|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Issue of significance** | **Country/ Level** | | | |
|  | ***Pan European*** | ***UK*** | ***Belgium*** | ***Spain*** |
| Number of donors & donor egg cycles | Data collected by ESHRE [1] for 2013 show that 39,000 egg donation treatments were performed in Europe from a total of almost 500,000 IVF cycles. Pregnancy rates were very high at around 50% per treatment, with delivery rates somewhat lower (fresh eggs 33%, frozen embryo transfers 25%, and embryo transfers from frozen eggs 21%). ESHRE data studies [1] have also found that around 50% of all European egg donation treatments are performed in Spain, most in overseas patients. Data from the Spanish national registry for IVF (for 2014) show that 8.5% of all fertility treatments in Spain were in foreign residents, the majority (66%) for egg donation.  Countries with the largest number of facilities in the EU are: Spain (394 ART clinics), Italy (196 tissue establishments in ART), Germany (182 tissue establishments in ART), France (188 tissue establishments in ART)22, and the UK (82 licenses to tissue establishments for oocyte, 119 for sperm, 82 for embryo, and 2 for other activities). | (2013 Figures)  Number of newly registering egg donors 1103; egg sharers 533 (total of 1636)  Number of cycles using donor eggs 1866 (fresh) 747 (frozen); donor embryos 410 (fresh) 283 (frozen) | (2014 figures) 836 cycles | The fertility rate in Spain is 1.32 (vs. 1.58 EU average)391.  As of 2015, Spain had 41 public and 197 private clinics.  According to ESHRE data, the number of fresh and FET cycles performed in 2012 was 31,203 and 11,736 respectively [2].  No number of registered egg donors is available. There is no registry of donors. Egg sharing is not allowed.  Number of cycles using donor eggs:  16630 (Fresh), 6692 (frozen), donor embryos 12541 (Frozen). No fresh donor embryo transfer. Total cycles 116.688.  Infertility treatment services provided in a publically funded setting are fully covered by the Spanish national healthcare system. Couples need to pay for medicines. Medicine reimbursement schemes vary by region (e.g. Cataluña reimburses 25%).  Spain is one of the main destination countries for infertility treatment. |
| Regulatory bodies/ professional guidance | European Commission Directive 2004/23/EC  ESHRE guidelines | Human Embryology Act 1990 (2008)  HFEA Code of Practice (version 8)  BICA Good Practice Guidelines (2012) | Law 1999: regulation of IVF Centres  Law 2003: embryo research  Law 2003: conditions reimbursement laboratory  Law 2006: reimbursement gonadotrophins  Law 2007: law on medically assisted reproduction and the disposition of supernumerary embryos and gametes  Law 2008: inspections reimbursement inseminations tissue and cell directives | Comisión Nacional Reproducción Humana Asistida (CNRHA). Human Assisted Reproduction Bill 2006  Royal Decree 1301/2006  Access to Medically AssistedReproduction (MAR) techniques was first regulated in 1988. At present, “Law 14/2006”394 provides the main legislative framework.  The public health system benefits from a positive reputation. Where infertility is concerned, patient representatives report couples tend to choose private fertility centres over clinics in the public healthcare system due to lengthy wait lists and information gaps. Eligibility for state funded treatment in the public healthcare system is subject to an infertility diagnosis.  There is no state funded campaigns on infertility. Healthcare professional organisations, patient associations and foundations provide information to the public through their websites.  **MAR centres:**  Information platform by Institute for the Study of Infertility  Infertility education blogs by Gestar MAR Group  **Foundations:**  Information portal by Fundació Puigvert  Information portal by Fundación Jímenez Díaz  According to patient organisations, patient groups are not very active in Spain. This is mainly due to the novelty of patient advocacy in Spain, as well as insufficient public funding for patient organisations. There are however two patient organisations that regularly undertake awareness raising activities in the area of infertility, namely the National Association for Infertility Problems and the National Infertility Network Association, which also serves as support group for couples affected by infertility. |
