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Patient Safety and Risk Management in IVF

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LEARNING OBJECTIVES

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- Apply risk-management principles in the IVF Clinics by:
  - identifying,
  - assessing and
  - reporting hazards and potential risks

PECULIAR CHARACTERISTICS OF IVF PATIENTS

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- Patient population usually knowledgeable about treatments
- Patient population highly motivated
- Success rates are important in the choice of practice and clinician
- Patients have high expectations as they cover the majority of treatment expenses

TOTAL QUALITY MANAGEMENT BASICS

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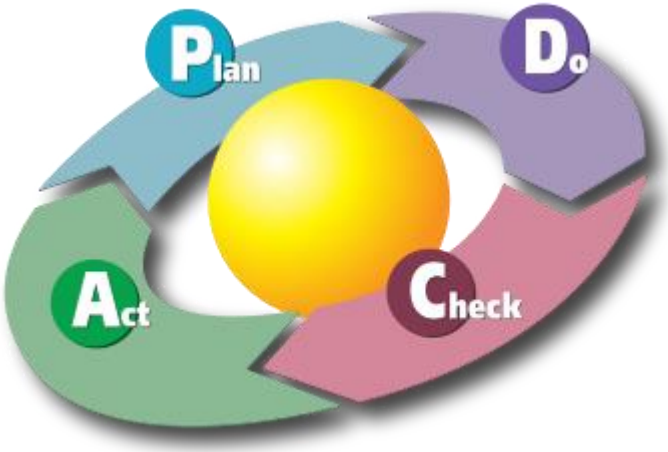
QUALITY MANAGEMENT

- Quality Control
- Quality Assurance
- Quality Improvement



RISK MANAGEMENT

- Risk Elimination
- Risk Avoidance
- Risk Minimization

SYSTEMS MANAGEMENT

- Indicators & Benchmarks
- Process Mapping
- Systems Analysis

RISK MANAGEMENT

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No organization is immune from a crisis so all must do their best to prepare for one.

Crisis – any situation that is threatening or could threaten to harm people or property, seriously interrupt business, damage reputation or negatively impact share value

APPROACHES TO RISK MANAGEMENT

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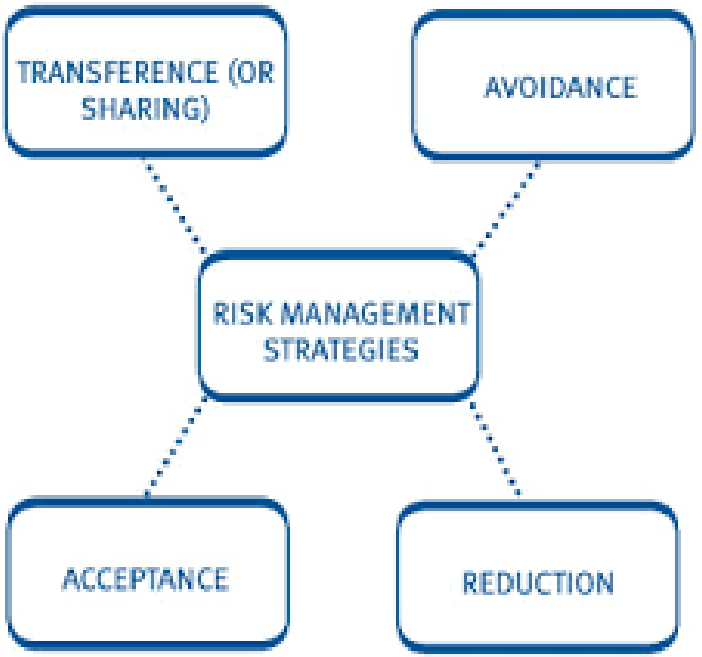
- ❑ Risk Avoidance
- ❑ Risk Reduction/Minimization
- ❑ Risk Transfer
- ❑ Risk Acceptance / Retention



RISK AVOIDANCE

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Risk avoidance

- Includes not performing an activity that could carry risk.
- An example would be not buying a property or business in order to not take on the liability that comes with it.
- Another would be not flying in order to not take the risk that the airplane were to be hijacked.
- Avoidance may seem the answer to all risks, but avoiding risks also means losing out on the potential gain that accepting (retaining) the risk may have allowed.
- Not entering a business to avoid the risk of loss also avoids the possibility of earning profits.

