

IVF WITNESSING AND ELECTRONIC SYSTEMS

FINAL REPORT

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1. BACKGROUND

The Human Fertilisation and Embryology Authority commissioned Dr Sally Adams and Dr Jane Carthey to carry out a study comparing the relative risks of manual double witnessing, bar-coding and electronic witnessing systems using radio frequency identification (RFID) to reduce the chance of IVF mix-ups in which the wrong sperm is used to fertilise a women's eggs. This work was commissioned to underpin advice the HFEA plans to issue later in 2006 to advise IVF clinics on the safety and efficacy of different types of witnessing systems.

Specifically, this report summarises the findings of a study which aimed to carry out a formal human factors assessment of current manual double and electronic witnessing systems and to advise on how to minimise the risks of human errors and systems failures. This work was commissioned following a series of adverse events at an English IVF clinic which were investigated by Professor Brian Toft¹. Of the four adverse events investigated by Toft (2004) two involved the incorrect identification of sperm samples; one involved the loss of embryos following a failure to check liquid nitrogen in a cryogenic freezer; and one involved the disposal of embryos following an administrative failure. Toft (2004) concluded that these adverse events were caused through a mixture of inadvertent human error and systems failure. Ninety-nine recommendations relating to human factors issues in the IVF process and the role of regulatory body in monitoring IVF clinics were made in this incident report.

2. INTRODUCTION

Manual checking procedures have traditionally been a routine aspect of health care practice and are used to match the intended care to the intended patient. Although there are various definitions in the research literature of the term 'mismatching', a recent report commissioned by the NPSA defined it in the following way: 'a mismatching event denotes a status of the medical process where patients are not correctly linked with their specimens or specified treatments'².

Mismatching incidents result from checking errors that occur at different points in healthcare processes including laboratory testing (Plebani, 1997)³, drug prescribing and administration⁴, surgery and blood transfusion (Stainsby et al., 2004)⁵. In the context of an IVF laboratory the key matching processes relate:

- to matching the correct patient eggs to the correct sperm (i.e. the patient's partners or intended donors) prior to fertilisation and
- to matching the correct embryos to the correct patient prior to embryo transfer.

The root causes of checking errors in other healthcare domains have been widely studied and, although they come from radically different healthcare settings, these are pertinent to understanding the potential causes of checking errors in IVF laboratories. There is less research on the causes of IVF misidentification errors although the high profile incident at Leeds General Infirmary, subsequent incident investigation by Professor Brian Toft and his work on involuntary automaticity (Toft and Mascie-Taylor, 2005)⁶ have provided important insights.

2.1 Root Causes of misidentification errors in other areas of healthcare

The clearest evidence of the frequency of misidentification errors can be seen in the blood transfusion sector. For example, an analysis of incident reports submitted to the Serious Hazards of Transfusion Medicine (SHOT) programme found that 156 out of 588 errors in 348 incidents were a 'failure to carry out the pre-transfusion bedside

check appropriately.⁵ The failure of bed side checking procedures (26.5% of all errors) included factors such as confusion over patients with similar names, checking being carried out away from the bedside, interruption between completion of checking and administration, and failure to notice compatibility and donation label discrepancies (Stainsby, Cohen and Jones et al 2004)⁵. In another study of errors in the administration of blood transfusions in a UK haematology outpatient clinic, the underlying causes included frequent interruptions and distractions whilst checking, the complexity of the activity, lack of education and training on a regular basis, human error and a perception that the procedure was not appropriate or efficient (Turner et al, 2003)⁷.

In 2003, the National Patient Safety Agency commissioned a report to examine mismatching. The Human Reliability Associates report considered manual checking procedures (i.e. those that do not rely on or make use of technological aids) in health care and other industries in the UK and abroad. The aim of this report was to identify ways in which methods used in the NHS to match patients and their care could be made more reliable. Although the literature (identified above) attempts to quantify the scale of mismatching, due to disparate aims and methods of studies in these areas it was impossible to reliably quantify patient safety incidents where mismatching is a feature. Furthermore, although guidelines and recommendations issued by major bodies place emphasis on enforcement of formal policies and procedures, there is little guidance on how enforcement should be carried out to reduce the risk of non-compliance. There is a lack of guidance on how to address underlying factors that may affect the policies/guidelines' effectiveness within the healthcare system. There is also a lack of evidence of risk assessment of checking processes.

Following this report, the NPSA produced a publication relating to the subject called 'Right patient – Right care' (NPSA, 2004).² This report summarises the evidence for bar-coding. In addition to using technology as a solution for checking failures, double checking procedures are often used in healthcare settings to provide an extra level of defence against errors and incidents. The premise behind double checking is that having two people carrying out the checking is safer than one person. Research evidence to support this is equivocal. For example, Toft and Mascie-Taylor (2005)⁶ identified how healthcare staff acting as double checkers may experience involuntary automaticity i.e. when a double check is not truly independent or when an independent checker goes through the motions of carrying out the check but does not identify discrepancies. In the context of an embryology laboratory, involuntary automaticity may lead to manual double witnessing checks not revealing discrepant patient information at key stages throughout the IVF process.

