

## **STANDARD: WITNESSING THE IDENTIFICATION OF SAMPLES AND PATIENTS/DONORS**

Centres shall have witnessing protocols in place to 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 shall be completed and recorded at the time the clinical or laboratory process/procedure takes place.

Witnessing protocols shall ensure that every sample of gametes or embryos can be identified at all stages of the laboratory and treatment process in order to prevent mismatches of gametes or embryos at any point of the laboratory or treatment process.

Use of electronic systems (such as bar coding and radio frequency identification) shall be suitable for use in the context of assisted conception.

## **GUIDANCE ON WITNESSING THE IDENTIFICATION OF SAMPLES AND PATIENTS/DONORS**

### **13.1 GENERAL**

13.1.1 Centres should have witnessing protocols in place to double check the identification of samples and the patients or donors to whom they relate, at the time each of the following clinical or laboratory procedure take place, in line with guidance in this section and HFEA model protocols:

a) egg collection:

- cross checking of identifying information provided by the egg provider against records and laboratory data sheet or cross checking of information entered into electronic system and allocation of barcode/RFID tag
- cross checking of information marked on egg collection dishes and lids against patient documentation\*

b) sperm collection:

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\* this step does not need to be manually witnessed if an electronic system (bar coding or RFID) is used for witnessing; \*\*as part of their risk assessment centres may consider that witnessing these steps is not necessary (for example if the system has forcing functions)

- cross checking of identifying information provided by the sperm provider against records, laboratory data sheet and sperm receptacle or cross checking of information entered into system and allocation of barcode/RFID tag

c) sperm preparation:

- cross checking of information on tubes to documentation and information on sperm receptacle(i.e. at the time the sperm sample is transferred onto a preparation column) \*

d) mixing sperm and eggs or injecting sperm into eggs:

- verification of identifying information on the dishes and tubes and confirmation that the sperm and eggs should be mixed/sperm should be injected into eggs

e) transfer of gametes or embryos between tubes/dishes:

- cross checking of information marked on dishes and tubes to the patient's/donor's documentation and information marked on dishes and tubes which the gametes or embryos are being transferred from\*\*

f) transfer of embryos into a woman:

- cross checking of identifying information provided by the patient against patient records/electronic system and laboratory data sheet and confirmation that these are the correct embryos to transfer

g) insemination of a woman with sperm prepared in the laboratory:

- cross checking of identifying information provided by the patient against patient records or cross checking of information entered into system and allocation of barcode/RFID tag
- verify the sperm provider's identifying information in the sperm provider's documentation/electronic system and on the sperm container and confirm that this is the correct sperm provider

h) placing gametes or embryos into cryopreservation:

- cross checking of identifying information on the storage container to the patient's/donor's documentation and information on the tube/dish which the gametes/embryos are being transferred from
- the location which the gametes or embryos are placed in the dewar

i) removal of gametes or embryos from cryopreservation:

- cross checking information on the storage container against information in the patient/donor records to confirm they are the correct gametes or embryos to remove
- cross referring information from the storage container and patient/donor documentation/information on the electronic system to the thaw dish/tube (and if applicable attaching a bar code/RFID tag to the thaw dish/tube)

j) disposal of gametes or embryos:

- cross checking information on the storage container against information in the patient/donor records to confirm they are the correct gametes or embryos to dispose

k) transporting gametes or embryos:

- cross checking information on the storage container against information in the patient records to check that these are the correct gametes or embryos to transport
- check that information on the storage container is correct

13.1.2 Each stage of the witnessing trail should check the patient's/donor's full name and a unique identifier. If at some stages (e.g. labelling donor sperm) it is not possible to label the dishes/tubes with the donor name then it should be ensured that the donor code used is uniquely identifying and the dishes/tubes should be labelled with the female patient's name and unique identifier as soon as possible.

## **13.2 RECORDS OF WITNESSING PROCEDURES**

13.2.1 The checking of identification of samples and patients/donors, and witnessing of these checks, should be recorded at the time the clinical and laboratory procedures (outlined in section 13.1) take place. This means that embryologists performing procedures which need to be witnessed can not work alone. This will ensure that the witnessing protocol has the maximum potential to identify possible errors in the treatment process at the time the procedures take place.

A record should be made in the patient/donor notes at the time the procedure takes place confirming:

- (a) the procedure undertaken; and
- (b) the date and time of the procedure; and
- (c) the signature of the person undertaking the procedure; and

(d) the signature of the witness to the procedure.

(Or where electronic witnessing is performed a hard copy of the details generated should be produced).

13.2.2 There should be a separate record of the name, job title and signature of every person who carries out or is a witness to laboratory and clinical procedures.