RISK REDUCTION/MINIMIZATION

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RISK TRANSFER

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RISK ACCEPTANCE

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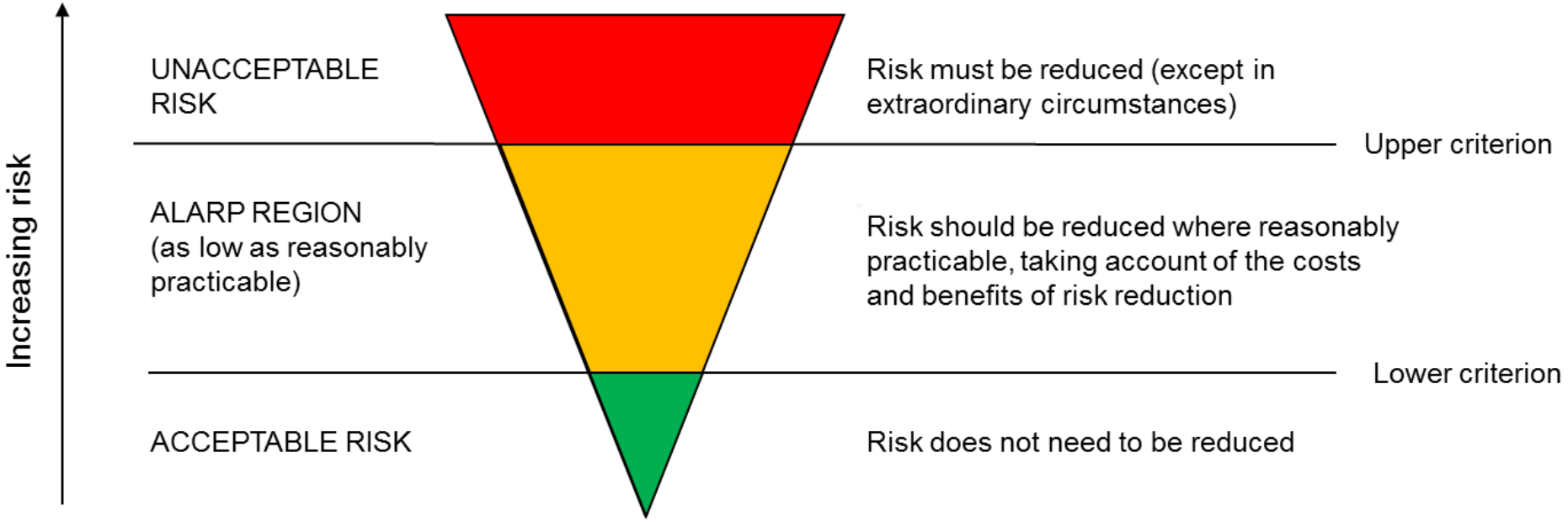

