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AFFILIATED SOCIETY GUIDELINE

UK Guidelines for the Medical and Laboratory Procurement and Use of Sperm, Egg and Embryo Donors (2025): Association of Reproductive and Clinical Scientists, British Fertility Society, British Association for Sexual Health and HIV, British HIV Association**,§

ARCS For the future of Reproductive Science

BFS British Fertility Society

BIOGRAPHY

The Association of Reproductive and Clinical Scientists (ARCS) is the professional body for those working in reproductive science in the UK and worldwide. Founded in 2020 (from BAS, ACE and ABA), ARCS strives to promote high standards of practice and advance the reproductive science profession through training, education and community.

The British Fertility Society (BFS) is a UK-based professional body for those working in fertility care and reproductive medicine. It promotes high standards of practice and advances the field through education, training, research, and collaboration among healthcare professionals.

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** This article, which has not been subject to independent externally peer review by the Editors has undergone stakeholder review and has been approved by the executive Committee/Boards of the Association of Reproductive and Clinical Scientists (ARCS), the British Fertility Society (BFS), the British Association for Sexual Health and HIV (BASHH) and the British HIV Association (BHIVA).

§ This article has been simultaneously co-published, with permission, in Reproductive BioMedicine Online (RBMO) and Human Fertility. The articles are identical except for minor stylistic and spelling differences in keeping with each journal's style. To view the co-published article please follow this link: https://doi.org/10.1080/14647273.2026.2639020

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KEY MESSAGE

These updated UK guidelines for the procurement and use of gamete/embryo donors emphasize accurate information and informed consent for donors and recipients. Minimization of infectious and hereditary risks through detailed history and screening, and risk assessment of known donors/donated embryos, aims to ensure health and long-term welfare for all involved in donor conception.

ABSTRACT

These guidelines replace the previous (2019) UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors and were achieved by a joint working group composed of representatives from the Association of Reproductive and Clinical Scientists (ARCS), the British Fertility Society (BFS), the British Association for Sexual Health and HIV (BASHH) and the British HIV Association (BHIVA), with review and comments from their respective memberships. It was written to guide best practice in clinics but is not intended as a tool to judge the practice of centres within the UK or beyond. Guidance on core information that should be supplied to all parties involved in donation is provided. Screening tests and standards required are summarized, as are specific considerations for known donation and embryo donation. The assessment of genetic risk and heritable disorders has been fundamentally reviewed in light of technological advances. Extended carrier screening is also discussed, although we do not suggest that this is routinely performed.

INTRODUCTION

The 2019 UK guidelines for the Medical and Laboratory Screening of Sperm, Egg and Embryo Donors (*Clarke et al., 2021*), describe best practice requirements for reproductive donation. Since their publication, the landscape of donor-assisted conception has changed markedly in the UK and internationally, as have the frequency and level of risk attributed to various diseases. A cross-organizational working party of the UK professional bodies was therefore formed to review and update the guidelines.

The primary objectives of these guidelines are:

- to guide the provision of factual, scientific and clinical information to donors, recipients and, where relevant, offspring
- to minimize the risk to recipients of donor sperm, eggs and embryos of acquiring an infection from the donor(s)
- to minimize the risk of any donor-conceived offspring being born with an infection or acquiring a serious heritable disorder from the donor(s)
- to ensure that where individuals or couples wish to use known donation, or where couples wish to donate embryos subsequent to their treatment, this is risk assessed and aligned with the principles of these guidelines.

The guidance on donor gamete/embryo procurement and testing is concordant with, and informed by, current guidance from the Human Fertilisation and Embryology Authority (HFEA) Code of Practice (*Human Fertilisation and Embryology Authority, 2023*), the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) Donor Selection Criteria Report (*Advisory Committee on the Safety of Blood, Tissues and Organs, 2017*), the guidelines from the British HIV Association (BHIVA; *Palfreeman et al., 2020*) and British Association for Sexual Health and HIV (BASHH; *British Association for Sexual Health and HIV, 2017*), EU regulation 2024/1938 on standards of quality and safety for Substances of Human Origin (*European Parliament and Council of the European Union, 2004*) and published guidance from the Practice Committee of the American Society for Reproductive Medicine and the Practice Committee for the Society for Assisted Reproductive Technology (*Practice Committee of the American Society for Reproductive and Practice Committee for the Society for Assisted Reproductive Technology, 2024*).

INFORMATION PROVISION TO POTENTIAL DONORS AND RECIPIENTS

Information is key to informed consent. All parties involved should understand the background regulations and legal and clinical guidance regarding the donation and subsequent use of gametes or embryos. Information should be made available to all parties from the outset. The European Society of Human Reproduction and Embryology (ESHRE) 'Good practice recommendations for information provision for those involved in reproductive donation' (*ESHRE Working Group on Reproductive Donation et al., 2022*) should be followed, as should the Association of Reproductive and Clinical Scientists statement relating to information provision (*Association of Reproductive and Clinical Scientists, 2023*).

