

# How do I know that these are my embryos?

Fact Sheet

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In short, the answer to this is, you don't! You have to accept the word of the scientist/clinician/nurse that those are indeed your embryos. Embryos do not have individual characteristics that can be used to identify them and so we have had to develop methodologies and protocols to ensure gametes and embryos are kept separate and readily identified.

## Overview

In this article I shall endeavour to put your minds at rest as to the identification and tracking of these precious commodities, to ensure that mistakes cannot occur. The process of identification generally falls into three categories.

- Patient identity verification and cross check with paperwork and tissue culture plasticware (the dishes and tubes that are going to be used for the procedure).

- Constant crosscheck and verification during insemination and other laboratory procedures. This would include any embryo freezing and subsequent thawing.

- Patient and embryo identity prior to embryo transfer.

Every IVF clinic has their own methods of separating and identifying embryos as they progress through the system. All IVF clinics have to work to minimum guidelines as laid down by our accrediting body, RTAC (Reproductive Technologies Accreditation

Committee). RTAC inspects IVF clinics every year and assesses all protocols in place. The concept of 'double witnessing' has been introduced by RTAC and vigorously policed over the past 15 years.

**RTAC guidelines state that each patient must be uniquely identifiable both in terms of where the embryos are at any one stage and in terms of the accompanying paperwork.** This usually takes the form of three identifiers, often the surname of the patient, birth date, and a unique laboratory number.

The process of identification starts with patient admission where details are checked both verbally and visually. Patients are asked to state their name and date of birth in front of two witnesses, usually the scientist and clinician or nurse whilst the witnesses check the paperwork and the identity bracelet. Identity bracelets are issued with personal details that identify you and your records. This is to ensure that everyone knows who you are. Remember that under general anaesthetic or sedation you won't be able to answer too many questions sensibly!

All tissue culture plasticware to be used must be marked with the three pieces of information that is unique to that patient undergoing that procedure. This marking must be indelible and be on both the bottom and the lid of the culture dish. These unique features must be checked against the accompanying paperwork and signed off by the scientist every time the embryos are moved (which may be up to 10 to 20 times during an IVF cycle).

In addition to these dish markings, **most laboratories have strict protocols in place that forbid the handling of more than one cohort of oocytes, sperm or embryos at any one given time.** Disposable pipettes, dishes and everything else that comes into contact with body fluids or gametes are always used, strictly on a one-use system (a disposable item is used and disposed of immediately). In a busy laboratory, where they are handling up to 50 separate patients at any one time, this is essential and rigorously policed. **Most laboratories have a rule in place that any movement of gametes between tubes and dishes has to be 'double witnessed' and signed for.** Protocols for a single person to

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'double witness' exist in small laboratories where it is often difficult to have an independent person available for reliable 'double witnessing'.

Computer software has been developed that enables a crosscheck to be made electronically (either with barcodes or radio frequency devices) and is available in some laboratories. This sounds a bit 'Big Brother' like but the fact is computers make mistakes a thousand times less than humans.

**At the time of embryo transfer, a patient ID check is carried out and crosschecked to both the paperwork and the dish containing the embryos, before the embryos are transferred.** RTAC guidelines suggest that an independent person conducts a further verification.

## In practical terms

As can be seen above there are a number of identification and verification steps that should help eliminate any mistakes, providing correct protocols are in place and adhered to. I will give a detailed example of what happens during a typical procedure at a clinic. A patient is referred for treatment and a unique record (including a physical file) is generated. This file stays at the clinic for a minimum of three years, after which it can be archived if thought to be inactive. When the patient appears for treatment the file is waiting and a series of patient 'stickers' and a bracelet are issued after the patient has checked the details are correct.

On entering day surgery, all consent forms are checked. The scientist assisting with the oocyte retrieval checks the identification (on the Embryology Record Sheet) with the patient bracelet. This embryology datasheet stays with the gametes/embryos throughout the whole process and is always referred to whenever the gametes or embryos are being handled. Plasticware and media prepared and labelled the day before, is checked and verified by a third person. After oocyte pick up (OPU), the oocytes are placed in

a specialised incubator where there are positions for individual dishes, which can be readily identified. The rule is "one position, one patient". This location is recorded on the Embryology Record Sheet.

Sperm is usually collected into containers labelled by the male partner and the details crosschecked by the andrology staff. Sperm preparation is always conducted in labelled tubes and, most importantly, only one patient at a time is dealt with. At insemination, the tube containing the sperm is crosschecked against the dishes containing the oocytes and the paperwork before the procedure is carried out. All steps are 'double witnessed'. A sticker from the tube used for insemination is removed from the tube and attached to the Embryology Record Sheet. Another check is conducted at the fertilisation assessment where the oocytes are treated to remove cumulus cells so that fertilisation can be determined. Again, only one patient is dealt with at any one time; crosschecks and signings are performed and recorded. Embryos are assessed every day and are moved between dishes to ensure they are receiving the correct conditions for optimal growth. Similar crosschecks must be carried out at this time.

Embryos for transfer are selected and placed in the embryo transfer dish (with the appropriate checking and signing). They are then taken, with the relevant paperwork, to day surgery ready for transfer. The patient is admitted again and has an identity bracelet. This is checked against the paperwork and the dish (containing the embryos) and verified by a third person (usually one of the attendant nurses). After discussing the results for that cycle with the patient the embryo(s) are loaded into a catheter and transferred.

Suitable excess embryos are frozen. These are selected from the culture dishes and prepared for freezing using a series of antifreeze solutions. Each cohort is kept

in separate dishes and embryos are frozen in individual straws. These straws are labelled with all the patient details. After freezing, the straws from one person are placed in a labelled container, sealed and kept in liquid nitrogen. Details of the storage position are kept with the file, on a card system and on a computer database. Each storage location is unique for one person

**These protocols ensure that there is a paper trail that can be followed and assessed at any time. Internal audits of IVF laboratories (policed by RTAC) are conducted to make sure checks are being done properly and conform to international standards.**

The number of crosschecks that are used might seem to be excessive but this has been deliberately built in to the system to attempt to make it 'fail-safe'. That is, if one set of required checks is missed or wrongly conducted then the next set should highlight this and correct it.

Even with the best-designed systems in place there is always room for human error and sometimes this can occur. A couple of these errors have made headlines internationally whereby the procedures in IVF laboratories have been shown to be at fault. **Vigilance on the part of the scientists, nurses and clinicians involved in the care of patients is very important and forms a central part of training in IVF laboratories. If a mistake is made anywhere then everyone (including the patients) is made aware and a decision is made on the best way forward for all involved.**

It is incumbent on the people in the IVF clinic to give you the best available treatment and this includes ensuring that you get your embryos and there is no possibility of mistakes being made. You have entrusted us to look after your precious embryos and we must make sure that is what we do. I believe that we do this to the best of our ability.

**Dr James Catt PhD**