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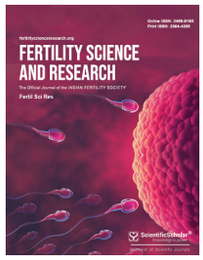

Review Article

Witnessing Systems in In Vitro Fertilisation Lab: Basics to Advanced

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ABSTRACT

The measures employed by fertility clinics to prevent Assisted Reproductive Technologies mix-ups are labelling of all labware and manual double-witnessing protocols. Advanced cutting-edge technological solutions for electronic witnessing are also being developed. One such recent innovation is the introduction of the Electronic Witnessing System (EWS) in infertility clinical practice. The goal of the EWS is to ensure accurate identification and prevent mix-ups. Critical points during the clinical and laboratory in vitro fertilisation (IVF) procedures are identified where mismatching of gametes and embryos may occur. These critical points are ovum pick-up, sperm collection, preparation of sperm, insemination[Intrauterine insemination (IUI), IVF, Intracytoplasmic sperm injection (ICSI)], transferring gametes and embryos between tubes or dishes, embryo transfer, and embryo or gamete cryopreservation.

Keywords: Barcode, Process, RFID, Witnessing, Workflow

INTRODUCTION

Infertility affects approximately 50 million couples globally, and patients are increasingly seeking medical intervention to conceive through in vitro fertilisation (IVF) procedures.[1] Success rate depends upon numerous factors, mainly patient-related variables, but also depends on new technologies and equipment incorporated in the laboratory. Sometimes, IVF procedural steps are susceptible to human errors with potentially deleterious consequences. For example, sample identification and mismatching errors may occur.

In fact, since the first known case of an Assisted Reproductive Technologies (ART) mix-up in 1987 in Manhattan, USA, the accidental use of incorrect gametes or embryos during ART procedures has been reported in centres around the world.[2] Even though the occurrence of ART mix-ups is rare, their consequences are devastating for both the couples and fertility centres, leading to complex legal actions against the clinics. Therefore, mechanisms to prevent these unintended accidents are currently being sought by the fertility clinics.

Measures to prevent ART mix-ups, such as labelling of all labware and manual double-witnessing protocols, are currently in place in fertility clinics worldwide. Advanced cutting-edge technological solutions for electronic witnessing are also being developed. One such recent innovation is the introduction of the Electronic Witnessing System (EWS) in infertility clinical practice.[3]

The goal of the EWS is to ensure accurate identification and prevent mix-ups. Critical points during the clinical and laboratory IVF procedures are identified where mismatching of gametes and embryos may occur. These critical points are[1]:

1. Ovum pick-up,
2. Sperm collection,
3. Preparation of sperm,
4. Insemination [Intrauterine insemination (IUI), IVF, intracytoplasmic sperm injection (ICSI)],
5. Transferring gametes and embryos between tubes or dishes,
6. Embryo transfer, and
7. Embryo or gamete cryopreservation.

TYPES OF WITNESSING SYSTEMS

Manual Witnessing

This is an old witnessing method used initially, a manual process where a second person independently verifies the accuracy and documents each step of the process, often using a paper checklist. It requires a trained witness, usually a fertility specialist or an embryologist. This person verifies the identity and handling of gametes or embryos at critical points. However, this mechanism of control has been shown to be vulnerable to human errors.[1] This type of manual system has limitations, as while it may help reduce errors, it's still susceptible to human fatigue and oversight. Dual-person inspection in IVF laboratories cannot fully avoid mix-ups or embryo transfer errors, and data transcription or entry is time-consuming and redundant, often leading to delays in completing medical records.[4]

Witnessing System Based on Silicon Barcodes

In this type of system, tiny biocompatible silicone barcodes are injected directly into oocytes or embryos to ensure accurate identification and tracking, preventing mix-ups and errors.[5,6] The barcodes are injected into the perivitelline space of eggs or embryos. This system facilitates sample tracking throughout the IVF process, from oocyte retrieval to embryo transfer, ensuring that the correct gametes and embryos are used at each stage. The system minimises the risk of human error, such as mixing of samples, ensures accurate identification and tracking, and contributes to improved patient safety and well-being. However, this type of system has limitations due to the high cost and complexity of implementation and maintenance. Such systems may not be suitable for all stages of the IVF process, such as blastocyst transfers, which limits their success and usage.

