** ▪ the survival rate and suitability for transfer of gametes and embryos after freezing and thawing for the particular clinic ▪ the live-birth rate following the use of the thawed gametes, tissues and embryos for the particular clinic ▪ the currently available information about outcomes for persons born from stored gametes or embryos

		▪ any limitations on use, specific to the clinic or the state or territory ▪ any limitations on storage times, specific to the clinic or the state or territory ▪ any circumstances under which the clinic may dispose of the gametes or embryos before the end of the consent period, including the clinic's policy for managing disputes that may arise between a couple for whom an embryo is stored ▪ the responsibilities of each party (including the clinic's) for stored gamete or embryos. **Provide counselling services - donor conception programmes (p. 26)** 4.4.1 individuals and couples involved in a donor conception programme must undergo counselling because of the complex nature of the issues involved. In addition to the requirements outlined in paragraph 4.3, counselling must include a detailed discussion of the following: ▪ the potential long-term psychosocial implications for each individual and each family involved, including the person who would be born and any other child within the family unit(s) who may be affected by that birth ▪ the potential significance of the biological connection, the right of persons born to know the details of their genetic origins, and the benefits of early disclosure ▪ the potential long-term psychological implications for a person born from an embryo that has undergone multiple reallocations ▪ the possibility that persons born may learn about their genetic origins from other sources (for example from family members or pathology testing) and may independently access information about their conception ▪ the possibility that persons born may attempt to make contact with the donor(s) in the future. 4.4.4. The use of an embryo created using both donor sperm and a donor egg (double donation) may have an increased psychological impact on the person who would be born due to the range of biological connections and social relationships that would be created and the potential significance of these for any persons born. When double donation is being considered, counselling should acknowledge the complexity of this practice. **Information provision - Exchange of information between all relevant parties (p. 32)** There should be voluntary exchange of information between persons born from donated gametes, gamete donors and gamete recipients (the parents), with the valid consent of all parties. The guidelines in this section specify the minimum level of information that should be accessible to all parties in a donor conception programme. **Information provision - Support the right to know the details of one's genetic origins (p. 33)** Persons born from donated gametes are entitled to know the details of their genetic origins. Counselling received by potential gamete recipients must explore the potential significance of the biological connection, the right of persons born to know the details of their genetic origins, and the benefits of early disclosure. Whilst recipients cannot be forced to disclose this information to their children, clinics have a role in encouraging and supporting early disclosure.

		5.6.1 Clinics must not use donated gametes in reproductive procedures unless the donor has consented to the release of their identifying information to the person(s) born as a result of the donation. 5.6.2 Clinics must not mix gametes in a way that allows the genetic origins of the person who would be born to be uncertain. This includes the attempted fertilisation of a human egg by human sperm from more than one donor at a time. 5.6.3 Clinics must: ▪ encourage gamete recipients to disclose to their children their genetic origins ▪ provide ongoing support to parents, to help them to understand the potential significance of the biological connection and the benefits of early disclosure ▪ assist parents to find effective ways of disclosing to their children their genetic origins ▪ provide persons born from donated gametes with a supportive environment within which to explore the possibility of meeting with the donor(s) and/or siblings. **Information provision - Provide gamete donors with relevant information concerning persons born using their donated gametes (p. 33)** Gamete donors are entitled to some information about any persons born as a result of their donation (in particular, to prepare them for possible future approaches by the persons born). 5.7.1 Clinics should provide gamete donors, on request, with non-identifying information about the number, age and sex of any persons born as a result of their donation. **Encourage the update of relevant information (p. 33)** 5.8.1 Clinics should inform potential gamete donors (or gamete providers for donated embryos) that it is a donor's ethical responsibility to keep the clinic informed about any changes to their health that may be relevant to any person born or the recipients of their donation and about changes to their contact details. 5.8.2. Clinics should encourage gamete recipients to disclose to the clinic any information about the person born that might be relevant to the health of the donor, the donor's offspring, or other persons born from the donated gametes. **Information provision - Provide persons born from donated gametes with information about the gamete donor (p. 34)** 5.9.1 A clinic that is approached by a person born from gametes donated at that clinic, who has reached the age of 18, must arrange for counselling by a professional with the appropriate training, skills, experience and competency to support their decision-making, prior to providing the following information, as a minimum: ▪ identifying information about the gamete donor

		▪ any identifying information that any person born from the gametes of the same donor has consented to being released. 5.9.2 A clinic that is approached by a person born from gametes donated at that clinic, who has not yet reached the age of 18, must arrange for counselling by a professional with the appropriate training, skills, experience and competency to support their decision-making and make a determination of the person's maturity and ability to appreciate the significance of the request (including any implications for any younger siblings). 5.9.3 Should the person born from donated gametes be assessed as sufficiently mature, the clinic must provide the information listed in 5.9.1, as a minimum.
Ethical and social considerations		**Valid consent - Obtain consent from all relevant parties for each specific procedure – donor conception programmes (p. 28)** 4.6.1 Consent for participation in a donor conception programme must include: ▪ provision of full details of the agreed arrangements including any limitations the donor(s) have placed on the use, storage or discard of the embryos (including reallocation) ▪ provision of advice to all parties about the donor's biological connection to any person who would be born using donated gametes or embryos, the potential significance of this connection to the person born and the benefits of early disclosure ▪ obtaining an acknowledgment from each party that they have received and understood the information provided about gamete or embryo donation, including an acknowledgement of the decision–making responsibilities of each party ▪ obtaining specific consent from the donor to make relevant information available to the recipients and any person born as a result of the donation ▪ obtaining specific consent from the potential recipient(s) to make the information available, on request, to the donor and an acknowledgement of their responsibility to the donor. 4.6.2 Potential gamete or embryo donors and gamete or embryo recipients should be allowed adequate time for consideration of information and the complex issues involved before consent is obtained. **Recognise the right of individuals or couples to withdraw or vary their consent (p. 29)** 4.7.1 Clinics must recognise that, with the exception of some specific issues relating to the donation of gametes and embryos, individuals and couples have the right to withdraw or vary their consent for ART activities. **Respect the privacy of all parties involved in ART procedures (p. 34)** 5.10.1 When approached by a person who was born from donated gametes who now seeks identifying information about their gamete donor, the clinic must examine the consent from the gamete donor and proceed as follows:

		▪ if the consent form does not include permission for release of identifying information (because the donation was made before the introduction of the 2004 edition of these Ethical Guidelines and the gamete donor has not come forward in response to the public information campaign, the clinic should make all reasonable efforts, consistent with the original consent document and the privacy rights of the donor, to contact the gamete donor and request their consent to the release of their information. ▪ if the consent form includes permission for release of identifying information, the clinic should make all reasonable efforts to notify the gamete donor of the request prior to the release of the information. This process should not, however, unreasonably delay the release of such information to the person born. 5.10.2 When approached by a person who was born from donated gametes who now seeks identifying information about others born from gametes donated from the same donor, the clinic must examine the consent from the individual(s) involved and proceed as follows: **(p. 35)** ▪ if consent has been registered by the individual(s) concerned, the information may be released. ▪ if consent has not been registered, clinics must not release identifying information or contact the individual(s). 5.10.3 Clinics must provide the donor with access to counselling by a professional with the appropriate training, skills, experience and competency, as part of the preparation for the release of identifying information. **Withdrawal of consent for donation (p. 35)** 5.12.1 A gamete donor can withdraw or vary consent for donation at any time before the treatment cycle of the recipient commences, or at any time before the creation of an embryo, whichever is sooner. **Allocation of donated embryos - Support the right to know the details of one's genetic origins (p.37)** 6.1.1 Donated embryos must only be used in reproductive treatment if all of the requirements in Chapter 5 for donated gametes are satisfied. 6.1.2 Clinics must ensure that the genetic origin of the person who would be born is certain. This includes not transferring multiple embryos, at any one time, where the embryos have different genetic origins.
Relevant legislation (list and key aspects)		National Health and Medical Research Council Act 1992 (NHMRC Act).
Miscellaneous		N/A

Table E.3 Extracted data for Denmark (AHR guidelines)

Denmark		
Author(s) **Title [year]**	Ministry of the Interior and Health (Denmark) BEK no. 1452 of 01/12/2025 (Current) Executive Order on Assisted Reproduction(7)	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		N/A
DAHR intervention(s) provided		Donation of fertilised human eggs is only permitted for research purposes. **(p. 2)** Donation of unfertilised human eggs may only take place if it is done for the purpose of to achieve a pregnancy in another woman or research.
Organisation	***Referral pathways***	N/A
	Service provider characteristic	N/A
	Timelines to access services	N/A
	Any other organisational aspects	The healthcare professional responsible for assisted reproduction treatment must report this to the distributing tissue establishment no later than 14 days after a confirmed viable pregnancy has been achieved as a result of assisted reproduction with donated sperm or eggs. The report must include information about the country of residence of the treated woman. If the viable pregnancy, is a sibling with the same donor who was previously used by a woman seeking treatment or a couple seeking treatment, this must be stated in the health care professional's report. **(p. 3)**
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	If a woman seeking treatment or a couple seeking treatment wishes to use a specific sperm donor that the single woman or couple themselves bring with them in connection with treatment at a regional council hospital, the hospital may refer to the fact that sperm donation, including testing and evaluation, must be carried out via an approved tissue centre (sperm bank). Expenses in connection with the approved tissue centre's (sperm bank's) testing and evaluation, etc., are borne by the woman seeking treatment or the couple seeking treatment. **(p.3)**
	Storage of donated gametes or embryos	Storage of human eggs may only take place for the purpose of: 1)later return to the woman who donated the egg 2)donation for research purposes, or 3)donation with the aim of inducing a pregnancy in another woman. **(p. 1)** However, the recipient of an egg may be determined or undetermined at the time of donation. Storage of human eggs may only be carried out for the purpose of treatment and research. Storage of semen may only be done for the purpose of 1) to achieve a pregnancy either in the man's own partner or in another woman, or 2) research. **(p. 2)**

	Access to and or disposal of stored donated gametes or embryos	Fertilised and unfertilised human eggs may be stored until the time when the woman, who will give birth to the child turns 46, after which the eggs must be destroyed**. (p.1)** The treating healthcare professional must ensure that the woman's stored unfertilised eggs are destroyed in in the event of her death, unless the eggs have been donated for the purposes of getting someone else pregnant or research. **(p. 2)** In the event of the woman's death or in the event of the couple's separation or divorce or the termination of cohabitation the treating healthcare professional must ensure that the stored fertilised eggs are destroyed. In the event of the man's death, the treating healthcare professional must ensure that stored fertilised eggs are destroyed, unless there is written consent from the man pursuant to the Act on Assisted Reproduction in connection with treatment, diagnostics and research.
	Any other management information	The tissue centre distributing eggs must ensure that the number of viable pregnancies in women residing in Denmark established with eggs from one donor recruited after 15 December 2013 does not exceed 12 with geographical spread. The tissue centre's calculation of the number must include all information about pregnancies, including information from reports. **(p. 2)** ▪ In cases where the number of pregnancies with eggs from one donor is at least 12, the tissue centre may exceptionally distribute eggs from a donor, provided that this is done solely for the purpose of using eggs from this donor to help with assisted reproduction for the purpose of having more siblings from the same donor, if the single person or one of the couple already has a child with a donor. ▪ Frozen eggs fertilised from one donor, where the number of viable pregnancies established with eggs from the same donor has subsequently exceeded 12, may, however, continue to be used. The tissue centre distributing sperm shall ensure that the number of viable pregnancies in women residing in Denmark established with sperm from one donor recruited after 1 March 2013 does not exceed 12 with geographical spread, For sperm donors recruited before 1 March 2013, the aim shall be that the number of pregnancies established with sperm from one donor does not exceed 25 with geographical spread. The tissue centre’s calculation of the number shall include all information about pregnancies, including information from reports. ▪ In cases where the number of pregnancies with sperm from one donor is at least 12, the sperm bank may exceptionally distribute sperm from a donor if this is done solely for the purpose of using the sperm from this donor for treatment with assisted reproduction with a view to more siblings from the same donor, if the single person or one of the couple already has a child with a donor. ▪ Frozen eggs fertilised with sperm from one donor, where the number of viable pregnancies established with sperm from the same donor has subsequently exceeded 12, can still be used.

		On the use of a donor's gametes in the event of an increased or established risk of transmission of a hereditary disease to a child (sibling deposit): (p. 4) When a tissue establishment or an authorized healthcare professional who has received gametes from a procurement site receives notification that a donor's gametes are subject to quarantine the tissue establishment or the authorised healthcare professional may not use gametes from this donor for assisted reproduction until the tissue establishment or the authorised healthcare professional has received notification that the quarantine has been lifted. Then a tissue establishment or an authorised healthcare professional receives notification of a permanent ban on the use of a donor's gametes, the tissue establishment or the authorised healthcare professional may no longer use gametes from this donor, unless the single person or one of the couple already has a child with the donor and the single person/couple has consented to the use of the donor's gametes after being informed about the risk of a possible known genetic disease and any consequences thereof.
Governance		N/A
Funding		If a woman seeking treatment or a couple seeking treatment wishes to use a specific sperm donor that the single woman or couple themselves bring with them in connection with treatment at a regional council hospital, the hospital may refer to the fact that sperm donation, including testing and evaluation, must be carried out via an approved tissue centre (sperm bank). **Expenses in connection with the approved tissue centre's (sperm bank's) testing and evaluation, etc., are borne by the woman seeking treatment or the couple seeking treatment. (p. 3)**
Counselling, communication and information provision		If storage of retrieved, unfertilised human eggs is carried out with a view to donation for research purposes or donation with a view to inducing pregnancy in another woman, the donating woman must, before the storage takes place, give written consent to the storage. **(p. 1)** Before storage of retrieved, fertilised human eggs takes place, the single woman or the couple must give written consent to storage. The woman or the couple in question must be informed beforehand, verbally and in writing, about the consequences of the storage. The woman or the couple in question must also declare that they have been made aware of the terms and conditions for storage stipulated in the Act on Assisted Reproduction in connection with treatment, diagnostics and research, and in this executive order. Donors of unfertilised eggs must give written consent to donation. Before doing so, the donor must be informed verbally and in writing about the consequences of donation. The donor must also declare that she has been made aware of the terms and conditions stipulated for donation in the Act on Assisted Reproduction in connection with treatment, diagnostics and research, etc. and in this executive order. The donor of unfertilised eggs may be anonymous or non-anonymous. In connection with the use of an anonymous egg donor, the tissue centre may only disclose information about the donor's skin colour, hair colour, eye colour, age, blood type, height and weight.

		The sperm donor must give written consent to donation. The donor must be informed verbally and in writing about the consequences of sperm donation. The donor must also declare his agreement with the terms and conditions stipulated for donation in the Act on Assisted Reproduction in connection with treatment, diagnostics and research, etc. and in this executive order. **(p. 2)** Sperm donors may be anonymous or non-anonymous. In connection with the use of an anonymous sperm donor, the tissue centre may only disclose information about the donor's skin colour, hair colour, eye colour, blood type, height and weight.
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		The tissue centre that collects or distributes eggs for donation purposes must ensure that the egg donor does not donate eggs more than six times in total. **(p. 2)** The tissue centre that distributes sperm must ensure that the sperm donor has not previously functioned or continues to function acts as a sperm donor in another sperm bank.

Table E.4 Extracted data for Denmark (Executive order on ART)

Denmark		
Author(s) **Title [year]**	Ministry of the Interior and Health (Denmark) BEK no. 316 of 27/03/2019 (Current) Executive Order on assessment of parental unfitness in connection with assisted reproduction treatment[8]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		[See Referral pathways for eligibility for treatment based on parental fitness] **Factors of importance for assessing parental unfitness (p. 1)** When assessing whether there is doubt about a woman's or a couple's unfitness to be a parent, the following may be included: ▪ any substance abuse problems in the woman or couple, ▪ the mental state of the woman or couple, which may affect the ability to care for a future child, ▪ circumstances that may result in the child being placed outside the home, or ▪ that one or both prospective parents already have a child who is placed outside the home because of family circumstances. Treatment with assisted reproduction may not be refused on the grounds of the woman's or the couple's sexual orientation, or racial, religious, ethnic and similar conditions.
DAHR intervention(s) provided		Refers to ART in general.
Organisation	***Referral pathways***	The healthcare professional who refers for treatment with assisted reproduction may, after consent, point out at the time of referral that there may be doubts about the woman's or couple's ability to care for a child after birth. **(p. 1)** In connection with the health professional assessment and decision on treatment with assisted reproduction, the treating health professional must consider whether there is any doubt about the ability of a single woman or a couple to care for a child after birth. ▪ If the responsible healthcare professional assesses that there is doubt about the ability of a single woman or a couple to care for a child after birth, the healthcare professional must, with the consent of the single woman or couple, submit information to the Regional council with a request that the regional council make a decision on whether assisted reproduction treatment can be initiated. ▪ For the regional council's case processing, the treating healthcare professional must submit an explanation of the health professional's doubts about the single woman's or couple's suitability for parenthood. ▪ In the event of a lack of consent from the single woman or couple to the disclosure of information to the regional council must refuse to initiate treatment with assisted reproduction.

		▪ The Regional Council shall decide whether assisted reproduction treatment may be initiated. The Regional Council may, with the consent of the single woman or couple, involve other expertise in the assessment of parental suitability before making a decision. Other expertise may be the general practitioner, the social authorities or others. Involvement of other expertise may only take place with the consent of the woman or the couple. If the woman or couple does not consent to the inclusion of other expertise, the regional council must it rejects the possibility of initiating treatment with assisted reproduction.
	Service provider characteristic	**Assessment of parental unfitness in connection with assisted reproduction treatment of a person who does not reside in this country (p.2)** According to the Act on Assisted Reproduction in connection with treatment, diagnostics and research etc., a healthcare professional must refuse treatment with assisted reproduction if the healthcare professional responsible for treatment with assisted reproduction of a single woman or a couple who do not reside in this country assesses that there is obvious doubt about the single woman's or couple's ability to provide the necessary care for a child after birth.
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		The Regional Council's decision may be appealed to the Danish Social Appeals Board within 4 weeks of the decision. The Regional Danish Appeals Board has the final administrative decision. Council must inform the woman or couple about the right to appeal. **(p. 2)**
Funding		N/A
Counselling, communication and information provision		N/A
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A

Miscellaneous		N/A

Table E.5 Extracted data for Denmark (Act on AHR 2019)

Denmark		
Author(s) **Title [year]**	Ministry of the Interior and Health (Denmark) LBK no 902 of 23/08/2019: Proclamation of the Act on Assisted Reproduction in Connection with Treatment, Diagnostics and Research, etc. [2019][9] ▪ Law no 129 Act amending the Act on Assisted Reproduction in connection with treatment, diagnostics and research, etc. (Amendment of the permitted storage period for human eggs retrieved on medical indications)[10] ▪ Law no 1212 Act amending the Act on Assisted Reproduction in connection with treatment, diagnostics and research, etc. (Fertility treatment for second child)[11] ▪ Law no 1213 Act amending the Act on Assisted Reproduction in connection with treatment, diagnostics and research, etc. (Legalization of partner egg donation without medical justification)[12]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**Definitions** Woman: a person with uterine or ovarian tissue Male: a person with at least one testicle. If the egg cell does not originate from the woman who is to give birth to the child, and the sperm does not originate from her partner, assisted reproduction may only be established where the use of both donated sperm and donated egg cell is justified on health grounds and either the sperm or the egg cell is donated in a non-anonymous form.**(p. 1 LBK no 902)** The regional councils may only provide treatment with assisted reproduction at their hospitals for the first and second children of single women. For couples, treatment may only be provided for the first and second children together. [Amended by Law no 1212] **(p. 1 Law no 1212)** To a single woman or a couple who has had a child through assisted reproduction and who, after completion of treatment, still have frozen eggs, the regional councils at their hospitals may, until the time when the woman who is to give birth to the child can no longer receive treatment with assisted reproduction [Amended by Law no 129], offer to freeze eggs with a view to enabling the single woman or couple to have more children.**(p. 1 Law no 129)** ▪ If the egg cell does not originate from the woman who is to give birth to the child, and the sperm does not originate from her partner [double donation], assisted reproduction may only be established where the use of both donated sperm and donated egg cell is justified on health grounds and either the sperm or the egg cell is donated in a non-anonymous form [Amended by Law no 1213]. **(p. 1 LBK no 902)** ▪ The requirement for medical justification above **does not apply** where the egg cell is donated by the partner of the woman who is going to give birth to the child.

		▪ Assisted reproduction may not be established in situations where a healthcare professional or a person under the responsibility of a healthcare professional is aware that the egg cell and sperm originate from genetically closely related or otherwise genetically more closely related persons. Assisted reproduction may not be established in situations where a healthcare professional or a person under the responsibility of a healthcare professional is aware that either the egg cell or sperm originate from relatives of the same sex in the descending or ascending line. **(p. 1 LBK no 902)** ▪ Assisted reproduction may not take place in cases where the woman who is to give birth to the child is older than 45 years. **(p. 1 LBK no 902)** ▪ If the healthcare professional responsible for assisted reproduction treatment of a person residing in this country assesses that there is doubt about the ability of a single woman or a couple to provide the necessary care for a child after birth, the healthcare professional must, with the consent of the single woman or couple, submit information to the regional council with a request that the regional council make a decision on whether assisted reproduction treatment can be initiated. In the absence of consent from the single woman or couple to disclose information to the regional council, the healthcare professional must refuse to initiate assisted reproduction treatment. The Regional Council shall decide whether assisted reproduction treatment may be initiated. The Regional Council may, with the consent of the single woman or couple, include other expertise in the assessment of parental suitability before treatment is initiated. In the absence of consent, the Regional Council shall refuse to initiate assisted reproduction treatment. **(p. 2 LBK no 902)**
DAHR intervention(s) provided		The Act applies to assisted reproduction in connection with treatment, diagnostics and research, etc., carried out by a healthcare professional or under the responsibility of a healthcare professional, where pregnancy in a woman is sought to be established in a way other than through sexual intercourse between a woman and a man. **(p. 1 LBK no 902)** Genetic examination of a fertilised egg may only be carried out in cases where there is a known and significantly increased risk of the child developing a serious hereditary disease. Furthermore, genetic testing may be carried out in connection with assisted reproduction outside the woman's body due to infertility, where such testing can detect or rule out a significant chromosomal abnormality. However, after investigation and health professional assessment, the Danish Patient Safety Agency may in specific cases grant permission for the use of preimplantation genetic diagnosis in assisted reproduction, where there are compelling considerations for the treatment of a child with a life-threatening illness in this family. **(p. 4 LBK no 902)** Assisted reproduction with selection of sperm cells or fertilised eggs before implantation in a woman's uterus with the aim of choosing the sex of the child may not be carried out unless this is done to prevent a sex-linked serious hereditary disease in the child. **(p. 2 LBK no 902)**

Organisation	***Referral pathways***	If the healthcare professional responsible for assisted reproduction treatment of a person residing in this country assesses that there is doubt about the ability of a single woman or a couple to provide the necessary care for a child after birth, the healthcare professional must, with the consent of the single woman or couple, submit information to the regional council with a request that the regional council make a decision on whether assisted reproduction treatment can be initiated. In the absence of consent from the single woman or couple to disclose information to the regional council, the healthcare professional must refuse to initiate assisted reproduction treatment. The Regional Council shall decide whether assisted reproduction treatment may be initiated. The Regional Council may, with the consent of the single woman or couple, include other expertise in the assessment of parental suitability before treatment is initiated. In the absence of consent, the Regional Council shall refuse to initiate assisted reproduction treatment. **(p.2 LBK nr 902)** **Note:** If the woman or couple does not reside in Denmark, and there is doubt about the ability of a single woman or a couple to provide the necessary care for a child after birth the healthcare professional must refuse assisted reproduction treatment.
	Service provider characteristic	Assisted reproduction using sperm cells that have been manipulated, including sorted, may not be carried out by persons who are not doctors or who are not under the responsibility of a doctor. **(p.3 LBK nr 902)** Treatment facilities report information to the Danish Patient Safety Agency about treatment with assisted reproduction.
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	[Not donor specific] Fertilised and unfertilised human eggs may be stored for up to 5 years, after which the eggs must be destroyed. The responsible physician may decide to extend the storage period beyond 5 years and until the time when the woman who is to give birth to the child can no longer receive treatment with assisted reproduction [amended by Law no 129], if the single woman or one party to the marriage, registered partnership or relationship suffers from a serious illness. The responsible physician may revoke a decision pursuant to the 2nd clause where the conditions under the 2nd clause are no longer met. **(p.3 LBK nr 902)** In the event of the woman's death or in the event of the couple's separation or divorce or the end of cohabitation termination, 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. **(p.3 LBK nr 902)** The treating healthcare professional must ensure that the stored sperm of the woman's spouse or partner is destroyed in the event of his or her death, unless there is written consent from the man pursuant.
	Any other management information	N/A
Governance		The Minister of Health may lay down further rules on donation, including anonymity and terms of compensation, on storage, on use, including the number of pregnancies per donor, and on the implantation of human eggs. **(p.3 LBK nr 902)** The Minister of Health may lay down further rules for donation, including anonymity and terms of compensation, and the use of donor sperm, including the number of pregnancies per donor, as well as the purposes for which donor sperm may be stored. The Danish Patient Safety Agency is authorised to lay down health regulations for the donation, use, processing and storage of human eggs. The Danish Patient Safety Agency is authorised to lay down health regulations for donation, use and storage of semen, including with a view to preventing the transmission of diseases.
Funding		N/A
Counselling, communication and information provision		[Not donated gamete specific]: Before treatment with assisted reproduction is initiated, written consent must be obtained from the woman and from her possible spouse, registered partner or partner. **(p.4 LBK nr 902)** May only be given on the basis of written and oral information about the effects and side effects of the treatment, including risks associated with the treatment. Before treatment is initiated, the treating healthcare professional must also inform the man that he can give his written consent to the woman using his sperm or eggs fertilised with his sperm for assisted reproduction treatment after the man's death, and about the consequences of not giving consent to this. At the man's request, the healthcare professional must obtain consent in accordance with the first paragraph, which may be 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 have been met. The treating healthcare professional must ensure that information is provided about the civil law implications of a woman or a couple receiving donated gametes in connection with assisted reproduction treatment.

		The treating healthcare professional must ensure that, before consent is given, information is provided about the civil law effects of the man's sperm or eggs fertilised with his sperm being used in assisted reproduction treatment after his death. **(p.3 LBK nr 902)**
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		N/A

Table E.6 Extracted data for Denmark (Agreement to help involuntarily childless people get pregnant)

Denmark		
Author(s)	Ministry of the Interior and Health	
Title [year]	New agreement to help involuntarily childless people get pregnant[13] (and implementation agreement[14])	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		[Website] Now single people and couples who are affected by involuntary childlessness get better help to get pregnant.
DAHR intervention(s) provided		[Website] The government and Danish Regions have just entered into an agreement that strengthens fertility treatment by providing up to three extra pregnancy attempts with test-tube treatment. [Website] Today, the rules are such that single people and couples are offered up to three attempts of test-tube treatment at public fertility clinics. The new agreement ensures that women and couples, based on a professional assessment, can have up to six attempts at public fertility clinics as early as this year.
Organisation	***Referral pathways***	N/A
	Service provider characteristic	[Website] The new offer of more attempts at fertility treatment will be introduced gradually. Thus, there will be an implementation period over 2024 to take into account the need for more staff resources and capacity for the fertility clinics. [Implementation document] The Government and the Danish Regions agree that the regions, if they assess that they have a need for this, will explore the possibility of collaboration with private clinics, for example by using tender agreements.
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		[Website] As a follow-up to the Finance Act agreement, the government and Danish Regions have now negotiated an implementation agreement that gives single people and couples more and better opportunities to get pregnant and have the family with children they dream of.

		[Implementation document] The Ministry of the Interior and Health and the Danish Regions will discuss the implementation in the autumn of 2024. The Government and the Danish Regions will work together to monitor developments in the area and the offer of multiple attempts at fertility treatment (IVF/ICSI) - including data regarding number of attempts and number of pregnancies based on fertility treatment. The agreement will be followed up in the spring of 2025. The Government and the Danish Regions are expected to enter into an agreement in the spring of 2024 on offers of assistance for a second child – including the financial framework and the use of private capacity.
Funding		[Website] Therefore, with the Finance Act for 2024, the government has taken the initiative to strengthen fertility treatment with DKK 45 million, which will be used to provide better services to the many people who need help to have children.
Counselling, communication and information provision		N/A
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		[Website] Therefore, with the Finance Act for 2024, the government has taken the initiative to strengthen fertility treatment with DKK 45 million, which will be used to provide better services to the many people who need help to have children.
Miscellaneous		N/A

Table E.7 Extracted data for Denmark (Agreement on fertility treatments for second child)

Denmark		
Author(s) **Title [year]**	Ministry of the interior and health New agreement provides twice as many fertility attempts for child number two[15] (and implementation agreement[16])	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		[Website] Single people and couples [Website] From the turn of the year, help for families who have difficulty having children will be strengthened. A new agreement between the government and the regions means that in the future, single people and couples can have twice as many fertility attempts to have a little brother or a little sister without co-paying. [Implementation document] It is important that the number of trials is based on a professional assessment, so that those who are offered more trials have a real chance of achieving a pregnancy. The trials are expanded within the rules set out in the law on access to treatment with artificial insemination.
DAHR intervention(s) provided		[Website] The government and Danish Regions have agreed to expand the offer of fertility treatment to child number two, so that in the future you can have up to six pregnancy attempts without co-paying. That is twice as many as today. [Implementation document] Today, in all regions, you can get up to three of the so-called IVF/ICSI treatments (test tube treatments) at public fertility clinics for a second child. The offer of up to six trials is offered to singles and couples who start a fertility treatment course after 1 January 2026, as well as singles and couples who are already in an active fertility treatment course as of 1 January 2026. [Website] **FACTS: How the government has strengthened fertility treatment** In recent years, the government has taken a number of initiatives to strengthen help for fertility treatment: ▪ doubling of pregnancy attempts for the second child: The government has allocated DKK 35 million in the 2026 budget so that couples and single people can double the number of pregnancy attempts from three to up to six for the second child ▪ twice as many attempts at pregnancy for the first child: In the 2024 Finance Act, the government allocated DKK 45 million annually for involuntarily childless people to have up to twice as many attempts at in vitro fertilization for their first child. Previously, it was only possible to get three treatments. From 1 October 2024, it has been possible to have up to six attempts for the first child ▪ fertility treatment for the second child without co-payment: Previously, you could not receive fertility treatment for the second child without co-payment. You can now

		▪ abolition of the time limit for freezing eggs: The 5-year time limit on freezing eggs retrieved without medical indication has been lifted. The amendment came into force on 1 January 2024. ▪ lesbians can donate eggs to their partner: It has become legal for lesbian couples to donate eggs to their partner without medical justification.
Organisation	***Referral pathways***	N/A
	Service provider characteristic	[Implementation document] Offering more fertility treatment trials will likely require more staff resources and generally additional capacity and equipment for fertility clinics. Implementation of up to six trials will begin in early 2026. The Government and the Danish Regions agree that it is crucial to use the total capacity of the health service to offer the opportunity for help with a second child to the largest possible target group as quickly as possible, including the regions using private capacity. The parties have previously agreed and agree that IVF and related fertility treatments can also be handled by private suppliers in the form of cooperation agreements to the extent needed to ensure rapid treatment and short waiting times.
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		[Implementation agreement] The Government and the Danish Regions will work together to monitor developments in the area and the offer of more fertility treatment trials for a second child (IVF/ICSI). The parties agree that the agreement will be followed up in the spring of 2027, and that the follow-up will be based on available data in the area.
Funding		[Implementation agreement] The 2026 Finance Act stipulates that DKK 35 million will be allocated annually from 2026 onwards to strengthen the fertility area. The government and the Danish Regions have agreed that the funds will be allocated to the regions, which within this framework must expand the number of IVF/ICSI trials, so that singles and couples will in future be offered up to six treatments with retrieved and fertilised eggs (IVF/ICSI treatments) for a second child.
Counselling, communication and information provision		N/A

Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		[Website] The possibility of having up to six fertility attempts for child number two without co-payment is part of the Finance Act agreement for 2026. The extended offer is valid from 1 January 2026.
Miscellaneous		N/A

Table E.8 Extracted data for Denmark (Guidance for healthcare professionals on AHR)

Denmark		
Author(s) **Title [year]**	Ministry of the Interior and Health ROAD No. 9351 of 26/05/2015 (Current) Guidance on the activities and obligations of healthcare professionals and tissue establishments in connection with assisted reproduction(17)	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		In this guide, a "woman" means a person with uterine or ovarian tissue. In this guide, a "man" means a person with at least one testicle. **Health requirements: (p. 4)** Prior to initiating assisted reproduction, a health assessment of the woman must be carried out. In cases of doubt, the authorised healthcare professional must ensure, if necessary by referring to another authority, a relevant health professional assessment of the health conditions. Based on the results of such a relevant health assessment, a woman may be informed of the risk that may be assumed to be associated with treatment or with pregnancy and childbirth in the specific case. Where there is a significantly increased health risk, including special conditions that entail an imminent risk to the development of the fetus, this must be remedied before assisted reproduction is initiated. In special cases, the authorised health professional may refuse to initiate assisted reproduction. **Parental unfitness:** [Extracted in BEK no 316] **Further eligibility: (p. 5)** ▪ Assisted reproduction may not be initiated or continued when the woman who is to give birth to the child is older than 45 years. This follows from section 6 of the Act on Assisted Reproduction. The Danish Health Authority interprets this to mean that treatment may not be initiated when the woman has reached the age of 46. ▪ It follows from the Act on Assisted Reproduction that the regional councils at their hospitals may only provide treatment with assisted reproduction to single women who do not have children and couples who do not have children together. A single woman or a couple who has had a child through assisted reproduction and who, after the end of treatment, still have frozen eggs, are, however, offered egg freezing in the public hospital system with a view to the couple or woman being able to have more children. Treatment in addition to this may also be offered in the public hospital system if the situation is covered by Risk-reducing treatment (PGD and patients with special diseases). Similarly, treatment of fertile and infertile couples where one or both parties are HIV, hepatitis B or C positive may be offered in the public sector as a highly specialised function in the speciality of gynaecology-obstetrics in collaboration with the speciality of infectious medicine. **Requirements for treatment indication, preliminary studies, etc: (p. 6)**

		Normally, treatment of involuntary infertility will not be initiated until the condition has persisted for at least 12 months, unless it must be considered hopeless in advance due to one or more significantly fertility-reducing biological factors in the couple or in the woman (including advanced age in the woman). The reason for waiting for at least the mentioned period is to ensure a sufficient strength of the treatment indication, to take into account that some couples achieve pregnancy naturally, and that it can be assumed that a treatment request made at the first consultation has been sufficiently clarified. Before treatment for involuntary infertility in couples is initiated, relevant investigations must be carried out to clarify the cause of possible biologically determined conception difficulties. The investigations usually include a gynaecological examination, ovulation determination, semen analysis and hysterosalpingography (HSG) or other examinations equivalent to this scope. These examinations will not necessarily be relevant to perform for single or lesbian couples. Before treatment is initiated, the infection marker status must be determined. Examination of infection markers must be performed at a laboratory that has a permit for this purpose from the Danish Health Authority under the Tissue Act. Regarding mandatory screening and testing of donors of unfertilised eggs or sperm, reference is made to Section 18 of the Tissue Executive Order and our guidance on quality and safety in the donation and testing of tissues and cells.
DAHR intervention(s) provided		Assisted reproduction is understood to mean that pregnancy is sought to be established in a way other than through sexual intercourse between a woman and a man. This includes both treatments where fertilised eggs are removed and/or implanted from a woman, as well as insemination, but does not include isolated follicle-stimulating and ovulation-inducing treatment with the aim of promoting pregnancy through subsequent sexual intercourse. **(p. 5)** Treatment may not be performed in situations where a healthcare professional or a person under the responsibility of a healthcare professional is aware that the egg cell and sperm originate from closely related or otherwise more closely related persons. The provision is aimed at treatments that involve non-anonymous donation of sperm or eggs, and applies, for example, to partner donation or the use of a known donor. See below with excerpts from the Act's comments on the understanding of the term "close relative". If spouses who are, for example, cousins, wish to undergo fertility treatment, this is not possible under the current rules. If the treating healthcare professional is in doubt as to whether the persons are closely related, the authorised healthcare professional must inquire about their possible relationship. If the treating authorised healthcare professional receives information that the parties have a genetic relationship, but is in doubt as to whether the persons are covered by the ban on assisted reproduction treatment as a result of their genetic relationship, a clinical genetics department may be consulted. If the parties, in response to questions from the authorised healthcare professional, state that they are not genetically related, the authorised healthcare professional should ensure that they sign a declaration of faith and honour stating that they are not genetically related.**(p. 6)** **Treatments not permitted: (p. 7)**

		▪ Treatment with genetic modification of egg cells or sperm cells or the creation of genetically identical fertilised eggs may not take place. These prohibitions mean, among other things, that gene therapy of gametes, hybridization of genetic material, nuclear transfer and "cloning" are not legal. ▪ Assisted reproduction may not be established unless the egg cells originate from the woman who is to be give birth to the child, or the sperm originates from her partner [NOTE: This is not in place now, double donation is allowed however, There must be a health related/medical indication. This means that the recipient must be produce eggs suitable for creating children. Either egg or semen must come from a non-anonymous donor. At least one of the donors must thus be with an 'extended profile', 'open' or 'known'.] ▪ Assisted reproduction with the selection of sperm cells or fertilised eggs before implantation in a woman's uterus, in order to choose the sex of the child in advance, may not be carried out unless this is done to prevent a serious sex-linked hereditary disease in the child. ▪ The further development of the fertilised egg into a human individual may not take place outside a woman's uterus. The fertilised egg may therefore not be implanted in a foreign uterus or a substitute for it. ▪ Egg implants (fertilised eggs, embryos) from aborted female foetuses, stillbirth's girls or deceased women. ▪ It is not permitted to sell, broker the sale or otherwise assist in the sale of unfertilised or fertilised human eggs. However, it is permitted to import eggs for processing, as long as the eggs are not purchased. In intrauterine insemination with the partner's sperm (IUI-H), the probability of achieving pregnancy decreases significantly after 3-4 stimulated IUI cycles, and further attempts are generally not professionally well-indicated. In intrauterine insemination with donor sperm (IUI-D), the same applies, although less pronounced. In IUI-D, if there are normal conditions in the tubae and a regular cycle, treatment with insemination in a spontaneous (unstimulated) cycle is offered from the start; if pregnancy is not achieved after three inseminations, up to three subsequent attempts with a stimulated cycle can be attempted. Further treatment attempts are generally not professionally well-indicated. Similarly, numerous studies have shown that there is no evidence that multiple insemination attempts in the same cycle increase the likelihood of pregnancy.**(p. 9)** [Impacts the definition of a cycle]: If pregnancy has not been achieved in a usual treatment cycle, where excess suitable embryos were frozen for later transfer to the woman, transfer of the frozen-thawed embryos in a natural/substituted cycle should usually be advised before a new treatment cycle with hormone stimulation and egg retrieval, etc., is considered. This minimizes the number of hormone-stimulated cycles. **(p. 9)** **ICSI**: In micro insemination, a single sperm cell is injected directly into an unfertilised egg. The treatment is used when the man has oligo- or azoospermia, fertilization defect due to sperm abnormalities, high concentration of antibodies in the semen, or there are previous failed fertilization attempts with conventional IVF. Possible treatment alternatives, including

		insemination with donor sperm, as well as the advantages and disadvantages/risks, are assumed to have been considered in consultation with the couple. Where the sperm quality indicates this, further investigation should be carried out. This may include, for example, hormone analyses, chromosome examination, testicular scanning and possibly testicular biopsies. If there is a lack of development of the sperm ducts, this may be due to carrier status for a mutation in the cystic fibrosis gene (CFTR). If carrier status is detected in the man, carrier diagnostics must also be offered to the woman, and genetic biology expertise must be involved. **(p. 9)** **Preimplantation genetic diagnosis (PGD) (pp. 10-18)** Genetic testing of a fertilised egg may take place where there is a known and significantly increased risk of giving birth to a child with a serious hereditary disease. The risk may be known due to familial occurrence, previous birth of an affected child, preconceptional carrier diagnosis, etc. In the case of a woman and her possible spouse or partner, where such a risk is known and the possibility of preimplantation genetic testing is being considered, counselling and examination must first be provided at a clinical genetics department. Preimplantation genetic testing must therefore not be offered solely on the basis of carrier testing in the parents, that is, without further genetic counselling of the couple. Many gene mutations manifest with different clinical severity. The characteristic is that the same disease picture (gene mutation) has different severity when different families (kinds) are compared, but within the same family the severity is often quite constant from generation to generation. It is therefore the severity of the disease in the affected family, and not the diagnosis alone, that is generally the decisive criterion for considering preimplantation genetic diagnosis. A “positive list” cannot be established, but will always be an in-depth, specific assessment, which must always involve genetic/hereditary biology expertise at a clinical genetics department. Genetic screening of fertilised eggs for hereditary diseases other than the serious hereditary disease(s) for which the known and significantly increased risk is directed in the treated woman/couple may not be offered. Genetic testing of a fertilised egg may be performed in the context of assisted reproduction outside the woman's body due to infertility, where such testing can detect or rule out a significant chromosomal abnormality. Examples of chromosomal abnormalities that would be covered by this in principle: ▪ Trisomy-21 (Down syndrome) ▪ Trisomy-18 ▪ Trisomy-13, 47, or XXY (Klinefelter) ▪ Any chromosomal change that is not compatible with long-term survival is included. It is assumed that in cases where PGD is offered counselling has been provided.

