Table of latest egg donation policies and guidelines

List of policies and guidelines included in table:

ASRM (2013). **Recommendations for gamete and embryo donation: A committee opinion**

ASRM (2014). **Repetitive oocyte donation: A committee opinion**

ASRM (2014). **Informed consent and the use of gametes and embryos for research: a committee opinion**

ASRM (2016). **Financial compensation of oocyte donors: an Ethics Committee opinion**

ASRM (2016). **Defining embryo donation: an Ethics committee opinion**

ASRM (2016). **Oocyte or embryo donation to women of advanced reproductive age: an Ethics Committee opinion**

ASRM (2017). **Using family members as gestational carriers**

ASRM (2018). **Informing offspring of their conception by gamete or embryo donation: an Ethics Committee opinion**

ASRM (2019). **Interests, obligations, and rights in gamete and embryo donation: an Ethics Committee opinion**

ASRM (2019). **Ethics committee updates two opinions (online article)**

Helen Clarke, Shona Harrison, Marta Jansa Perez & Jackson Kirkman-Brown on behalf of the Association of Clinical Embryologists, the Association of Biomedical Andrologists, the British Fertility Society, and the British Andrology Society (2019). **UK guidelines for the medical and laboratory procurement and use of sperm, oocyte and embryo donors**

BICA (2012). **BICA Guidelines for Good Practice in Infertility Counselling. Third edition**

NICE (2013). **Fertility: assessment and treatment for people with fertility problems**