EWS

An EWS is a technology that uses barcodes or radiofrequency identification (RFID) tags and automated tracking to ensure accuracy and traceability of patient samples, viz. eggs, sperm, and embryos, throughout the IVF process. It helps in minimising the risk of mix-ups and human error in the IVF process. EWS is one of the recent advancements in the field of IVF that uses RFID technology to monitor all critical work carried out in each stage of the IVF procedure cycle.[7] This new type of tracking system adds an extra layer of security to each step of the IVF process by assisting with the identification of patients and traceability of their reproductive cells or gametes. Essentially, the tracking system ensures that the eggs, embryos and sperm belonging to patient are used in the treatment. Every culture dish, specimen tube or plasticware consumable that is used at any point in the IVF process is labelled with a unique barcode or RFID tag that links each item to the intended patient's chart. Each time a patient's eggs, embryos or sperm are handled in the lab, the embryologist will scan the barcode or RFID tag as additional confirmation that the dishes are correctly labelled and belong to the intended patient.

EWSs use barcode scanning or RFID tags for patient and sample identification. RFID tags are a type of tracking system that uses radio frequency to search, identify, track, and communicate with items and people. These identification systems help mitigate the risk of human error during the transfer or movement of samples from one dish or tube to the other and safeguard every step of the IVF cycle. RFID tags are circular or rectangular in shape and stick to the side of the plasticware used for clinical processing of the IVF samples. They are patient-specific and can record all credentials of the patient, like name, personal data, blood group, fingerprint and face.

WORKING PRINCIPLE OF EWSs

Barcode-Based EWS

As the name suggests, in a barcode-based EWS, barcodes are used for tracking patient and sample data for centralised recording in a computer software system. A laser light from a scanner is shone on the barcode label surface, and its reflection is captured by a sensor to read a barcode. However, barcodes have no read and write capabilities and hence have limitations. These systems are very labour-intensive, as the samples must be scanned individually at each step. The operator must remember the sequence of the process and manually scan each dish or piece of plasticware during the process. This inconvenience results in skipping errors and hence lower adoption of these systems. Hence, more recently, there has been innovation in EWS development, leading to the development of RFID-based EWSs.

RFID-Based EWS

RFID, or Radio-Frequency Identification, is a technology that uses radio waves to identify and track objects, without physical contact, using tags and readers. An RFID-based EWS in IVF is an innovative approach to ensure the accuracy, security, and traceability of the procedures, particularly when handling biological samples, such as eggs, sperm, and embryos. The technology integrates RFID to track and authenticate the various stages of the IVF process, offering enhanced patient safety and reducing the chances of human error.

FUNCTIONING OF AN RFID-BASED EWS IN IVF

Patient Identification

- **RFID Wristbands/Tags:** Each patient or donor is issued a unique RFID tag or wristband that contains a unique identifier. This tag is linked to the patient's medical record, ensuring that all procedures and samples are correctly matched to the patient.
- **Real-Time Tracking:** The RFID system ensures that every patient's sample is accurately identified at every stage of the IVF process, from egg retrieval to fertilisation, embryo culture, and transfer.

Tracking Biological Samples

- **Sample Tracking:** Eggs, sperm, and embryos are tagged with RFID labels at each stage. For instance, during egg retrieval, the egg collection dish or container is tagged with an RFID label. This allows the system to track every sample, ensuring that no mix-ups occur.
- **Real-Time Data:** As the samples move through various phases, e.g., fertilisation and embryo culture, RFID readers located at different points in the IVF laboratory automatically update the system with the sample status, location and timestamp.

Ensuring Witnessing and Authentication

- **Electronic Witnessing:** RFID readers act as 'electronic witnesses' to confirm that the right sperm is combined with the right egg and the right embryo is transferred to the correct patient. The RFID system can record the personnel involved, timestamp each action, and store the information securely for legal or regulatory purposes.
- **Two-Person Verification:** RFID can be linked to a two-person verification system, where two authorised individuals, e.g., a lab technician and an embryologist, must scan their RFID credentials to confirm that a procedure is being performed correctly.

