LABORATORY ERRORS: STRATEGIES TO PREVENT ERRORS STRATEGIES TO HANDLE ERRORS

Carli Chapman

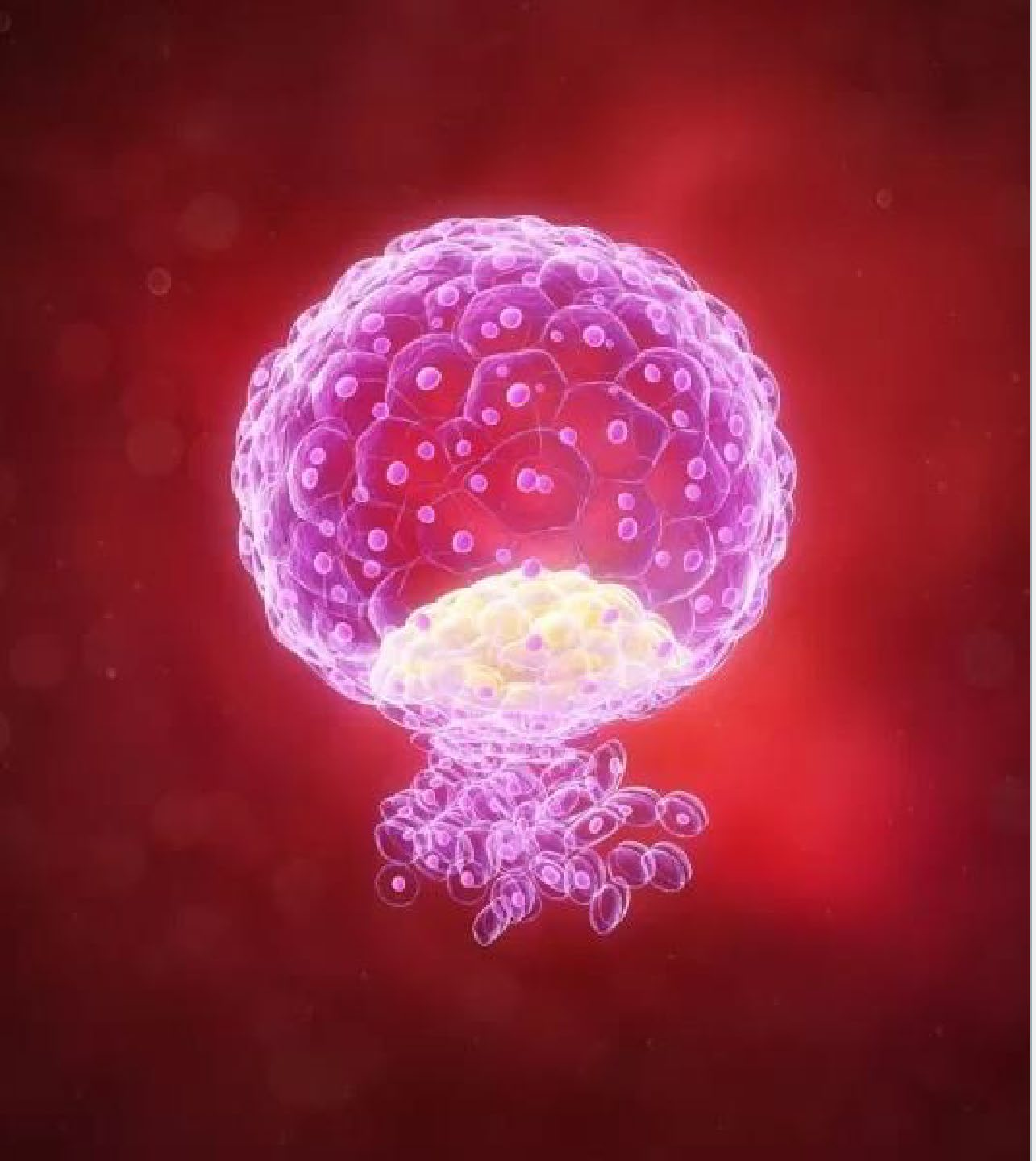
Kindbody

OBJECTIVES:

- Review information on error identification
- Review strategies to prevent errors
- Discuss how to talk through real life scenarios
- *All laboratorians need to have strategies for error prevention*

Disclosures:

Nothing to Disclose



BACKGROUND

ART has positively impacted human reproduction

ART procedures have become increasingly more complex

ART Programs have accidentally become large biorepositories

Errors may go undetected


TERRAHUMAN

LABORATORY ERRORS

PREANALYTICAL:

