


18. Witnessing and assuring patient and donor identification

This guidance note contains:

Mandatory requirements

- Extracts from licence conditions

 Refer to principles 7, 8, 9 and 10

HFEA guidance

- Witnessing clinical and laboratory procedures
- Keeping a record of witnessing
- Witnessing training
- Appropriate person to witness
- Interruptions and distractions in the clinic and laboratory
- Patient and donor identification
- Risk assessment
- Risk assessment: electronic witnessing systems
- Risk assessment: barcoding
- Risk assessment: radio frequency identification systems



Mandatory requirements

Licence conditions

- T71 Centres must have in place robust and effective processes to ensure that no mismatches of gametes or embryos or identification errors occur. Centres must double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process. These checks must be completed and recorded at the time the relevant clinical or laboratory process/procedure takes place. A record must be kept in each patient's/donor's medical record.



HFEA guidance

Witnessing clinical and laboratory procedures

- 18.1** Witnessing protocols should ensure that every sample of gametes or embryos can be identified at all stages of the laboratory and treatment process to prevent any mismatches of gametes or embryos.
- 18.2** Centres should have witnessing protocols relevant to their local systems and conditions, based on HFEA model protocols. Where appropriate, clinics may adapt HFEA model protocols to take into account their local systems.

See also:

- **Relevant HFEA model protocols at:**
www.hfea.gov.uk/docs/witnessing-protocols.pdf

- 18.3** Electronic systems such as barcoding and radio frequency identification (RFID) for assisted conception are appropriate, subject to a risk assessment as set out at 18.31–18.38.



18.4 Witnessing protocols should be followed when any of the following clinical or laboratory procedures take place:

(a) Collecting eggs

- Cross-check identifying information that the egg provider gives against records and laboratory data sheets, or cross-check information entered into the electronic system and the allocation of the barcode or RFID tag.
- Cross-check information marked on egg collection dishes and lids against the patient's medical records. This step does not need to be manually witnessed if an electronic system (barcoding or RFID) is being used.

(b) Collecting sperm

- Cross-check identifying information that the sperm provider gives against records, the laboratory data sheet and sperm receptacle, or cross-check information entered into the system and the allocation of the barcode or RFID tag.

(c) Preparing sperm

- Cross-check information on tubes against the documents and information on the sperm receptacle (when the sperm sample is transferred onto a preparation column). This step does not need to be manually witnessed if an electronic system (barcoding or RFID) is being used.

(d) Mixing sperm and eggs or injecting sperm into eggs

- Verify identifying information on the dishes and tubes and confirm that the sperm and eggs should be mixed or the sperm injected into eggs.

(e) Transferring gametes or embryos between tubes or dishes

- Cross-check information marked on dishes and tubes against the patient's or donor's records, and the information marked on the dishes and tubes that the gametes or embryos are being transferred from.

(f) Transferring embryos into a woman

- Cross-check identifying information that the patient provides against the patient's medical records or the electronic system (or both) and the laboratory data sheet, and confirm that these are the correct embryos to transfer.

(g) Inseminating a woman with sperm prepared in the laboratory

- Cross-check identifying information that the patient provides against the patient's medical records, or cross-check information entered into the electronic system and the allocation of a barcode or RFID tag.
- Verify the sperm provider's identifying information in their records, the electronic system and on the sperm container, and confirm that this is the correct sperm provider.

(h) Placing gametes or embryos into cryopreservation

- Cross-check identifying information on the storage container against the patient's or donor's records and the information on the tube or dish that the gametes or embryos are being transferred from.
- Cross-check where in the dewar the gametes or embryos are placed.

(i) Removing gametes or embryos from cryopreservation

- Cross-check information on the storage container against information in the patient or donor records to confirm they are the correct gametes or embryos to remove.
- Cross-check information from the storage container and the patient or donor records or their information on the electronic system against the thaw dish or tube (and, if applicable, attach a barcode or RFID tag to the thaw dish or tube).



18.4 (cont)

(j) Disposing of gametes or embryos

- Cross-check information on the storage container against information in the patient or donor records to confirm they are the correct gametes or embryos to dispose of.

(k) Transporting gametes or embryos

- Cross-check information on the storage container against information in the patient's medical records to check that these are the correct gametes or embryos to transport.
- Check that information on the storage container is correct.

18.5 Each stage of the witnessing trail should check the patient's or donor's full name and their unique identifying code. Whenever it is not possible to label the dishes or tubes with the donor's name:

- (a) the donor code should uniquely identify that donor, and
- (b) the dishes or tubes should be labelled with the female patient's name and unique identifying code as soon as possible.

Keeping a record of witnessing

18.6 The checking of identifying samples, patients and donors, and the witnessing of these checks, should be recorded when the clinical and laboratory procedures take place. This means that embryologists performing procedures that need to be witnessed cannot work alone. This will ensure that the witnessing protocol has the maximum potential to identify errors in the treatment process at the time the procedures take place.