		The Danish Health Authority may, in special cases, grant permission for the use of preimplantation genetic diagnosis in assisted reproduction, where there are compelling considerations for a child with a life-threatening illness in this family. In specific cases, the Agency may allow the use of PGD with selection of embryos by tissue type with or without selection of embryos, depending on whether there is also a risk of transmission of a serious hereditary disease in the family. This creates the possibility that a healthy child with the same tissue type as the sick brother or sister can subsequently be born, which will make it possible to establish sibling donation of stem cells. Any permission must be based on a specific health professional assessment of the situation of the sick child and the family. It must also be ensured that all other curative treatment options can be considered exhausted. [Information on how a doctor who treats a life-threatening child submits the application of PGT to the Danish Health Authority is included but was not extracted as not deemed relevant]. **Known donor:** A known donor is known to the recipient or recipients at the time of donation. The known donor can be an adult who a single woman or a cohabiting couple meets and who agrees to donate under agreed terms. Co-maternity/paternity must be determined before known donation can take place. Treatment with a known donor does not include the situation where the woman or couple must have fertility treatment with sperm from an anonymous donor/non-anonymous donor that they have chosen from a sperm bank. **Sperm donation:** Sperm donation can take place with a known heterologous sperm donor (always non-anonymous) and with an unknown heterologous sperm donor (anonymous or non-anonymous). All authorised healthcare professionals can use sperm from a known donor in connection with assisted reproduction. With regard to the treatment of patients in the public hospital system who wish to use non-anonymous sperm, it is noted that it is expected that the regions will to a certain extent offer treatment with both anonymous and non-anonymous donated sperm. The specific product range will be determined regionally. **Egg donation:** Donation from an egg donor who is known to a recipient and intended for use in the treatment of this recipient, has not been legally possible in Denmark until now. It is now legal to use unfertilised eggs (oocytes) based on both anonymous and non-anonymous donation. It will also be legal for a fertility clinic, or for several fertility clinics in association, to organize an egg donation programme based on so-called crossed anonymous donation (see below). **Cross-donation of eggs:** The latest amendment to the law has introduced the possibility of "cross-donation". This means that a woman or a couple in need of receiving an egg for treatment finds a donor themselves who donates to a pool to which several other donors have also donated. The woman/couple will then be guaranteed to be able to receive an egg from the pool, but from another donor whose identity they do not know. They will also be anonymous donors in the sense of the law if no other information can be obtained about them (from the recipients who receive their eggs) at the time of donation or later, other than that corresponding to the basic

		profile (information about the donor's skin colour, hair colour, eye colour, blood type, age, height and weight).
Organisation	***Referral pathways***	N/A
	Service provider characteristic	N/A
	Timelines to access services	N/A
	Any other organisational aspects	Women treated with donated eggs should be informed that they should inform the prenatal diagnostic service that they are egg donors if pregnancy is achieved. This allows the risk assessment to be adapted to the donor's age. **(p. 4)**
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	When deciding on the donation of eggs from a known donor, it is the responsibility of the treating healthcare professional to test the donor's motives to ensure that the donation is truly voluntary. This is best done during an initial conversation with her where the intended recipient is not present, for example in connection with the donor interview, which, according to the provisions of the Tissue Act, must be conducted as part of the assessment of whether the donor is suitable. It should be discussed here whether the woman is clear about her choice of donation form. **(p. 17)** If it appears during the interview that the woman has felt under a certain amount of pressure, for example, that she does not feel able to refuse a request for donation from a friend, family member or similar relationship, and that she herself experiences that the act is not voluntary, then the woman cannot be accepted as a suitable donor. This must subsequently be communicated to the intended recipient, without providing further details as to why the woman is not considered suitable. **(p. 17)** This is done to avoid the cancellation having negative consequences for the relationship between the prospective donor and the prospective recipient. **(p. 17)** When ordering from a sperm bank, the woman or couple reserves one of the 12 pregnancies for this donor. Once all 12 pregnancies have been reserved, the sperm bank will not provide further sperm from this donor until any reservations are released, for example because pregnancy was not achieved with this donor and the woman or couple does not wish to continue with this donor. The donor sperm will normally be purchased from the sperm bank by the woman or couple themselves or purchased through the fertility clinic, which in turn has purchased it from the sperm bank. Many women or couples today purchase donor sperm via the sperm bank websites and have it distributed to a fertility clinic. If a sperm bank has depots at fertility clinics (called "loan tanks") from which fertility clinics can purchase sperm straws, the sperm bank must, upon achieving 12 pregnancies for a donor, notify these fertility clinics that they may no longer use sperm from this donor for anything other than sibling depots. **(p. 20)**

	Storage of donated gametes or embryos	[Information on storage is out of date as it refers to a 5-year period which has now been amended.] Stored unfertilised and fertilised eggs must be destroyed in the event of the woman's death. Fertilised eggs must also be destroyed in the event of the couple's separation, divorce or termination of cohabitation. **This does not apply where the fertilised egg is fertilised with donor sperm.** The above applies to all couples regardless of gender. **(p. 14)** Fertilised eggs can be used to establish a pregnancy after the man's death. The Danish National Board of Health recommends that a written agreement be entered into between the couple and the tissue centre storing the fertilised egg(s) regarding whether and – if so – under what conditions the fertilised eggs can be used after the man's death. Stored unfertilised eggs must be destroyed in the event of the woman's death. **(p. 14)**
	Access to and or disposal of stored donated gametes or embryos	There are no rules regarding the destruction of donor sperm. The previous requirement for destruction of the spouse's or partner's stored sperm in the event of death has been repealed by an amendment to the Assisted Reproduction Act. Whether stored sperm must in future be destroyed upon the death of the spouse or partner can be regulated by agreement between the man and the tissue centre (fertility clinic or sperm bank) where the sperm/embryos are deposited. **(p. 14)** For example, an agreement can be made between the man and the fertility clinic/sperm bank to provide sperm to the deceased donor's partner for the purpose of assisted reproduction treatment, or to provide it to others. **(p. 14)** **Quarantine or ban of sperm:** Where a woman/couple has purchased donor sperm from the sperm bank and subsequently has the donor sperm delivered for processing and possible storage in a depot at the clinic, the clinic must inform the woman of the permanent ban on use. **(p. 21)** When a sperm donor's sperm is subject to a permanent ban on use because there is a risk that the donor's sperm may transmit a hereditary disease, sperm from that donor may no longer be provided for fertility treatment of women or couples. The same applies if the number of pregnancies exceeds the maximum number, which for sperm donors recruited after 1 March 2013 is 12 pregnancies. An exception to this is, however, delivery via “sibling depot”. This means that the single person or one of the couples can still receive sperm from this donor if they already have a sibling with this sperm donor. This also means that if a couple who have a child with the help of donor sperm get divorced, they can each have a child in their respective new relationship with the help of donor sperm. The same applies in cases where the woman is single or where both women in a relationship want to carry a child. **(p. 26)**
	Any other management information	Fertility clinics are obliged to report viable pregnancies to the sperm bank after assisted reproduction with donor sperm. It is irrelevant how the sperm was purchased, as long as it was

		supplied by a Danish sperm bank. If there are full siblings from the same donor, the clinic must also report this. The fertility clinic must provide the country of residence when reporting. **(p. 21)** Suspicion of hereditary risk in a donor arises when illness, death, developmental defect or serious malformation is detected in a donor child either during pregnancy, at birth or later during the child's upbringing, and where this may be due to genetic conditions in either the mother, a donor, or both, or where the circumstances may indicate that donor sperm may have been contaminated with infectious germs. **(p. 21)** Tissue establishments and procurement sites must report information about serious adverse events or side effects that may have an impact on or be related to the quality and safety of tissues and cells and that can be attributed to the procurement, testing, processing, storage or distribution of tissues and cells. The report must be made to the Danish Health Authority. Authorised healthcare professionals who use gametes as part of patient treatment are, obliged to report serious adverse reactions of possible significance for the safety of the use of tissue/cells from a donor to the Danish Health Authority and to the sperm bank from which the sperm was requested. An essential prerequisite for healthcare professionals to comply with this obligation is that the treating authorised healthcare professional or the sperm bank receives feedback on the occurrence of serious adverse reactions from the women/couples treated in question. It is therefore important that the woman/couple is thoroughly informed about the importance of reporting a serious adverse reaction to the treating healthcare professional or the sperm bank. **(p. 21)** From 1 December 2013, healthcare professionals who treat a child born with the help of sperm or eggs from a donor, or who treat a person who has donated sperm or eggs, have a duty to report genetic diseases in the child or person to relevant tissue centres and the Danish Health Authority. The duty arises from the moment the healthcare professional becomes aware that the child was born with the help of sperm or eggs or that the person has been an egg or sperm donor. **(p. 22)** This change has been implemented to improve the ability of tissue centres to initiate relevant follow-up on both genetic disease in a child born with the help of sperm or eggs from a donor (other than a partner) and genetic disease in a donor of sperm or eggs. The healthcare professional has a duty to make the report to the extent that the healthcare professional can identify the relevant tissue centre(s) (for example, the fertility clinic used by the child's mother, or the sperm/egg bank or fertility clinic where the donor donated sperm or eggs) and the relevant donor number. The healthcare professional is expected to either look up this information in the patient's medical record or request it from the patient. **(p. 22)** A report to the sperm bank, to the treating healthcare professional or to the Danish National Board of Health may therefore, depending on the circumstances, also come from a maternity ward, from a paediatric or clinical genetic specialist/department where the examination has taken place, or from a general practitioner. **(p. 22)**

Governance		N/A
Funding		Women and couples often have the option of purchasing multiple sperm and storing them frozen for a fee at a sperm bank or fertility clinic. This is typically called "storing" the donor sperm, and the woman or couple becomes the custodian. The idea of purchasing and owning donor sperm, even if it is not to be used in the short term, may be, for example, to ensure that you can have full siblings at a later date in the future. It may happen that at some point the woman or couple believes that they have now had the number of children they want with the sperm they have lying around. In this situation, it could be considered to sell the last sperm in the depot. We must point out that it is not permitted for a depot owner to sell or transfer ownership of these sperm to other women, other couples or other tissue centres. We would consider this to be distribution of donor sperm, which is not permitted without permission from the Danish Health Authority. However, the owner of the depot would be able to sell his depot back to the tissue centre if the tissue centre wishes to purchase it. Some tissue centres also offer customers the option to reserve sperm from a specific donor. In this case, it is not specific sperm that is purchased, but only the right to receive donor sperm from a specific donor. **(p. 18)**
Counselling, communication and information provision		Assisted reproductive treatment requires written consent from the woman for the treatment. Written consent for the use of frozen, thawed fertilised human eggs must be obtained before each treatment cycle. Consent must also be obtained before allogeneic gamete donation, and consent must be obtained before storage of unfertilised and fertilised eggs). **(p. 3)** It will often be sufficient documentation for consent that it appears from the medical record that the treating physician has seen the written consent. This could be the case, for example, where there is a single donation and removal from another location in the same hospital or abroad. This may also be the case in connection with autologous transplantation of ovarian and testicular tissue, where the patient will later have the tissue transplanted back. **(p. 3)** The following information must be provided by the fertility clinic both in writing and orally to the woman/couple. The written information must also be available on the clinic's website. **Treatment effectiveness (p. 3)** Information on the prospect of successful treatment outcome with assisted reproduction must, among other things, highlight the probability of achieving a viable pregnancy of a child with the treatment in question, calculated per treatment cycle started. The information must include conditions in the woman/man that are important for the individual prognosis, for example the woman's age or a combination of several fertility-reducing factors in the couple. It is not sufficient to provide information on average success rates for a larger patient population. The information must, to the greatest extent possible, be based on the individual clinic's own achieved, documentable treatment results. In the case of assisted reproduction treatment, the fertility clinic must provide information about the civil law consequences of the donation and the treatment, including in relation to paternity. **Treatment complications**: **(p. 4)**

		The fertility clinic must provide information about possible complications and risks of the treatment, such as the risk of overstimulation, infection, ectopic pregnancy, or multiple pregnancy. If there is no consensus in the relevant professional circles about the magnitude of the possible risks, this must also be mentioned. Women treated with donated eggs should be informed that they should inform the prenatal diagnostic service that they are egg donors if pregnancy is achieved. This allows the risk assessment to be adapted to the donor's age. **Infection and hereditary risk**: **(p. 4)** When treating in connection with heterologous egg or sperm donation and when selling sperm to private individuals in connection with home insemination, information must also be provided about the risk of infection and inheritance for the recipient and their future child. This obligation lies with both fertility clinics and sperm banks. Information must be provided about how donors are selected and tested for diseases and that it cannot be ruled out that the future child will inherit a disease when donating gametes, as not all hereditary diseases are tested or can be tested for. The woman/couple must be informed about the importance of reporting back to the clinic if the unborn child is unexpectedly born with a disease that may be hereditary. It is assumed that in cases where PGD is offered counselling has been provided. A prerequisite for receiving sperm from a donor, where in this situation there is a known risk that a genetic disease may be transmitted to the child, is that the woman or couple is thoroughly informed about the risk of a possible known genetic disease and any consequences thereof, and on that basis consents to receive the sperm despite the risk.
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		**Egg Transfer (pp. 9-22)** The doctor must decide, in consultation with the woman/couple, whether to transfer one or two fertilised eggs in a treatment cycle, taking into account the guidelines below. This requires that the woman/couple be informed about the relationship between the number of fertilised eggs transferred and the probability of pregnancy, respectively the probability of multiple pregnancy and any complications associated with this. In light of the experience gained over a number of years with elective single embryo transfer in selected groups of women, the following principles for SET treatment must be followed in future in relation to fresh and thawed embryos. Compliance with these principles in all clinics is a prerequisite for the necessary reduction in the number of multiple pregnancies. This can be achieved with largely unchanged effectiveness of the treatment.

		Transfer with fresh fertilised eggs/embryos: One embryo can be transferred, in special cases two embryos, but never three embryos. *Transfer with thawed fertilised eggs/embryos:* A maximum of one embryo is transferred, in special cases two. There is freedom of choice regarding the form of donation, both for the individual donor and for the single woman or couple who wishes to receive treatment with donated eggs or sperm. According to the Act on Assisted Reproduction, donation of gametes can be done anonymously or non-anonymously. Tissue centres that distribute sperm and fertility clinics that collect eggs must ensure that the sperm donor has not previously functioned or continues to function as a sperm donor in another sperm bank/fertility clinic in Denmark or abroad13). The requirement can be considered fulfilled if the donor makes a written and sworn declaration to this effect, which must be stored and archived in the sperm bank/fertility clinic (the distributing/collecting tissue centre). The maximum number of viable pregnancies after one sperm donor is 25 before and 12 after March 1, 2013. There are different rules regarding how many viable pregnancies can be achieved with a single sperm donor. Viable pregnancy should be understood as an intrauterine gestational sac and heartbeat. If a significantly increased risk (basically 1 percent or more) of a sperm donor transmitting a disease to a child cannot be ruled out, the responsible person must immediately arrange to quarantine the donor's sperm. A written notice of quarantine of sperm straws from the donor must then be sent to all clinics, authorised healthcare professionals and possibly private individuals who have collected sperm from the donor in question. The sperm bank must also notify the Danish Health Authority.

Table E.9 Extracted data for Denmark (Fertility treatment + AHR)

Denmark		
Author(s): Title [year]	Information from multiple sources on public funding: Rigshospitalet: The Fertility Clinic [2026][18] Triangelen Fertility Clinic: Fertility treatment via a public health referral at Trianglen[19] [2026] LGBT Familie: Access to assisted reproduction[20] [2026] Fertility Clinic Skive: Fertility Treatment[21] [2026]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		Women over 41 can still receive a referral for fertility evaluation, However, if fertility treatment (for example, IVF-treatment) is initiated, it will be self-funded. You are generally required to have attempted pregnancy for at least 12 months if you are under 30-35 years old and there are no obvious causes for the condition. In other cases, you may be referred earlier. Fertility treatment cannot be performed after a woman turns 46. In public clinics, treatment is only offered if the woman is referred before she turns 40, and treatment is not provided after the age of 41. Women can receive fertility treatment from private gynaecologists or private fertility clinics, regardless of the number of children they have, up until the age of 45. There is no age limit regarding the man's age. Single women and lesbian couples have the same rights to treatment as others. Fertility treatment is not offered to women with a BMI over 35. There must be a treatment indication for assisted reproduction treatment. This means that if a person who can become pregnant and a person who can produce sperm together want assisted reproduction treatment, the treatment can generally only begin after 12 months of unsuccessful attempts to achieve pregnancy without treatment. This does not apply to single people who want to be pregnant, or couples consisting of two people who are assigned the gender female at birth. Examples of those offered IUI in Skive Fertility Clinic: ▪ Couples where the man has a normal/slightly reduced semen quality and the woman has normal fallopian tube function. ▪ Single women with normal fallopian tube function. ▪ Lesbian couples where the woman being treated has normal fallopian tube function. Examples of those offered IVF/ICSI in Skive Fertility Clinic: Couples with a medical reason to use IVF:

		▪ The woman's fallopian tubes are blocked or not functioning ▪ PCO/PCOS (see "Specific factors affecting your chances of becoming pregnant") ▪ Endometriosis (see "Specific factors affecting your chances of becoming pregnant") ▪ Low semen quality and previous sterilisation ▪ Unexplained infertility ▪ Single women ▪ Lesbian couple
DAHR intervention(s) provided		Three IUI and six IVF/ICSI treatments for patients where there is a reasonable chance of pregnancy by carrying out additional treatment. There is no guaranteed number of treatment attempts in the public system, but typically 3-6 attempts are offered. There is always an ongoing individual assessment of the treatment, and in some cases, fewer attempts may be offered if the chances of success are deemed very low. The use of frozen eggs is not counted as a new treatment attempt. Frozen eggs can be stored for up to five years. The storage period may be extended in exceptional cases, such as when one partner in a couple has a serious illness.
Organisation	***Referral pathways***	The clinic treats childless couples who have already been examined by their own physician, a medical specialist or a hospital ward to establish the reasons for their infertility. The referral for IVF-treatment at a public hospital must be sent before the woman turns 40 years old. You are eligible for public assistance for IVF treatment for your first and second shared child. For men, there is no legal age limit for a referral to fertility evaluation. If you have a male partner, he must also obtain a referral from his general practitioner. If you are a female couple and both wish to undergo evaluation, both of you must have a referral. If only one of you will begin fertility treatment, only that person needs a referral. However, the future co-parent must participate in the initial consultation at the clinic, where consent forms will be completed, and treatment information will be provided.
	Service provider characteristic	In Denmark PGT is centralised to the Fertility Department at Rigshospitalet and the Fertility Clinic at Aalborg University Hospital and is performed in close collaboration with the Departments of Clinical Genetics at both sites.
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	N/A

	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		**What does a referral from your Danish General Practitioner or Gynaecologist cover at Trianglen?** ▪ Initial consultation ▪ Evaluation: ○ blood tests (for both men and women) ○ semen analysis ○ HyCoSy (HysteroContrastUltrasonographY to check fallopian tube patency) ▪ Insemination Treatment* [IUI] up to age 41 years in a female. In general: Fertility treatment is free at public hospitals. You are entitled to free assistance for your first child. From December 1, 2024, there is a political agreement to provide free assistance for having a second child. However, you will need to pay for medication for both the first and second attempt. Assisted reproduction treatment is not covered by the rules on expanded free hospital choice. This means that you do not have the right to use a private fertility clinic without paying for it yourself, even if there is a waiting time for treatment at a public fertility clinic. However, it is possible to receive assisted reproduction treatment in the form of insemination treatment from a private specialist with public funding. At the regional hospitals, assisted reproduction treatment in the form of in vitro fertilization (IVF/ICSI) for the first and second child is available free of charge. This applies to both singles and couples. This means that in vitro fertilization (IVF/ICSI) for the purpose of having a second child can be carried out free of charge at the regional hospitals if couples and singles have frozen fertilised eggs from previous treatment (FER), or if it is in the case of insemination treatment (IUI). **Partner egg donation without medical justification** It is possible for couples consisting of two people with uterine or ovarian tissue to make use of partner egg donation without medical reasons. This means that if you are a couple consisting of two women, a woman and a trans masculine person, or two trans masculine people, it will be possible to donate eggs to your partner, who will then carry the pregnancy and give birth to the child. The person who donates their egg to their partner will be considered a known donor. The same requirements will continue to be imposed for screening, assessment and treatment of the donor, among other things, as currently apply to partner egg donation for medical reasons.

		The treatment is offered at private fertility clinics against payment.
Counselling, communication and information provision		N/A
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		N/A

Table E.10 Extracted data for England (IVF guidance)

England		
Author(s)	UK Government	
Title [year]	Guidance - NHS-funded in vitro fertilisation (IVF) in England[22] [2025]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		▪ Referrals to fertility treatment to have followed two years of regular unprotected intercourse (in the absence of any known cause of infertility) for heterosexual couples or following six rounds of artificial insemination for female same-sex couples. ▪ A body mass index (BMI) of between 19 and 30 for the woman conceiving. ▪ Both partners to be non-smokers.
DAHR intervention(s) provided		**Access requirements for female same-sex couples, by ICB**

ICB	Number of artificial insemination cycles required
Bath and North East Somerset, Swindon and Wiltshire	10 cycles of self-funded artificial insemination, 4 of which should be IUI
Bedfordshire, Luton and Milton Keynes	6 cycles of self-funded artificial insemination
Birmingham and Solihull	6 cycles of self-funded artificial insemination
Black Country	6 cycles of self-funded artificial insemination
Bristol, North Somerset and South Gloucestershire	6 cycles of self-funded artificial insemination
Buckinghamshire, Oxfordshire and Berkshire West	12 cycles of self-funded artificial insemination, 6 of which should be IUI
Cambridgeshire and Peterborough	12 cycles of self-funded artificial insemination
Cornwall and the Isles of Scilly	12 cycles of self-funded artificial insemination, 6 of which should be IUI
Cheshire and Merseyside	Policy under review

		Coventry and Warwickshire	6 cycles of self-funded artificial insemination
		Derby and Derbyshire	6 cycles of self-funded artificial insemination
		Devon	6 cycles of self-funded artificial insemination
		Dorset	6 cycles of self-funded artificial insemination
		Frimley	12 cycles of self-funded artificial insemination, 6 of which should be IUI
		Gloucestershire	6 cycles of self-funded artificial insemination
		Greater Manchester	Policy under review
		Hampshire and Isle of Wight	12 cycles of self-funded artificial insemination
		Herefordshire and Worcestershire	6 cycles of self-funded artificial insemination
		Hertfordshire and West Essex	6 cycles of self-funded artificial insemination
		Humber and North Yorkshire	Policy under review
		Kent and Medway	6 cycles of self-funded artificial insemination
		Lancashire and South Cumbria	12 cycles of self-funded artificial insemination
		Leicester, Leicestershire and Rutland	Policy under review
		Lincolnshire	Unknown (individual CCG policies apply)
		Mid and South Essex	6 cycles of self-funded artificial insemination
		Norfolk and Waveney	6 cycles of self-funded artificial insemination

		North Central London	6 cycles of self-funded artificial insemination
		Northamptonshire	Evidence of subfertility as per local CCG policy
		North East and North Cumbria	6 cycles of self-funded artificial insemination
		North East London	6 cycles (3 cycles for women aged over 36) of self-funded artificial insemination
		North West London	12 cycles of self-funded artificial insemination, 6 of which should be IUI
		Nottingham and Nottinghamshire	Evidence of subfertility as per local CCG policy
		Shropshire, Telford and Wrekin	6 cycles of self-funded artificial insemination
		Somerset	6 cycles of NHS-funded artificial insemination
		South East London	6 cycles (3 cycles for women aged over 36) of self-funded artificial insemination
		South West London	12 cycles of self-funded artificial insemination
		South Yorkshire	6 cycles of NHS-funded artificial insemination
		Staffordshire and Stoke-on-Trent	6 cycles of self-funded artificial insemination
		Suffolk and North East Essex	6 cycles of self-funded artificial insemination
		Surrey Heartlands	6 cycles of NHS-funded artificial insemination
		Sussex	6 cycles of self-funded artificial insemination
		West Yorkshire	6 cycles of NHS-funded artificial insemination
Organisation	***Referral pathways***	N/A	

	Service provider characteristic	N/A
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		N/A
Counselling, communication and information provision		N/A
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		N/A

Table E.11 Data extracted for England (Policy Assisted Conception for Infertility)

England		
Author(s)	NHS Staffordshire and Stoke-on-Trent	
Title [year]	Commissioning Policy Assisted Conception for Infertility[23] [2023]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**Eligibility Criteria for infertility service (pp. 10-13)** **Female's age** ▪ Any treatment cycle will not be commenced if the patient is less than 23 years of age but a referral into tertiary care must be made before the female reaches her 39th birthday. ▪ Females aged 35 – 39 years will be offered treatment provided their predicted ovarian reserve is found to be satisfactory, since this provides useful information regarding likely response to treatment. Although there is continuing debate around the most effective test, AMH is the test of choice for many providers since it has been found to be reliable and can be performed at any stage of the cycle. An AMH >3 will be required for all females 35 years or over for access to IVF treatment. ▪ > 39 years old at the point of entering tertiary care may be referred for tests/investigations in secondary care but should be advised that it is unlikely they will be eligible for NHS funded IVF/ICSI in tertiary care due to the time required for any secondary care tests and/or treatments. ▪ It is the responsibility of service providers to ensure that couples meeting the eligibility criteria have been referred into tertiary care for their IVF/ICSI treatment before the 39th birthday of the female undergoing treatment. If the patient does not undergo their treatment within the 6 months following their 39th birthday they will no longer be eligible for NHS funding. **BMI**: The woman should have a BMI between 19 and 30 (measured in a clinical setting) at the time of commencing treatment within tertiary care. Females who are overweight or underweight will be offered referral to dieticians/lifestyle interventions in order to improve their BMI. Females with a BMI of less than 19 and greater than 30 will not be funded. **Male's age**: There is no upper age limit for the male partner as there is limited evidence to suggest sperm quality deteriorates with age. **Infertility**: Couples who have an identified medical cause for their fertility problems OR have unexplained infertility of at least one year duration. Infertility is defined as the failure of a female of reproductive age to conceive after 1 year of regular unprotected vaginal intercourse, in the absence of any known medical cause of infertility. The above definition cannot be applied in: ▪ same sex female couples those unable to have vaginal intercourse due to a clinically diagnosed physical disability.

		Infertility may be demonstrated by the failure to conceive after 6 cycles of self-funded donor insemination/IUI during the previous 12 months, undertaken at a Human Fertilisation and Embryology Authority (HFEA) license clinic, in the absence of any known reproductive pathology ▪ **Same sex male couples** will not be able to access fertility treatment within their relationship but may be eligible for some assistance if there are medical infertility issues in both partners and both partners fit the above criteria for funding. These cases will be considered via the Individual Funding Request process on the basis of exceptionality. ▪ **Couples who previously** paid for fertility treatment privately can receive 1 NHS-funded cycle if they haven't had more than two complete private cycles. Once a partner completes NHS-funded fertility treatment (regardless of outcome), they've used their NHS entitlement and cannot receive additional NHS-funded cycles with their current or any future partners. o This is not applicable where same–sex couples or couples with a physical disability have self-funded **donor insemination/IUI** for the purpose of demonstrating infertility in line with criterion 4 above. ▪ Couples are ineligible if previous sterilisation has taken place in either partner, even if it has been reversed ▪ Couples should be in a stable relationship of at least two years duration and should be married, or cohabiting, with each other. Couples should also be seen together within primary, secondary and tertiary services as fertility treatment concerns both partners. ▪ Couples must not have a living child from their current or any previous relationships, regardless of whether the child resides with them. This includes any adopted child within their current or previous relationship. Once accepted for treatment, should a child be adopted or a pregnancy leads to a live birth the couple will no longer be eligible for treatment. Foster children are **not included** within this criterion**.** ▪ Where couples smoke, only those who agree to take part in a supportive programme of smoking cessation will be accepted on any assisted conception or IVF waiting list and should be non- smoking for at least 28 days at the time of commencing investigations within secondary care. ▪ Consideration should be given to any alcohol or substance misuse by the couple. The above are a requirement of the HFEA and the following HFEA guidance should be used when making these decisions.
DAHR intervention(s) provided		**Important Note:** The ICB will **not routinely fund donor sperm** but will fund the associated IVF/ICSI treatment in line with the eligibility criteria within this policy providing the sperms meet the criteria set out by the treating provider unit. Patients wishing to access donor sperm treatments must make their own arrangements but are advised to check with the treating provider unit to ensure HFEA guidelines before accessing donated sperms. **(p.15)** **Donor Eggs (p. 15)** Oocyte donation may be commissioned as part of a cycle in cases where it is clinically appropriate; ▪ Premature ovarian failure ▪ Gonadal dysgenesis including Turner Syndrome

		▪ Bilateral oophorectomy Ovarian failure following chemotherapy or radiotherapy NHS funding would not normally be available for women outside these groups who do not respond to follicular stimulation. Oocyte donations will be sourced by the provider.
Organisation	***Referral pathways***	Referrers must ensure patients are aware of the requirements for initial investigations and potential secondary care treatment and the timing implications of these. These stages may take up to 12 months before a referral to tertiary services can be completed. Referrers must be aware that if these early stages are not initiated with sufficient time prior to the woman's 39th birthday, patients may be ineligible for tertiary services. **(p. 10)**
	Service provider characteristic	N/A
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		**Commissioned Services (p. 14)** ▪ IVF/ICSI Staffordshire and Stoke-on-Trent ICB will commission one funded partial cycle of IVF/ICSI for couples with unexplained fertility, mild endometriosis or mild male factor infertility taking into account patient choice. ▪ One partial cycle of IVF/ICSI treatment is defined as one fresh cycle including ovulation induction, egg retrieval, fertilisation and one embryo transfer where viable embryos are available. A cycle includes appropriate diagnostic tests, scans and pharmacological therapy. ▪ As part of the partial cycle, the ICB will fund either one fresh, blastocyst or frozen transfer. ▪ Where no viable embryos are available for transfer, a partial cycle is deemed complete following egg retrieval. ▪ The ICB will not fund any subsequent frozen embryo transfers following the initial fresh, blastocyst or frozen embryo transfer. **Single Embryo Transfer (p. 14)** ▪ Patients will receive a single embryo transfer (whether fresh or frozen) in line with NICE guidance, unless there is a clear clinical justification for not doing so. A maximum of two embryos will be transferred per procedure (either fresh or frozen). ▪ For females aged between 37-39 years double embryo transfer may be considered if no top-quality embryo is available.

		▪ All providers are required to have a multiple birth minimisation strategy in line with the HFEA Code of Practice. **Not funded (p. 8)** ▪ Pre-implantation genetic diagnosis (PGD) is not covered by this policy as it is the commissioning responsibility of NHS England ▪ The eligibility criteria do not apply to the use of assisted conception techniques other than infertility, for example in families with serious inherited diseases where IVF is used to screen out embryos carrying the disease or to preserve fertility for someone about to undergo treatment that may render them infertile. ▪ Surgical Sperm retrieval is not covered by this policy as it is the commissioning responsibility of NHS England ▪ Will not provide fertility treatment for couples where their infertility arises wholly or partly from sterilisation in either partner. on fertility problems6 states that there is no apparent health benefit from Intra Uterine Insemination (IUI) and there are potential risks associated with IUI both with and without stimulation when compared with expectant management (that is, encouraging conception through unprotected vaginal intercourse). In light of this recommendation and the evidence of a poor response rate, the ICB will not fund IUI, either with or without ovarian stimulation. Cases may be considered via the ICB's Individual Funding Request route but must demonstrate robust, clinical exceptionality.
Counselling, communication and information provision		▪ The referring clinician must ensure that patients are aware of the implications of IVF/ICSI treatment, and the commitment required, before making a referral to tertiary care for assisted conception. If there is any doubt over the couple's ability to make the necessary commitment to comply with the treatment regime, they must be referred for counselling, in the first instance, to establish whether assisted conception is appropriate for them. **(p. 10)** ▪ The referring clinician must ensure that couples are aware of the implications of IVF treatment and the commitments required before making a referral for assisted conception. **(p. 12)**
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		▪ **The National Institute for Health and Care Excellence (NICE) Clinical Guideline** CG156 'Fertility problems: assessment and treatment' (2013) available on their website at Overview | Fertility problems: assessment and treatment | Guidance | NICE ▪ **The Human Fertilisation and Embryology Authority (HFEA) document** 'The Possible Best Start to Life' (2007) Our campaign to reduce multiple births | HFEA ▪ **The Human Fertilisation and Embryology Authority Act 2008 Human Fertilisation and Embryology Act 2008 (legislation.gov.uk)** ▪ **The Human Fertilisation and Embryology Authority Code of practice 2021 Code of Practice 9th edition** – revised October 2021 (hfea.gov.uk) ▪ **The National Institute for Health and Care Excellence (NICE) Clinical Knowledge Summary:** Infertility (2018) Infertility | Health topics A to Z | CKS | NICE

Miscellaneous		**Cancelled Cycles** A cancelled cycle is defined by NICE as 'egg collection not undertaken'. Where IVF is charged by providers as an inclusive price, a cancelled cycle will not be charged. Couples will be eligible for one cancelled cycle as part of their NHS treatment where the cycle is cancelled for medical reasons. Cycles cancelled for social reasons are considered a treatment attempt and no further cycles will be funded.

Table E.12 Extracted data for England (Assisted Conception Policy 2017)

England		
Author(s)	NHS Cambridgeshire & Peterborough	
Title [year]	Clinical Threshold Policy - Assisted Conception[24] [2017]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**Couples will be eligible to receive IVF/ICSI where they meet the specified referral criteria (pp. 1-5)** ▪ Maternal age: Women aged 23 to less than 43 years at the start of treatment. ▪ For women >40 years, there must be a discussion of the additional implications of IVF and pregnancy at this stage. ▪ Paternal age is 23 years up to and including 55 years of age. ▪ Number of cycles is ne full/abandoned cycle. ▪ There should be shared decision making between patients and providers to agree the funding for this cycle. If the choice is made to count the abandoned cycle as NHS funded, no further cycles will be NHS funded. ▪ NHS funding is not available (whether self-funded or NHS funded) if couples have received three or more cycles and the woman is <40 years. If the woman is >40 and they have received one cycle then NHS funding is not available. ▪ Couples are ineligible if previous sterilisation has taken place (either partner), even if it has been reversed. ▪ Women must have a BMI of 19 to ≤30kg/m^2 and the male partner must have a BMI <35kg/m^2. Patients outside of this range will not be added to the waiting list and should be referred back to their referring clinician and/or general practitioner for weight management advice and support if required. In female same sex couples, BMI criteria should only apply to the partner undergoing fertility treatment. ▪ Couples who smoke will not be eligible for NHS funded specialist assisted reproduction assessment or treatment and should be informed of this criterion at the earliest possible opportunity. They should be provided with information about the impact of smoking on their ability to conceive naturally, the adverse health impacts of passive smoking on any children and smoking cessation support should be provided as necessary. ▪ Both partners must be non-smoking at the time of referral from secondary care to specialist IVF services and maintained during treatment. This applies equally for same-sex couples as passive smoking may affect the fertility of the partner undergoing fertility treatment. Smoking status should be ascertained by carbon monoxide testing in secondary care and specialist IVF services. ▪ Couples are ineligible for treatment if there are any living children from the current or any previous relationships, regardless of whether the child resides with them. This includes any adopted child within their current or previous relationships. ▪ Providers must meet the statutory requirements to ensure the welfare of the child. This includes HFEA's Code of Practice which considers the 'welfare of the child which may be born'

		and takes into account the importance of a stable and supportive environment for children as well as the pre-existing health status of the parents. ▪ Both partners must be registered with a GP Practice within the CCG and be eligible for NHS care for at least 12 months prior to referral from primary care to secondary care. ▪ To be eligible, the patient should have an Anti-Mullerian Hormone level of more than 5.4pmol/l or Antral Follicle Count of ≥ 4 measured in the last three months of referral from secondary care to the specialist IVF provider. If both tests are done, both criteria must be met. **The minimum investigations required prior to referral to the Tertiary centre:** **Female**: Laparoscopy and/or hysteroscopy and/or hysterosalpingogram or ultrasound scan where appropriate. Rubella antibodies. Must be immune (unless non-responder after 2 vaccinations). Chlamydia screening. Hepatitis B including core antibodies, Hepatitis C and HIV status, within the 3 months before treatment and repeated every 2 years. **(p. 1)** **Male**: Preliminary Semen Analysis and appropriate investigations where abnormal (including genetics). Hepatitis B including core antibodies, Hepatitis C and HIV status, within the 3 months before treatment and repeated every 2 years. **(p. 4)** Treatment may be denied on other medical grounds not explicitly covered here. **Same sex couples:** Same-sex couples are entitled to treatment on the NHS following at least 12 cycles of unsuccessful artificial insemination over three years (this is self-funded or three IUI may be NHS funded if they have gained Exceptional Case Panel approval). **Important Note:** ▪ Couples must meet eligibility criteria as for heterosexual couples. However, BMI eligibility criteria only apply to the female partner undergoing fertility treatment. As for heterosexual couples, couples with a diagnosed cause of absolute infertility will have immediate access to services. ▪ Donor semen is used for same sex couples as part of IVF/ICSI treatment. **Egg donation:** ▪ Available to women who have undergone premature ovarian insufficiency (amenorrhoea >6 months and a raised FSH >25 on two occasions >1 month apart) due to an identifiable pathological or iatrogenic cause before the age of 40 years or to avoid transmission of inherited disorders to a child where the couple meet the other eligibility criteria. **Important Note**: The patient may be able to provide an egg donor; alternatively, the patient can be placed on the waiting list, until an altruistic donor becomes available. If either of the couple exceeds the age criteria prior to a donor egg becoming available, they will no longer be eligible for treatment.

DAHR intervention(s) provided		**Policy Cover: (pp 1-3)** The entitlement and service that will be provided by NHS Cambridgeshire and Peterborough (ICB) for In Vitro Fertilisation (IVF) and Intracytoplasmic Sperm Injection (ICSI). Specialist Fertility Treatments within the scope of this policy are: ▪ In-vitro fertilisation (IVF) and Intra-cytoplasmic sperm injection (ICSI). ▪ Donor Insemination (DI). ▪ Intrauterine Insemination (IUI) unstimulated. ▪ Sperm, embryo and male gonadal tissue cryostorage and replacement techniques. ▪ Egg donation where no other treatment is available. ▪ Egg and sperm storage for patients undergoing cancer treatment. ▪ Surrogacy. **Treatments excluded from this policy:** ▪ Pre-implantation Genetic Diagnosis and associated IVF/ICSI. This service is commissioned by NHS England. ▪ Specialist Fertility Services for members of the Armed Forces are commissioned separately by NHS England. ▪ Surgical sperm retrieval methods are the commissioning responsibility of NHS England. ▪ A maximum of three transfers of embryos (one fresh plus two frozen). **Number of embryos per transfer:** Embryo transfers should be as per HFEA guidance and generally this would be: ▪ Women aged 23 to 39 years – one embryo may be transferred per procedure. ▪ Women aged between 40 to less than 43 years – TWO embryos may be considered for transfer per procedure. **IUI (Unstimulated):** Due to poor clinical evidence, IUI will only be offered under exceptional circumstances. A maximum of three cycles of intrauterine insemination (IUI) will only be offered if prior approval for funding is obtained from the CCG.
Organisation	***Referral pathways***	N/A
	Service provider characteristic	N/A
	Timelines to access services	**Duration of sub-fertility:** Couples should be referred from primary care after 12 months of unexplained infertility. Couples with unexplained infertility must have infertility of at least three years (two years for women 36+ years) of ovulatory cycles, despite regular unprotected vaginal sexual intercourse with the partner seeking treatment, or 12 cycles of artificial insemination over a period of three years to be eligible for NHS funded IVF. If the woman has a miscarriage, the couple will wait for a further 3 years (two years for women 36+ years) of unexplained infertility from the date of the miscarriage to be eligible for NHS funded IVF. Couples with a diagnosed

		cause of absolute infertility which precludes any possibility of natural conception, and who meet other eligibility criteria, will have immediate access to NHS funded assisted reproduction services. **Important Note** There is no wait for couples with a diagnosed cause of infertility – see below: ▪ tubal damage, which includes moderate or severe distortion not amenable to tubal surgery ▪ premature menopause (defined as amenorrhoea for a period more than six months together with a raised FSH >25 and occurring before age 40 years) ▪ male factor infertility. Results of semen analysis conducted as part of an initial assessment should be compared with the following World Health Organisation reference values as follows: o semen volume: 1.5 ml or more o pH: 7.2 or more o sperm concentration: 15 million spermatozoa per ml or more o total sperm number: 39 million spermatozoa per ejaculate or more o total motility (percentage of progressive motility and non-progressive o motility): 40% or more motile or 32% or more with progressive motility o vitality: 58% or more live spermatozoa o sperm morphology (percentage of normal forms): 4% or more. ▪ endometriosis where specialist opinion is that IVF is the correct treatment. ▪ cancer treatment causing infertility necessitating IVF/ICSI (eligibility criteria still apply).
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		**Private treatment/part funding: (p. 6)** ▪ patients meeting NHS criteria, but taking up private treatment, will not be able to retrospectively apply for treatment costs. ▪ patients will not be able to pay for any part of the treatment within a cycle of NHS fertility treatment. This includes, but is not limited to, any drugs (including drugs prescribed by the couple's GP), recommended treatment that is outside the scope of the service specification agreed with the Secondary or Tertiary Provider or experimental treatments.
Counselling, communication and information provision		N/A

Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		N/A

Table E.13 Data extracted for England (Assisted Conception)

England		
Author(s) **Title [year]**	NHS Devon Assisted Conception[25] [2022]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		If the woman is **aged under 40**, they should be offered one cycle of IVF if: ▪ they have been trying to get pregnant through regular unprotected sexual intercourse for a total of two years or ▪ they are using artificial insemination to conceive and have not become pregnant after 12 cycles – at least six of these cycles should have been using intrauterine insemination ▪ they **require donor sperm** for a clinical indication. **(p. 2)** However, if tests show that there appears to be no chance of the woman conceiving naturally, and that IVF is the only treatment that is likely to help, they should be referred straightaway for IVF. No woman may receive an NHS funded IVF cycle if she has previously received a total of three cycles, whether self- or NHS-funded. This is because the chances of having a baby falls with the number of unsuccessful cycles of IVF. The woman's doctor should also take into account how the woman has responded to any previous IVF treatment and what the outcome was when deciding how effective and safe further IVF would be for that individual. If a woman turns 40 during a cycle of IVF, they can finish the current cycle. They will still be able to have up to one frozen embryo transfer episode from their most recent episode of ovarian stimulation since this counts as part of the same cycle. A 'cycle' of IVF is defined in this policy as one fresh and one frozen implantation of embryos. A frozen embryo transfer episode will only be available if there are embryos generated from the fresh cycle suitable for freezing. **(p. 2)** **Population (p. 6):** **Weight –** Women must have a BMI (body mass index) of more than 19 and less than 30; Men must have a BMI of less than 30. **Smoking** – Both partners should be objectively confirmed non-smokers. There is insufficient evidence currently to suggest nicotine replacement therapies or electronic cigarettes (e-cigarettes) have a negative effect on the outcome of assisted reproduction techniques and therefore patients who use them should not be excluded from NHS treatment. **Welfare of the child** – In order to take into account the welfare of the child, the clinician should consider factors which are likely to cause serious physical, psychological or medical harm, either to the child to be born or to any existing children of the family. Previous children **(pp. 6-7):** ▪ There should be no living children from the current relationship, and ▪ At least one partner must have no living children from previous relationships. This includes biological and legally adopted children and offspring who are adults.

		▪ Relationship – The stability of the relationship is very important for the welfare of children; couples must be in a stable relationship for at least two years to be entitled to receive NHS-funded assisted reproduction techniques. ▪ Previous assisted conception – The couple has not previously received NHS funded assisted reproduction techniques. This applies unless failure of NHS-funded IUI is required to access IVF.
DAHR intervention(s) provided		**Intrauterine insemination (IUI) (p. 3)** Unstimulated IUI will only be funded under the circumstances below. Consider up to 12 cycles of unstimulated intrauterine insemination as a treatment option in the following groups as an alternative to vaginal sexual intercourse: ▪ people who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem who are using partner **or donor sperm**. ▪ people with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive). ▪ For people in same-sex couples who have not conceived after six cycles of privately **funded donor or partner insemination**, despite evidence of normal ovulation, tubal patency and semen analysis, the NHS will offer six cycles of unstimulated intrauterine insemination procedures before IVF is considered. ▪ For people with unexplained infertility, mild endometriosis or 'mild male factor infertility', who are having regular unprotected sexual intercourse: ○ do not routinely offer intrauterine insemination, either with or without ovarian stimulation (exceptional circumstances include, for example, when people have social, cultural or religious objections to IVF) ○ advise them to try to conceive for a total of two years (this can include up to one year before their fertility investigations) before IVF will be considered. For IUI for donor insemination for clinical indications, see **Donor Insemination** below. **Donor insemination is** funded for: ▪ azoospermia ▪ severe deficits in semen quality in couples who do not wish to undergo ICSI ▪ where there is a high risk of transmitting a genetic disorder to the offspring ▪ where there is a high risk of transmitting infectious disease to the offspring or woman from the man, and ▪ severe rhesus isoimmunisation. Also following IVF egg retrieval when no living sperm produced on day of treatment. **The tariff covers transport of sperm; and storage for the NHS funded cycle only**. Donor sperm required for a clinical indication may be used for: one cycle of IVF or unstimulated IUI followed by one cycle of IVF, if IUI is unsuccessful. There will be no requirement for a couple to undergo a specified number of cycles of unstimulated IUI before receiving IVF. Up to six cycles of unstimulated IUI may be offered dependent on the availability of donor sperm or three cycles

		of stimulated IUI followed by one cycle of IVF, if IUI is unsuccessful. Before starting treatment by donor insemination, it is important to confirm that the woman is ovulating. Women with a history that is suggestive of tubal damage should be offered tubal assessment before treatment. Women with no risk factors in their history should be offered tubal assessment if clinically indicated. The use of egg donation is funded for: ▪ premature ovarian failure ▪ gonadal dysgenesis including Turner Syndrome ▪ bilateral oophorectomy ▪ ovarian failure following chemotherapy or radiotherapy, and also where there is a high risk of transmitting a genetic disorder to the offspring.
Organisation	***Referral pathways***	N/A
	Service provider characteristic	N/A
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		The NHS in Devon will fund cryopreservation of embryos remaining for up to one year as a result of IVF treatment. Patients who wish to store embryos beyond one year would be required to fund the storage themselves. **(p. 2)** Ovarian reserve testing Antral Follicle Count (AFC), Anti-Mullerian Hormone (AMH) or Follicle-Stimulating Hormone (FSH) testing will be funded for the targeted treatment of individual women. Drug use should be in line with National Institute for Health and Care Excellence (NICE) Clinical Guideline 156 on Fertility. Surrogacy If required due to congenital absence of the uterus or malignancy. Funding is approved for the creation of embryos and storage for five years or until implantation has been performed (whichever is the sooner). Funding is not approved for finding a suitable surrogate or for treatments that are not routinely commissioned.

