TECHNICAL BULLETIN 4

Patient and Sample Identification

September 2012

From time to time RTAC will become aware of issues, questions or comments where it may consider assisting units enhance the quality of their service to patients. A Technical Bulletin is an educational communication to all units, and Bodies certifying units to the RTAC Code of Practice, offering advice and guidance. It is not enforceable.

Introduction

This technical bulletin was commissioned by the FSA Board to help units translate the concepts of patient and sample identification into principles which units could use in creating their own processes, and to provide worked examples for units that wanted them.

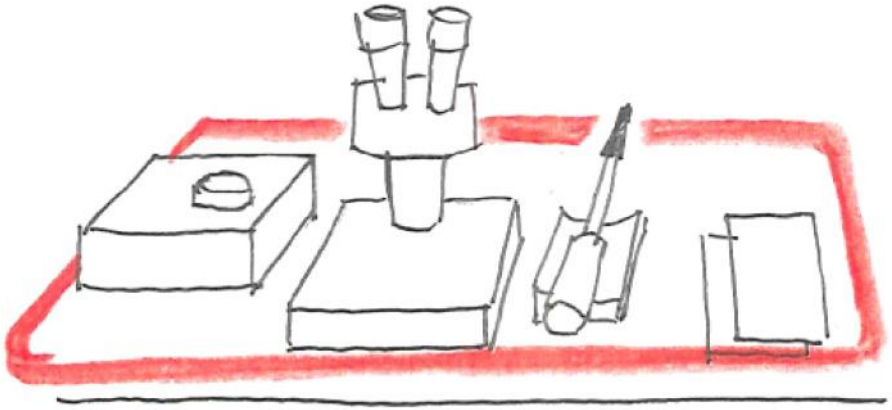
RTAC created a project group which reviewed and summarised:

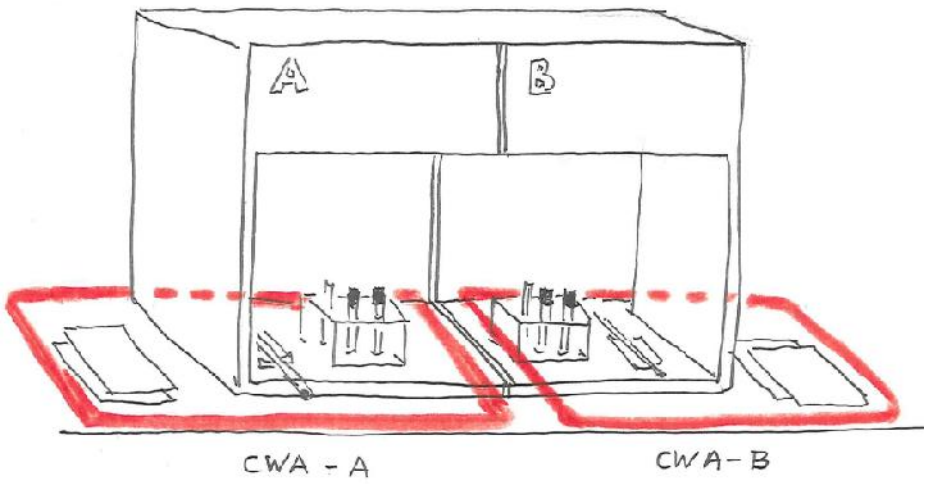
- Patient and sample identification guidelines from other countries or organisations (eg. HFEA)
- General problems and solutions associated with retentive checking, especially in the health sector, but also in other industries such as aviation (eg. Involuntary automaticity, Swiss Cheese model)
- Steps taken to reduce identification errors in non-ART areas of medicine (eg. WHO surgical checklist)
- Known identification errors in ART and causes where available (eg. HFEA reports, news reports). This group set up a website to anonymously collect cases from around the world..

The background papers are available at from the FSA secretariat. The working group then collated this material and distilled it into principles. The table also contains, *in italic*, commentary, suggestions, and some worked examples.