Similarly, other problems with double checking have been identified in the research literature relating to:

- independent redundancy (where two double checkers do not behave independently as expected in a double checking process and the redundancy that is anticipated in their cognitive processes which is the key process that ensures one checker will identify failures with another checker breaks down),
- attentional blindness (where limitations with people's cognitive resources mean that they do not perceive discrepant information) ,
- ambiguous accountability (where it is unclear which member of staff is responsible for which checks and checks are omitted as a result).

Common types of checking failures which have been identified in previous research are as follows:

- Check omitted
- Incomplete check is carried out
- Check is performed with involuntary automaticity (REF) and is therefore not a true check
- Check is carried out too late/too early.

2.2 Bar coding and radio frequency identification systems

Bar-coding

Over the last five years bar-coding has been increasingly recommended as a potential solution to reduce the frequency of patient misidentification errors caused by manual checking processes (Bates et al., 2001)⁴. Amongst the healthcare settings where these systems have been previously used are blood transfusion, drug administration, pathology laboratories and operating theatres. The premise behind the introduction of bar coding technology is to reduce the number of manual human checks required and thereby reduce the opportunities for checking failures made by healthcare staff.

There are very few robust critical evaluations of the impact of new technologies like bar-coding on the frequency of misidentification errors and adverse events. One recent review revealed a paucity of controlled, generalizable studies confirming the benefits of technologies (including bar-coding) intended to reduce medication errors and adverse drug events (Oren, Shaffer and Guglielmo, 2003).⁸ Another study has shown that bedside checking failures are still the most common cause of ABO incompatible transfusions when bar-coding is in place (Ahrens, Pruss, Kiesewetter, Salama (2005).⁹ There is even less evidence of the efficacy of bar-coding as a means to improve patient safety in the embryology laboratory.

There is increasing evidence that the assumption that new technologies like bar-coding can provide a full-proof solution to misidentification errors is flawed. A more realistic viewpoint is that whilst eliminating or reducing the frequency of some types of errors, new technologies like bar coding and radio frequency identification actually introduce a new generation of errors and pathways to incidents. Evidence suggests that as well as reducing some types of errors, bar-coding identification systems in medication administration may introduce a new generation of errors into the clinical process (Cummings, Ratko and Matuszewski, 2005¹⁰; Patterson, Rogers, Chapman & Render, 2002, 2006^{11,12}). Hence the assumption that new technology can eliminate checking failures may be over-simplistic. Amongst the issues identified so far in drug administration (where bar-coding systems have been most widely used) are the following:

- Errors can occur in the printed barcode label (patient or drug).
- Procedures may contain loopholes that enable users to circumvent key steps, thus negating error safeguards.
- Interfacing between various hospital computer systems can be problematic.
- Barcode scanning can interrupt nurse workflow processes, leading to frustration and fatigue among staff.
- Barcode equipment must be reliable, readily available, and user-friendly to be used effectively.

- Select barcode technologies may lack certain desirable features/functions, which limit their usefulness. Cummings, Ratko and Matuszewski, (2005)¹⁰

Other side effects of introducing bar-coding technology have been identified in observational studies which have looked at how nurses use bar-coding drug administration systems in US hospitals (Patterson et al. (2002, 2006).^{11,12} These two studies showed that:

- (i) nurses were sometimes confused by the actions of the bar coding system.
- (ii) there was degraded coordination between nurses and doctors as a result of using the bar-coding system.
- (iii) nurses showed a decreased ability to deviate from routine sequences.
- (iv) nurses displayed non-compliance with recommended practices as a way to improve efficiency, especially during busy periods.

These findings need to be considered in relation to the implementation of bar-coding in an IVF laboratory setting.

Similarly, there is evidence that healthcare staff will manually over-ride alarms generated by new technology (van der Sijs, Aarts, Vulto, and Berg, 2006).¹³ Hence it is important to both rationalise the number of alarms generated and ensure that there are built-in forcing functions or barriers which prevent health care staff from circumventing or not responding to alerts.

Radio Frequency Identification (RFID)

In 1945 Léon Theremin invented an espionage tool for the Soviet government. Even though this device was a passive covert listening device, not an identification tag, it has been attributed the first known device and a predecessor to RFID technology. Another early work exploring RFID is the landmark 1948 paper by Harry Stockman, titled "Communication by Means of Reflected Power" (Proceedings of the IRE, pp 1196-1204, October 1948).¹⁴ Stockman predicted that "...considerable research and development work has to be done before the remaining basic problems in reflected-power communication are solved, and before the field of useful applications is explored." It is only in recent years that RFID has developed into a technology which provides healthcare a variety of opportunities to improve tagging, patient safety, etc. Little formal research has been conducted on RFID and one could suggest that many of the criticisms associated with bar-coding are equally applicable to RFID.