18.7 When the procedure takes place, a record should be made in the patient or donor notes stating:

- (a) the procedure
- (b) the date and time of the procedure
- (c) the signature of the person doing the procedure, and
- (d) the signature of the witness.

A hard copy of electronic witnessing should be retained.

18.8 There should be a separate record of the name, job title and signature of everyone who carries out or witnesses laboratory and clinical procedures.

Witnessing training

18.9 Centres should have an induction programme for new staff to ensure they understand the principles of witnessing and follow the centre's protocols.

18.10 Staff should receive appropriate training if a new system for witnessing is introduced.

See also guidance note:

- [2 – Staff](#)

Appropriate person to witness

18.11 Centres should consider who is the most appropriate person to witness clinical and laboratory procedures. This will usually be someone who has completed the centre's training programme for new staff, and refresher training (as appropriate), to ensure they fully understand the principles of witnessing procedures and follow the centre's protocols. For exceptions to this, refer to paragraphs 18.13 and 18.14.

18.12 At egg collection and embryo transfer, the appropriate person to witness is another embryologist, clinician or nurse.



- 18.13** At sperm collection, centres may consider the patient or donor to be the appropriate person to witness the cross-checking of their identifying information against their records, the laboratory data sheet and the sperm receptacle.
- 18.14** Insemination centres performing intrauterine insemination (IUI) with partner sperm may consider the patient to be the appropriate person to verify the sperm provider's details.

Interruptions and distractions in the clinic and laboratory

- 18.15** The centre should consider the implications of distractions in the clinic and laboratory, such as from phones and external noise, and ensure they are minimised.
- 18.16** When considering the protocol it uses for witnessing procedures, and the most appropriate person to witness checks, the centre may wish to take into account the implications of interruptions to the work of laboratory and clinical staff, particularly embryologists performing critical procedures. Interrupting and returning to a task is a common source of human error.

Patient and donor identification

- 18.17** Centres should establish procedures to ensure patients, donors, and their gametes and embryos are accurately identified.
- At the assessment stage, centres should use appropriate evidence to verify the identity of donors and self-referred patients seeking treatment (eg, passport or photocard driving licence).
- 18.18** When collecting eggs or sperm, transferring embryos and carrying out insemination, staff should ask patients and donors to give their own identifying information (full name and date of birth), rather than asking the donor or patient to confirm or reject information read out to them.
- 18.19** Centres should consider how patients and donors with disabilities or whose first language is not English will be asked to identify themselves. If possible, centres should provide an independent interpreter for patients and donors whose first language is not English.
- 18.20** All samples of gametes and embryos should be labelled with at least the patient's or donor's full name and a unique identifier. If at some stages (eg, labelling donor sperm) it is not possible to label the dishes or tubes with the donor name:
- the donor code should uniquely identify that donor, and
 - the dishes or tubes should be labelled with the female patient's name and unique identifier as soon as possible.
- 18.21** Centres should allocate a unique identifier to each sample of gametes or embryos to ensure it can be accurately identified at all stages of the laboratory and treatment process. This identifier could, for example, comprise two or more of the following:
- the patient's or donor's date of birth
 - hospital number
 - NHS number/CHI (Community Health Index) number, or
 - a donor code.
- 18.22** Centres should consider the most appropriate way to label dishes or tubes when they are likely to be seen by the patient.
- 18.23** Centres should consider when to change the labelling from showing the donor's or male partner's identifying information to the female patient's identifying information. Centres may consider it appropriate to label all dishes and tubes with both partners' names and identifying codes throughout.



18.24 Centres should ensure that other patients' or donors' gametes or embryos are not introduced into the critical working area until the procedure is complete. In particular, during sperm preparation, no more than one sample should be processed in the critical working area at any one time. However, it is acceptable for centres to cryopreserve gametes or embryos from more than one patient at one time, provided that procedures are in place to keep the samples separate.

See also guidance note:

- [19 – Traceability](#)

Risk assessment

- 18.25** Centres should do a risk assessment before introducing or changing witnessing protocols. Centres should consider integrating protocols into the whole laboratory and clinical process and risk-reduction procedures. Centres may wish to identify and specify key points when mismatching of gametes and embryos is most likely to occur.
- 18.26** Centres should be aware of the risks associated with staff doing repetitive activities. The risk of mismatching gametes and embryos is higher when repetitive activities are taking place. Centres should bear this in mind when selecting the most appropriate person to witness procedures. Similarly, when using witnesses, centres should consider staff workload and hours, and should ensure staff take regular breaks.
- 18.27** Centres should have formal risk control measures to minimise the risk of writing incorrect or incomplete identifying data on patient's medical records. There is a risk of error when copying details from sample containers and patient's records to other records. The risk is particularly high when a record sheet becomes separated from the patient's records and is relied on during a witnessed step.
- 18.28** As part of a quality review, audits of the patient's medical records should include checking for transcription errors (or omissions) in patient identifiers, such as the misspelling of names and the absence of unique identifiers on a record sheet, particularly in laboratory records.
- 18.29** Centres should check their compliance with witnessing protocols regularly, including during the audit of their quality management system.
- 18.30** As part of their risk assessment for sperm preparation, centres may consider witnessing the cross-checking of information on tubes only at the start and end of the procedure, not at every stage in it.