	Aspect	Principles *with commentary and suggestions*
1	Summary statement	Units must have robust and effective processes to correctly identify people and their sperm, oocytes, embryos and reproductive tissue.
		These guidelines are primarily designed when sperm, oocytes, embryos and tissue are used or stored with the intention of creating a child. They may also be used in other circumstances, such as returning non-viable embryos to a person for disposal.
2	Critical Work Area (CWA)	A critical work area contains only one person's or couple's sperm, oocytes, embryos or tissue at a time. The critical work area must be labelled with the patient's identifiers – which could be the labelling of the vessels themselves.
3		The unit must define critical work areas and how they are used
		Carefully defining critical work areas is key to preventing sample cross-over. Examples include: • *An area where all the material for a single sperm preparation is located - the semen pot, test-tubes with density, medium for washing the pellet, tube for the final sperm suspension, pipettes.* • *A microscope, heated stage and moving device (eg pipette) used to denude eggs* • *A procedure room PLUS an adjacent embryology workstation in the case of oocyte collection or embryo transfer. An embryology workstation and an embryo transfer room that are <u>not adjacent</u>, or an embryology workstation that serves more than one procedure room, are separate critical work areas.* • *Illustrated examples of Critical Work Areas:* *Desk or counter where a person hands over a semen container to a lab staff member:*

Embryology workstation consisting of a microscope, warmed stage, warm block, pipette holder and bench space for record:



		Laminar flow cabinet for sperm washing with adjacent bench space for records:  *The working group had differences in opinion on whether or not paperwork should be inside the critical working area. If outside, it should be placed in a designated area unique to that particular critical work area (eg. bench space adjacent to a laminar flow cabinet)*
4		The critical work area must be clear before use
		Critical work areas are only safe if they are totally cleared of samples, tubes, pipettes, paperwork, etc, between procedures.
5	Critical Identification Point (CIP)	Units must identify and document the critical identification points where samples come into the unit, change vessels, change identity, or leave the unit.
6		Critical identification points include: • Collecting oocytes

		• Receiving sperm from a man who has produced a sample
		• Collecting ovarian or testicular tissue
		• Changing the identity of a sample. Eg:
		  o Sperm donor's name (eg. on a collection container) to donor code (eg. on straws)
		  o Donor's oocytes allocated to the recipient woman
		  o Donors' embryo allocated to the recipient woman
		  o Embryo allocated to the surrogate
		• Adding sperm to oocytes
		• Transferring sperm, eggs, embryos or tissue between vessels. Eg.
		  o Steps in sperm preparation
		  o Steps in embryo culture
		  o Freezing sperm, oocytes, embryos and tissue
		  o Thawing sperm, oocytes, embryos and tissue
		• Inseminating a woman
		• Transferring embryos into a woman
		• Disposing of viable sperm, oocytes, embryos, or tissue
		• Receiving sperm, oocytes, embryos or tissue into the unit (import)
		• Sending sperm, oocytes, embryos and tissue out of the unit (export)

		Documenting when and how samples change identity is particularly important. (Eg. The point where donated oocytes are identified with the recipient's identifiers instead of the donor's identifiers)
7		The unit must specify when identification checks should take place within the process. The time and number of checks must ensure that any possible error would be detected.
		Generally checks should occur AFTER samples, vessels and records enter the critical work area but BEFORE any samples change vessel - if what goes into a critical work area is correct, what comes out should be correct. *Checking must occur before an irreversible error can occur.* *Eg. Checking should be done before adding sperm to oocytes in IVF*

		Eg. Checking may be done after all the steps in sperm preparation have been completed by checking all the vessels in the critical work area. This does not prevent an error, but catches an error before the sperm is used for insemination. When checking is done after completing a process, the unit must ensure that there is no way an error could be unidentified.
8	Double checking	Double checking must occur at every critical identification point

9		Double checking must involve two independent checks. The checks must be made by:
		• The person responsible for the procedure and:
		  o A second person, OR
		  o A machine system designed for sample identification (eg. RFID, barcode)
		• The second person may be a patient or donor for some critical identification points (eg. when receiving sperm in to the unit, at insemination)