- LABELING
- UNCLEAR ORDERS
- PATIENT IDENTIFICATION

ANALYTICAL – PROCEDURAL

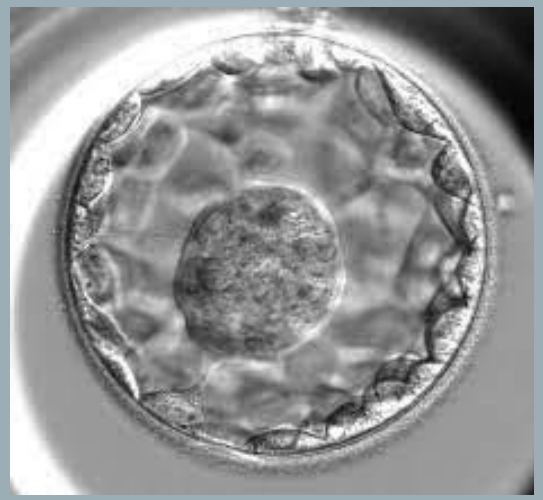
POST-ANALYTICAL

- RECORDING AND REPORTING
- DATA INTERPRETATION

PREVALENCE OF ERRORS

- Non conformance
- Minimal
- Moderate
- Significant
- Major

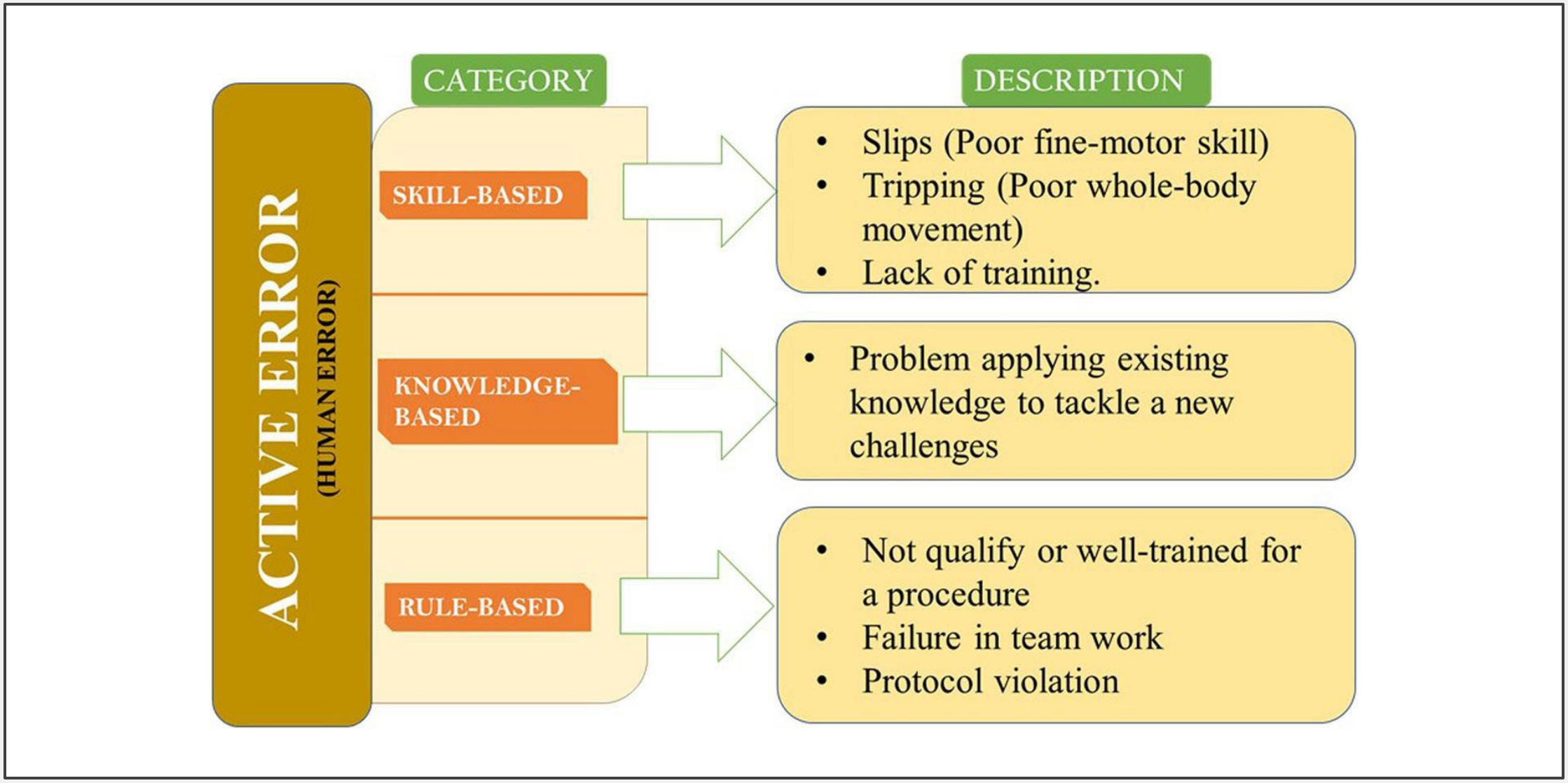
IS IT A LABORATORY ERROR????



