



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

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# 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%  
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

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# Process phases and Failures mode

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

EWS = electronic RPN = relative risk priority.

32 failure modes

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).

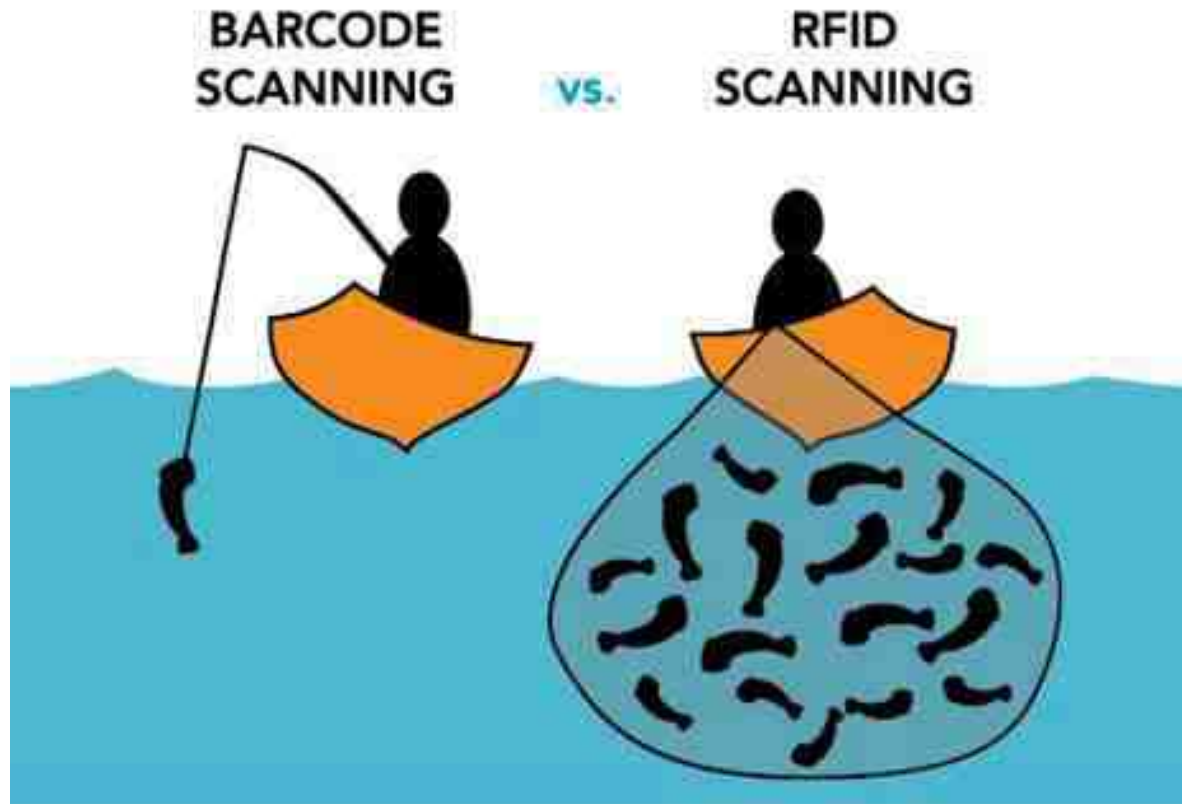
# Most relevant risk modes

Most relevant risk modes	Process phase	Before EWS implementation					Failure modes and possible consequences	Cause of failure
		O	S	D	RPN			
1. Operating theatre list not respected	oocyte retrieval	3	5	2	30	Failure in patient identification, oocyte mismatch	Team communication failure	
2. Incorrect tube/ dish labelling	oocyte retrieval	3	4	2	24	Failure in cell identification, partial or total loss of oocytes	Inappropriate labelling system	
3. Contemporaneous sample collections	sperm collection	3	5	2	30	Failure in patient identification, sperm mismatch	Heavy workload and distraction	
4. Incorrect pot labelling	sperm collection	3	4	2	24	Failure in cell identification, partial or total loss of sperm	Inappropriate labelling system	
5. Operating theatre list not respected	embryo transfer	3	5	2	30	Failure in patient identification, embryo mismatch	Team communication failure	
6. Contemporaneous thawing of different samples	cryopreservation	3	5	2	30	Failure in straw identification, gamete/ embryo mismatch	Heavy workload and distraction	

D = detection; EWS = electronic witnessing system; O = occurrence; RPN = risk priority number; S = severity.