Some authors have suggested that radio frequency identification (RFID) systems are the solution to those problems identified with bar-coding (Ahrens N, et al., 2005⁹; Roark and Miguel, 2006).¹⁵ Replacing one type of technology with another may not be the way forward; rather irrespective of whether bar-coding or RFID is used the key to their effectiveness is likely to be designing the technology to be integrated into the healthcare context in which it will be used. Whether introducing bar coding, RFID or any other technology into healthcare it is essential that it is designed to take account of the cognitive limitations and information processing capacity of the human operator (Perrin and Simpson, 2004).¹⁶

3. AIMS AND OBJECTIVES

The objectives of the project (as stated in the project specification document) were as follows:

- To consider where the HFEAs current manual double witnessing protocol can be improved in the light of evidence on the avoidance of human error and systems failure.
- To develop manual witnessing protocols for use by IVF clinics in association with bar code and RFID based electronic witnessing systems.

4. APPROACH

4.1 Familiarisation with the IVF process

The human factors experts reviewed the following material in order familiarise themselves with the IVF process:

- HFEA Directions on records of witnessing clinical and laboratory procedures
- HFEA protocol for witnessing clinical and laboratory procedures
- Brian Toft's incident report – Independent review of the circumstances surrounding four adverse events that occurred in the Reproductive Medicine Units at The Leeds Teaching Hospitals NHS Trust, West Yorkshire.
- Information on www about the IVF process from a variety of sources but including www.fertilityconnect.com, www.hfea.gov.uk, www.IVF.net.

An initial visit was made to one of the two IVF clinics involved in this project on 3rd April, 2006. During this visit a senior embryologist was interviewed by the two human factors experts (SA and JC) using a 'talk through' method to define the key steps of the IVF process. The purpose of this interview was as follows:

- To ensure that both HF experts had a good understanding of the IVF/ICSI process prior to carrying out observations.

4.2 Observations in Embryology Laboratories

Observations were carried out by two human factors experts in the embryology laboratories at two IVF Clinics; Holly House Hospital IVF Centre in Essex and the Hewitt Fertility Centre in Liverpool. The dates of these observations are listed below:

19th- 20th April 2006: Hewitt Fertility Centre, Liverpool

24th April, 2006: Holly House Hospital, Essex

Two human factors experts observed in each IVF laboratory. Table 1 summarises the number of elements of the IVF process observed during these visits:

Table 1: Number of procedures witnessed

	Total number of procedures observed	
	Hewitt Fertility Centre	Holly House IVF Centre
Egg collections/retrieval	12	3
Sperm sampling/washing	4	2
Egg washing/freezing	2	0
Embryo transfers	4	3
ICSI/IVF procedures	3	3

4.3 Analysis of IVF incidents

An analysis of HFEA incidents was also carried out. Twenty two incident reports were provided to the consultants by HFEA. These reports occurred between 28/3/03 and 18/4/06. Table 2 provides a simple frequency count of errors per activity failure.

4.4 Risk Assessment Process

Patient safety risk assessments are careful examinations of systems to identify factors that could potentially cause or contribute to patient harm. They facilitate decisions of whether adequate precautions are being taken to ensure timely and safe provision of care/services, or if further measures are needed to prevent harm. They aim to make sure as far as possible, that patients are not harmed by the actions of healthcare staff or unsafe conditions.

Risk assessment in this context aims to answer 3 interrelated questions:

1. What can go wrong?
2. How bad are the consequences?
3. Is there a need for action?

Draft process maps for the IVF process at Essex and Liverpool were generated by the human factors specialists based on the findings of the 'talk through' interview, observations in embryology laboratories and procedures provided to the team by the HFEA and both IVF clinics. These process maps show the IVF process where manual witnessing, bar coding and RFD is used in the two centres involved in this study. The final versions of the process maps are shown in Appendix 1. The drafts were reviewed by a senior embryologist from each site for accuracy and adjustments were made to them in terms of use technical language and sequence of parts of the IVF process.

The process maps were then subjected to a formal risk assessment, where each task in the IVF process was assessed in terms of:

1. What could go wrong? (seriousness and likelihood)
2. Possible main causes (why?)
3. Most likely consequences
4. Current controls in place to prevent or mitigate error
5. Recommendations were considered in some places

Both human factors specialists carried out the risk assessment, working through each of the boxes on the process maps iteratively to identify what could go wrong at each stage of the IVF process. The risk assessment records for both Essex and Liverpool can be found in Appendix 2. At the end of appendix 2. Table 3 summarises the more general risks identified for manual double witnessing, RFID and bar-coding.

