Digital Health Clinical Safety

Meabh Smith, Digital Health Clinical Safety Lead, HSE
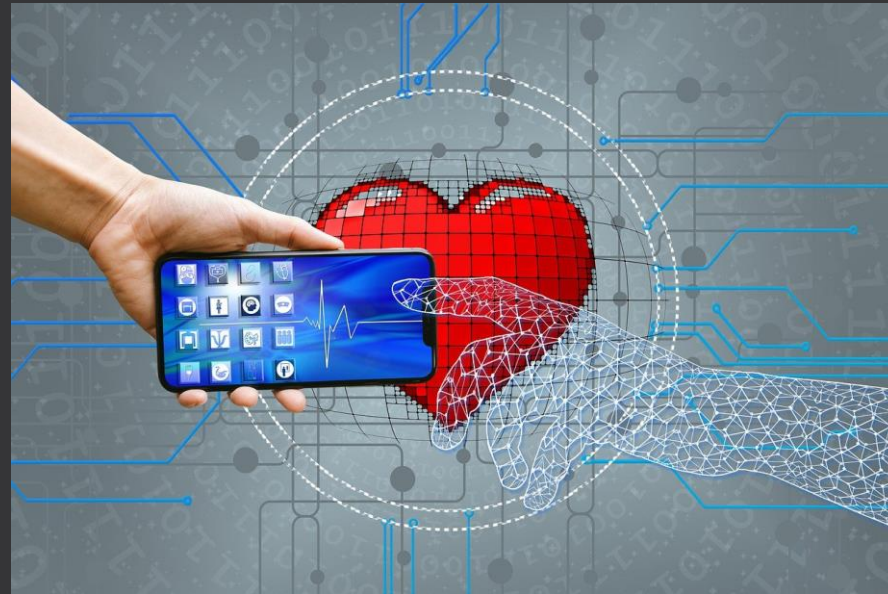

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Seirbhís Sláinte
Níos Fearr
á Forbairt | Building a
Better Health
Service

Apps, Wearables, Digital Systems, AI Algorithms, Clinical Decision Support

Approach is evolving

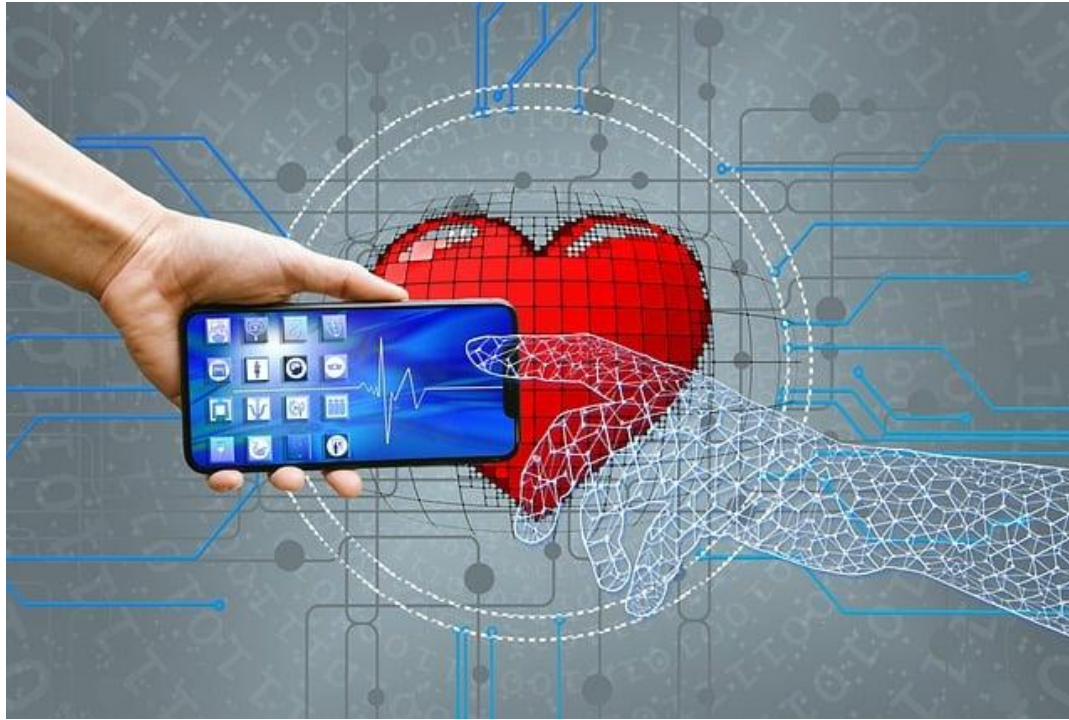Learning from other jurisdictions

At this stage fine-tuning guidance:

Relevant standards

Hazard Management

Safety Case Development

Management of all aspects of risk relating to Digital Health including patient safety and service provision.