HFEA (2019): **Code of Practice 9th edition**

|  |  |  |
| --- | --- | --- |
| **Organisation / year / authors** | **Title** | **Main points** |
| American Society for Reproductive Medicine (ASRM), (2013) | Recommendations for gamete and embryo donation: A committee opinion | * These guidelines for the screening and testing of gamete and embryo donation apply to potential donors in the US. Because the prevalence of STIs and genetic diseases may vary in other locales, these guidelines may not be appropriate for other countries or individuals who come to the US from other countries. Whereas the FDA does not require screening or testing of the recipients of donated gametes, the ASRM recommends testing of recipients as described (pg 47) * This document provides the latest recommendations for evaluation of potential sperm, oocyte, and embryo donors, incorporating recent information about optimal screening and testing for STIs, genetic diseases and psychological assessments.   **Guidelines for oocyte donation (pg 53)**   * Psychological evaluation and counselling is strongly recommended for the oocyte donor and her partner (if applicable). * If the prospective donor is over 34 years of age, the age of the donor should be revealed to the recipient as part of the informed consent discussion concerning cytogenetic risks and the effect of donor age on pregnancy rates * A complete personal and sexual history should be obtained to exclude as donors individuals who might be at high risk for HIV, STIs or other infections that might be transmissible via gamete donation   **Guidelines for cryopreserved embryo donation (pg 58)**  **Psychological assessment of donors and recipients (pg 60)**  **Psychological guidelines for embryo donation (pg 61)** |
| American Society for Reproductive Medicine (ASRM), (2014) | Repetitive oocyte donation: A committee opinion | * Whereas the recipient derives a clear and tangible benefit from oocyte donation, the donor derives benefit only through a sense of altruism and/or financial compensation for her services. Therefore, the question arises as to whether to limit the number of times that a given oocyte donor might donate her gametes. * Risks of repetitive oocyte donation: inadvertent consanguinity, controlled ovarian stimulation, procedural risks, cancer, future ovarian reserve, psychological risks * Currently, there are no clearly documented long term risks associated with oocyte donation and as such no definitive data upon which to base absolute recommendations. However, because of the possible health risks outlined, it is prudent to limit the number of stimulated cycles for a given oocyte to 6 (pg 2) |
| American Society for Reproductive Medicine, (ASRM), (2014) | Informed consent and the use of  gametes and embryos for research: a  committee opinion | * Research donors (those who donate gametes or embryos specifically for research) should be provided the specific categories of research and disposition of their gametes or embryos before collection (gametes) or creation (embryos) for research and research activities are initiated. As with other research, the informed consent process should address the specific goals, objectives, and procedures of the project. * Donors must be informed that research using donated gametes or embryos may have commercial value and that the act of donation does not confer a right to such commercial value. * Donors of gametes or embryos for research or reproduction should be advised that if genomic sequencing is performed, information about their genetic information might be published, thereby creating the potential that genetic information about them or their close relatives may be linked to their identities or the identities of their relatives. |
| American Society for Reproductive Medicine, (ASRM), (2016) | Financial compensation of oocyte  donors: an Ethics Committee opinion | * Financial compensation of women donating oocytes for infertility therapy or for research is justified on ethical grounds and should acknowledge the time, inconvenience, and discomfort associated with screening, ovarian stimulation, and oocyte retrieval, and not vary according to the planned use of the oocytes, the number or quality of oocytes retrieved, the number or outcome of prior donation cycles, or the donor's ethnic or other personal characteristics * Compensation should be structured to acknowledge the time, inconvenience, and discomfort associated with screening, ovarian stimulation, and oocyte retrieval. Compensation should not vary according to the planned use of the oocytes, the number or quality of oocytes retrieved, the number or outcome of prior donation cycles, or the donor's ethnic or other personal characteristics. * To discourage inappropriate decisions to donate oocytes, programs should adopt effective information disclosure and counseling processes. Donors independently recruited by prospective oocyte recipients or agencies should undergo the same disclosure and counseling process as donors recruited by the program. * Oocyte-sharing programs should formulate and disclose clear policies on the eligibility criteria for participants and on how oocytes will be allocated, especially if a low number of oocytes or oocytes of varying quality are produced. * Treating physicians owe the same duties to oocyte donors as to any other patients. Programs should ensure equitable and fair provision of services to donors. * Programs should adopt and disclose policies regarding coverage of an oocyte donor's medical costs should she experience complications from the procedure (pg e15) |
| American Society for Reproductive Medicine, (ASRM), (2016) | Defining embryo donation: an Ethics committee opinion | * The ethical appropriateness of patients donating embryos to other patients for family building, or for research, is well established and is affirmed by this Committee. The use of the term ‘‘adoption’’ for embryos is inaccurate and should be avoided. * Individuals or couples who seek assistance in forming or procuring embryos for their own reproductive use are entitled to the same procreative privacy that accompanies natural conception. There is no justification for applying the language and components of adoption to patients who already face burdensome medical procedures in the pursuit of their family formation goals |