5. MAIN FINDINGS

5.1 Analysis of IVF incident reports

The main findings of the analysis of IVF incident reports is shown in Table 2:

Table 2: Incident Reports Error Typology and Frequency

Error Type	Frequency
Storage failures (embryo's, eggs, semen)	5
Labelling failures (embryos, semen) (no label, date missing, id mix up, lid transfer)	5
Form completion failures (sperm, IUI) (no counter signatures, witnessing errors)	4
Eggs not inseminated	1
Failure to split eggs as per protocol	1
Incorrect embryo selected for transfer (recovered)	1
Wrong sperm used to inseminate egg (recovered)	1
Discrepancies in patient records/samples	1
Frozen embryos failure (lost straw lost embryo)	2
Embryo's sent to receiving centre with inadequate screen/prep/communication	1

Table 2 shows that storage and labelling failures were the most frequent types of incidents, followed by errors relating to form completion (for example, when the manual double witnessing form was not completed or was completed incorrectly).

Due to the small sample of incident reports we cannot draw conclusions about the representativeness of the error types and frequencies shown in Table 2. However, the error types do seem to support the findings of the risk assessment (see Appendix 2) which has identified risks relating to storage, labelling, written double witnessing form completion and failures in the clinical aspects of the IVF process, particularly around the potential for mismatching between eggs and sperm.

Furthermore, our observations in the two embryology laboratories identified the following risks which relate to those identified in the incident reports. These are summarised in Table 3.

Table 3: Error types identified in incident reports and observed risks

Error Types identified in incident reports	Observed risks
Storage failures (embryo's, eggs, semen)	Practice of storing two patient's eggs per shelf in the incubator increases the risks of a selection error when removing eggs from the incubator.
Labelling failures (embryos, semen) (no label, date missing, id mix up, lid transfer)	Poor adhesiveness of RFID labels on test tubes has led embryologists to sellotape the labels onto the tubes because of the risk of them falling off.
Form completion failures (sperm, IUI) (no counter signatures, witnessing errors)	Practice of completing the manual double witnessing form in chunks, rather than immediately following a manual double witness check (due to workload and time pressure).
Eggs not inseminated	Not observed
Failure to split eggs as per protocol	Not observed
Incorrect embryo selected for transfer (recovered)	Not observed
Wrong sperm used to inseminate egg (recovered)	Not observed
Discrepancies in patient records/samples	Not observed
Frozen embryos failure (lost straw lost embryo)	Practice of carrying out embryo freezing on more than one patient's embryos at a time leads to increased risk in this area.
Embryo's sent to receiving centre with inadequate screen/ prep/communication	Not observed

5.2 Implications for the main objectives of this study

There were two main objectives in the project specification for this work. These are discussed in this section in light of the findings of the incident analysis, risk assessment and observations.

To reiterate, the first objective of this study was as follows:

To consider where the HFEAs current manual double witnessing protocol can be improved in the light of evidence on the avoidance of human error and systems failure.

A thorough understanding of the process maps and their associated risk record in conjunction with a review of the HFEAs current manual double witness protocol would suggest that the following issues should be considered to reduce human error and system failure.

1. Firstly, embryologists need to be provided with a manual double witnessing protocol which is set in the context of the whole IVF process. The existing protocol focuses largely on where manual double witness checks should be carried out and is not embedded in the context of the whole IVF process. From a human factors perspective, procedures are more meaningful to front-

line staff who have to use them when the broader context of the work flow is provided and they can see the whole task sequence.

2. One element of the existing protocol is to develop and use a unique patient identifier for patient's who have similar names. The authors of this report think that this could introduce more risks into the process due to the memory limitations of human operators. For example, during our observations at one of the IVF centres, there were two patients on the same operating list whose surname was 'Jones.' Assigning a unique identifier to each of these patients increases the cognitive workload of a team of embryologists who are already working in a busy laboratory. It effectively means that they have to process which unique identifier relates to each patient when all of the written information they make reference to relies on the patient's name. When working in a social context of a busy embryology laboratory in which the demands of manual double witnessing already cause interruptions to an embryologists work flow it is fairly likely that a patient identifier mismatch would occur.(i.e. where one patient's unique identifier is confused with another patients).
3. The current HFEA protocol only tells embryologists where manual double witnessing should occur in the IVF process, not by whom and how (for most checks). In practice this means that any embryologist can be called away from a task to double witness for a colleague. There is a need to identify and specify points at which a mismatch is most likely to occur if a task sequence is interrupted by double witnessing demands and ensure that embryologists who are carrying out such tasks can complete them without being interrupted. Alternatively, staff resources permitting, it is worthwhile considering allocating one specific member of the team as the double witness partner for laboratory colleagues for one hour time periods.
4. Checking patient/partner identity when English is not the patient's first language or a patient has learning disabilities/cognitive impairment needs further consideration in terms of best practice.
5. For sperm preparation there needs to be a specific point of sampling on arrival in the lab.
6. In light of the observations, although manual double witnessing is an essential safeguard, where the laboratory is busy it may actually have a side effect of increasing risk by creating distractions and interruptions in the process.
7. There is a significant risk that the high number of witnessing points in the existing double witnessing protocol increases the risks of non-compliance because staff will become complacent and over-confident that all of the checks up and downstream in the process will identify errors. Our observations provide tentative support for rationalising the number of witnessing points in the existing protocol for the following reasons; firstly, the embryologists we spoke to highlighted the issue of continuously being interrupted from their tasks by the need to double witness for a colleague. They reported that they enter the double witness process with the name of the patient's eggs/sperm they have been working on in their mind and then have to quickly transfer to remember and check another patient's/partner's information before reverting back to the name of the patient whose eggs/sperm they were originally working on. Secondly, we observed a degradation in the completeness of manual double witness checks as staff

proceeded through the egg collection and sperm preparation processes. Whereas staff started off using all of the key information in the first double witness checks they sometimes only used partial information further along in the process. This is symptomatic of the numerous checks in the existing protocol coupled with high workload and time pressure in the embryology laboratory.

