Risk Management
IVDR – ISO 22367:2020
Reduction of Medical Errors by
Risk Management & Continuous Improvement

F. Vanstapel
EFLM Committee Quality and Regulations

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Scope ISO 22367:2020

- Applies to
  - all aspects described in ISO 15189
  - pre- to examination to post-examination aspects
    accurate transmission of test results into the electronic medical record
    technical and management processes
- Does not specify acceptable levels of risk
- Does not apply to risks
  from clinical decisions made by healthcare providers

ISO 22367:2020 – General principles

- Safety and Hazards – Risk/Probability of Incident/Malfunction/Misuse
- **Risk of Harm – Severity of Harm**

Informative rather than Prescriptive

- Risk management plan
  - Plan
  - Risk Assessment (Analysis & Evaluation)
- Risk Control
  - Opportunity / Impact
  - Control measures
  - **Tolerated Residual Risk**
- Risk Management
  - **Evaluate effectiveness of measures**
  - Acceptability of residual risk
- **Risk/benefit analysis**
- Risk Monitoring
  - **Surveillance**
  - **Continuous improvement**

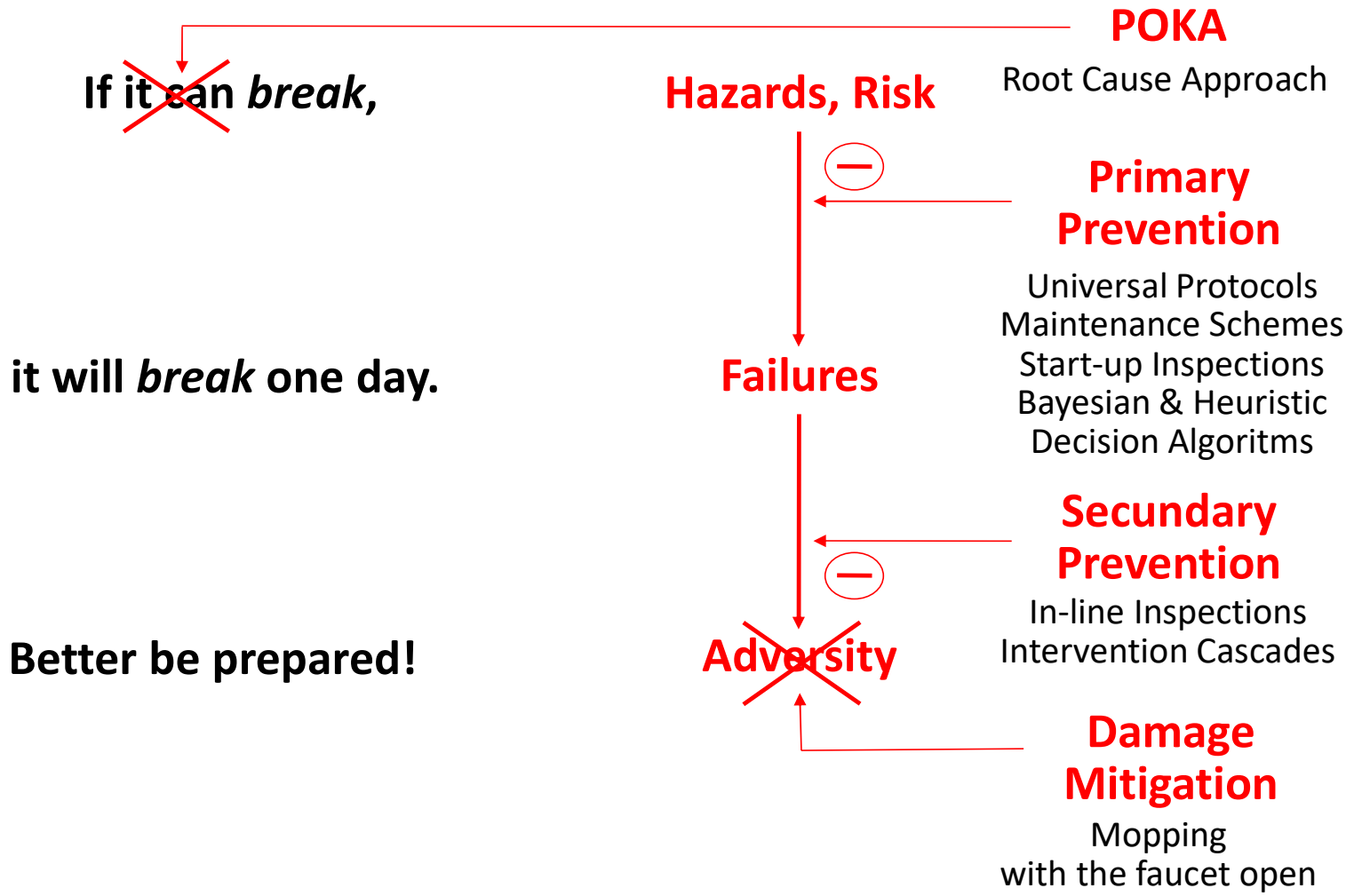
Conceived as a Plan-Do-Check-Act cycle

Setpoint
Positive return on investment
Benefit / Residual Risk

Multidimensional nature of Risk

- Seriousness of (IVDR ANN VIII rule 1)
  - Condition to be diagnosed
  - Diagnostic purpose = actions linked to the results
  - Irreparable damage / unacceptable damage / curable damage / preventable damage
- Causes for mistreatment (IVDR ANN VIII rule 3.j)
  (irrespective of condition or purpose)
  - Analytical/Clinical performance (false positives and negatives) (IVDR clinical performance)
  - Robustness of "Total" diagnostic chain (from pre-pre to post-post analytical)
- Time to detection of error / Opportunity for prevention
- Impact
  - Frequency * Seriousness
  - At level of individual patient
  - At population level
  - Operators and Bystanders
  - System wide
  - Opportunities for primary / secondary prevention
  - Benefit/Cost of CAPA