Data Integrity and Security

- **Audit Trail:** All RFID readings are logged in a secure database, creating an audit trail that ensures transparency and accountability. This data can be used to review the entire IVF process for quality control and regulatory compliance.
- **Alerts and Notifications:** The system can automatically generate alerts to notify the embryologist in case there is any mismatch or deviation from the procedure, e.g., incorrect pairing of egg and sperm, thus preventing errors.

Integration with IVF Laboratory System

- The RFID system can be integrated with the IVF laboratory's existing software systems, such as the Laboratory Information Management System, to ensure seamless data flow and better management of patient and sample information.
- The system can generate reports on the status of each procedure, track the number of embryos transferred, and monitor the outcome of each IVF cycle.

Patient Privacy

- **Privacy:** Since the RFID system is tied to a unique identifier rather than personally identifiable information, it can help protect patient privacy while still ensuring data accuracy and traceability.

BENEFITS OF AN RFID-BASED EWS

1. **Accuracy and Efficiency:** RFID technology ensures that all samples and patients are properly tracked. It reduces the chances of error or mistakes.
2. **Increased Security:** The system minimises the risk of mix-ups and contamination by continuously monitoring and recording the movement of samples.
3. **Compliance:** The audit trail generated by RFID can assist in meeting regulatory standards and providing the traceability required in IVF procedures.
4. **Transparency and Accountability:** Both patients and clinicians can have confidence that every step in the IVF process is accurately recorded and can be reviewed at any time.

CHALLENGES AND CONSIDERATIONS OF AN RFID-BASED EWS

1. **Costs:** The initial implementation of an RFID system may be high due to the need for hardware and software integration.

2. **Technology Adoption:** IVF clinics need to train staff and ensure smooth integration with existing systems.
3. **Security and Data Privacy:** The system needs to ensure that data security protocols are followed to prevent unauthorised access to sensitive patient information.

The above challenges are manageable with the advent of technology and adoption.

HOW DOES AN EWS WORK?

- It starts with assigning unique ID cards to the patients.
- Their data and biometric credentials, i.e., fingerprint and face, are recorded on the system.
- Role of the patient is assigned as patient, recipient, or donor.
- Each dish and piece of plasticware holding the patient's sample is tagged and assigned to their credentials.
- Egg collection and semen collection jars are linked to unique ID cards.
- Each dish and piece of plasticware is connected and matched with the piece of the previous dish or plasticware before starting the procedure.
- Every work area in the IVF lab detects wireless signals from these RFID tags. An antenna is built into the readers. This antenna emits the radio waves to transmit signals that activate the tag. The information present on the tag is translated to the detector. The software in the computer decodes that specific radio frequency and displays details of the patient/dish/tube, which is then verified with the data in the software. One such system, the SURETY™ Witness System, has successfully filed a patent for the unique design of its compact RF detector, which consists of a circular antenna inserted in the light source itself. This unique compact design helps to avoid false mismatches, which are prone to happen in other RFID-based witness systems.

Here is a schematic of how the RFID tag information is passed to the computer [Figures 1 and 2].

ADVANTAGES OF AN RFID-BASED SYSTEM OVER A BARCODE-BASED EWS

There are two significant advantages of an RFID-based witnessing over a barcode-based system:

- An RFID system safeguards against the users unintentionally working on multiple patients' eggs or sperm simultaneously.

Figure 1: A typical setup of an electronic witnessing system (EWS).

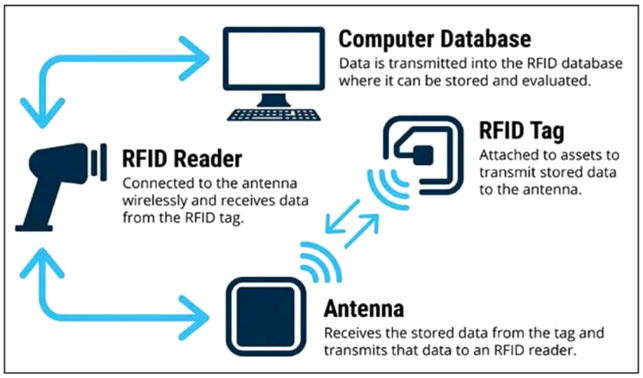


Figure 2: Schematic flow of the radiofrequency identification (RFID) tag information.