		Egg donors Egg donors should be screened for both infectious and genetic diseases in accordance with the 'UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors' (2008). The NHS will not fund the payment of egg donors. Egg sharing is funded as long as the NHS does not subsidise treatment for the donor beyond that which is required for treatment of the recipient. **IMPORTANT! – Same-sex couple (p. 6)** If a same-sex couple has a diagnosed fertility problem on investigation then their sub-fertility will be treated. However, NHS funding **will not be available** for donor sperm for female same-sex couples or surrogacy arrangements for male same-sex couples. This is on the basis that unless they are medically sub-fertile their childlessness is due to the absence of gametes of the opposite sex. The clinician should discuss with the couple the feasibility and preparedness of the other partner trying to conceive before proceeding to interventions involving the sub-fertile partner.
Counselling, communication and information provision		N/A
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		Abandoned IVF or ICSI cycle **(p. 5)** An additional cycle to be funded where: ▪ The cycle has been abandoned for clinical reasons prior to egg retrieval ▪ There was no fertilisation of the eggs or no embryos suitable for transfer one further IVF cycle will be funded after an abandoned cycle. ICSI may be offered if clinically appropriate (see ICSI for criteria). Further IVF cycles will not be funded after any subsequent abandoned cycle. Abandoned fresh embryo transfer After oocyte retrieval, if a fresh embryo transfer is not possible for clinical reasons, storage for up to one year and up to two frozen embryo transfers will be funded for the NHS cycle. Abandoned frozen embryo transfer If a frozen embryo transfer was intended but is not possible for clinical reasons and the treatment is cancelled prior to warming the embryo, storage for up to one year and one further frozen embryo transfer will be funded. Cryopreservation for preserving fertility Cryopreservation for preserving fertility is covered by a separate policy.

Table E.14 Extracted data for England (Policy for Assisted Conception Services 2022)

England		
Author(s) **Title [year]**	NHS Lancashire and South Cumbria Policy for Assisted Conception Services[26] [2022]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**Eligibility (pp. 3-4)** ▪ The patient, and their partner in the case of couples, must not have a living biological or adopted child from their current or any previous relationship. ▪ The patient, and their partner in the case of couples, must not have a living biological or adopted child from their current or any previous relationship. ▪ Neither partner has previously had a treatment unit or part of a treatment unit of assisted conception irrespective of the source of funding of that treatment unit, unless it can be clearly demonstrated that: o the unit of treatment was undertaken to demonstrate the presence of clinical infertility. o the unit of treatment was in a different relationship. AND EITHER o the cause of the infertility was attributable predominantly to the other partner in that relationship. OR The treatment was not related to clinical infertility. ▪ The female partner is between 18 years and 42 years of age. Treatment must commence before the female partners 43rd birthday. ▪ Additionally, if the **funding package includes harvesting of eggs from a donor**, then the donor has not yet reached the age of 40 years and has no evidence of infertility. ▪ Neither partner has been previously sterilised. ▪ The female partner seeking to become pregnant has a body mass index in the range 19-30. ▪ The female partner is a non-smoker and commits to remain so throughout the treatment unit and until the completion of any resulting pregnancy. For the purposes of this policy the use of an e-cigarette is considered equivalent to non-smoking status. ▪ The other partner (when applicable) is a non-smoker and commits to remain so throughout the treatment unit. ▪ If the female partner is aged 40-42, a treatment unit will be offered provided the following two additional criteria are fulfilled: o there is no evidence of low ovarian reserve o there has been a discussion of the additional implications of pregnancy and IVF at this age. The ICB will **not commission** any form of assisted conception services or treatment **leading to surrogacy** for those in surrogacy arrangements. (that is, the use of a third party to bear a child for another couple). This is because of the numerous legal and ethical issues involved. Scope of policy – gametes donor **(p. 11)** ▪ The scope of this policy is limited to the commissioning of tertiary fertility services and includes intra-uterine insemination (IUI), intracytoplasmic sperm injection (ICSI) and in vitro fertilisation

		(IVF). This may also include the provision of donor sperm and donor eggs and the storage of gametes and embryos. ▪ Specific patient subgroups: Women in same-sex relationships who have unexplained infertility after donor insemination. ▪ Single women who have unexplained infertility after donor insemination. **Note: (p. 13)** Although the age limit for treatment relies mainly on the Principle of Effectiveness, the purpose of this policy is to restore fertility to people who, without their medical conditions would have good fertility. The lower chance of natural conception in a population of normal older women (compared with a population of normal younger women) is itself a reason why this policy does not offer assisted conception services (irrespective of whether they use their own or donated eggs) to women older than the levels set in NICE guidance (CG156). Therefore, the age criteria, and the application of the age criteria to the recipient as well as the donor in the case of donated eggs, rely in part on the Principle of Appropriateness.
DAHR intervention(s) provided		**Sperm and Egg Donation (p. 7)** Sperm and egg donation will be funded if: ▪ it is required as part of an approved treatment unit and ▪ the **eligibility criteria** at section 1 of the policy are fulfilled and ▪ the patient, or for couples one of the partners, is able to make a contribution to the **child's genome**. ▪ Assisted conception to create an **embryo** entirely from third party gametes will **not be funded.**
Organisation	***Referral pathways***	▪ The ICB will commission services that fall within the scope of this policy only when they are offered by service providers within its portfolio of service agreements or are available on the Free Choice Network in line with the General Policy for IFR Decision Making. ▪ In all respects the ICB will comply with legal requirements which take precedence over other provisions of this policy. **(p. 10)**
	Service provider characteristic	N/A
	Timelines to access services	A person/couple should be offered further clinical assessment and investigation if they are of reproductive age and have not conceived after: ▪ one year of regular (that is, 2-3 times per week) unprotected vaginal sexual intercourse with the same partner OR ▪ six cycles of artificial insemination (with partner or donor sperm). **(p. 5)** **Wait list: (p. 7)** Where there is a lack of **donor eggs** available patients who are eligible for treatment with donor eggs, in line with NICE recommendations, will be placed on a hospital waiting list, where these exist. Patients will be placed on the waiting list for an initial period of **three years**, after which they will be reviewed to assess whether the fertility policy eligibility criteria are still met. Funding is dependent on the patient fulfilling the eligibility criteria of the policy at the time treatment commences.

	Any other organisational aspects	**Treatment Unit:** A treatment unit is the currency used to describe **the amount of assisted conception** treatment to which a patient is eligible. A treatment unit is defined as EITHER: A - Up to 12 separate attempts at IUI, each in a different menstrual cycle OR B - One programme of IVF treatment comprising: ▪ ovarian Stimulation ▪ induction of ovulation ▪ harvesting of resultant eggs ▪ harvesting of semen ▪ fertilisation ▪ storage of eggs/ semen/ embryos in accordance with section. Transfer of any resultant fresh and frozen embryo(s) on as many separate occasions as required until either, a pregnancy leading to a live birth is achieved or there are no embryos remaining. ▪ The ICB will define a unit as cancelled if it fails to reach the stage of an attempt to harvest eggs. ▪ For the purposes of this policy a unit will be counted as cancelled on only one occasion in the lifetime of a woman. Otherwise, if a unit has been partially completed it will count as a whole unit for the purposes of calculating future eligibility for assisted conception services. ▪ If a unit is cancelled due to low ovarian reserve this should be taken into account when considering suitability for further IVF treatment. ▪ In the event of a treatment unit failing as a result of an error within the service provider the ICB expects the service provider to offer a repeat treatment unit. The failed treatment unit will not count towards the woman's lifetime allowance as such a failed unit does not give any indication of the probability of future success. ▪ IUI is likely to be offered using the partners' own gametes only when either; it is impossible for them to have sexual intercourse, or when the sperm has been frozen in accordance with the criteria in this policy and the couple are now eligible for assisted conception services.
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	**Embryo, Egg and Sperm Storage** ▪ The storage of gametes or embryos when assisted conception procedures produce more gametes or embryos than can be used immediately. ▪ The ICB will fund the freezing and storage of surplus eggs or embryos where assisted conception treatments have produced more eggs or embryos than can be used for immediate transfer to the uterus. However, eligibility for funding for ongoing storage will only be provided in line with this policy. ▪ The ICB will not provide funding for the storage of surplus sperm / semen except in accordance with below. ▪ The storage of gametes or embryos for the purposes of fertility preservation.

		▪ The ICB will commission the harvesting and storage of gametes for patients who are on the cancer pathway, such that clinical advice is that treatment is required immediately, that will remove or irreversibly damage the gonads or may prevent the production of gametes. ▪ The ICB will commission the storage of gametes when they have been retrieved for the purposes of fertility preservation as part of an established NHS pathway of care.
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		**Uterine transplantation** is a new technique for which some successes have been reported, but it is too early to determine the overall success rate of the procedure, or to determine the rate of side effects and **complications for the donor**, the recipient and the baby. Therefore, the ICB considers that assisted conception is likely to be less cost effective when a transplanted uterus is used, than otherwise, and it seeks to make best use of the budget available for assisted conception services. Policy in relation to the use of a transplanted uterus is therefore based on the Principle of Cost-Effectiveness. **(p. 14)**
Counselling, communication and information provision		N/A
Ethical and social considerations		The ICB recognises that surrogacy and gamete donation may give rise to a number of ethical and legal considerations. Those concerns are within the scope of the Principle of Ethics. **(p. 15)**
Relevant legislation (list and key aspects)		N/A
Miscellaneous		N/A

Table E.15 Extracted data for England (Fertility Policy 2023)

England		
Author(s)	NHS North East London	
Title [year]	North East London Integrated Care Board (ICB) Fertility Policy[27] [2023]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		Assisted conception treatments are funded for eligible women or people trying to get pregnant who are aged < 43 years. **(p. 6)** **Note:** Referring clinicians should be aware of the work up time required by the provider and ensure that referrals are made in time for women to start egg retrieval before their 43rd birthday. ▪ The woman or person trying to get pregnant must have a body mass index (BMI) of between 19 and 30 at the time treatment begins. ▪ The woman or person trying to get pregnant must be a non-smoker and continue to be a non-smoker throughout treatment. The man or partner providing sperm for assisted conception treatment must be a non-smoker. ▪ Assisted conception treatment will not be offered to couples who have a child together or people who are trying to have a baby on their own who already have a child. ▪ Assisted conception treatment will be offered to eligible couples where neither partner has a child, or where one of the partners has a child from a previous relationship, but the other does not. **Note:** For the purposes of this policy, 'child' is living son or daughter, regardless of their age or where they live. Foster children are not included in these restrictions. Couples: neither partner in a couple should have undergone sterilisation. People who are trying to have a baby on their own: should not have undergone sterilisation. The above still applies if sterilisation reversal has unsuccessfully been attempted. Ovarian reserve is considered low where: ▪ antral follicle count (AFC) is less than or equal to 4 ▪ anti-Müllerian hormone (AMH) is less than or equal to 5.4 pmol/l ▪ follicle-stimulating hormone (FSH) is greater than 8.9 IU/l If two or three of the above measures show low ovarian reserve, assisted conception, treatment will not be offered. If no or one of the above measures show low ovarian reserve, treatment may be offered if appropriate. **Note:** ovarian reserve testing will be undertaken by fertility clinics; patients can therefore be referred prior to receiving these test results, if they fulfil the remaining eligibility criteria.
DAHR intervention(s) provided		**Intra uterine insemination (IUI) and IVF using donor sperm (p. 9)** Up to six cycles of unstimulated IUI using donor sperm is funded for eligible patients where there is evidence of normal ovulation and tubal patency and either: ▪ obstructive or non-obstructive azoospermia

<table>
<tr><td></td><td></td><td>▪ severe deficits in semen quality in couples who do not wish to undergo ICSI
▪ a high risk of transmitting a genetic or infectious disorder to the child and/or partner
▪ severe rhesus isoimmunisation
▪ individuals, or couples trying to conceive using donor insemination who have not conceived after six self-funded IUI cycles.

Where appropriate, IVF using donor sperm will be funded for the above groups.

NEL ICB will fund the cost of the IUI and/ or IVF, <u>but the donor sperm will need to be sourced and paid for by the patient.</u>

IVF using donor eggs (p. 9)
IVF using donor eggs will be funded for eligible patients who have:
▪ premature ovarian failure
▪ gonadal dysgenesis including Turner syndrome
▪ undergone bilateral oophorectomy
▪ a high risk of transmitting a genetic disorder to the offspring.
For eligible patients, IVF using donor eggs will be available as per sections 7–10 of this policy. Note, ovarian reserve criteria do not need to be met by patients undergoing IVF using donor eggs.

NEL ICB will fund the cost of the IVF, <u>but the donor eggs will need to be sourced and paid for by the patient.</u>

Note: There are significant practical and logistical issues relating to NHS funding of donor sperm and eggs. NEL ICB intends to fund donor sperm and eggs for use in NHS funded assisted conception treatments in the future once arrangements have been put in place to resolve these issues.</td></tr>
<tr><td rowspan="2">Organisation</td><td>Referral pathways</td><td>People trying to conceive through artificial insemination (p. 8)
If there is a known clinical cause of infertility or a history of predisposing factors for infertility, patients can be referred for specialist consultation. Otherwise, referral for assessment and investigations can be made for people of reproductive age who have not become pregnant after six self-funded cycles of intrauterine insemination (IUI). If the woman or person trying to get pregnant is aged 36 or over then such assessment and investigations should be considered after three cycles of IUI. Where investigations show there is no chance of pregnancy with expectant management and where IVF is the only effective treatment, eligible patients can be referred for consideration of NHS funded IVF without delay. Otherwise, IVF can be offered to eligible patients who have not conceived after 12 cycles of IUI. If the woman or person trying to get pregnant is aged 36 or over, IVF can be offered after six cycles of IUI. Note, up to six cycles of NHS funded IUI may be available to eligible patients.</td></tr>
<tr><td>Service provider characteristic</td><td>N/A</td></tr>
</table>

	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	**Cryopreservation (freezing) of eggs**, embryos and sperm will be funded for eligible patients who do not currently have fertility problems but are either: ▪ due to undergo a gonadotoxic treatment; this may include patients undergoing interventions for gender affirmation, or ▪ have a medical condition that, in their case, is likely to progress such that it will lead to infertility in the future. To access cryopreservation and storage of sperm, eggs or embryos, fertility preservation patients do not need to meet the eligibility criteria outlined in the above. However, fertility preservation patients who require cryopreservation of eggs or embryos must be: ▪ well enough to undergo ovarian stimulation and egg collection, and this will not worsen their condition, and ▪ enough time is available before the start of their gonadotoxic treatment, where applicable. **(p. 10)** For patients aged under 32 years at the time of cryopreservation: storage of sperm, embryos and eggs will be funded until the patient reaches their 43rd birthday. For patients aged 32 and over at the time of cryopreservation: storage of sperm, embryos and eggs will be funded for 10 years duration. NHS funding of storage will end sooner where: ▪ fertility has been established through tests or conception, or ▪ the patient dies and no written consent has been left permitting posthumous use. **(p. 10)** ▪ To access assisted conception treatments using cryopreserved sperm, eggs or embryos, fertility preservation patients must meet the same eligibility criteria as other patients with fertility problems. An exception to this is that fertility preservation patients do not need to fulfil the ovarian reserve criteria to access IVF using their cryopreserved eggs or embryos. Ovarian tissue cryopreservation is not routinely funded for adults. **(p. 10)**
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		The North East London Integrated Care Board (NEL ICB) provides funding for assisted conception treatments under specific eligibility criteria outlined in their fertility policy **(p. 2)** Preimplantation genetic diagnosis (PGD) is not funded by NEL ICB because this is commissioned by NHS England. **(p. 2)**

Counselling, communication and information provision		N/A
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		**Provision of IVF:** patients need to fulfil the eligibility criteria outlined in sections above. For the purposes of this policy, a full IVF cycle is defined as one episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s). The cycle may be with or without intracytoplasmic sperm injection (ICSI). All frozen embryos should be transferred before starting the next NHS funded fresh IVF cycle. Embryo transfer strategies outlined in NICE CG156 should be followed to minimise the number of multiple births. Storage of cryopreserved supernumerary embryos will be funded for a maximum of two years following each fresh cycle. Natural cycle IVF is not routinely funded. **(p. 7)** **For >40:** For eligible patients requiring IVF where the woman or person trying to get pregnant is aged under 40, NEL ICB will fund up to three full IVF cycles. If the patient reaches the age of 40 during treatment, the current full cycle will be completed but no further full cycles will be available. Treatment will not be funded for patients aged under 40 years old who have previously had three fresh cycles of IVF, including privately funded cycles. This means if a patient has had one previous fresh IVF cycle, up to two NHS funded full IVF cycles will be funded. If a patient has had two previous fresh IVF cycles, one NHS funded full IVF cycle will be funded. **(p. 7)** **Between 40 – 42:** For eligible patients requiring IVF where the woman or person trying to get pregnant is aged 40–42, NEL ICB will fund one full IVF cycle. Treatment will not be funded for patients aged 40–42 years old who have previously had any IVF treatment, including privately funded cycles. Before starting treatment, patients aged 40–42 years old should be made aware of the additional implications of IVF and pregnancy at this age. **(p. 7)** **Abandoned cycle:** One abandoned cycle (defined as a cycle where an egg collection procedure has not been undertaken) does not count towards the number of cycles funded. However, further cycles will not be started if the treating doctor thinks it would be clinically inappropriate. **(p. 7)**

Table E.16 Extracted data for England (Access to Infertility Treatment Policy 2025)

England		
Author(s) **Title [year]**	NHS Humber and North Yorkshire ICB, NHS South Yorkshire ICB, NHS West Yorkshire ICB Access to Infertility Treatment Commissioning Policy Document[28] [2025]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**Eligibility Criteria (pp. 14 – 16) at the point of referral to, and throughout, specialist care:** ▪ women aged between 40–42 will need further assessment within specialist care to ascertain whether they are eligible. ▪ neither partner should have any living children (this includes adopted children but not fostered) from their relationship together or any previous relationship. ▪ woman intending to become pregnant must be between the ages of 18 – 42 years. Referrers should be mindful of the woman's age at the point of referral and the age limit for new cycles. **IVF cycles funded by South Yorkshire ICB** ▪ Women in SY ICB aged between 18-39 years who meet the eligibility criteria for infertility will receive1 full cycle of IVF treatment with their own eggs, with or without ICSI. ▪ Women in SY ICB aged 40–42 years who meet the eligibility criteria for infertility will receive 1 full cycle of IVF treatment with their own eggs, with or without ICSI. provided the following criteria are fulfilled: ▪ they have never previously had IVF treatment ▪ there is no evidence of low ovarian reserve using one of the following measures AFC of less than or equal to 4, AMH of less than or equal to 5.4 pmol/l, FSH greater than 8.9 IU/l ▪ there has been a discussion of the additional implications of IVF and pregnancy at this age ▪ where IVF is the only effective treatment, women aged between 40-42 should be referred directly to a specialist team for IVF treatment. Where an individual feels that they have exceptional circumstances that would merit consideration of an additional cycle being funded by the NHS they should speak to their doctor about submitting an individual funding request to the ICB. **Pre-Referral Requirements for Specialist Care** ▪ The female patient's **BMI should be between 19 and 30** prior to referral to specialist services and throughout treatment. In the case of same sex couples, the BMI range applies to the patient(s) intending to undergo fertility procedures. Patients with a higher BMI should be referred for healthy lifestyle interventions including weight management advice. Patients should not be re-referred to specialist services until their BMI is within the recommended range. ▪ GP should discuss smoking with couples prior to referral to secondary care and support their efforts to stop by referring to a **smoking cessation programme**. Smoking adversely affects

		the success rate of the treatment and the pregnancy outcome. Couples must be **non-smoking for 28 days** to access any fertility treatment and must continue to be non-smoking throughout treatment. **Currently there is limited and uncertain evidence around the safety of vaping and nicotine products, but sole use of e-cigarettes, without the concurrent use of tobacco, is classified as non-smoking for the purposes of this policy. If it is suspected that patients continue to smoke then carbon monoxide (CO) testing may be considered.** ▪ Couples must give assurances that **their alcohol intake** is within current Department of Health guidelines and that they are not currently using recreational drugs. ▪ The ICB will not fund IVF treatment for patients who have been sterilised, including those who have undergone reversal of sterilisation. ▪ The chance of pregnancy decreases with successive cycles so all previous self-funded or NHS funded cycles will be taken into consideration when assessing a couple's ability to benefit from treatment and will count towards the total number of cycles that may be 15 offered by the NHS. This includes where either person has had a previous cycle with a previous partner. ▪ Couples must have been co-habiting in a stable relationship for a minimum of two years at the same address. ▪ Welfare of the Child HFEA guidance concerning the welfare of the child should be followed.
DAHR intervention(s) provided		Specialist fertility services include IUI, ICSI and IVF. They may also include the provision of donor sperm and donor eggs. The majority of treatment in the UK is statutorily regulated by the Human Fertility and Embryo Authority (HFEA). All specialist providers of fertility services must be licensed with the HFEA in order to be commissioned under this policy **(p. 6)** **IUI and DI (Donor insemination): (p. 11)** IUI and DI are separate from IVF treatment; however, the couple may then access IVF treatment if appropriate. ▪ People who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem or people in same sex relationships or other specific conditions with infertility who are using partner or donor sperm (as per the definition of infertility): up to 6 cycles of IUI may be funded where clinically appropriate, followed by further assisted conception if required. In some circumstances, IUI may be impractical or not desired and so is not a requirement to access further fertility treatment. IUI will not be funded as a treatment after IVF treatment. ▪ Couples with unexplained infertility, who are having regular unprotected sexual intercourse: IUI either with or without ovarian stimulation will not be funded routinely (exceptional circumstances may include, for example, when people have social, cultural or religious objections to IVF), instead couples should try to conceive for a total of two years (this can include up to one year before their fertility investigations) before IVF will be considered, in keeping with current NICE guidance.

		▪ Women with anovulatory infertility: ovulation induction with gonadotrophin therapy may be funded for up to six cycles, followed by further assisted conception if required. In some circumstances, IUI may be impractical or not desired and so is not a requirement to access further fertility treatment. IUI will not be funded as a treatment after IVF treatment. **Donor Gametes including azoospermia**: **(p. 12)** ▪ Patients who require donor gametes will be placed on the waiting list for an initial period of up to 3 years, after which they will be reviewed to assess whether the fertility policy eligibility criteria are still met. ▪ If it is anticipated that there will be difficulty finding a suitable donor and there is evidence of exceptionality the clinician may consider an IFR application to source from alternative providers. **Donor Sperm (p. 12)** ▪ Where **clinically indicated up to six cycles of donor** insemination will be offered. The cost of **donor sperm is included in the funding of treatment for which it is required**, to be commissioned in accordance with this policy and the funding policy of the ICB. ▪ Couples **who request the use of a known clinically appropriate sperm donor will be responsible for all costs associated** with the donor, including transportation costs. The ICB will fund the IUI/IVF/ICSI treatment at an accredited provider in line with the criteria in this policy, providing it meets the criteria defined by the HFEA. **Donor Eggs (p. 12)** ▪ Patients eligible for treatment with donor eggs, in line with NICE recommendations, will be placed on the waiting list for treatment. Unfortunately, the availability of donor eggs remains severely limited in the UK. There is, therefore, no guarantee that eligible patients will be able to proceed with treatment. ▪ Couples who request the use of **a known clinically appropriate egg donor will be responsible for all costs associated with the donor**, including transportation costs. The ICB will fund the associated IUI/IVF/ICSI treatment at an accredited provider in line with the criteria in this policy, providing it meets the criteria defined by the HFEA. **Surrogacy (p. 13)** Any costs associated with the use of a surrogacy arrangement will not be covered by funding from the ICB. It will, however, fund the screening and provision of fertility treatment (IVF treatment and storage) to identified (fertile) surrogates, where this is the most suitable treatment for a couple's infertility problem and the couple meets the eligibility criteria for specialist fertility services set out in this policy.

Organisation	***Referral pathways***	**Infertility Problems (p. 10)** The care pathway begins in primary care, where the first stage of treatment is general lifestyle advice and support to increase a couple's chances of conception without the need for medical intervention. If primary care interventions are not effective, initial assessment such as semen analysis and female hormone profile will take place. Following these initial diagnostics, it may be appropriate for the couple to be referred to secondary care services where further investigation and potential treatments will be carried out, such as hormonal therapies to stimulate ovulation. It may be appropriate at this stage for the primary care clinician to consider and discuss the care pathway and potential eligibility for IVF. It may also be appropriate for healthy lifestyle interventions to be further discussed. If secondary care interventions are not successful and the couple fulfils the eligibility criteria, they may then be referred through to specialist care for assessment for assisted conception techniques such as IVF, DI, IUI, and ICSI. ***Referral pathways- Overarching Principles*** ▪ All clinically appropriate individuals / couples are entitled to medical advice and investigation. Couples may be referred to a secondary care clinic for further investigation. ▪ Treatment limits are per couple and per individual. Referrals should be as a couple and include demographic information for both partners in heterosexual and same-sex relationships. **(p. 12)**
	Service provider characteristic	N/A
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	The cost of egg and sperm storage will be included in the funding of treatment for which it is required, to be commissioned in accordance with this policy and the funding policy of the ICB. Storage will be funded by the ICB for a maximum of three years or until six months post successful live birth, whichever is the shorter. This will be explained by the provider prior to the commencement of treatment. Following this period continued storage may be self-funded. Any embryos frozen prior to implementation of this policy will be funded by the ICB to remain frozen for a maximum period of three years from the date of policy adoption. Any embryo storage funded privately prior to the implementation of this policy will remain privately funded. **(p. 12)**
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		N/A

Counselling, communication and information provision		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. **(p. 7)** Information should be provided in the following formats: ▪ face to face and remote discussions with couples ▪ appointments should be face to face if clinically indicated or patients' preference. ▪ written information and advice ▪ culturally sensitive and gender inclusive ▪ sensitive to those with additional needs for example, physical or cognitive, or those for whom English is not their first language ▪ sensitive to couples' needs and preferences. **(p. 8)** As infertility and infertility treatments have a number of psychosocial effects on couples, access to psychological support prior to and during treatment should be considered as integral to the care pathway. **(p. 8)** **Treatment for infertility problems** may include counselling, lifestyle advice, drug treatments, surgery and assisted conception techniques such as IVF. **(p. 10)** **Providers of specialist fertility services are expected to: (p. 10)** ▪ support appropriate interventions to promote lifestyle behaviour changes which are likely to have a positive impact on the outcome of assisted conception techniques and resulting pregnancies. ▪ use any appointment or meeting as an opportunity to ask couples about their general lifestyle including smoking, alcohol consumption, recreational drug use, physical activity and eating habits. If they practice unhealthy behaviours, explain how health services can support people to change behaviour and sustain a healthy lifestyle. ▪ offer those who would benefit a referral to local wellbeing services and / or locally commissioned lifestyle services. For those that are unable or do not want to attend support services direct them to appropriate self-help information. ▪ record this in the patient record or accepted local equivalent. **Counselling and Psychological Support** As infertility and its treatment has a number of negative psychosocial effects, access to counselling and psychological support should be offered to the couple prior to and during treatment.
Ethical and social considerations		**Equality** The ICB is committed to creating an environment where everyone is treated equitably and the potential for discrimination is identified and mitigated. As a result of preforming the screening analysis, the policy may possibly have an adverse effect on people who share protected characteristics and further actions are recommended in the equality impact assessment.

Relevant legislation (list and key aspects)		1. **Human Fertilisation and Embryology Authority (HFEA)** - Regulates IVF/ICSI clinics and provides guidance for patients. 2. **NHS England "Who Pays?"3 Guidance (April 2024)** - Explains which NHS commissioner is responsible for commissioning and paying for an individual's NHS care. 3. **HM Government Overseas NHS Visitors: Implementing the Charging Regulations** - Guidance on NHS cost recovery for overseas visitors. 4. **Department of Health Guidance on NHS patients who wish to pay for additional private care (March 2009)** - Rules for patients paying for private healthcare while receiving NHS care.
Miscellaneous		N/A

Table E.17 Extracted data for France (Procreation)

France		
Author(s) **Title [year]**	Agence de la biomedicine Procreation: Questions and testimonials[29] [2026]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**Are there any criteria required to carry out medically assisted procreation?** Medically assisted reproduction is now accessible to all women, whether they are in a relationship with a man, a woman or single. A medical evaluation of both members of the couple or the unmarried woman is mandatory before treatment. In addition, Decree No. 2021-1243 of 28 September 2021 sets age criteria for the removal and collection of gametes and their use in medically assisted procreation, self-preservation with a view to the preservation of the Fertility or in the absence of medical reasons: ▪ egg retrieval until day 43rd Birthday for the woman and sperm collection until 60th birthday for the man ▪ use of gametes and Embryos until the day of the 45th Birthday for women and 60th anniversary for men or the other member of the couple if it is a female couple. The use of gametes collected and stored for medically assisted reproduction purposes (in the context of ART or self-preservation) may be carried out, subject to the following dual age conditions of the members of the couple: ▪ up to the age of forty-four for women, unmarried or within the couple, who are destined to carry the child, for example, until the eve of the 45th birthday ▪ up to the age of fifty-nine with the spouse, for example, until the day before the 60th birthday. **Is it necessary to prove cohabitation and its duration?** The condition of stability of the couple (marriage or proof of living together for at least two years) has been abolished since the law of 7 July 2011 on bioethics. The reality of the couple is an obligation to be able to access ART care. If two people come to a centre as a couple to receive ART care, the donation centre must ensure that the couple is genuine. A couple is defined as any couple composed of a man and a woman or two women. The members of the couple may or may not be married or bound by a civil solidarity pact. Indeed, it is important to remember that in the event of divorce (or divorce application), separation, death or revocation of the consent of one of the members of the couple, any transfer of Embryos frozen or any artificial insemination is made impossible when the request for ART coverage has been made by a couple. **For female couples, do you have to be married?** Every couple consisting of a man and a woman or two women or any unmarried woman have access to medically assisted procreation. As recalled in the circular of 21 September 2021 presenting the provisions on medically assisted procreation resulting from Law No. 2021-1017 of 2 August 2021 on bioethics, medically assisted procreation is open to all couples, regardless of

		their marital status. Thus, it is not necessary for the couple to be married to benefit from medically assisted procreation and the early joint recognition system. The same applies to the joint recognition of the transitional mechanism provided for in IV of article 6 of the law on bioethics, which is applicable to female couples who have had recourse to medically assisted procreation abroad before the law: women do not have to be married in order to be able to have joint recognition established before the notary. Moreover, the possible separation of the couple after medically assisted procreation does not change anything: even if separated, women can make a joint recognition before the notary provided that at the time of medically assisted procreation, these two women were in a couple (married, in a civil partnership or cohabiting) and that they had recourse to medically assisted procreation as part of a joint parental project. The condition of stability of the couple (marriage or proof of living together for at least two years) was abolished by Law No. 2011-814 of 7 July 2011 on bioethics. The use of ART is now conditional on the existence of a parental project. The new Article L. 2141-2 of the Public Health Code provides that medically assisted procreation "is intended to respond to a parental project" and that "any couple consisting of a man and a woman or two women or any unmarried woman shall have access to medically assisted procreation after the individual interviews of the applicants with the members of the multidisciplinary clinical-biological medical team carried out in accordance with the procedures provided for in Article L. 2141-10 ». This parental project can be carried out by: ▪ a couple of people of different sexes, whether married, bound by a civil solidarity pact or living together ▪ a couple of women, regardless of their marital status ▪ an unmarried woman. **Is the social assessment of single women and female couples requesting ART mandatory?** The law does not provide for an obligation to carry out a social assessment before an ART, regardless of the applicants' marital status. All requests for ART are subject to a medical evaluation by the multidisciplinary clinical-biological team of the ART centres. In order to harmonise practices across the country and prevent any risk of discrimination, the composition of this team is now set by decree. The role of the medical team of the ART centre is therefore to support couples or unmarried women in their parental project. To do this, the doctor at the ART centre carries out an assessment to choose the most suitable solution for the couple or unmarried woman who wishes to benefit from ART. After a clinical examination, the doctor prescribes the simplest and least invasive examinations to the couple or unmarried woman before considering more sophisticated examinations if necessary. In addition, French law requires that the implementation of medically assisted procreation be preceded by several private meetings between the couple or single woman and the members of the centre's multidisciplinary clinical-biological medical team.
DAHR intervention(s) provided		**In a female couple, is it possible to carry out a simultaneous embryo transfer in both members of the couple?**

		Yes, it is possible to transfer Embryos in both women in the couple. However, each woman will only be able to benefit from the transfer of embryos conceived with donor sperm and her own oocytes or egg donation but in no case from an embryo conceived with the oocytes of her partner. Indeed, the so-called ROPA method (reception of oocytes from the partner) is not authorised in France. This prohibition is based on: ▪ on the one hand, on the principle of the anonymity of donation in France between the donor and the recipient ▪ on the other hand, on the fact that an oocyte retrieval, except for use in the context of IVF for the benefit of the person removed, immediately or subsequently (self-preservation), cannot have any other purpose than an anonymous donation. So, there are two distinct procedures of stimulation, IVF and Embryos**:** a procedure for each of the women. These are two separate parenting projects. For this reason, two separate consents and two separate RCAs are required**.** **Is consent to medically assisted reproduction with a third-party donor valid for several births?** Consent to medically assisted procreation with the intervention of a third-party gamete donor (spermatozoa or oocytes) must be drawn up before a notary for each new child project. After a birth, consent must therefore be renewed, even when there are still Embryos frozen. **Can I benefit from a double sperm and oocyte donation in France?** Yes, the bioethics law of 2 August 2021 authorises medically assisted reproduction with double gamete donation (oocytes and spermatozoa) for couples and unmarried women who meet the age conditions defined by decree. **When do we know that we must have recourse to ART?** Contact the general practitioner or gynaecologist who usually follows you. He/she will carry out an initial assessment and refer you if necessary to a specialized colleague or a multidisciplinary centre for Assisted Reproduction (ART). Consult without too much delay: If you are a woman and you are 35 years of age or older If you are a woman and you have: ▪ cycles that are too long (more than 35 days) or too short (less than 22 days) ▪ known severe endometriosis or very painful periods ▪ previously had a tubal infection, a proboscis. If you are a man and you have: ▪ ever had testicular torsion or any testicular involvement Whether you are a man or a woman, if you have: ▪ ever had a genital infection, ▪ ever had a sexually transmitted disease (chlamydia)

		▪ already received medical treatment that could impact your Fertility ▪ sexual difficulties, whatever the causes. **When is in vitro fertilization used?** In vitro fertilization (IVF) can be proposed: ▪ couples composed of a man and a woman ▪ female couples, and ▪ single women. It is the medical team that determines the most appropriate ART technique for each case. It may be indicated in particular ▪ in the event of an abnormality in the woman's reproductive function (for example, when there is an abnormality of the fallopian tubes or severe endometriosis) ▪ and/or in the event of an abnormality in the man's reproductive function (for example too low sperm count) ▪ in case of failure of intrauterine insemination, even if no cause has been identified.
Organisation	***Referral pathways***	**I will probably have to resort to ART, what should I do?** Contact the general practitioner or gynaecologist who usually follows you. He/she will carry out an initial assessment and refer you if necessary to a specialised colleague or a multidisciplinary centre for Assisted Reproduction (ART). **This doctor may then refer you to an ART centre.** **How does the medically assisted reproduction pathway work? What are the different stages?** The assisted reproduction technique proposed by the medical team depends on the results of the clinical-biological assessments carried out by the couple or the unmarried woman. French law requires that the implementation of medically assisted procreation be preceded by several private interviews between the couple or the unmarried woman and the members of the centre's multidisciplinary clinical-biological medical team (Art. L.2141-10 of the Public Health Code). It provides for a reflection period of one month before signing the consent to medically assisted procreation. Doctors in the assisted reproduction centres must: ▪ check the motivation of both members of the couple or the unmarried woman ▪ conduct a medical evaluation of both members of the couple or the unmarried woman ▪ fully inform both members of the couple or the unmarried woman, in the light of the state of scientific knowledge, of the possibilities of success or failure of assisted reproduction techniques, their side effects and their short- and long-term risks. The couple or the unmarried woman may then be offered either artificial insemination or in vitro fertilization (classic or with micro injection of sperm– ICSI, possibly with gametes from a third-party donor), or an embryo reception.

		Can the application for medically assisted reproduction be refused? Yes, a request for medically assisted reproduction can be refused. Any request for medically assisted procreation must be evaluated by the clinical-biological medical team of the medically assisted procreation centre. In addition to meeting the age conditions set by the decree of 28 September 2021 by the applicants, the medical team must ensure the feasibility of the process. The possibility of refusing or postponing medically assisted reproduction is a medical decision. The Bioethics Act provides that the grounds for refusal of coverage in the context of medically assisted procreation are communicated in writing to applicants as soon as they request them to the medically assisted procreation centre. **Is an appointment with a psychologist mandatory?** No, French law requires that the implementation of medically assisted procreation be preceded by several private interviews between the couple or the unmarried woman and the members of the centre's multidisciplinary clinical-biological medical team (Art. L.2141-10 of the Public Health Code). The doctors of the ART centre must: ▪ check the motivation of both members of the couple or the unmarried woman ▪ carry out a medical evaluation of both members of the couple or the unmarried woman ▪ to fully inform, in the light of the state of scientific knowledge, both members of the couple or the unmarried woman of the possibilities of success or failure of medically assisted reproduction techniques, of their side effects and their short and long-term risks, as well as of their arduousness and the constraints they may entail. From the beginning of the treatment, an interview with a psychologist and/or psychiatrist is offered to the couple or the unmarried woman and can be repeated throughout the process. Psychologists or psychiatrists in ART centres are available to listen to couples or unmarried women and can provide them with support.
	Service provider characteristic	**Can I register in several assisted reproduction centres to benefit more quickly from gamete donation?** Although there is nothing in the law prohibiting registration in several assisted reproduction centres, it is not advisable to register in several centres at the same time. Indeed, by doing so, you slow down all the routes, yours and that of others. **Is it possible to be followed in a private assisted reproduction centre?** Yes, it is possible to be treated in a private assisted reproduction centre.
	Timelines to access services	**What are the deadlines for accessing a medically assisted reproduction pathway in France?** The time taken to cover medically assisted reproduction for couples or unmarried women depends on many specific criteria such as the results of the Fertility carried out by the Centre for Assisted Reproduction, the technique proposed by the centre's medical team, the use of a third-party donor, the centre's human resources, the centre's infrastructure, etc. **What are the deadlines for sperm donation in the different donation centres?**

		Sperm donation includes a medical check-up as well as several sperm collections (the number of sperm collections will depend on the sperm characteristics: sperm count and motility). The centre organises appointments according to the availability of the candidate donor. The course can thus be completed in a few weeks or months. For people who have recourse to medically assisted reproduction with sperm donation, it takes an average of between 6 and 12 months between the start of the procedure at the donation centre and the allocation of the sperm to the couple or the unmarried woman. However, these delays may vary depending on the region and the requests for matching with recipient persons for which donors with the same physical characteristics are rarer. In order to reduce these delays, the Biomedicine Agency is conducting a vast national communication campaign on gamete donation in order to raise awareness among the public of donor age and thus recruit new donors. **What are the deadlines for egg donation in the different CECOS?** Egg donation takes place in five stages and it takes on average less than six months for the entire procedure. For people who have recourse to ART with egg donation, it takes an average of between 12 and 30 months between the start of the procedure in the donation centre and the allocation of the eggs to the recipients. However, these delays may vary in the case of matching with recipient persons for whom donors with the same physical characteristics are rarer. This is why the Biomedicine Agency is conducting a national communication campaign on gamete donation in order to raise awareness among the public of donor age and thus recruit new donors.
	Any other organisational aspects	**If the couple of women has started a journey in a foreign clinic, do they have to start from scratch if they go to a French centre?** Couples and unmarried women can continue their medically assisted reproduction course in France when it has been initiated abroad if: ▪ the donation procedure has respected the principles of free of charge and anonymity (couples and unmarried women will have to obtain an authorization to import gametes or to move Embryos issued by the Biomedicine Agency) ▪ the use of gametes is done in an authorised centre and in compliance with the age conditions specified by Decree No. 2021-1243 of September 28, 2021. In addition, if the female couple wishes to continue their medically assisted reproduction journey in France with gametes or Embryos kept abroad, the importer must obtain an authorization to import gametes or to move Embryos issued by the Biomedicine Agency.
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	**Is it mandatory to consult a gynaecologist specialising in medically assisted reproduction before contacting the sperm donation centre?** The medically assisted reproduction process with sperm donation involves several stages, in any order. The professionals to meet are the: ▪ doctor specialising in reproductive medicine. He can practice in the city or in a health establishment ▪ practitioner of the donation centre

		▪ psychologist at the donation centre, whose one-off consultation is highly recommended. His role is to accompany you in your parental project ▪ notary, for the signing of the consent (and advance recognition, if applicable). **In the context of gamete donation, is matching on physical characteristics mandatory?** No, matching is not mandatory but it must be offered to the couple or to the unmarried woman receiving a gamete or Embryos. This matching is carried out by the medical team of the ART centre as far as possible. When requested, matching shall take into account, as far as possible, the main physical characteristics such as the applicants' skin or eye colour. Recipients are advised that this match is not always possible, given the rarity of certain physical characteristics among donors, and may result in long waiting times. In the field, health professionals are noticing a lack of gamete donors (oocytes and spermatozoa) of various geographical origins. **The rules for assigning gametes** The decree of 14 April 2022 indicates that information on the possibility of matching on the basis of physical criteria and its modalities is provided during interviews prior to medically assisted procreation. The physician will notify the recipient(s): ▪ that the match does not guarantee resemblance to the child ▪ and the resulting waiting times. The single woman or the couple then has a month to think about it before indicating their choice of whether or not to match.
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	**What are the choices for surplus embryos if I no longer want a child?** When the person(s) concerned no longer wishes to have children, several choices are available to him or her regarding the Embryos supernumeraries: ▪ donate it to people waiting for gamete donation ▪ donate it to scientific research ▪ to stop their retention. Each year, a letter is sent by the ART centre. This is a form that allows you to express your choice regarding the continued conservation of your embryos. **What happens if I request that the storage of my surplus embryos be stopped?** If you decide to stop the retention of Embryos, the medical team at your ART centre will destroy them after thawing the glitter in which they are stored. At any time, you can decide to interrupt your parental project by sending a letter to the ART centre. The Embryos will then be destroyed. **What is a third-party donor in ART?** The third-party gamete donor (also called a donor) is the person who has donated the gametes (oocytes or spermatozoa) used by a couple or an unmarried woman for insemination or to

		conceive Embryos as part of a parental project. At the end of the parental project, if the couple or the unmarried woman gives their consent, some of these Embryos conceived from gametes from third-party donors can be offered at the reception (for example, given to another couple or another unmarried woman). For these embryos intended for reception, the following are considered to be third-party donors: ▪ the donor(s) of the spermatozoa and/or oocytes that enabled their conception ▪ the couple or the unmarried woman who has accepted that her Embryos are hosted by another couple or another unmarried woman. **Which gametes and embryos can no longer be used on 31 March 2025?** The following are concerned: ▪ gametes from third-party donors who have not accepted access to their identity and DNI ▪ the embryos offered for reception but not yet allocated to another couple or another unmarried woman), from third-party donors of embryos who have not accepted access to their identity and DNI. **Which gametes and embryos can continue to be used from 31 March 2025?** **The following are concerned:** *Gametes* ▪ its gametes preserved for its own ART journey, in the future, whether or not it is certain to date (for example, gametes preserved for autologous use) ▪ gametes from third-party donors who have consented to access to their identity and DNI. *Embryos* ▪ the embryos conceived with the gametes of both members of the couple (for medically assisted reproduction pathways without recourse to a third-party gamete or Embryos) ▪ the embryos conceived with the gametes of one or two third-party donors who have consented to access to their identity and DNI ▪ the embryos conceived with the gametes of one or two third party donors who have not consented to access to their identity and DNI but have already been stored on 31 March 2025 by the centres for an already identified unmarried couple or woman (embryos so-called supernumeraries) ▪ the embryos offered for childcare already all located to a couple or an unmarried woman on 31 March 2025 ▪ the embryos offered for reception not allocated to a couple or an unmarried woman but for which all the third-party donors have consented to access to their identity and DNI. For "supernumerary" embryos and embryos allocated to beneficiaries, a certificate must be signed by the couple or unmarried woman stating that they are aware that the children born from the use of these embryos will not be guaranteed to be able to access, when they reach the age of majority and if they so wish, the identity and non-identifying data of the third-party donor.

