Digital Clinical Safety

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What is Digital Clinical Safety?

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'Digital clinical safety' refers to the avoidance of harm to patients and staff as a result of technologies manufactured, implemented and used in the health service. It is important across digital systems' lifecycles and is part of a culture of patient safety focused on learning from best practice and speaking up about emerging risks.

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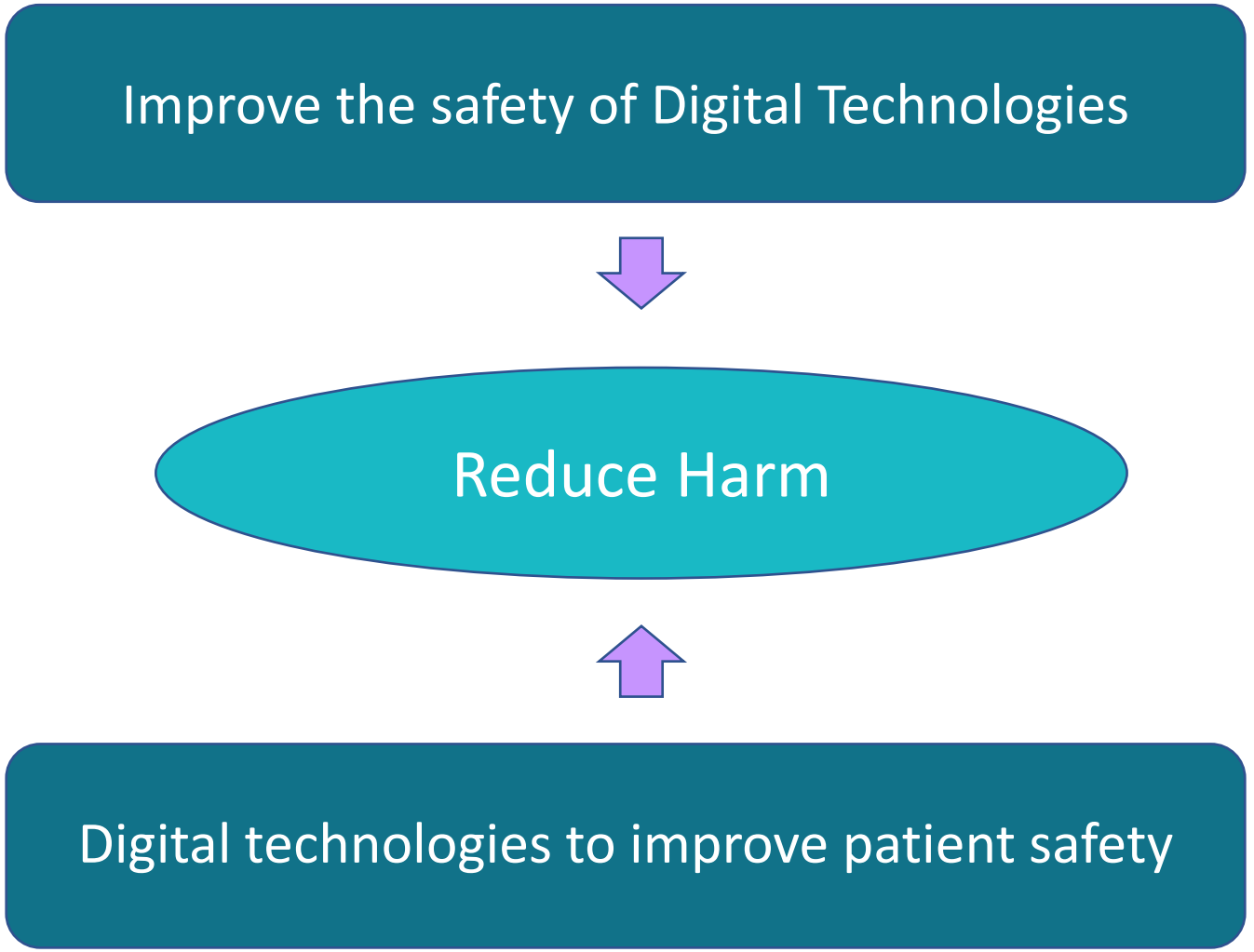

Safety Standards

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Information standards are the mechanism by which requirements are introduced that the NHS, it's commissioned services and IT system suppliers must conform.