See also guidance note:

- [23 – The quality management system](#)

Risk assessment: electronic witnessing systems

- 18.31** Before introducing new electronic systems or protocols for witnessing, centres should do a risk assessment covering the following:
- Centres should ensure that any system will not harm gametes and embryos. In establishing that this is the case, centres should consider what the supplier or manufacturer has done to satisfy itself that the system will not harm gametes and embryos (eg, commissioned independent reports or carried out irradiance readings).
 - Centres should be aware that the reliability and safety of different electronic systems may vary.
 - Centres should evaluate the evidence that the supplier or manufacturer provides to support the safety and reliability of its system (eg, false positive and negative matches and breakdown), plus any other relevant studies.



18.31 (cont)

- (d) Any software should be fully tested, quality assured and risk assessed.
- (e) Centres should consider what the manufacturer has done to ensure that any labels and tags will continue to be effective when placed in long-term cryostorage.

18.32 Centres should be aware that although they cannot completely eliminate the potential for human error in any electronic witnessing system, effective risk assessment should mitigate this.

18.33 If centres use an electronic system (barcode or RFID) with 'forcing functions' (which prevent the user omitting key matching tasks in the process by preventing them from proceeding with subsequent task steps), then as part of their risk assessment they may wish to consider that manually witnessing transfer steps are not necessary. This exemption should not apply however to mixing sperm and eggs; injecting sperm into eggs; and placing eggs and sperm into and removing them from cryopreservation.

18.34 Centres should consider any potential loopholes in the system that could allow users to circumvent key steps, thus negating safeguards against error. Centres should consider implementing a system that allocates a unique identifier to each system user.

18.35 Centres should not rely solely on electronic systems to check the identity of patients, donors and samples. Centres should follow protocols for witnessing in line with HFEA model protocols; these include several manual witnessing steps.

18.36 Centres should have procedures to ensure that all witnessing steps can still be done if the electronic system fails, and that witnessing staff maintain their manual witnessing skills for all critical steps.

18.37 In addition to using the electronic system of identification (information stored on barcodes or RFID tags), centres should continue to manually label all culture dishes, tubes, lids and straws with the patient's full name and unique identifier. If the electronic identification fails (for example losing a barcode label or RFID tag from a sample), centres should revert to manual identification.

18.38 Centres should consider whether the barcode or RFID tags are suitable for use on storage containers (ie, are able to withstand long periods of cryopreservation).

Risk assessment: barcoding

18.39 Centres considering installing a barcode system should consider as part of their risk assessment:

- (a) the type and power of light used in the barcode equipment
- (b) the length of time the gametes and embryos are likely to be exposed to it, and
- (c) whether exposure to this light is likely to harm the gametes and embryos.

18.40 Although there is substantial evidence about using barcodes with human tissue, as far as the HFEA is aware no independent studies have yet been done on the effect of light on human gametes and embryos. So the HFEA does not have enough evidence to consider barcoding to be risk free.

18.41 Barcoding equipment may use a range of light sources. The HFEA is aware of two types of barcoding systems marketed for use in assisted conception: those using white-light-emitting diodes and those using laser light.

18.42 Considering the evidence of damage to human cells from some powers of laser light, centres must weigh up the degree of possible risk of using laser light barcoding systems. Centres should only consider using class 1 or 2 lasers.

18.43 Barcode equipment that uses ultraviolet or infrared light should not be used. These sources of radiation are known to heat, and so potentially damage human cells.



Risk assessment: radio frequency identification systems

- 18.44** Centres considering installing an RFID system should, as part of their risk assessment, consider the frequency of the radio waves used in the RFID system and whether exposure to them is likely to harm gametes and embryos. Centres should be aware that detectable changes in temperature may result in DNA damage. Centres should do this risk assessment in the context of other risk factors in the centre and the environment (eg, mobile phone signals).
- 18.45** Although there is evidence for the use of RFID in a medical setting, as far as the HFEA is aware no independent studies have yet been done on the effect of electromagnetic radiation on human gametes and embryos. So there is not yet a compelling evidence base to enable the HFEA to consider RFID systems to be risk free.

