Measuring human error in the IVF laboratory using an electronic witnessing system

A.R. Thornhill[1,2], X. Orriols Brunetti[1], S. Bird[1]

[1]The Bridge Centre, London, United Kingdom; [2]Department of Biosciences, University of Kent, Canterbury, United Kingdom

SUMMARY

RI-Witness™ is an electronic witnessing system using Radio Frequency Identification (RFID) technology to track samples at predefined procedural steps in IVF laboratories worldwide to prevent mix-ups and provide an automated solution for mandatory double-witnessing. We assessed the (i) true mismatch rate (introducing pre-allocated samples to workstations whilst another patient's samples are present); (ii) distribution and duration of mismatches (iii) incidence of additional unplanned interventions caused by electronic witnessing. 1757 patients were treated involving 21523 witness steps and 24473 RFID microchips (tags). 164/21523 (0.76%) events required tag allocation via administrative over-riding (e.g. steps outside approved process flow-charts). RI-Witness™ identified a low true mismatch rate (0.11%) which compares favourably with published error rates of <1% for similar laboratory activities. In practical terms this means that embryologists introduced the mismatched samples together in a flowhood on average once every 1000 witness steps. All mismatches were rectified in <10 seconds and were not confined to specific procedures or times. Aside from mandatory manual double witnessing steps, only 1% of all electronic witness steps required additional intervention from a second person.

INTRODUCTION

Following a series of high profile incidents involving misidentification in the UK and their extensive investigation and root cause analysis, the Human Fertilisation and Embryology Authority mandated manual double witnessing (MDW) for all IVF laboratory processes involving gametes or embryos to reduce the risk of misidentification of patient samples. Manual double witnessing can be defined as the "double checking performed on all clinical and laboratory procedures" with the

expectation that if an 'operator' makes an error, it will be caught by the other 'witness'. Although MDW is a safeguard and mandatory requirement in the UK whose apparent value is self-evident, evidence suggests it may not be as safe and effective as it should be. In busy laboratories, MDW may actually have the unintended consequence of increasing risk by creating distractions and interruptions in the process (1) and adds additional witnessing paperwork to an already busy working environment. Numerous problems with double checking have been identified previously relating to independent redundancy, attentional blindness and ambiguous accountability (1). Common checking failures include: check omission, check incomplete, involuntary automaticity (2) and non-contemporaneous checking. Furthermore, the effects of involuntary automaticity (2,3) can reduce the effectiveness of double witnessing because attention levels decrease when the same action is performed repeatedly by the same person. For these reasons several alternative options have been developed and trialled in order to replace the majority of manual witnessing steps in IVF: (i) systems based on barcode labels (4), (ii) systems based on silicon barcodes that are injected directly into eggs or embryos (5) and (iii) systems based on Radio Frequency Identification technology (6,7). RFID systems have two major advantages over barcoding. First, RFID has inbuilt defences to prevent embryologists working on more than one patient's eggs or sperm at a time. Second, RFID has an in-built forcing function preventing embryologists from omitting key task steps in the process. Finally, we considered the direct introduction of silicon barcodes into eggs and embryos as too labour-intensive and not sufficiently validated in the clinical setting. For these reasons, we opted to use the Research Instruments electronic witnessing system (RI-Witness™) based on RFID technology.

Mismatching incidents, some of which can have lethal consequences, result from checking errors that occur at different points in a variety of different healthcare processes. In IVF if misidentification occurs and goes unnoticed during virtually any process involving gametes and embryos, the end result may be catastrophic for the patient (s). Certain processes (e.g., mixing of eggs and sperm and transfer of embryos to the uterus) are seen as critical since they represent 'the point of no return' in terms of being able to rescue the situation or ameliorate the incident. Other processes (such as transferring an embryo to the incorrect patient's dish) can also lead to catastrophic incidents. Such errors can however be rectified even if identified after the fact. Evidence from the blood-transfusion sector highlights errors caused by similar process failures as are found in IVF (including interruptions, distractions, failure to carry out checks) but, to date, it has been difficult to reliably quantify and compare patient safety incidents where mismatching is a feature (1).