		Under what conditions can embryos from third-party donors stored by couples or unmarried women be used after 31/03/25? These embryos may be used by the couple or unmarried woman for whom they were conceived or to whom they were allocated, and then kept, even after 31/03/25, in compliance with the conditions applicable to ART, in particular age conditions. For this use to be possible, a certificate must be signed by the couple or the unmarried woman. This certificate will indicate that the couple or unmarried woman is aware of the fact that the children born from the use of these Embryos will not be guaranteed to be able to access, when they reach the age of majority and if they wish, the identity and non-identifying data of the third-party donor. **When must this certificate be signed?** ART centres are responsible for signing this certificate by the couple or the unmarried woman. Thus, depending on the organisation of each ART centre, the certificate may be signed: ▪ after delivery of an information letter to all couples or unmarried women who have Embryos from third-party donors who have not consented to access to their identity and DNI, in the ART centre ▪ on the occasion of the annual reminder letter sent by the ART centre for the continuation of embryo conservation ▪ at the latest, before any embryo transfer from a third-party donor who has not consented to access to his or her identity and DNI. This signed certificate will be kept in the medical file of the couple or unmarried woman, which is itself kept within the ART centre. A copy of this certificate is sent to the donation centre that issued the gametes. **What happens if the unmarried couple or woman, after receiving this information, refuses to use the embryos without guaranteed access to origins?** In this case, the couple or the unmarried woman does not sign the certificate. This choice implies that the couple or the unmarried woman completely renounces the use of these embryos. They may be donated to research or their conservation may be terminated (they may not be offered for reception to another beneficiary of an ART). In compliance with the conditions applicable to ART, in particular age conditions, other embryos may be conceived or given to this unmarried couple or woman thanks to third-party donors who have consented to access to their identity and non-identifying data. **How can a couple or a woman know if the embryos stored for them are from a third-party donor who has consented to access to their identity and non-identifying data?** Couples or women concerned can contact the ART centre which keeps these embryos to get that information. The ART centre will forward the request to the donation centre if necessary. **What to do if the ART attempt fails?**

		Beyond the obvious sadness linked to the announcement of the failure of an attempt, hope is most often there for the future. If there are embryos frozen, transferring them in a future cycle will add chances to this attempt. If not, your doctor's analysis of the data of your attempt will allow him or her to consider with you whether or not to continue treatment.
	Any other management information	N/A
Governance		**What is the Biomedicine Agency?** The Biomedicine Agency is a national agency of the State under the supervision of the Ministry of Health. It was created by the 2004 bioethics law. It carries out its missions in the fields of organ, tissue and cell harvesting and transplantation, as well as in the fields of human reproduction, embryology and genetics The Biomedicine Agency does everything possible to ensure that each patient receives the care they need, in compliance with the rules of health safety, ethics and equity. Through its expertise, it is the reference authority on the medical, scientific and ethical aspects of these issues. In the area of medically assisted procreation, the Agency: ▪ manages the gamete and Embryos ▪ manages the authorisations of medically assisted reproduction (ART) techniques, ▪ aims to improve access to ART ▪ evaluates practices, ▪ promotes egg donation and sperm donation. Finally, it is responsible for informing the general public in close collaboration with health professionals.
Funding		**Does the date of 31 March 2025 have an impact on the financial coverage of ART by health insurance?** The end of the transitional period on 31 March 2025 has no impact on the terms and conditions of financial coverage of ART procedures by the health insurance, whether they are carried out in France or abroad. **Can I benefit from financial coverage from health insurance in the context of ART carried out abroad?** It is important to note that not all countries, including those belonging to the European Union, impose the same rules and standards on practices related to Assisted Reproduction (ART), which can have consequences on the quality and safety of care. In France, these activities are strictly regulated. ART centres and the practitioners who practise there are issued with an authorisation that attests to the good quality of care and compliance with the rules of good practice. The activities of the centres are evaluated annually by the Biomedicine Agency. Clinical and biological medically assisted reproduction care carried out outside France is scheduled care subject to prior authorisation by the health insurance fund in order to be able to benefit from financial coverage.

		What is the financial support of ART? ART procedures are 100% covered by the Health Insurance within the limit of: ▪ six inseminations (only one artificial insemination per cycle) to achieve pregnancy ▪ four attempts at in vitro fertilization (IVF) to achieve pregnancy. The onset of pregnancy resets the counters. **Can I benefit from medically assisted reproduction if I live in France but my spouse lives abroad? How does the reimbursement of expenses work?** It is possible for you to have recourse to ART in France, even if your spouse officially lives abroad. If you have not yet made an official request to an ART centre in France, you can contact the centre nearest you. The medical team will be able to assist you in your process and carry out the necessary examinations and assessments. Health insurance in France covers 100% of the costs related to an ART procedure in France after agreement with your French primary fund. In the case of a member of the couple living abroad, it is advisable to contact the Caisse Primaire d'Assurance Maladie directly, which will be able to provide you with all the information you need to help you with your project**.**
Counselling, communication and information provision		**Who should donor people who wish to assert their right of access to their origins turn to?** Since September 1, 2022, the Commission for Access to Third-Party Donor Data for Persons Born from Medically Assisted Procreation (CAPADD) has been responding to requests from people born from donation. This Commission is attached to the Ministry of Health and Prevention. **What donor information can the donor recipient have access to?** The person resulting from a donation can have access to: non-identifying data of people who have donated gametes or their Embryos: ▪ age ▪ general condition at the time of donation ▪ physical characteristics ▪ family and professional situation ▪ country of birth ▪ motivations for their donation, written by them. and the identity of the donor. This access is only possible if the donor who donated before 1 September 2022 has agreed to have his or her identity and non-identifying data revealed to the person resulting from the donation who requests it. For people who make a donation after September 1, 2022, this consent to access their identifying data and/or identity for the people resulting from their donation is mandatory. **What is the right of access to origins?** People born of gamete donation or Embryos will be able, when they reach the age of majority, to have access to the identity of their donor but also to non-identifying information about him/her.

		Indeed, since September 1, 2022, the Commission for Access to Third-Party Donor Data for Persons Born from Medically Assisted Procreation (CAPADD) has been responding to requests from people born from donation. This Commission is placed under the Ministry of Health and Prevention, accompanied by a register, it collects data relating to people who have donated their gametes before September 1, 2022 who come forward to CAPADD in order to consent to access their non-identifying data and their identity. Please note that for people who donate after September 1, 2022, this consent is mandatory in order to help people born from a donation in the quest for their origins. No parent-child relationship can be established between the person born from gamete donation or Embryos and the donor.
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		**What the bioethics law that governs medically assisted procreation (ART or ART) says:** (Bioethics Law No. 2004-800 of 6 August 2004 amended in 2011 and 2021) The implementation of medically assisted reproduction is indicated for: ▪ couples composed of a man and a woman ▪ single women and female couples. ART is practiced in licensed facilities and by practitioners who are competent in these activities. Individuals receiving ART must be of childbearing age. In France, it is forbidden to practice: ▪ surrogacy (surrogacy) ▪ the ROPA method (Reception of Eggs from the Partner) ▪ post-mortem ART. Since 2021, it has been authorised to use a double donation of gametes (oocytes and spermatozoa).
Miscellaneous		**What happens on March 31, 2025 for ART procedures with a third-party donor?** The law of 2 August 2021 on bioethics establishes the right for people born from medically assisted reproduction (ART) with a third-party donor to know their origins when they reach the age of majority. This right includes access to the donor's identity (ID) and non-identifying data (NID). Since 1st September 2022, the consent of donors to the transmission of their identity and their DNI is an essential condition for the donation of oocytes, spermatozoa and Embryos. But gametes and embryos collected before that date, for which this consent was not obtained, nevertheless remained usable. March 31, 2025 marks the full implementation of the law: ▪ regarding gametes, from March 31, 2025, no more attempts at medically assisted procreation may be made with gametes for which the third-party donor has not consented to the transmission of his or her identity and DNIs. In other words, the stock of gametes for which the third-party donor has not consented, on that date, to the transmission of these data can no longer be used. Any allocation of gametes before 31 March 2025 must take this deadline into account

		▪ concerning the Embryos, from 31 March 2025, no embryos from third-party donors, for which the third-party donors have not consented to the transmission of their identity and their DNIs, offered for reception and not yet allocated to one or more beneficiaries of medically assisted procreation (ART), may no longer be used. **Can we have information about the donor and/or the donor? Are the donor anonymous?** Gamete donation remains free, voluntary and anonymous. The third-party donor and the people who receive the donation do not know each other's identities. Beneficiaries of medically assisted reproduction with a third-party donor may not have access to information concerning the third-party donor or the latter may have access to information concerning persons born from his or her donation. The 2021 bioethics law allows a right of access to origins for people born of a donation only. Thus, they will be able, when they reach the age of majority and if they wish, to access non-identifying data and the identity of the donor by contacting the Commission for Access to Third-Party Donor Data for Persons Born of Medically Assisted Procreation (CAPADD). This Commission is placed under the Ministry of Health and Prevention, and this data is strictly personal. No parent-child relationship can be established between the person born from gamete donation or Embryos and the giver. The parents of this child remain the woman or couple who wanted it, and who carried out the medically assisted reproduction process and who saw it born. The donor has no responsibility towards the child born from his donation. **Is it possible to continue in France an ART process started abroad with CRYOS sperm (by importing the sperm)?** No, the sale and purchase of gametes is strictly prohibited in France, because it contravenes the principle of free donation mentioned in the Public Health Code. As for private gamete banks, implanted abroad and selling sperm straws on the Internet with a view to carrying out ART, not only is this practice illegal, but it is also risky because it offers no guarantee in terms of health safety, quality, and effectiveness of use. Any person who obtains or helps to obtain gametes (spermatozoa or oocytes) in exchange for payment is liable to be criminally sanctioned. According to Article 511-9 of the Criminal Code, "the fact of obtaining gametes (editor's note: spermatozoa or oocytes) in return for payment, whatever the form, with the exception of payment for the services provided by establishments carrying out the preparation and storage of these gametes, is punishable by five years' imprisonment and a fine of 75,000 euros. The act of providing one's intermediary to promote the obtaining of gametes in return for payment, whatever the form, or of handing over to third parties, for consideration, gametes from donations shall be punishable by the same penalties." In very specific cases and to meet a specific need of French people, a laboratory authorised for medically assisted reproduction activities may apply for the import of spermatozoa from abroad under two conditions: ▪ the donation procedure complies with all the French conditions established by law; ▪ the use of spermatozoa will be carried out as part of a medically assisted reproduction approach in accordance with the practices authorised in France.

		The donation of gametes and embryos was an anonymous gesture, is this still the case? Gamete donation remains free, voluntary and anonymous. The third-party donor and the people who receive the donation do not know each other's identities. The 2021 bioethics law nevertheless allows a right of access to origins for people born from a donation. Thus, when they reach the age of majority and if they wish, they will be able to access non-identifying data and the identity of the donor. This data is strictly personal. **What is early joint recognition?** Early joint recognition concerns female couples engaged in a medically assisted reproduction project with a third-party donor. This is the only case in which a double maternal filiation can be established with regard to a child without an adoption procedure. This recognition takes place before the child is conceived and is carried out before a notary at the same time as the consent to ART. Even if the recognition will have an effect, for the establishment of filiation, only for the woman who does not give birth to the child, this recognition must be made jointly. It is, in fact, the existence of a parental project of the couple, enshrined in this joint recognition, which allows the establishment of the double maternal filiation bond (art. 342-11 new C. civ.). Finally, there is no provision requiring female couples who have made an early joint recognition before the notary to have recourse to ART at a French ART centre. The early joint recognition made before a notary produces its effects in France when the child's birth is declared, regardless of whether the ART was carried out on the national territory or abroad. The advance joint recognition is given to the civil registrar by one of the two women or, where applicable, by the person responsible for declaring the birth. The use of a French notary is also required for French nationals living abroad wishing to use ART with a third-party donor. The civil registrar does not have to question the date of establishment of the advance joint recognition, in the absence of a textual provision to this effect. The simple indication of the early joint recognition in the birth certificate, given to the civil registrar at the latest when the child's birth is declared, makes it possible to establish filiation with regard to the other woman. The civil registrar indicates this in the child's birth certificate, as is the case for all other methods of establishing filiation.

Table E.18 Extracted data for France (ART)

France		
Author(s) **Title [year]**	L'Assurance Maladie Medically Assisted Reproduction (ART)[30] [2026]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		Medically assisted procreation (ART) is intended to respond to a parental project. Access to ART is possible if you are in one of the following three situations: ▪ a heterosexual couple ▪ a couple of two women ▪ an unmarried woman. No discrimination in access to ART is possible, particularly on the basis of sexual orientation or marital status. Both members of the couple or the unmarried woman must give their prior consent to artificial insemination or embryo transfer. When you are in a relationship, the following situations are obstacles to insemination or embryo transfer: ▪ the death of one of the members of the couple ▪ an application for divorce or legal separation or its implementation by mutual consent ▪ the termination of cohabitation ▪ One of the members of the couple withdraws their consent in writing. **Age criteria are set for ART.** For the collection or collection in an ART project, the age conditions are as follows: ▪ the collection of oocytes can be performed in women up to their 43rd birthday ▪ sperm collection can be carried out in men up to the age of 60. ART can be carried out: ▪ until his or her 45th birthday in the woman, unmarried or within the couple, who will bear the child ▪ until their 60th birthday for the person in the couple who will not carry the child. For information, there are rules of good clinical and biological practice (defined by the decree of 11 April 2008) that health establishments, biomedical analysis laboratories and organisations authorised to carry out one or more medically assisted reproduction activities must follow during ART for female and unmarried couples. **Notarial procedures for medically assisted reproduction** The couple or the unmarried (single) woman who uses ART with the intervention of a third-party gamete donor or ART with embryo, must carry out an early recognition before a notary. Unless it is demonstrated that the child is not the result of medically assisted procreation, no parent-child relationship can be established between the child and the third-party donor.

<table>
<tr><td rowspan="1">DAHR intervention(s) provided</td><td></td><td>In France, it is forbidden to practice:
▪ surrogacy (surrogacy)
▪ the ROPA method (recipient of eggs from the partner): in a couple of women, one of the women provides the eggs, which are fertilised in the laboratory using donor sperm. The embryos obtained are then transferred to the uterus of the other woman in the couple
▪ post-mortem ART (or ART).

However, since 2021, it has been allowed to use double gamete donation (oocytes and spermatozoa).

ART for preimplantation diagnosis
Preimplantation genetic diagnosis (PGD) is offered to couples with "a high probability of giving birth to a child with a genetic disease of particular seriousness recognised as incurable at the time of diagnosis" (Article L2131-4 of the Civil Code). It consists of carrying out a genetic diagnosis using cells taken from an embryo obtained by in vitro fertilization (IVF). PGD represents an alternative to prenatal diagnosis whose only recourse was medical termination of pregnancy, in the event of fetal damage. Each request for preimplantation diagnosis is studied by the multidisciplinary centre for prenatal diagnosis (CPDPN) present in each region, which must validate the indication for PGD. PGD itself can be performed in one of the five centres in France.</td></tr>
<tr><td rowspan="4">Organisation</td><td>Referral pathways</td><td>[See Service Public extracted document]</td></tr>
<tr><td>Service provider characteristic</td><td>The location of the ART
Clinical or biological activities of medically assisted procreation may only be carried out in authorised establishments. Authorisations are issued by the director general of the regional health agency (ARS).
ART is led by a multidisciplinary team:
▪ a gynaecologist-obstetrician or a gynaecologist or endocrinologist for oocytes and embryo transfer
▪ a urologist or a general surgical surgeon or an obstetrician-gynaecologist for sperm retrieval
▪ a medical biologist and a laboratory technician for ART or ART laboratory activities
▪ a psychiatrist, psychologist or nurse with expertise in psychiatry, if necessary, outside the centre, asked for the preliminary interview
▪ a social worker if necessary.</td></tr>
<tr><td>Timelines to access services</td><td>N/A</td></tr>
<tr><td>Any other organisational aspects</td><td>N/A</td></tr>
</table>

Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	**Allocation of gametes and embryos according to the chronological order of registration of applicants** Gametes and embryos are allocated according to the chronological order of registration of the applicants, that is, the date of validation of the file. The criteria of marital status, sexual orientation, whether or not they have children, the designation by the applicant(s) of a person who volunteers to make a donation to an anonymous third party, or the geographical origin of the applicants, may not lead to prioritisation, exclusion or restriction of access to donation. However, the allocation period takes into account the existence of a disease that could lead to a loss of opportunity if the ART attempt is postponed, and the matching on certain medical risk factors (negative blood rhesus, etc.) or the request by the recipient couple or the recipient woman for a match based on physical criteria (skin, eye colour, of the hair), which is carried out as far as possible.
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		[See Service Public extracted document]
Counselling, communication and information provision		N/A
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		If you use ART, you are entitled to leave of absence for the medical acts necessary for the protocol. You must present proof of your absence if your employer requests it. These absences are considered as actual working time for the purpose of determining the duration of paid leave and for seniority. These absences must not result in a reduction in pay. The person with whom you live as a couple also has leave of absence to go to three of these medical examinations. **Clinical and biological medically assisted reproduction care carried out outside France falls under "programmed care subject to prior authorisation".** This is care that is the main reason for your travel to another Member State of the European Union/European Economic Area or to Switzerland.

		Please note: the verification of gametes without ART care is not subject to prior authorisation and is covered according to French tariffs, after advance payment of the costs on your part. To be covered by the Health Insurance, you have to take steps before ART

Table E.19 Extracted data for France (Donation and use of gametes)

France		
Author(s) **Title [year]**	LegiFrance Public Health Code: Chapter IV: Donation and use of gametes. (Articles L1244-1 to L1244-9)[31] [2025]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		N/A
DAHR intervention(s) provided		Article L1244-3: Artificial insemination with fresh donor sperm and the mixing of sperm are prohibited.
Organisation	***Referral pathways***	N/A
	Service provider characteristic	N/A
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	Article L1244-4: The use of gametes from the same donor may not deliberately lead to the birth of more than ten children.
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	Article L1244-2: The donor's consent is obtained in writing and can be revoked at any time up to the use of the gametes.
	Any other management information	N/A
Governance		N/A
Funding		N/A
Counselling, communication and information provision		N/A
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A

Miscellaneous		Article L1244-6: A doctor may access non-identifying medical information, in case of medical necessity, for the benefit of a person conceived from gametes from a donation or for the benefit of a gamete donor.

Table E.20 Extracted data for France (ART)

France		
Author(s) **Title [year]**	Service Public Medically assisted procreation (ART)[32] [2025]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		ART can allow a heterosexual couple or a couple of two women or an unmarried woman to have a child. It aims to respond to a parental project. No discrimination in access to ART is possible, particularly on the basis of sexual orientation or marital status. There are different techniques. They are taken care of in the same way for everyone. ART can be carried out: ▪ until his or her 45th birthday in the case of the woman, unmarried or in the couple, who is destined to carry the child ▪ until his 60th birthday with the member of the couple who will not be carrying the child. [See DAHR interventions for who specific methods are offered to]
DAHR intervention(s) provided		Surrogacy is prohibited. Artificial insemination can be done with one of the following techniques: ▪ spouse's sperm (spouse, civil partner or cohabiting partner) ▪ frozen sperm from a donor. This artificial insemination is performed by a doctor specialised in fertility, in most cases without hospitalization. Most often, the woman undergoes hormonal treatment (ovarian stimulation) beforehand. IVF can be performed: ▪ with the woman's egg and donor sperm ▪ or with the partner's sperm and a frozen egg from a donor ▪ or in some cases, with donor sperm and donor egg. The use of one or more gamete donations is proposed in the following cases: ▪ risk of transmitting a genetic disease to the child ▪ infertility in either member of the applicant couple ▪ ART in a single woman. Embryo reception may be offered in the following cases: ▪ risk of transmitting a genetic disease to the child ▪ infertility in either member of the applicant couple ▪ ART in a single woman. The embryo is offered for reception by a donor couple or a single donor woman, then transferred to the woman's uterus:

		▪ recipient alone ▪ or within a couple. Double gamete donation (sperm and egg) is allowed. Thus, an embryo can be conceived with gametes that do not come from either member of the couple. The heterosexual couple or the couple made up of two women or the unmarried woman must first give their consent to a notary. [See funding on how many cycles are offered]
Organisation	***Referral pathways***	To benefit from ART with egg/sperm or embryo donation, the couple's request is evaluated by the clinicobiological medical team of the ART centre and accompanied by several interviews with the professionals of this team. The interviews include the following: ▪ motivations of the applicant(s) ▪ procedure related to access to non-identifying data (for example, age, family and professional situation, country of birth) and the identity of the third-party donor by the adult born of the donation ▪ ART techniques and their consequences. After the last information interview, the couple or unmarried woman has a one-month reflection period. An additional period of reflection may be deemed necessary in the interest of the unborn child. After this period, the couple or unmarried woman must confirm their request for ART in writing with the doctor. The medical profession may accept, postpone or refuse the request for ART. **Agreement:** The clinical-biological medical team confirms its agreement to continue the ART process. This agreement is the result of: ▪ the probability of success of the art approach ▪ and the meeting of the conditions conducive to the reception of a child in good conditions. **Postponement or refusal:** The reasons for the postponement or refusal of ART are communicated in writing to applicants upon request to the centre.
	Service provider characteristic	N/A
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	N/A

	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		The acts of ART are 100% covered by the Health Insurance for a maximum of: ▪ six inseminations (only one artificial insemination per cycle) to achieve pregnancy ▪ four attempts at IVF to get pregnant. This care is the same for everyone (heterosexual couple, couple of two women, unmarried woman).
Counselling, communication and information provision		See Referral pathway.
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		Relevant legislation has been included for extraction.
Miscellaneous		**What access to origins for the person born from ART with a third-party donor?** It all depends on the date of birth of the person requesting access to origins. The application is made by the person once they reach the age of majority. **Person born from donations made and used before September 1, 2022** This request for access to origins comes from the person born of the donation, once he or she has reached the age of majority. This access to origins depends on the donor's consent to the communication of his or her identity and non-identifying data (for example, age, family situation, country of birth). **Before September 1, 2022**, this communication was not an obligation for the donor. The donor may voluntarily contact the CAPADD to give his consent to the transmission of this information to the people born from his donation. This agreement can also be given by the donor to this commission when the latter contacts him following a request for access to origins.

Table E.21 Extracted data for Germany (Embryo Protection Act 1990)

Germany		
Author(s) **Title [year]**	Federal Ministry of Justice and Consumer Protection Act for the Protection of Embryos (Embryo Protection Act - ESchG)[33] [1990]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		N/A
DAHR intervention(s) provided		AHR using donated eggs. [Note: this Act focuses on what is prohibited] **Misuse of Reproductive Techniques (p. 1)** (1) Anyone who: 1. transfers a foreign unfertilised egg cell to a woman, 2. attempts to artificially fertilize an egg cell for a purpose other than to bring about a pregnancy in the woman from whom the egg cell originates, shall be punished with imprisonment for up to three years or with a fine. 3. attempts to transfer more than three embryos to one woman within one cycle, 4. attempts to transfer more than three oocytes within one cycle by intratubal gamete transfer fertilize 5. attempts to fertilize more of a woman's eggs than are transferred to her within one cycle should, 6. removes an embryo from a woman before it has completed implantation in the uterus in order to transfer it to another woman or to use it for a purpose other than its preservation, or 7. undertakes to perform artificial insemination on a woman who is willing to permanently relinquish her child to a third party after birth (surrogate mother) or to transfer a human embryo to her. (2) The same penalty shall apply to anyone who: 1. artificially causes a human sperm cell to penetrate a human egg cell, or 2. artificially introduces a human sperm cell into a human egg cell without intending to cause a pregnancy in the woman from whom the egg cell originated. (3) shall not be punished: 1. the woman from whom the egg cell or embryo originates, as well as the Woman to whom the egg cell is transferred or to whom the embryo is to be transferred, and 2. the surrogate mother and the person who will be permanently caring for the child wants to record.

		(4) attempting to commit the offense shall be punishable. **Prohibited sex choice (p. 2)** Anyone who attempts to artificially fertilise a human egg cell with a sperm cell selected according to its sex chromosome is liable to imprisonment for up to one year or a fine. This does not apply if the selection of the sperm cell by a physician serves to protect the child from developing Duchenne muscular dystrophy or a similarly serious sex-linked hereditary disease, and the disease threatening the child has been recognized as correspondingly serious by the competent authority under state law. **Preimplantation genetic diagnosis; authorization to issue regulation** (1) Anyone who genetically tests cells of an embryo in vitro before its intrauterine transfer (preimplantation genetic diagnosis) shall be punished with imprisonment for up to one year or with a fine. (2) If, due to the genetic predisposition of the woman from whom the egg originated, or of the man from whom the sperm originated, or of both, there is a high risk of a serious hereditary disease in their offspring, it is not unlawful for a person to genetically test cells of the embryo in vitro for the risk of this disease before intrauterine transfer, with the written consent of the woman from whom the egg originated, in accordance with generally accepted medical science and technology. It is also not unlawful for a person to carry out preimplantation genetic diagnosis with the written consent of the woman from whom the egg originated to detect a serious defect in the embryo that is highly likely to lead to a stillbirth or miscarriage. (3) Preimplantation genetic diagnosis may only be undertaken: 1. after information and advice on the medical, psychological and social consequences of the woman 2. after an interdisciplinary ethics committee at the approved centres for preimplantation genetic diagnosis, has examined compliance and issued a positive assessment and 3. by a qualified physician in centres approved for preimplantation genetic diagnosis, which have the necessary diagnostic, medical and technical capabilities to carry out the preimplantation genetic diagnosis procedures. The procedures performed within the framework of preimplantation genetic diagnosis, including those rejected by the ethics committees, are reported by the accredited centres to a central office in anonymized form and documented there. The Federal Government, with the consent of the Federal Council, determines the details by statutory instrument. 1. Regarding the number and requirements for the accreditation of centres in which the Preimplantation genetic diagnosis may be performed, including the qualifications of the doctors working there and the duration of their authorization,

		2. on the establishment, composition, procedures and financing of ethics committees for preimplantation genetic diagnosis, 3. for the establishment and design of the central office responsible for the documentation of [events] within the framework of 4. Regarding the requirements for reporting findings obtained through preimplantation genetic diagnosis Measures to the central office and the requirements for documentation. (4) Anyone who performs preimplantation genetic diagnosis contrary to the above commits an administrative offense. This offense may be punished by a fine of up to fifty thousand euros. (5) No physician is obliged to carry out or participate in a measure above. The person concerned shall not suffer any disadvantage as a result of their failure to participate. (6) The Federal Government shall prepare a report every four years on the experience gained with preimplantation genetic diagnosis. Based on central documentation and anonymized data, the report shall include the number of procedures performed annually and a scientific evaluation.
Organisation	***Referral pathways***	N/A
	Service provider characteristic	N/A
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	**Misuse of human embryos (p. 1)** (1) Anyone who sells or gives away, acquires or uses a human embryo produced extracorporeally or taken from a woman before the completion of its implantation in the uterus for a purpose other than its preservation shall be punished with imprisonment for up to three years or with a fine. (2) Likewise, anyone who causes a human embryo to develop further outside the body for a purpose other than to produce a pregnancy shall be punished. (3) Attempting to commit this offense is a punishable offense.
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	**Unauthorised fertilization, unauthorised embryo transfer and artificial fertilization after death (p. 3)** (1) Anyone who commits an offense against the law shall be punished with imprisonment for up to three years or with a fine. 1. It undertakes to artificially fertilise an egg cell without the woman whose egg cell is fertilised, and the man whose sperm cell is used for fertilisation has given his consent 2. it attempts to transfer an embryo to a woman without her consent, or 3. knowingly artificially fertilises an egg cell with the sperm of a man after his death. (2) In the case of paragraph 1 no. 3, the woman undergoing artificial insemination shall not be punished.

	Any other management information	N/A
Governance		N/A
Funding		N/A
Counselling, communication and information provision		N/A
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		N/A

Table E.22 Extracted data for Germany (IVF registry)

Germany		
Author(s) **Title [year]**	Deutsches IVF register D.I.R. Annual 2023 – The German IVF-Registry(34) [2024]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		N/A
DAHR intervention(s) provided		The changes in reproductive medicine announced in the 2021–2025 coalition agreement have been discussed but nothing has been decided. The report of the Commission on Reproductive Self-Determination and Reproductive Medicine has been available to the Federal Government since April 24, 2024. On the subject of egg donation, it states: "the reasoning on which the legislator based the ban on egg donation in 1990, particularly the goal of avoiding split motherhood, must today be regarded as outdated and no longer convincing." The commission did not address the legalisation of elective single embryo transfers or the legalisation of pronuclear stage donation. A representative of medical ethics in the commission, Prof. Claudia Wiesemann from Göttingen, is quoted in the German Medical Journal of April 16, 2024, as saying: "selection of the best developing embryo is not only legitimate but ethically imperative." **(p. 208)**
Organisation	***Referral pathways***	N/A
	Service provider characteristic	N/A
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A

Funding		**Small Politics –** **Cost Coverage for ART (p. 208)** Thee cost coverage for assisted reproductive technology (ART) continues to impose a significant financial burden on affected couples. Federal funds have been reduced, and state funds are no longer or still not available in many states. Most recently, the state of North Rhine-Westphalia announced the discontinuation of funding as of January 1, 2025, after applications were no longer processed in 2024 due to unclear financing. From a medical perspective, in cases of tubal sterility, microsurgical fertilization is routinely financed, yet another therapy for the same condition can only be billed as a benefit by statutory health insurance at 50%. A 100% benefit within the framework of § 27a of the German Social Code (SGB V) would be a fair social legislative decision that honours the financial, emotional, and time investment of couples who take on the responsibility of wanting to become parents.
Counselling, communication and information provision		N/A
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		N/A

Table E.23 Extracted data for Germany (Cost coverage associated with induced pregnancy)

Germany		
Author(s) **Title [year]**	Federal Republic of Germany Apply for cost coverage for measures to induce pregnancy[35] [2026]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		Before starting treatment, you must submit a treatment plan drawn up by a doctor (attending physician or the fertility centre) to the health insurance company for approval. If you have been diagnosed by a doctor as being unable to conceive naturally and artificial insemination is suitable, the statutory health insurance funds will cover part of the costs under certain conditions. The main requirements are: ▪ you cannot become pregnant naturally ▪ from a medical point of view, artificial insemination measures are suitable for bringing about a pregnancy ▪ you are married and use your own egg and sperm cells. The statutory health insurance funds cannot cover artificial insemination with sperm or egg donation from a third party. ▪ women must be 25 to 39 years old; men 25 to 49 years old. It often takes several attempts at artificial insemination for you to become pregnant. Artificial insemination measures may only be carried out at the expense of the statutory health insurance funds if there is a reasonable chance that the chosen treatment method will result in pregnancy. The Federal Joint Committee stipulates further details in its guidelines on artificial insemination. According to these guidelines, there is no longer a sufficient chance of success for the respective treatment measures if: ▪ in the case of insemination in a spontaneous cycle up to eight times ▪ up to three times in the case of insemination following hormonal stimulation ▪ up to three times in the case of in vitro fertilization ▪ up to twice for intratubal gamete transfer ▪ up to three times in the case of intracytoplasmic sperm injection ▪ without a clinically proven pregnancy having occurred. Under certain conditions, you can receive further grants from the federal government and some federal states, for example if you are in a same-sex relationship or are unmarried.
DAHR intervention(s) provided		Artificial insemination
Organisation	***Referral pathways***	N/A
	Service provider characteristic	N/A
	Timelines to access services	N/A

	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		If you have been diagnosed by a doctor as being unable to conceive naturally and artificial insemination is suitable, the statutory health insurance funds will cover part of the costs under certain conditions. The statutory health insurance companies will cover 50 percent of the costs of the measures approved in the treatment plan. Treatments on the man's body are covered by the man's health insurance, treatments on the woman's body are covered by the woman's health insurance. In addition to the statutory subsidy of 50 percent of the costs of approved artificial insemination measures, health insurance companies can regulate higher subsidies in their statutes. **Procedure** Normally, the procedure is as follows: ▪ if your fertility treatment has a chance of success, your gynaecologist will usually refer you to a fertility centre ▪ the fertility centre will draw up a treatment plan ▪ the treatment plan serves as an application for cost sharing ▪ you can submit the application by post and - with many statutory health insurance companies - online or in person at the office ▪ send the completed sample form of the treatment plan with both copies as well as any other required documents by post to the health insurance company of the woman and the man (if you are insured with different health insurance companies) ▪ the health insurance company will check your application and issue you with a cost coverage certificate ▪ the authorizations are issued on forms and hard copies ▪ you give the cost coverage certificate to your doctor ▪ your doctor will bill your health insurance company directly via your electronic health card. You will receive an invoice for your own contribution.

Counselling, communication and information provision		N/A
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		N/A

Table E.24 Extracted data for Germany (Fertility Information Portal)

Germany		
Author(s) **Title [year]**	Federal Ministry for Family Affairs, Senior Citizens, Women and Youth Fertility Information Portal[36] [2026]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		See funding for individual state eligibilities. All of these eligibilities include that there must be a certified chance of success of fertility treatment and a medical diagnosis of infertility.
DAHR intervention(s) provided		IVF and or ICSI (1st to 4th cycles)
Organisation	***Referral pathways***	N/A
	Service provider characteristic	N/A
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		The potential subsidy amounts to up to 25 percent of the out-of-pocket expenses remaining for the couple after billing their health insurance. The out-of-pocket expenses for married couples are generally reduced by up to 25 percent for the first three attempts. For the fourth attempt, the out-of-pocket expenses for married couples are reduced to up to 50 percent, as health insurance companies generally do not cover the fourth attempt. For unmarried couples living together, the out-of-pocket expenses are generally reduced by up to 12.5 percent for the first three attempts and by up to 25 percent for the fourth attempt. The different levels of out-of-pocket costs for married and unmarried couples are due to the fact that, according to § 27a SGB V, only married couples receive benefits from statutory health insurance for medical fertility treatments.

		For each federal state: **Baden-Württemberg:** The state of Baden-Württemberg does not participate in the federal initiative "Help and Support for Unwanted Childlessness". Therefore, financial support is not granted there. **Bavaria:** The state of Baden-Württemberg does not participate in the federal initiative "Help and Support for Unwanted Childlessness". Therefore, financial support is not granted there. **Berlin:** Financial support from federal and state funds is currently only available for married and unmarried heterosexual couples, in which only egg and sperm cells of the partners are used. Heterosexual couples who are dependent on sperm donation can apply for funding from the state of Berlin. Further information can be obtained from the State Office for Health and Social Affairs as the responsible licensing authority of the state. Financial support from federal and state funds is currently only available for married and unmarried heterosexual couples. Same-sex female civil partnerships under the Civil Partnership Act or same-sex female married couples and same-sex female couples living in a long-term non-marital partnership can apply for funding from funds from the State of Berlin. Further information can be obtained from the State Office for Health and Social Affairs as the responsible licensing authority of the state. **Bradenburg:** The state of Brandenburg does not participate in the federal initiative "Help and support for involuntary childlessness". Therefore, financial support is not granted there. **Bremen:** For the use of donated germs or sperm 'Unfortunately, no financial support is granted because, according to § 27a SGB V, only the egg and sperm cells of the (spouse) partners may be used for fertility treatment (homologous insemination).' Financial support from federal and state funds is currently only available for married and unmarried heterosexual couples. Same-sex female civil partnerships under the Civil Partnership Act or same-sex female married couples and same-sex female couples who live in a long-term non-marital cohabitation can apply for funding from funds from the Free Hanseatic City of Bremen. In the case of same-sex married couples, civil partnerships or same-sex couples living in a non-marital cohabitation in which at least one person has female reproductive organs, Bremen grants up to 50% of the couples' remaining co-payment for the first to fourth treatment cycles after settlement with the health insurance company and, if applicable, the aid office, but no more than for the 1st to 3rd attempt:

		€ 1,200.00 for in vitro fertilization and € 1,300.00 for an intracytoplasmic sperm injection; at most, however, for the 4th attempt: € 1,600.00 for in vitro fertilization and € 1,700.00 for an intracytoplasmic sperm injection **Hamburg:** The state of Hamburg does not participate in the federal initiative "Help and support for involuntary childlessness". Therefore, financial support is not granted there. **Hesse:** Heterosexual couple: The state of Hesse grants financial support for the 4th treatment cycle. Funding for all other treatment cycles is therefore not possible. Financial support from federal and state funds is currently only available for married and unmarried heterosexual couples. **Mecklenburg-Western Pomerania:** Financial support from federal and state funds is currently only available for married and unmarried heterosexual couples. For heterosexual couples with donated gametes unfortunately, no financial support is granted because, according to § 27a SGB V, only the egg and sperm cells of the (spouse) partners may be used for fertility treatment (homologous insemination). **Lower Saxony:** Financial support from federal and state funds is currently only available for married and unmarried heterosexual couples. For heterosexual couples with donated gametes unfortunately, no financial support is granted because, according to § 27a SGB V, only the egg and sperm cells of the (spouse) partners may be used for fertility treatment (homologous insemination). **North Rhine-Westphalia:** The state of North Rhine-Westphalia does not participate in the federal initiative "Help and support in cases of involuntary childlessness". Therefore, financial support is not granted there. **Rhineland-Palatinate:** Financial support from federal and state funds is currently only available for married and unmarried heterosexual couples. For heterosexual couples with donated gametes unfortunately, no financial support is granted because, according to § 27a SGB V, only the egg and sperm cells of the (spouse) partners may be used for fertility treatment (homologous insemination). Same-sex female civil partnerships under the Civil Partnership Act or same-sex female married couples and same-sex female couples who live in a long-term non-marital cohabitation can apply for funding from funds from the state of Rhineland-Palatinate. Further information can be obtained from the State Office for Social Affairs, Youth and Care as the responsible granting authority of the state.

		Saarland: Financial support from federal and state funds is currently only available for married and unmarried heterosexual couples. For heterosexual couples with donated gametes unfortunately, no financial support is granted because, according to § 27a SGB V, only the egg and sperm cells of the (spouse) partners may be used for fertility treatment (homologous insemination). Same-sex female civil partnerships under the Civil Partnership Act or same-sex female married couples and same-sex female couples who live in a long-term non-marital partnership can apply for funding from Saarland funds. Further information will be provided by the State Office for Social Affairs as the competent granting authority of the Land." **Saxony:** Financial support from federal and state funds is currently only available for married and unmarried heterosexual couples. For heterosexual couples with donated gametes unfortunately, no financial support is granted because, according to § 27a SGB V, only the egg and sperm cells of the (spouse) partners may be used for fertility treatment (homologous insemination). **Saxony Anhalt:** Financial support from federal and state funds is currently only available for married and unmarried heterosexual couples. For heterosexual couples with donated gametes unfortunately, no financial support is granted because, according to § 27a SGB V, only the egg and sperm cells of the (spouse) partners may be used for fertility treatment (homologous insemination). Schleswig-Holstein: The state of Schleswig-Holstein does not participate in the federal initiative "Help and support for involuntary childlessness". Therefore, financial support is not granted there.
Counselling, communication and information provision		For rainbow families, there are also associations and counselling centres that specialise in the special legal concerns of these family constellations. I would like to encourage you to turn to such counselling centres. They often meet people there who have already given a lot of thought to what kind of support can help them in their situation.
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		N/A

Table E.25 Extracted data for Germany (Guideline for ART measure)

Germany		
Author(s) **Title [year]**	Federal Ministry for Family Affairs, Senior Citizens, Women and Youth Guideline of the Federal Ministry for Family Affairs, Senior Citizens, Women and Youth on the granting of subsidies for the promotion of ART measures [2015][37]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		The recipients of the grant are: **(p. 3)** 1. Married couple or 2. Couples who live in a non-marital partnership and **<u>Who undergo IVF and or ICSI.</u>** A cohabiting relationship is a long-term, committed partnership between a man and a woman that precludes any other form of cohabitation and is characterized by a strong emotional bond. It is considered to exist when, in the opinion of the treating physician, the unmarried woman lives with the unmarried man in a stable partnership and he acknowledges paternity of any child conceived in this way. Grant requirements **(p. 3)** (1) Grants may only be awarded if: (a) The pair are as defined as above (b) Has his main residence in the federal territory (c) Treatment in a reproductive facility within the federal territory (2) Only treatments in which the respective federal state of residence participates by implementing its own funding programmes in a financial amount at least equal to that of the Federal Government (paragraph 6, subparagraph 3) are eligible for funding (3) Only the actual treatment costs incurred are eligible for funding. Administrative costs will not be reimbursed (4) The same applies to persons who are not covered by statutory health insurance.
DAHR intervention(s) provided		N/A
Organisation	***Referral pathways***	N/A
	Service provider characteristic	N/A
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A

	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		The Federal Government has set itself the goal of supporting involuntarily childless couples in to provide financial support for the use of assisted reproductive technologies. The federal government will only provide funding where the states contribute at least the same amount as the federal government. **(p. 2)** The financial support is part of a comprehensive overall concept with other areas of action. These include better education about the causes and consequences of involuntary childlessness, improvements in the area psychosocial counselling and the review of applicable regulations Adoption regulations. The Federal Government considers it important to make the situation of couples with an unfulfilled desire to have children clearly visible in our society, to destigmatize the topic of artificial insemination and to contribute to the acceptance and destigmatization of women and couples. Treatments performed in the first to fourth weeks of life are eligible for funding. Treatment cycle according to the type of in-vitro fertilization (IVF) and intracytoplasmic sperm injection (ICSI). **(p. 3)** Type, scope and amount of the grants **(p. 4)** (1) The grant shall be awarded as a non-repayable subsidy in the form of co-financing within the framework of project funding. (2) The Federal Ministry for Family Affairs, Senior Citizens, Women and Youth (BMFSFJ) shall decide on exceptions to the financing method in individual cases. (3) Grants are awarded for the first to fourth treatments: (a) For married couples, the subsidy amounts to up to 25% of the amount they receive after settlement with the (statutory or private). Health insurance covers the remaining out-of-pocket expenses. (b) For couples living in a non-marital partnership, the subsidy for the first to third treatment amounts to up to 12.5% and for the fourth treatment to up to 25% of their remaining out-of-pocket expenses.
Counselling, communication and information provision		N/A

Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		There is no legal entitlement to the granting of a subsidy. The granting authority decides at its own discretion within the framework of the available budgetary resources. **(p. 3)**
Miscellaneous		N/A

Table E.26 Extracted data for Germany (Statutory Health Insurance and Artificial Insemination Act 1988)

Germany		
Author(s) **Title [year]**	Federal Ministry of Justice and Consumer Protection Social Code (SGB) Fifth Book (V) - Statutory Health Insurance - (Article 1 of the Act of 20 December 1988, Federal Law Gazette I p. 2477) § 27a Artificial Insemination(38) [1988]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		The benefits of medical treatment shall also include medical measures to induce pregnancy if: 1. These measures are necessary according to medical findings, 2. According to a medical diagnosis, there is a sufficient prospect that the measures will bring about a pregnancy; there is no longer a sufficient prospect if the measure has been carried out three times without success, 3. The persons who wish to avail themselves of these measures are married to each other 4. Only egg and sperm cells of the spouses are used, and 5. Before carrying out the measures, the spouses have been informed of such treatment be a doctor who does not carry out the treatment themselves, taking into account their medical and psychosocial aspects, and the doctor has referred them to one of the doctors or one of the institutions to which a licence has been granted in accordance with Section 121a. 1. Paragraph 1 shall also apply to inseminations carried out after stimulation procedures in which there is an increased risk of pregnancies with three or more embryos. In the case of other inseminations, subsection 1 not 2 second half-sentence and no.5 shall not apply. 2. Entitlements to benefits in kind pursuant to subsection (1) shall exist only for insured persons who have reached the age of 25; the entitlement does not apply to female insured persons who have reached the age of 40 and to male insured persons who have reached the age of 50. Before the start of treatment, a treatment plan must be submitted to the health insurance company for approval. 3. [Not extracted as related to fertility preservation].
DAHR intervention(s) provided		N/A
Organisation	***Referral pathways***	N/A
	Service provider characteristic	N/A
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A

	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		[5] In the guidelines pursuant to Section 92, the Federal Joint Committee shall determine the medical details of the prerequisites, nature and scope of the measures pursuant to subsections (1) and (4).
Funding		[3] The health insurance fund covers 50 per cent of the costs approved by the treatment plan for the measures carried out on its insured person.
Counselling, communication and information provision		N/A
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		N/A

Table E.27 Extracted data for Northern Ireland (Eligibility for funded IVF)

Northern Ireland		
Author(s) **Title [year]**	Department of Health Eligibility for HSC funded IVF and related treatments effective from 1st June 2019[39] [2020]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		Criteria for referral for investigation **(pp. 1-2)** In the absence of any known cause of infertility, a woman of reproductive age should be offered further clinical assessment and investigation (along with her partner, where appropriate) where: ▪ she has not conceived after one year of unprotected vaginal sexual intercourse, or ▪ if using artificial insemination (with either partner or donor sperm), she has not conceived after four cycles of artificial insemination. Earlier referral for specialist consultation should be made where clinically indicated. Unless otherwise clinically indicated, women trying to conceive using artificial insemination, who have not conceived after four cycles of donor or partner insemination, should be offered four cycles of unstimulated intrauterine insemination (IUI) before referral for IVF is considered. **Provision of IVF** Where: ▪ a fertility problem has been demonstrated at investigation; or ▪ a woman has not conceived after two years of regular unprotected vaginal ▪ intercourse (including the year prior to being referred for investigation) or eight ▪ cycles of artificial insemination (where at least four are by IUI). ▪ one cycle of IVF, with or without ICSI, and one frozen embryo transfer, should be offered for: ○ women aged under 40 or ○ women aged between 40 and 42 who have never previously had IVF treatment and where there is no evidence of low ovarian reserve and there has been a discussion of the additional implications of IVF and pregnancy in this age group. **Further eligibility criteria** Provision of IUI and IVF/ICSI is subject to the following conditions: ▪ the woman has a body mass index of at least 19.0kg/m2 and up to and including 30.0kg/m2 ▪ neither the woman, nor her partner, has had three or more IVF cycles previously (including both publicly funded and private treatment). ▪ neither the woman, nor her partner, has undergone a voluntary sterilisation procedure, even if reversed. This does not include conditions where sterilisation occurs as a result of another medical problem.