Key principles include family limit and donor anonymity:

- The UK has a 10-family limit. However, when donor gametes are imported from or exported beyond UK borders, further families may exist or be created according to legislative limits elsewhere. Recommendations from the European 'donor quota' consensus paper (*Janssens et al., 2015*) state that donors used internationally should be limited to no more than 100 families. However, consideration should be given to current debate and the arguments of psychosocial professionals who suggest that total family numbers should be significantly lower. Prospective parents should be made aware of why larger family numbers globally may be undesirable and of the potential for psychological harm from large unmanageable genetic networks (*Indekeu et al., 2022*).
- Gamete donation limits should be established by the number of families, rather than the number of offspring, to enable parents to have more than one child conceived from the same donor. Where parents separate after a live birth, each legal parent from the original donor-conceived family has the right to further treatment with the same donor, and all resulting offspring will be classed as a single family.
- Prospective parents should be provided with clear information on the number 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 disclose their policy in distributing gametes and in counting offspring as they apply in the international sphere.

- Use of donors where information regarding family limits is not transparently available, regulated and accurately recorded should be phased out.

Altruistic donation is anonymous at the time of treatment, although UK law allows for donor-conceived individuals to access identifying information once they reach the age of 18 years. However, the routine availability of affordable DNA ancestry testing has resulted in an unprecedented increase of accessible genetic technology being available to individuals. Direct-to-consumer genetic testing (DTCGT) may be undertaken without counselling, often without consideration for the implication of results, but provides the realistic possibility of identification of donors and donor offspring/siblings outside of regulation and support (*Crawshaw, 2018*; *ESHRE Working Group on Reproductive Donation et al., 2022*). The implications of DTCGT should therefore be clearly explained to all donors and recipients, including possible inadvertent identification of an individual if any blood relation undergoes such testing (*Association of Reproductive and Clinical Scientists, 2023*).

Given the greater potential for the unsupported discovery of being donor conceived, and the considerable upset that this may cause, the implications of DTCGT must be discussed and early parental disclosure encouraged by clinics in accordance with Human Fertilisation and Embryology Act 1990 (Section 13(6C)) and the HFEA Code of Practice, which states 'When people seek treatment using donor gametes or embryos, they must be given information 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.' Resources including those from the HFEA, ESHRE and the ConnecteDNA project (https://sites.manchester.ac.uk/connecte-d-n-a/) provide healthcare professionals with relevant information and recommendations for opening these discussions with prospective patients.

Implications counselling

All donors and recipients should have implications counselling, provided independently and separately from their clinical care team. Specific pre-existing guidelines on the non-medical counselling of donors and recipients are available for counsellors (*Crawshaw et al., 2013*; *ESHRE Working Group on Reproductive Donation et al., 2022*; *Wilde et al., 2014*) and should be considered alongside these guidelines. The purpose of this counselling is not to provide information about donation processes, which all donors and recipients should have already received, but to explore the current and future implications of that situation and ensure truly informed consent.

Notably, unlike other jurisdictions, UK law allows gamete donors to withdraw consent at any time before insemination or embryo transfer. It is important for recipients to be aware that if a donor withdraws consent, any embryos in storage cannot be used in treatment and must be allowed to perish. A one-year cooling-off period applies to frozen embryos after withdrawal of consent, allowing time for counselling and further consideration.

DONOR RECRUITMENT

The following guidance points relate to all forms of gamete and embryo donation, including known donation and surrogacy. Notably, while steps must be taken to minimize the risk to recipients and offspring, there may be scenarios where exceptions can be made for known donors, for example those exceeding age limits. However, when exceptions are made, the recipients(s) should be made aware of any increase in risk to them and/or their offspring and this should be fully documented in their medical notes.

Identification

All donors must provide government-issued photographic ID or an equivalent. A copy should be taken, and the identity of the donor checked at every donation.

Age limits

All donors must be aged 18 years or older. It is recommended that egg donors should be no older than 35 years at the time of donation (up to their 36th birthday). It is well recognized that success rates in IVF decrease with increasing age of the oocyte provider, with the best results obtained for oocyte providers under 35 years of age (*Human Fertilisation and Embryology Authority, 2025*). Oocyte providers older than 34 years have a progressively higher likelihood of multiple chromosomal abnormalities, and a higher risk of a child with genetic abnormality (*Elmerdahl Frederiksen et al., 2024*; *Franasiak et al., 2014*). Increasing maternal age is also associated with increased risk of miscarriage (*Khalil et al., 2013*).