Consequences of No/Poor Risk Management

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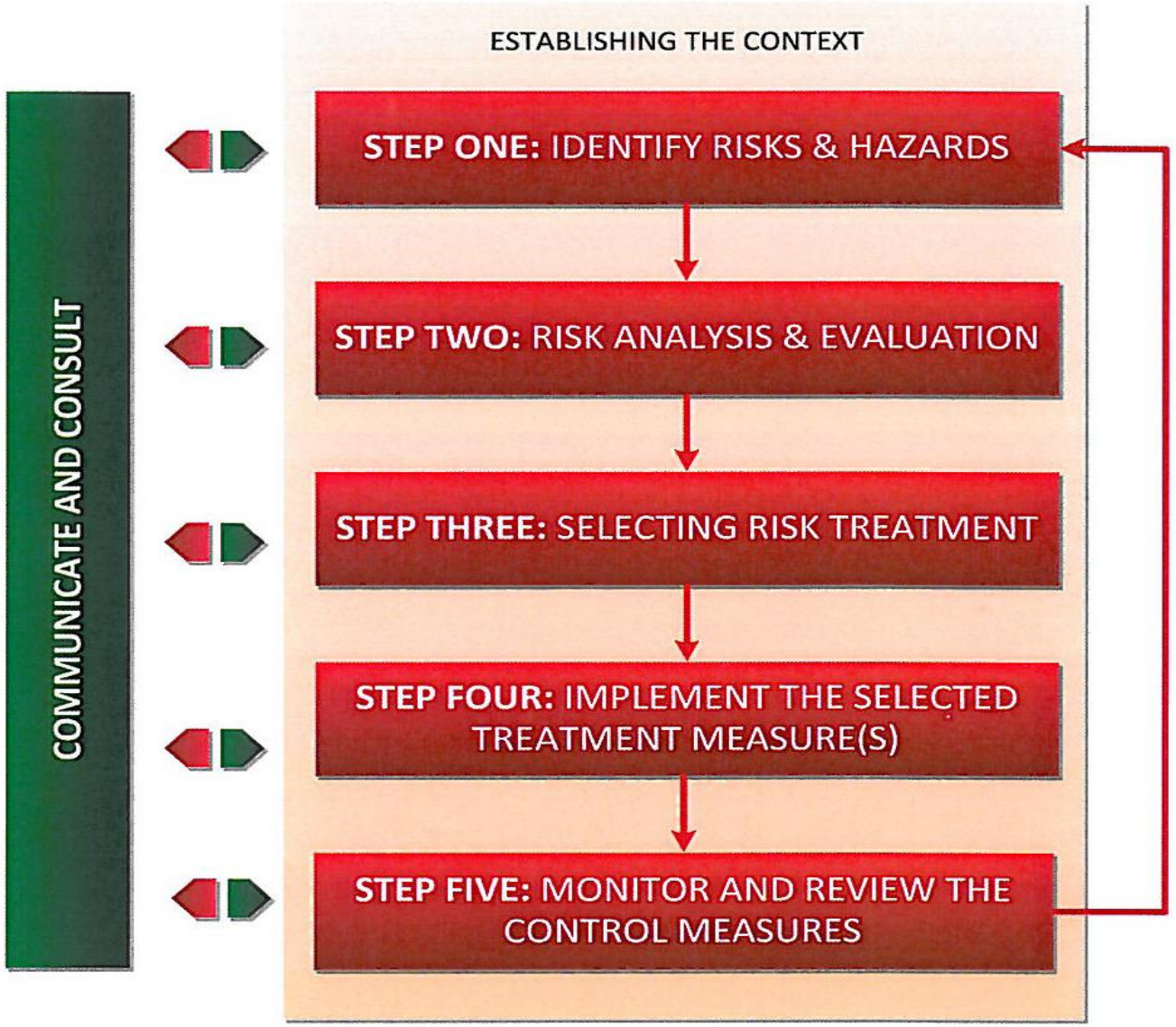
- ❑ More resources will be spent on correcting problems
- ❑ There will be no ability to respond rapidly to such events
- ❑ Recovery from such events will be very difficult and/or costly
- ❑ Decisions will be made with incomplete information and/or inadequate knowledge of their possible future implications
- ❑ Overall probability of success will be reduced
- ❑ The organization will always be in a state of crisis

RISK MANAGEMENT PROCESS



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RISK MANAGEMENT PROCESS

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IDENTIFY RISKS & HAZARDS

IDENTIFICATION RISKS

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- ❑ Wrong Man/Woman (not partner)
- ❑ Failure to match patient's gametes
- ❑ Failure of ID verification / witness
- ❑ Mislabeling of tubes during handling/preparation
- ❑ Mix-up of gametes and embryos

SAMPLE DETORIATION RISKS

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- ❑ Lost or damaged during transit to lab
- ❑ Husband fails to observe abstinence period
- ❑ Medications / recreational drugs affecting sample
- ❑ Damage to sample during processing/handling
- ❑ Deterioration of Specimen between Sperm Preparation and insemination
- ❑ Exposure of oocytes to low temperature during insemination
- ❑ Storage tank failure during cryopreservation storage
- ❑ Power failure causing loss of gametes and embryos

PHYSICAL RISKS

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- Fire Risk

- Equipment Malfunction
  Electricity Fluctuation/Power Shutdown,
  misuse/ mishandling,
  manufacturer defects
  Incorrect centrifuge speeds during washing
  Non-approved products/devices

- Data lost and interruption of care - IT failure.

- Water Supply Interruption/ Shut down

SAFETY RISKS

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- Clinical Severe reaction to a drug
- Over-response to medication - OHSS
- Cryobanking: safety and security of storage
- Unauthorized access

CHEMICAL RISKS

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- Liquid nitrogen spillage

- Reduced concentration of Oxygen in Cryo Room
  due to high room temp or during topping up of storage dewers.