		Identification checks have up to five dimensions: • *People providing or receiving material* • *Sample(s) (eg. sperm, oocytes, embryos, tissue)* • *Vessel(s) (eg. Petri dishes, tubes, straws)* • *Procedure (eg. insemination, embryo transfer, disposal)* • *Instructions (eg. the consent and/or management plan to show that the procedure is requested and authorised)*
		There are different opinions in the literature about whether double checking should be shared (eg. read out aloud) or not (eg. read silently). *The advantage of reading aloud is that it involves two senses – sight and sound – and that patterns that might be confused with one sense (eg. inversion of numbers) may not be confused with the other sense.* *The advantage of reading silently is that the second checker is not influenced by the first checker.* *Medicine generally uses reading aloud (eg. before surgery and giving medications) so the working group suggests that ART should also use this approach.*

		Double checking is a minimum – it can be reassuring to involve the patient as a third person, for instance at embryo transfer.
10		Identification checks must be recorded at the time they are done
		The person responsible for the procedure should perform his or check before performing the procedure, and record the check at the completion of the procedure. Thus the record covers both the check and the completion of the procedure. *The person doing the second check should perform his or her check before the procedure, and record the check at that time.*
11		There must be a record of identification checks. The record must include: • The process checked • Date and time • Signatures of the people performing the check, or an electronic equivalent.
12		The unit must retain a register of the signatures of staff authorised to perform identification checks
13		The record of checking identification should be part of the person's medical record
14		The unit should consider mapping process to conveniently document requirements

<table>
<tr><td></td><td></td><td>Example of process map for IUI:
<table>
<tr><th>Step</th><th>CWA</th><th>Person responsible</th><th>Expected second checker</th><th>Record of checking</th></tr>
<tr><td>Lab receives semen pot</td><td>Lab reception window</td><td>Lab member on reception duty</td><td>Person dropping off semen pot</td><td>Semen request form</td></tr>
<tr><td>Sperm wash</td><td>Laminar flow workstation</td><td>Andrology technician</td><td>Lab staff member</td><td>Semen work sheet</td></tr>
<tr><td>Catheter filled from sample tube</td><td>Procedure room</td><td>Nurse performing IUI</td><td>Women being inseminated</td><td>Consent form</td></tr>
</table></td></tr>
<tr><td>15</td><td rowspan="3">When single checking is permitted</td><td>Single checking is permitted when there are no other sperm, oocytes, embryos or tissue being processed in the same laboratory over the same period of time

(Eg. when there is only one sperm preparation and the sperm is used for insemination before the next sample is received into the laboratory</td></tr>
<tr><td>16</td><td>A unit must undertake a risk analysis and document the circumstances when single checking is permitted</td></tr>
<tr><td></td><td>It is recommended that single checking is only performed when the circumstances for single checking are met, AND a second person is not available to perform an independent second check.</td></tr>
<tr><td>17</td><td rowspan="3">Patient and sample identifiers</td><td>Patient and sample identification must normally include three identifiers such as:
Full name
Date of birth
Unit’s unique identifier for the person or couple</td></tr>
<tr><td>18</td><td>In PGD the embryo, and not the person, must be given a unique identifier.</td></tr>
<tr><td></td><td>The same key identifiers need to be on paper work used during checking.</td></tr>
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19		Where there is insufficient space for the three identifiers (eg. on a Petri dish), two identifiers may be used, of which one must be the unit's unique identifier:
		• Eg. embryo culture dish
		  o Name
		  o Unit's unique identifier for the person or couple
		• Eg. Straw containing donor sperm
		  o Donor code (= a particular type of unique identifier)
		  o Date of freezing