Sperm donors should be no older than 45 years at the time of donation (up to their 46th birthday). Published data suggest a decrease in reproductive success related to sperm provider age beyond 40–50 years (*Horta et al., 2019*; *Martins da Silva and Anderson, 2022*). A systematic review indicated no negative effects from the use of sperm donors up to and including 45 years of age (*Ghuman et al., 2016*). In agreement with this, a substantial perinatal birth cohort study reported increased risks, including higher rates of miscarriage, when paternal age was over 45 years (*du Fosse et al., 2020*; *Khandwala et al., 2018*).

Initial assessment

For efficiency, prospective donors may have an initial assessment of feasibility and compliance with donation guidelines via telephone, e-mail or other means. This could include capturing the age of the potential donor, and a simple medical, personal and family history, with subsequent exclusion of those who do not meet requirements.

Full assessment

Donors must be selected on the basis of their age, health and medical history (HFEA license condition T52). A comprehensive medical, personal and three-generation family history should be taken and checked in person by suitably clinically trained staff (such as healthcare scientists, nurses or doctors), with reference to medical records when required. Attention should be paid to identifying any factor that might increase the risk of transmission of a genetic disorder.

Lifestyle factors that may increase a donor's risk of acquiring, and potentially transmitting, an infection must also be considered (Supplementary Information). There are no widely available tests to detect latent human papillomavirus (HPV) or herpes simplex virus (HSV); therefore all donors should be specifically asked about genital warts or ulcers associated with these infections. Prospective donors with evidence of high-risk behaviour, such as multiple episodes of bacterial sexually transmitted infections (STI), chemsex (sexual activity intentionally under the influence of specific psychoactive drugs used to enhance, disinhibit or prolong sexual experiences) or unprotected sexual intercourse with multiple partners, should not be accepted.

There should also be an assessment of an individual's suitability to donate, including

lifestyle. Recreational drug users and individuals drinking excessive quantities of alcohol should be deferred from altruistic donation. Smoking increases oxidative stress and is associated with DNA damage in both eggs and sperm (*Budani and Tiboni, 2017*; *Du and Tuo, 2023*); given the negative impacts of smoking on reproductive outcomes (*Minguez-Alarcon et al., 2018*, *Zenzes, 2000*, *Kim et al., 2025*), smokers should be deferred from altruistic donation.

Specific risks associated with superovulation and oocyte retrieval should be evaluated for potential egg donors. Contact with a potential donor's general practitioner is strongly advised to obtain an independent assessment of donor suitability. Appropriate consent must be secured prior to contact. When a general practitioner has no knowledge of a donor, the recruiting clinic must consider this in their assessment and determine whether further testing or enquiry is required.

Physical examination

Sperm donors should undergo physical examination by an appropriately trained clinician. This is primarily to detect STI (e.g. urethral discharge) and identify inherited congenital abnormalities (e.g. hypospadias) or evidence of high-risk behaviour (e.g. intravenous drug use). Egg donors should undergo transvaginal ultrasonography to assess ovarian accessibility and morphology and exclude gynaecological conditions that might contraindicate or significantly complicate ovarian stimulation and oocyte collection, including ovarian cysts or large uterine fibroids.

Fertility potential

Gamete donors should not demonstrate any sign of reduced fertility that could be directly attributed to, or suggested by, their gamete quality. Egg donors should have a normal ovarian reserve, indicated by hormonal or ultrasonography findings, and no suspicion of reduced oocyte quality. Sperm donors should have normal semen analysis values in accordance with the latest World Health Organization (WHO) manual, both pre-cryopreservation and post-thawing (*World Health Organization, 2021*). Recipient treatment should not be deliberately escalated based on the quality of donated sperm, for example from intrauterine insemination to intracytoplasmic sperm injection (ICSI). However, it is acceptable to use ICSI for in vitro fertilisation (IVF) patients if the post-thaw sperm parameters do not fulfil the centre's minimal requirements for IVF on the day of treatment.

Infection screening

Donors with an active infection or an infection transmissible by donation should not be accepted. Testing of specimens should be performed by a United Kingdom Accreditation Service (UKAS) or equivalently accredited laboratory (ISO 15189:2022). Assuming that validated screening assays are performed by accredited laboratories, any residual risk of transmission of infection from donor to recipient or offspring arises from gamete or embryo donations being made during the 'window of infection', the time between exposure to an infectious agent and the first point at which the presence of the screening target becomes detectable (*Advisory Committee on the Safety of Blood, 2017*). Screening should be carried out by clinicians with access to genitourinary medicine and virology services where required.

Identification of active infectious disease or evidence of previous infection and seroconversion is likely to require treatment and contact tracing, and individuals should be referred to an appropriate specialist team.