**FMEA analysis of most relevant risk modes identified before and after the implementation of the electronic witnessing system (EWS).**

# Barcode vs RFID



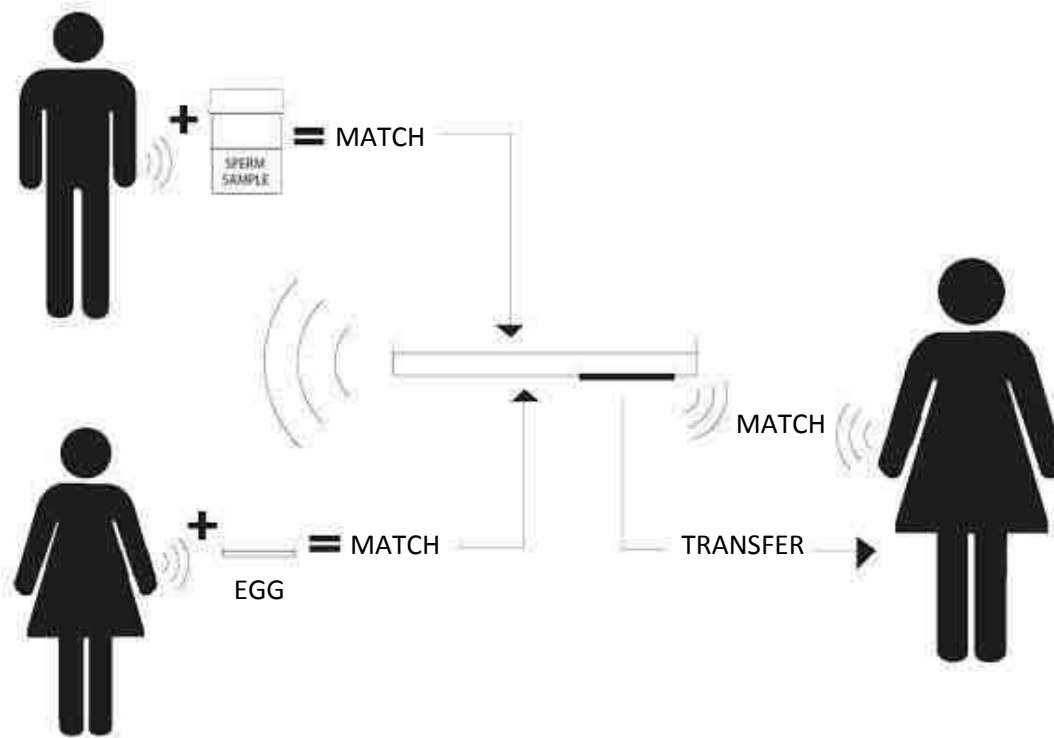
Manual

Automatic

Human factor

# RFID technology in IVF

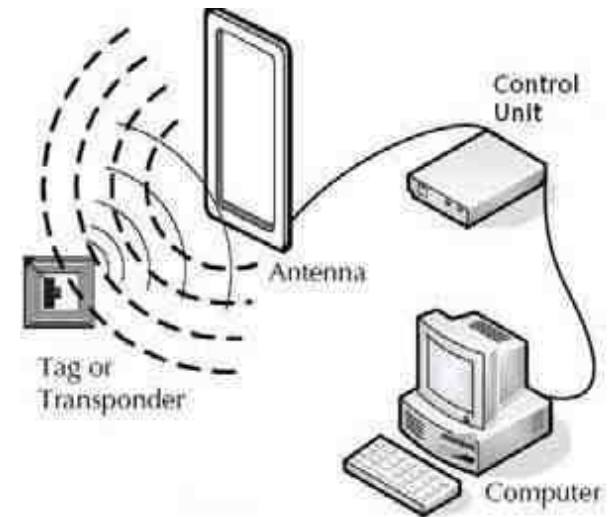
- Helps to eliminate “mix-up” errors in IVF labs by electronically identifying patients and containers



# 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

The screenshot displays the IVF-Witness software interface. At the top, it shows 'Current Patient: 12345 Helen Smith'. Below this is a 'Recent History' table with columns for 'Date/Time' and 'Operator'. The table contains two entries: 'Egg Prep' on '09/08/2007 14:38' by 'Rob', and 'Assign Egg Wash' on '09/08/2007 14:36' by 'Rob'. To the right of the table is a 'Log Out' button and the text 'Operator Rob'. The main work area shows two petri dishes, each labeled 'Egg Wash Dish [1] 12345 Helen Smith' and 'Egg Culture Dish [1] 12345 Helen Smith'. At the bottom, it says 'Work Area 2 Samples in Work Area'.