8. HFEA needs a quality assurance process in place to check the translation of the national protocols into local protocols and inspectors should do this as part of their assessment work.

Objective Two

The second objective of the work was as follows:

To develop manual witnessing protocols for use by IVF clinics in association with bar code and RFID based electronic witnessing systems.

Some suggestions for key elements of these protocols are listed below. However, final decisions on the need for manual double witnessing points in the IVF process, in conjunction with a bar coding system, needs to consider the following issues:

- The reliability of the bar coding system. Reliability may differ between the bar coding systems developed by different manufacturers and there needs to be an evaluation of the evidence for the reliability of each system in terms of false positive and false negative matches, equipment breakdown etc. Local protocols may need to be tailored in light of evidence pertaining to different levels of reliability across bar code systems.
- The functionality of the bar coding system. Whereas some bar coding systems are designed to cue staff to the next step in the task sequence others are not. Furthermore, some bar coding systems (like the one used in Liverpool) do not contain 'forcing functions' which prevent the embryologist omitting key matching tasks in the process by preventing them from proceeding with subsequent task steps. Where a bar coding system lacks forcing functions there will have to be an increased reliance on manual double witnessing in local protocols.

6. SUGGESTED KEY ELEMENTS FOR A BARCODE PROCEDURE

Sperm Sampling

- Barcode should not be generated the day before but on the day the sperm is prepared and the egg collection will take place.
- Generation of barcodes on the day of the procedures by the embryologist in the laboratory should be double witnessed by a second embryologist.. Upon receipt of the specimen pot, the embryologist in conjunction with the partner scans the pot, the envelope in which the specimen pot will be placed and confirms that the bar code label information relates to this partner and his spouse/girlfriend. Once specimen has been produced it should be placed in the envelope which should also have a bar code label on it. This should be double witnessed by the nurse and the patient's partner.

- The envelope should then be transported to the embryology laboratory and only one partner's sample should be transported at a time.
- On arrival in the laboratory, both the envelope and the sperm specimen pot should be scanned again. The bar code information on the specimen pot should be compared to the information on the test tubes and test tube rack. A second embryologist should double witness to confirm that the information on all is concordant.
- Only one sperm sample should ever be manipulated and in the hood at any one time (as per existing practice).
- If more test tubes are introduced then there needs to be a repeat check between either new test tube and specimen pot or new test tube and old test tubes. This should be double witnessed.
- One final double witness point at the end of sperm preparation is required for bar coding because other partners test tubes can be in the hood).
- For each of the double witness points above there should be a written record that the eggs and sperm have been double witnessed. This written record must be completed immediately after the double witness check has been carried out.

Egg collection:

- Embryologist should provide the patient with an ID card at the final scan prior to egg collection which contains both the patient and partner's photos.
- Nurse witnesses that the patient/partner identity is correct against medical records. Checking that the patient has their ID card.
- Operating theatre double witness check for patient identity against patient notes and laboratory sheet; patient's ID card is scanned by bar code PDA.
- Verbal confirmation of the patient's name, partner's name, DoB is carried out using an open ended question. Embryologist and clinician are responsible for this check and they use the information provided to cross check against the bar code scanner reading, the medical notes and laboratory sheet.
- Embryologist and clinician sign to confirm that the patient identification has been carried out by signing a double witness form immediately following the verbal patient identification has been cross checked with the other sources of information.
- Egg collection dishes should be labelled with bar codes. Once the bar code labels are attached they should be matched using bar code reader.
- Double witnessing point here in the procedure to confirm that the bar code labels attached to the egg collection dishes are those for the patient who has just been verbally identified.
- For bar code systems where another patient's eggs, an unlabelled dish or egg collection dish belonging to another patient could be put into the hood without generating an alarm it is essential to double witness every time the eggs are transferred between culture dishes. For bar coding systems which do

generate an alarm if another patient's dishes or an unlabelled dish is bought into the hood this may not be essential (in those cases where the manufacturer of the system has demonstrated its reliability through a formal evaluation process).

- Bar code matching should be repeated throughout the IVF process wherever there is a transfer between dishes, e.g. from the egg collection dish to the stripping dish for ICSI.