DCB0129 and DCB0160 are Digital Clinical Safety Standards and compliance is **mandated under the Health and Social Care Act 2012**

DCB0129	DCB0160
Manufacturers of Health IT Systems	**Healthcare Organisation** implementing Health IT Systems
Clinical Safety Officer	Clinical Safety Officer
Understand processes	Understand processes
Undertake Risk Assessment	Undertake Risk Assessment
Complete Deliverables: Clinical Risk Management Plan, Hazard Log and Clinical Safety Case Report	Complete Deliverables: Clinical Risk Management Plan, Hazard Log and Clinical Safety Case Report
Post-deployment surveillance & ongoing review	Post-deployment surveillance and ongoing review

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Transfer of Risk

Deliverables

(Robust Body of Evidence)

Clinical Risk Management Plan	**How** are you going to compile your evidence?
Clinical Safety Case Report	**What** is your evidence?
Hazard Log (Hazard Workshop)	Hazards and mitigations

Digital Technology Assessment Criteria (DTAC)

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Brings together legislation and best practice

Designed to be used by healthcare organisations to assess suppliers at the point of procurement

Sets out what is expected from suppliers to engage with the NHS and Social Care.

DTAC

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Code	Question	Options	Supporting information	Scoring criteria
C1.1	Have you undertaken Clinical Risk Management activities for this product which comply with DCB0129?	Yes | No	The DCB0129 standard applies to organisations that are responsible for the development and maintenance of health IT systems. A health IT system is defined as "'product used to provide electronic information for health and social care purposes".	To pass, the developer is required to confirm that they have undertaken Clinical Risk Management activities in compliance with DCB0129.

DTAC

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C1.1.2	Please supply your Clinical Safety Case Report and Hazard Log	Provided | No evidence available	Specifically, your DTAC submission should include: • A summary of the product and its intended use • A summary of clinical risk management activities • A summary of hazards identified which you have been unable to mitigate to as low as it is reasonably practicable • The clear identification of hazards which will require user or commissioner action to reach acceptable mitigation (for example, training and business process change) It should not include the hazard log in the body of the document - this should be supplied separately.	To pass, the developer is required to submit the Clinical Safety Case Report and Hazard Log that is compliant with the requirements set out in DCB0129. This should be commensurate with the scale and clinical functionality of the product and address the clinical risk management activities specified with the standard. The Clinical Safety Case Report should present the arguments and supporting evidence that provides a compelling, comprehensible and valid case that a system is safe for a given application in a given environment at the defined point in the products lifecycle. It should provide the reader with a summary of all the relevant knowledge that has been acquired relating to the clinical risks associated with the product at that point in the life cycle:

Clinical Safety Process

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System

People

Process

Clinical Safety Process

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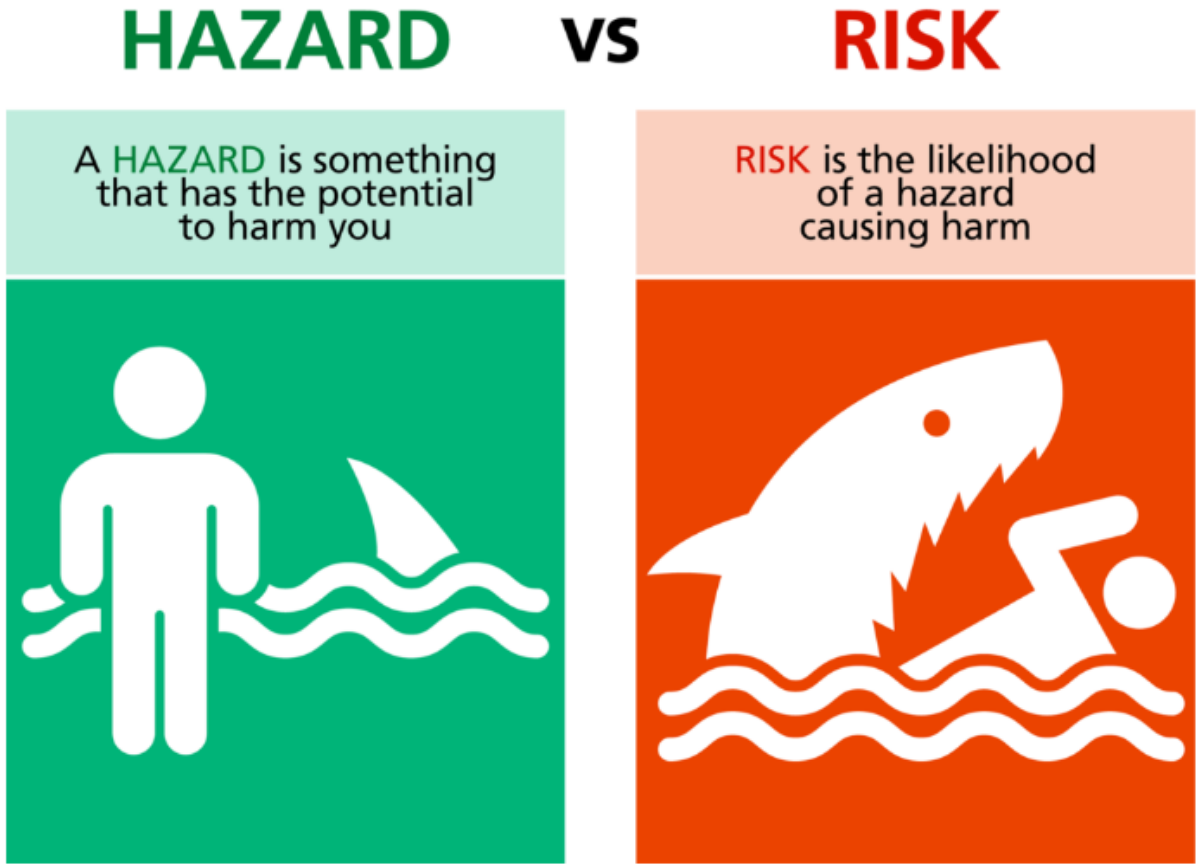
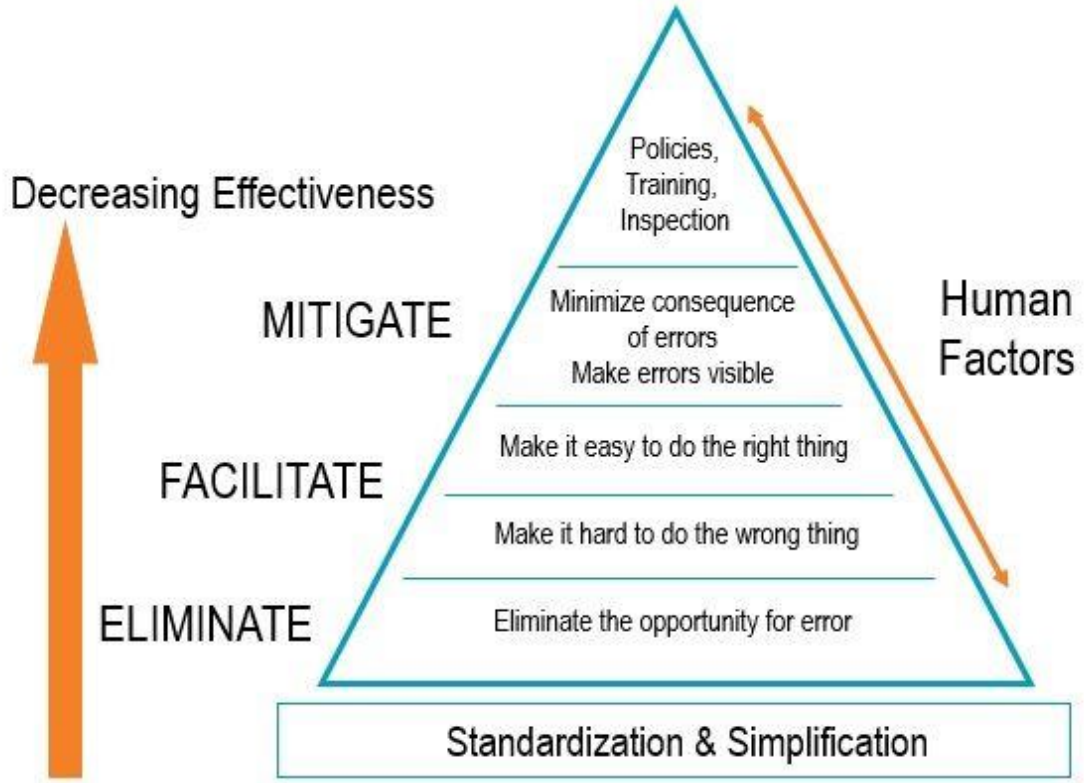