The consequences of misidentification errors in IVF are grave; ranging from legal challenges, regulatory conditions and sanctions, reduced patient confidence and patronage and even, in extreme cases, clinic closure. Electronic witnessing was introduced in our IVF laboratory to prevent mix-ups and provide an automated solu-

tion for mandatory double-witnessing. In this retrospective analysis, we had three objectives:

1. For the system to be adopted and accepted within a busy laboratory, it needed to be user-friendly and not introduce more problems than it solved. We determined the incidence of additional interventions. For example, how many times a second embryologist is needed to manually double witness a step that could and should have been witnessed electronically for any reason.
2. We wished to analyse the distribution and duration of mismatches.
3. We assessed the true mismatch rate (i.e. the proportion of mismatches corresponding to situations where there is an actual risk of mixing gametes or embryos from different patients).

MATERIALS AND METHODS

The commercially available RFID system - RI-Witness™ (Research Instruments Ltd, Falmouth, Cornwall, UK) uses self-adhesive RFID microchips (tags) that are placed on all dishes and tubes containing gametes or embryos. All workstations are equipped with readers and touch screens that register all tagged culture-ware and the actions performed according to the tagged culture-ware present. Laboratories can design their own custom flowchart incorporating every specific procedure that they perform. RFID technology maintains a time-stamped history of the tasks completed for patients by specific staff throughout the laboratory-based treatment process. The system provides a visual and audible alarm if a sample mismatch occurs within the working area and this information is maintained in the log for each patient. Electronic witnessing was introduced in our laboratory in December 2010. The system was validated by performing MDW in parallel for a 4 month period. Thereafter, performance reviews were conducted approximately quarterly to assess administrative override events, mismatches and RFID microchip (tag) failures. The study period described here includes retrospective analysis of all treatment cycles from December 2010 up to and including April 2012. Results were analysed under the following categories: Administrative overriding of the system, mismatches and unplanned intervention with the following definitions:

Administrative Overriding (AO): defined as culture-ware (dishes or tubes) manually introduced into the system without using the automated electronic witnessing function. These actions required a designated user with specific rights and permissions and were sub-categorised as: Required (R): including server or power failure and exceptional procedures outside of routine protocol (e.g. embryo transfer procedure cancelled and embryo needs to be moved from the transfer dish to a culture dish); Practitioner (P): human error or witness system used incorrectly; System (S): including tag failure (a broken or defective tag not recognised by the system), incorrect flow-chart configuration or patient not recognised on the database.

Mismatches: A mismatching event occurs in the medical process when patients

are not correctly linked with their specimens or specified treatments. The categories of mismatches we encountered were: (F) Forced: encountered during training or in early donation cycles when the flowchart was not optimised; (U) Use/Proximity: tags outside of the workstation inappropriately pre-assigned identities because of their proximity to the workstation; (T) True: tagged culture-ware (dishes and /or tubes) from two different patients in treatment co-located in the same workstation (even during discard procedures or if an empty dish is present, as still there is a "theoretical" risk of misidentifying patient samples). Failure to identify a true mismatch could lead to a catastrophic error.

Unplanned intervention: This category is a measure of the cost of the system to implement and maintain. Any event requiring additional effort in the laboratory (e.g. an additional MDW step) without additional clinical or safety gain is classified as an unplanned (and unnecessary) intervention including administrative overrides (including tag failures), and mismatches but excluding those steps absolutely requiring a second manual witness per standard operating procedure (SOP) and/or mandatory requirements.