| Kinds of donation permitted | Anonymous or non-anonymous; countries left to decide their own regulations on this  In Germany, egg donation is not allowed, while elsewhere in Europe it is allowed with either donor anonymity (as in France, Greece, Hungary, Italy, Poland, Portugal, Slovenia, and Spain), or non-anonymity (as in Austria, Finland, Netherlands, Sweden and UK). Both anonymous and non-anonymous egg donation are allowed in Belgium.  Italy (May 2014) lifted the ban on the use of donor gametes for reproduction in general. | Anonymous – prior to 2005 [3]  Non- anonymous  Egg –sharing  Known or unknown donors  Treatment that involves replacing the gametes of close relatives who are genetically related is permitted (eg. sister-to-sister egg donation) | Known donation (for the parents), anonymous (for parents and child)  In practice most egg donations are by known persons but that does not mean that the child is informed. There is also the possibility of cross-donation. | Only anonymous donation is permitted. No egg sharing. Anonymous cross-donation is allowed in public hospitals. Direct close relative donation is not allowed. |
| Criteria for egg providers |  | MANDATORY  Donors must be selected on the basis of their age, health and medical history  GUIDANCE  Age: 18 - 36 unless exceptional circumstances which should be recorded [4]  Health – Mandatory screening (see below). Those without risks must be preferred to those known to have abnormality. The Centre should consider family history of heritable disorders; personal history of transmissible infection; implications of donation for donor and their family including any children they have now or may have in the future; implications for DCC.  Identity must be verified. | The donors have to be of legal age. Eggs can be collected up to the age of 45.  In practice, some centres only accept donors from the age of 21. Most maintain an age limit of 35. Between 35 and 38, the recipient will be informed and may refuse the donor. Above 38 only known donors are considered. | MANDATORY  Donors must be selected on the basis of their age, health and medical history. Donors must be between 18 and 35.  GUIDANCE:  There are three different kind of tests performed. Genetic, medical and psychological. Genetic tests are usually limited to karyotype, some clinics offer extra genetic tests, and genetic compatibility test with sperm provider. Medical tests include echography, family history, infectious disorders, and gynecological check. Psychological tests involve personality tests and check of motivation and life habits.  According to patient representatives, there is a gap in accessible information on: the process (from screening and diagnosis to treatment), wait times and services offered (e.g. treatment options have limitations due to donation dependency). |
| Policies around whether providers have a child themselves or not |  | No mandatory or HFEA guidance on this. Note: the majority of newly registered donors in 2013 did not have a child themselves [5]. | No rules exist in this regard. | Donors with proven fertility welcome but no official or mandatory policy on this issue. |
| Compensation | Member States interpretation of what is considered compensation and incentive does vary.  In Europe, most Member States allow compensation for egg donors (Art 12.1 of EU Directive on Tissues and Cells), but the amount is determined solely at national level.  An ESHRE survey [1] of 63 centres performing egg donation in 11 European countries found substantial differences: in France only reimbursement of proven expenses was provided; in Portugal a specific sum of €627 was paid; in the UK a fixed amount of £750 was given to cover any financial losses incurred in connection with the donation; in Spain the fixed amount was generally €900 (with some variability)  EU Member States are bound by the EU Directive for Tissues and Cells (EUTCD), and most have signed up to the Oviedo Convention, which forbids payment for the exchange of human tissues but permits compensation which is strictly limited to making good the expenses and inconveniences related to the donation (EUTCD 2004, article 12.1). | £750 + reasonable expenses (travel, accommodation, childcare)  Benefits in Kind - donors may receive licensed services (IVF treatment, storage – egg banking/freezing, faster access to treatment) in return for donation in the course of a donation cycle | The 2007 law on medically assisted reproduction states that reimbursement of expenses (compensation for transport costs and loss of salary) is allowed. The specific conditions will be fixed in a royal decree (that has never been issued).  According to the ESHRE 2014 study, the amount fluctuates between centres from 500 to 2000€ [1]. | Up to 1000 Euros, settled by the CNRHA.  Some clinics offer a bring-a-donor scheme of 150 euros for each donor that brings another donor. |
| Number of recipients per donor |  | Max of 10 families; six-family alert to other clinics where embryos or gametes should not be used for a new family without authorisation from the primary centre. | There is a maximum of 6 women (no limit on the number of children).  ROPA is frequently performed but presumably these donations are not considered as donations. | The policy is clear: maximum 6 children born for each gamete donor. There is no way to check this figure, though, for no registry exists. |