Bacterial infections. To minimize the risk of transmission of bacterial infections all prospective donors should screen negative prior to and following donation. The guidelines in TABLE 1 should be followed according to the HFEA Code of Practice (*Human Fertilisation and Embryology Authority, 2023*), BASHH and BHIVA guidance on STI testing (see their websites) and EU regulation 2024/1938 (*European Parliament and Council of the European Union, 2004*).

- **Syphilis** is caused by infection with *Treponema pallidum*. It is transmitted by direct contact with an infectious lesion during vaginal, anal or oral sex. It can also be transmitted from an infected gestational carrier to the unborn child during pregnancy (vertical transmission), leading to congenital syphilis.
- **Gonorrhoea** is caused by infection with *Neisseria gonorrhoeae*. The primary sites of infection are the mucous membranes of the urethra, endocervix, rectum, pharynx and conjunctiva. Transmission is by direct inoculation of infected secretions through unprotected vaginal, anal or oral sex.
- **Chlamydia** genital infection is caused by *Chlamydia trachomatis*. Infection is primarily through penetrative unprotected sexual intercourse.

A history of chlamydia or gonorrhoea infection is not an exclusion criterion if adequate treatment has been given, the donor does not report any recent high-risk behaviour and they are shown to be negative at the time of donation. However, a deferral period of 3 months after the detection and treatment of an STI is recommended.

TABLE 1 SCREENING GUIDANCE FOR BACTERIAL INFECTIONS FOR SPERM, EGG AND EMBRYO DONORS

Bacteria	*Neisseria gonorrhoeae*	*Chlamydia trachomatis*	*Treponema pallidum* (syphilis)
Testing method	NAAT: first-pass urine or vaginal swab Also: rectal swab for donors who practise anal sex		Serological testing
Testing frequency (sperm)	Two (or fewer) weeks prior to first donation Intermittent testing during donation. Suggested frequency is every 90 days		
Testing frequency (eggs)	Within 30 days prior to egg collection		60 days prior to donation + at start of ovarian stimulation
Quarantine testing (sperm)	90 days after donation (or creation of embryos for surrogacy)		
Quarantine testing (eggs)	90 days after donation No quarantine required if eggs are used fresh to create embryos		

NAAT, nucleic acid amplification testing.

TABLE 2 SCREENING GUIDANCE FOR BLOOD-BORNE VIRAL INFECTIONS FOR SPERM, EGG AND EMBRYO DONORS

Virus	HIV	Hepatitis B	Hepatitis C	HTLV
Testing method	Anti-HIV-I and -II Ab or HIV Ag combination ± HIV RNA PCR (NAAT)	HBsAg + Anti-HBc ± HBV DNA PCR (NAAT)	Anti-HCV IgG ± HCV RNA PCR (NAAT)	Anti-HTLV-I and -II
Testing frequency (sperm)	Prior to first donation Intermittent testing during donation. Suggested frequency is every 90 days			
Testing frequency (eggs)	Start of ovarian stimulation: retest after quarantine No fewer than 90 days prior to donation (serology + NAAT) + at start of ovarian stimulation (serology + NAAT) if eggs are used fresh to create embryos			
Quarantine testing (sperm)	Serology + NAAT: 90 days after last donation Serology only: 180 days after last donation			
Quarantine testing (eggs)	Serology + NAAT: 90 days after egg donation and freeze Serology only: 180 days after egg donation and freeze No quarantine required if eggs are used fresh to create embryos			

Ab, antibody; Ag, antigen; c, core; HBV, hepatitis B; HCV, hepatitis C; HIV, human immunodeficiency virus; HTLV, human T-cell lymphotropic virus; IgG, immunoglobulin G; NAAT, nucleic acid amplification testing; PCR, polymerase chain reaction; s, surface.

Viral infections.

- **HSV** causes cold sores (commonly HSV-1) and genital herpes (commonly HSV-2). Both viruses are common and contagious, and cause lifelong infection that is currently incurable. Due to the perceived high risk of HSV transmission, individuals with a past or present genital HSV infection should not be accepted as donors.
- **HPV** is a known cause of cervical and several other cancers. It is the primary focus of the UK National Health Service Cervical Screening Programme and its prevention is targeted through childhood immunization (implemented in 2008 for girls and expanded to include boys from 2019). Individuals with active genital wart infection are not suitable to donate gametes.

Blood-borne viral infections. To minimize the risk of transmission of blood-borne viral infections all prospective donors should screen negative prior to and after donation. The guidelines in TABLE 2 should be followed according to the HFEA code of practice (*Human Fertilisation and Embryology Authority, 2023*), BASHH (*BASHH, 2017*), BHIVA (*Palfreeman et al., 2020*) and SaBTO (*Advisory Committee on the Safety of Blood, Tissues and Organs, 2017*) guidelines and EU regulation 2024/1938 (*European Parliament and Council of the European Union, 2004*).