- SHIPPING COMPANY LOSES A PACKAGE OF SAMPLES (SPERM, EGGS, EMBRYOS, BX)?
- A VITRIFIED SAMPLE IS NOT RECOVERED AT THAW?
- EMBRYO NOT RECOVERED AFTER DIFFICULT TRANSFER ATTEMPT?
- WRONG EMBRYO THAWED?

ACTIVE ERRORS

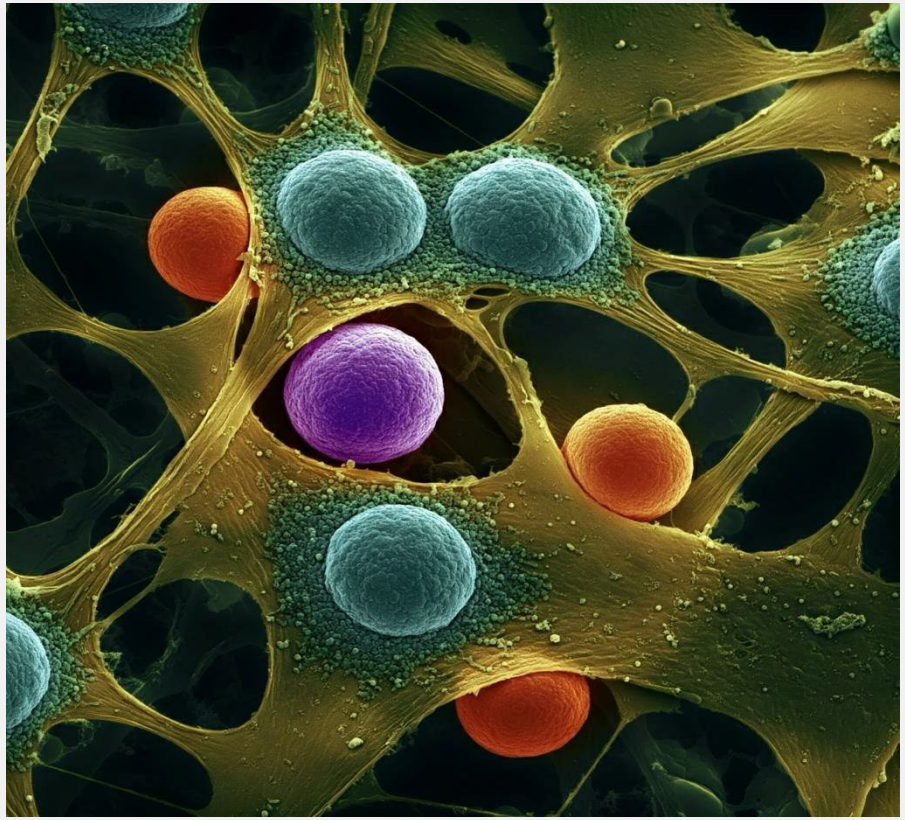
LATENT ERRORS


ACTIVE ERROR
(HUMAN ERROR)
CATEGORY
DESCRIPTION
SKILL-BASED
KNOWLEDGE-BASED
RULE-BASED
• Slips (Poor fine-motor skill)
• Tripping (Poor whole-body movement)
• Lack of training.
• Problem applying existing knowledge to tackle a new challenges
• Not qualify or well-trained for a procedure
• Failure in team work
• Protocol violation

LATENT ERRORS

- INEFFICIENCIES
  - UNDERSTAFFING
  - MICROMANAGEMENT
  - INSUFFICIENT OR POORLY MAINTAINED EQUIPMENT

ART PROGRAM



- PROVIDER TEAM
- NURSING TEAM
- ULTRASOUND TEAM
- CLINICAL STAFF TEAM
- ADMINISTRATIVE TEAMS
- ENDOCRINE TEAM
- ANDROLOGY TEAM
- TISSUE LOGISTICS
- COMPLIANCE