| ‘Matching’ policies |  | GUIDANCE clinics are not expected to match ethnicity subject to a ‘welfare of the child’ assessment (and if the recipient is agreeable). | Matching is presumably performed but given the shortage of donors, very little matching is possible (apart from ethnic origin). | Matching is left to the medical staff. Clinics use to follow the following criteria: blood group, eye colour, skin colour, hair colour and physical complexion. |
| Consent procedures (including from providers partner) |  | MANDATORY – centre must obtain written and verbal informed consent from egg provider that gametes may be used in the treatment of others incl. on number of families.  GUIDANCE  Before consent donor should be informed of: Screening tests & the possibility it may reveal unsuspected conditions and practical implications of this; scope of genetic testing; importance of informing clinic of any health info that may come to light in the future that could affect the recipient or dcc; details of procedure and risks; legal parenthood; restriction on use of gametes or embryos when number of donor families reaches 10; information that must be collected about the donor and held on the HFEA register; right of HFEA to disclose non- identifying information to prospective recipients; HFEA legal obligation to disclose identifying information to dcc (if donation took place after 2005) aged 18+; importance of this information to dcc and keeping their contact details up to date so they can be informed of such a request; that the donor is liable for passing on inherited conditions they knew about or ‘ought to have reasonably known about’ but failed to disclose; procedure to withdraw consent; non patient donors can withdraw before egg recovery without incurring a fee. Consent must include number of families. Centre not required to obtain consent of the donor’s partner or spouse. However, they should encourage them to seek their partners support for the donation of their gametes.  Donor must consent to clinic to disclose to or approach their GP for health information; failure to consent does not exclude donor. | Centres must obtain informed consent in writing at the start of the cycle. | MANDATORY |
| Health screening | prospective donors are screened from a medical perspective (physical examination, cultures, blood test, blood type, infectious diseases such as HIV, Hepatitis B and C, gonorrhoea and chlamydia), meeting requirements laid down in Directive 2004/23/EC as well as additional national requirements; they get a psychological intake (motivation for donation, lifestyle); and sometimes they are screened for hereditary diseases (for example, cystic fibrosis or blood disorders). | MANDATORY - tests must be carried out by an accredited laboratory  Must be screened for genetic, (for recessive genes known to be prevalent in donors ethnic background); physical and mental disability and infectious diseases and health risks to themselves (e.g. Superovulation, sedation risks or psychological consequences of being a donor) those without these risks must be preferred to those known to have abnormality. | There is nothing in the present laws. Presumably the regulation is indirectly through the 2004 European Cells and Tissues directive [6]. | MANDATORY - tests are usually carried out at the, and by, the centre |
| Requirements for counselling | ESHRE have not issued guidelines in regard to counselling for donors. | MANDATORY - All prospective donors should be given a chance to receive proper counselling.  GUIDANCE -  (i) Providers who request information about DCC should be informed that counselling might be beneficial to them  (ii) If excluded as a donor the clinic must explain why sensitively and offer counselling; for those refused due to a physical or psychological problem they must provide assistance for the individual to seek relevant treatment or counselling  (iii) Written consent is required for eggs to be frozen and stored.  BICA guidelines [7]:  It is expected that a minimum of 2 counselling sessions are made available to people considering egg donation.  