About Patient Safety.

From planning to decommissioning.

Learning from Others

- Standards: DCB0129 & DCB0160 (DTAC)

- Vendors selling to the NHS will have met NHS Digital Safety Standards.

- ISO 14971:2019 Medical devices — Application of risk management to medical devices;
  - Responsibilities of vendors and health care organisations;

- We do not have these. We are unlikely to have equivalents in the short term.

- We will have guidelines.

- We will build a community.

- We can follow best practice: NHS, Defence, Automotive, Aero

-> Safety Case: Hazard Log + Safety Case Report

What do we do?

Risk Management

International Standards

Medical Device Regulations

IT Governance

Procurement Rules
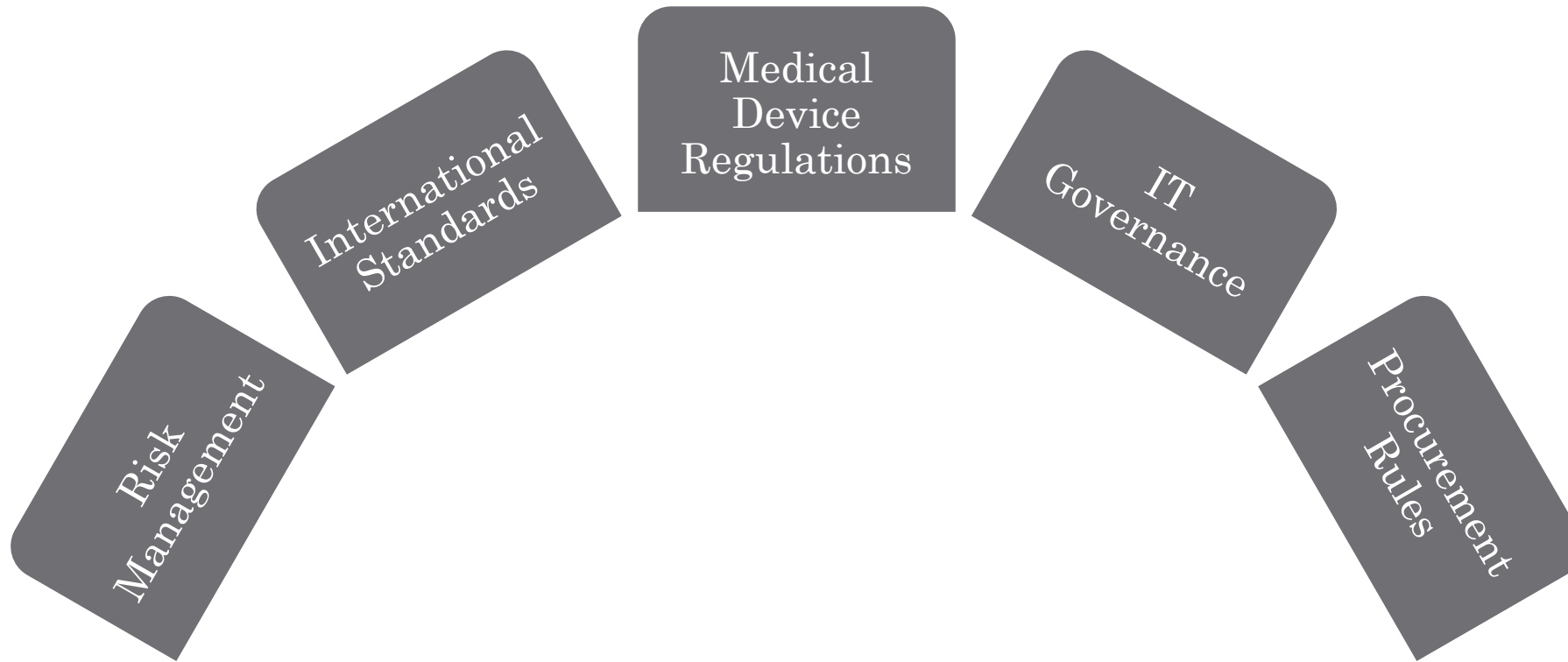
Vendors have an expectation that the health system has standards and Clinical Safety Officers & Engineers – these roles are in the early stages of evolution.

Digital Clinical Safety Process

Scope of Project

Digital Clinical Safety Plan

- Who will work on Digital Clinical Safety?
- Who gives authority to the process?
- When is the process started & completed?