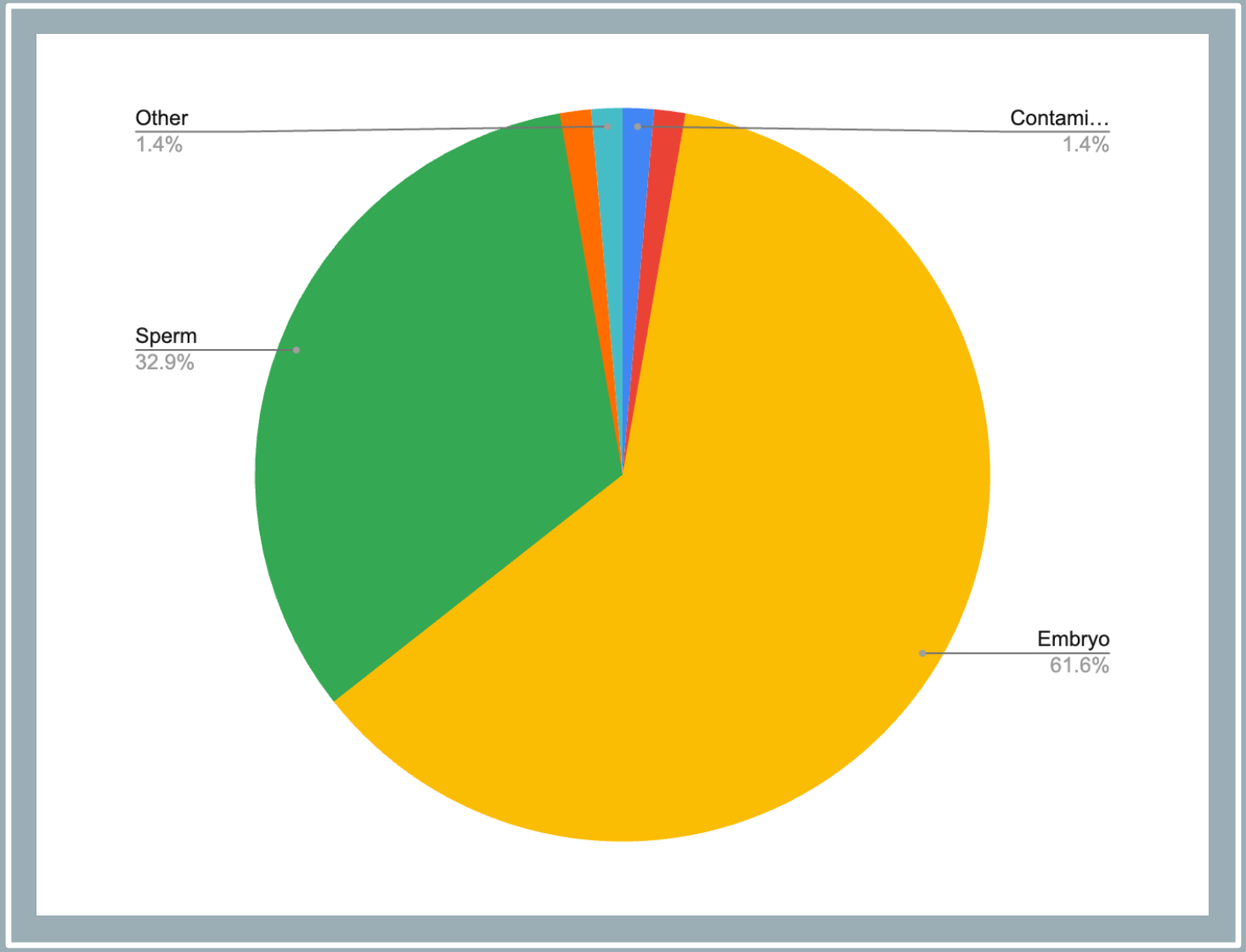
RISK ASSESSMENTS

REACTIVE

- REPORTING AN ERROR AFTER THE EVENT
- ROOT CAUSE ANALYSIS

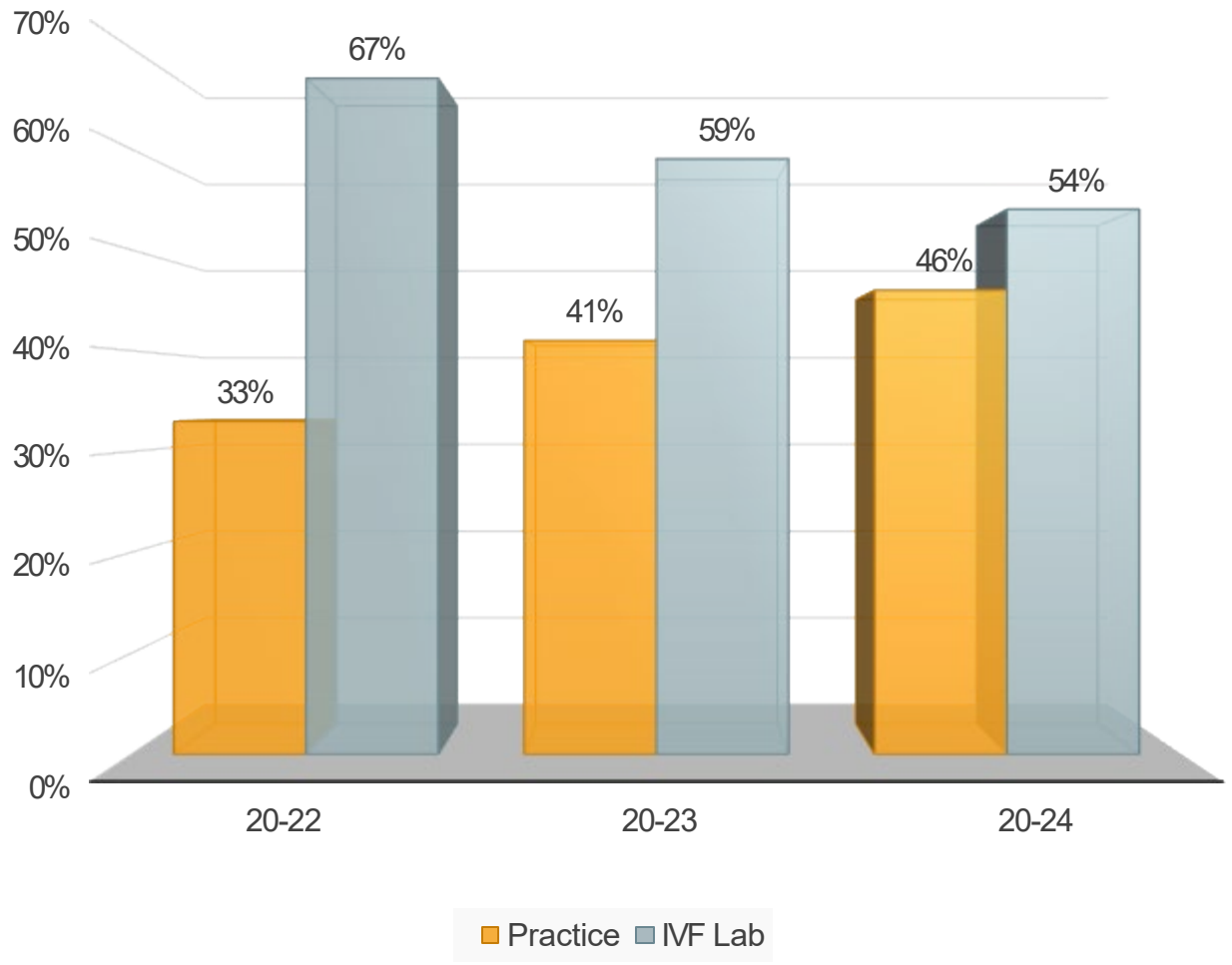
PROACTIVE

- FAILURE EFFECTS MODE ANALYSIS
- JOB HAZARDS ASSESSMENT
- RISK MATRIX
- DATA ANALYTICS



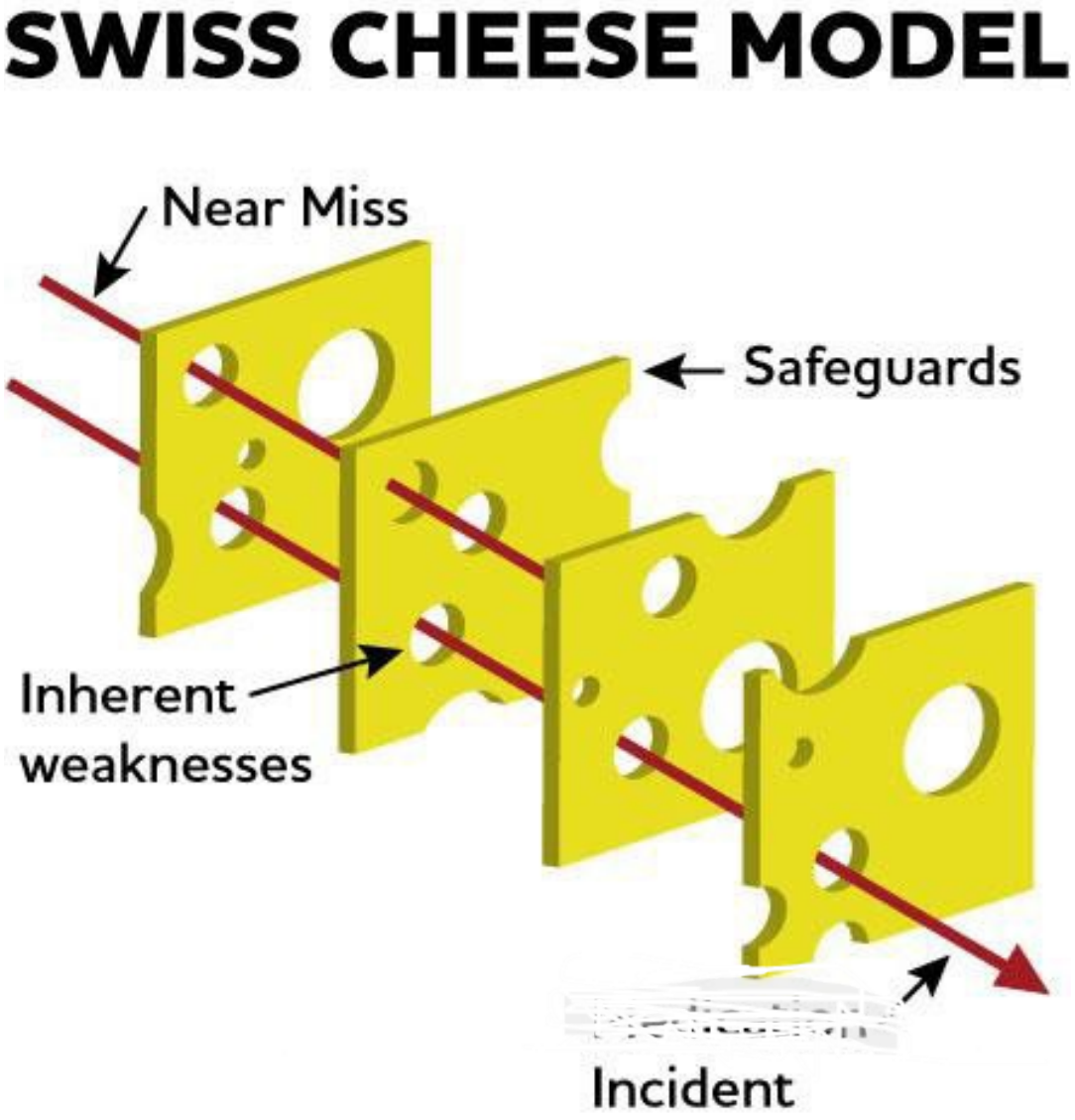
WORLDWIDE LAWSUITS 2022-2023

REI PROTECT


70%
60%
50%
40%
30%
20%
10%
0%
67%
59%
54%
46%
41%
33%
20-22
20-23
20-24
Practice
IVF Lab

ERROR CHAIN

- Concept that many contributing factors typically lead to an accident NOT one single event
- Most contributing factors to the error chain stem from human-factor related errors
- Can be controlled with
  - GOOD COMMUNICATION
  - KNOWLEDGE, SKILLS, ATTITIUDE
  - GOOD TEMAWORK