ERCONOMICS RISK

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- Risk of noise and interruption in IVF Lab from phone

- Risk of Musculoskeletal Disorders, Pain, discomfort, Poor body posture

BIOLOGICAL RISK

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- ❑ Sample contaminating lab (e.g. spillage, leaky container)
- ❑ Use of incorrect / dirty pipettes
- ❑ Microbial contamination in the final sperm preparation
- ❑ Poor Air Quality
- ❑ Positive Negative Pressure in CSSD and IVF LAB

BIOLOGICAL RISK

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- Medical Waste
- Needle stick Injury with sharps used pipettes.
- Air Conditioning Failure - High room temperature in the IVF lab can cause incubator failure resulting in compromising embryo quality.
- Risk of cross contamination/infection from contaminated surfaces/equipment.
- Inappropriate/ Unsuitable disinfectant and/or Supplies

STAFFING RISKS

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- Insufficient staff – Overworked
- Inexperienced staff - Poorly-trained staff
- Unprofessional staff (don't accept responsibility)
- Inability to cope with the workload without compromising safety
- Education, experience, aptitude, training,
- Disengaged employees / low employees engagement

STAFF NON COMETENCIES RISKS

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- ❑ Inconsistent inter- and intra-operator assessment of semen analysis
- ❑ Inaccurate semen analysis (poor methodology and/or technical errors)
- ❑ Inadequate completion of paperwork / incorrect paperwork used
- ❑ Inappropriate or incorrect timing of insemination
- ❑ Not inseminating correct number of oocytes
- ❑ Inseminating with incorrect number of sperms

REGULATORY NON COMPLAINCE RISK

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- ❑ Couple not married - no Marriage Certificate
- ❑ Consents not signed by couple (ART treatment, OPU, ET, Freezing etc.)
- ❑ Wrong number of embryos transferred by age group
- ❑ MOH approvals not sorted before freezing of Embryos
- ❑ Unlicensed Professionals

OTHER HIGH RISKS

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- Unrecognized incid

- Inadequate disaster planning

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Risk Assessment/Analysis

RISK EXPOSURE RATING

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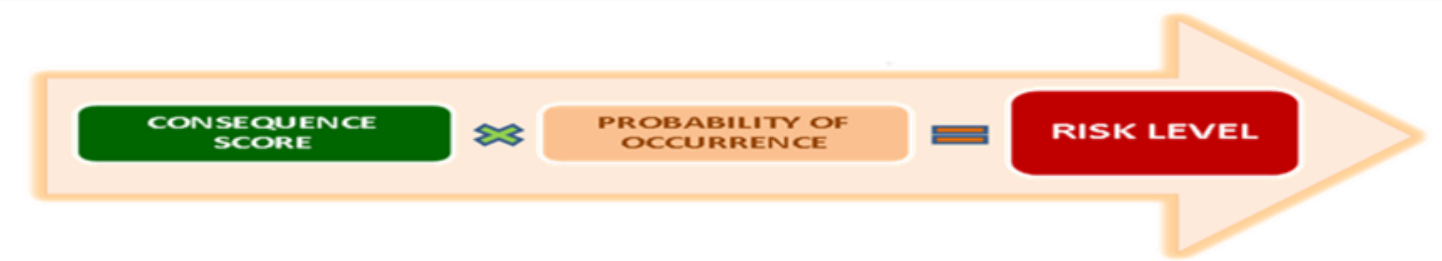

Table 1: Likelihood Scores

Score	Descriptor	Frequency of event	Timescales
1	Highly Unlikely	May occur in exceptional circumstances	5 years +
2	Unlikely	Could occur at some time	Six month – a year
3	Possible	May occur occasionally	Monthly
4	Likely	Could occur in most circumstances	Weekly
5	Very Likely	Could occur frequently	Daily

Table 2: Organizational Consequence Score

Score	Descriptor	
1 GREEN	Negligible/ Insignificant	No obvious harm/injury. Incident does not require medical treatment, property damage may have occurred.
2 GREEN	Minor	First aid treatment, where medical treatment not required (e.g. minor cuts and burns). Non-permanent harm up to 1 month
3 AMBER	Moderate	Medical treatment required, lost time injury from 1-5 days (e.g. minor strains).
4 RED	Major	Extensive injuries, lost time injury >5 days, permanent disability (e.g. broken bones, major strains).
5 RED	Catastrophic	Death

Table 3 RISK MATRIX

	Likelihood				
Consequences	1	2	3	4	5
	Highly Unlikely	Unlikely	Possible	Likely	Very Likely
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

For grading risk, the scores obtained from the risk matrix are assigned grades as follows:

	1 - 3	Low Risk	Maintain Existing Control
	4 - 6	Moderate Risk	Review Existing Control
	8 - 12	High Risk	Improve Existing Control
	15 - 25	Extreme Risk	Improve Existing Control Immediately

RISK MANAGEMENT PROCESS

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Selection of Risk Treatment/ Risk Control

SELECTION OF RISK TREATMENT/ RISK CONTROL

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	CONTROL GROUP	DESCRIPTION
1	**Management**	Identify the **management systems/structures** required to control risk.
2	**Policies and Procedures**	The **policies and procedures** in place to control the risk.
3	**Contingencies**	**Emergency plans/ alternative arrangements** that intervene should the risk become apparent.
4	**Active Controls**	Implementation of **immediate actions** required.
5	**Passive Controls**	Activity/information/legislation, **outside your direct control,** which may have an effect of reducing the risk.