| American Society for Reproductive Medicine, (ASRM) (2016) | Oocyte or embryo donation to women of advanced reproductive age: an Ethics Committee opinion | * **Abstract:** Advanced reproductive age (ARA) is a risk factor for female infertility, pregnancy loss, fetal anomalies, stillbirth, and obstetric complications. Oocyte donation reverses the age-related decline in implantation and birth rates of women in their 40s and 50s and restores pregnancy potential beyond menopause. However, obstetrical complications in older patients remain high, particularly related to operative delivery and hypertensive and cardiovascular risks. Physicians should perform a thorough medical evaluation designed to assess the physical fitness of a patient for pregnancy before deciding to attempt transfer of embryos to any woman of advanced reproductive age (>45 years). Embryo transfer should be strongly discouraged or denied to women of ARA with underlying conditions that increase or exacerbate obstetrical risks. Because of concerns related to the high-risk nature of pregnancy, as well as longevity, treatment of women over the age of 55 should generally be discouraged. |
| American Society for Reproductive Medicine, (ASRM), (2017) | Using family members as gamete donors or gestational carriers (Ethics Committee) | * The use of adult intrafamilial gamete donors and gestational surrogates is generally ethically acceptable except when such arrangements are consanguineous or simulate incestuous unions. * To enhance the likelihood that familial collaboration will be a positive experience, the involvement of professionals representing multiple disciplines, including physicians, nurses, and counselors, should be anticipated for a thorough assessment. Adequate time is essential to evaluate proposals for these arrangements. Prospective donors or surrogates should have a physician whose responsibility it is to care for them and be their advocate (pg 1140) * All ART programs should develop policies and procedures for dealing with requests for the use of family members as donors or surrogates. Although programs have no obligation to provide such services, the Ethics Committee finds that many intrafamilial reproductive arrangements, including both intragenerational and some intergenerational arrangements, will be ethically acceptable and satisfying, but that others should be rejected on grounds of consanguinity or because of the difficulty in assuring free, informed consent. The most problematic requests are usually a parent requesting the involvement of his or her child in gamete donation or surrogacy. In these cases, and when the assessment reveals consistent concerns about undue pressures on the prospective donor or surrogate, or about unhealthy family dynamics, the program is ethically justified in denying access to these procedures (pg 1141) |
| American Society for Reproductive Medicine, (ASRM) (2018) | Informing offspring of their  conception by gamete or embryo  donation: an Ethics  Committee opinion | * This document discusses the ethical implications of informing offspring about their conception using gamete or embryo donation * Providers, mental health professionals, academics, and donor-conceived persons have called for more openness in donor conception in order to protect the interests of offspring. Because of each person's fundamental interest in knowing their genetic heritage and the importance of their ability to make informed healthcare decisions in the future, the Ethics Committee supports disclosure about the fact of their donor conception to offspring. It also supports the gathering and storage of medical and genetic history information that can be provided to offspring if they request. It recognizes, however, that decisions about disclosure are highly personal and it is the recipient parents' choice whether to disclose the fact of donor conception to their offspring. The Committee encourages ART programs; sperm, oocyte, and embryo banks; and oocyte and embryo donation programs to develop flexible policies to accommodate the varying information-sharing preferences of donors, recipients, and donor-conceived offspring (pg 604) |
| American Society for Reproductive Medicine, (ASRM) (2019) | Interests, obligations, and rights in  gamete and embryo donation:  an Ethics Committee opinion | * Donors should be given clear notice that although they may withdraw from the donation process at any point, they no longer have dispositional control over their donated gametes or embryos once procured unless a valid contract between the parties provides otherwise (pg 664) * Another area of uncertainty relates to the independent interests that donors may have in the treatment process and its outcomes. Whereas some donors may be content with simply providing their gametes or embryos, others may be interested in knowing more personal information about the recipients or the outcome of their donation, including any complications that may arise (1). These interests may conflict with the interests of programs providing clinical services, recipients, and individuals born from donation regarding privacy, autonomy, or information sharing (2). At present, there is little consensus about how best to balance these competing interests. As with many transactions involving health care, much will depend on initial expectations, disclosures, and agreed terms that donors, recipients, and programs set for the relationship. (pg 665)   **Donor preferences to learn the outcome of the donation (pg 668)**   * The donor may have other interests not necessarily covered in the consent process, such as the request to be informed about the outcome of the participation. This could include news about whether a pregnancy resulted and a birth occurred, and whether the baby was born healthy. Arguably, programs are not ethically bound to reveal the outcome because: 1) other kinds of