Systems of Prevention



Pro-active
Recognize Hazards & Manage Risk

- **Design phase: At Set-up Time** of methods & procedures
- Risk management recipe
  - **Failure-Mode Effects Analysis**
  - **Identify steps critical for the desired outcome = patient care**
  - **Risk management : Lean = Robust**
    - **Scrap what is superfluous**
    - **Retain what is essential**
    - **Manage critical elements**
    - **Provide for appropriate maintenance**
    - **Culture of communication**

Reactive
Detect Failures & Manage Risk & Adversities

- Life-cycle of methods and procedures:
  Feedback-phase: Registration and analysis of non-conformities
- => Selection of projects : Risk Analysis Matrix
  - Frequency
  - Urgency
  - Opportunity
- Risk management recipe:
  - Secondary Prevention: Detection & Mitigation / Containment & Corrective Action
  - **Root-Cause Analysis and Primary Prevention**

How Risk Management generates Value

Risk Analysis

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Strategic Planning

Weighing for Impact, Urgency, Business Goals & Opportunities

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Failure Mode Analysis & Root Cause Analysis

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Robust = Lean Procedures &

Manage Critical Infrastructure

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Reduced Error Rate

Increased Up-Time

Increased Availability

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Reduced Costs

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Increased Quality / Costs

ISO 22367 – Tools / Shortcomings

- Tools
  - Fault trees
  - Failure Mode Effect Analysis

- Shortcomings
  - Qualitative analysis translated into Pseudo-Quantitative Score
  - Focus on Risk Reduction i.s.o. Risk Prevention
  - Focus on Control activities i.s.o. Primary Prevention / Fail-Proof Design

ISO 15189 Accreditation of Competence

- Topic of the accreditation:
  Competence to set-up and deliver a fit-for purpose diagnostic service
- Audit of Risk Management:
  - Standard applied?
    - All elements of standard formally present in the labs documentation?
    - Does lab apply its implementation of the standard as stated in its own documentation?
      - Thoroughly?
      - At the planned frequency?
      - CAPA registration and follow-up?

This is were most citations will refer to

  - Does auditor feel confident about the competence?
    - Quality of analysis?
    - Quality of actions?

This is were most discussions about citations will originate

A mundane example: Glucose

False low and false high result have different consequences

- False high glucose:
  - treatment with insulin of false high Glc can kill patient
  - delayed treatment of true high Glc tolerable
- False low glucose:
  - infusion with glucose unlikely to kill patient
  - but delayed treatment of true low Glc can kill patient

Audit: Questions to ask / What did the lab do?

- Did the lab define absurd and sentinel values?
- Does lab release results as soon as cooked or after (delayed) confirmation/validation?
- Are medical validation rules triggered/evaluated at the time of producing the results?
  - blood gases, ionogram, anion gap, osmolality
- Do action cascades differ for high and low glucose?

What the example shows

- The total process extends to
  the desirable clinical response to “actionable” results
- Medical competence is required to address the topic appropriately
- Internal evaluation of associated laboratory data
  should be part of the risk-reduction action cascade
- Triggers may require evaluation in several passes,
  as the results become available
- Not withstanding limited scope of ISO 22378
  The treating physician is held to proper diligence
  - Has to ask for / look for associated test results
  - Has to give proper instructions to nursing staff
    (slow infusions, clinical follow-up of patient, follow-up of potassium, …)
- But the latter does not reduce the labs own responsibility

What the example means for the auditor

- A formal pseudo-quantitative matrix might have missed the essentials
- The auditor has to be medically competent,
  and not shun away from that competence
- Risk management evaluates the “total” process for the effect of potential failures on patient safety (ISO 15189 4.14.6)
  Reporting is the last opportunity for secondary preventive measures (ISO 15189 5.9.1.b)
- Value added auditing:
  was attention given to fail-proof design of processes?
- Citations can be objective, nonderogatory, and above all nontrivial
  - ISO 15189:2012 4.14.6 5.9.1.b
    Observed during the audit of alarm triggers.
    The laboratory defined upper and lower alarm values for blood glucose (5.9.1.b). These are defined to reduce risk for patient safety (4.14.6).
    For blood glucose action cascades are identical for both limits,
    although the medical urgency and associated risks of mistreatment differ.

Value-added internal / external auditing

- The system / lead author is typically presented with
  System-wide formal FMEA analysis
  with quantitative summaries of compound risk scores
  - Is the total (diagnostic) process cycle covered?
  - Is grading done consistently?
  - KPI's?
    - To support that grading?
    - To evaluate effectiveness of risk management?
  - CAPA registrations?
    - Do they evaluate Severity, Impact, Root Cause, Opportunities?
    - Do they result in generic / ad-hoc - primary / secondary risk management strategies?
    - Is effectiveness of measures evaluated?
  - Management Review & Follow-up of Retained Actions?

- The technical auditor is typically presented with validation files / technical records
  - Do they refer to intended use & fail-proof design?
  - Do they identify critical components/steps?
  - Do they result in preventive measures?
  - Are action cascades (Validation, Reporting, iQC, …) adequate to mitigate relevant medical risks?