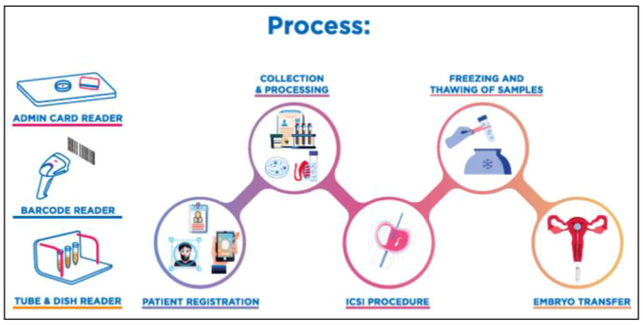


Figure 3: Assisted reproductive technologies (ART) process. ICSI: Intracytoplasmic sperm injection.

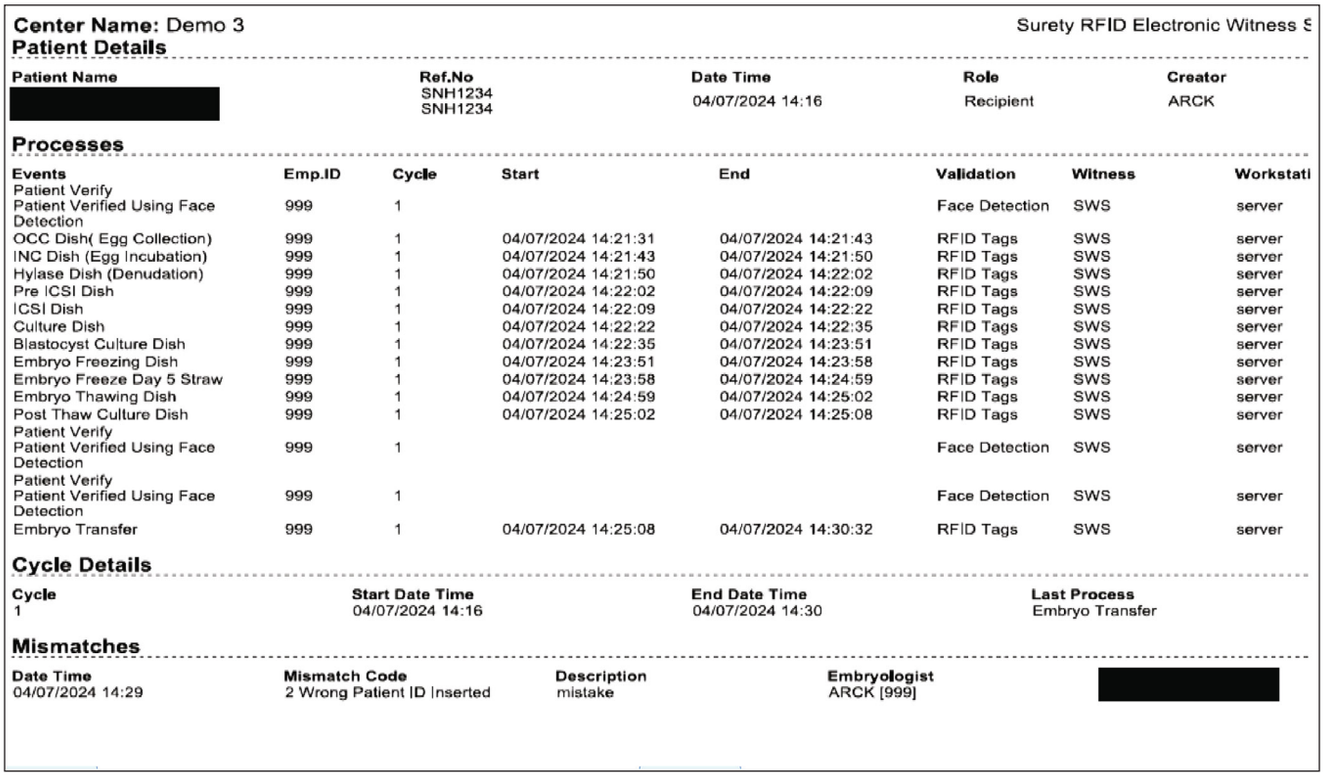
- An RFID system records each step of the ART procedure, preventing the omission of crucial steps. The adoption of these types of EWS is swiftly expanding across the IVF clinics globally.[4]

Given below is a comparison between the two types of systems [Table 1].