ICSI/IVF

- For bar code systems where another patient's eggs and sperm could be put into the hood without generating an alarm it is essential to double witness at the start of the ICSI IVF procedure. For bar coding systems which do not generate an alarm if another patient's dishes or an unlabelled dish is bought into the hood this is essential.
- Manual double witnessing of sperm and egg dish at the point prior to fertilisation. This provides a final error recovery point and ensures embryologists are reasonably kept abreast of manual double witnessing process.

Embryo transfer

- Operating theatre double witness check for patient identity against patient notes and laboratory sheet; patient's ID card is scanned by bar code PDA.
- Verbal confirmation of the patient's name, partner's name, DoB using an open ended question. Embryologist and clinician are responsible for this check.
- Embryologist and clinician sign to confirm that the patient identification.
- Manually double witness the embryos retrieved from the incubator are for the correct patient.

Embryo freezing

- One patient's embryos in the hood at a time.
- Colour coding of embryo dishes and straws should be used so that embryo storage.
- Need to ensure that the bar code on the straw matches the bar code on the embryo dish by scanning both.

7. SUGGESTED PROTOCOL FOR RFID

- RFID label should not be generated the day before but on the day the sperm is prepared and the egg collection will take place.
- Patient identification card produced for patient and partner. This contains information on the names of both parties, DOB and hospital numbers for the women and a photo of each partner.
- Every time there is a double witnessing point it should be recorded at time of witnessing.

Sperm Sample

- Nurse witnesses that the correct patient and partner are present for the required treatment by verbally checking their identity with an open-ended question and cross checking the patients' response with the medical records and a patient identification card.
- RFID assigned to patient on day of procedure by the embryologist, witnessed by a second embryologist. They double witness the RFID tag going on to the specimen pot and send it to the ward. Upon receipt of the specimen pot the nurse in conjunction with the partner scans the pot and confirms that the barcode label info relates to this partner and his spouse/girlfriend. The integrity of the adhesive used on the labels will need to be fully tested prior to this solution being implemented. On completion of a specimen being produced it should be placed in an envelope. This process should be double witnessed by the nurse and the partner.
- Only one sperm sample is transported to the laboratory at a time.
- On arrival at the lab the sample pot should be scanned again. The RFID information on the specimen pot should be compared with information on the test tube. A second embryologist should double witness to confirm that the information on all tubes/pots matches.
- Only one sperm sample should ever be manipulated on the hood at any one time.
- Embryologist accepts completion of the sperm preparation process on computer.

Egg Collection

- Nurse witnesses that the correct patient and partner for required treatment with medical records.
- Patients id card is scanned by RFID PDA. Then complete a verbal witnessing of the patients name and DOB using an open ended question by the embryologist and clinician.
- Embryologist enters patient name and DOB into computer to assign RFID tag to EWD. If patient name and DOB is incorrect, the system will ALARM with a mismatch.
- The RFID system is continuously monitoring the movement of eggs/sperm and their manipulations therefore the need for MDW is precluded.

ICSI/IVF

- Manual double witnessing of sperm and egg dish of designated couples sample required. This provides a final error recovery point and ensures embryologists are kept abreast of manual double witnessing process.

Embryo Transfer

- Patients id card is scanned by RFID PDA. Then complete a verbal witnessing of the patients name and DOB using an open ended question by the embryologist and patient.

- The RFID system is continuously monitoring the movement of eggs/sperm and their manipulations therefore the need for MDW is precluded.

Embryo Freezing

- Only one patients embryo's should be in the hood at any one time.
- RFID code attached to the colour coded straw, RFID system confirms transfer.

Please note that the protocols for both bar coding and RFID have been developed based upon our observations of those systems in use in Liverpool and Essex respectively. We recognise that bar coding and RFID systems used in other centres may have different functionality. It is therefore essential that local protocols are developed in the context of a human factors appraisal of each system's functionality.

8. DISCUSSION

The principle risks of manual double witnessing, RFID and bar-coding have been summarised in Appendix 2 and in the Main Findings section of this report. The risk assessment process and observations identified a wide range of potential errors which could occur in each of the IVF centres we had access to. These include:

- Omissions of key double witnessing points due to time pressure, workload, the numerous checking points in the process and distractions (amongst other factors).
- Failure to record when double witness checks have been carried out; either immediately after the checking process or altogether.
- Equipment failures in bar coding and RFID which could lead to checking errors.
- Degradation in the manual double witness checks as embryologists proceed through the sperm preparation and egg collection task sequence – with incomplete checks being carried out.
- Potential errors in the technical performance of IVF tasks during sperm preparation, egg collection, embryo transfer, ICSI and IVF.
- Labelling errors leading to incorrect patient identifiers on culture dishes and test tubes
- Storage problems which may lead to the wrong sperm or eggs being selected from an incubator or hood.