Hazard Log

- Identification
- Analysis
- Mitigation

Clinical Safety Case

- Hazard Log
- Clinical Safety Report
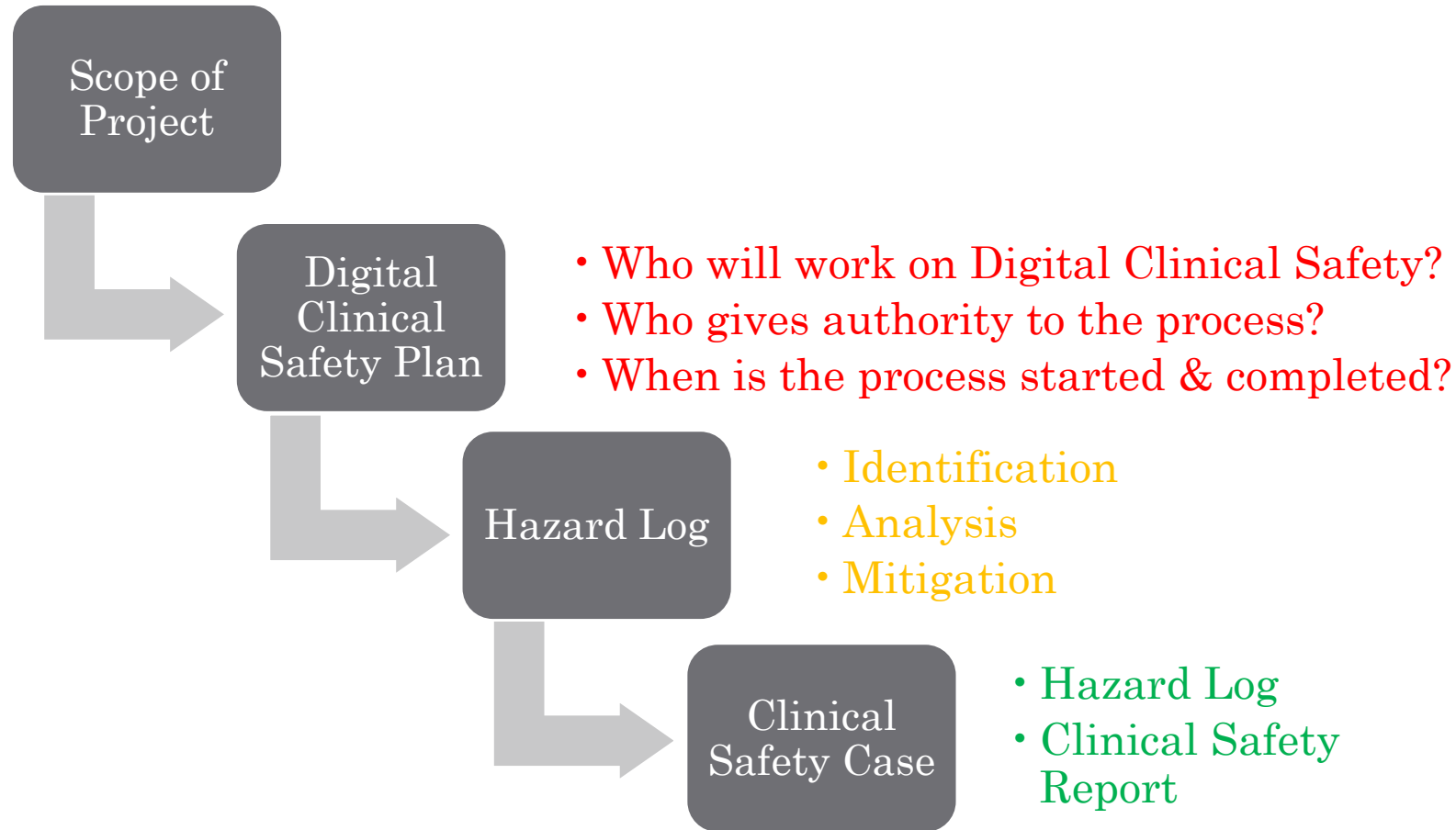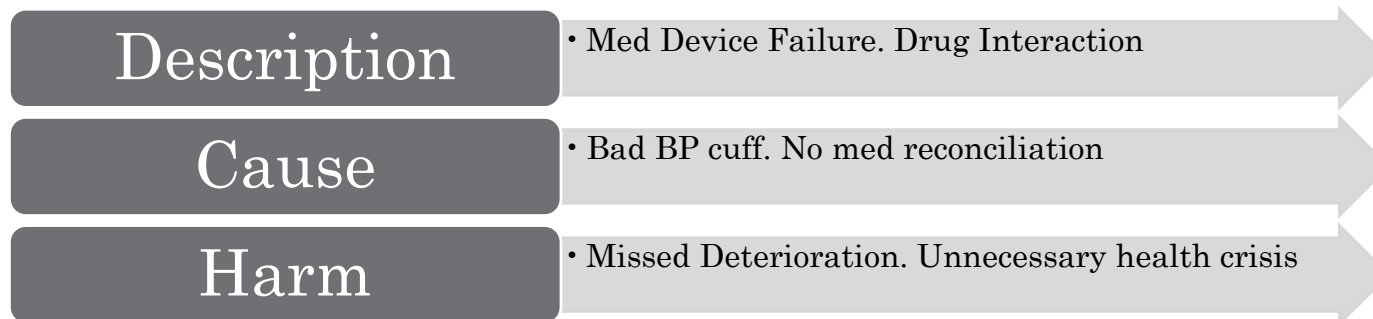
Hazard VS Risk