Table 1: Comparison between barcode and RFID based electronic witnessing systems.

Attribute	Barcode-based system	RFID-based system
Ease of scan	In a barcode-based system, there is a need to scan each dish, lined up or individually placed side-by-side in the line of sight for the scanner to read and verify that they are compatible. Samples are required to be moved out of the work area for scanning.	In an RFID-based system, dishes can be read simultaneously, automatically allowing the embryologist to work uninterruptedly.
Dependency on the operator	Barcode security relies on the operator remembering to perform check scans. There is no automatic alert or action if the embryologist forgets to scan the barcode.	An RFID-based system automatically monitors the work area under the microscope constantly, so that there is no chance of oversight or escape.
Alerts automatically	Using a barcode system, two unrelated samples can be placed in the same work area and may even be unintentionally manipulated.	In an RFID-based system, the work area is the viewing area under the microscope. If two incompatible samples are placed under the microscope, the RFID detector alerts the embryologist about the mismatch, visually and audibly. It does not allow the embryologist to proceed further until the error is resolved.
Interruption of workflow	In both barcode and manual methods, specific movements in the IVF cycle are logged manually. The workflow is interrupted during checks.	This is not the case in RFID-based systems, as monitoring is done continuously whenever any activity is performed under the microscope.

RFID: Radiofrequency identification, IVF: In vitro fertilisation.



Center Name: Demo 3 — Surety RFID Electronic Witness S

Patient Details

Patient Name	Ref.No	Date Time	Role	Creator
[redacted]	SNH1234 SNH1234	04/07/2024 14:16	Recipient	ARCK

Processes

Events	Emp.ID	Cycle	Start	End	Validation	Witness	Workstati
Patient Verify Patient Verified Using Face Detection	999	1			Face Detection	SWS	server
OCC Dish(Egg Collection)	999	1	04/07/2024 14:21:31	04/07/2024 14:21:43	RFID Tags	SWS	server
INC Dish (Egg Incubation)	999	1	04/07/2024 14:21:43	04/07/2024 14:21:50	RFID Tags	SWS	server
Hylase Dish (Denudation)	999	1	04/07/2024 14:21:50	04/07/2024 14:22:02	RFID Tags	SWS	server
Pre ICSI Dish	999	1	04/07/2024 14:22:02	04/07/2024 14:22:09	RFID Tags	SWS	server
ICSI Dish	999	1	04/07/2024 14:22:09	04/07/2024 14:22:22	RFID Tags	SWS	server
Culture Dish	999	1	04/07/2024 14:22:22	04/07/2024 14:22:35	RFID Tags	SWS	server
Blastocyst Culture Dish	999	1	04/07/2024 14:22:35	04/07/2024 14:23:51	RFID Tags	SWS	server
Embryo Freezing Dish	999	1	04/07/2024 14:23:51	04/07/2024 14:23:58	RFID Tags	SWS	server
Embryo Freeze Day 5 Straw	999	1	04/07/2024 14:23:58	04/07/2024 14:24:59	RFID Tags	SWS	server
Embryo Thawing Dish	999	1	04/07/2024 14:24:59	04/07/2024 14:25:02	RFID Tags	SWS	server
Post Thaw Culture Dish	999	1	04/07/2024 14:25:02	04/07/2024 14:25:08	RFID Tags	SWS	server
Patient Verify Patient Verified Using Face Detection	999	1			Face Detection	SWS	server
Patient Verify Patient Verified Using Face Detection	999	1			Face Detection	SWS	server
Embryo Transfer	999	1	04/07/2024 14:25:08	04/07/2024 14:30:32	RFID Tags	SWS	server

Cycle Details

Cycle	Start Date Time	End Date Time	Last Process
1	04/07/2024 14:16	04/07/2024 14:30	Embryo Transfer

Mismatches

Date Time	Mismatch Code	Description	Embryologist	
04/07/2024 14:29	2 Wrong Patient ID Inserted	mistake	ARCK [999]	[redacted]

Figure 4: An example of a detailed patient-wise report. OCC: Oocyte cumulus complex, ICSI: Intracytoplasmic sperm injection, RFID: Radio-frequency identification.