Gamete donors should be provided with verbal and written information about the availability of counselling; relevant community and other support organisations; the HFE Act 1990; the existence and purpose of the HFEA Register; their legal status in relation to the child that may be born; the possibility of future changes to legislation; contact details for the HFEA; the information that may be given to recipients, donors and donor conceived people and when it may be received; the legal requirement to offer counselling to donor-conceived people if they request information from the HFEA Register; the Donor-Sibling Register; the possibility and implications of information sharing through online social networking sites in order to identify donors or donor-conceived half- siblings; the recruitment, screening and matching of donors; the posthumous use of sperm, eggs and embryos; the donor’s right to withdraw consent; the Congenital Disabilities (Civil Liability) Act 1976; relevant organisations that offer support; relevant literature. | The fertility centres have a duty to general information provision and a duty to provide the donors with honest information regarding the collection of the gametes and the consequences of their use. | Psychological counselling is strongly advised but it is not mandatory. |
| Conditions that can be placed on a donation |  | Number of families that can receive donor eggs; cannot place conditions that do not comply with Equality Act 2010 (e.g. that discriminate based on age, gender, ethnicity, sexual orientation, religious beliefs); whether frozen and stored eggs the eggs can be donated for someone else’s treatment, or used for research or training - in the case of known donation, the donation is conditional upon it being used by a particular recipient. | Missing information | The law suggests that informed consent should be sought again when frozen eggs may be used for research or training. |
| Information sharing (a) rights of donors to information about donor-conceived children |  | MANDATORY - If requested, centres must provide information on the number of births, sex, year of birth. They cannot find out the identity of any children born, or their parents. | Missing information | Donors have no access to information about donor-conceived children. |
| Information sharing (b) rights of donor-conceived children to information about egg provider |  | From 16+ can request non- identifying biographical information including family history.  From 18+ can request egg providers full name, date of birth, district where born, last known address; the centre should tell donors it will make reasonable efforts to get in touch with them and forewarn them if such a request has been made. | The child has no right to information. | Medical, non-identifying information about donor may be disclosed to recipients and offspring, after they turn 18.  Identity can be disclosed for medical reasons only in the case of life-threatening diseases. |
| Information sharing (c) rights to information about siblings and of DC siblings/other family members to information regarding donation |  | Donor-conceived people can (from the age of 16) ask how many donor-conceived siblings are also recorded on the Register, whether they are boys or girls and the year in which they were born.  Since April 2010, children conceived in licensed UK clinics after August 1991 have been able to register from their 18thbirthday onwards to have contact with half-siblings from the same donor by mutual consent. There is no right to know about children conceived into the family of the donor.  Children in the donor’s family do not have the right to contact children conceived by donation by a parent or parents into another family [8]. | The child has no right to information. | Prohibited under anonymity rule |
| Information sharing (d) information available to prospective recipients about the egg provider |  | GUIDANCE to encourage providers to make available non- identifying biographical information.  When donating, the egg provider will be asked for the following information:   * ethnic group * marital status * the number of children they already have and their gender * physical characteristics * details of screening tests and medical history * a goodwill message to any potential children conceived following donation * a personal description. | Only medical data can be provided to the recipients. | Very limited information is provided. Basically:   * ethnic group * marital status * physical characteristics * a personal description. |
| Information sharing (e) donor health information and who this is shared with |  | GUIDANCE- Donor can decide whether or not they want to find out about unsuspected genetic conditions or carriers of (through the birth of an affected child) and whether or not their GP is informed; donor referred for appropriate medical care and counselling.  The clinic and HFEA have rights to this information and parents of dcc will be notified of the above and offered counselling  The donor has a duty to inform clinic if they find out they are carrier or affected by a previously unsuspected genetic condition (through birth of an affected child) | Information on the health of the donor that can be important for the well-being of the child can be shared with the recipients and with the general practitioner of the parents or the child. | Missing information |