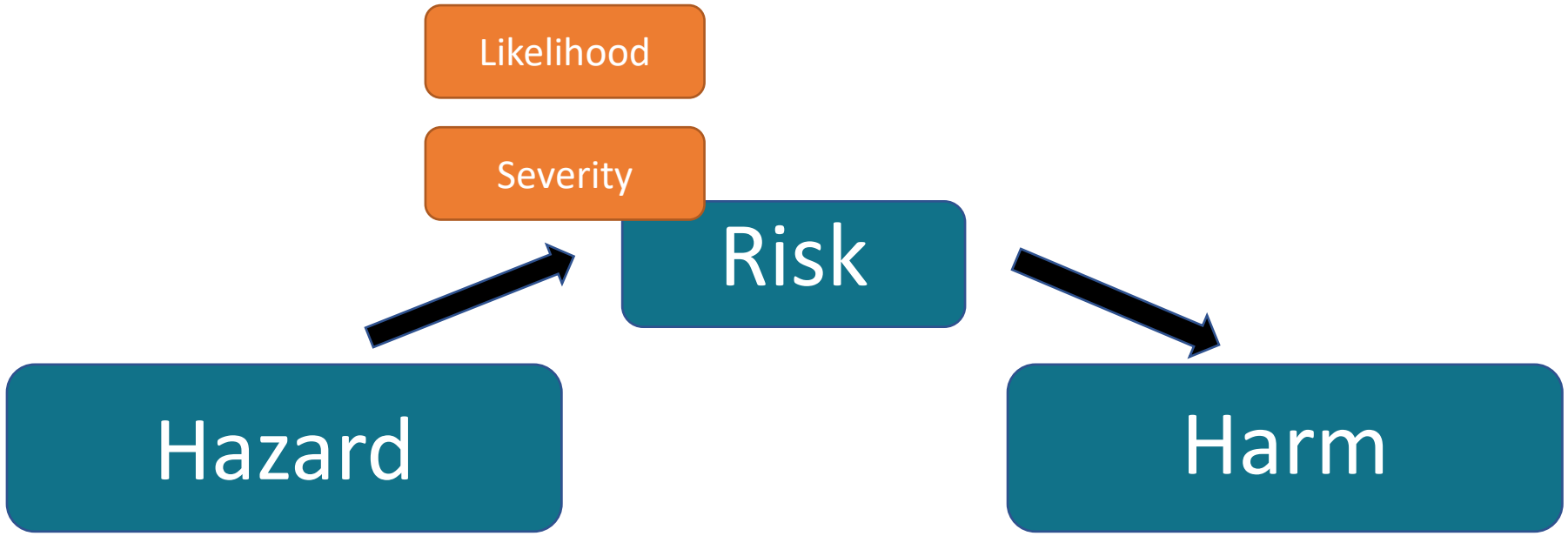
Clinical Safety