		▪ treatment will only be provided to people who have been assessed by the clinic as meeting HFEA requirements on the welfare of any child who may be born as a result and of any other child who may be affected by the birth. **Smoking** - Women who smoke should be informed this is likely to reduce their fertility. Women should be encouraged to abstain from smoking for three months prior to IVF. **Alcohol** - Women who are trying to become pregnant should be informed that drinking no more than 1 - 2 units of alcohol once or twice per week and avoiding intoxication reduces the risk of harming a developing foetus. Men should be advised that excessive alcohol intake is detrimental to semen quality. (New recommendation will be provided in near future). **BMI** - Women with a BMI over 30.0kg/m2 are likely to take longer to conceive and men with a BMI over 30.0kg/m2 are more likely to have reduced fertility. Women with a BMI over 30.0kg/m2 and who are not ovulating should be informed that losing weight is likely to increase their chance of conception. Women with BMI over 30.0kg/m2 should be referred to a group programme involving exercise and dietary advice to lose weight.
DAHR intervention(s) provided		N/A
Organisation	***Referral pathways***	N/A
	Service provider characteristic	N/A
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		N/A
Counselling, communication and information provision		N/A

Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		N/A

Table E.28 Extracted data for Northern Ireland (Fertility Centre)

Northern Ireland		
Author(s) **Title [year]**	Belfast Health and Social Care Trust Regional Fertility Centre[40] [2025]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**Medical criteria for IVF or ICSI treatment** In vitro fertilisation (IVF) and intracytoplasmic sperm injection (ICSI) are both types of assisted conception. The treatment for both is the same. The only difference is the method of fertilisation used in the laboratory. The decision on which treatment is more suitable for you will depend on certain medical criteria and best clinical practice, including your body mass index (BMI).
DAHR intervention(s) provided		There is a shortage of egg and sperm donors in the UK. This can result in you waiting a longer time before you are treated. **Embryo donation:** For some couples who have both an egg and sperm problem, treatment using embryos (fertilised eggs) from another couple may be the only appropriate treatment. A couple who have had treatment at the RFC and have stored embryos they no longer intend to use in treatment may consider donating embryos to another couple. **Egg donation:** For some women treatment, using eggs donates from others is the only treatment option available to them. Some women have become sterile due to surgery or chemotherapy treatment for cancer, some may have undergone an early menopause or have some other hormonal condition and some may carry a genetic condition which is passed on by females. Egg donation may be by a known donor, such as a friend or a family member, or anonymously by someone wishing to donate eggs. **In vitro fertilisation (IVF):** IVF is suitable for women with damaged fallopian tubes or men with lower semen quality. In addition, a large number of couples with unexplained infertility may benefit from IVF treatment. IVF may also be suitable for women who are unable to produce eggs (using egg donation) or who do not have a uterus (using surrogacy).
Organisation	***Referral pathways***	You need to be referred by a GP or hospital consultant to access NHS services in the Regional Fertility Centre. There are four stages of fertility treatment (generally): ▪ Consultation – when we receive a referral from your GP or consultant ▪ 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.
	Service provider characteristic	N/A
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	The Regional Fertility Centre can **store sperm** samples for patients who are about to undergo a treatment or procedure that may affect their long-term fertility, such as chemotherapy, radiotherapy or certain types of surgery. If you require this sperm storage service, you will be referred by the doctor supervising your treatment. Sperm samples may be stored for up to 55 years. Before your sperm sample is placed in storage, we must check that you do not carry HIV or hepatitis. Blood tests will be arranged by the referring doctor. You will also need to complete the necessary consent forms before your sperm is placed in storage. Consent may be withdrawn or amended at any time should your circumstances change.
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		N/A
Counselling, communication and information provision		N/A
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		N/A

Table E.29 Extracted data for Portugal (Assisted Reproduction and Assisted Procreation)

Portugal		
Author(s) **Title [year]**	The National Council for Medically Assisted Reproduction, The National Council for Medically Assisted Procreation (CNPMA)[41][2026]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		When after a year of regular sexual intercourse, without any contraception, a viable pregnancy does not occur, marital infertility is considered to exist. Recent data indicate that about 10% of couples have a diagnosis of infertility and that about half of these couples will need medically assisted reproduction (ART) treatments. This type of treatment also becomes inevitable in the cases of women without a partner or couples of women, whose access to PMA treatments was enshrined after the publication of Law No. 17/2016, of 20 June. The CNPMA decided that PGT-A does not require prior authorization as long as the technique used allows the study of all chromosomes and at least one of the following indications is verified: ▪ advanced female age (39 years or older) ▪ repeated embryo implantation failures after IVF/ICSI (three or more transfers) ▪ recurrent clinical abortions (two or more) of unknown cause (excluding biochemical pregnancy) ▪ previous pregnancy with chromosomal number abnormality or unbalanced structural anomaly ▪ performed an embryonic biopsy already authorised for PGT-M. [FAQ] The legal minimum limit is 18 years old. The maximum limit is, for women, 50 years. There is no maximum limit for the male partner. However, these treatments are only publicly funded if they are carried out before the woman's 40th birthday (for in vitro fertilization (IVF) and intracytoplasmic sperm microinjection ICSI techniques)] or before the woman's 42nd birthday (in the case of artificial insemination). **[FAQ] Can foreign citizens use PMA treatments in Portugal?** Yes, as long as it is within the legally defined age limits. But only those who are registered as users of the National Health Service will be able to benefit from public funding. **[Citizens – oocyte donation]** Despite the spectacular advances in reproductive medicine and fertility treatments, which solve a very significant part of infertility situations, many cases will only be solved by donation. A treatment with oocyte donation can be justified in several situations: ▪ early ovarian failure ▪ absence or congenital insufficiency of the ovaries ▪ in situations of repeated failure in fertility treatments using the woman's own oocytes, usually due to their poor quality, or a number considered insufficient ▪ in situations of late motherhood. from the age of 38, in addition to the decrease in the number of oocytes, a large number of them may have genetic alterations, which can make a normal pregnancy unfeasible.

		[Citizens – sperm donation] A treatment with sperm donation can be justified in several situations: ▪ in situations of absence of sperm production (azoospermia) ▪ surgical removal of the testicles ▪ severe situations of poor sperm quality ▪ in treatments of couples of women or women without a partner. **[Citizens – embryo donation]** In situations where it is impossible to obtain a pregnancy because there is a problem with both oocytes and sperm, a double donation of these cells can be used or, alternatively, an embryo donation. The donation of embryos is only possible with the express consent of the beneficiaries holding the rights over such embryos. These are invariably the result of ART treatments, in which viable surplus embryos are obtained which, by legal obligation, will have to be cryopreserved. In the event of non-use, and after a period that can vary between 3 -6 years, they can be donated, as long as this option has been foreseen by the respective beneficiaries.
DAHR intervention(s) provided		**Artificial Insemination (AI)** Main indications: ▪ ovulation problems ▪ slight changes in sperm number and motility ▪ sexual dysfunctions ▪ infertility of unexplained cause of short duration (situation in which after the couple's study there is no explanation for infertility) ▪ need to resort to sperm donation due to lack of sperm production (secretory azoospermia). ▪ insemination using donated sperm is also an indication for women without a partner or couples of women. **In Vitro Fertilization (IVF)** The use of IVF has a much broader scope than that of AI. The most frequent indications are: ▪ bilateral obstruction or absence of the fallopian tubes ▪ endometriosis ▪ failure of simpler treatments such as ovulation induction and IUI. **Intracytoplasmic Sperm Microinjection (ICSI)** ICSI has the following main indications: ▪ severe male infertility. ▪ cases of zero or very low fertilization in a previous IVF. **PGT:** The current designation of preimplantation genetic testing (PGT) is broad, followed by the abbreviation of the alteration researched: monogenic diseases (PGT-M - Preimplantation Genetic Testing for Monogenic diseases), structural chromosomal abnormalities (PGT-SR - Preimplantation Genetic Testing for chromosomal Structural Rearrangements) and aneuploidies (PGT-A -

		Preimplantation Genetic Testing for Aneuploidy). The performance of preimplantation genetic tests for monogenic diseases (PGT-M) and structural chromosomal abnormalities (PGT-SR) is only possible after the guidance and opinion of a physician specialised in Medical Genetics and the recognition of the scientific value of the techniques used for preimplantation genetic testing for diagnosis, treatment or prevention of serious genetic diseases, as such considered by the CNPMA. In the absence of a legal definition of serious illness, the CNPMA understands that the concept applies to illnesses that cause significant distress and/or premature death. The CNPMA also outlines a list of situations for which the prior application for authorization for Preimplantation Genetic Testing of Monogenic Diseases (PGT-M) is waived. **[FAQ] Is there a limit to the number of ART treatments that can be done?** Beyond clinical reasonableness, there is no definitive limit. However, it is generally agreed that after 4 unsuccessful embryo transfers, the likelihood of further treatments resulting in pregnancy is very low. In public centres, each couple (or woman without a partner) is entitled to undergo 3 artificial inseminations and three cycles of in vitro fertilisation (IVF) / intracytoplasmic sperm microinjection (ICSI) as long as the beneficiary's age limit is not exceeded. Cryopreserved embryo transfers are not included in the count of this three cycle limit.
Organisation	***Referral pathways***	N/A
	Service provider characteristic	**[FAQ] Where can ART treatments be done?** In centres (public and private) expressly authorised to perform ART techniques.
	Timelines to access services	N/A
	Any other organisational aspects	**[Import and export of reproductive cells]** **Importing reproductive cells:** The importation of reproductive cells can only be done by centres authorised to administer PMA techniques and with express authorization from the CNPMA. To apply for authorization for the import of reproductive cells, the centres must submit the request to the CNPMA, by filling in the specific model created by the Council for this purpose. The granting of authorization for the import of reproductive cells is issued for a period of one year**.** **Access to the identity of donors and the authorisation of applications authorisation for the import of reproductive cells** The introduction of a new paradigm in the Portuguese legal system with regard to access to the identity of the donor, requires that the CNPMA, taking into account its competences, take a position on the procedures to be adopted by the ART centres in relation to the importation of gametes. Thus, the authorisation to import reproductive cells is limited to countries where access to the donor's civil identity is not legally impeded, As a result of the above, the CNPMA decided as follows: i) Given the legal regime currently in force, ART centres may only request the import of gametes from European Union countries where there is a regime of non-anonymity of the donor(s). ii) The effects of gamete import authorizations already granted are restricted to the import of gametes from non-anonymous donors.

		Export of reproductive cells: The export of reproductive cells can only be done by centres authorised to administer PMA techniques and with express authorization from the CNPMA. Although the shortage of reproductive cells has always been a reality of the PMA in Portugal (a panorama that, moreover, unfortunately has not undergone significant changes), this entity cannot fail to pronounce on the phenomenon of export, also expressed in the Law. Resolution No. 02/IV, of October 27, 2023, aims to comply with the legal provisions relating to this matter, defining on the one hand the conditions that guarantee the principle of national self-sufficiency, also establishing the procedures to be followed for the export of reproductive cells. The Centre that intends to distribute or export reproductive cells may only carry out such activity after obtaining the prior, annual authorisation from the CNPMA, having verified all the requirements contained in this resolution and by filling in a form approved by the CNPMA. After the authorization provided for in the previous number, the distributing or exporting enter must make public to the other national Centres that perform ART techniques that it has gametes available for distribution. In cases where a National Centre has a shortage of gametes whose characteristics are compatible with those of the gametes available at the distributing or exporting Centre, the latter shall be obliged to distribute these cells to that National Centre. The distribution or export of reproductive cells shall contain the express identification of the institution of destination for inspection purposes. The receiving institution (in the case of European Union countries) must be registered in the Compendium of Tissue and Cell Banks of the European Union. **Transport of gametes and embryos between national centres:** In accordance with the provisions of the "Requirements and Parameters for the Operation of ART Centres", the transport of gametes, gonadal tissue and embryos from one Centre to another must be carried out in a container suitable for the transport of biological materials and that guarantees the safety and quality of the material transported. The identification of the content must be accurate and in such a way as to prevent unauthorised alterations. The material transported must be accompanied by the information listed in the above-mentioned document. The receiving Site shall establish a procedure for receiving gametes, gonadal tissue or embryos from another Centre to ensure that: ▪ the requirements for specific information regarding the products received are met ▪ the products arrive in conditions suitable for their safety and quality. **Transport of gametes and embryos by the beneficiary(ies):** If the beneficiary chooses to transport the gametes/embryos between Centres, in order to ensure the requirements of quality, safety and traceability, he/she will have to sign the Term of Responsibility prepared by the CNPMA.
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A

	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	**[FAQ] What happens to embryos that are not used in the treatment of ART?** PMA treatments aim at the birth of a single, healthy child. For this reason, it is increasingly common to opt for the transfer of only one or two embryos. There is, however, the possibility that more viable embryos will result than will be transferred. All viable embryos that are not transferred will be cryopreserved for a maximum period of three years, extendable for another three years, at the request of the couples. According to the choice of the beneficiary(ies), the cryopreserved embryos can be used later or donated to other beneficiaries and/or for scientific research. In the absence of any of these options and after the period provided for by law, the embryos are thawed and disposed of. **[FAQ] Is post-mortem insemination lawful?** Law no. 72/2021, of 12 November, made the seventh amendment to Law no. 32/2006, of 26 July (medically assisted procreation), allowing the use of medically assisted procreation techniques through insemination with semen after the death of the donor, in cases of clearly established and consented parental projects. Under the law, insemination with semen after the death of the donor will depend on the verification of the following conditions: ▪ The semen must have been collected based on a well-founded fear of future sterility, for the purpose of insemination of the woman with whom the man was married or living in a de facto union and the donor dies during the period established for the conservation of the semen ▪ The elapse of a minimum period of six months, except for weighty clinical reasons duly attested by the doctor who accompanies the procedure, and a maximum of three years, between the death of the husband or de facto partner and the beginning of the post-mortem insemination procedures, with a maximum number of attempts being made identical to that set for public centres. The law also determines that insemination with semen from the husband or de facto partner, as well as the post-mortem implantation of an embryo, can only occur for the realization of a single pregnancy resulting in a complete and living birth**.** **[FAQ] Is post-mortem insemination resulting from donation lawful?** Under the combined terms of arts. 26, 22 and 22-A of Law no. 32/2006, of 26 July, in its current wording, it is lawful, after the death of one of the members of the couple, to transfer an embryo resulting from donation or to carry out an insemination with donated semen. Under the terms provided for in arts. 26, 22 and 22-A of Law no. 32/2006, of 26 July, the transfer of embryo resulting from donation or insemination with donated semen depends, however, on the verification of the following requirements: ▪ The existence of a clearly established and consented parental project ▪ The elapse of a period of not less than six months after the death of the member of the couple, except for weighty clinical reasons duly attested by the doctor who accompanies the procedure ▪ The procedures must begin within a maximum period of three years from the death of the member of the couple, and a maximum number of attempts may be made identical to that set for public centres

		▪ Insemination with semen, as well as post-mortem implantation of an embryo, may only occur for the realization of a single pregnancy resulting in complete and living birth ▪ Consent to post-mortem insemination must be reduced to writing or recorded on videograms, after informing the author of its legal consequences ▪ The consent document authorising post-mortem insemination is communicated to the National Council for Medically Assisted Procreation for the purposes of its centralised registration.
	Any other management information	N/A
Governance		Requests for authorization for PGT-M must be addressed to the CNPMA, by the director of the PMA Centre, and the file must include, namely, the report of the doctor with the specialty of Medical Genetics. **[Inspection and inspection actions]** INSPECTION ACTIONS TO SPLC CENTERS | Legal framework: The CNPMA is the competent authority responsible for ensuring quality and safety in relation to the donation, collection, analysis, processing, storage and distribution of reproductive cells, and is responsible for monitoring the activity of the centres where PMA techniques are administered and the centres where gametes or human embryos are preserved, supervising compliance with the Law, in conjunction with the competent public entities. It is the responsibility of the General Inspection of Health Activities (IGAS), in conjunction with the CNPMA, to carry out audits, inspections and inspections of public and private centres that provide PMA techniques. The inspection actions aim to monitor compliance with the laws and regulations relating to MAR activities and procedures and the adoption of best practices regarding compliance with the requirements and operating parameters and the applicable legal and regulatory provisions. They can be done through ordinary, global, thematic or reassessment and extraordinary.
Funding		N/A
Counselling, communication and information provision		**Informed Consent Models** Before starting the therapeutic processes of ART, the beneficiary person(s) must give their consent expressly and in writing. For free and informed consent, the beneficiary person(s) must be properly informed about the known benefits and risks resulting from the use of these techniques, as well as their ethical, social and legal implications. **[FAQ] What does informed consent consist of?** Informed consent is the written document in which beneficiaries are informed of the known benefits and risks resulting from the use of ART techniques, as well as their ethical, social and legal implications, and where beneficiaries, when affixing their signature, express their consent to the use of these techniques in a free and informed manner.
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A

Miscellaneous		**[FAQ] Gamete donation: Who? Where? How?** The donation of gametes (sperm and oocytes) is enshrined in Portuguese legislation and can be carried out by any citizen considered healthy, namely without a history of genetic diseases, sexually transmitted diseases or others considered serious and who, in addition, also meets the following requirements. In the case of women: ▪ Be between 18 and 34 years old ▪ Have donated oocytes on less than four occasions ▪ Have donated oocytes for more than 3 months. In the case of man: ▪ Be between 18 and 45 years old ▪ Have fathered children in fewer than eight different families. Donations can be made at the Public Gamete Bank (based at CMIN - CH in Porto, or at the Harvest Centres, CH and University of Coimbra and CH Lisboa Central - Maternidade Dr. Alfredo da Costa) or at private centres expressly authorised for this purpose. The way in which these donations can be made differs significantly in men and women. If in the case of sperm donation there is no need to use any medication, oocyte donation implies the stimulation of the ovaries with specific drugs for this purpose. The collection of these oocytes is carried out under light sedation, after which the donation is considered to have taken place. For more information, see the SPMR website. **Registries in LDC** Medically Assisted Procreation (ART) techniques have very particular technical-scientific characteristics and social implications, which justifies the existence of specific legislation. A relevant aspect is the need for detailed objectification of its practice and its consequences. Hence the obligation to have systematic records that allow a detailed view of the characteristics of the beneficiaries, the technical aspects of the treatments and their results, information whose relevance in the health of those who needed to resort to these techniques and the children resulting from them is undeniable. The systematic national register using IT platforms specifically designed for this purpose started on 1 January 2013, replacing the previous, less detailed version based on inappropriate methodology. Its generic purpose is, therefore, to monitor the practice of the activity in ART, to evaluate the effectiveness of these treatments and to monitor the outcomes of children born as a result of the use of these techniques. Two different types of registries are implemented called "Registry of Activity in LDCs" and "Registry of Donors, Beneficiaries and Children Born Using Third-Party Donations". Taking into account the evolution of techniques and the legal changes that have occurred, the platforms have undergone constant updates since their design, and Portugal continues to have one of the most modern PMA registration systems in Europe. The analysis of the data thus recorded allows not only the preparation of national annual reports but also participation in the European register and the world register.

		Registration of Activity in PMA: Here is recorded detailed information on in vitro fertilization (IVF), intracytoplasmic sperm microinjection (ICSI), cryopreserved embryo transfer and artificial inseminations, whether these treatments are intramarital treatments or using gamete donation (sperm and/or eggs) or embryos. In addition to strict technical data, information on pregnancy and the characteristics of its outcome (type of delivery, age of gestation at birth, number and health of newborns, as well as their health status and development after the first year of life) are also recorded. It is also on this platform that the procedures for preserving reproductive potential are recorded. The data are entered online by the centres authorised to practise these techniques and do not include any identifying element of the persons benefiting from these treatments. To the effort of the centres to comply with this registration, it is essential to add the collaboration of the beneficiaries of the techniques, through the sending of the results of the treatments (outcome of pregnancies and characterization of the children's health at the end of the 1st year of life). **Registration of Donors, Beneficiaries and Children Born Using Third-Party Donations:** On this platform, not the details of the technical procedures, but information regarding gamete and/or embryo donors, the beneficiaries of these techniques and children born using third-party donations, are also inserted by the centres, so that the legal determinations regarding the limits on what each participant can have access to can be complied with. It should be noted that the information entered in this register is reserved, under an encryption regime, which can only be exceeded, in the situations provided for by law, by the simultaneous introduction of codes in the possession of the President and Vice-President of the CNPMA. This platform guarantees traceability from the donor to the information about the children born using that donation, through the assignment of a code (the system guarantees the assignment of a unique sequential code, the 'single European code', associated with the identity of the donor, complemented by each donation and its applications and results).

Table E.30 Extracted data for Portugal (Medically assisted procreation Law 2006)

Portugal		
Author(s) **Title [year]**	Diario Da Republica Law No. 32/2006 of 26 July Medically assisted procreation[42] [2006]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**Article 4** **Recourse to the PMA** 1. ART techniques are a subsidiary, and not an alternative, method of procreation. 2. The use of ART techniques may only be made upon diagnosis of infertility or, where appropriate, for the treatment of a serious illness or the risk of transmission of diseases of genetic, infectious or other origin. 3. PMA techniques can also be used by all women regardless of the diagnosis of infertility. **Article 6** **Beneficiaries** 1. Couples of different sexes or couples of women respectively married or living in conditions similar to those of spouses, as well as all women, regardless of marital status and sexual orientation, may use ART techniques. 2. The techniques may 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. **Article 10** **Sperm, oocyte and embryo donation** 1. Oocytes, sperm or embryos donated by third parties may be used when, in view of the objectively available medical and scientific knowledge, it is not possible to obtain pregnancy or pregnancy without a serious genetic disease through the use of any technique that uses the gametes of the beneficiaries and provided that effective conditions are ensured to guarantee the quality of gametes. 2. Donors may not be considered as parents of the child to be born. **Article 29** **Applications [PGD]** 1. The PGD is intended for people from families with alterations that cause early death or serious illness, when there is a high risk of transmission to their offspring. 2. The specific medical indications for possible PGD are determined by current good practice and are included in the recommendations of national and international professional organisations in the area and are periodically reviewed.
DAHR intervention(s) provided		**Article 2** **Scope** 1. This law applies to the following ART techniques:

		a) artificial insemination b) in vitro fertilization c) intracytoplasmic sperm injection d) transfer of embryos, gametes or zygotes e) pre-implantation genetic diagnosis f) other equivalent or subsidiary laboratory techniques for gametic or embryonic manipulation. 2. This law shall also apply to the situations of surrogacy provided for in article 8. **Article 7** **Prohibited Purposes** 1. Reproductive cloning with the aim of creating human beings genetically identical to others shall be prohibited. 2. ART techniques may not be used to improve certain non-medical characteristics of the unborn child, namely the choice of sex. 3. Cases in which there is a high risk of a sex-related genetic disease, and for which direct detection by pre-implantation genetic diagnosis is not yet possible, or where the need to obtain a compatible HLA (human leukocyte antigen) group for the purpose of treating a serious disease is considerable, shall be excepted from the provisions of the preceding paragraph. 4. PMA techniques may not be used for the purpose of producing chimeras or hybrids. The application of preimplantation genetic diagnosis techniques in multifactorial diseases where the predictive value of the genetic test is very low is prohibited. **Article 19 [applies to IVF also]** **Insemination with donor semen** 1. Insemination with donor semen is permitted when the pregnancy cannot be obtained in any other way. 2. The donor's semen must be cryopreserved. **Article 24** **General principle** 1. In vitro fertilization, only the number of embryos considered necessary for the success of the process should be created, in accordance with good clinical practice and the principles of informed consent. 2. The number of oocytes to be inseminated in each process must take into account the clinical situation of the couple and the general indication for the prevention of multiple pregnancy. **Article 28** **Aneuploidy screening and preimplantation genetic diagnosis** 1. Preimplantation genetic diagnosis (PGD) aims to identify embryos that do not have a serious anomaly, before their transfer to the woman's uterus, using ART techniques.

		2. The application, under the guidance of a responsible specialist doctor, of genetic screening for aneuploidies in the embryos to be transferred is permitted in order to reduce the risk of chromosomal alterations and thus increase the chances of success of ART techniques. 3. The application, under the guidance of a specialist physician in charge, of PGD techniques that have recognised scientific value for the diagnosis, treatment or prevention of serious genetic diseases, as such considered by the National Council for Medically Assisted Procreation, is permitted. 4. ART centres that wish to apply PGD techniques must have or articulate with a multidisciplinary team that includes specialists in reproductive medicine, embryologists, medical geneticists, cytogeneticists and molecular geneticists.
Organisation	***Referral pathways***	**Article 11** **Medical decision and conscientious objection** 1. It is the responsibility of the physician in charge to propose to the beneficiaries the ART technique that scientifically appears to be most appropriate when other treatments have not been successful, do not offer prospects of success or are not convenient according to the precepts of medical knowledge. 2. No health professional may be obliged to supervise or collaborate in the performance of any of the ART techniques if, for medical or ethical reasons, he or she does not consider it necessary. 3. The professional's refusal must specify the clinical or other reasons that motivate it, namely conscientious objection.
	Service provider characteristic	**Article 5** **Authorised centres and qualified persons** 1. ART techniques, including those carried out in the context of surrogacy situations provided for in article 8, may only be administered in public or private centres expressly authorised for this purpose by the Minister of Health. 2. The following are defined in a specific law, namely: a) The qualifications required of medical teams and other health personnel b) The method and criteria for periodic evaluation of technical quality c) Situations in which the operating authorization can be revoked.
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	**Article 18** **Buying or selling eggs, semen or embryos and other biological material** The purchase or sale of eggs, semen or embryos or any biological material resulting from the application of ART techniques is prohibited.
	Storage of donated gametes or embryos	**Article 16a** **Fate of sperm, oocytes, testicular tissue and ovarian tissue** 1. Spermatozoa, oocytes, testicular tissue and ovarian tissue, which are collected and not used, shall be cryopreserved for a maximum period of five years.

		2. At the request of the beneficiaries, in duly justified situations, the director of the medically assisted reproduction centre (PMA) may assume responsibility for extending the period of cryopreservation of spermatozoa, oocytes, testicular tissue and ovarian tissue for a new period of five years, successively renewable for the same period. 3. Without prejudice to the extension of the period provided for in the preceding paragraph, after the expiry of the five-year period, spermatozoa, oocytes, testicular tissue and ovarian tissue may be destroyed or donated for scientific research if no other destination is given to them. 4. The destination of spermatozoa, oocytes, testicular tissue and ovarian tissue for the purposes of scientific research, under the terms provided for in the preceding paragraph, may only be verified with the free, informed consent, expressly and in writing, of the original beneficiaries, through informed consent forms drawn up by the National Council for Medically Assisted Procreation, presented to the responsible doctor. 5. Once the donation has been consented, without the spermatozoa, oocytes, testicular tissue and ovarian tissue having been used in a research project within 10 years of cryopreservation, they may be thawed and eliminated, as determined by the director of the ART centre. 6. If donation is not consented to, as soon as any of the periods above have elapsed, spermatozoa, oocytes, testicular tissue and ovarian tissue may be thawed and eliminated, as determined by the director of the ART centre. **Article 25** **Fate of embryos** 1. Embryos which, under the terms of the preceding article, do not have to be transferred, must be cryopreserved, and the beneficiaries undertake to use them in a new embryo transfer process within a maximum period of three years. 2. At the request of the beneficiaries, in duly justified situations, the director of the centre may assume responsibility for extending the period of cryopreservation of embryos for a further period of three years. 3. After the three-year period, without prejudice to the situations provided for, embryos may be donated to other beneficiaries whose medical indication of infertility so advises, the decisive facts being subject to registration, or donated for scientific research. 4. The fate of the embryos provided for in the preceding paragraph may only be verified with the consent of the original beneficiaries or of the surviving beneficiary, mutatis mutandis. 5. Embryos whose morphological characterisation does not indicate minimum conditions of viability shall not be subject to the above. 6. If donation is consented, without the embryos having been used by other beneficiaries or in a research project within six years of cryopreservation, they may be thawed and eliminated, as determined by the director of the centre. 7. If donation is not permitted, as soon as any of the periods indicated above have elapsed, the embryos may be thawed and eliminated, by determination of the director of the centre, previously communicated to the National Council for Medically Assisted Procreation.

	Access to and or disposal of stored donated gametes or embryos	[See storage of donated gametes or embryos] **Article 22** **Post mortem insemination** 1. In order to implement a clearly established and consented parental project, and after the period considered adjusted to the appropriate consideration of the decision, it is lawful, after the death of the husband or de facto partner: a) Proceed with the post-mortem transfer of embryos b) Perform an insemination with semen from the deceased person. 2. The provisions of the preceding paragraph shall apply to cases in which semen is collected, on the basis of a well-founded fear of future sterility, for the purpose of insemination of the woman with whom the man is married or living in a de facto union and the donor dies during the period established for the preservation of semen. 3. Semen collected on the basis of a well-founded fear of future sterility, without consent having been given for post-mortem insemination, shall be destroyed if the person dies during the period established for its conservation. 4. The period referred to above shall not be less than six months, except for weighty clinical reasons duly attested by the doctor accompanying the procedure. 5. Procedures must begin within a maximum period of three years from the death of the husband or de facto partner, and a maximum number of attempts may be made identical to that established for public centres. 6. Insemination with semen from the husband or de facto partner, as well as the post-mortem implantation of an embryo, may only occur for the realization of a single pregnancy resulting in complete and living birth. 7. Whoever so requests is provided with psychological support in the context of the decision to carry out post-mortem insemination, as well as during and after the respective procedure. **Article 22a** **Consent requirements for post-mortem insemination** 1. The consent for post-mortem insemination shall be reduced to writing or recorded on a videogram, after informing the donor of its legal consequences. 2. The consent referred to above may be included in the document in which the informed consent provided for is given, provided that it is contained in an autonomous clause. 3. The document authorising the post-mortem insemination referred to in the preceding paragraphs shall be communicated to the National Council for Medically Assisted Procreation for the purposes of its centralised registration.
	Any other management information	N/A
Governance		**Article 30** **National Council for Medically Assisted Procreation**

		1. The National Council for Medically Assisted Procreation, hereinafter referred to as the CNPMA, is hereby created, which is generally responsible for pronouncing on ethical, social and legal issues of the PMA. 2. The CNPMA's duties are, in particular: a) To update scientific information on PMA and on the techniques regulated by this legislation b) To establish the conditions under which the centres where the ART techniques are administered must be authorised, as well as the centres where gametes or embryos are preserved c) To monitor the activity of the centres referred to in the previous paragraph, supervising compliance with this law, in conjunction with the competent public entities d) To give an opinion on the authorisation of new centres, as well as on situations of suspension or revocation of such authorisation e) To give an opinion on the establishment of stem cell banks, as well as on the destination of the biological material resulting from their closure f) To establish guidelines related to the DGPI g) To assess, approving or rejecting, research projects involving embryos h) To approve the document through which the beneficiaries of the ART techniques give their consent i) To provide information related to donors j) To pronounce on the implementation of ART techniques in the National Health Service l) To gather the information, carry out its scientific treatment and evaluating the medical, sanitary and psycho-sociological results of the practice of PMA m) To define the model of the annual activity reports of the LDC centres n) To receive and evaluate the reports provided for in the previous paragraph o) To contribute to the dissemination of the available techniques and to the debate on their applicability p) To centralise all relevant information on the application of ART techniques, namely the registration of donors, including surrogate mothers, beneficiaries and children born q) To decide on a case-by-case basis on the use of ART techniques for the selection of HLA-compatible groups for the purpose of treating serious illness. 3. The CNPMA shall submit to the Assembly of the Republic and to the Ministries of Health and Science and Technology an annual report on its activities and on the activities of public and private services, describing the state of the use of ART techniques, formulating the recommendations it deems relevant, namely on the legislative changes necessary to adapt the practice of ART to scientific developments, technological, cultural and social. **Article 31** **Composition and Mandate** 1st - The CNPMA is composed of nine personalities of recognized merit who guarantee special qualification in the field of ethical, scientific, social and legal issues of PMA. 2nd - The members of the CNPMA are designated as follows: a) Five personalities elected by the Legislative Assembly

		b) Four personalities appointed by the members of the Government who oversee health and science. 3rd - The members of the Council elect from among themselves a president and a vice-president. 4th - The term of office of the members of the Council is five years. 5th - Each member of the Council may serve one or more terms. 6th - The members of the CNPMA remain in full exercise of their functions until the inauguration of the new members.
Funding		**Article 17** **Charges** 1. Centres authorised to provide ART techniques may not, in calculating the remuneration required, attribute any value to the donated genetic material or to the donated embryos. 2. The use of ART techniques within the scope of the National Health Service shall be supported by the conditions that may be defined in a specific diploma, taking into account the opinion of the National Council for Medically Assisted Procreation.
Counselling, communication and information provision		**Article 14** **Consent** 1. Beneficiaries must give their free, informed consent, expressly and in writing, to the responsible doctor. 2. For the purposes of the preceding paragraph, beneficiaries shall be informed in advance, in writing, of all known benefits and risks resulting from the use of ART techniques, as well as their ethical, social and legal implications. 3. The information contained in the preceding paragraph shall be contained in a document, to be approved by the National Council for Medically Assisted Procreation, through which the beneficiaries give their consent. 4. The consent of the beneficiaries may be freely revoked by any of them until the start of the therapeutic processes of ART. 5. The provisions shall apply to the surrogate mother, in which case her consent may be freely revoked until the moment of registration of the child born. 6. In the situations provided for in article 8, the beneficiaries and the surrogate mother shall also be informed, in writing, of the significance of the surrogate's influence on embryonic and foetal development. **Article 15** **Confidentiality** 1. Whoever, in any way, becomes aware of the identity of participants in ART techniques, including surrogacy situations, is obliged to maintain confidentiality about their identity and about the act of ART itself. 2. Persons born as a result of ART processes using gamete or embryo donation may, from the competent health services, obtain information of a genetic nature concerning them, as well as, provided that they are 18 years of age or older, obtain information on the civil identification of the donor from the National Council for Medically Assisted Procreation.

		3. Persons born as a result of ART processes, using the donation of gametes or embryos, provided that they are 16 years of age or older, may obtain information on the possible existence of a legal impediment to a projected marriage. 4. 'civil identification' shall mean the full name of the donor. 5. Without prejudice to the provisions of the preceding paragraphs, information on the identity of the donor may also be obtained for weighty reasons recognised by a court decision. 6. The birth certificate may not, under any circumstances, including in situations of surrogacy, contain an indication that the child was born from the application of ART techniques.
Ethical and social considerations		**Article 3** **Dignity and non-discrimination** 1. ART techniques, including those carried out in the context of surrogacy, must respect the human dignity of all persons involved. 2. Discrimination on the basis of genetic heritage or the fact that one was born as a result of the use of ART techniques is prohibited. **Article 12** **Beneficiaries' rights** The rights of the beneficiaries are: (a) not to be subjected to techniques which do not offer a reasonable probability of success or the use of which would entail significant risks to the health of the mother or child (b) to be assisted in a suitable medical environment that has all the material and human conditions required for the correct execution of the advisable technique (c) be properly informed of the likely medical, social and legal implications of the proposed treatments (d) to know the reasons that motivate the refusal of ART techniques (e) to be informed of the conditions under which it would be possible for them to have recourse to adoption and of the social relevance of this institute.
Relevant legislation (list and key aspects)		This law regulates the use of medically assisted reproduction (ART) techniques.
Miscellaneous		**Article 13** **Duties of beneficiaries** 1. The duties of the beneficiaries are: (a) Provide all the information requested by the medical team or that they deem relevant for the correct diagnosis of their clinical situation and for the success of the technique to which they are going to be submitted. (b) Strictly observe all the prescriptions of the medical team, both during the diagnosis phase and during the different stages of the ART process. 2. In order to assess the medical, health and psychosociological results of the ART processes as a whole, the beneficiaries shall provide all information related to the health and development of children born using these techniques.

		Article 20 [applies to IVF using donor semen or eggs also] **Determining parenthood** 1. If the use of medically assisted procreation techniques provided for in this law results in the birth of a child, the child shall also be considered as the child of the person who, with the beneficiary, has consented to the use of the technique in question, namely the person who is married or in a de facto union, and the respective parenthood is established at the time of registration. 2. For the purposes of the preceding paragraph, and in the event of absence at the time of registration of the person who gave consent, a document proving that consent has been given may be produced in the same act, and the respective parenthood shall be established. 3. If only the consent of the person submitted to the ART technique has taken place, only the birth registration shall be drawn up with their established parenthood, without the need for a subsequent ex officio verification process. 4. The establishment of parenthood may be challenged by the person who is married or living in a de facto union with the person undergoing the ART technique, if it is proven that there was no consent or that the child was not born from the insemination for which consent was given.

Table E.31 Extracted data for Portugal (Quality and Safety law of tissues and cells 2009)

Portugal		
Author(s) **Title [year]**	Diario Da Republica Law No. 12/2009: Establishes the legal framework for quality and safety relating to the donation, collection, analysis, processing, preservation, storage, distribution and application of tissues and cells of human origin, transposing into national law Directives No. 2004/23/EC of the European Parliament and of the Council of 31 March, 2006/17/EC of the Commission of 8 February and 2006/86/EC, of 24 October[43] [2009]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		N/A
DAHR intervention(s) provided		N/A
Organisation	***Referral pathways***	N/A
	Service provider characteristic	**Article 5** **Authorisation** 2. No activity relating to the collection of human reproductive cells and embryonic stem cells or other cells and tissues collected within the scope of the application of medically assisted reproduction techniques may be carried out outside authorised centres in accordance with the conditions established by the CNPMA.
	Timelines to access services	N/A
	Any other organisational aspects	**Article 8** **Traceability** 3. Medically assisted reproduction (ART) centres that select, evaluate and harvest reproductive cells from third donors and apply ART techniques using third-party donation, shall have a system for assigning a unique number to each donation and to each product associated with it, integrated into the donor register; beneficiaries and children born using a third-party donation, created and managed by the CNPMA.
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	**Article 9** **Import and export of human tissues and cells** 1. Tissues or cells intended for use in human beings may be imported from third countries only where: a) They originate from tissue and cell banks authorised for these activities and comply with the quality requirements provided for in this law b) Ensure all the traceability requirements provided for in this law c) ensure a system for reporting serious adverse reactions and incidents equivalent to that provided for in this law. 2. Imports of tissues or cells from third countries and exports to third countries may only be made by tissue and cell banks that are duly authorised for such activities, in accordance with this law

		and upon authorisation, in accordance with their respective area of competence, by the ASST and the CNPMA, pursuant to paragraphs 4 and 5 below. 3. All necessary measures shall also be taken to ensure that exports of tissues and cells to third countries are carried out through tissue and cell banks authorised for such activities. 4. Requests for the import of tissues and cells must mention the institution of origin and shall only be authorised, in accordance with their respective area of competence, by the ASST or the CNPMA when: a) There is a proven benefit in the use of the tissues or cells that are intended to be applied b) the purpose of the tissues or cells is for human application c) There is no availability in the national tissue banks or cells d) For reasons of compatibility justified by a doctor. 5. Applications for the export of tissues and cells must identify the institution of destination and shall only be authorised, in accordance with their respective area of competence, by the ASST or the CNPMA when there is sufficient availability of tissues and cells in national tissue banks or for justified compatibility reasons. 6. In cases of emergency, the import or export of tissues and cells may be authorised directly, in accordance with their respective area of competence, by ASST or by the CNPMA, provided that the supplier has accreditation, designation, licensing or authorisation in accordance with the provisions of this law or equivalent quality and safety standards. 7. The provisions of the preceding paragraphs shall apply to the movement of tissues and cells from third countries and the European Union.
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	**Article 11** **Reporting of serious incidents and adverse reactions** 5. In the case of assisted reproduction, any type of incorrect identification or exchange of gametes or embryos is considered to be a serious adverse event, and all persons and collection bodies responsible for its application in human beings that perform assisted reproduction must notify such incidents to the CNPMA.
Governance		**Article 4** **Competent authorities** 3. The CNPMA, as the competent authority, is responsible for ensuring the quality and safety of the donation, collection, analysis, processing, storage and distribution of reproductive cells and human embryonic stem cells. 6. The CNPMA shall be responsible for monitoring the activity of the centres where medically assisted procreation techniques are provided and the centres where gametes or human embryos are preserved and for supervising compliance with the law, in conjunction with the competent public entities.

		Article 4 **Authorisation** With regard to reproductive cells and embryonic stem cells and when such acts are carried out within the scope of the application of medically assisted reproduction techniques or the preservation of gametes, the CNPMA shall exercise the following: a) Authorising tissue and cell banks with regard to the activities of collection, analysis, storage and distribution in accordance with this law b) Authorising the harvesting units with regard to harvesting activities c) Authorising the services responsible for the application of tissues or cells to human beings d) To authorise the processes of preparation of tissues and cells. For the purposes of the authorisation provided for in the preceding paragraph, information shall be communicated to CNPMA. In order to assess the process leading to the issuance of the authorisation, the agreements concluded between a bank and third parties, including the collection units, shall be examined. The services may not make any substantial change to their activities and processes for the preparation of tissues and cells without the prior written approval of the CNPMA. **Article 6** **Inspection and control measures** 1. In matters within its competence, ASST shall periodically carry out inspections or other appropriate control measures on the collection units, tissue and cell banks and services responsible for their application, and the interval between them shall not exceed two years, in order to ensure compliance with the provisions of this law. 2. For the purposes of the preceding paragraph, ASST has the following powers: a) inspect the collection units, the tissue and cell banks and the departments responsible for their implementation, as well as the premises of third parties whom the authorisation holder has entrusted with the application of part of the procedures b) Evaluating and verifying the procedures and activities in the collection units, in the tissue and cell banks, in the services responsible for their application and in the facilities of third parties c) Collecting samples for examinations and analyses d) examine any documents or other records relating to the subject matter of the inspection. 3. ASST shall communicate in writing to the heads of the services the result of the inspections carried out pursuant to the preceding paragraphs. 4. ASST shall establish guidelines relating to the conditions of inspection and control measures, as well as the training and qualification of the professionals involved in order to ensure high competence and performance. 5. In the event of adverse reactions or serious or suspected adverse reactions, ASST shall organise inspections or other control measures, as appropriate.

