Error Management and Risk

Preventing, identifying and managing errors in high-complexity healthcare settings

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CHAPTER 1

Healthcare errors — real cases

Why talk about error

In a stem cell transplant programme, an assisted reproduction centre, a cell therapy laboratory, human error is one of the leading causes of adverse events. A mature quality system does not seek to eliminate error — that is physiologically impossible — but builds defensive barriers to prevent, intercept and manage it before it reaches the patient.

Cases that changed the rules

International healthcare news offers landmark cases that have driven profound regulatory and organisational changes. We cite them not for sensationalism, but because each case taught something fundamental about prevention.

- IVF: embryo mix-up between 4 couples at the same centre — root cause was an identification error, absence of a witnessing system
- Utrecht (2015-2016): 26 women inseminated with the wrong sperm — a systematic error undetected for months
- Rome, San Filippo Neri: liquid nitrogen failure destroys 94 embryos and 130 oocytes, affecting approximately 40 couples — lack of environmental monitoring and emergency plan
- Ohio (USA): freezer failure destroys over 4,000 embryos, 950 people affected, 47 lawsuits — absence of redundant alarms and disaster recovery procedures

Is every error preventable? No. But every error is a source of organisational learning. The right question is not "who made the mistake" but "what allowed the error to reach the patient".

CHAPTER 2

Error — taxonomy

Rasmussen's classification

In 1986, Jens Rasmussen proposed a taxonomy of human error that remains fundamental for understanding how and why people make mistakes. Each type of error has different causes and requires different prevention strategies.

Slips and lapses

A slip is an observable, unplanned action: the operator knows what to do but performs a different action from the one intended. A lapse is a memory failure: the operator forgets a step, skips a check, omits a record. Both occur during routine activities and are typical of skill-based operations, where the action is automatic.

Mistakes

A mistake is a planning error: the operator chooses the wrong objective or an inadequate means to achieve the correct objective. Unlike slips and lapses, a mistake concerns reasoning, not execution.

The three performance levels

- Skill-based: routine, automatic actions. Typical errors: slips and lapses. Prevention: checklists, forcing functions, double-checks
- Rule-based: actions guided by known procedures. Typical error: applying the wrong rule or failing to apply the correct one. Prevention: training, clear procedures, decision trees

- Knowledge-based: novel situations with no applicable rule. Typical error: flawed reasoning under pressure. Prevention: simulations, team briefings, expert supervision

CHAPTER 3

Active and — latent errors

James Reason's model

The "Swiss cheese" model by James Reason distinguishes two fundamental categories of error that interact dynamically within every organisation.

Active errors

These are errors committed by frontline operators with immediate effect. The nurse who administers the wrong drug, the biologist who confuses two samples, the physician who misinterprets a report. Active errors are visible, identifiable and often attributable to a single operator. But stopping there is an analytical error.

Latent errors

These are dormant conditions within the organisation that do not directly cause harm but create the conditions for active errors to occur and reach the patient. Excessively long shifts, ambiguous procedures, unmaintained equipment, insufficient training, production pressure: all are latent errors that erode defensive barriers.

Two philosophies compared

Organisational culture determines the approach to error. The "find the culprit" philosophy leads to individual punishment, fear of reporting and error repetition. The "find the causes" philosophy leads to systemic analysis, facilitated reporting and organisational improvement. Error is ineliminable: it must become a source of learning, not punishment.

"Finding the culprit" is convenient but ineffective. "Finding the causes" is demanding but is the only approach that produces real and lasting improvement.

CHAPTER 4

FMEA: preventive — risk analysis

What is FMEA

Failure Mode and Effects Analysis is a preventive analysis tool that identifies potential process failure modes before they occur. Unlike RCA, which analyses events that have already happened, FMEA works proactively.

The Risk Priority Number

The core of FMEA is the calculation of the Risk Priority Number (RPN), obtained by multiplying three factors, each rated on a scale of 1-10:

- Severity (S): gravity of the consequences if the failure occurs. 1 = negligible impact, 10 = catastrophic harm
- Occurrence (O): likelihood that the failure will occur. 1 = almost impossible, 10 = almost certain
- Detectability (D): ability to intercept the failure before it reaches the patient. 1 = always detected, 10 = undetectable

How it is used in practice

RPN = S x O x D. The score ranges from 1 to 1,000. Risks with the highest RPN require priority mitigation actions. The goal is not to eliminate risk — that is impossible — but to reduce the RPN to acceptable levels by acting on detectability (adding controls), occurrence (modifying the process) or, where possible, severity (adding protective barriers).

Application in transplant programmes

ICMED applies FMEA to the critical processes of transplant programmes: from collection to cryopreservation, from conditioning administration to infusion. Each process is broken down into phases, each phase analysed for potential failure modes, each risk quantified and treated.

CHAPTER 5

RCA: finding — the root cause

What is Root Cause Analysis

RCA is a structured, systematic analysis that, starting from an adverse event or near miss, traces back to the deep causes that made it possible. It does not stop at the apparent cause ("the operator made a mistake") but digs down to the organisational, systemic and latent causes.

The 5 phases of RCA

- Information gathering: documentation, interviews, physical evidence — as soon as possible within 24-48 hours of the event
- Fact reconstruction: assembly of an accurate, shared chronological narrative among all actors involved
- Identification of contributing factors: circumstances, conditions and decisions that favoured the event
- Determination of root causes: in-depth analysis of the organisational and systemic factors underlying the event
- Definition of corrective actions: targeted interventions on root causes with responsible parties, deadlines and effectiveness verification

Analysis tools

- Narrative chronology: minute-by-minute reconstruction of the event
- Timeline: temporal visualisation of actions, decisions and conditions

- Ishikawa (fishbone) diagram: cause categorisation (method, machine, material, manpower, environment, measurement)
- Five Whys: chain of "why" questions down to the root cause
- Barrier analysis: verification of barriers that should have intercepted the error
- Change analysis: comparison between normal conditions and those at the time of the event

CHAPTER 6

The ICMED — approach

ICMED integrates error management and risk management into every consulting and training project. The approach is pragmatic: not academic theory but concrete tools applicable to the daily reality of healthcare centres.

Training and culture

Specific ECM courses on error culture, Rasmussen's taxonomy, Reason's model, FMEA and RCA. Training involves all levels of the organisation, from management to operational staff, because error culture is a collective responsibility.

Digital tools

- IAAPP: Risk Assessment module with integrated evaluation, automatic RPN calculation and AI dashboard for trend monitoring
- Automatic linkage between risks, non-conformities, CAPA and management review — every report generates a traceable workflow
- Event registry with automatic classification and trend analysis by type, area, severity and recurrence

Field experience

Over 100 healthcare facilities supported across 5 countries on 3 continents. Every centre has a history of errors and near misses that, when correctly analysed, become the most valuable knowledge asset for continuous improvement.

LEARN MORE

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