Process

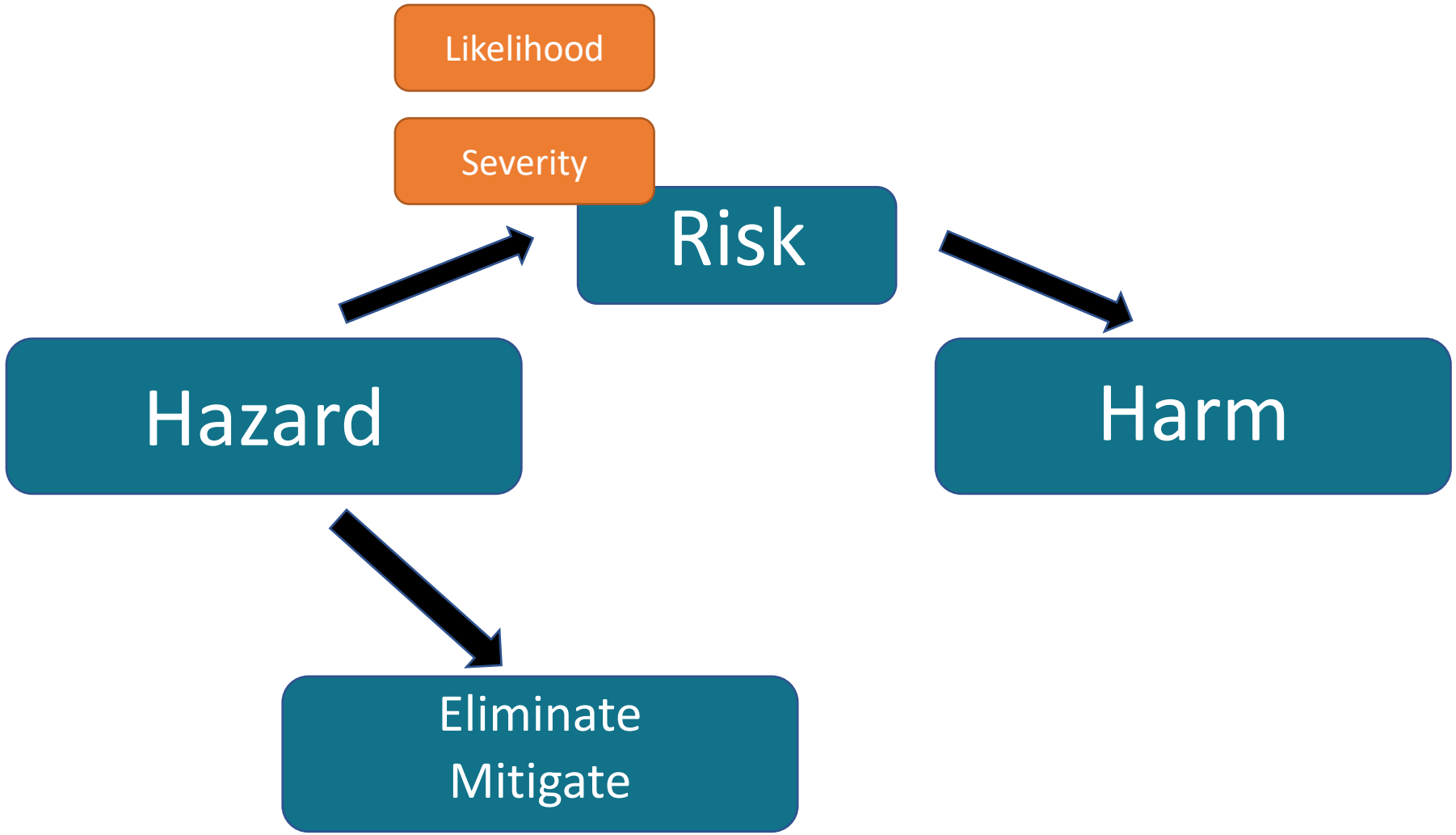


