IVF Witness: Safeguarding the daily work by Radio Frequency Identification (RFID) systems?

Ronny Janssens - Quality Manager
Disclosure

I declare that no commercial or financial interest has influenced the content of this presentation
Introduction

Embryology lab is like air traffic control room – Zero tolerance for errors

10% estimated error rate in UK clinical procedures!
Identification: Good IVF laboratory practice

- Couple linked in database
- Double labelling system: name + unique code
- Disposable materials – single use
- All carriers are labelled
- Separation in time and space
- Double witness by second operator at every step
UK Risk Assessment

Considerations/Limitations

- Need presence of second operator
- Time consuming
- Distraction
- “Autopilot” - Involuntary automaticity (Toft et al. HSMR, 2005)
- Perceptual blindness
- Protocols may not be followed
- Workload
- Paperwork
Failure mode and effects analysis of witnessing protocols for ensuring traceability during in vitro fertilization

Laura Rienzi
Senior Embryologist; GENERA Centres for Reproductive Medicine
Laboratory Director; Rome, Marostica, Umbertide, Napoli
Process phases, number of process steps, number of failure modes, and relative risk priority numbers (RPN) before the implementation of the electronic witnessing system (EWS).

Rienzi et al. RBM online, 2015

<table>
<thead>
<tr>
<th>Process phases</th>
<th>Process steps n (%)</th>
<th>Failure modes n (%)</th>
<th>High/moderate risk modes without EWS (RPN &gt;15)</th>
<th>Highest RPN without EWS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. oocyte retrieval</td>
<td>4 (21.1)</td>
<td>8 (25.0)</td>
<td>2</td>
<td>30</td>
</tr>
<tr>
<td>2. sperm collection</td>
<td>2 (10.5)</td>
<td>5 (15.6)</td>
<td>2</td>
<td>30</td>
</tr>
<tr>
<td>3. gamete processing</td>
<td>2 (10.5)</td>
<td>4 (12.5)</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>4. insemination</td>
<td>3 (15.8)</td>
<td>3 (9.4)</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>5. embryo culture</td>
<td>1 (0.5)</td>
<td>2 (6.3)</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>6. embryo transfer</td>
<td>3 (15.8)</td>
<td>4 (12.5)</td>
<td>1</td>
<td>30</td>
</tr>
<tr>
<td>7. cryopreservation</td>
<td>4 (21.1)</td>
<td>6 (18.8)</td>
<td>1</td>
<td>30</td>
</tr>
</tbody>
</table>

EWS = electronic RPN = relative risk priority.
FMEA analysis of most relevant risk modes identified before and after the implementation of the electronic witnessing system (EWS).
Barcode vs RFID

Manual

Human factor

Automatic
RFID technology in IVF

- Helps to eliminate “mix-up” errors in IVF labs by electronically identifying patients and containers.
How does it work?

IVF Witness relies on 3 components:

1. RFID Tag readers on workstations
2. RFID Tags
3. Software – sample recognition

→ Consumables: ‘tagged’ with an adhesive RFID label
→ RFID label generates a unique signal
→ This signal is used to uniquely assign the item
→ Every time an item enters the read range it is detected and identified in the database
Step 1 - Workstations

Each workstation is fitted with a RFID reader and monitored 24 / 7.
Hardware Components
Step 2 – RFID tags

Test tubes and Petri dishes are tagged with a label containing an RFID microchip.

Gametes/embryos move from container to container. The microchips are read by the RFID sensors.
Step 3 - sample recognition software

A complete record of the cycle is created and the system knows what the next step in the IVF cycle for this patient is.

Confirm each action and continue.
Mismatches
Start-up

- Hardware installation
- Interface IVF software
- Workflow configuration
- SOPs & training
  1. Assignment of ID cards – Administration, nursing
  2. Culture dish preparation
  3. Software: intuitive
QM tools

● Traceability
  → EUTCD
  → ISO 15189
  → Who – what - when

● Stock/badge control

● Audits
  → Competence assessment
  → Productivity
Safety

Is the technology safe?

**YES**

- MEA tests (wavelengths and tags)
- 6 years without any negative effects
- CE marked
- RFID frequency 13.56MHz, 1.4 W max
RFID-label and temperature

- IVF Round Dish without label
- IVF Round Dish with label
Benefits

- **Prevention of errors:** ALL containers are checked automatically and instantaneous

- Gives a “guarantee” of identity
  A container belonging to a patient cannot have been used with containers belonging to other patient(s)

- Runs in parallel and independently of the human readable identifiers on containers

- Checking and recording interferes minimally with procedures
Benefits

- Done in **real time**
- Full traceability of operators (individual login)
- Batch control and management
- Compliments procedures
  - Direct data entry
  - Provides a detailed audit trail
- Competitive advantage
  - Gives patients reassurance and confidence
- Reduced liability risks
Conclusions

- IVF is a high risk activity for identification errors
- RFID technology can be used to identify and track biological material
- Hardware installation on workareas
- Reliable, safe and effective in preventing - reducing the risk of IVF mix-ups
- Increased level of confidence
Risk mode 1 = operating theatre list not respected at oocyte retrieval; risk mode 2 = incorrect tubes/dishes labelling; risk mode 3 = contemporaneous sperm samples collections; risk mode 4 = incorrect sperm plot labelling; risk mode 5 = operating theatre list not respected at embryo transfer; risk mode 6 = contemporaneous thawing of different samples.
To finish...

- Anxiety
  - Less flexible
  - Novel technology
  - Changes in working habits

- Optimism
  - Safe
  - Easy to adapt
  - Increased confidence
Thank you for your attention