- **Hepatitis B** is a small (3200 base pair) DNA virus with a viral envelope. It is carried in blood, semen and body fluids and infects and damages the liver. Infection can be acute (short and severe) or chronic (long term), resulting in a high risk of death from cirrhosis and liver cancer. It is the most widespread form of hepatitis worldwide. Transmission occurs through sexual contact, sharing needles, syringes or other drug-injection equipment, or during pregnancy or delivery.
- **Hepatitis C** virus is a single-stranded RNA virus that is carried in the blood and body fluids, and which infects and damages the liver. The virus can cause both acute (short-term) and chronic (long-term) illness but is now relatively easily treated with a short course of oral therapy, resulting in very high (97%) cure rates.
- **Human immunodeficiency viruses** (HIV) 1 and 2 are retroviruses that cause HIV infection and lead to acquired immunodeficiency syndrome (AIDS) if untreated. In most cases, HIV is an STI and occurs by contact with, or transfer of, blood, pre-ejaculate, semen or vaginal fluid. Non-sexual transmission can occur from an infected pregnant person to their infant through breast milk. An HIV-positive pregnant person can transmit HIV to their baby during both pregnancy and childbirth through exposure to their blood or vaginal fluid as HIV is present as both free virus particles and virus within infected immune cells.
  The human immunodeficiency virus is classified into two main types: HIV-1 and HIV-2. HIV-1 was discovered first and is prevalent worldwide. HIV-2 has a much lower incidence, is mostly confined to West Africa and is rarely encountered in the UK. HIV-1 and HIV-2 share many similarities, although HIV-2 is characterized by lower transmissibility and reduced likelihood of progression to AIDS.
- **Human T-cell lymphotropic viruses** (HTLV) 1 and 2 are retroviruses implicated in several diseases including adult T-cell leukaemia/lymphoma and HTLV-1-associated myelopathy. HTLV-2 is closely related to HTLV-1 and may be linked to cutaneous T-cell lymphoma. HTLV transmission may be from mother to child, predominantly through breastfeeding, but also during pregnancy and birth, as well as unprotected sexual intercourse and blood contact, including the transfusion of infected cellular products or sharing of needles and syringes.

All prospective donors should have no markers of hepatitis B infection (hepatitis B surface antigen, anti-hepatitis B core antigen) and should screen negative for hepatitis C virus, HIV-1 and -2 and HTLV-1 and -2 (*Advisory Committee on the Safety of Blood, Tissue and Organs, 2017*). Screening for HIV infection should include a combined HIV antigen/antibody assay.

Nucleic acid amplification testing (NAAT) detects viral nucleic acid (DNA or RNA) and can quantify viral load. Combining hepatitis B, hepatitis C and HIV serology with NAAT reduces the period during which these infections are undetectable. **A combination of serological testing and NAAT is therefore recommended to maximize the overall sensitivity of the donor testing programme.** If NAAT is

employed, it must be in conjunction with, and not replace, serology testing (*Stramer et al., 2011*).

Cytomegalovirus. In prospective sperm, egg and embryo donors, cytomegalovirus (CMV) antibody screening should be performed using validated enzyme immunoassay tests that detect total CMV antibody (immunoglobulin [Ig] G and IgM). In addition, NAAT for CMV may also be used, if available. Testing should take place prior to and after donation. Given that sperm donation often occurs over several months, sperm donors should, in addition, be tested intermittently during donation (the suggested frequency being every 90 days).
Congenital CMV infection affects 0.5% of live births in high-income settings. Although many infected infants are asymptomatic at birth (*Marsico and Kimberlin, 2017*), the implications can be significant (*Shi et al., 2018*) with lifelong consequences, including sensorineural hearing loss and significant intellectual disability, for up to 1 in 4 children (*Jones et al., 2023*). The risk of infection associated with donor gametes is unknown, but iatrogenic transmission can be avoided by screening gamete donors to exclude those who are infectious (*Griffiths, 2002*). Any individual who tests positive for CMV IgM should defer donation for 12 months. In addition, the following guidance should be followed:

- It is always preferable to recruit CMV (IgG and IgM)-negative donors.
- CMV (IgG)-positive (IgM-negative) donors may be recruited but the use of their gametes/embryos should ideally be limited to CMV-positive recipients. Where a CMV-negative recipient requests a CMV-positive donor, due to phenotype preference or previous use, the recipient should be made aware of, and acknowledge, the associated risks.
- If a donor who is initially seronegative seroconverts during donation, their gametes must not be used for treatment.