| Registers | Only a few Member States reported having a national register for oocyte donors: Only Slovenia, Bulgaria, Hungary, Portugal, Finland and the UK. | A voluntary register of pre -2005 donors held by the NGDT (?)  Donor Registry **-**since April 2005, identifying information about donors is held on the HFEA Register and may be given to any child born from donation once they are 18 years old.  An anonymised register is held by HFEA and contains information, shown on a treatment cycle basis, such as:   * reasons for infertility * the age of patients at treatment * number of embryos transferred   Donor-conceived people are able to get in touch with others who share the same donor, their genetic siblings, through the Donor Sibling Link (DSL). | No register is foreseen in the current law. | Only clinic-based registry exists, with all information, including personal one. This is part of their donors’ portfolio, but it is not shared outside the clinic.  Access to Medically Assisted Reproduction (MAR) is addressed under the “National Law 14/2006”,413 which evolved from the “National Law 35/1988”414. The law authorises the National Commission for Assisted Human Reproduction415 to provide advice and guidance on the use of MAR. The same law requires establishment of an Official Registry that records donor information, type of donation and MAR centres’ activities. In 1993, the Spanish Society of Fertility, the professional organisation representing fertility healthcare providers, established a parallel official registry416. This registry is now official and mandatory for all MAR centres. It includes information on the activity of MAR centres but not donor information417. All Spanish clinics are required to submit cycle data to  418 the registry . |
| Legal parenthood arrangements |  | When donation and treatment goes through a licensed clinic, by law, the woman having treatment is considered to be the baby’s mother, not the woman who donated the eggs. The donor cannot make a claim for or be responsible for the child.  Couples affected by the parenthood law need to consent to parenthood, prior to treatment being provided, using consent forms at their clinic.  Since 2009 it has been possible for the partner in a same sex couple to be registered as the second parent to a child born from licensed fertility treatment. | The rules of parentage as determined in the Civil Code apply in favour of the intentional parents.  The donor cannot make a claim regarding parental rights and the connected inheritance rights. The same applies to the recipients of the donor gametes. | The baby conceived through egg donation is entirely and irrevocably the recipient’s baby. Paternity is extended to husband automatically. It is also possible for the partner in a same sex couple to be registered as the second parent to a child born from licensed fertility treatment. |
| Import/ export regulations and further information. | The European Union Tissues and Cells Directives (EUTCD) introduced common safety and quality standards for human tissues and cells across the European Union (EU). The purpose of the directives was to facilitate a safer and easier exchange of tissues and cells (including human eggs and sperm) between member states and to improve safety standards for European citizens.  There is hardly any cross-border exchange of oocytes between Member States for reporting countries.  There is hardly any import and export of oocytes or it is very limited for reporting countries.  Possibly it is more feasible for patients and/or oocyte donors to travel than for oocytes to be distributed, or imported.  Information is limited as data are unavailable for a significant number of Member States. For other Member States, data are incomplete and cross-border distribution, import and export is barely specified per country, making it impossible to map flows of gametes. | MANDATORY - transfers of embryos and gametes within the EEA can only be made to clinics that have been “accredited, designated, authorised or licensed” by the EEA state.  Various forms of consent must be obtained, including from the donor who must consent in writing to the import/export of eggs/ embryos.  Only 45 imports were noted in 2013. Russian Federation, Republic of Ireland and USA were the three main importers of eggs into the UK. | Import of gametes is possible from a recognised tissue bank. | Spanish egg banks and clinics are known to provide eggs abroad (to Italy, for instance) and nationwide. The law is unclear about this for it was approved in 2006, when egg freezing was still experimental. |