- Risk register is used to document & manage risks throughout lifecycle of a project.
  - Project management
  - Different risk categories

- Hazard logs are used in safety-critical industries to document & manage hazards that could potentially cause harm. ***Focuses on safety rather than broader business risks.***
  - Identify, assess and control hazards to ensure safety

DRAFT Patient Safety Risk/Hazard LOG (Date)

Number	Date Entered	Hazard/Risk Name	Hazard Description	Hazard Cause	Potential patient safety impact	Initial hazard rating: likelihood	Initial hazard rating: consequence	Initial Risk Score (Date)	Revised hazard rating: likelihood	Revised hazard rating: consequence	Revised Risk Score (Date)	Mitigation for Consideration (Date)	Actions Suggested/Required	Status	Follow-up Resp

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Hazard Log

- Multiple approaches

- Recommend: a transdisciplinary group including a patient partner, clinical, admin, technical (medical devices & IT systems) & SWIFT methodology:
  - **S**tructured
  - **W**hat
  - **IF**
  - **T**echnique

- Invite everyone to compile a list what they think could go wrong.

Description	• Med Device Failure. Drug Interaction
Cause	• Bad BP cuff. No med reconciliation
Harm	• Missed Deterioration. Unnecessary health crisis

Rate: Consequence & Likelihood

Likelihood Category	Interpretation
Very high	Certain or almost certain; highly likely to occur
High	Not certain but very possible; reasonably expected to occur in the majority of cases
Medium	Possible
Low	Could occur but in the great majority of occasions will not
Very low	Negligible or nearly negligible possibility of occurring

Category	Interpretation	
	Consequence	# Patients Affected
Extreme	Death	Multiple
	Permanent life-changing incapacity and any condition from which the prognosis is death or permanent life-changing incapacity from which recovery is not expected in the short-term.	Multiple
Major	Death	Single
	Permanent life-changing incapacity and any condition from which the prognosis is death or permanent life-changing incapacity from which recovery is not expected in the short-term.	Single
	Severe Injury or Severe incapacity from which recovery is expected in the short-term.	Multiple
	Severe psychological trauma	Multiple
Moderate	Severe Injury or Severe incapacity from which recovery is expected in the short-term.	Single
	Severe psychological trauma	Single
	Minor injury or injuries from which recovery is not expected in the short term.	Multiple
	Significant psychological trauma	Multiple
Minor	Minor injury or injuries from which recovery is not expected in the short term	Single
	Significant psychological trauma	Single
	Minor injury from which recovery is expected in the short term	Multiple
	Minor psychological upset; inconvenience	Multiple
Negligible	Minor injury from which recovery is expected in the short term; minor psychological upset; inconvenience; any negligible consequence	Single

RISK MATRIX	Negligible (1)	Minor (2)	Moderate (3)	Major (4)	Extreme (5)
Almost Certain (5)	5	10	15	20	25
Likely (4)	4	8	12	16	20
Possible (3)	3	6	9	12	15
Unlikely (2)	2	4	6	8	10
Rare/Remote (1)	1	2	3	4	5

Risk Acceptability

Red: Unacceptable level of risk. Mandatory elimination or control to reduce risk to an acceptable level.

Orange (10-12): Unacceptable level of risk. Mandatory elimination or control to reduce risk to an acceptable level.

Orange (6-9): Undesirable level of risk. Attempts should be made to eliminate or control to reduce risk to an acceptable level. Acceptable when further risk reduction is impractical.

Green (3-5): Tolerable where further risk reduction is impractical.

Green (1-2) Acceptable, no further action required.