Recent History	Date/Time	Operator
Egg Prep	09/08/2007 14:38	Rob
Assign Egg Wash	09/08/2007 14:36	Rob

Operator Rob Log Out

Egg Wash Dish [1] 12345 Helen Smith

Egg Culture Dish [1] 12345 Helen Smith

Work Area 2 Samples in Work Area

**When a sample is in the work area, the patient details, the dish type and the history of the IVF procedure is registered and displayed.**

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

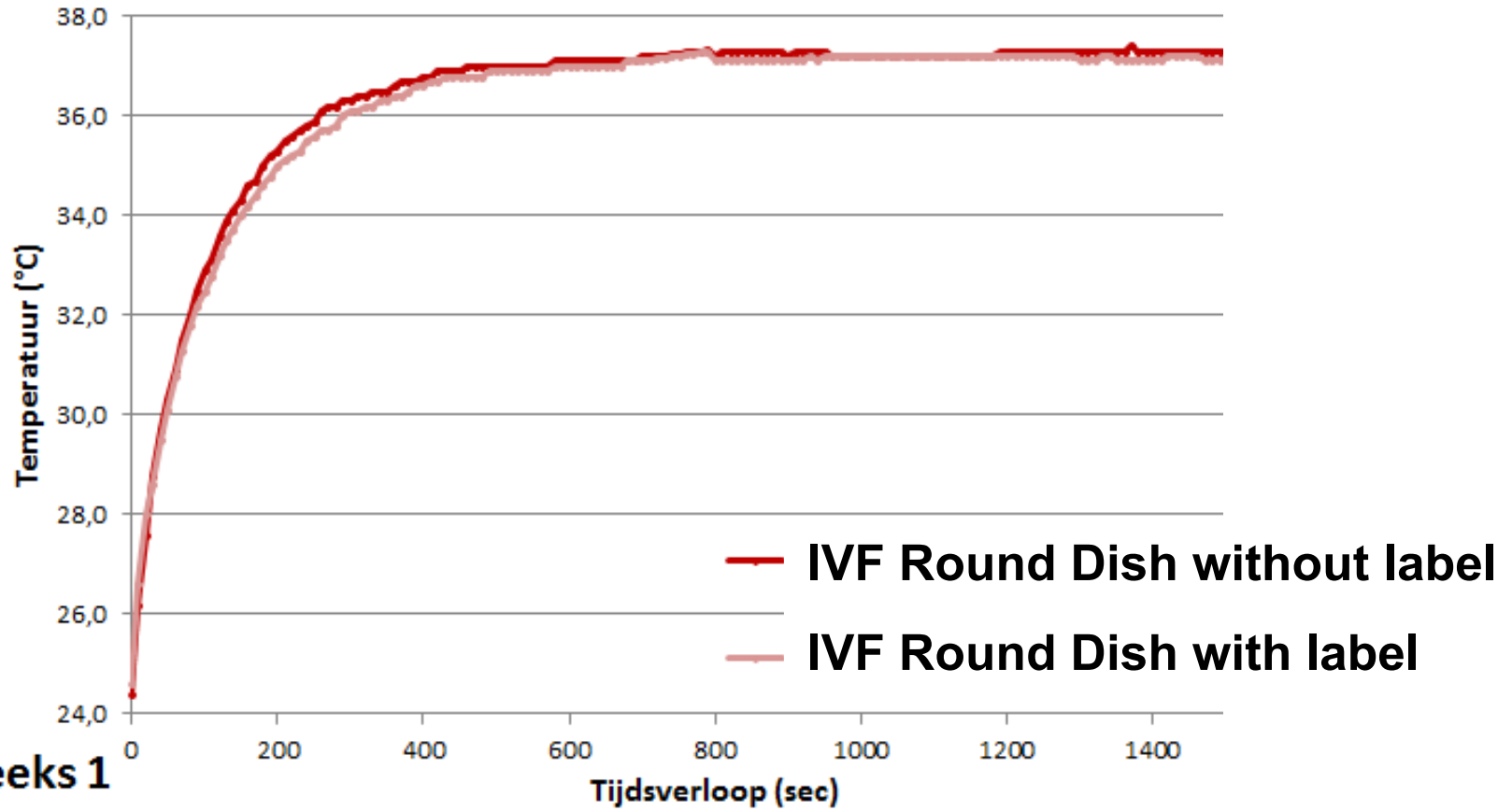
Is the technology safe?