anonymous tissue donation, the donation is made without regard to the outcome; 2) news of a successful pregnancy may unexpectedly cause distress to the donor; 3) news of an unsuccessful pregnancy may cause distress or cause the donor to develop unwarranted fertility concerns that affect her or his own family planning; and 4) the donor's gametes may result in frozen embryos or gametes that may be utilized in a cycle at a time very distant from the original procurement, and the donor may be unprepared to receive this information at a later date or the contact may place an undue burden on the clinic * Nevertheless, because there are no data from studies to support either side of the argument regarding the disclosure or nondisclosure of the outcome of the cycle, it is ethically acceptable for programs not to inform donors whether a pregnancy occurs. * Donors may ask to specify the categories of people to whom their gametes or embryos will be given. For example, a donor may want to donate only to younger-aged couples or to married or same-sex couples. Programs may agree to accommodate requests related to age, marital status, health status, sexual orientation, race, religion, or education. However, programs may also refuse to allow donors to participate if restrictions are demanded. The principal argument for directed donation is that it respects the donor's autonomy and recognizes that the donor has the right to specify the type of person to receive this gift. Donations to designated individuals are acceptable, but a program may decline to participate for good-faith reasons. In some situations, the direction could be contrary to clinic policy … This suggests that it is ethically acceptable to select recipients in anonymous gamete donation without regard to the donor's preferences, and donors should be counseled to this effect. (pg 667) |
| American Society for Reproductive Medicine, (ASRM), (2019) | Ethics Committee Updates Two Opinions (online article) <https://www.asrm.org/news-and-publications/news-and-research/press-releases-and-bulletins/fertility-treatment-when-the-prognosis-is-very-poor-or-futile/> | * The Ethics Committee of the American Society for Reproductive Medicine has updated two of its opinions: “Fertility treatment when the prognosis is very poor or futile” and “Interests, obligations, and rights in gamete and embryo donation.” * The Committee recommends that clinics develop patient-centered policies to protect patients’ interests in doing everything they can to have a child and in making their own decisions, while also facilitating evidence-based assessments to support clinicians’ duty to provide beneficial care. This duty includes a responsibility to refrain from providing treatment which is almost certain to fail. * Patient-centered decision-making means that refusing treatment to protect a fertility center’s success rates is never justifiable, just as providing treatment that will not help the patient, but will result in financial gain for the provider, is never justified. * All decisions to refuse to initiate, or to continue, treatment should be made as part of a shared-decision-making process including physician and patients. This process of shared decision-making calls for the physician to periodically review the treatment plan with the patients. * The Committee finds that donors, recipients and clinic programs have ongoing moral relationships with each other that extend into the future, beyond the time of provision of gametes or embryos. As medical knowledge and technology, social norms, and the legal landscape evolve through the lifetimes of participants and their children, these relationships will likely need to be reevaluated. Clinics should make it clear, at the time of the donation, that promises of anonymity or future contact cannot be assured. * Because the foundational interests of all parties relate to health- physical and psychological- donors and recipients have, at minimum, an obligation to authorize the appropriate disclosure of non-identifying medical information. |
| Helen Clarke, Shona Harrison, Marta Jansa Perez & Jackson Kirkman-Brownon on behalf of the Association of Clinical Embryologists, the Association of Biomedical Andrologists, the British Fertility Society, and the British Andrology Society (2019) | UK guidelines for the medical and laboratory  procurement and use of sperm, oocyte and  embryo donors | * This article updates the 2008 UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors. * Changes with regard to transmissible disease screening include: (i) extended guidance regarding history taking, risk factors and deferral periods; (ii) recommended quarantine period for donors screened by Nucleic Acid Testing (NAT) and serology is now 3 months; (iii) recommended quarantine period for donors screened by serology alone is legally required to be 6 months; (iv) if donor oocytes, or embryos created with donor oocytes, are cryopreserved then the quarantine period should be observed as best practice. We further recommend that consideration be given to HPV vaccination of women who outside of insemination may not be exposed to HPV * **Provides guidelines for information provision to potential donors and recipients (pg 2):**  1. The offspring number created per donor used internationally should be limited to not more than 100 families. Consideration should be given to the arguments of the psychosocial professionals who suggest numbers nearer to 10 (and the UK legal limits) 2. Gamete donation limits should be established in a number of families, rather than in individual offspring, wherever possible. This enables optimal possibilities for parents to have children from the same donor 3. Prospective parents should be provided with clear information on the limits, if any, of families or offspring that may be created by a donor and the duration of time over which donations from a given donor will be offered to others for treatment; gamete banks should be open over their policy in distributing gametes and in counting offspring as they apply in the international sphere. 4. Clinical teams should provide support, guidance and information on the availability and implications of genetic ancestry testing, and the possible inevitability and lack of control over identity that an individual may have if a blood relation undergoes such testing. This applies to donors, recipients and their families.  * Also reviews guidelines on: **initial assessment of donors (age limits, general medical and surgical history), medical assessment, STIs, screening tests for heritable diseases, ongoing monitoring of donation and other health and donation considerations (pg 3-11)** |