Travel-related infections. Details of recent travel should be taken prior to donating and at each donation visit. Depending on the destination and disease risk, it may be necessary to defer donation for a defined period with or without additional testing. Up-to-date guidance on geographical infection risk is provided by the UK Health Security Agency through the National Travel Health Network and Centre and should be consulted when assessing potential travel-related risks (www.travelhealthpro.org.uk/countries). Advice includes the following:

- **Zika virus** is primarily transmitted by the bite of an infected female *Aedes* mosquito. Sexual transmission has also been reported (*Sakkas et al., 2018*). The first symptoms usually develop within 3–12 days, although this can be variable. Zika virus infection during pregnancy is a cause of microcephaly and other congenital abnormalities. Zika infection in pregnancy also increases pregnancy complications such as fetal loss, stillbirth and preterm birth. Individuals travelling to an area with a high or moderate risk of Zika virus transmission should defer donation by 3 months (sperm donation) or 2 months (egg donation) after their return.
- **Ebola virus** causes an acute, serious illness that is often fatal if untreated. Ebola spreads through human-to-human transmission via direct contact (through broken skin or mucous membranes) with the blood, secretions, organs or other bodily fluids of infected people, and with surfaces and materials (e.g. bedding or clothing) contaminated with these fluids. After leaving an affected area at the time of an Ebola outbreak, sperm donors should defer donation for 2 years and egg donors should defer donation for 6 months (*Advisory Committee on Dangerous Pathogens, 2018*). Anyone who has been diagnosed with Ebola in the past should be excluded from donating as it is known that survivors can shed the virus on a longer term basis (*Deen et al., 2017*).

Other travel-related infections relevant to gamete donation, for example mpox, malaria, West Nile virus and *Trypanosoma cruzi*, have not been included in these guidelines. Appropriate advice should be sought alongside a risk-minimization approach. Further information is available from the Joint United Kingdom Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (www.transfusionguidelines.org/dsg/gdri).

Transmissible spongiform encephalopathies. Earlier guidelines included a detailed discussion of the risks of transmissible spongiform encephalopathies such as Creutzfeldt–Jakob disease through sperm, egg and embryo donation. Given the indeterminate risk of transmitting transmissible spongiform encephalopathies through gamete and embryo donation, it is suggested that donors should not be accepted if they have been diagnosed with a prion-related disease or have first-degree family member (s) with this diagnosis, have undergone invasive neurosurgical procedures, or have received human pituitary-derived growth hormone, cornea, sclera or dura mater.

There are currently no agreed means of identifying risk factors or testing potential donors to exclude those at risk of developing variant Creutzfeldt–Jakob disease. Until these are developed it is recommended that the above exclusion criteria are implemented to safeguard against infection.

Severe acute respiratory syndrome coronavirus 2. The coronavirus (COVID-19) pandemic led to a complete cessation of fertility treatments in the UK and major disruption worldwide. In the current post-pandemic situation COVID-19 testing is no longer routinely recommended for individuals who become unwell. However, we recommend that donation should be paused for 28 days in the event of any febrile illness lasting longer than 48 hours.

Infections visible in semen. Infections of the male reproductive tract may be visible in semen, including bacterial rods or cocci, *Trichomonas* and *Schistosoma*. If pathogens are observed in semen, or there are lymphocytes/round cells above WHO normal levels (*WHO, 2021*), donation should be halted while relevant investigations are carried out and only resumed once any infection identified has been treated and has resolved.

Heritable and transmissible non-infectious diseases

A donor should have no significant heritable condition, defined as any genetic condition that has a major adverse effect on the health or life prognosis of the resulting child. When taking a medical history, enquiries should be made to establish that the potential donor does not have:

- any disease with a known or reliably indicated significant genetic component, such as cleft lip or palate, congenital hip dislocation, neural tube defect, congenital heart malformation, clubfoot, hypospadias, debilitating asthma, epileptic disorder, severe hypertension, type 1 diabetes, psychosis, rheumatoid arthritis or a severe

refractive disorder as these have an increased chance of occurring in the offspring of an affected individual
- a significant dominant Mendelian disorder that is, or meets the requirements for, HFEA preimplantation genetic testing (PGT) licensing
- a chromosomal rearrangement that may result in genetic imbalance resulting in congenital anomalies, systemic disorders and/or developmental issues.

Enquiries should also be made to establish that the potential donor's genetic parents, grandparents, siblings and offspring are free of:

- any significant genetic disorder
- non-trivial disorders showing Mendelian inheritance in the following categories:
  - autosomal dominant or X-linked disorders, such as Huntington's disease
  - autosomal recessive diseases, particularly if they have a high frequency in the population, for example cystic fibrosis
- a chromosomal abnormality (unless the donor has a normal karyotype)
- a history of any mitochondrial disorders (egg and embryo donors only).