		6. ASST shall also carry out inspections or other control measures at the request of the competent authorities of another Member State, provided that justified, in any case of incident or serious adverse reaction. 7. With regard to reproductive cells and embryonic stem cells, and when such acts are carried out within the scope of the application of medically assisted reproduction techniques or the preservation of gametes, it is incumbent upon the CNPMA, in conjunction with the General Inspection of Health Activities, hereinafter referred to as IGAS, to exercise their powers.
Funding		N/A
Counselling, communication and information provision		N/A
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		N/A

Table E.32 Extracted data for Portugal (Medicines Ordinance 2024)

Portugal		
Author(s) **Title [year]**	Diario Da Republica Ordinance No. 300/2024/1, of 25 November[44] [2024]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		N/A
DAHR intervention(s) provided		N/A
Organisation	***Referral pathways***	N/A
	Service provider characteristic	**Article 3** **Statute of limitations** Medicines covered by the exceptional regime provided for in this Ordinance may only be prescribed by doctors in the context of infertility treatment, and the prescribing physician must affix an express mention of this Ordinance to the prescription.
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		**Article 1** **Purpose** Medicines intended for the treatment of infertility, especially for medically assisted procreation, are reimbursed by step A (90%), under the terms of this Ordinance. **Article 2** **Medicines covered**

		1. Medicinal products benefiting from the exceptional reimbursement scheme, provided for in the preceding article, are those containing the active substances below, which is an integral part thereof. [Pharmacotherapeutic groups and subgroups ▪ Pituitary antagonists ▪ Cetrorrelix ▪ Ganirrelix ▪ Ovulation stimulants and gonadotropins ▪ Corifollitropin alfa ▪ Follitropin alfa ▪ Follitropin alfa + Lutropin alfa ▪ Follitropin beta ▪ Chorionic gonadotropin ▪ Lutropin alfa ▪ Menotropin ▪ Urofollitropin ▪ Analogues of gonadotropin-releasing hormone ▪ Goserrelin ▪ Triptorreline ▪ Progestogens ▪ Progesterone] 2. The inclusion of medicinal products in this exceptional reimbursement scheme depends on the application of the respective marketing authorisation holders, as defined in Decree-Law No. 97/2015, of 1 June, as amended by Decree-Law No. 115/2017, of 7 September. 3. Medicinal products and their presentations that may benefit from the exceptional reimbursement regime provided for in article 1 of this Ministerial Order shall be subject to approval by the member of the Government responsible for the health area, and the respective active substances listed in the annex to this Ministerial Order may be amended by resolution of the Board of Directors of INFARMED, I. P., published on its website.
Counselling, communication and information provision		N/A
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		N/A

Table E.33 Extracted data for Portugal (Regulatory Decree on medically ART techniques)

Portugal		
Author(s) **Title [year]**	Diario Da Republica Regulatory Decree No. 6/2016[45] [2016]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**Article 1** **Purpose** This regulatory decree regulates: a) Articles 5 and 16(2) of Law No. 32/2006, of 26 July, which regulates the use of medically assisted reproduction (ART) techniques b) Law No. 17/2016, of 20 June, guaranteeing access to PMA for all women. **Article 5** **Medically assisted reproduction techniques** 1. In the application of ART techniques, preference shall be given to artificial insemination, unless there is a clinical reason for the use of another ART technique. 2. In the case of couples of women, the decision regarding the member of the couple who undergoes artificial insemination or in vitro fertilization rests with the couple, unless there is a weighty clinical reason that does not advise the performance of the ART technique on that woman. 3. In situations where there is a medical indication for the simultaneous donation of oocytes and spermatozoa donated by third parties, the use of embryo donation shall be privileged. 4. Regardless of whether the beneficiary is a different-sex couple, a female couple or a woman without a partner, if the director of the ART centre considers it necessary to carry out a psychological assessment prior to the application of the ART techniques, he or she must declare it to the beneficiary, and this assessment may not be carried out without the latter's prior consent. 5. 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. 6. The psychological assessment shall always be carried out by a doctor specialising in psychiatry or by a clinical psychologist. **Article 6** **Use of medically assisted reproduction techniques in the National Health Service** 1. Access to ART techniques within the scope of the National Health Service (SNS) by couples of women or by women, regardless of a diagnosis of infertility, marital status and sexual orientation, must comply with the same criteria that are applied to couples of different sex with access to ART techniques under Law No. 32/2006, of 26 July, in its original version. 3. Consultations and complementary acts prescribed in the SNS within the scope of the PMA to couples of different sexes, couples of women or women without a partner shall be considered

		acts provided within the scope of family planning for the purposes of the application of user fee. 4. In the SNS a couple of women is not allowed to undergo ART treatment at the same time.
DAHR intervention(s) provided		N/A
Organisation	***Referral pathways***	2. Referral to the SNS of different-sex couples, female couples or women without a partner, shall be carried out by primary health care or SNS hospital entities to the PMA Centres that are part of the referral network.
	Service provider characteristic	**Article 2** **Authorised Centre** 1. A centre authorised to provide ART techniques is the set of human, material and organisational resources that make it possible to carry out ART, authorised in accordance with the provisions of article 5 of Law No 32/2006 of 26 July, as amended by Laws No 59/2007 of 4 September, 17/2016 of 20 June and 25/2016 of 22 August. 2. Centres may be public or private and must be expressly authorised for this purpose by the member of the Government responsible for the health area, after hearing the National Council for Medically Assisted Procreation (CNPMA). 3. The centres referred to in the preceding paragraph may be authorised to carry out all the ART techniques provided for in article 2 of Law No 32/2006 of 26 July, as amended by Laws No 59/2007 of 4 September, No 17/2016 of 20 June and No 25/2016 of 22 August 2016, for the exclusive performance of the artificial insemination technique or for the selection of donors and the preservation of gametes. 4. The application of the ART techniques provided for in article 2 of Law No. 32/2006 of 26 July, as amended by Laws No. 59/2007 of 4 September, 17/2016 of 20 June and 25/2016 of 22 August, to couples of women and to women regardless of a diagnosis of infertility, marital status and sexual orientation, may only be provided in public or private PMA Centres, duly authorised by the Ministry of Health, after hearing the National Council for Medically Assisted Procreation, under the terms of this regulatory decree.
	Timelines to access services	**Article 7** **Uniformity of waiting times** The existence of different waiting times for ART treatments is prohibited, depending on whether the beneficiary is a different-sex couple, a couple of women or women without a partner, without prejudice to the priorities established based on objective criteria of clinical severity.
	Any other organisational aspects	**Article 8** **Medical teams** 1. The director is responsible for the centre authorised to provide ART techniques, hereinafter referred to as the ART centre. 2. The director of the PMA centre is a doctor specialised in gynaecology/obstetrics, medical genetics, endocrinology or urology, recognised by the Portuguese Medical Association, with a minimum of three years' experience in the area of PMA. 3. ART centres shall have at least two doctors specialising in gynaecology/obstetrics, preferably with the sub-speciality of reproductive medicine, one of whom may be the director.

		4. The experience of the director of the PMA centre is proven through the curriculum and measured by the CNPMA. 5. The provisions of 2 and 3 shall not apply to centres authorised exclusively for artificial insemination, nor to centres authorised exclusively for the selection of donors and the preservation of gametes. **Article 9** **Other health personnel** 1. PMA centres shall have staff with experience and skills compatible with PMA, comprising at least two technicians holding a bachelor's degree or higher degree in the areas of medicine, biology, biochemistry or pharmacy. 2. The provisions of the preceding paragraphs shall not apply to centres authorised exclusively for artificial insemination, nor to centres authorised exclusively for the selection of donors and the preservation of gametes. **Article 10** **Staff assigned to centres exclusively dedicated to artificial insemination** Centres dedicated exclusively to artificial insemination must have a team consisting of at least one gynaecologist/obstetrician and a licensed technician with experience and skills compatible with ART.
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		**Article 3** **Application for authorisation** 1. The application for authorisation of a centre to provide ART techniques shall be made by submitting an application, preferably by electronic means, addressed to the member of the Government responsible for the health area and delivered to the territorially competent regional health administration depending on the location of the centre. 2. The application shall contain: a) The identification details of the applicant, namely the civil, taxpayer and residence identification numbers, in the case of a natural person, and access code to the permanent certificate, in the case of a legal person

		b) The elements that prove the existence of medical teams and other legally required health personnel c) The location of the establishment and its name d) The identification of the director of the centre e) A description of the human resources to be made available f) The description of the facilities and equipment. 3. The application shall be accompanied by a certificate from the commercial registry if the applicant does not have the permanent certificate. **Article 4** **Instruction** It is up to the territorially competent regional health administration to instruct the authorisation process of public or private centres that wish to provide ART techniques.
Funding		N/A
Counselling, communication and information provision		N/A
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		N/A

Table E.34 Extracted data for Scotland (NHS Scotland – Subfertility)

<table>
<tr><th colspan="3">Scotland</th></tr>
<tr><td>Author(s)
Title [year]</td><td colspan="2">Multiple resources
▪ NHS Scotland: Access Criteria NHS IVF Treatment Scotland[46] [2017]
▪ NHS Scotland: Right Decision Service: Infertility[47] [2025]
▪ Aberdeen Fertility Center[48] [2025]</td></tr>
<tr><td>Focus Area</td><td>Sub-focus area</td><td>Information extracted</td></tr>
<tr><td>Population(s) and eligibility criteria</td><td></td><td>Diagnosis
Subfertility with an appropriate cause of any duration – all couples:
▪ unexplained subfertility of two years – heterosexual couples
▪ unexplained subfertility following six cycles of donor insemination – same sex couples.

Access criteria all couples IVF:
▪ live within Lothian or the Borders.
▪ both partners must be non-smoking and nicotine free for at least three months before referral for treatment and continue to be non-smoking and nicotine free during treatment.
▪ both partners must abstain from illegal and abusive substances.
▪ both partners must be Methadone free for at least one year prior to referral to treatment.
▪ neither partner should drink alcohol prior to or during the period of treatment.
▪ BMI of female partner must be above 18.5 and below 30.
▪ neither partner to have undergone voluntary sterilisation or who have undertaken reversal of sterilisation, even if sterilisation reversal has been self-funded.
▪ couples can access treatment if one partner has no living biological child.
▪ NHS funding will not be provided to couples where either partner has already received the number of NHS funded IVF treatment cycles supported by NHS Scotland regardless of where in the UK they received treatment.
▪ no individual (male or female) can access more than the number of NHS funded IVF treatment cycles supported by NHS Scotland under any circumstances, even if they are in a new relationship.
▪ fresh cycles of treatment must be initiated by the date of the female partner’s 40th birthday and all subsequent frozen embryo transfers must be completed before the woman’s 41st birthday. If the female partner turns 40 during her first fresh cycle of treatment, no further fresh cycles will be offered. Each individual treatment cycle, including all frozen transfers, must be completed within 12 months of starting treatment, or (as set out above) before the date of the female partners 41st birthday if this is reached first.
▪ couples must have been co-habiting in a stable relationship for a minimum of two years at the same address.
▪ NHS treatment may be given to those patients who have previously paid for IVF treatment, if in the treating clinician’s view, the individual clinical circumstances warrant further treatment.

Who to refer, who not to refer, how to refer</td></tr>
</table>

		Who to refer Couples with no obvious cause for fertility problems who have been having unprotected intercourse for a year or more. Couple with an obvious cause for infertility oligo or amenorrhea, known tubal block or abnormal semen analysis should be referred straight away, and should not have to wait for a year. Same sex couples can be referred to the infertility clinic. **Who not to refer** Couples where the female partner, or partner wishing to become pregnant, is older than 42 years Couples where the female partner, or partner wishing to become pregnant, has a BMI of 35 or greater. Single people.
DAHR intervention(s) provided		N/A
Organisation	***Referral pathways***	Eligible patients may be offered up to three cycles of IVF/ICSI where there is a reasonable expectation of a live birth – for new referrals only from Primary and Secondary Care from 1 April 2017. Patients referred prior to 1 April 2017 may be offered up to two cycles of IVF/ICSI. Before accepting a referral to the infertility clinic the following information is needed: ▪ names and CHIs of both partners ▪ luteal phase progesterone (unless oligo or amenorrhea). This should be done 7 days before the date of the next expected period ▪ rubella status- serology if not vaccinated against rubella. If vaccinated then serology is not needed. ▪ chlamydia and gonorrhoea status for the female partner or partner intending to get pregnant ▪ BMI for partner intending to become pregnant ▪ if periods are irregular or absent, or luteal phase progesterone is less than 20, then we also require ▪ LH, FSH, Estradiol, Testosterone, Prolactin and TSH. These blood tests should be done on day 2-3 of the cycle, unless periods are more than 6 weeks apart. If periods are more than 6 weeks apart these bloods should be done without waiting for the next period. ▪ semen analysis for the male partner- result must be attached to the referral. ▪ if IVF is required the following criteria need to be met. ▪ if donor insemination for same sex couples is required the same criteria apply.
	Service provider characteristic	N/A
	Timelines to access services	N/A
	Any other organisational aspects	**Definition of one full cycle of IVF** One fresh cycle includes ovarian stimulation, egg retrieval, fertilisation, and transfer of fresh embryo (if appropriate), followed by the freezing of suitable embryos and the subsequent replacement of these, provided the couple still fulfil all access criteria. If suitable embryos are frozen these must be transferred before the next NHS funded stimulated treatment cycle.

		Single embryo transfer: Patients with a good prognosis are always expected to have single embryo transfer and this will be discussed with patients at clinic appointments. The single biggest risk of fertility treatment is a multiple pregnancy. Further information can be downloaded from the information section of the Fertility Network UK website or ask staff at your clinic for a copy of Fertility Network's leaflet. **Number of cycles for couples if female partner aged 40 to 42 years old** In very specific circumstances, for couples where the woman is aged from the day after her 40th birthday, who meet all other criteria, one cycle of treatment may be funded. Couples must have been screened for treatment by the time of the female partners 42nd birthday at the latest, and all treatment including any subsequent frozen embryo transfers must be completed by the time the female partner reaches 42 + 364 days. All of the following criteria must additionally be met: ▪ They have never previously had IVF treatment (NHS or private) ▪ There is no evidence of poor ovarian reserve and if, in the treating clinician's view it is in the patients' interest ▪ There has been a robust discussion of the additional implications of IVF and pregnancy at this age.
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	**Frozen embryos** Should circumstances change and couples no longer meet the NHS eligibility criteria, self-funding for any future transfers will be required.
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		N/A
Counselling, communication and information provision		N/A
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		N/A

Table E.35 Extracted data for Scotland (Assisted Conception)

Scotland		
Author(s) **Title [year]**	Ninewells Dundee Assisted Conception Unit[49] [2025]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**Egg sharing:** There is currently a great shortage of egg donors. For that reason we are able to ask women undergoing IVF/ICSI to consider sharing their eggs; in exchange for this, they receive subsidised treatment. This is called egg-sharing. Only certain women are suitable to be egg-share donors, equally not all women are suitable to be egg-share recipients. In order to become an egg share recipient you must: ▪ be under the age of 42 years. Requests from women over 42 years will be considered on an individual basis. ▪ be in good health. ▪ be within a healthy weight range, with a Body Mass Index (BMI) of less than 30. ▪ be a non-smoker, if receiving NHS funded treatment. An appointment will be arranged with our independent counsellor to discuss the implications of using donated eggs.
DAHR intervention(s) provided		**Egg donation (p. 12)** Primary or premature ovarian failure has been estimated to occur in approximately 1% of women. For such women, their only hope of a pregnancy lies in the use of eggs donated by a healthy female volunteer. The same technique may also apply to women whose ovaries have been removed or where she is at risk of passing on some genetic disorder. This treatment may also be recommended to some couples with previous failed IVF attempts. Separate information leaflets are available. **Egg sharing** We also carry out egg sharing, where patients can receive self-funded treatment at a significantly reduced cost in exchange for donating some of their eggs. If you are interested in this, please ask for further information. Egg sharing/donation is not anonymous. Since 1st April 2005, the law allows people conceived through donation to find out who their donor was, once they reach the age of 18. Please refer to the information leaflet 'What you need to know about donating sperm, eggs or embryos', produced by the HFEA.
Organisation	***Referral pathways***	**How the eggs are shared:** If 12 or more eggs are collected, then they are shared between the donor and the recipient. If an even number of eggs is collected, each will receive half; if an odd number of eggs are collected, the extra egg is given to the donor. If less than 12 eggs are collected, splitting the number will not give a good chance of success to either the donor or the recipient. In this case the donor will keep all the eggs, in which case there would be no charge to the recipient. On the day of egg collection your partner needs to produce his sample and you both need to check all consent forms are completed. You will be called the next day to confirm fertilisation and will also be updated on Day 3 and Day 5 of embryo development. Any suitable embryos will be frozen on Day 5. This allows future treatment to be planned using a Frozen Embryo Transfer cycle. We make every effort to ensure a good response in terms of number of eggs, but this cannot be guaranteed. The donor can withdraw consent to donate their eggs at any time up until the embryos are transferred. This would also apply to any surplus embryos in frozen storage.

<table>
<tr><td></td><td>Service provider characteristic</td><td>N/A</td></tr>
<tr><td></td><td>Timelines to access services</td><td>N/A</td></tr>
<tr><td></td><td>Any other organisational aspects</td><td>Number of Attempts at IVF/ICSI: Should the first attempt fail, we will make further attempts if that is what you wish but if it is decided that further treatment is unlikely to be of benefit, you will be advised of this. Following each cycle, a full review of the outcome will be discussed. For those that are eligible for NHS treatment, you will be entitled to up to two treatment cycles (up to three for patients referred from 1st April 2017), provided you meet the eligibility criteria. Following each cycle, a full review of the outcome will be discussed. If it is decided that treatment is unlikely to be of benefit, further treatment will not be offered and your NHS entitlement will be withdrawn. Transfer of frozen embryos is not counted as a separate cycle for NHS funded patients.</td></tr>
<tr><td rowspan="4">Donor material management</td><td>Arrangement(s) for attaining donated gametes or embryos</td><td>N/A</td></tr>
<tr><td>Storage of donated gametes or embryos</td><td>N/A</td></tr>
<tr><td>Access to and or disposal of stored donated gametes or embryos</td><td>N/A</td></tr>
<tr><td>Any other management information</td><td>N/A</td></tr>
<tr><td>Governance</td><td></td><td>N/A</td></tr>
<tr><td>Funding</td><td></td><td>Cost (p. 12)
If you are eligible for NHS funded treatment, then there will be no costs payable by you. If you are funding your own treatment, please see the separate leaflet on costs. Please note that there is currently no charge made for freezing embryos, but there will be a cost for subsequent frozen embryo transfer cycle(s).

<table><tr><th>Treatment Provided</th><th>Price</th></tr><tr><td>IVF:
includes pre-treatment assessment, initial consultation, treatment monitoring scans, compulsory screening tests, egg collection, sperm preparation and insemination, embryoscope time lapse-monitoring of your embryos, single embryo transfer,</td><td>£4550.00</td></tr></table></td></tr>
</table>

		pregnancy scan, counselling sessions (if required), vitrification of surplus embryos and first year of storage. **Does not include drugs package, which are individualised. Please see drug package section.**	
		ICSI: includes pre-treatment assessment, initial consultation, treatment monitoring scans, compulsory screening tests, egg collection, sperm preparation and egg injection, embryoscope time lapse-monitoring of your embryos, single embryo transfer, pregnancy scan, counselling sessions (if required), vitrification of surplus embryos and first year of storage. **Does not include drugs package, which is individualised. Please see drug package section.**	£4850.00
		Shared Motherhood: Includes pre-treatment assessment, initial consultation, implications counselling, treatment monitoring scans, compulsory screening tests, egg collection, sperm preparation and insemination/injection, embryoscope time lapse-monitoring of your embryos, single embryo transfer, pregnancy scan, vitrification of surplus embryos and first year of storage. **Donor Sperm is not included in price** **Does not include drugs package, which is individualised. Please see drug package section.**	IVF £4550.00 ICSI £4850.00
		Drugs packages: Includes down-regulation drugs (injections), ovarian stimulation (FSH injections), trigger injection (HCG and/or Buserelin) and progesterone (Crinone) luteal support.	
		GnRH agonist / antagonist and **150 iU FSH**	£850.00
		GnRH agonist / antagonist and **225 iU FSH**	£950.00
		GnRH agonist / antagonist and **300 iU FSH**	£1050.00
		Lubion injections	£180.00
		Frozen Embryo Transfers	
		FET Natural Cycle Includes consultation, ovulation predictor kit, treatment monitoring scans, standard medication, embryo thaw and transfer, pregnancy scan.	£1600.00
		FET HRT (medicated cycle) Includes consultation, standard medication, treatment monitoring scans, embryo thaw and transfer, pregnancy scan.	£1800.00
		Fertility Preservation	
		Egg Freezing – Fertility Preservation includes pre-treatment assessment, initial consultation, treatment monitoring scans, compulsory screening tests, egg collection, freezing of eggs, first year of storage and counselling sessions (if required).	£3500.00

		Does not include drugs package, which is individualised. Please see drug package section.	
		Use of frozen eggs: includes review consultation, standard medication, treatment monitoring scans, thawing of eggs, intracytoplasmic sperm injection (ICSI), embryoscope time lapse-monitoring of your embryos, single embryo transfer, pregnancy scan, counselling sessions (if required), vitrification of surplus embryos and first year of storage.	£2100.00
		Embryo Freezing – Fertility Preservation includes pre-treatment assessment, initial consultation, treatment monitoring scans, compulsory screening tests, egg collection, embryoscope time lapse-monitoring of your embryos, vitrification of embryos, first year of storage and counselling sessions (if required). **Does not include drugs package, which is individualised. Please see drug package section.**	£4850.00
		Sperm Freezing – Fertility Preservation / treatment back up includes consultation, compulsory screening tests, sperm freezing, first year of storage and counselling sessions (if required).	£650.00
		Treatment with Donor Sperm or Eggs: known donors only	
		Known egg donor treatment package includes donor pre-treatment assessment, initial consultation, implications counselling, treatment monitoring scans, egg collection Plus intracytoplasmic sperm injection (ICSI), embryoscope with time lapse-monitoring of embryos, vitrification of all embryos and first year of storage, recipient consultation, blood tests, implications counselling, standard medication, treatment monitoring scans, recipient single embryo transfer, pregnancy scan. **Does not include egg donor drugs package, which is individualised. Please see drug package section.** **Does not include compulsory donor screening tests. See below**	£6000.00
		Known sperm donor includes consultation, sperm freezing, first year of storage and implications counselling. **Does not include compulsory donor screening tests. See below**	£650.00
		Screening of known donors (eggs or sperm). includes all compulsory screening tests, including genetics, and rescreening following quarantine	£2070.00
		Surrogacy Treatment: Due to the complex nature of surrogacy, the cost will depend on your individual circumstances. This will be discussed with you at your initial consultation.	Information on enquiry
		Screening of full (host, gestational) surrogate: compulsory screening tests and ultrasound scan **Screening of partial (straight, traditional) surrogate: see egg donor screening costs**	£660.00
		Intrauterine Insemination (IUI) – using your partners sperm	

		Unstimulated Intrauterine Insemination (IUI)	£1000.00
		Stimulated IUI with Letrozole	£1000.00
		Stimulated IUI with Gonadotrophins	£1385.00
		Donor Insemination (DI) – using donor sperm	
		Unstimulated Donor insemination (DI)	£1000.00
		Stimulated DI with Letrozole	£1000.00
		Stimulated DI with Gonadotrophins	£1385.00
		European Sperm Bank (ESB) donor sperm	Information on enquiry
		NHS donor sperm used for sibling pregnancies	£550.00
		Additional services- if required:	
		Compulsory blood tests [Hepatitis B (HBsAg, anti-HepB core), Hepatitis C, HIV 1&2]	£190.00
		Diagnostic semen analysis	£170.00
		Post Vasectomy semen analysis	£170.00
		Sperm DNA fragmentation test	£495.00
		Female fertility assessment (pelvic ultrasound scan + AMH)	£250.00
		Recurrent miscarriage screen	£720.00
		SSR pre-assessment screening: Includes karyotype, Y micro deletions, Cystic Fibrosis mutations, LH, FSH, prolactin and testosterone levels, compulsory blood tests [Hepatitis B (HBsAg, anti-HepB core), Hepatitis C, HIV 1&2]	£1120.00
		Surgical sperm retrieval (SSR)	£1350.00
		Storage Fees – National Charges	
		1 year storage	£275.00
		2 years' storage	£525.00
		5 years' storage	£1275.00
		Transport of gametes to another Centre (excluding Courier service costs). Please note you will be required to arrange your own Courier Service to transport any gametes you wish to move.	
		Transfer of embryos, eggs, or sperm to/from another centre within the UK	£300.00
		Transfer of embryos, eggs, or sperm to/from another centre out with the UK	£550.00

Counselling, communication and information provision		N/A
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		N/A

Table E.36 Extracted data for Scotland (Edinburgh Fertility Centre)

Scotland		
Author(s) **Title [year]**	Edinburgh Fertility Centre A Guide for Prospective Patients[50] [2025]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		N/A
DAHR intervention(s) provided		**Treatments available In-vitro fertilisation (IVF)** was originally developed to overcome the problem of fallopian tube blockage but it is also indicated for the treatment of certain couples with long-standing unexplained infertility, endometriosis and male factor infertility. The technique involves removal of eggs (oocytes) from the ovaries, fertilisation with sperm in the laboratory to create embryos, which can then be transferred directly into the womb (uterus) in a procedure known as embryo transfer. Intracytoplasmic Sperm Injection (ICSI) is offered to couples with male factor infertility after investigation and assessment, if clinically appropriate. In a natural menstrual cycle women produce only one (or at most two) eggs, but during the IVF cycle of treatment, the woman is given a course of drug treatment, to stimulate the development of several eggs. These eggs can be collected, frozen and stored for use in the future or put together with **sperm (this can be partner sperm or donor sperm)** to create embryos. We aim to replace one embryo (or in specific circumstances, a maximum of two embryos) into the womb during any one treatment, and any other good quality embryos can be frozen and replaced in the womb during later treatment cycles. You may be undergoing treatment to create and store eggs or embryos for future use. If this is the case, some parts of the process outlined below will be deferred until you wish to use the eggs or embryos. **(p. 3)**
Organisation	***Referral pathways***	Entering the treatment programme The majority of individuals/ couples entering the assisted conception programme will already have undergone full investigations and discussion of treatment options in the Fertility Clinic of the Royal Infirmary of Edinburgh. For those who have attended other clinics, it is necessary to have a letter of referral from a fertility specialist with a summary of all investigations and treatment carried out. With your permission, we may have to write to your general practitioner[s] and other medical practitioners involved in your care, requesting any relevant information prior to treatment, and informing your general practitioner of your proposed treatment. You will be given an initial appointment at the Assisted Conception Unit (ACU) clinic, prior to your appointment with a doctor, where you will have the following tests; AMH blood test, height, weight, blood pressure and Carbon Monoxide test. At your medical appointment you will receive detailed information about the treatments, risks involved and further visits. If you are self-funding your treatment, all fees are required to be paid before the treatment can start. You may be offered an ultrasound scan and blood tests at this appointment. You should have had an up-to-date cervical smear test. If you have not had a recent smear, please visit your GP to arrange this before your treatment starts. Please inform our staff if your recent cervical smear was abnormal. **(p. 4)** **Fertility treatment packages [Webpage]**

		Fertility Consultation For single people who cannot currently access NHS Fertility Services. Initial consultation to discuss Fertility options which includes AMH testing. £360 **IVF and ICSI treatments Treatment packages** Fully inclusive package including pre-treatment assessment consultation, scans, screening tests, blood tests, medications, egg collection, embryo transfer, pregnancy scan, one follow-up consultation, up to three counselling sessions, and first year of storage. £6,900 (£500 non-refundable deposit paid prior to first consultation) **Fertility preservation packages** **Stage 1: Egg Freezing** Fully inclusive package including consultation, treatment planning visits, all scans, blood tests, medication, egg collection, freezing of eggs, one follow-up consultation and first year of storage. £4,760 **Stage 2: Use of Frozen Eggs** Fully inclusive package including consultation, treatment planning visits, all scans, blood tests, medication, thawing, ICSI of thawed eggs, embryo transfer, follow up consultation and first counselling session. £2,460 **Donor Egg Recipient Treatment Package – known Donor** Fully Inclusive package includes: The recipient's initial consultation, blood tests, treatment planning & consents preparation, recipient implications counselling. Treatment preparation for both donor and recipient including ultrasound scans and monitoring, medication, egg collection, semen analysis sperm preparation on day of operation, embryo transfer, freezing of any additional embryos, HCG blood test, pregnancy scan, one doctor follow-up appointment. First year of embryo storage. *If freezing of sperm is needed then there is an addition charge £8,500 **Screening of known egg donor – for use with above package.** Includes initial consultation, all screening tests, and implications counselling x 2 sessions. £1,900 **IVF/ICSI with donor sperm** Inclusive package includes: The recipient's initial consultation, blood tests, treatment planning & consents preparation, and recipient implications counselling. Treatment preparation for recipients including ultrasound scans and monitoring, medication, egg collection, semen analysis, freezing and storage of donor sperm in preparation for treatment, preparation of frozen sperm on day of operation, embryo transfer, freezing of any additional embryos, Hcg blood test, pregnancy scan, one doctor follow-up appointment. First year of embryo storage. * Donor Sperm is not included in price (price available on request) £7,050 (£500 non-refundable deposit paid prior to first consultation)

		Shared Motherhood Fully Inclusive package includes: The recipient's initial consultation, blood tests, treatment planning & consents preparation, recipient implications counselling. Treatment preparation for both partners including ultrasound scans and monitoring, medication, egg collection, sperm preparation on day of operation, embryo transfer, freezing of any additional embryos, HCG blood test, pregnancy scan, one doctor follow-up appointment. First year of embryo storage. * Donor Sperm is not included in price (price available on request) £8,100 **Intra-uterine insemination (IUI) with donor sperm *** Includes consultation, consents, scans, screening tests, blood tests, sperm preparation, pregnancy scan, and one follow-up consultation. * Donor Sperm is not included in price (price available on request) **Package available to single women, same sex couples or for sibling use. £1,010 **Donor Embryo Recipients** Fully inclusive package including initial consultation, treatment planning visits, all screening tests of donor and recipient, all scans, blood tests, medication, embryo transfer, pregnancy scan, implications counselling, and one follow-up consultation. £4,500 **Egg and sperm storage** The Edinburgh Fertility Centre offers comprehensive fertility treatment services in the United Kingdom. Our state-of-the-art facilities provide secure and reliable egg and sperm freezing storage for individuals and couples. Renewal charges after first year of storage. National charges are as follows 1 yr £275 2 yrs £525 5 yrs £1,275
	Service provider characteristic	N/A
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	Storage period If you have any embryo(s) or gametes in storage please note that the storage period starts on the date of storage and that you have given us consent to store for the duration specified on your treatment consent forms (WT +/- MT) or gamete storage (GS) form. We have a legal obligation to review consent to storage forms at regular intervals and to thaw/ discard embryos if we do not have valid consent to continue storage. In order to contact you to check

		your wishes with regard to continued storage of your embryo(s) it is very important we have up to date details (address, telephone number(s)). We will attempt to contact you in advance of the date your consent expires. The current statutory storage period is up to 55 years, with consent requiring renewal at 10-year intervals. You will consent to store for up to 10 years initially. Extensions must be done before the current consent expires. If at any time you wish to discuss changing your consent form or extending the storage period please contact the Centre for advice. If you are storing embryos, both the sperm and egg providers must provide written consent to extend storage. Please be aware you may be required to pay storage fees if you are a self-funding patient or you no longer meet the NHS Access Criteria. **(p. 16)**
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		N/A
Counselling, communication and information provision		**Counselling [Webpage]** You can come and talk about anything that is troubling you while you are planning, undergoing, or have had fertility treatment at the Edinburgh Fertility Centre. The service offers emotional support before, during or after, what can be a stressful time. Fear of treatment outcome, pain of loss and crisis of meaning are some of the issues people bring. Often it is helpful to simply talk through the treatment and look at options for the future with support and understanding. The aim of counselling is to encourage people to find their own solutions in a safe and supportive space. If you are considering storing sperm, eggs or embryos for later use, or treatment using donated sperm, eggs or embryos, you will be asked to attend counselling to discuss the implications of your treatment. This special kind of counselling is called "implications counselling".
Ethical and social considerations		**What are the risks of using donated sperm, eggs or embryos? (p. 17)** If you use donated gametes or embryos, we minimise the risks as much as possible. Donors must answer a series of questions designed to ensure that they are suitable. The donors' family histories for inherited diseases are checked. All donors go through stringent screening checks to ensure they are not carrying infections, such as HIV, Hepatitis B and C, cytomegalovirus (CMV), syphilis and gonorrhoea. Donated sperm and eggs (if not used fresh) is quarantined for three to six months whilst the donor is being screened. There are limits on the numbers of families created by each donor where donor gametes are used. Please be aware that although we carry out comprehensive screening, it is not possible to screen for every disease. If you are considering using donated sperm, eggs or embryos you will be given further information about these issues.

		In addition, if your treatment involves the use of donated gametes, the following will be discussed: ▪ a child's potential need to know about their origins and whether you are prepared for the questions which may arise while the child is growing up ▪ the possible attitudes of other members of the family towards the child, and towards their status in your family ▪ the implications for the welfare of the child if the donor is personally known within the child's family and social circle ▪ an explanation of who will be the legal parents of any child produced as a result of treatment with donated gametes ▪ these issues will be discussed in detail at your 'implications counselling' appointment which is a pre-requisite before donor gametes or embryos can be used.
Relevant legislation (list and key aspects)		Legal aspects and parental responsibility Under the terms of the Human Fertilisation and Embryology Act (1990), the HFEA licenses and regulates centres which practice IVF/donor insemination. Any child born to a married woman following IVF/donor insemination will be legally the child of the husband unless he did not consent to his wife's treatment. If you (and your partner) wish to find out more about the definition of legal parenthood, please look up the HFEA website, www.hfea.gov.uk and search for legal parenthood. The meaning will be clearly defined and if you have any queries, please ask us for clarification. Unmarried couples are recommended to seek their own legal advice about the partner's rights and responsibilities in relation to the potential child who may be born as a result of the treatment if they have concerns. If you are not clear as to the definition of legal parenthood, we advise that you seek legal advice. **(p. 16)** If donor sperm, eggs or embryos are used you will be asked to complete additional HFEA consent forms relating to legal parenthood. Please note, men wishing to donate embryos originally created for the treatment of their partner and themselves and those wanting to have treatment using these embryos should be aware of the uncertain legal status of the men when the embryo is used to treat single women. Each party should seek independent legal advice and refer to the HFEA's website (www.hfea.gov.uk) for further information on this issue. **(p. 17)**
Miscellaneous		**What are the risks of using donated sperm, eggs or embryos? (p. 14)** If you use donated gametes or embryos, we minimise the risks as much as possible. Donors must answer a series of questions designed to ensure that they are suitable. The donors' family histories for inherited diseases are checked. All donors go through stringent screening checks to ensure they are not carrying infections, such as HIV, Hepatitis B and C, cytomegalovirus (CMV), syphilis and gonorrhoea. Donated sperm and eggs (if not used fresh) is quarantined for three to six months whilst the donor is being screened. There are limits on the numbers of families created by each donor where donor gametes are used. Please be aware that although we carry out comprehensive screening, it is not possible to screen for every disease. If you are considering using donated sperm, eggs or embryos you will be given further information about these issues.

Table E.37 Extracted data for Scotland (Assisted Conception Service)

Scotland		
Author(s) **Title [year]**	Glasgow Royal Infirmary Assisted Conception Service[51] [2026]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		Reasons for not offering treatment: ▪ BMI less than 18.5 or greater than 30 ▪ smoking or vaping ▪ we are obliged by law to take into account the welfare of any child likely to be born after fertility treatment. In order to assess this, we may ask your permission to contact other professionals. There may be circumstances where treatment cannot be offered if concerns are raised with respect to the welfare of any child born as a result of treatment. ▪ certain complex medical issues where pregnancy would carry significant risks ▪ same sex couples will not be eligible if they already have a child in the home and both have consented to legal parenthood of that child.
DAHR intervention(s) provided		▪ Gonadotropin Ovulation Induction and Intrauterine Insemination (OI/UI) ▪ Intracytoplasmic Sperm Injection (ICSI) ▪ Pre Implementation Genetic Test (PGT) **(p. 6)** In Vitro Fertilisation (IVF) IVF refers to a treatment where fertilisation of mature eggs is performed in the laboratory. This is by mixing them with a partner or donor's sperm in a sterile dish. The treatment itself involves stimulation of the ovaries with daily hormone injections while monitoring the response regularly using blood samples (to check hormone levels) and transvaginal ultrasound scans (to observe the ovarian response). Usually after 10-14 days of treatment, we will give you a booster injection of a different hormone to mature the eggs, which are then collected from the ovaries 38 hours later. Once the eggs are collected, we will prepare a sample of your partner's sperm (or, if applicable, suitable donor sperm) and mix them with your eggs in an attempt to bring about fertilisation (that is, formation of an embryo). In 2-5 days, any embryos produced that are of the right quality will be ready for transfer into the uterus. The transfer procedure itself is quite straightforward and is similar to having a cervical smear. (If there are more embryos than the maximum we are allowed to put in place at any one time, then the remainder may be frozen if they are of a good quality and can be thawed and used in a later treatment cycle.) We will arrange to give you a pregnancy test to find out if the treatment has been successful. If it hasn't, further treatment options may be offered to you at a later date. Donated Semen Insemination (also known as IUI by Donor: IUID) Donor insemination is one of the treatments of choice when the male partner is unable to produce sperm or where a known genetic defect exists. Donated sperm is thoroughly screened for genetically inherited disorders and sexually transmitted diseases. It is then frozen and quarantined according to current Human Fertilisation Embryology Authority (HFEA) guidelines. Wherever possible, the donor's physical characteristics (for example, hair and eye colouring, height) are matched to those of the receiving

		couple. This procedure can happen as an outpatient. If the female partner has a regular menstrual cycle, then no drug therapy may be needed. The donated sperm is thawed and prepared before being inserted directly into the uterus. This is done using a fine catheter (tube), a technique similar to having a cervical smear. The best time for insemination and conception is when ovulation occurs. This is established by using regular blood tests from the female partner. We will arrange to give you a pregnancy test to find out if the treatment has been successful. If it hasn't, further treatment options may be offered to you at a later date **(p. 5)** Oocyte Donation Programme: Some women who suffer from a premature menopause or who are known carriers of a genetic disorder are suitable for this type of treatment. In this treatment a known or anonymous egg donor undergoes stimulation of her ovaries using hormone injections, followed by collection of her eggs which are then fertilised using your partner's sperm. Embryos formed in this way are then transferred into your uterus. We will arrange to give you a pregnancy test to find out if the treatment has been successful. If it hasn't, further treatment options may be offered to you at a later date. We have very few anonymous egg donors, so the waiting time for this treatment can be very long. If a friend or relative of yours is willing to donate their eggs to you the waiting time can be reduced. Other services available include: ▪ storage of sperm for future use ▪ storage of eggs for future use ▪ pre-implantation genetic diagnosis. **(p. 7)**
Organisation	***Referral pathways***	Most clinic appointments are being carried out over the phone. At your first consultation a Specialist Fertility Nurse or a Doctor will phone you, take a detailed medical history from you both and ask for your current BMI. This appointment will last around 30 minutes. They will recommend any further investigations, treatments or advise if you are not eligible for NHS treatment. If your clinic appointment is in person please attend the ACS unit at Glasgow Royal Infirmary. We may weigh you, do an internal scan and take some blood samples. Please note that to be eligible for NHS funded treatment you must meet the criteria set by the Scottish Government Referral: Eligible patients who are new referrals from 1st April 2017 may be offered up to three cycles of IVF/ICSI where there is a reasonable expectation of a live birth. Eligible Patients referred before the 1st of April 2017 may be offered up to two cycles of IVF/ICSI where there is a reasonable expectation of a live birth. Referral for treatment can only be made if all access criteria are fulfilled, as noted below. Should the first cycle of treatment be unsuccessful all access criteria must be met before a subsequent cycle can commence. ▪ Infertility with an appropriate cause, of any duration ▪ Unexplained infertility of two years – heterosexual couples ▪ Unexplained infertility following six cycles of donor insemination All patients should be referred by their GP or Doctor at their local hospital. We ask that a number of tests are performed before you are referred. For the female partner these are: an up-to-date

		smear test, a vaginal swab for Chlamydia, a progesterone check for ovulation and for the female to provide evidence of 2 MMR vaccinations. For the male partner this is at least one sperm count. Under certain circumstances 2 sperm counts may be required. Once we have received the referral letter and the results from the investigations required, an appointment will be made for you to attend the ACS Unit to see a Doctor or a Nurse. If appropriate, arrangements may be made for a blood test to assess Anti-Mullerian hormone (AMH) and a sperm count prior to your appointment.
	Service provider characteristic	The Assisted Conception Service at Glasgow Royal Infirmary is a state-of-the-art facility providing assisted conception services to patients throughout Scotland.
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	When embryos are frozen as part of a treatment cycle, they can be stored for the time period you have consented to. Once you are ready to start an embryo transfer cycle there are a few steps we need to go through to ensure you, and your partner are fully consented and meet the NHS access criteria. Then, to maximise your chance of success, we ensure your endometrium is prepared and ready for the embryo transfer. When you phone the booking line to book an FET, they will take some information from you and bring your notes the weekly FET scheduling meeting. Due to the high demand for FET cycles, we may not be able to book the 1st time you call. Waiting times for FET cycles can be around 3 months. When you start an FET cycle, we will check your smear is in date and your BMI is 18.5-30. Please ensure you meet both requirements before phoning to book. In ACS, we have 4 types of Frozen Embryo Transfer (FET) cycles. The doctor will advise which one is most appropriate for you, depending on your menstrual cycle, medical history and any previous embryo transfers.
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		N/A
Counselling, communication and information provision		The experience of fertility difficulties is almost always distressing and disruptive for any individual or couple. Powerful feelings can emerge – shock, anger, sadness, envy, guilt, anxiety, isolation, sense of worthlessness and, particularly, fear for the future.

		The situation can also put a great strain on relationships which are normally loving and comfortable whether with a partner, family members or friendships. It is not always easy for others to fully understand how such a profound life crisis feels or how it affects so many aspects of day-to-day living. The experience of fertility problems is unique and complex and is often described as an "emotional rollercoaster." Counselling is available before, during and after treatment. Meeting with our counsellors can offer you a safe, discreet and quiet place where you can explore difficult feelings and find ways of making the situation more manageable. You may want to talk through your options, prepare for treatment or have support during or after treatment. For those who are considering treatment using donor eggs, sperm or embryos or who may be considering surrogacy, it is an HFEA requirement to meet with the counsellors to look at the implications of such treatment both in the short and longer term for both the adults and for the potential children who may be born through donor conception. For those considering becoming a donor either to help known recipients or as an altruistic donor, it is also an HFEA requirement to meet with one of the counsellors to explore the implication of donation. For both donors and recipients, this is a confidential and supportive service and can greatly help in making a positive decision for your own future and reduce some of the fears and more difficult feelings which may arise. How? When you have been referred to the ACS Unit and have been accepted as a patient of the service (including being on the waiting list for treatment), you can either ask to be referred to the counsellors by a member of clinical or nursing staff or you can directly refer yourself (see below). The counselling service is independent and confidential. There is no payment for counselling. You may need only one session of counselling, or you may decide, with the counsellors, that further sessions would be helpful. If you are considering treatment with donor eggs, sperm or embryos, or thinking of becoming a donor, you will be referred by a member of staff to the counselling service prior to moving forward to treatment.
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		Screening tests and Initial Appointments Please note, not all patients will require all tests. Your nurse or doctor will advise on which ones you'll need, depending on which treatment you're having. ▪ Transvaginal scan (TVS) ▪ Semen analysis ▪ Anti-Mullerian Hormone (AMH) ▪ A full blood count (FBC) ▪ Haemoglobinopathy Screen

		▪ Cytomegalovirus (CMV) ▪ Chlamydia test ▪ Vaginal swab to test ▪ Cervical Screen ▪ Human Immunodeficiency Virus (HIV) ▪ Hepatitis B ▪ Hepatitis C.