| British Infertility Counselling Association (BICA), 2012  Compiled and edited by: Marilyn Crawshaw, Jennie Hunt, Jim Monach & Sheila Pike | BICA Guidelines for  Good Practice in Infertility Counselling. Third edition | **Good quality of care (pg 75)**   * All clients are entitled to good standards of care from their counselling practitioners. This requires counsellors to maintain professional competence, to develop good relationships with clients and colleagues and to uphold professional values and ethics.   **Counselling for infertility and assisted conception (pg 76)**   * Purpose is 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’ * Counselling may be an on-going process and can be continued, or take place for the first time, after a course of treatment has been completed   **Gamete and embryo donation, egg and sperm sharing and surrogacy (pg 77)**   * A referral to the counsellor should be routinely offered, strongly encouraged and people expected to take it up * A minimum of 2 counselling sessions should be made available to people considering involvement in these treatments. * Those involved in donation should be given additional information on:   + the information that may be provided to recipients, donors and donor conceived people and when   + 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.   **Counselling people who travel overseas for treatment (pg 78)**   * Counsellors may be working in licensed centres that have selected carefully the overseas clinics that are recommended to patients on the basis of high standards of care being offered. They may therefore feel assured, or have the opportunity to seek assurance, that the centre provides or has access to the information listed below. Other counsellors may see clients who are travelling independently of licensed centre involvement. * In addition counsellors should encourage clients to reflect on the implications of seeking treatment that is not legal in the UK, for example sex selection for nonmedical reasons or the use of anonymous donors |
| NICE, 2013 | Fertility: assessment and  treatment for people with fertility problems (full guidelines) | **Oocyte donation and egg sharing recommendations**   * Recommendation 190 - 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' (pg 397) * Recommendation 191 - Oocyte donors should be offered information regarding the potential risks of ovarian stimulation and oocyte collection * Recommendation 192 - 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. * Recommendation 193 - All people considering participation in an 'egg-sharing' scheme should be counselled about its particular implication (pg 399) * Research recommendation 38 - Research is needed to evaluate the effectiveness of counselling in relation to oocyte donation and ‘egg sharing’ in terms of the long-term psychological and social implications of these practices (pg. 399) |
| HFEA (2019) | Code of practice (9th edition) | **Counselling and patient support (pg 26)**   * The law requires counselling to be offered when:   + (a) a woman or couple seeks treatment with donated gametes or embryos (including mitochondrial donation)   + (b) an individual or couple seeks treatment that will create embryos in vitro   + (c) an individual or couple seeks to store their gametes or embryos (for exceptions see Schedule 3 of the HFE Act 1990 (as amended), paragraphs 9 or 10)   + (d) an individual or couple seeks to donate their gametes or embryos for the treatment of others (including mitochondrial donation)   + (e) an individual seeks to donate their gametes for use in non-medical fertility services   + (f) an individual or couple seeks to donate their embryos for research purposes or for training people in embryo biopsy, embryo storage or other embryological purposes   + (g) an individual seeks to provide their gametes or cells for the creation of embryos or human admixed embryos for research (for exceptions, see mandatory requirements outlined in guidance note 22 – research and training)   + (h) a woman provides embryos (obtained by lavage) for any purpose   + (i) written notice is served by a man or woman consenting to the man being treated as the legal father or parent of any child born as a result of the woman’s treatment, or   + (j) written notice is served by a woman, or her female partner, consenting to the partner being treated as the legal parent of any child born as a result of the woman’s treatment. * **3.5** The centre should provide proper counselling throughout the treatment, donation or storage processes, and afterwards if requested. Counselling should routinely be offered following adverse events and/or unsuccessful outcomes. If a person who has previously donated gametes or embryos (including mitochondrial donation), or received treatment, requests further counselling at any point, the centre should take all practicable steps to help them obtain it. Group sessions may be offered in addition to individual and couple sessions.   **Information to be provided prior to consent (pg 32)**   * **4.1** Centres must provide information and offer counselling for people about the implications of treatment. Centres should ensure that all patients are prepared for treatment. Preparation for treatment includes the provision of information, the discussion of the implications involved, and the offer of counselling * **4.5** Before treatment is offered, the centre should give the woman seeking treatment and her partner, if applicable, information about:   + (a) the centre’s policy on selecting patients   + (b) the centre’s statutory duty to take account of the welfare of any resulting or affected child   + (c) the expected waiting time for treatment   + (d) fertility treatments available, including any treatment add ons which may be offered and the evidence supporting their use; any information should explain that treatment add ons refers to the technologies and treatments listed on the treatment add ons page of the HFEA website: [www.hfea.gov.uk/treatments/explore-all-treatments/treatment-add-ons/](http://www.hfea.gov.uk/treatments/explore-all-treatments/treatment-add-ons/)   + (e) the availability of facilities for freezing and storing eggs, sperm and embryos   + (f) where patients are freezing and storing eggs, sperm or embryos, the centre should provide information about future use including information about consent to posthumous use and the duration of storage   + (g) the importance of informing the treatment centre about the eventual outcome of the treatment (including if no live birth results)   **Information about the risks of treatment (pg 35)**   * Before treatment is offered, the centre should give the woman seeking treatment and her partner, if applicable, information about: * (a) the potential immediate and longer-term risks of the treatment and any treatment add ons used, including the risks to the patient and the possibility of any children conceived having developmental and birth defects * (b) the nature and potential risks of any alternative treatment options available so the patient can make an informed decision about their treatment * (c) the possibility of developing ovarian hyperstimulation syndrome (OHSS); any information provided should include the possible symptoms of OHSS, what the woman being treated should do and who to contact if experiencing symptoms of OHSS * (d) the nature and potential risks (immediate and longer term) of using emerging or unproven treatments, including reference to the clinic’s experience and wider evidence base * (e) the potential risk of emotional distress associated with negative outcomes both during and after treatment   **Key changes in 9th edition** [**https://www.hfea.gov.uk/media/2609/june-2018-code-of-practice-9th-edition-draft.pdf**](https://www.hfea.gov.uk/media/2609/june-2018-code-of-practice-9th-edition-draft.pdf)**:**  The Code was open for public consultation for six weeks from 23 April 2018. We received 108 responses from a wide range of clinic staff and other stakeholders, ten of which were responses from organisations including the British Fertility Society, British Infertility Counselling Association, Donor Conception Network and Surrogacy UK.  As part of their strategy for 2017-2020, they aimed to improve the emotional experience of care before, during and after treatment or donation.  1.12.  The following areas of guidance are to be introduced or updated in this new edition of the Code of Practice:   * + leadership   + patient support   + information provision to patients   + implications of treatment and consent   + counselling   + extension of storage   + consent   + surrogacy   + screening   + egg sharing   + OHSS   + data protection   + import and export of gametes   + Single European Code   + data submission   + corrections, clarifications and minor amendments minor consent form changes   **Patient support – proposed changes (pg 6)**  As part of our strategy for 2017-2020, we aim to improve the emotional experience of care before,  during and after treatment or donation. Many clinics already do an excellent job in supporting their  patients, but this is not universal. We propose new guidance to help strengthen patient support  from staff at all levels, in every clinic. We hope to raise the standard of patient care by proposing  that all clinics set out a policy outlining how patients, donors and their partners will receive  appropriate psychosocial support from all staff before, during and after treatment. We have also placed more emphasis on patient support throughout the Code.  **Information provision to patients – proposed changes (pg. 7)**   * We want to ensure that patients receive good quality, unbiased information before giving consent to treatment and/or storage, including the same standard of information for emerging or unproven treatment add ons as they are given for established treatments. * During Summer 2017 we ran a patient survey to find out how patients feel about the information they receive before giving consent. We explored the findings from this survey during a clinic workshop held in November 2017.   + We have redrafted our guidance to make the following key changes:   + a new structure to our guidance breaking down requirements into focused subheadings   + explicit requirements for information relating to treatment add ons   + centres to provide information about the effectiveness of treatments and treatment add ons   + encouragement for centres to display their success rates ‘per embryo transferred’ to provide easier comparison to HFEA statistics presented in this format.   **Implications of treatment and consent (pg 8)**   * We revised our guidance to make it clear that discussion of the implications of egg sharing is mandatory as a part of informed consent, including where the offer of counselling has been refused, but we didn’t specify that this discussion needed to be with a counsellor. Our revised surrogacy guidance proposes the same but specifies that the discussion needed to be with a counsellor.   **Egg sharing – proposed changes (pg 15)**   * We have reviewed our guidance on egg sharing to address an overly informal culture in some clinics on the provision of information to patients in relation to donation treatment and the special nature of both egg donation and egg sharing. * When the Code of Practice was updated in April 2017, our guidance on egg sharing was changed to explicitly rule out 'egg giving'. However, the guidance does make a provision for ‘exceptional circumstances’ where deferring treatment to the egg provider is appropriate. We asked our working group and attendees at our regional workshops whether there are enough examples of what could constitute ‘exceptional circumstances’ for this to be useful, or whether it is confusing and could be harmfully misinterpreted. Clinic staff felt that there are no ‘exceptional circumstances’ where the egg provider should donate all the eggs collected in the initial cycle and that where deferring treatment to the egg provider is appropriate, egg or embryo freezing should be offered where possible. In the very rare event that this is not possible, the centre can contact their inspector.   **Consultation responses**   * **11.3** 61% of respondents agreed that this change is a feasible requirement. Some respondents were concerned that patients would be forced to freeze their eggs or embryos when they may prefer to donate all of the eggs collected in that cycle. However, the wording only requires clinics to offer their patients egg or embryo freezing. It is important that this is offered so that egg providers are not made to undergo a subsequent cycle with associated risks. It is also important that clinics discuss all possibilities with the egg provider and ensure they are emotionally supported. Since the consultation, we have updated the guidance so that it no longer refers to deferral of treatment as an ‘exceptional’ circumstance. * **11.4** Inspection findings have suggested that we should introduce guidance on the fair distribution of eggs in an egg sharing arrangement. We have introduced a requirement for centres to distribute eggs evenly between the provider and the recipient(s) and to be clear about who will receive the additional egg if an odd number is collected. 83% of respondents agreed that this is a feasible requirement for clinics. * **11.5** We proposed that, should the gamete provider choose not to have counselling, clinics should record the reason for refusal and discuss the implications of donation with the gamete provider. In addition, separate agreements between the clinic and the gamete provider, and between the clinic and recipient, should confirm that the gamete provider and the recipient have received information about the implications of treatment. Although 64% of respondents agreed that the new guidance would be effective in ensuring prospective gamete providers and recipients in ‘a benefits in kind’ arrangement receive appropriate information prior to consent, some respondents were concerned that, by not mentioning that counsellors are trained to deliver this information, there was a risk that this could be delivered by clinic staff who were not sufficiently knowledgeable or experienced to discuss implications. Since the consultation, we have updated guidance on the discussion of implications to (see section 5 above) to remove the term ‘implications counselling’ and ensure that our guidance in this area is consistent for surrogacy and treatment involving third party donation all types of treatment. * **12.1** Ovarian hyperstimulation syndrome (OHSS) is a potentially serious side effect which can develop in reaction to the drug treatment necessary for IVF. We propose changes to our guidance to support improvements to the prevention, care and follow up of patients affected by OHSS, changes are proposed to. * **12.2** These changes include that all ‘severe’ and ‘critical’ cases of OHSS must be reported to the HFEA, irrespective of whether these involved a hospital admission. This brings our reporting requirements into line with OHSS severity classification set out in the relevant RCOG Green Top Guideline, which doesn’t include hospital admission nor its duration.   **Single European Code (SEC) – new section in 9th edition**   * The EU Commission Directive 2004/23/EC sets out standards of quality and safety for donation, procurement, testing, processing, preservation and distribution of all human tissue and cells intended for human application. It also sets out that, to facilitate traceability, it is necessary to establish a unique identifier applied to tissues and cells (including reproductive cells) distributed in the EU (by way of a Single European Code). The SEC must provide information on the main characteristics and properties of the tissues and cells.   **Corrections, clarifications and minor amendments**   * **17.1** The following corrections and minor clarifications have been made:   • correcting reference in 11.18 of the Code, and 11.34(l) (see Annex J)  • changing the word ‘gender’ to ‘anatomical sex’ in 29.6   * ‘Centres should be aware that for some patients, gender identity and anatomical sex may be distinct and different. Centres treating trans patients or donors with gender dysphoria or gender identity disorder should ensure that they take account of the particular needs of these patients and make appropriate changes to relevant processes and practices to accommodate their needs.’ * **18.2** We are also adding in the guide to consent for the ‘Your consent to donating your sperm’ (MD)   and ‘Your consent to donating your eggs’ (WD) forms that clinics should discuss with donors the  implications of placing a restriction on their donation which might exclude a recipient with a  protected characteristic. |
| European Commission | European Commission Report (2006) on the Regulation of Reproductive Cell Donation in the European Union | The report sets out the principles of donation:  (a) Confidentiality (measures ensuring that all data collated, including genetic information, has been rendered anonymous so that the donor and the recipient are no longer identifiable);  (b) Anonymity (measures regulating the disclosure of the identity of the donor. This could mean either that the donor must by law remain anonymous or, on the contrary, that the donor must by law forego his/her anonymity and  (c) Non-Remuneration for the donation (measures preventing organ trade or trafficking).  For the donation of reproductive cells, some Member States have maximum limits for reimbursement (Spain, UK) while others indicate the range within which compensation can be paid.  The report states that “the importation and exportation of egg cells remains unregulated in the majority of countries” (**pg 5**) |