If there is any evidence of the above, an appropriately qualified clinical geneticist should evaluate the risk, and the donor should be offered relevant screening.

If a potential donor was adopted, does not have medical information about any of their genetic parents or grandparents, or were themselves conceived with donor gametes or embryo, acceptance as a donor is generally not recommended. However, this may be considered on a case-by-case basis, with risk assessment and further screening if required. Full records must be kept of the decision to accept or reject a donor, and recipients must be informed of the implications of proceeding with gametes or embryos from a donor who has a limited family history available.

Screening tests for genetic conditions

All genetic testing should be carried out in a laboratory accredited by UKAS or equivalent for the tests involved. This should be performed in collaboration with clinical genetics and follow the strategy agreed by the UK Genetic Testing Network (http://www.ukgtn.nhs.uk). Adequate pre- and post-test information and genetic counselling must be available.

Karyotyping. All prospective donors should be karyotyped. The frequency of balanced translocations is less than 2 per 1000, and previously unsuspected cytogenetic abnormalities are often detected during the routine screening of egg (*Ravel et al., 2007*) and sperm (*Ravel et al., 2006*) donors. A potential donor found to have a significant chromosomal abnormality or rearrangement should not be accepted for donation.

Single-gene conditions. Testing for all donors should include cystic fibrosis and haemoglobinopathies (alpha- and beta-thalassaemia and sickle cell disease). Genetic testing for glucose-6-phosphate dehydrogenase deficiency should be considered in Mediterranean populations. Genetic testing for Tay–Sachs disease should be undertaken in (Ashkenazi) Jews of Eastern European descent.

Ordinarily, a donor should not be heterozygous for an autosomal recessive gene. However, a recessive gene disorder is not an absolute contraindication to donation provided that recipient(s) are tested to exclude the possibility of the recessive disorder in any offspring, have undertaken genetic counselling and are fully informed of and consent to the risks associated with proceeding with treatment. Support of an appropriately qualified clinical geneticist should be obtained, and full records kept.

Extended carrier screening. Extended carrier screening (ECS) is often performed on donors, especially those imported into the UK from commercial sperm and egg banks (*Elson et al., 2024*). ECS is intended to identify a range of genetic conditions, specifically recessive and X-linked disorders, to reduce the risk of passing on inherited disorders to the offspring and thus requires recipient testing for donor matching. However, ECS can lead to difficult decision making, a potential overemphasis on rare conditions and the exclusion of otherwise healthy donors based on uncertain or poorly understood genetic findings. As such, ECS is not currently recommended.

Where ECS of a donor has occurred, recipient screening for identified recessive disorder(s) may be offered using a UKAS or equivalently ISO-accredited laboratory, where this is supported by appropriate genetic counselling and informed consent.

Blood group and Rhesus antigen testing

Blood group testing/matching is not necessary for routine donation. However, the use of donor gametes and embryos creates the potential for Rhesus incompatibility. Rhesus D-negative pregnant mothers who are not known to be already sensitized to the Rhesus D antigen should be managed following the National Institute for Health and Care Excellence guidelines (*National Institute for Health and Care Excellence, 2008*) with routine antenatal anti-D prophylaxis.

ASSESSMENT DURING DONATION

At the time of each donation, donors should be asked to confirm their contact details. They should also be asked to report any changes in personal or family medical history since their last visit, including medication and immunizations, as well as potential infection risks (e.g. acupuncture, botox, colonic irrigation, tattoo, piercing or needlestick/sharps injury), travel history and sexual history, specifically whether they have had unprotected sexual intercourse and/or anal sex with a new/casual partner or been treated for any STI since their last visit. Donors must be instructed to declare if they experience any clinical sign(s) of STI at any time during the donation period, in which case further donation should be halted, STI screening undertaken and advice sought from a genitourinary medicine specialist.

QUARANTINE

Donated gametes/embryos should be cryopreserved and quarantined before use in treatment. The length of quarantine is determined by the testing method (serological with or without NAAT) and the infection window period (**TABLES 1** and **2**). The minimum quarantine period for combined serology and NAAT is 90 days. If NAAT is not available, serology testing alone can be used but a longer quarantine period (180 days) must be observed. In the UK, availability of HIV-2 RNA testing is limited to a few laboratories. The diagnosis of acute primary HIV-2 infection can only be made on the basis of HIV-2 antibody seroconversion. Serology alone is adequate to allow release from quarantine at 90 days, even with third-generation testing (*British HIV Association, 2021*).

Quarantine should be followed where donor eggs are cryopreserved for egg banks as this is best practice. However, it is acknowledged that donor eggs may be used fresh to create embryos for immediate use in treatment and/or cryostorage. In such cases the quarantine period may be waived if combined serology and NAAT is carried out a minimum 3 months (90 days) prior to donation and again at the time of egg donation (with negative results available prior to embryo transfer), and all other screening conditions are met (see TABLES 1 and 2).