		Units should consider two separate codes for donors to reduce the impact of a transcription error. Eg. A donor could have two codes, ABC and 123, just as a non-donor has a name and unique identifier
20		Three identifiers must be used for vessels stored long-term, such as frozen sperm, oocytes, embryos and tissue.
21		Two identifiers may be used for vessels used for less than 7 days duration (eg. a sperm preparation, fresh embryo culture)
22		The unit must describe the process it used for establishing the identity of samples banked before these principles were introduced, if the sample identification process was weaker than those described here.
23	Labelling vessels	Units should minimise pre-labelling vessels
		This is general principle for pathology laboratories, but pre-labelling is widely used in ART where vessels need to be equilibrated or set up for a particular patient in advance. However, pre-labelling is often done where it is not needed, such as when giving out semen pots. *Many of the sample identification errors and near misses reported in the RTAC sample id survey involved transcription errors. Machine printed labels will prevent misspellings.* *However, some embryologists are concerned about the VOCs potentially given off by adhesives used in the labels.*
24	Identifying people	When identifying a person as part of ART treatment, the unit personnel must: • Ask the person their name • Ask the person their date of birth

		• Ask the person to spell their name • Ask the person for their address
		While a unique identifier (either given by the unit of the health system) is one of the three identifiers for putting on vessels, a patient may not know this identifier or could get it wrong because it has no intrinsic meaning for him or her. Hence asking for the address, which the patient knows.
		Special consideration must be given to requests to use or dispose of sperm, oocytes, embryos and tissue when the person making the request cannot be identified in person. (eg. A written request by a man to dispose of his banked sperm.) These guidelines do not cover this aspect.
25		Clinic recruited donors must be identified, at least at the initial identification, using a photograph, name and date of birth from their driver's licence or passport
26		Units are encouraged to use photo-identification for other types of people whose sperm, oocytes, embryos and tissue are used for treatment
27	Training	People performing checks must be trained so that they are familiar with the unit's procedures. Their training must be recorded if they are not a registered health professional
		The person performing the second check must understand what procedure is taking place, since the check covers both the identity of the person or sample and the instruction or procedure ('right person, right procedure')
28	Authority	The unit must give every person performing a check the authority to repeat the check or stop the process if that person has any degree of uncertainty about identification
		Permission to say 'stop' has to be supported at all levels, especially by doctors. *There are many examples in medicine and aviation where a more junior member of the team had reservations about what was happening but felt they could not raise it with more senior members.*
29	Handling uncertainty	The unit must have a written process for making decisions on what to do next when a person performing a check has any degree of uncertainty about identification.

		It is strongly recommended that a third person, preferably more senior, be involved in resolving any uncertainty.
30	Reducing risk	Internal audit must cover all steps in the patient and sampling identification processes
31		Every identification error or near-miss must be recorded by the unit's quality system. It is suggested a Root Cause Analysis (RCA) be performed.

32		The unit must have hazard control plans to identify and mitigate factors known to increase the chance of misidentification. Hazard control plans should cover:
		• Guidelines on staff workload, including:
		  o Maximum of hours than can be worked without a break, and the nature of the break
		  o Maximum hours worked in a day
		  o Maximum days worked in a row
		• Interruptions
		• Recognising staff tiredness or other factors that may impair concentration
		• Last minute changes to scheduling of procedures

		Preparing hazard control plans helps identify potential risks, and to find remedies proactively. There is an extensive literature, quoted in the RTAC discussion document, covering: • *Involuntary automaticity – doing familiar tasks automatically* • *Cognitive concentration – adjusting the level of concentration according to the demands of the task* • *De-compensation – eg. less concentration once a demanding task or period is over* *It is sobering to note that 3 of the 9 sample identification errors volunteered in the RTAC sample ID survey occurred despite printed labels and two person checks. Staff rushing and people waiting for them were cited by those involved as major contributing causes.* *Considering the 'Swiss cheese model' for errors occurring, preparation of hazard control plans is a way of identifying what defences are in place (slices of cheese) and where holes might occur.*

33		Units must perform a risk assessment before changing an existing identification process.
34		Units must identify what level of training is needed when a patient or sample identification process is changed, and undertake and record that training.
35		The unit must have a written contingency plan that describes what to if a machine system used for second check breaks down or is unavailable.

Summary for the workplace

Know the boundary of the CWA Check the CWA is empty before starting Double check everything coming into the CWA Double check every change of identity
Check: • Patient • Sample • Vessels • Procedure • Instructions
When checking: • Total focus on checking • Look for discrepancies • Look and say, then • Listen and look • Sign off promptly