RESULTS

The study period comprised 1757 treatment cycles involving 21523 witness steps and 24473 tags. Fewer than 1% steps required tag allocation via administrative over-riding of the system (AO) 164/21523 (0.76%) of which practitioner errors (P) accounted for 42 (0.20 %); 74 (0.34%) events (R) related to power cuts, server failure and exceptional procedures outside of protocol; 48 (0.22%) events were system errors (S). Considering the evolution of the administrative override events, 48 were recorded during the validation period, with a drop to an average of 23 per month thereafter. Within each quarterly period analyzed, the number of AO events related to Practitioner errors clearly decreased over time (17, 11, 5, 5, 2, 2). In the entire study period, we recorded only 54 mismatches of which 25 were the result of donation procedures (when the process flowchart was still not optimised) or during training thereby 'forcing' a mismatch (F) and 6 were use/proximity (U) mismatches. The true mismatch rate (T) was 0.11% (23/21523) with each rectified in <10 seconds and not confined to specific procedures or times. Over the 6 quarterly review periods, this rate has been remarkably consistent and always under 0.2% (ranging from 0.05% to 0.18%). According to these data, embryologists inadvertently bring dishes or tubes from different patients to the same workstation approximately once every 1000 witness steps on average. Any automated laboratory system needs to be robust to deal with the rigours of exposure to different reagents, temperature changes, humidity and other factors present in the laboratory yet still perform effectively. In this study, 24473 RFID tags were used, but only 17 (0.07%) fractured, became unusable or were defective; a tag failure rate of less than 1 in a 1000. Aside from mandatory double manual-witnessing steps, only 1% of all electronic witness steps required additional intervention from a second person.

CONCLUSIONS

RI-Witness™ accurately records all applicable laboratory procedures, identifying a low true mismatch rate (0.11%) which compares favourably with published error rates of <1% for similar laboratory activities (4,8,9). All true mismatches were rectified in <10 seconds suggesting that transfer of a sample into another dish would not have been possible in the time following the system alert. A regular review of electronic witnessing data has allowed us to create key performance indicators for this important part of our practice. In addition to the critical detection and prevention of human errors, the software associated with RI-Witness™ allows assessment of staffing levels, time-keeping, productivity, competency, training and consumable traceability. Other benefits include reduced staff distractions and stress, increased staff efficiency, SOP compliance and auditing. All parameters can be audited against treatment outcomes since every single process step of every cycle is time-stamped according to specific operators, thereby providing an unprecedented opportunity to improve quality of care through targeted operator improvements and ultimately improve patient outcomes. Considering the consistency of this true mismatch rate in our periodic analyses and with corroborative data from other clinics, it should be possible to provide an industry benchmark for human error in IVF. In many countries it is either a mandatory requirement and/or good medical practice ot provide patients with information about clinical risks (e.g. of ovarian hyperstimulation syndrome, OHSS) prior to treatment starting. Robust information regarding the type and incidence of human errors in the IVF laboratory could help inform and prepare patients for those rare but inevitable events. Given the importance of identifiability and the availability of proven technology to effectively eliminate the chance of catastrophic incidents resulting from human error in the IVF laboratory, it is unclear why clinics continue to take such avoidable risks.

REFERENCES

1. Adams S. and Carthey J. IVF witnessing and electronic systems final report. (2006) Commissioned by Human Fertilisation and Embryology Authority, UK. http://www.hfea.gov.uk/docs/Witnessing_samples_id_report.pdf
2. Toft B, Mascie-Taylor H Involuntary automaticity: a work-system induced risk to safe health care. Health Services Management Research 18: 211–216 (2005).
3. 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. (2005).
4. Schnauffer K, Kingsland C, Troup S. Barcode labelling in the IVF laboratory. Human Reprod (abstract) 214:i79 (2005**).**
5. Novo S, Barrios L, Santaló J, et al. A novel embryo identification system by direct tagging of mouse embryos using silicon-based barcodes. Hum Reprod 6 (1):96-105 (2011).

6. Glew AM, Hoha K, Graves J, et al. Radio frequency identity tags 'RFID' for electronic witnessing of IVF laboratory procedures. Fertil Steril 86 (3) S170 (2006).
7. Thornhill AR, Brunetti XO, Bird S et al. Reducing human error in IVF with electronic witnessing. Fertil Steril 96, Issue 3, Supplement, S179 (2011).
8. Valenstein P. Patient Identification Accuracy. Q-Tracks (QT1) 2004 Annual Summary. Northfield, Ill: College of American Pathologists (2005).
9. Carraro P and Plebani M. Errors in a Stat Laboratory: Types and Frequencies 10 Years Later. Clinical Chemistry 53:7 1338–1342 (2007).