- In a complex system (ART Program), hazards are prevented by a series of barriers (procedures, policies)
- Each barrier has an unintended weakness (gaps or holes) which are inconsistent
- When the gaps align an accident or mistake can occur

Failure Modes & Effects Analysis

Failure Modes & Effects Analysis (FMEA) is a risk management tool that identifies the influence of potential failures in a process in order to prevent them or create contingency plans.

COMPREHENSIVE PROTOCOL OF TRACEABILITY DURING IVF

- 7 representative Italian IVF Centers
- 21 Month duration
- Teams of LD, QC/QA, Embryologists, Providers, Nurses, Administration PLUS a Risk Analysis Specialist and a specialist in Human Factor

- Risk Priority Number = (O)(S)(D)

Patient and/or cell identification, labeling and witnessing process

239 Failure Modes Described

Human Witnessing is Vulnerable

COMPREHENSIVE PROTOCOL OF TRACEABILITY DURING IVF

- Not labeling aspirates that come from the OR into the lab
- Patient sperm ID
- Incomplete labeling
- Aspirate gets left behind and new procedure starts
- Multiple people may be involved in rooming patient
- Denudation

. . . ANALYSIS OF 79713 EW POINTS

- 11210 consecutive treatment cycles
- 79713 points
- 16 critical mismatches (0.02%)
- 138 MM (0.19%)

- MM & CMMs were different during different times of day
- MM highest 12 – 2 PM
- CMM after 4 PM
- Weekday, weekends, holidays did not influence MM or CMM
- Experience did not influence CMM

PEOPLE PROBLEMS

- Incomplete crosscheck
- Involuntary automaticity
- Non contemporaneous checking
- Control omission