So what?

- Treat, Transfer or Terminate

  - Red (>12): Unacceptable level of risk. Mandatory elimination or control to reduce risk to an acceptable level.

  - **Orange (10-12):** Unacceptable level of risk. Mandatory elimination or control to reduce risk to an acceptable level.

- Treat, Tolerate:

  - Orange (6-9): Undesirable level of risk. Attempts should be made to eliminate or control to reduce risk to an acceptable level. Acceptable when further risk reduction is impractical.

  - Green (3-5): Tolerable where further risk reduction is impractical.

Mitigate the Risk

Design/Tech	People	Process
Initial	Training	SOPs
Updates	Fit	BCPs
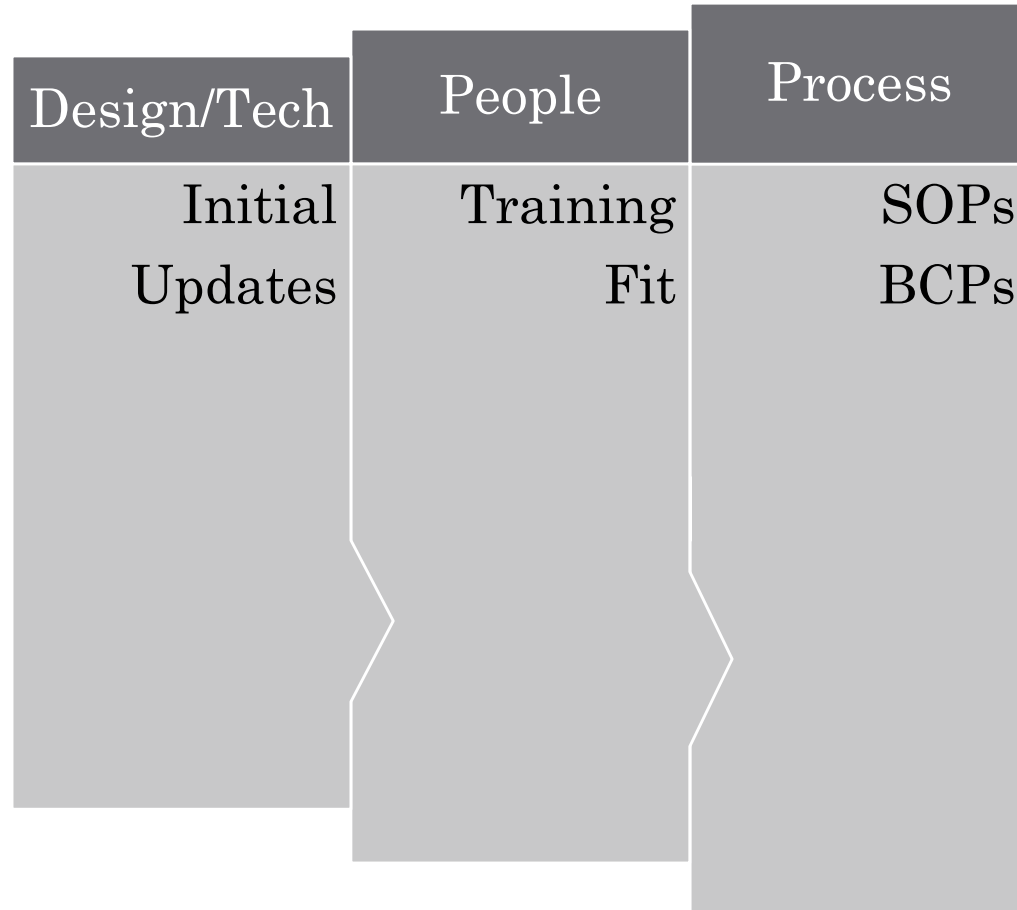
- Keep risks open until they are minimised.
- Risk rate again after mitigation.

Hazard Log Methodology Recap

Compilation of possible hazards using SWIFT methodology

Define risk scoring process for the Hazards

Define "Risk Acceptability"

Score risks and take action to mitigate

Reduce risk rating for identified hazards to an acceptable level

Maintain and review the hazard log

Summarise this process into a Safety Case

Safety Case

- Hazard Log

- Safety Case Report
  - Narrative description of the Hazard Log and Risk Mitigation process.

Why?

There is evidence from other jurisdictions that Digital Health Systems can indirectly cause serious harm

Anticipate and address before an incident! Cheaper and faster than fixing problems later.

There is no going back – we will see an acceleration of Digital Health

Advice

- For further information and advice, contact the Digital Health Clinical Safety Lead:

  Meabh.smith1@hse.ie