### **13.3 RISK ASSESSMENT OF WITNESSING SYSTEM**

13.3.1 Centres should conduct a risk assessment before introducing any new protocols for witnessing. Consideration needs to be given to integrating protocols into the whole laboratory and clinical process and risk reduction procedures. Centres may wish to identify and specify key points at which a mismatch is most likely to occur.

13.3.2 Centres should be aware of the concept of 'involuntary automaticity'<sup>1</sup> particularly in relation to considering who the most appropriate person to witness procedures and the workload of laboratory and clinical staff. This concept is recognised to compromise the effectiveness of witnessing to prevent mismatches of gametes and embryos. Consideration should be given to the appropriate work load and working hours for laboratory and clinical staff. Staff should comply with the need to take regular breaks.

13.3.3 Centres should have in place 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.

13.3.4 Centres should ensure that compliance with witnessing protocols is checked regularly, including at the time of the centre's quality management system audit.

### **13.4 APPROPRIATE PERSON TO WITNESS**

13.4.1 Centres should give consideration to who is the most appropriate person to witness clinical and laboratory procedures. An appropriate person to witness is a person who has completed the centre's training programme for new staff, and refresher training (as appropriate), to ensure that the principles of witnessing procedures are fully understood and that the centre-specific protocols are followed.

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

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<sup>1</sup> Brian Toft and Hugo Mascie-Taylor. 'Involuntary automaticity: a work system induced risk to safe health care'. Health Services Management Research 18: 211-216, 2005.

13.4.3 At sperm collection centres may consider the patient/donor to be the appropriate person to witness the cross checking of their identifying information against their records, laboratory data sheet and/or sperm receptacle.

13.4.4 At insemination centres performing IUI may consider the patient to be the appropriate person to verify the sperm provider's details.

### **13.5 INTERRUPTIONS AND DISTRACTIONS IN THE CLINIC AND LABORATORY**

13.5.1 Consideration should be given to the implications of distractions in the clinic and laboratory e.g. from telephones. Centres should, wherever possible, ensure that distractions within the clinic and laboratory are minimised.

13.5.2 When considering the protocol used for witnessing procedures and the most appropriate person to carry out these checks centres 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.

### **13.6 TRAINING**

13.6.1 Centres should ensure that there is an induction programme in place for new staff to ensure that the principles of witnessing are fully understood and that centre specific protocols are followed.

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

### **13.7 PATIENT AND DONOR IDENTIFICATION**

13.7.1 Centres should establish procedures to ensure the accurate identification of patients and donors and their gametes and embryos.

13.7.2 At the patient/donor assessment stage, centres should take all reasonable steps to verify the identity of donors, and patients seeking treatment who have referred themselves, by appropriate evidence (e.g. passport or photocard driving licence).

13.7.3 Upon egg or sperm collection, embryo transfer and sperm insemination patients and donors should be asked to actively supply the identifying information (full name and date of birth) requested by verbally stating it, rather than confirming or rejecting information read out by a member of staff.

13.7.4 Centres should give consideration to how patients and donors with disabilities (e.g. sight impaired, hearing impaired, learning difficulties) and patients and donors whose first language is not English will be asked to identify themselves actively. In the case of patients and donors whose first language is not English, wherever possible an independent interpreter should be used.

## **13.8 IDENTIFICATION OF SAMPLES**

13.8.1 Centres should allocate a unique identifier to each sample of gametes or embryos, from both patients and donors, to ensure they can be accurately identified at all stages of the laboratory and treatment process. This identifier could, for example, include the patient's/donor's date of birth and/or hospital/NHS number and/or donor code.

13.8.2 All samples of gametes and embryos should be labelled with at least the patient's/donor's full name and a unique identifier. If at some stages (e.g. labelling donor sperm) it is not possible to label the dishes/tubes with the donor name then it should be ensured that the donor code used is uniquely identifying and the dishes/tubes should be labelled with the female patient's name and unique identifier as soon as possible.

13.8.3 Centres should give consideration to the most appropriate way to label dishes/tubes when it is possible that they will be in sight of the patient (e.g. at embryo transfer or insemination).

13.8.4 Consideration should be given to the most suitable stage for labelling to change from the donor's/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 the entire laboratory and treatment process.

13.8.5 Centres should be aware of the risks of treating and processing the gametes or embryos of patients/donors with similar names contemporaneously.

13.8.6 Once a check has taken place centres should ensure that gametes or embryos from other patients or donors are not introduced into the critical working area (e.g. the hood) until the procedure has been completed. 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.

13.8.7 When sperm samples are produced at home centres should ensure that protocols are in place to make sure the sperm receptacle is clearly labelled with the sperm providers full name and unique identifier, that the identity of the sperm provider is confirmed and the sperm provider confirms that the sample is his.

## **13.9 IUI/GIFT WITH PARTNER SPERM**

13.9.1 Centres should follow witnessing protocols, in line with the model protocols suggested by the HFEA, for the relevant procedures.