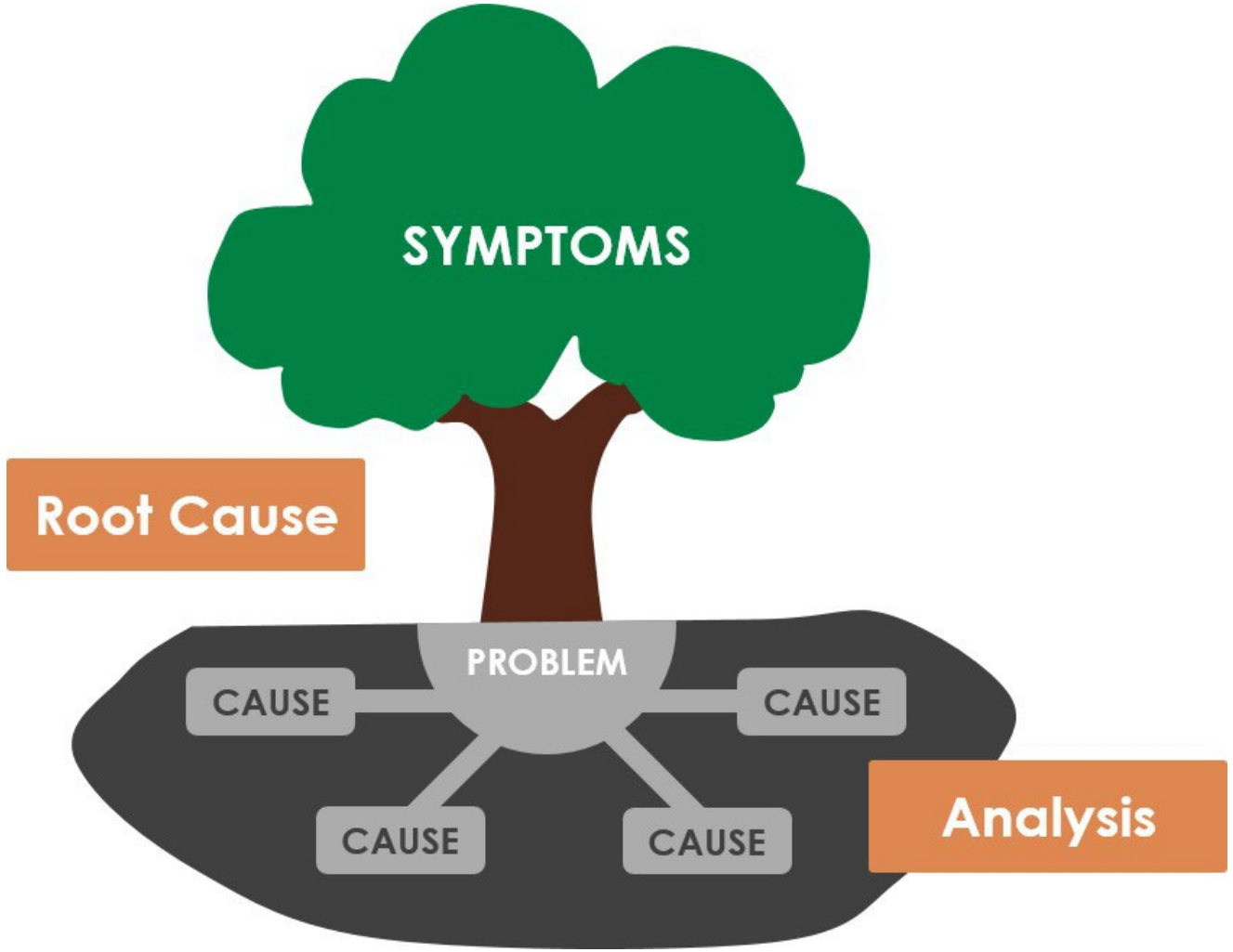
- Check lists
- Clear definition of witnessing Process
- Reduce the number of witness steps to critical steps
- Final Checks
- EWS strongly advisable

RESPONSE TO AN ERROR

- ALWAYS REPORT
  - Loop in MP Provider early
- DO NOT PROCEDE
- PRESERVE DOCUMENTATION

- Be *Mindful* of is really an error?
- Remain calm
- Minimize conversation
- Start RCA

ROOT CAUSE ANALYSIS



(MAYBE) TRUE STORIES

- Jane Doe calls clinic and wants to move forward with genetic screening of her frozen embryo
- Informed the lab
- “they said: It was nowhere to be found”
- Lab was not informed that patient had treatment under of different name Jane Smith and had recently changed her name
- Embryo located as soon as lab had enough information to identify patient

(MAYBE) TRUE STORIES

- “accidentally destroyed at least two other embryos, one current and two former employees said. One was dropped on the ground”.