RELEASE OF DONOR MATERIAL

A medical practitioner must take final responsibility for the release of donor gametes/embryos for treatment. Where gametes/embryos are imported from other centres, the treating clinic should take responsibility to ensure that these guidelines are followed as well as the legal requirements included in the HFEA Code of Practice (*Human Fertilisation and Embryology Authority, 2023*).

KNOWN DONATION

Although these guidelines and recommendations are expected to be applied in full to altruistic donation, they are primarily intended to guide clinics rather than to be used as a tool to judge the practice of centres within the UK or beyond. Notably, in cases of known donation, embryo donation and surrogacy there is greater tolerance of deviation from certain recommendations, such as donor age. Nonetheless all reasonable steps must be taken to minimize the risk of transmissible or heritable disease(s) being passed to the recipient or to donor-conceived offspring. Any relevant concerns should be raised and be transparent to all involved. Recipient(s) should be fully informed of any information of note relating to either the donor or their family and anything that may impinge upon the welfare or health of their child, or upon the chances of a successful outcome and healthy live birth.

HIV status in known donation

Gamete donation from people with HIV to a known recipient is permitted in the UK, subject to antiretroviral treatment for at least 6 months prior to donation and a sustained undetectable viral load. The recipient must be aware of their known donor's HIV diagnosis and provide informed consent (*Advisory Committee on the Safety of Blood, Tissues and Organs, 2023*).

EMBRYO DONATION

It is recognized that donor embryos surplus to patients' own requirements are a limited resource and that clinics may consider their use to constitute 'exceptional circumstances'. However, clinics are expected to scrutinize and screen the egg and sperm providers of donor embryos following these guidelines wherever possible. For example, donated embryos may not satisfy all donor gamete screening requirements prior to their creation. All reasonable steps must be taken to minimize the risk of transmissible disease to the recipients and offspring, including carrying out the appropriate post-quarantine screening. It is also recognized that many embryos will have been created with sperm that were not evaluated or exposed to the rigorous selection processes, such as freeze-thaw survival, required of sperm donors. Nevertheless, caution should be applied to the donation of embryos created following ICSI for male subfertility. Due to a higher risk of genetic abnormality, donation is not advised where there is severe male factor infertility (<5 million/ml) (*Dohle et al., 2002*) or surgical sperm retrieval has been undertaken for non-obstructive azoospermia.

The age of each gamete donor at the time of embryo creation should be documented and considered, as it may influence embryo quality and reproductive outcomes. When using embryos created with gametes from donors who exceed the recommended age range, particularly older egg donors, clinical risk assessment should be undertaken. This may include a consideration of PGT for aneuploidies.

In the event that embryos are donated in the absence of full compliance with the guidelines for the screening of gamete donors, prospective recipients should be appropriately counselled before consent to their use regarding the decreased chances of live birth and any increased risk to them or their donor-conceived offspring. The reasons for using embryos donated without full compliance with these guidelines should be recorded in the recipients' medical notes.

INTRA-RELATIONSHIP DONATION/SHARED MOTHERHOOD

Shared motherhood is a scenario where one partner provides eggs to be used with donated sperm to create embryos for transfer into their partner. This is no longer considered as gamete donation and therefore there is no need to screen the egg provider as an egg donor.

ONGOING MONITORING OF DONATION

Clinic staff should monitor the use and clinical outcomes of gamete/embryo donation. Use of specific donors should be discontinued if success rates are below reasonable expectations and/or unsuccessful in generating live births. The use of donor gametes should be suspended if any adverse outcomes are reported in donor-conceived offspring until these have been adequately investigated. If a genetic condition is diagnosed in a donor-conceived child, both donor and donated sperm should, if possible, be tested for the genetic condition because of the risk of germline mosaicism (*Chalas et al., 2020*; *Ejerskov et al., 2016*). Importing gametes (or embryos) from other centres does not exempt a clinic from monitoring treatment outcomes. It is also expected that adverse events related to imports are reported to the distributing centre.

Donors should be actively encouraged to keep their contact information updated. Donors should be made aware that, if their contact information is incorrect, the HFEA may release their identifying data to donor-conceived offspring without them having been informed in advance. If possible, clinic staff should take consent to trace and contact donors using alternative clinical systems if they are lost to follow-up. Clinic staff must also stress to donors the importance of updating the centre regarding any new diagnosis affecting the donor or a first-degree relative that could have medical relevance for donor-conceived offspring.

DATA AVAILABILITY

No data was used for the research described in the article.

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AUTHOR CONTRIBUTIONS

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SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.rbmo.2026.105524.

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