SALIENT FEATURES OF RFID-BASED EWS

- Unique design of the RF detector and placement to avoid false mismatch.
- AI-based face recognition and fingerprint recognition for witnessing.
- Very small tags for an uninterrupted view of the embryologist.

- User-friendly application.
- Flowchart, witness point diagrams and protocols can be created according to the clinic's needs.
- Substantial data is generated, which helps in intralab or clinic-group comparisons.
- The signals are identified, tracked and recorded at each step of the ART process.
- An EWS can manage preimplantation genetic testing (PGT) procedures and cryopreservation procedures as well, and the tags can withstand cryopreservation temperatures (−196°C).

Given below is a schematic of an ART process [Figure 3].

On top of the security of gametes and embryos, these witness systems can also be used to improve other aspects of the lab, such as

- Keeping patient records,
- Scheduling appointments,
- Daily overview of procedures,
- Inventory management, and
- Workflow management of staff.

Different reports can be generated related to patient cycles, mismatch errors, and consumable reports per cycle [Figure 4].

CONCLUSION ON USE OF EWSs IN THE IN VITRO FERTILITY PROCEDURES

EWSs have been in use in assisted reproduction for over a decade. Increased media reporting of errors and an acknowledgement of the stress placed on laboratory staff have led to recognition of the wider benefits of such systems beyond their witnessing function.[8] EWSs are user-friendly, and it takes hardly any time to get acquainted. After getting initial information and confirmation from the clinic, mapping of locations for readers and sensors is carried out, followed by installation of hardware and software. A witness point diagram in the form of a flowchart is created according to the centre's needs, requirements and the workflow. A demo is run to test the step-by-step process mentioned in the witness point diagram. For a certain period, the system is validated where human double-checking and witnessing using RFID are carried out simultaneously.

Adoption of an EWS is considered to be the ultimate tool to safeguard the identification of gametes and embryos. However, this is only possible when used correctly and requires proper training and attention from the clinicians. Though mix-ups or mismatches are rare events, the necessity of incorporating witnessing systems is increasing. IVF clinics could face legal challenges and regulatory sanctions, while patients would have to cope with the psychological damage and loss of confidence in the IVF process. A survey was carried out for 'Patients' awareness and concerns about a possible mismatch error and their satisfaction level in response to integration of the witnessing system in clinical procedures'. It was observed that from a psychological perspective, witnessing the system increased patients' well-being and, very importantly, confidence in the clinic during IVF procedures and helped in minimising additional stress that could overload the patient's emotional balance while undergoing treatment.[2] On the other hand, considering the mismatch of gametes can stake the reputation of a clinic, leading to catastrophic effects, the clinician's and embryologist's perspectives also changed, and they find complete peace of mind. It also helps clinicians and embryologists to keep transparency with patients, making them feel involved in the ART process.[2] The system and its reports generate useful data that can be used in productivity analysis of the clinic and also help in research activities.[5]

An EWS can improve laboratory efficiency by reducing the time required for witnessing procedures and by minimising process interruptions. When applied correctly, an EWS can replace manual witnessing in the medically assisted reproduction lab to prevent sample mix-up.[5] The EWS is well perceived by embryologists and IVF laboratory managers, as it enhances their confidence and peace of mind with regard to witnessing compliance, procedure safety and process accuracy.

Author contribution: Dr. Sarabpreet Singh is an embryologist & is heading the Department of Clinical embryology & Andrology at Artemis Hospitals, Gurgaon. He has provided the medical content in the article & integrated it with the technical inputs provided by the co-author. Parminder JS Sandhu is a healthcare entrepreneur and Founder at RIVDX Systems Private Limited. He is the subject matter expert on the EWS. He's researched various systems and provided engineering and system inputs in compilation of this article.

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