### **13.10 USE OF ELECTRONIC WITNESSING SYSTEMS (BAR CODING AND RADIO FREQUENCY IDENTIFICATION)**

13.10.1 Centres should conduct a risk assessment before introducing any new system or protocols for witnessing which should cover the following:

- Centres should ensure that the supplier/manufacturer of the system demonstrates that it is fit for use in the context of assisted conception.
- Centres should be aware that reliability and safety of electronic systems may differ depending on the type of system. Centres should evaluate the evidence for the safety and reliability of the system based on data supplied by the system supplier/manufacturer (e.g. false positive and negative matches, equipment breakdown) and any relevant studies. The software used should be fully tested, quality assured and risk assessed. Centres should consider how the manufacturer is satisfied that the labels/tags used in the system will continue to be effective when placed in long term cryostorage.
- Centres should ensure that any new system implemented will not cause harm to gametes and embryos. Centres should consider how the supplier/manufacturer satisfies itself that the system will not cause harm to gametes and embryos (for example whether the manufacturer has commissioned any independent reports as part of their quality assurance or carried out irradiance readings).

This risk assessment should be conducted in the context of risk factors which are already present. Consideration needs to be given to integrating the system used into the whole laboratory and clinical process and risk reduction procedures.

13.10.2 Centres should be aware that the potential for human error to be unintentionally introduced into an electronic witnessing system can never be totally eliminated. However, effective risk assessment should reduce or mitigate this risk.

13.10.3 Centres should consider the importance of electronic systems to have forcing functions to prevent users proceeding with a procedure before completing the necessary checks and in built defences to prevent users working on more than one patient's/donor's gametes or embryos at any one time. If a system is used which lacks these forcing functions and in built defences then centres should assess the risk at each stage of the clinical and laboratory process.

13.10.4 Centres should give consideration to any potential loopholes in the system which could allow users to circumvent key steps, thus negating error safeguards. Centres should give consideration to implementing a system that allows the allocation of a unique identifier (e.g. a fingerprint) to each system user which allows them to log onto the system.

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

13.10.6 Centres should have procedures in place to ensure that all witnessing steps can be completed in the event of electronic system failure. Consideration should be given to the most effective way for staff to maintain their manual witnessing skills for all critical steps to ensure that checks can still be carried out, at all critical steps, in the possible event of electronic system failure.

13.10.7 In addition to the electronic system of identification (information stored on bar codes or RFID tags) centres should continue to manually label all culture dishes/tubes (plus lids) and straws with the patient's full name and unique identifier. In any event of electronic identification failure (for example loss of a bar code label or RFID tag from a sample) centres should revert to methods of manual identification.

13.10.8 Centres will need to consider whether the barcodes or RFID tags used are suitable for use on storage containers (i.e. able to withstand long periods of cryopreservation).

## **13.11 BAR CODING SYSTEMS**

13.11.1 Centres considering installing a bar coding system should, as part of their risk assessment, consider the type and power of light used in the bar code equipment and the length of time which gametes and embryos are likely to be exposed to it. Centres should consider whether exposure to this light is likely to result in harm to gametes and embryos. Centres should conduct this risk assessment in the context of other risk factors in the centre and the environment (e.g. light used in microscopes).

13.11.2 While there is a substantial evidence base concerning the use of bar coding with human tissue, as far as the HFEA is aware no independent studies have yet been conducted on the effect of light on human gametes and embryos. Consequently there is not yet a compelling evidence base to enable the HFEA to categorically consider the use of bar coding systems to be risk free.

13.11.3 Bar coding equipment may use a range of light sources. The HFEA is aware of two types of bar coding systems which are marketed for use in an assisted conception setting: those which use white light emitting diodes and those which use laser light.

13.11.4 Taking into account that there is evidence of damage to human cells from some powers of laser light, centres will need to consider the degree of possible risk involved with using laser light bar coding systems. Centres should ensure that they only consider using class 1 or 2 lasers.

13.11.5 Bar code equipment which uses ultraviolet or infrared light should not be used as these sources of radiation are known to have heating, and therefore potentially damaging, effects on human cells.

## **13.12 RADIO FREQUENCY IDENTIFICATION SYSTEMS (RFID)**

13.12.1 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 result in harm to gametes and embryos. Centres should be aware that detectable changes in temperature may result in DNA damage. Centres should conduct this risk assessment in the context of other risk factors in the centre and the environment (e.g. mobile phone signals).

13.12.2 While there is an evidence base for the use of RFID in a medical setting as far as the HFEA is aware no independent studies have yet been conducted on the effect of electromagnetic radiation on human gametes and embryos. Consequently there is not yet a compelling evidence base to enable the HFEA to categorically consider use of RFID systems to be risk free.