**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

## Incubator 35.5



Meetreeks 1

# 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

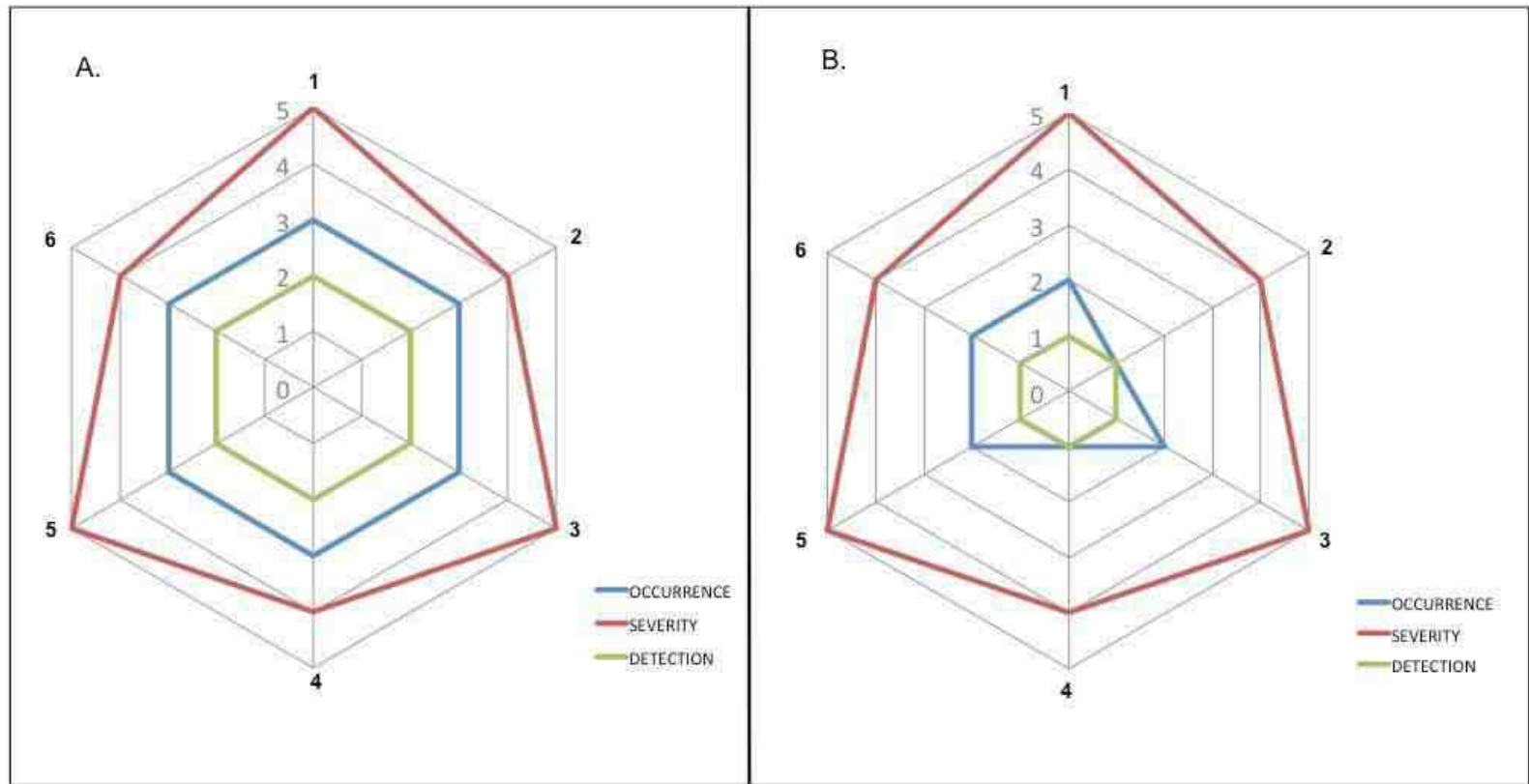


# Conclusions

- 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



# Graphical representation of severity, occurrence and detectability



**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



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