| Storage – how long, where, notifications? |  | The basic maximum storage period is ten years.  When this period comes to an end, the eggs, sperm or embryos must be allowed to perish unless the extended storage rules apply.  Special rules allow extended storage for people storing eggs, sperm or embryos because they are prematurely infertile.  Storage can be extended in ten-year periods up to an overall maximum of 55 years.  The law says that, at each renewal, the gamete providers must consent to extending the storage, and a doctor must confirm in writing that either gamete provider (or the intended recipient if the gametes/embryos are from a donor) is 'prematurely infertile'. | There is no storage limit for donor gametes. The centre where the gametes are stored decides. | Sperm: until donor is alive.  Eggs: until the donor is still fertile, according to specific medical considerations. |
| Donor follow- up policies |  | Nothing in HFEA Guidance – likely to be a clinic level policy  BICA – aim to provide emotional support before, during and after treatment or donation of gametes and embryos, particularly if the person is experiencing stress, ambivalence or distress. However, no concrete guidelines for follow-up appear to be set out. |  | Routinely, a medical and gynaecological check is provided to donors one week after egg retrieval. During treatment, the clinics provide donors with a 24/7 hotline to call for any sort of problem. |
| Advertising regulations | EC report 2016: Twenty Member States (BE, BG, CY, DE, EL, ES, FR, HR, IE, IT, LT, LU, LV, MT, NL, PL, RO, SE, SI, UK) and Norway confirmed having taken measures to promote VUD of tissues and cells. As set out in article 12(2) of Directive 2004/23/EC, Member States shall take all necessary measures to ensure that any promotion and publicity activities in support of the donation of human tissues and cells comply with the guidelines or legislative provisions laid down at national level. Legal requirements or guidelines concerning posting donation offers (e.g. donation of sperm or oocytes) by individuals in newspapers, social media or other means are in place in seven countries (BE, DE, EL, FR, HR, PL, SI). In Belgium and France, national legislation prohibits any form of advertising on procurement or activities related to human body material. In Croatia, Germany, Greece and Poland, posting such advertisements is illegal and punishable with imprisonment. | GUIDANCE - Should not refer to possibility of financial gain or similar advantage although may refer to compensation; should be written with regard to the sensitive issues involved in recruiting donors. | “in Belgium advertisements are only allowed as part of public awareness campaigns” (EC, 2016)  (i.e centres are not allowed to recruit donors for themselves in the sense that they would mention themselves as the place where a woman can come to donate.) | Advertisement is allowed but compensation cannot be mentioned.  “Spain specified that its national donation system does not allow promotional campaigns for individual patients and that no specific measures to promote VUD were taken in the ART sector.” (EC, 2016) |

[1] ESHRE. Egg donation. <https://www.eshre.eu/Press-Room/Resources.aspx>

[2] ESHRE & Fertility Europe A POLICY AUDIT ON FERTILITY Analysis of 9 EU Countries March 2017https://fertilityeurope.eu/wp-content/uploads/2018/03/EPAF\_FINAL.pdf

[3] Current HFEA guidelines state that anonymous donors should be informed they have the right to re-register as identifiable and this is encouraged

[4] Approximately 10% of newly registered egg donors in the UK were aged 36+ in 2013 (n=171)

[5] In 2013 approx. 60% (n=989) of newly registered egg donors in the UK did not have a child themselves

[6] <https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/economiclandscapes_humantissuescells_en.pdf>

[7] Source: https://www.bica.net/item/1/BICA/Guidelines-for-Good-Practice-in-Fertility-Counselling-4th-Edition-2019.html (this replaced earlier versions)

[8] Source: <https://www.dcnetwork.org/your-childs-rights>

Additional sources  
C. Calhaz-Jorge, C. de Geyter, M.S. Kupka, J. de Mouzon, K. Erb, E. Mocanu, T. Motrenko, G. Scaravelli, C. Wyns, V. Goossens, and The European IVF-monitoring (EIM) Consortium for the European Society of Human Reproduction and Embryology (ESHRE) [Assisted reproductive technology in Europe, 2012: results generated from European registers by ESHRE](http://humrep.oxfordjournals.org/content/31/8/1638.long), First published online: June 19, 2016 Hum. Reprod. (2016) 31 (8): 1638-1652. doi: 10.1093/humrep/dew151

Assisted Reproductive Technology National Summary Report, Belgium 2014. College van Geneesheren Reproductieve Geneeskunde Collège de Médecins Médecine de la Reproduction College of Physicians Reproductive Medicine.[**https://www.belrap.be/Documents/Reports/Global/BelrapSummaryReport2014.pdf**](https://www.belrap.be/Documents/Reports/Global/BelrapSummaryReport2014.pdf)