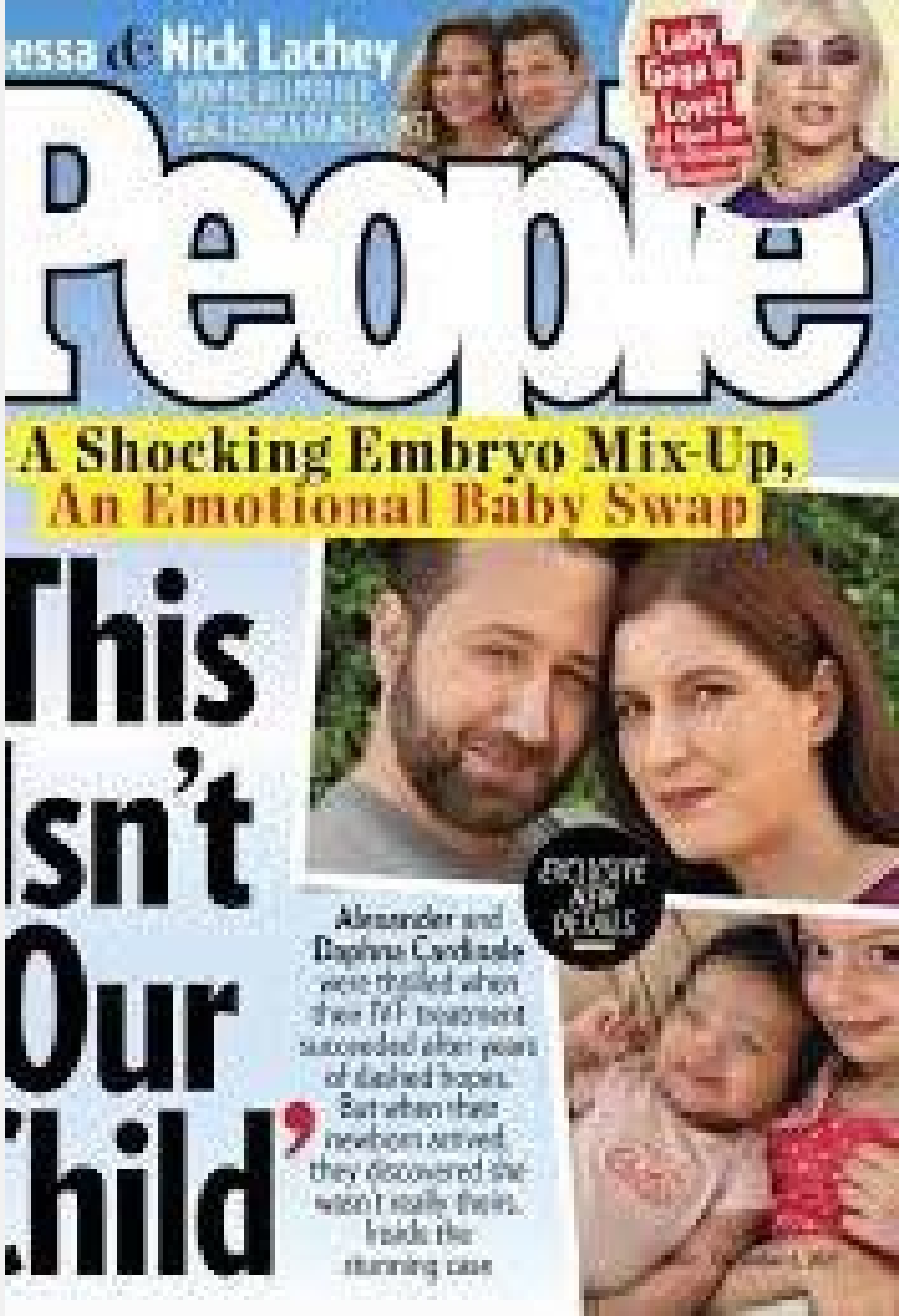
- SKILLS BASED HUMAN ERROR
- Moderate error rate has been reported to be around 0.18%
- Errors that MAY reduce the chance of success

PREVENTION!!!!!!!!!

- Use printed not handwritten labels
- Use human double witnessing sparingly to minimize disruptions
- Label aspirates
- Train personnel rooming male patients
- Manage schedules
- Staff appropriately
- Use non-scientific staff for data management
- Critically evaluate any non-conformance for information as to why why why

PROBABILITIES

- 2022 SART Data
- 389,993 IVF cycles
- Roughly 7 procedures per cycle
- 2.73 Million individual steps
- Not impossible but extremely rare



RECAP

- FEMA best way to prevent errors by identifying and correcting weaknesses before an error occurs
- Major errors are rare, but devastating
- No error or miscommunication should be ignored
- ART teams are complex and often have competing goals
- Safety is everyone's business
- EWS provide the best double witnessing results

THANK YOU

REFERENCES

Primary Author	Title
*Chibuzor Williams Ifenatuoha1**	*Errors in IVF laboratories: risks assessments and mitigations*
L. Rienzi1,,*	*Comprehensive protocol of traceability during IVF: the result of a multientre FEMA*
*Denny Sakkas**	*Types and frequency of nonconformances in an IVF laboratory*
Maria Forbrig	*Risk factors for mismatch in the ART laboratory: an analysis of 73719 EW points*
Anar Murphy, Ph.D.	*Legal Case Study of Severe IVF Incidents Worldwide: Causes, Consequences, and High Emotional, Financial, and Reputational Costs to Patients and Providers*
	Comparison of electronic versus manual witness of procedures within the in vitro fertilization laboratory: impact on timing and efficiency
M. W. Janssens	*Approaching risk analysis and risk management in the fertility laboratory and semen bank*
Jaideep Malhotra,	*ISAR Consensus Guidelines on Safety and Ethical Practices in In vitro Fertilization Clinics*
Yaling Hew	*Review Artificial Intelligence in IVF Laboratories: Elevating Outcomes Through Precision and Efficiency*