RISK MANAGEMENT PROCESS

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Implementation of Risk Treatment/ Risk Control

IMPLEMENTATION OF RISK TREATMENT/RISK CONTROL

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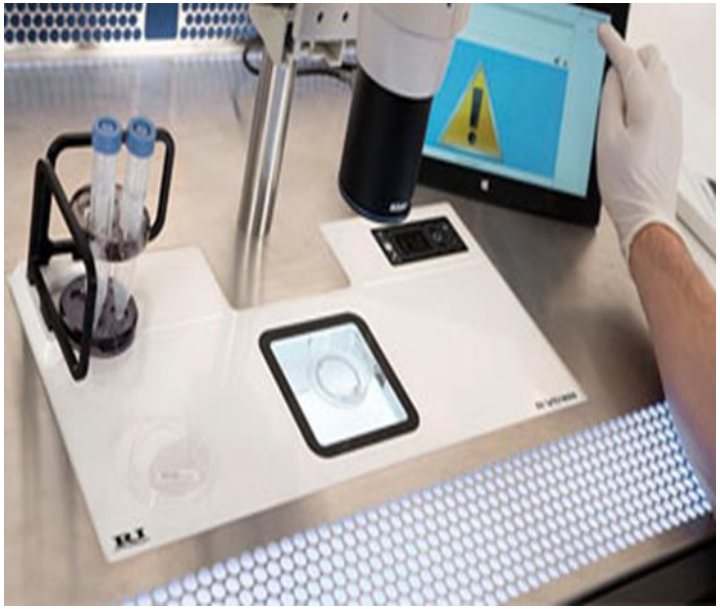
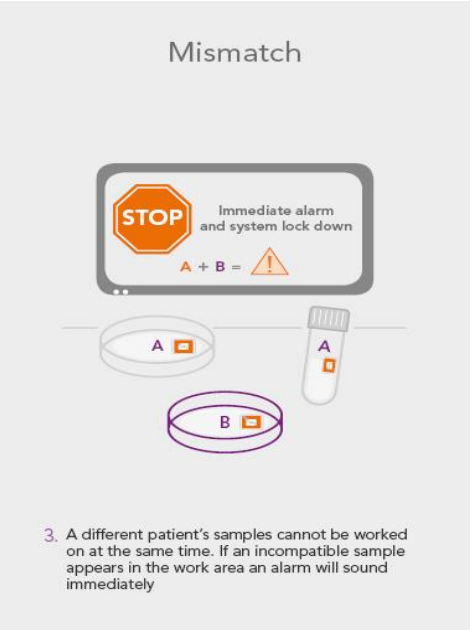
RI Witness system



2. RI Witness RFID tags allow you to identify, track and record when samples are moved from one dish to another at each step of the process



3. A different patient's samples cannot be worked on at the same time. If an incompatible sample appears in the work area an alarm will sound immediately

IMPLEMENTATION OF RISK TREATMENT/RISK CONTROL

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RISK MANAGEMENT PROCESS

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MONITORING & REVIEW

Surveillance Program

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INCIDENT REPORTING

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Report all:

- ❑ Adverse events
- ❑ Adverse reactions
- ❑ Admissions to hospi
  - ❑ OHSS
  - ❑ Bleeding
  - ❑ Infection
- ❑ Unexpected surgery
- ❑ Incidents
- ❑ Non-conformances

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Effective Risk Management = A cultural Shift

From

“Fire-Fighting” and “Crisis Management”

To

Planning and Pro-active Decision-Making

THE 1ST IVF LABORATORY ACCREDITED BY THE COLLEGE OF AMERICAN PATHOLOGISTS (CAP) IN THE UAE

CAP ACCREDITED
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REFRENCES

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- Mortimer, D. (2004b) Setting up risk management systems in IVF laboratories. Clinical Risk, 10 CrossRef | Google Scholar: 128–137