Throughout the study some other notable areas of risk were identified which are worth highlighting. These are discussed below:

The observations undertaken as part of this research identified variability between embryologists in one laboratory in terms of how they carried out manual double witness checks. Whereas some of the embryologists use a simultaneous repeating process where both staff say the name out loud, others use a procedure where one embryologist reads the name out loud and a second embryologist confirms that this is the correct information on the tubes, in dishes, etc. In addition to this at Liverpool during manual witnessing of sperm samples and during egg collection we observed the embryologists repeat patients and partner's name and DoB on first check but then just use the names of the patient and the partner later in the process. It is suggested that where a manual double witness is needed within the process the

importance of complete checking is re-emphasised to staff. However, as we have stated previously, the combined effects of a HFEA protocol which has numerous manual double witness points, together with a busy embryology laboratory creates the preconditions for non-compliance with checking protocols. It is therefore important to amend the existing HFEA manual double witnessing protocol to increase the likelihood that where manual double witnessing checks are required they will be complied with fully.

Review of the incident data would suggest problems associated with witnessing form completion is not just a theoretical risk as identified within the risk assessment, but is an error affecting service delivery. The signing of the witnessing form is a good defence against witnessing failures if completed at appropriate task points. Our observations identified practices where embryologists sign components of the witnessing form in chunks rather than as discrete tasks. This is a risk because it reduces the recovery opportunities for errors and omissions upstream to be identified and mitigated.

The patient identification card in operation at Liverpool is an important visual defence which could reduce patient misidentification risks. The identification card should contain both the male and female patient's photos and personal identification details. We observed one case in which the male partner had not attended the pre-admission scan and the ID card only contained the female patient's photograph. This scenario could potentially reduce the effectiveness of an otherwise good safety barrier.

During the egg freezing process observed at Liverpool the embryologist worked on more than one patient's eggs at a time in the hood. The egg collection dishes and pipettes were colour coded and the associated equipment was provided in a separate working space within the hood. The researchers had some concerns about the risks associated with freezing more than one patient's embryos at a time in a busy working environment, where egg freezing is carried out around other tasks, and there are a large number of distractions due to manual double witnessing demands.

Fertility centres also need to consider how best to manage infectious patients in the laboratory and to ensure that embryologists have easy access to the infection control procedures for dealing with such patients. The researchers observed a situation where a HEP C positive patient was admitted for an egg collection procedure. No protective clothing was to hand, consequently the staff had to search for it when the patient was being brought to the operating room.

During the observations at both centres we also observed embryologists matching samples within the bar coding and RFID systems using someone else's ID. It is therefore suggested that each embryologist is provided with a unique identifier, preferably using finger print technology.

The main problem the embryologists initially experienced with the RFID system was getting used to working in a smaller workspace but this in itself is a physical barrier which decreases the opportunity to work on more than one patient at a time. After the initial introduction of the electronic witnessing system there were several mismatches caused by embryologists lack of familiarity with how close you could let another patient's sample drift within the electronic sensor area. This has had a positive impact on improving working practices and reducing the likelihood of mismatch. For example embryologists used to review a group of embryos (from different patients) on the hood in one go, but because RFID alarms and records a mismatch embryologists only ever work on one patients embryos at a time.

From a human factors perspective, the RFID system has two major advantages over the bar coding system that we observed. Firstly, as stated previously, RFID has in-built defences to prevent embryologists working on more than one patient's eggs or sperm at a time. Secondly, RFID has an in-built forcing function which prevents embryologists from omitting key task steps in the process. The RFID system at Essex is designed to prevent staff proceeding with task steps further in a sequence without having completed preceding steps first. In contrast, the bar-coding system at Liverpool does not have this functionality. It is therefore more prone to omitting key steps in the IVF process. There is a greater risk that embryologists will omit key task steps due to attentional lapses or non-compliance. Laboratories where embryologists are continuously distracted by the double witnessing demands of other colleagues are particularly vulnerable because the human factors literature suggests that interrupting and returning to a task is a common source of human error (Reason, 2001). It is however important to note that some types of bar coding system have been designed with this functionality in place. Thirdly, the interface of the RFID system is better designed than the bar coding system interface. The former uses icons of egg collection dishes and warning signs to alert embryologists to the system's understanding of which tasks are currently being carried out. Whereas the RFID interface uses colours, the bar coding interface is monochrome and contains drop down menu lists (which in themselves create an increased potential for a selection error).

On the morning of the visit to observe the RFID system, a cable had come out of the electronic witnessing system whilst the hood was being cleaned. This led the embryologists to have to diagnose and fix the problem. It is therefore important to consider the types of staff who have access to an embryology laboratory who could inadvertently compromise a bar-code or RFID system, for example, cleaners and porters.

The RFID system, like any technology, is prone to major technical failure. During one of our visits we observed such a failure. Due to a software upgrade and a fault on the RFID system, all RFID labelled dishes and tubes were unknown when placed under the hood, indicating a computer memory failure and the need to rely on manual witnessing. HFEA therefore needs assurance from the suppliers of RFID technology that the software has been fully tested, quality assured and risk assessed before it is fully launched within the fertility arena. Linked with this software vulnerability is the need to consider the likelihood and impact of viruses and worms on RFID technology.