Table E.38 Extracted data for Scotland (NHS criteria for Donor Insemination)

Scotland		
Author(s)	Edinburgh Fertility Centre	
Title [year]	Access Criteria for NHS Funded Donor Insemination - Patient Information[52] [2023]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**Eligibility criteria: (p. 1)** ▪ be in a couple and live in Lothian or the Borders. ▪ have been co-habiting (at the same address) in a stable relationship for a minimum of two years. ▪ neither partner had voluntary sterilisation nor who have undertaken ▪ reversal of sterilisation, even if reversal has been self-funded. ▪ have one partner with no living biological child. Same sex couples who have previously conceived through assisted conception and are both named on the resulting child's birth certificate are not eligible for future treatment. ▪ body Mass Index The prospective birth mother must have a BMI above 18.5 and below 30. Couples should be aware that a normal BMI is best for both partners. ▪ smoking Both partners must not smoke, vape or use nicotine for at least three months before referral for treatment and couples must continue to be non-smoking and nicotine free during treatment. ▪ alcohol and Drugs Both partners must abstain from illegal and abusive substances ▪ both partners must be Methadone free for at least one year prior to referral for treatment. ▪ neither partner should drink alcohol prior to or during the period of treatment. ▪ treatment must start before the prospective birth mother's 40th birthday. ▪ welfare of the Child Couples must satisfy the requirements of a Welfare of the Child Assessment.
DAHR intervention(s) provided		**Number of cycles: (p.2)** Up to **six cycles of Donor Insemination** may be undertaken where there is a reasonable expectation of a live birth. Clinical judgement should be applied to determine this. After three to six unsuccessful cycles of Donor Insemination, the couple can be referred for IVF with donor sperm. If the prospective birth mother is referred to as 38 or 39 years old, the couple will be provided with the option to start IVF treatment with donor sperm instead of starting Donor Insemination Treatment. If a couple is referred when the female partner is 39, the couple will most likely receive one NHS IVF cycle. Once a couple has started IVF Treatment, they are no longer eligible for Donor Insemination treatment. No individual can access more than 6 NHS funded Donor Insemination cycles, under any circumstances, even if they are in a new relationship.
Organisation	***Referral pathways***	N/A
	Service provider characteristic	N/A

	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		**Self-funded Donor Insemination (full sibling only) (p.2)** In the event that NHS funded Donor Insemination treatment has been successful, there is a small possibility that we can offer couples the option to self-fund additional cycles of Donor Insemination treatment for a full sibling. The additional criteria to be met are: **Sperm Donor** Sperm must remain available from the original donor as used in the successful NHS funded cycle. Where sperm is no longer available, the centre may attempt to contact the original donor, however they are under no obligation to provide another donation. **Recipient** The recipient of any self-funded cycles of Donor Insemination must match that of the recipient in the successful NHS funded cycle (that is, the birth mother). **Number of Cycles** Up to four cycles of self-funded Donor Insemination treatment can be offered to each couple. Due to capacity, we are only able to treat one couple per month. Please contact a member of the team for an updated position on waiting times. **Price** Cycles must be paid for in advance, with a minimum of two cycles purchased at a time before treatment can start. Any unused cycles following the completion of treatment will be refunded.
Counselling, communication and information provision		N/A
Ethical and social considerations		N/A

Relevant legislation (list and key aspects)		N/A
Miscellaneous		N/A

Table E.39 Extracted data for Scotland (National Infertility group report 2016)

Scotland		
Author(s) **Title [year]**	Scottish Government National infertility group report[53] [2016]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		Couples must meet specific criteria to access NHS-funded assisted conception services: **(p. 38)** ▪ infertility with an appropriate cause or unexplained infertility for 2 years (heterosexual couples) or after six to eight cycles of donor insemination (same-sex couples) ▪ both partners must be non-smoking and nicotine-free for at least three months before referral and during treatment ▪ female partner's BMI must be between 18.5 and 30 ▪ couples must have no child under the age of 16 living in their home ▪ couples must have been cohabiting in a stable relationship for at least two years ▪ fresh cycles must be initiated before the female partner's 40th birthday, and frozen transfers must be completed before her 41st birthday ▪ couples where either partner has undergone voluntary sterilization are not eligible, even if reversal was self-funded ▪ couples are eligible for up to two cycles of IVF/ICSI, with a reasonable expectation of live birth. **Medical conditions: (p. 38)** GPs, referring and treating clinicians must take into account other serious medical conditions, such as (but not limited to) diabetes, epilepsy, congenital heart disease, chronic renal failure and rheumatoid arthritis and clinicians should take care that women who receive medical treatment are medically safe to become pregnant, before committing to treatment. Pre-conception counselling with an appropriate specialist should be offered if appropriate.
DAHR intervention(s) provided		In Scotland commissions cycles of IVF/ICSI from one of the four specialist tertiary referral Centres providing NHS treatment (Aberdeen, Dundee, Edinburgh and Glasgow). **IVF full cycle: (p.36)** One fresh cycle includes ovulation induction, egg retrieval, fertilisation, transfer of fresh embryos followed by freezing of suitable embryos and subsequent replacement of these, provided the couple still fulfil access criteria. Self-funding for replacement will be required if the couple no longer fulfil access criteria. If suitable embryos are frozen then these should be transferred before the next stimulated treatment cycle as this will avoid ovulation induction and egg collection, both of which carry risks for the woman. Patients who require access to donated gametes (sperm or eggs) are still receiving patchy access across Scotland to this service.

Organisation	***Referral pathways***	Levels of Care: **(p. 5)** Level I: Initial investigation and management by primary care teams, including basic history-taking, clinical examination, and laboratory investigations. Level II: Further investigation and management by special interest teams in general hospital gynaecology departments, including tubal patency testing, ovulation induction, and intrauterine insemination (IUI). Level III: Specialist care provided by four tertiary referral centres in Scotland (Aberdeen, Dundee, Edinburgh, and Glasgow). These centres offer assisted conception techniques requiring a license from the Human Fertilisation and Embryology Authority (HFEA), including IVF and ICSI.
	Service provider characteristic	N/A
	Timelines to access services	Couples should ideally be seen in secondary care within 12 weeks from referral from GP. Baseline investigations should be completed and simple treatment in secondary care ideally commenced, (for example, ovulation induction for ovulatory problem, ideally within 18 weeks. Examples of when the clock should be stopped include: **(p. 55)** ▪ diagnosis of unexplained infertility when treatment may be deferred until duration of infertility two years ▪ when access criteria not met ▪ when referred to tertiary care.
	Any other organisational aspects	The Scottish Pre-implantation Genetic Diagnosis (PGD) service15 is centrally funded by National Services Division (NSD)16 and was designated as a national service in 2005. The PGD service carries out genetic testing for fetal chromosome abnormalities at two Centres in Scotland – Glasgow Royal Infirmary, and the Royal Infirmary of Edinburgh. Approximately 30 NHS funded PGD treatment cycles are carried out in both Edinburgh and Glasgow annually.
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		The Scottish Government is funding Infertility Network Scotland, an organisation which provides help, information and support to patients (both present and past), to assist with this. **(p. 11)** Infertility Network Scotland's core role is to support patients undergoing treatment, and to work with NHS Boards, Clinics and Health Professionals to ensure a better patient experience.

		Infertility Network Scotland13 liaises regularly with all Health Boards and offer a service to provide patient representation at any Health Board meetings to discuss fertility services.
Funding		There is the cost commissioning Boards pay the tertiary Centres for a cycle of treatment, there is the cost patients who are self-funding in the four Centres pay, and there is the charge the Scottish Government has paid per cycle for additional treatment **(p. 36)**
Counselling, communication and information provision		All Centres in Scotland have their own independent counsellor linked to the tertiary Centre, which is more than the HFEA legally require of each Centre. The Group is satisfied with counselling services that are provided in licensed clinics providing NHS treatment in Scotland on a regular 9-5 basis. Infertility Network Scotland raised concerns about the availability of crisis counselling. The Group agreed that patients should be signposted to out of hours crisis counselling already available, including NHS 2422 which provides advice for patients who feel anxious or depressed. Additionally, consideration should be given to developing specific information to give to NHS 2422 to help staff provide assistance to patients undergoing assisted conception treatment, who require help out of hours. **(p. 15)**
Ethical and social considerations		No treatment services regulated by the HFEA may be provided unless account has been taken of the welfare of any child who may be born as a result (including the need of that child for supportive parenting) and of any other child who may be affected by the birth. **(p. 38)** NHS Boards should be reminded that there should be no discrimination in the provision of infertility services on the grounds of race, faith, gender identity, sexual orientation or disability. **(p. 38)**
Relevant legislation (list and key aspects)		▪ Equality Act 2010 ▪ Human Fertilisation and Embryology Act 1990
Miscellaneous		**IVF provision in the rest of the UK (p. 58)** England Provision in England varies depending on where patients live. In April 2013 responsibility for the commissioning of fertility services was handed to local GP-led Clinical Commissioning Groups (CCGs). It seems clear that the reorganisation of commissioning arrangements in England has not addressed the inequity of access to treatment across the country, and in some parts of England, access has reduced over the past 2 years or is no longer available on the NHS. In 2015 Fertility Fairnes conducted an audit of every Clinical Commissioning Group (CCG) in England. This found that just 18% of CCGs provide the NICE recommended three cycles, with 24% offering two cycles and 57% offering one cycle. When compared with data from 2014, these numbers reveal a 7% fall in CCGs offering two cycles of IVF, and a corresponding rise in the number of one cycle providers. Additionally, at least 44% of CCGs do not offer a 'full cycle' as defined by NICE, and in place for all NHS patients in Scotland. There are, however, areas of good practice within England, including the North East, where all eligible couples can access three full cycles of IVF. Wales Provision in Wales is for 2 full cycles of IVF for eligible couples, waiting times are similar to Scotland, with patients being seen within 12 months. Criteria in Wales is similar to Scotland, although couples with a child in the home not biologically related to one partner can access treatment. Northern Ireland Provision in Northern Ireland is for all couples, regardless of whether

		they have children, to access one fresh cycle of IVF, with a limit of one frozen transfer. Waiting times remain longer than in Scotland and Wales.

Table E.40 Extracted data for Sweden (Genetic Integrity Act 2006)

Sweden		
Author(s) **Title [year]**	Ministry of Health and Welfare Act (2006:351) on genetic integrity etc.(54) [2006] Amended by Government bill 2017/18:155 [More modern rules on assisted reproduction and parenthood](55)	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		Chapter 6. Insemination [Section 1b] If the woman is married or in a cohabiting relationship, insemination may only be performed if the husband or cohabiting partner has consented to it in writing. Law (2016:18) **Special examination** [Section 3] In the event of an insemination with donor sperm, the doctor shall consider whether it is appropriate for the insemination to take place, taking into account the medical, psychological and social circumstances of the spouses, cohabitants or single women. The insemination may only be carried out if it can be assumed that the future child will grow up in good conditions. If insemination is refused, the spouses, cohabitants or the single woman may request that the National Board of Health and Welfare examine the matter. Law (2016:18) [This special examination also applies to Chapter 7 Fertilisation outside the body] **<u>Chapter 7. Fertilization outside the body</u>** **Special conditions for treatment with a donated fertilised egg** [Section 3a] An egg that has been fertilised for insertion into a woman's body may be inserted into the body of another woman only if: 1. the first woman treated, and, if she is married or cohabiting, also her husband or cohabiting partner, has consented to it in writing, 2. the first woman treated, and, if she is married or cohabiting, also her husband or cohabiting partner, is the parent of at least one child, and 3. it is the first woman treated's own egg that has been fertilised or, if she is married or cohabiting partner, the egg has been fertilised with sperm from her husband or cohabiting partner. Consent according to the first paragraph may be revoked until its implementation has taken place. Act (2018:1283)
DAHR intervention(s) provided		Chapter 4 Prenatal diagnosis, genetic prenatal diagnosis and preimplantation genetic diagnosis: **Conditions for prenatal diagnosis**

		[Section 1] All pregnant women shall be offered general information about prenatal diagnosis. A pregnant woman who has a medically determined increased risk of giving birth to a damaged child shall be offered additional information about genetic prenatal diagnosis. After receiving the information, the woman decides, in consultation with the doctor, whether she should undergo prenatal diagnosis or genetic prenatal diagnosis. The pregnant woman shall receive all information about the health of the fetus that has been obtained during prenatal diagnosis. Information about the fetus that does not concern its health shall only be disclosed if the woman requests it. **Conditions for preimplantation genetic diagnosis** [Section 2] Preimplantation genetic diagnosis may only be used if the man or woman carries a predisposition for a serious monogenic or chromosomal hereditary disease, which entails a high risk of having a child with a genetic disease or injury. The treatment must not be used to select a trait but must only be aimed at ensuring that the child does not inherit a predisposition for the disease or injury in question. Preimplantation genetic diagnosis may not be used without permission from the National Board of Health and Welfare to try to have a child with such a gene set that the child could become a donor of blood stem cells for a seriously ill sibling. Permission may only be granted if there are exceptional reasons to allow use.
Organisation	***Referral pathways***	N/A
	Service provider characteristic	**Chapter 6. Insemination** [Section 2] Insemination with sperm from a man to whom the woman is not married or cohabiting may not, without permission from the Health and Social Care Inspectorate, be carried out other than at publicly funded hospitals. Such insemination shall be carried out under the supervision of a physician with specialist competence in gynaecology and obstetrics. Act (2013:1147) **Chapter 7. Fertilisation outside the body** [Section 4] Fertilisation of eggs from a woman, into whose body the egg is to be inserted, with sperm from the woman's husband or cohabitant may not be carried out except in publicly funded hospitals without permission from the Health and Social Care Inspectorate. This also applies to the insertion of the egg into the woman's body. If the egg does not come from the woman or the sperm does not come from the woman's husband or partner, fertilization and implantation of eggs may not be carried out without permission from the Health and Social Care Inspectorate, except at hospitals that have healthcare units where higher education for medical degrees and research is conducted. Law (2018:1283)

	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	**<u>Chapter 6. Insemination</u>** **Choosing a sperm donor** [Section 4] In the event of an insemination referred to in Section 2, the doctor selects a suitable sperm donor. Sperm from a deceased donor may not be used in an insemination. Information about the donor shall be recorded in a special journal. The journal shall be kept for at least 70 years. Law (2018:1283) **<u>Chapter 7. Fertilisation outside the body</u>** **Donor selection** [Section 6] In the case of a treatment referred to in Section 4, second paragraph, the doctor selects eggs or sperm from a suitable donor or a suitable donated fertilised egg. Eggs or sperm from a deceased donor may not be used for fertilization. Donor information must be recorded in a special journal. The journal must be kept for at least 70 years. Law (2018:1283)
	Storage of donated gametes or embryos	[Section 4] A fertilised egg may be stored in a frozen state for a maximum of ten years. An egg that has been the subject of a somatic cell nuclear transfer may be stored in a frozen state for a maximum of five years. The National Board of Health and Welfare may extend the periods in accordance with Section 6. The time during which the egg has been frozen is not included in the time during which testing may be carried out according to Section 3. Law (2018:1283) [Section 6] If there are exceptional reasons, the National Board of Health and Welfare may, in special cases, allow the period for storage in a frozen state according to Section 4 to be extended. If consent is given, the National Board of Health and Welfare shall determine the additional period during which storage may take place. Consent may be subject to conditions. It may be revoked if the conditions are violated or if there are other grounds for revocation. **Sperm introduction** [Section 7] Frozen sperm may not be brought into the country without permission from the National Board of Health and Welfare.

	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		N/A
Counselling, communication and information provision		**<u>Chapter 5. Measures for research or treatment purposes with human eggs</u>** [Section 1] Procedures in accordance with the provisions of this chapter with human eggs that have been fertilised or have been the subject of somatic cell nuclear transfer require that the donors of eggs, sperm or body cells have been informed of the purpose of the procedure and have subsequently given their consent. If fertilisation has taken place in accordance with Chapter 7, it is also required that a woman or man in the treated couple who is not a donor of eggs or sperm has been informed of the purpose of the procedure and has subsequently given their consent. The same applies to a single woman who is not a donor of eggs. Law (2018:1283) **<u>Chapter 6. Insemination</u>** [Section 1a] A donor of sperm must be of legal age. The donor must give written consent to the sperm being used for insemination. The donor may withdraw his consent until the insemination has taken place. Law (2018:1283). **Right to information** [Section 5] A person who has been conceived through insemination as referred to in Section 2 has, if he or she has reached sufficient maturity, the right to access the information about the donor recorded in the hospital's special medical record. Law (2018:1283) [Section 5a] Upon written request from the person who has been conceived through insemination as referred to in Section 2 and who has reached sufficient maturity, information about him or her shall be entered in the special record containing information about the donor. The request shall also be entered in the special record. A person who has conceived through insemination, and who has reached sufficient maturity, has the right to access the information recorded in the special medical record and which relates to other persons who have conceived with sperm from the same donor. Law (2018:1283) [Section 5b] If someone has reason to believe that he or she has been conceived through insemination, the social welfare committee is obliged, upon request, to help him or her find out whether there is any information recorded in a special record. Law (2018:1283)

		[The above right to information applies to Chapter 7. Treatment outside of the body, also].
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		Chapter 1. Introductory provisions [Section 1]: This Act provides for restrictions on the use of certain biotechnology developed for medical purposes and certain legal effects of such use. The purpose of the law is to protect the integrity of the individual. [Section 2] The Act applies to: ▪ the use of genetic examinations and genetic information and gene therapy, ▪ genetic examination during general health examinations, ▪ prenatal diagnosis and preimplantation genetic diagnosis, ▪ measures for research or treatment purposes with human eggs, ▪ insemination, and ▪ fertilisation outside the body. The law also contains liability provisions for trade in human biological material. **Other related legislation** [Section 3] The Patients' Act (2014:821) and the Health and Medical Services Act (2017:30) contain fundamental provisions on patient self-determination and respect for the equal value of people in health and medical services, and the Patient Safety Act (2010:659) provides for obligations for health and medical personnel. The Biobank Act (2023:38) regulates how human biological material, with respect for the integrity of the individual, may be collected for and preserved in a biobank and used for certain purposes. Relationship to other data protection regulations [Section 4] This Act contains provisions supplementing Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). When processing personal data under this Act, the Act (2018:218) with supplementary provisions to the EU Data Protection Regulation and regulations issued in connection with that Act shall apply, unless otherwise provided for in this Act or regulations issued in connection with the Act. Act (2018:443).
Miscellaneous		N/A

Table E.41 Extracted data for Sweden (Assisted reproduction with donated gametes guidelines 2016)

Sweden		
Author(s) **Title [year]**	The National Board of Health and Welfare Assisted reproduction with donated gametes guidelines[56] [2016]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		In the case of donation treatment, assisted fertilisation with donated gametes, a special assessment must be made of whether it is appropriate for the treatment to take place, taking into account the medical, psychological and social conditions of the spouses, cohabitants or the single person. Treatment may only be carried out if it can be assumed that the future child will grow up under good conditions. The special assessment should take into account the age, health status and any disabilities, living conditions and attitude towards telling the child about its biological origin of the couple or the single woman. Consideration should also be given to the couple's relationship or the single person's social network. There are provisions that a doctor must conduct a special examination when the donor of sperm or eggs to be used in assisted fertilization is a person other than the spouse, registered partner or cohabitant. The doctor must assess whether it is appropriate for the assisted fertilization to take place, taking into account the applicant's medical, psychological and social circumstances. The assessment should take into account the couple's or single person's **(p. 8):** ▪ Age: According to general guidelines, the assessment of the suitability of assisted fertilization should be based on the couple's or single person's ability and capacity to function as parents. The assessment should therefore take into account the age of the couple or single person. This means at least an 18-year perspective, when applicants must function as parents at least until the child reaches adulthood (but in practice also into young adulthood). **(p. 16)** Advanced age of applicants is an example of one of the risk factors that the health and medical services have to consider in the assessment, but it is not possible to specify any specific age limit based on the research. **(p. 17)** ▪ Health status and any functional impairments: Physical or mental illness or extensive functional impairment, which can mean reduced capacity and parental ability during a child's upbringing, risky use/abuse of alcohol/drugs/medicines are, according to research, examples of risk factors for children coming to harm. Other forms of abuse and dependence can also constitute risk factors. **(p.17)** An illness that is well managed through, for example, through adequate medication or treatment, does not necessarily mean that parenting ability is negatively affected. Society supports efforts to compensate for any limitations that come with the. The assessment also takes into account how any assistive devices compensate for any functional impairment, as well as what help and support the person receives. The applicant needs to be able to have close and continuous physical and psychological contact with the child and be able to provide for the child's needs for care and safety. **(p. 18)** ▪ Living conditions: If previous children have been exposed to a lack of care or have been taken into care, if there are serious deficiencies in the ability to provide for themselves and/or their house, as well as if there is serious crime, are risk factors for children to come to harm. **(p. 18)**

		▪ Attitude towards telling the child about its biological origin: The reason why this aspect is included as one of the factors in the general advice is that the legislation gives children who have been conceived through donation the right to know their genetic origin and to receive information about the donor. A person who has been conceived through donation treatment in Sweden and who has reached sufficient maturity has the right to access information about the donor in the healthcare system. **(p. 22)** ▪ Previously neglected children: Known deficiencies in parental ability, such as previous children of the applicant having been neglected or exposed and/or taken into care by society, are an obvious risk that a new child will be at risk of exposure. **(p. 18)** ▪ Serious crime: Crime such as violent crimes, assaults, and crimes that indicate impulsiveness, poor judgment, lack of empathy and lack of respect for integrity, or other serious crimes, pose a clear risk of lack of parental capacity, of children being exposed to neglect, violence or abuse, or of witnessing violence in the family. **(p. 18)** ▪ Relational aspects: Signs of violence, control or other difficult problems in close relationships, uncertainty about the relationship and if the request for donation treatment is not well thought out, are risk factors for children being harmed. **(p. 19)** ▪ Uncertainty about relationship: An important prerequisite for someone to undergo donation treatment as a single person is that the person is actually single. This means that the person is neither married, a registered partner or a cohabitant. There may be reasons why a person living in a relationship chooses to seek donation treatment as a single person, for example if there is conflicts in the relationship (for example, about parenthood), or whether there are risk factors in the partner or in the relationship that could result in a negative decision if they came to the attention of the healthcare provider. If such a relationship is suspected, the investigation may need to be further investigated in this regard. If a single applicant has recently separated, there may be reasons to go into more depth in the investigation into what this means for the decision about donation treatment and parenthood. A prerequisite for couples applying for donation treatment is that the relationship is stable and lasting. **(p. 19)** ▪ Request for donation treatment not well thought out: Couples undergoing donation treatment must be able to handle the fact that one of the parents will have no genetic connection to the potential child. The person must also be able to handle the fact that the child may have a genetic connection to another family, where there may also be genetic half-siblings. A single parent needs to have thought through how to address the child's questions about why they only have one parent. If the applicant has not decided what this means or is ambivalent, given these circumstances, the desire to undergo donation treatment does not appear to have been sufficiently processed and thought out. **(p. 20)** ▪ Social networks: A well-functioning social network is an important aspect of the life situation and thus social conditions are investigated for both couples and single people. Lack of a well-functioning social network, and thus lack of opportunity for sufficient support and relief, are examples of a risk factor to take into account. **(p. 21)** ▪ Assessment of the applicant's insight and attitude: A person who becomes a parent through donation and who thus lacks a genetic connection to the potential child must be able to deal with this fact. The applicant must also be able to deal with the fact that the child has a different

		genetic origin with a genetic connection to other people. If the applicant has not taken a position on what this means or is ambivalent about these circumstances, there is a risk that a potential child will not receive knowledge of his or her origin from his or her parent. **(p. 22)** A professional with behavioural science expertise should participate in examining the psychological and social well-being of the couple or the single person. In this investigation, conversations should be held with the single person, with the couple together and with each spouse, cohabitant or registered partner separately. In order to obtain sufficient basis for the overall assessment to be made it may sometimes be necessary, especially in cases of doubt, to have several conversations with each applicant. **(p. 9)** **The aim is to ensure the best interests of the child** Some basic prerequisites are a positive attitude towards children and parenting, a readiness to put one's own needs second, and the ability to be sensitive and caring. Good parenting skills depend on a number of personal characteristics but also factors in the environment and the life situation itself. The assessment requires knowledge of which parenting skills and prerequisites enable a secure attachment and promote children's health and development. **(p. 10)** **Registry information** To support the special assessment, information may need to be obtained from various registers or other healthcare institutions. This requires consent from the applicant for the information to be released, and certain information can only be requested by the applicant themselves. The purpose of obtaining information from registers is to ensure that existing information about some of the most serious risk factors for children being harmed is not missed, such as convictions for violent crimes or abuse or documentation of previous serious shortcomings in parenting. Information can be obtained either on indication or routinely. **(p. 12)** The special assessment is based on an overall assessment of the circumstances in the individual case, where the person responsible for the decision weighs up various factors that may be important for a child's opportunity to grow up in good conditions. **(p. 13)** **Medical assessment (p. 13):** What is usually included for the medical assessment in connection with donation treatment is the following: ▪ medical history for applicants (both partners in pairs) including medical history (somatic and mental), medication, surgeries, sick leave, vaccinations, hereditary factors, previous pregnancies and births ▪ health declarations ▪ weighing and measuring ▪ infection samples. If necessary, additional measures are sometimes taken, such as: ▪ chromosome cultivation ▪ consultation with the patient's treating physician

		▪ ordering medical records and reports ▪ genetic counselling. Other elements may also be included. The purpose of the medical assessment is, among other things, to ensure that the treatment or pregnancy does not endanger the health of the potential child and the person who will carry it. The special assessment of the suitability of the donation treatment to take place may result in a decision to: ▪ it is appropriate for the donation treatment to take place or ▪ that donation treatment cannot be permitted. **(p. 14)**
DAHR intervention(s) provided		Assisted fertilization can be performed in Swedish healthcare through insemination or fertilisation outside the body (so-called in vitro fertilisation, IVF). Treatment can be performed with the applicant's own or donated gametes.
Organisation	***Referral pathways***	N/A
	Service provider characteristic	The psychosocial assessment for the special examination: A professional with behavioural science expertise should participate in the assessment of the couple's or single woman's psychological and social conditions. The assessment should include interviews with the single woman, the couple together, and each spouse, cohabitant or registered partner separately. **(p. 11)**
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	If the donation treatment is intended to be done with a known donor special focus should be placed on how well-thought out the decision is. If the donor is a close relative, it can be difficult to predict in advance how it may affect relationships and what it may mean emotionally for both the potential child and the parent, as well as the donor. If a couple wishes to use gametes from a known donor, the doctor must therefore, among other things, examine the motives of the people involved for this and their ability to manage their mutual relationships in a good way in the future. **(p. 20)**
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		The couple or single person should be given individually tailored information about the results of the special examination. If assisted fertilisation is not permitted due to what emerged from the examination, the doctor must provide information about the reasons why the treatment is not considered appropriate and that the couple or the single person can request that the National

		Board of Health and Welfare to review the matter. The decision to not allow assisted fertilization and the reasons for this must be documented. The applicant can also receive information about how the decision is reviewed and contact details for the unit at the National Board of Health and Welfare to which the applicant can turn. **(p. 9)**
Funding		N/A
Counselling, communication and information provision		The couple or single person should be given individually tailored information about the results of the special examination. If assisted fertilization is not permitted due to what emerged from the examination, the doctor must provide information about the reasons why the treatment is not considered appropriate and that the couple or the single person can request that the National Board of Health and Welfare review the matter. The decision not to allow assisted fertilization and the reasons for this must be documented. The applicant can also receive information about how the decision is reviewed and contact details for the unit at the National Board of Health and Welfare to which the applicant can turn. **(p. 9)** It may be useful to explain to the applicant that the examination is motivated by the fact that society assumes responsibility in donation treatment, primarily for the child, but also in relation to the donor. It can be reassuring for applicants to initially receive information about how the investigation is carried out and that it is carried out to meet children's needs for a safe upbringing. **(p. 12)** The investigation itself can be seen as an opportunity for applicants to reflect on and strengthen their readiness for parenthood. It can also be good to ask about applicants' expectations, concerns and beliefs before the investigation in order to be able to provide clarifications that can create trust in the contact. Conversations with applicants can involve a meeting between different value systems regarding views on children and what is discussed with children, children's rights and children's relationship with adults. This can be a good opportunity to explain that children's right to know their genetic origin follows from the Genetic Integrity Act and Article 7 of the Convention on the Rights of the Child. The fact that children need to know their genetic origin is also based on knowledge from research about what is best for children's identity and self-image, health and development. **(p. 23)** **Information about telling children about their genetic origins (p.24)** The couple or single person needs to gain insight into and understand the importance and the benefits of telling the child about its genetic origin early on. In donation treatment, applicants often feel confident in their decision and are then also prepared to tell their child about its genetic origin. Nevertheless, it can be difficult for them to know when and how this should happen. Resistance can also arise, especially from the parent who has no genetic connection to the child, which is difficult to understand in advance. The basis for the parents to both want and be able to tell the child is that they are given good information about this in connection with the special assessment.

		An essential part of the information provided to parents consists of the reasons why the legislation gives the child this right and what we know from research about children's need to know.
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		Provisions on assisted fertilization are found in the Genetic Integrity Act and the Ordinance (2006:358) on Genetic Integrity etc. Further provisions are contained in the National Board of Health and Welfare's regulations (SOSFS 2009:30) on the donation and use of tissues and cells. Furthermore, there are provisions in the National Board of Health and Welfare's regulations and general advice (SOSFS 2009:32) on the use of tissues and cells in healthcare and clinical research, etc.
Miscellaneous		N/A

Table E.42 Extracted data for Sweden (County council – funded assisted reproduction)

<table>
<tr><th colspan="3">Sweden</th></tr>
<tr><td>Author(s)
Title [year]</td><td colspan="2">SALAR (Swedish Association of Local Authorities and Regions)
Recommendations for homogeneity in county councils’ and regions’ publicly funded assisted reproduction offers[57] [2016]</td></tr>
<tr><th>Focus Area</th><th>Sub-focus area</th><th>Information extracted</th></tr>
<tr><td>Population(s) and eligibility criteria</td><td></td><td>County council-funded assisted reproduction is offered to couples without joint or adopted children and to single women who are not previously registered guardians of a child.

During medical assessment prior to treatment, the woman's health must be given special consideration.

Assisted fertilisation in cases of HIV, HTLV I/II, hepatitis B/C and syphilis is carried out in accordance with SOSFS 2009:32. The Swedish National Board of Health and Welfare's regulations and general advice on the use of tissues and cells in healthcare and clinical research. (p. 2)

[See DAHR interventions for specific requirements for interventions]

Upper age limits:
The first part concerns the treated woman where the following applies:
▪ IVF treatment
▪ Intrauterine insemination (with partner's or donor's sperm)
▪ Treatment with egg donation
▪ Fertility preservation measures.

Should be started before the woman's 40th birthday, any remaining frozen embryos can be transferred until the treated woman's 45th birthday.

The second part concerns men: For fertility preservation measures for men, the man's age should not exceed 56 years.

Lower age limits: SKL believes that the lower age limit for applying for assisted reproduction should be on par with the age limit that applies for applications for adoption, that is, 25 years.

Investigation and treatment – a process (p. 5)
Same-sex or opposite-sex couples who have difficulty having children can seek help from the healthcare system for an investigation of involuntary infertility. If opposite-sex couples have tried to have a child for a year without a pregnancy, they can receive help with investigation and treatment from the healthcare system. If it is known that there are medical reasons for the infertility, the couple does not need to wait a year for an investigation. Single women who want a child can also seek help from the healthcare system.</td></tr>
</table>

		The investigation is carried out at a gynaecological clinic, a women's clinic at a hospital or a private fertility clinic. The investigation regarding assisted reproduction shall include an examination to assess whether, for heterosexual couples, there is a reasonable possibility of having children naturally and, for heterosexual and same-sex couples and single women, whether they have the medical conditions to become pregnant. After the investigation, it is decided individually for each couple/single woman which treatment the healthcare system offers, and the choice of treatment depends on which cause(s) have been found for the infertility. Assisted reproduction is one of these measures. **Current family constellation (p. 5)** The county council shall offer outpatient care to those who are covered by another county council's responsibility for health and medical care. These patients are not covered by the county council's care guarantee. Otherwise, care shall be provided on the same terms as those that apply to its own residents. If the patient is covered by another county council's responsibility for health and medical care, that county council shall be responsible for the costs of care that the patient is provided with support. However, this does not apply if that county council requires referral for care and these referral rules are not followed. The recommendation states that county council-funded assisted reproduction should be offered to couples without joint or adopted children or to single women who are not registered guardians of any children. If the family makeup changes, a new assessment is made based on the new situation. As an alternative, it has been discussed that the number of attempts should be personal. SKL believes that this is not a suitable alternative for several reasons. First, that it would disadvantage both the woman and a new partner. Another reason against such a solution is that with today's record management, it is not possible for the county councils to follow up on whether individuals in a different family constellation have undergone assisted reproduction. Even if this were to become technically feasible in the future, the option to block their record information will in all likelihood remain, which means that healthcare will also not be able to check the individuals' information in the future.
DAHR intervention(s) provided		Start of assisted fertilisation with egg retrieval is defined as the start of drug treatment with follicle-stimulating hormones or ovulation-stimulating hormones or in connection with the first insemination if treatment is done in a natural cycle. Start of treatment with retrieval of cryopreserved fertilised eggs (embryos) is defined as the thawing of embryos regardless of whether they can be transferred. Start of treatment with retrieval of cryopreserved unfertilised eggs defined as the thawing of eggs for fertilisation. A single woman is defined as a woman who is not married, has a registered partner or lives in a cohabiting relationship (SOSFS 2009:32). The definition also applies to women-to-men, who retain their reproductive capacity. **(p. 2)**

		Prerequisites for insemination with donated sperm (p. 3) Insemination should be chosen first if it is deemed possible. An examination of the woman should be without objection for the possibility of achieving pregnancy through insemination. The medical assessment determines which treatment method is appropriate. **Requirements for sperm donation in IVF (p. 3)** The woman has obstacles to natural fertilisation, but good ovarian capacity. **Number of treatments (p. 4)** ▪ Three IVF treatments with egg retrieval can be performed if medically justified. If egg retrieval results in all eggs being frozen unfertilised, the corresponding treatment with thawing and fertilisation of these eggs should be offered. ▪ Six treatments with intrauterine insemination (sperm donated or partners sperm). Alternatively, a combination of intrauterine insemination and IVF with donated sperm can be offered. ▪ For women who experience a new obstacle to natural fertilisation during an ongoing intrauterine insemination treatment programme, the possibility of sperm donation during IVF may exist. ▪ If IVF treatment results in good quality embryos, these can be frozen. ▪ In the first instance, all frozen embryos should be returned before new treatment with follicle-stimulating hormone is started.
Organisation	***Referral pathways***	N/A
	Service provider characteristic	Patient Lag **(p. 6)** The Patient Act came into force on 1 January 2015. The purpose of the Act is to strengthen and clarify the position of patients and to promote patient integrity, self-determination and participation. This is done by, among other things, giving a patient the opportunity to freely choose providers of publicly funded outpatient care within or outside their own county council, under certain conditions. The Act means that the county council cannot prioritize its own residents over patients who reside in other county councils, or vice versa. The basic rule is that it is the medical needs that should form the basis for priorities, not which county council the patient comes from.
	Timelines to access services	The woman/couple cannot postpone treatment that has already begun without agreement with the treating clinic. In general, the woman/couple must have completed treatment within 24 months of the first treatment starting. The care guarantee applies to publicly funded assisted reproduction. This means that the investigation phase of involuntarily childless patients must begin within three months of first contact. If a treatment is dependent on, for example, egg or sperm donation, the care guarantee time limits start when these are in place. **(p. 2)**
	Any other organisational aspects	N/A

Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		Patient Care fee **(p. 3)** The care fee for the patient in connection with assisted reproduction is determined by the county councils in accordance with Section 26 and Section 26a of the Health and Medical Services Act.
Counselling, communication and information provision		N/A
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		**Treatment conditions – sperm donor (p. 4)** ▪ Should be younger than 46 years old, healthy and have no hereditary diseases in the family ▪ Be tested for sexually transmitted diseases (chlamydia, gonorrhoea), HIV, HTLV I/II, hepatitis B/C and syphilis or other communicable diseases. (SOSFS 2009:30, appendix 5) ▪ Psychological assessment must be carried out ▪ A donor must give written consent for the sperm to be used for insemination and/or fertilisation outside the body ▪ The donor has the right to withdraw their consent until insemination has taken place ▪ A donor can contribute to children in a maximum of six families. This means that a donor can contribute to siblings who have the same genetic mother in the six families where the donor has previously contributed to children.

Table E.43 Extracted data for Sweden (Use of tissue and cells in healthcare and clinical research)

Sweden		
Author(s) **Title [year]**	The National Board of Health and Welfare SOSFS 2009:32 Use of tissues and cells in healthcare and clinical research, etc.[58] and the associated appendix[59]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**Assessment and information prior to assisted reproduction** [Section 5] An examination shall be carried out to assess whether: 1. spouses and cohabitants have reasonable opportunities to have children naturally and, 2. spouses, registered partners and cohabitants have the medical conditions to become pregnant through assisted reproduction. [Section 7] The recipient (the woman) shall be tested for the presence of markers for the following infectious agents: ▪ HIV 1 and HIV 2 ▪ Hepatitis B ▪ Hepatitis C ▪ HTLV I and HTLV II ▪ Treponema pallidum (Syphilis). [Section 8] In certain circumstances, additional tests may be required depending on the woman's background, such as tests for the presence of malaria, tuberculosis, CMV, toxoplasmosis, EBV, Trypanosoma cruzi and Leishmaniasis. [Section 9] Assisted fertilisation may only be performed if it is deemed unlikely that any infection or disease specified in Sections 7 and 8 can be transmitted to the child through fertilisation. Information about the results of the tests should be documented. The woman should be informed about the results and their consequences. [Section 10] An assessment shall also be made to ensure whether it is appropriate for the safety of the woman or the child for her to undergo a pregnancy. If the pregnancy or any other infection or disease other than those specified in Sections 7 and 8 may endanger the life or health of the woman or the child, assisted conception may not be performed. *[Note: Special consideration when using donated gametes not extracted as this is covered in the donated gametes guidelines already extracted]*
DAHR intervention(s) provided		[Section 15] During the same menstrual cycle, a woman may not be inseminated with sperm from more than one donor. Eggs from more than one woman may not be placed into one at the same time another woman's body after fertilisation outside the body. [Section 16] After fertilisation outside a woman's body, as a rule, only one fertilised egg may be introduced into the woman's body. If the risk of twin pregnancy is assessed as

		low, two fertilised eggs may be introduced. The couple should be informed about the risks that a twin pregnancy may pose and be offered a conversation with a paediatrician.
Organisation	***Referral pathways***	N/A
	Service provider characteristic	**<u>Chapter 4. Assisted fertilisation</u>** Permission in certain cases Section 1. Chapter 6, Section 2 and Chapter 7, Section 4 of the Genetic Integrity etc. Act (2006:351) contain provisions on requirements for permission from the National Board of Health and Welfare to perform assisted fertilisation at healthcare facilities that are not publicly funded in cases where the donor and recipient are married or cohabiting. *[Note: This has been amended since and includes single women]* Section 2. An application for a permit pursuant to Section 1 shall be made by the healthcare provider. The application shall contain information about the planned activity. 1. Purpose 2. Scope 3. Organisation and 4. Management system. The application must also contain information about the name of the doctor who has medical responsibility for the operation and the doctor's qualifications. If the activity also includes the handling of gametes as referred to in the Act (2008:286) on quality and safety standards for handling human tissues and cells, an application for a permit must also be made in accordance with that Act.
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	**Use of gametes** [Section 14] In Chapter 6, Section 4 and Chapter 7, Section 6 of the Genetic Integrity etc. Act (2006:351) there are provisions stating that sperm or eggs from a deceased donor may not be used in assisted fertilisation. There should be documented procedures that ensure that the physician checks before each treatment whether the donor of sperm or eggs is still alive and that

		donated sperm or eggs are not used if the donor has died. Nor may a fertilised egg (embryo) be used if the sperm or egg used for fertilisation originates from a deceased donor.
	Any other management information	**Chapter 5. Documentation, archiving and reporting Documentation** **Common provisions** [Section 1] The documentation on the final use of tissues and cells shall contain information on: **1.** which tissue establishment (name, address and telephone number) or, in the case of direct distribution, which healthcare institution (name, address and telephone number) has provided the tissues or cells, **2.** the date (year, month and day) of final use, **3.** the identity of the recipient, **4.** which tissue or cells have been used and their special characteristics, **5.** the identity of the tissues or cells (except for gametes for treatment within the couple), **6.** which doctor or dentist has been responsible for the use of the receiver, and **7.** type of final use of tissues and cells that have not been used on the recipient. **Assisted fertilisation** [Section 2] In the case of assisted reproduction, the woman's medical record shall also contain information about: 1. which of the fertilisation attempts has led to pregnancy, and 2. the consent of the spouse, registered partner or cohabitant. [Section 3] In Chapter 6, Section 4 and Chapter 7, Section 6, third paragraph of the Genetic Integrity etc. Act (2006:351) there are provisions that in cases of assisted fertilisation where the donor and recipient are not married or cohabiting, a special record shall be kept to ensure the child's right to information about their genetic origin. **Chapter 6. Reporting of abnormal events** **Serious adverse events and serious side effects** [Section 1] The operations manager shall, on quality and safety standards for handling human tissues and cells, be responsible for ensuring that the tissue establishment that has distributed the tissues or cells that have been used on the recipient is notified without delay of: 1. serious adverse events that may affect the quality and safety of tissues and cells, 2. serious adverse reactions suspected or observed during or after use that may be attributable to the quality and safety of the tissues and cells, 3. detected transport damage that may have resulted in contamination of distributed tissues and cells, and 4. errors in packaging, packaging labelling or accompanying documentation (delivery note).

		In the case of direct distribution, the information must be reported to the tissue establishment that, is responsible for ensuring that serious adverse events and serious side effects are investigated and reported in accordance with the same regulations. **Infectious diseases** [Section 4] If a contagious disease covered by the Communicable Diseases Act (2004:168) has been diagnosed or suspected in a recipient, the operations manager shall ensure that a report and an investigation are made in accordance with the same act.
Governance		N/A
Funding		N/A
Counselling, communication and information provision		**Consent** [Section 3] The written consent of the spouse, registered partner or cohabitant pursuant to Chapter 6, Section 1 of the Genetic Integrity etc. Act (2006:351) to insemination being performed must be submitted. The spouse's, registered partner's or cohabitant's written consent pursuant to Chapter 7, Section 3 of the Genetic Integrity etc. Act to the transfer of a fertilised egg (embryo) into the body of the other spouse, partner or cohabitant must be submitted. If the fertilised egg has been stored in a frozen state, the consent of the spouse, registered partner or cohabitant must be obtained again. Once the physician responsible for the treatment has received the consent, he or she must confirm it by signing the consent document. [Section 4] The responsible physician shall inform the couple about the meaning of consent. Information shall be provided that: 1. the consent is valid until further notice from the date the consent document is signed 2. a revocation can be made orally or in writing 3. the responsible physician shall be immediately notified that consent has been withdrawn, and a revocation is valid from the time the doctor was notified about the recall. If consent is revoked, the physician must confirm this by signing the consent document in connection with the notification of the revocation. The couple shall also be informed that consent from a donor of gametes, in cases where the donor is a person other than the spouse, registered partner or cohabitant, may be revoked in accordance with Chapter 7, Section 2 of the Genetic Integrity etc. Act (2006:351) until an egg has been fertilised. The child's right to information shall be ensured by ensuring that the information allows full traceability to information about the donor's identity that is saved in the register that, must be kept at the tissue establishment that has provided the sperm or egg that has been used in fertilisation.

Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		N/A

Table E.44 Extracted data for United Kingdom (UK) (Fertility)

UK		
Author(s) **Title [year]**	Fertility Network UK Fertility Network UK[60] [2025]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		N/A
DAHR intervention(s) provided		**Egg sharing programmes** Some clinics offer egg sharing programmes. Egg sharing involves a woman undertaking fertility treatment who donates some of her eggs to the clinic where she is receiving treatment. In return, the clinic can reduce the cost of fertility treatment. **IVF** Treatment cycles for the donor and the recipient can be run at the same time. Treatment of the egg donors is the same as for normal IVF, with drugs to control the donor's hormones following which stimulation of the ovaries with one of the gonadotrophin drugs takes place. The cycle is monitored as for a normal IVF cycle and the eggs are collected by the transvaginal ultrasound recovery technique, which is carried out under sedation. The collected eggs are inseminated with the sperm of the egg recipient's partner or a donor and, if fertilisation occurs, embryos are transferred "fresh" directly to the recipient. Another method is to obtain eggs from the donor, inseminate them with the recipient's partner's or donor's sperm, freeze any resulting embryos and transfer these at a later date to the recipient. Some couples prefer the latter system, as it can be confirmed that the egg donor is HIV negative six months after first freezing the embryos. Unlike treatment with sperm donation, the six months wait for the HIV status of donor eggs is not mandatory. The success of treatment using donor eggs is usually better than that of normal IVF. Egg donation is a complex procedure and requires extensive consultation and counselling of both the donor, the recipient and their partners.
Organisation	***Referral pathways***	Referral An important advocacy role for the GP is to ensure appropriate referral for infertile couples. Appropriate referral can be achieved following initial assessment, investigation and diagnosis. A couple with identified tubal infertility or male factor infertility will require referral to a specialist fertility centre for in-vitro fertilisation (IVF) or intracytoplasmic sperm injection (ICSI) treatment. Some ovulation disorders may be managed in general practice. For couples requiring referral this will be dictated by local commissioning arrangements and may be to a local secondary care gynaecology service or specialist fertility centre. Unexplained infertility. A working diagnosis of unexplained infertility may be reached in primary care for a woman aged less than 36 years with normal mid-luteal progesterone,

		HSG, and semen analysis for her partner. Although it is an unsatisfactory diagnosis with no agreed diagnostic threshold, the couple's chance of achieving a pregnancy in the next two years is about 46%. Referral for IVF after two years of infertility is then appropriate. For NHS referrals, the GP needs to be aware of local clinical and social exclusion criteria for assisted conception. Commonly these are female age, female BMI and whether the couple have a child in the current or a previous relationship. The majority of IVF cycles in the UK are delivered privately, commonly as a result of couples failing to meet social and/or clinical criteria to allow access to NHS funding. Assisted reproduction: Intrauterine insemination has a diminishing role in the latest NICE guideline. It is still considered for couples using partner or donor sperm, same sex couples and following sperm washing in HIV positive men. Tubal surgery is still an option for women with mild tubal disease. IVF is the mainstay treatment for women with tubal infertility or women with unexplained infertility who have not conceived after two years of regular unprotected intercourse. ICSI remains the treatment of choice for male factor infertility. Currently NICE recommends single embryo transfer in an IVF cycle for women under 37 years. Double embryo transfer is considered in older women or additional IVF cycles. Summary: GPs continue to be the first point of contact for couples struggling to conceive. The initial investigation of the infertile couple can be performed in general practice and is essential to ensure appropriate management and onward referral. These include assessment of ovulation with mid-luteal progesterone and/or AMH and day 2–5 FSH, male factor with semen analysis and tubal status with HSG. Management strategies for primary care include obesity management and may include ovulation induction for a small cohort of infertile couples. Watchful waiting is appropriate for women aged less than 36 years and where no cause for infertility has been identified following initial investigations described above. Following initial assessment couples with male factor infertility or tubal infertility should be referred to specialist units that can deliver IVF/ICSI treatments.
	Service provider characteristic	N/A
	Timelines to access services	N/A
	Any other organisational aspects	N/A

Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	The recruitment of egg donors has been a challenge and some, but not all clinics in the UK have shortages of donors. Some clinics do not offer donor treatment or may only offer egg donation to those who are happy to use an anonymous donor from overseas, so you may need to contact a few clinics to find one which has UK egg donors. There are two main sources of egg donors: young women undergoing IVF treatment who agree to share their eggs with a recipient or young women who offer to give their eggs for altruistic reasons. HFEA guidelines allow altruistic egg donors to receive up to £750 as compensation, with a provision to claim an excess to cover higher expenses (such as for travel, accommodation or childcare). Egg donors should usually be no older than 35 years of age. Some women may choose to use known donors, such as a sister or a friend, and this is permitted. Most donors in the UK are not known at the time of treatment, but a child born from the donation will be able to find out about them once they reach the age of 18.
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		N/A
Counselling, communication and information provision		Gamete donation, whether it be sperm, egg or embryo, may initially sound appealing but often evokes a wide range of emotional, social and religious thoughts. It is therefore extremely important that clinics performing such treatments provide extensive counselling to help couples to discuss, identify with and accept the issues involved in donor treatment.
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A
Miscellaneous		N/A

Table E.45 Extracted data for the United Kingdom (UK) (Fertility problems)

UK		
Author(s) **Title [year]**	National Institute for Health and Care Excellence Fertility problems: assessment and treatment [CG 156][61] [2017]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**Woman < 40 (pp. 28-29)** ▪ who have not conceived after two years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), offer three full cycles of IVF, with or without ICSI. ▪ If the woman reaches the age of 40 during treatment, complete the current full cycle but do not offer further full cycles. ▪ any previous full IVF cycle, whether self- or NHS funded, should count towards the total of three full cycles that should be offered by the NHS. **Women aged 40 to 42 years** who have not conceived after two years of regular unprotected intercourse or 12 cycles of artificial insemination (where six or more are by intrauterine insemination), offer one full cycle of IVF, with or without ICSI, provided the following three criteria are fulfilled: ▪ they have never previously had IVF treatment ▪ there is no evidence of low ovarian reserve ▪ there has been a discussion of the additional implications of IVF and pregnancy at this age. **Woman BMI** ▪ should ideally be in the range 19 to 30 before commencing assisted reproduction.
DAHR intervention(s) provided		**Indications for donor insemination (pp. 35-36)** The use of donor insemination is considered effective in managing fertility problems associated with the following conditions: ▪ obstructive azoospermia ▪ non-obstructive azoospermia ▪ severe deficits in semen quality in couples who do not wish to undergo intracytoplasmic sperm injection (ICSI). Donor insemination should be considered in conditions such as: ▪ where there is a high risk of transmitting a genetic disorder to the offspring ▪ where there is a high risk of transmitting infectious disease to the offspring or woman from the man ▪ severe rhesus isoimmunisation. **Screening of sperm donors** Units undertaking semen donor recruitment and the cryopreservation of donor spermatozoa for treatment purposes should follow the UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors (2008) describing the selection and screening of donors.

		Assessments to offer the woman (p. 37) ▪ Before starting treatment by donor insemination (for conditions listed in recommendations above), it is important to confirm that the woman is ovulating. ▪ Women with a history that is suggestive of tubal damage should be offered tubal assessment before treatment. ▪ Women with no risk factors in their history should be offered tubal assessment after three cycles if treatment by donor insemination (for conditions listed in recommendations above has been unsuccessful. (p.37) ▪ Women who are ovulating regularly should be offered a minimum of 6 cycles of donor insemination (for conditions listed in recommendations above without ovarian stimulation to reduce the risk of multiple pregnancy and its consequences. **Oocyte donation (p. 38)** **Indications for oocyte donation** The use of donor oocytes is considered effective in managing fertility problems associated with the following conditions: ▪ premature ovarian failure ▪ gonadal dysgenesis, including Turner syndrome ▪ bilateral oophorectomy ▪ ovarian failure following chemotherapy or radiotherapy ▪ certain cases of IVF treatment failure. Oocyte donation should also be considered in certain cases where there is a high risk of transmitting a genetic disorder to the offspring. **Screening of oocyte donors (p. 38)** Before donation is undertaken, oocyte donors should be screened for both infectious and genetic diseases in accordance with the UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors. **Intrauterine insemination (p. 26)** Consider unstimulated intrauterine insemination as a treatment option in the following groups as an alternative to vaginal sexual intercourse: ▪ people who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem who are using partner or donor sperm ▪ people in same-sex relationships. ▪ For people in recommendation above who have not conceived after six cycles of donor or partner insemination, despite evidence of normal ovulation, tubal patency and semen analysis, offer a further six cycles of unstimulated intrauterine insemination before IVF is considered. **IFV procedure: (p. 29)**

		Healthcare providers should define a cancelled IVF cycle as one where an egg collection procedure is not undertaken. However, cancelled cycles due to low ovarian reserve should be taken into account when considering suitability for further IVF treatment. ▪ Pre-treatment with either the oral contraceptive pill or a progestogen ▪ Down-regulation: Use regimens to avoid premature luteinising hormone surges in gonadotrophin-stimulated IVF treatment cycles. ▪ Ovarian Stimulation ▪ Monitoring ▪ Ovulation trigger ▪ Oocyte and Sperm Retrieval ▪ Fertilisation ▪ Embryo Transfer ▪ Progesterone support.
Organisation	***Referral pathways***	N/A
	Service provider characteristic	N/A
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	**Oocyte donation and 'egg sharing' (p. 38)** Oocyte donors should be offered information regarding the potential risks of ovarian stimulation and oocyte collection.
	Storage of donated gametes or embryos	**Cryopreservation of semen, oocytes and embryos (p. 39)** When considering and using cryopreservation for people before starting chemotherapy or radiotherapy that is likely to affect their fertility, follow recommendations in the guidance on management on the effects of cancer treatment on reproductive functions by the Royal College of Physicians, the Royal College of Radiologists, the Royal College of Obstetricians and Gynaecologists. At diagnosis, the impact of the cancer and its treatment on future fertility should be discussed between the person diagnosed with cancer and their cancer team. When deciding to offer fertility preservation to people diagnosed with cancer, take into account the following factors: ▪ diagnosis ▪ treatment plan ▪ expected outcome of subsequent fertility treatment ▪ prognosis of the cancer treatment ▪ viability of stored or post-thawed material.
	Access to and or disposal of stored donated gametes or embryos	N/A

	Any other management information	N/A
Governance		**Fertility problems: assessment and treatment (Clinical Guideline 156)** is established through the National Institute for Health and Care Excellence (NICE), which develops, updates, and oversees the guideline using its formal evidence-based guideline development process.
Funding		N/A
Counselling, communication and information provision		**Information provision (p. 27)** People should be informed that the consumption of more than 1 unit of alcohol per day reduces the effectiveness of assisted reproduction procedures, including IVF. People should be informed that maternal and paternal smoking can adversely affect the success rates of assisted reproduction procedures, including IVF treatment. People should be informed that maternal caffeine consumption has adverse effects on the success rates of assisted reproduction procedures, including IVF treatment. **Information and counselling (p. 36)** Couples should be offered information about the relative merits of ICSI and donor insemination in a context that allows equal access to both treatment options. Couples considering donor insemination should be offered counselling from someone who is independent of the treatment unit regarding all the physical and psychological implications of treatment for themselves and potential children. All potential semen donors should be offered counselling from someone who is independent of the treatment unit regarding the implications for themselves and their genetic children, including any potential children resulting from donated semen. Oocyte recipients and donors should be offered counselling from someone who is independent of the treatment unit regarding the physical and psychological implications of treatment for themselves and their genetic children, including any potential children resulting from donated oocytes. All people considering participation in an 'egg-sharing' scheme should be counselled about its particular implications. **Providing information (p. 6)** Couples who experience problems in conceiving should be seen together because both partners are affected by decisions surrounding investigation and treatment. 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.
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		N/A

Miscellaneous		N/A

Table E.46 Extracted data for the United Kingdom (UK) (Donation)

UK		
Author(s) **Title [year]**	Human Fertilisation & Embryology Authority (HFEA) Donation[62] [2025]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		Donor conception eligibility Using donated sperm, eggs or embryos is a major decision and you should take your time to think about whether it's right for you. You may want to discuss your feelings with friends, family or a professional counsellor before going ahead. A clinic is likely to recommend donor conception if: ▪ you're not producing eggs or sperm of your own ▪ your own sperm or eggs are unlikely to result in a pregnancy ▪ you have a high risk of passing on an inherited disease ▪ you're in a same sex couple, or ▪ you're single.
DAHR intervention(s) provided		This process outlines a single cycle of IVF following the most commonly used procedure. You may find that your treatment is slightly different depending on your history and what your clinic thinks is best for you. ▪ Usually, the first step is to use medication to stimulate the ovaries to produce eggs. There are different ways this can be done. One way is to suppress natural hormones before taking hormone medication to stimulate the ovaries. This treatment, often called a long protocol, involves taking a daily injection or nasal spray to suppress hormone production. A scan checks the woman's natural cycle is fully suppressed. If it is, hormone treatment (usually gonadotrophin) is started to boost the number of eggs the body produces. ▪ Some clinics may use the 'antagonist protocol'. This involves taking medication (an antagonist) to suppress your hormones for a few days after you have taken the hormone medication (usually gonadotrophin) to boost the number of eggs the body produces. ▪ Whichever way the ovaries are stimulated to produce eggs, you will be closely monitored for a few days by the clinic. This may involve having blood tests or ultrasound scans. ▪ The eggs will be collected whilst under sedation or general anaesthetic. The procedure takes around half an hour and you may feel a little sore or bruised. ▪ Whilst the eggs are being collected, the man will be asked to come to the clinic to produce a sperm sample, or your donor sperm will be taken from the freezer, for mixing with your eggs. ▪ Medication will help to prepare the lining of the womb. This is usually taken as a pessary or gel which you can insert yourself into the vagina / rectum. ▪ The eggs will be mixed with the sperm in a laboratory. The aim is for the eggs and sperm to fertilise to create an embryo. ▪ If fertilisation happens, the resulting embryo(s), will be monitored to check how it's/they're developing. ▪ Two to five days after fertilisation, the embryo(s) will be transferred to the womb. You won't need any kind of anaesthetic for this unless you have a condition that would make the procedure painful. You'll be given a date to do a pregnancy test.

Organisation	***Referral pathways***	When a couple present to their GP for fertility issues, they will be offered some standard tests. For the woman this will include scans, bloods, and a referral to a gynaecologist. For the man, however, he'll likely get a standard semen analysis and little else. From here it tends to follow a standard path, which often leads a couple towards IVF with treatment mainly focused on the woman. If the man has a suboptimal semen analysis, he's usually offered some generic advice and reassured that IVF or ICSI (intra-cytoplasmic sperm injection) will help.
	Service provider characteristic	Compensation As a donor in the UK it's illegal for someone to pay you anything more than reasonable expenses. Find out more about expenses on the egg and sperm donation pages.
	Timelines to access services	The safest option is to either find a donor from your clinic or find your own donor/donation and use them in your treatment at the clinic. This ensures the donor will be given health checks and supported through the process with information and counselling, minimising the chance of something going wrong further down the line. ▪ Some clinics have a list of sperm, egg or embryo donors that you can choose from. Waiting lists can be long however, particularly if you're after something specific – choose a clinic to view current donor waiting times. ▪ If you'd like to use a friend or someone you know, you can have treatment with their donation at your clinic. Be aware there are restrictions on mixing sperm and eggs between close relatives – talk to your clinic for more info. ▪ Use sperm, eggs or embryos from abroad. It's possible for UK clinics to import sperm, eggs or embryos from abroad. However, there are strict conditions that need to be met. You'll need to find a licenced UK clinic who offers import/export services. ▪ There are an increasing number of websites which offer services which match women with sperm donors. Donors and recipients may then meet and arrange insemination privately, without attending a clinic. These websites are not regulated by the HFEA. If you are considering using these services it is important to bear in mind the very real risks and consequences of obtaining sperm in this way.
	Any other organisational aspects	**Next steps?** Before you make a decision about using a donor you might want to explore the Donor Conception Network, which is a community of people who have used donors in their treatment. If you decide to go ahead, you'll probably want to start thinking about how you'd like to find a donor and which clinic you'd like to use. Your clinic should give you the option of talking to a counsellor to help you think through all the complex issues and ensure you're completely comfortable with your decision. Once you've found a clinic, they'll discuss your treatment options, which could include intrauterine insemination (IUI) and in vitro fertilisation (IVF).
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	**Finding a donor** You can choose to use a donor who you do not know by going to a fertility clinic. You will not know the identity of the donor, but you will be able to access anonymous information about them (such as height and eye colour) from your clinic. Your child will be able to access anonymous information about their donor when they're 16 years old and they will be able to find out their identity when they're 18 years old.

		Alternatively, you can use a donor who you already know or who you have met via an introduction website. You and the donor may either go to a fertility clinic or undergo a private arrangement (i.e., the donor provides his sperm sample directly to you). If you join an introduction website, keep in mind that these sites can vary enormously in how much support they provide. Some provide very useful information, whilst others act merely as a forum to meet donors.
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		**In the UK, it's illegal to pay a donor anything other than expenses. This means that most donors donate for altruistic reasons rather than financial gain.** The expenses limit is £45 for sperm and embryo donors and £985 for egg donors (per cycle of donation.) Normally the donor's expenses should be covered in your overall treatment cost but double check with your clinic.
Counselling, communication and information provision		**What can I find out about a potential donor?** If you use a donor through your fertility clinic, you'll be able to find out: ▪ a physical description (height, weight, eye and hair colour) ▪ the year and country of birth ▪ their ethnicity ▪ whether they had any children at the time of donation, how many and their gender ▪ their marital status ▪ their medical history ▪ a personal description and goodwill message to any potential children (if they chose to write one at the time of their donation). You won't be able to find out any information that might reveal who the donor is. **If I/we want two or more children born from the same donor(s), is that possible?** Yes, providing the sperm, eggs or embryos are available. You should talk to your clinic about the fact you may want to use the same donor in the future. Reserving sperm, eggs or embryos may incur a fee. Donation law It's not possible to donate your sperm, eggs or embryos anonymously. This means that when a child conceived with your donation reaches 18, they'll be able to ask for your name and address. **Clinics in the UK regulated** At regulated clinics, the donor is screened for infectious diseases, such as chlamydia and HIV, and is offered counselling and information about their rights and obligations.

		The donor's sperm can only be used to create up to 10 families and they will be compensated up to £45 for each clinic visit in line with the requirements set by the HFEA. If you have fertility treatment using a donor at a UK clinic the donor will not: ▪ be the legal parent of the child born ▪ have any legal obligation to the child ▪ be named on the birth certificate ▪ have any rights over how the child will be brought up, or ▪ be required to support the child financially. You will have parental responsibility and, if you are married or in a civil partnership, your spouse will automatically be the child's second legal parent. If you are in a relationship, your partner will be the second legal parent if you both sign the relevant legal parenthood consent form.
Ethical and social considerations		**Does the donor have any rights to children conceived from their donation?** If you're having treatment at a licensed fertility clinic in the UK, your donor will have no legal rights or responsibilities to any children born with their sperm, eggs or embryos. This means: ▪ They will have no legal obligation to any children conceived from their donation. ▪ They won't be named on the birth certificate. ▪ They won't have any rights over how the child will be brought up. ▪ They won't be required to support the child financially. If you don't have treatment with a licensed clinic the situation is more complicated. There's a risk that your donor will be considered a parent by law – with all the rights and responsibilities that brings. Talk to a solicitor to find out more about how this applies to you. **Same donor family limits** In the UK, a donor's eggs, sperm, or embryos may only be used to create children in up to ten families. This limit doesn't include the donor's own family. This means your donor-conceived children could have genetic half-siblings in up to nine other donor families, as well as any children the donor may have themselves. The 10-family limit is something that people using sperm donation are more likely to need to consider than those using egg donation. This is because it is rare for an egg donor to be used to create ten families. The 10-family limit does not apply to donors who donate outside of a licensed clinic through a private arrangement. Some donors may donate both privately and through a licensed clinic. UK donors who reach the 10-family limit here can still have their donations exported and used abroad, potentially creating more families outside the UK where different limits (or no limits) may apply. You can discuss with individual sperm banks if and where donor sperm stored with them are used globally. **Note:** Donated eggs, sperm, or embryos imported into the UK may also be used in the country where they were originally donated and/or exported to other countries, not just the UK The 10-family limit does not apply to private donations made outside licensed clinics – also known as unregulated donation. Some donors may donate both privately and through a licensed clinic.
Relevant legislation (list and key aspects)		N/A

Miscellaneous		N/A

Table E.47 Extracted data for the United Kingdom (UK) (Human Fertilisation and Embryology Act 2008)

UK		
Author(s) **Title [year]**	Legislation.gov.uk Human Fertilisation and Embryology Act 2008[63] [2008]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		N/A
DAHR intervention(s) provided		N/A
Organisation	***Referral pathways***	N/A
	Service provider characteristic	N/A
	Timelines to access services	N/A
	Any other organisational aspects	N/A
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		**Conditions of licenses for treatment** (6) A woman shall not be provided with treatment services of a kind unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper. (6A) A woman shall not be provided with treatment services after the happening of any event unless (before or after the event) she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services after the happening of that event, and have been provided with such relevant information as is proper. (6B) The intended second parent is a reference to— (a) any man as respects whom the agreed fatherhood conditions in section 37 of the Human Fertilisation and Embryology Act 2008 (“the 2008 Act”) are for the time being satisfied in relation to treatment provided to the woman mentioned, and

		(b) any woman as respects whom the agreed female parenthood conditions are for the time being satisfied in relation to treatment provided to the woman mentioned. (6C) In the case of treatment services (use of gametes of a person not receiving those services) or use of embryo taken from a woman not receiving those service), the information provided by virtue must include such information as is proper about— (a) the importance of informing any resulting child at an early age that the child results from the gametes of a person who is not a parent of the child, and (b) suitable methods of informing such a child of that fact. (6D) Where the person responsible receives from a person ("X") notice under section 37(1)(c) or 44(1)(c) of the 2008 Act of X's withdrawal of consent to X being treated as the parent of any child resulting from the provision of treatment services to a woman ("W"), the person responsible— (a) must notify W in writing of the receipt of the notice from X, and (b) no person to whom the license applies may place an embryo or sperm and eggs in W, or artificially inseminate W, until W has been so notified. (6E) Where the person responsible receives from a woman ("W") who has previously given notice under section 37(1)(b) or 44(1)(b) of the 2008 Act that she consents to another person ("X") being treated as a parent of any child resulting from the provision of treatment services to W— (a) notice under section 37(1)(c) or 44(1)(c) of the 2008 Act of the withdrawal of W's consent, or (b) a notice under section 37(1)(b) or 44(1)(b) of the 2008 Act in respect of a person other than X, the person responsible must take reasonable steps to notify X in writing of the receipt of the notice mentioned in paragraph (a) or (b)." (4) After subsection (7) insert— "(8) Subsections (9) and (10) apply in determining any of the following— (a) the people who are to provide gametes for use in pursuance of the license in a case where consent is required under paragraph 5 of Schedule 3 for the use in question; (b) the woman from whom an embryo is to be taken for use in pursuance of the license, in a case where her consent is required under paragraph 7 of Schedule 3 for the use of the embryo; (c) which of two or more embryos to place in a woman. (9) Persons or embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop— (a) a serious physical or mental disability, (b) a serious illness, or (c) any other serious medical condition, must not be preferred to those that are not known to have such an abnormality. (10) Embryos that are known to be of a particular sex and to carry a particular risk, compared with embryos of that sex in general, that any resulting child will have or develop— (a) a gender-related serious physical or mental disability,

		(b) a gender-related serious illness, or (c) any other gender-related serious medical condition, must not be preferred to those that are not known to carry such a risk. (11) For the purposes of subsection (10), a physical or mental disability, illness or other medical condition is gender-related if— (a) it affects only one sex, or (b) it affects one sex significantly more than the other. (12) No embryo appropriated for the purpose mentioned in paragraph 1(1)(ca) of Schedule 2 (training in embryological techniques) shall be kept or used for the provision of treatment services. (13) The person responsible shall comply with any requirement imposed on that person by section 31ZD." (5) After Schedule 3 to the 1990 Act insert the Schedule set out in Schedule 4 to this Act (circumstances in which offer of counselling required as condition of license for treatment). (6) In any license under paragraph 1 of Schedule 2 to the 1990 Act (licenses for treatment) that is in force immediately before the commencement of subsection (2)(b) of this section, the condition required by virtue of section 13(5) of that Act is to have effect as the condition required by that provision as amended by subsection (2)(b) of this section. **31 Register of information** (1) The Authority shall keep a register which is to contain any information which falls within subsection (2) and which— (a) immediately before the coming into force of section 24 of the Human Fertilisation and Embryology Act 2008, was contained in the register kept under this section by the Authority, or (b) is obtained by the Authority. (2) Subject to subsection (3), information falls within this subsection if it relates to— (a) the provision for any identifiable individual of treatment services other than basic partner treatment services, (b) the procurement or distribution of any sperm, other than sperm which is partner-donated sperm and has not been stored, in the course of providing non-medical fertility services for any identifiable individual, (c) the keeping of the gametes of any identifiable individual or of an embryo taken from any identifiable woman, (d) the use of the gametes of any identifiable individual other than their use for the purpose of basic partner treatment services, or (e) the use of an embryo taken from any identifiable woman, or if it shows that any identifiable individual is a relevant individual.

		(3) Information does not fall within subsection (2) if it is provided to the Authority for the purposes of any voluntary contact register as defined by section 31ZF(1). (4) In this section "relevant individual" means an individual who was or may have been born in consequence of— (a) treatment services, other than basic partner treatment services, or (b) the procurement or distribution of any sperm (other than partner-donated sperm which has not been stored) in the course of providing non-medical fertility services.
Funding		N/A
Counselling, communication and information provision		Information provision: **31Z A Request for information as to genetic parentage etc.** (1) A person who has attained the age of 16 ("the applicant") may by notice to the Authority require the Authority to comply with a request under subsection (2). (2) The applicant may request the Authority to give the applicant notice stating whether or not the information contained in the register shows that a person ("the donor") other than a parent of the applicant would or might, but for the relevant statutory provisions, be the parent of the applicant, and if it does show that— (a) giving the applicant so much of that information as relates to the donor as the Authority is required by regulations to give (but no other information), or (b) stating whether or not that information shows that there are other persons of whom the donor is not the parent but would or might, but for the relevant statutory provisions, be the parent and if so— (i) the number of those other persons, (ii) the sex of each of them, and (iii) the year of birth of each of them. (3) The Authority shall comply with a request under subsection (2) if— (a) the information contained in the register shows that the applicant is a relevant individual, and (b) the applicant has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request. (4) Where a request is made under subsection (2)(a) and the applicant has not attained the age of 18 when the applicant gives notice to the Authority under subsection (1), regulations cannot require the Authority to give the applicant any information which identifies the donor. (5) Regulations cannot require the Authority to give any information as to the identity of a person whose gametes have been used or from whom an embryo has been taken if a person to whom a licence applied was provided with the information at a time when the Authority could not have been required to give information of the kind in question. (6) The Authority need not comply with a request made under subsection (2)(b) by any applicant if it considers that special circumstances exist which increase the likelihood that compliance with the request would enable the applicant— (a) to identify the donor, in a case where the Authority is not required by regulations under subsection (2)(a) to give the applicant information which identifies the donor, or (b) to identify any person about whom information is given under subsection (2)(b).

		(7) In this section— ▪ "relevant individual" has the same meaning as in section 31; ▪ "the relevant statutory provisions" means sections 27 to 29 of this Act and sections 33 to 47 of the Human Fertilisation and Embryology Act 2008. **Power of Authority to inform donor of request for information** (1) Where— (a) the Authority has received from a person ("the applicant") a notice containing a request under subsection (2)(a) of section 31ZA, and (b) compliance by the Authority with its duty under that section has involved or will involve giving the applicant information relating to a person other than the parent of the applicant who would or might, but for the relevant statutory provisions, be a parent of the applicant ("the donor"), the Authority may notify the donor that a request under section 31ZA(2)(a) has been made, but may not disclose the identity of the applicant or any information relating to the applicant. (2) In this section "the relevant statutory provisions" has the same meaning as in section 31ZA. **31ZDProvision to donor of information about resulting children** (1) This section applies where a person ("the donor") has consented under Schedule 3 (whether before or after the coming into force of this section) to— (a) the use of the donor's gametes, or an embryo the creation of which was brought about using the donor's gametes, for the purposes of treatment services provided under a licence, or (b) the use of the donor's gametes for the purposes of non-medical fertility services provided under a license. (2) In subsection (1)— (a) "treatment services" do not include treatment services provided to the donor, or to the donor and another person together, and (b) "non-medical fertility services" do not include any services involving partner-donated sperm. (3) The donor may by notice request the appropriate person to give the donor notice stating— (a) the number of persons of whom the donor is not a parent but would or might, but for the relevant statutory provisions, be a parent by virtue of the use of the gametes or embryos to which the consent relates, (b) the sex of each of those persons, and (c) the year of birth of each of those persons. (4) Subject to subsections (5) to (7), the appropriate person shall notify the donor whether the appropriate person holds the information mentioned in subsection (3) and, if the appropriate person does so, shall comply with the request.

		(5) The appropriate person need not comply with a request under subsection (3) if the appropriate person considers that special circumstances exist which increase the likelihood that compliance with the request would enable the donor to identify any of the persons falling within paragraphs (a) to (c) of subsection (3). (6) In the case of a donor who consented as described in subsection (1)(a), the Authority need not comply with a request made to it under subsection (3) where the person who held the licence referred to in subsection (1)(a) continues to hold a licence under paragraph 1 of Schedule 2, unless the donor has previously made a request under subsection (3) to the person responsible and the person responsible— (a) has notified the donor that the information concerned is not held, or (b) has failed to comply with the request within a reasonable period. (7) In the case of a donor who consented as described in subsection (1)(b), the Authority need not comply with a request made to it under subsection (3) where the person who held the licence referred to in subsection (1)(b) continues to hold a licence under paragraph 1A of Schedule 2, unless the donor has previously made a request under subsection (3) to the person responsible and the person responsible— (a) has notified the donor that the information concerned is not held, or (b) has failed to comply with the request within a reasonable period. (8) In this section "the appropriate person" means— (a) in the case of a donor who consented as described in paragraph (a) of subsection (1)— (i) where the person who held the licence referred to in that paragraph continues to hold a licence under paragraph 1 of Schedule 2, the person responsible, or (ii) the Authority, and (b) in the case of a donor who consented as described in paragraph (b) of subsection (1)— (i) where the person who held the licence referred to in that paragraph continues to hold a licence under paragraph 1A of Schedule 2, the person responsible, or (ii) the Authority. (9) In this section "the relevant statutory provisions" has the same meaning as in section 31ZA. **31ZEProvision of information about donor-conceived genetic siblings** (1) For the purposes of this section two relevant individuals are donor-conceived genetic siblings of each other if a person ("the donor") who is not the parent of either of them would or might, but for the relevant statutory provisions, be the parent of both of them. (2) Where— (a) the information on the register shows that a relevant individual ("A") is the donor-conceived genetic sibling of another relevant individual ("B"), (b) A has provided information to the Authority ("the agreed information") which consists of or includes information which enables A to be identified with the request that it should be disclosed to— (i) any donor-conceived genetic sibling of A, or

		(ii) such siblings of A of a specified description which includes B, and (c) the conditions in subsection (3) are satisfied, then, subject to subsection (4), the Authority shall disclose the agreed information to B. (3) The conditions referred to in subsection (2)(c) are— (a) that each of A and B has attained the age of 18, (b) that B has requested the disclosure to B of information about any donor-conceived genetic sibling of B, and (c) that each of A and B has been given a suitable opportunity to receive proper counselling about the implications of disclosure under subsection (2). (4) The Authority need not disclose any information under subsection (2) if it considers that the disclosure of information will lead to A or B identifying the donor unless— (a) the donor has consented to the donor's identity being disclosed to A or B, or (b) were A or B to make a request under section 31ZA(2)(a), the Authority would be required by regulations under that provision to give A or B information which would identify the donor. (5) In this section— ▪ "relevant individual" has the same meaning as in section 31; ▪ "the relevant statutory provisions" has the same meaning as in section 31ZA.
Ethical and social considerations		**Use of sperm, or transfer of embryo, after death of man providing sperm** (1) If— (a) the child has been carried by W as a result of the placing in her of an embryo or of sperm and eggs or her artificial insemination (b) the creation of the embryo carried by W was brought about by using the sperm of a man after his death, or the creation of the embryo was brought about using the sperm of a man before his death but the embryo was placed in W after his death (c) the man consented in writing (and did not withdraw the consent)— (i) to the use of his sperm after his death which brought about the creation of the embryo carried by W or (as the case may be) to the placing in W after his death of the embryo which was brought about using his sperm before his death, and (ii) to being treated for the purpose mentioned in subsection (3) as the father of any resulting child, (d) W has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (3) as the father of the child, and (e) no-one else is to be treated— (i) as the father of the child by virtue of section 35 or 36 or by virtue of section 38(2) or (3), or (ii) as a parent of the child by virtue of section 42 or 43 or by virtue of adoption, then the man is to be treated for the purpose mentioned in subsection (3) as the father of the child.

		(2) Subsection (1) applies whether W was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or of the sperm and eggs or of her artificial insemination. (3) The purpose referred to in subsection (1) is the purpose of enabling the man's particulars to be entered as the particulars of the child's father in a relevant register of births. (4) In the application of this section to Scotland, for any reference to a period of 42 days there is substituted a reference to a period of 21 days.
Relevant legislation (list and key aspects)		N/A
Miscellaneous		N/A

Table E.48 Extracted data for Wales (Specialist Fertility Services)

Wales		
Author(s) **Title [year]**	Multiple resources ▪ Welsh Health Specialised Service Commissioning: CP38 Specialised Services Commissioning Policy: Specialist Fertility Services(64) [2017] ▪ Wales Fertility Institute(65) [2025]	
Focus Area	**Sub-focus area**	**Information extracted**
Population(s) and eligibility criteria		**Clinical Indications – general principles (p.12)** **IVF/ICSI** Infertility in heterosexual couples is the failure to conceive after regular unprotected sexual intercourse for two years. Where there is clear reproductive pathology, couples/single women/men with infertility of any duration will be considered. This will include couples that cannot achieve full sexual intercourse due to disability. There are a number of situations where referral before two years may be appropriate: ▪ Same sex couples, single women and single men will be considered where **subfertility** is demonstrated**.** ▪ Male same sex couples and single men should refer to the section on surrogacy. **3.2.7 Sub-fertility (p.16)** Criteria – Sub-fertility must be demonstrated before there can be access to NHS funded IVF treatment. Sub-fertility for heterosexual couples is defined as inability to conceive after 2 years unprotected intercourse or a fertility problem demonstrated at investigation. Sub-fertility for same sex couples/single women/single men is defined as no live birth following insemination at or just prior to the known time of ovulation on at least six non-stimulated cycles or a fertility problem demonstrated at investigation. For same sex couples/single women/single men, the non-stimulated cycles may be achieved through a private arrangement or through NHS-provided IUI with donor sperm. Intra-uterine insemination (IUI) is not funded by WHSSC. Funding for IUI is the responsibility of the Health Boards. Where donor sperm is needed to undertake IUI, the donated sperm will be funded by WHSSC, but not the IUI procedure. **Further Eligibility criteria (p.15)** **Female Age** ▪ Women at least 20 years old to access IVF treatment. Women who are aged less than 40 years and who meet the access criteria are entitled to two cycles of IVF with or without ICSI. However, if the woman reaches the age of 40 during the first cycle of treatment they will **not** be entitled to a second cycle of IVF. ▪ Women aged between 40 and 42 years (up to their 43rd birthday) who meet the access criteria are entitled to one cycle of IVF with or without ICSI provided the following 3 criteria are also fulfilled: ○ they have never previously had IVF treatment ○ there is no evidence of low ovarian reserve

		○ there has been a discussion of the additional implications of IVF and pregnancy at this age. **Male age** Men must be aged 55 years or younger in order to access IVF treatment. **Existing Children** IVF on the NHS is available for: ▪ couples where one of the partners does not have any living children (biological or adopted) ▪ single women or men who do not have any living children (biological or adopted) **Body Mass (p. 16)** ▪ Women accessing IVF treatment must have a body mass index (BMI) of between at least 19 and up to and including 30. Female patients with a BMI below 19 that are ovulating normally may be treated at the discretion of the treating clinician. Patients outside this range will not be added to the waiting list and should be referred back to their general practitioner for management where required. ▪ Men who have a BMI of 30 or over should be informed that they are likely to have reduced fertility. **Sterilisation (p. 16)** Sub-fertility is not the result of a sterilisation procedure in either partner/single woman/single man (this does not include conditions where sterilisation occurs as a result of another medical problem). Couples/single women/single men who have undertaken a reversal should not be referred for treatment. **Smoking (p. 16)** Where either of the couple/single woman/single man smokes the patient is not eligible. Only patients who agree to take part in a supported programme of smoking cessation will be accepted on the IVF treatment waiting list and must be non-smoking at time of treatment. **History of previous treatment (p. 16)** For single patients, three or more IVF cycles by the patient will exclude any further NHS IVF treatment. For couples, three or more IVF cycles by either partner will exclude any further NHS IVF Treatment. Previous cycles whether NHS or privately funded will be taken into account. **Change of Partner whilst waiting for IVF treatment (p.17)** If a couple consent to treatment but during the waiting period for treatment the couple break up then treatment cannot commence. If one or both of the partners wish to proceed with treatment with either a new partner or by themselves then the clinic that is providing the treatment needs to be notified. The new couple/individual will need to attend a consultation where the fertility history of the couple/individual needs to be reviewed, treatment options explained and discussed and if the couple/individual still meet the eligibility criteria consent to proceed with

		treatment.
DAHR intervention(s) provided		**Donor Insemination (p. 13)** The use of donor insemination is considered effective in managing fertility problems associated with the following conditions: ▪ obstructive azoospermia ▪ non-obstructive azoospermia ▪ severe oligospermia ▪ infectious disease in the male partner (such as HIV) ▪ severe rhesus isoimmunisation ▪ severe deficits in semen quality in couples who do not wish to undergo intracytoplasmic sperm injection. Donor insemination should also be considered in certain cases where there is a high risk of transmitting a genetic disorder to the offspring. Donor insemination is also used for same sex couples and single patients. Intra-uterine insemination (IUI) is not funded by WHSSC. Funding for IUI is the responsibility of the Health Boards. Where donor sperm is needed to undertake IUI, the donated sperm will be funded by WHSSC, but not the IUI procedure. **Use of Donor Eggs** Egg donation may be offered where no other treatment is available. The patient must be able to identify and provide a donor, either through altruistic egg donation or through an individual agreement (for example, with a friend or relative). WHSSC **will not** fund IVF for patients participating in the egg sharing schemes that may operate within fertility clinics. Egg donation may be available to women who have undergone premature ovarian failure due to an identifiable pathological or iatrogenic cause or to avoid transmission of inherited disorders to a child where the couple meet the other access criteria.
Organisation	***Referral pathways***	**Referral pathways (p.17)** Patients who experience problems with fertility will attend their GP practice to discuss their options. The patients will normally be assessed within primary and secondary care. A woman of reproductive age who has not been conceived after 1 year of unprotected vaginal sexual intercourse, in the absence of any known cause of infertility, should be **referred to secondary care fertility services** for further clinical assessment and investigation along with her partner. Patients with unexplained infertility who have not conceived after two years (this can include up to **one year before** their fertility investigations) should be **referred for IVF treatment.** However there are a number of situations where referral before two years may be appropriate. Where investigations show there is no chance of pregnancy with expectant management and where specialised fertility services are the only effective treatment, refer the patient directly to a specialist team for IVF treatment. This can include: **3.3.2 Pre-disposing factor (p. 18)**

		Where a woman is 36 years or over, or there is a history of predisposing factors or disability (for example, amenorrhoea, oligomenorrhoea, pelvic inflammatory disease or with men undescended testes). In these circumstances earlier investigation should be offered. A decision to refer a patient for specialised fertility services will be based on: ▪ the access criteria contained in this policy and the NICE guidelines which underpin them ▪ individual clinical assessment against clinical guidelines and patient suitability. The **generic referral form**, which assesses the patient's eligibility against the access criteria must be used by the referring clinician and countersigned by the tertiary centre. **Referrers should:** ▪ advise patients of their ability to access treatment under this policy in order that patients can make informed decisions about their options to have a child, ▪ inform the patient that this treatment is not routinely funded outside the criteria in this policy, and ▪ refer via the agreed pathway. **Clinician considering treatment should:** ▪ discuss all the alternative treatment with the patient ▪ advise the patient of any side effect and risks of the potential treatment ▪ inform the patient that treatment is not routinely funded outside of ▪ the criteria in the policy and ▪ confirm that there is contractual agreement with WHSSC for the treatment.
	Service provider characteristic	**Providers** There are three providers of specialist fertility services for Welsh patients. These are: **(p. 18)** ▪ Liverpool Women's NHS Foundation Trust (The Hewitt Centre at the Liverpool Women's Hospital) ▪ The Shrewsbury and Telford Hospital NHS Trust (Shropshire and MidWales Fertility Centre at Shrewsbury Hospital) ▪ Abertawe Bro Morgannwg University Health Board (Wales Fertility Institute at Neath Port Talbot Hospital and Wales Fertility Institute at University Hospital for Wales).
	Timelines to access services	**Waiting time** **First cycle of IVF/ ICSI (p. 9)** Following referral into specialised fertility services patients should be offered an outpatient appointment within the 26-week referral to treatment target. As the normal waiting times targets do not apply to IVF treatment for clinical reasons the referral to treatment clock is stopped at the first attended outpatient consultation. Couples with unexplained infertility will only be listed for IVF, with or without ICSI, treatment if it is demonstrated that the couple has not conceived after two years (this can include up to a one year before their fertility investigations) of regular unprotected sexual intercourse. Couples must have been cohabiting in a stable relationship for a minimum of two years. Same sex couples/single women/single men with unexplained infertility will only be listed for IVF, with or without ICSI, treatment if it is demonstrated that they have not

		conceived following insemination at or just prior to the known time of ovulation on at least six non-stimulated cycles. Patients should be seen in the order they were placed on the waiting list for treatment. However patients can be expedited for treatment if there is clinical justification for doing so. Patients with the following clinical indications may expedited: Endometriosis, tubal disease, male infertility or if the female is over 36 years of age. Clinics should have a robust documented process for expediting treatment. Patients presenting for their first IVF/ICSI cycle must wait for a minimum of twelve months before treatment as many will conceive normally during this period. This is applied by all the Clinics providing a service to Welsh patients. Couples can be expedited before the twelve-month waiting time if there is a clinical justification for doing so. Further information is available to clinics with regards to expediting treatment in the "Guidance for Clinics" document. **Second cycle** Patients presenting for their second cycle will not be treated as a new referral. IVF, with or without ICSI, treatment is specifically excluded from the referral to treatment targets for clinical reasons, however any patient who is seen in clinic and deemed to be suitable for a second IVF cycle will be treated in line with the referral to treatment guidance for planned procedures, that is, a maximum wait of 26 weeks following the new decision to treat being communicated to the patient. These waiting times are applied by all the providers providing a service to Welsh patients.
	Any other organisational aspects	**3.5 Exclusions (p.19)** Patients who do not meet the access criteria are excluded from accessing NHS funded specialist fertility services. Referral under this policy does not cover the following group: ▪ pre-implantation and genetic diagnosis (PGD) – although PGD is not covered within this policy, it is subject to a separate commissioning policy ▪ patients undergoing medical or surgical treatment which may impact on fertility. Access to cryopreservation of eggs, sperms and embryos is subject to a separate commissioning policy.
Donor material management	***Arrangement(s) for attaining donated gametes or embryos***	N/A
	Storage of donated gametes or embryos	N/A
	Access to and or disposal of stored donated gametes or embryos	N/A
	Any other management information	N/A
Governance		N/A
Funding		N/A

Counselling, communication and information provision		**Counselling** The impact of fertility issues and treatment can sometimes be overwhelming. Support from our counsellors at any time throughout your care can be comforting and provide additional support. Counselling is a requirement when having treatment that involves donated sperm or eggs, surrogacy or fertility preservation.
Ethical and social considerations		N/A
Relevant legislation (list and key aspects)		▪ Human Fertilisation and Embryology Act (HFEA) ▪ Equality Impact Assessment (EQIA) - Equality Act 2010.
Miscellaneous		N/A

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