On a related note it is also important to consider the potential side effects of a total reliance on technology to match sperm samples, eggs and embryos. It is possible that sole reliance on a bar coding or RFID system may de-skill embryologists in the process of manual double witnessing. This may be a particular problem for junior or inexperienced embryologists. Consideration should therefore be given to how to maintain manual double witnessing skills alongside the introduction of new technologies to ensure that staff can work safely in the event of system breakdowns.

The researchers were impressed by the RFID technology in terms of its ability to maintain a history of the tasks completed for patients throughout the fertility process for each patient. The system provides a visual and audible alarm if a sample mismatch occurs within the hood area and this information is maintained in the log for each patient. However, the human factors and ergonomic considerations of technology design need further consideration e.g. VDU screen is not easily visible by the embryologist when working. The bar code system also needs further human

factors input to improve equipment design and functionality e.g. capability to work technology in an optimally lit environment, a flat base plate etc.

9. RECOMMENDATIONS

The recommendations below are made on the basis of a limited number of observations in embryology laboratories at only two IVF clinics. This needs to be borne in mind when prioritising future work in this area; in particular the fact that the human factors specialists only spent five man days observing in the laboratories.

1. While RFID and bar coding have potential to reduce mismatching errors they can also breed a new generation of errors. RFID and bar coding should therefore only be introduced into embryology laboratories following a formal human factors assessment which evaluates the 'fit' between the system, its functionality and the social context of the embryology laboratory in which it will be used.
2. HFEAs existing manual double witnessing protocol needs to be amended in light of the issues raised in this report; most notably risks associated with the allocation of unique patient identifiers for patients with similar names, the number of manual double witness checks in the existing protocol and the need to embed this protocol within the broader context of the IVF process.
3. HFEA needs a quality assurance process in place to check the translation of the national protocols into local protocols and inspectors should do this as part of their assessment work.
4. HFEA should develop a standard for bar coding and RFID system manufacturers to ensure that the system's design meets key specifications that may have important ramifications for misidentification, for example, built-in forcing functions to ensure that embryologists cannot omit key task steps.
5. Specific feedback needs to be given to each of the IVF centres who kindly participated in this study about aspects of practice highlighted in the discussion section of this report.

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11. KEY REFERENCES

1. Toft B. Independent review of the circumstances surrounding four adverse events that occurred in the Reproductive Medicine Units at the Leeds Teaching Hospitals NHS Trust, West Yorkshire.
2. National Patient Safety Agency. Right Patient, Right care. 2004.
3. Plebani M and Carraro, Mistakes in a stat laboratory: types and frequency. Clin Chem. 1997 Aug;43(8 Pt 1):1348-51.

4. Bates DW, Cohen M, Leape LL, Overhage JM, Shabot MM, Sheridan T. Reducing the frequency of errors in medicine using information technology. *J Am Med Inform Assoc.* 2001 Jul-Aug;8(4):299-308.
5. Stainsby, D, Williamson, Jones H and Cohen H. 6 Years of shot reporting--its influence on UK blood safety. *Transfus Apher Sci.* 2004;31(2):123-31.
6. Toft B and Mascie-Taylor 2005. Involuntary automaticity: a work system induced risk to safe health care. *Health Services Management Research,* 2005. 18: 211-217.
7. Turner CL, Casbard AC, Murphy MF. Barcode technology: its role in increasing the safety of blood transfusion. *Transfusion.* 2003;43(9):1200-9.2003
8. Oren E, Shaffer ER, Guglielmo BJ. Impact of emerging technologies on medication errors and adverse drug events. *Am J Health Syst Pharm.* 2003 Jul 15;60(14):1447-58
9. Ahrens N, Pruss A, Kiesewetter H, Salama A. Failure of bedside ABO testing is still the most common cause of incorrect blood transfusion in the Barcode era. *Transfus Apher Sci.* 2005 Aug;33(1):25-9.
10. Cummings J, Ratko T, Matuszewski, MS. Barcoding to Enhance Patient Safety. *Barcoding and RFID*
11. Patterson ES, Cook RI, Render ML. Improving patient safety by identifying side effects from introducing bar coding in medication administration. *J Am Med Inform Assoc.* 2002;9(5):540-53.
12. Patterson ES, Rogers ML, Chapman RJ, Render ML. Compliance with intended use of Bar Code Medication Administration in acute and long-term care: an observational study. *Hum Factors.* 2006;48(1):15-22.
13. van der Sijs H, Aarts J, Vulto A, Berg M. Overriding of drug safety alerts in computerized physician order entry. *J Am Med Inform Assoc.* 2006;13(2):138-47
14. Stockman, H. "Communication by Means of Reflected Power". *Proceedings of the IRE,* pp 1196-1204, October 1948).
15. Roark DC, Miguel K. RFID: bar coding's replacement? *Nurs Manage.* 2006;37(2):28-31.
16. Perrin RA and Simpson N. RFID and bar codes--critical importance in enhancing safe patient care. *J Healthc Inf Manag.* 2004;18(4):33-9.