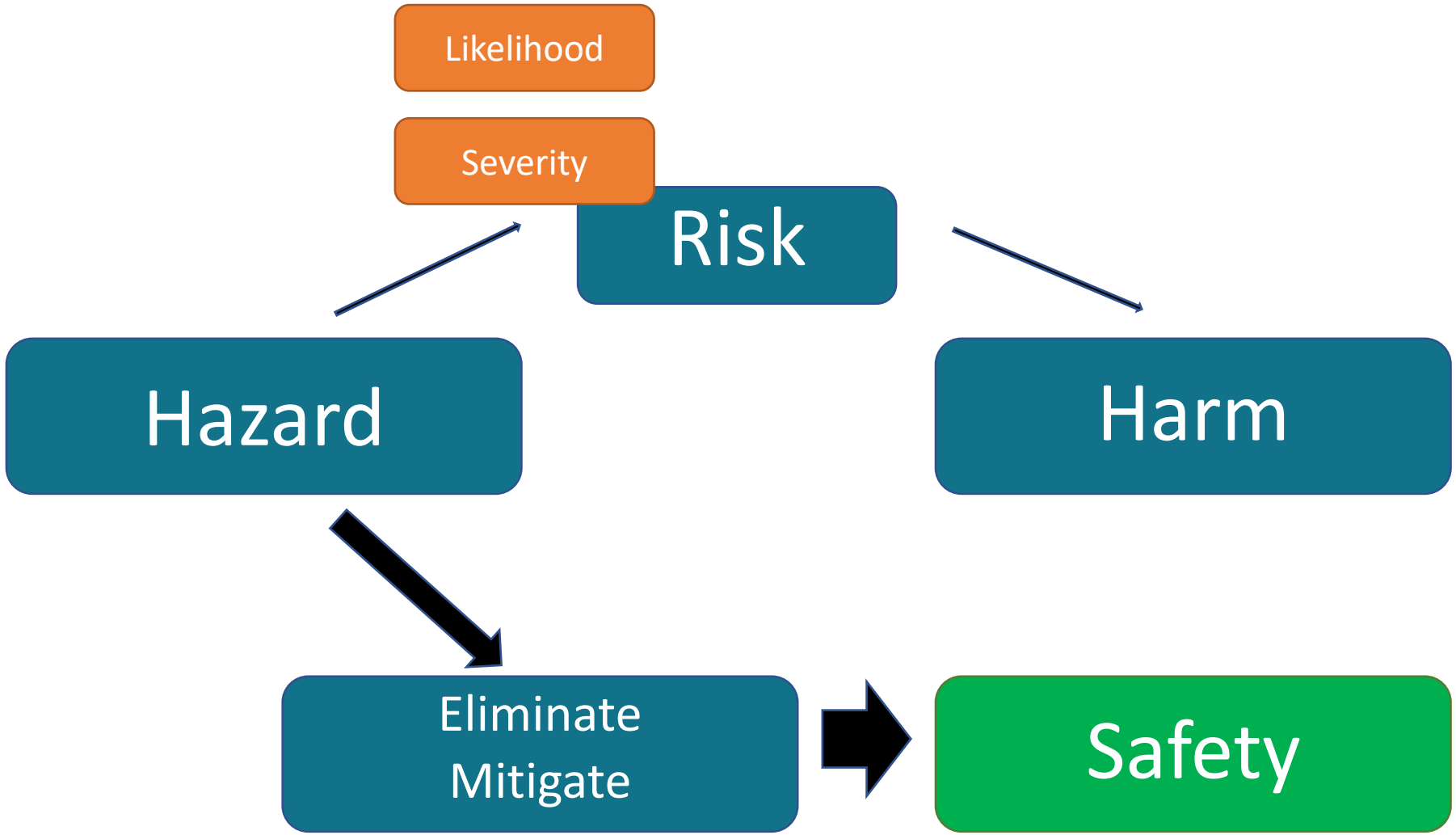
Mitigations

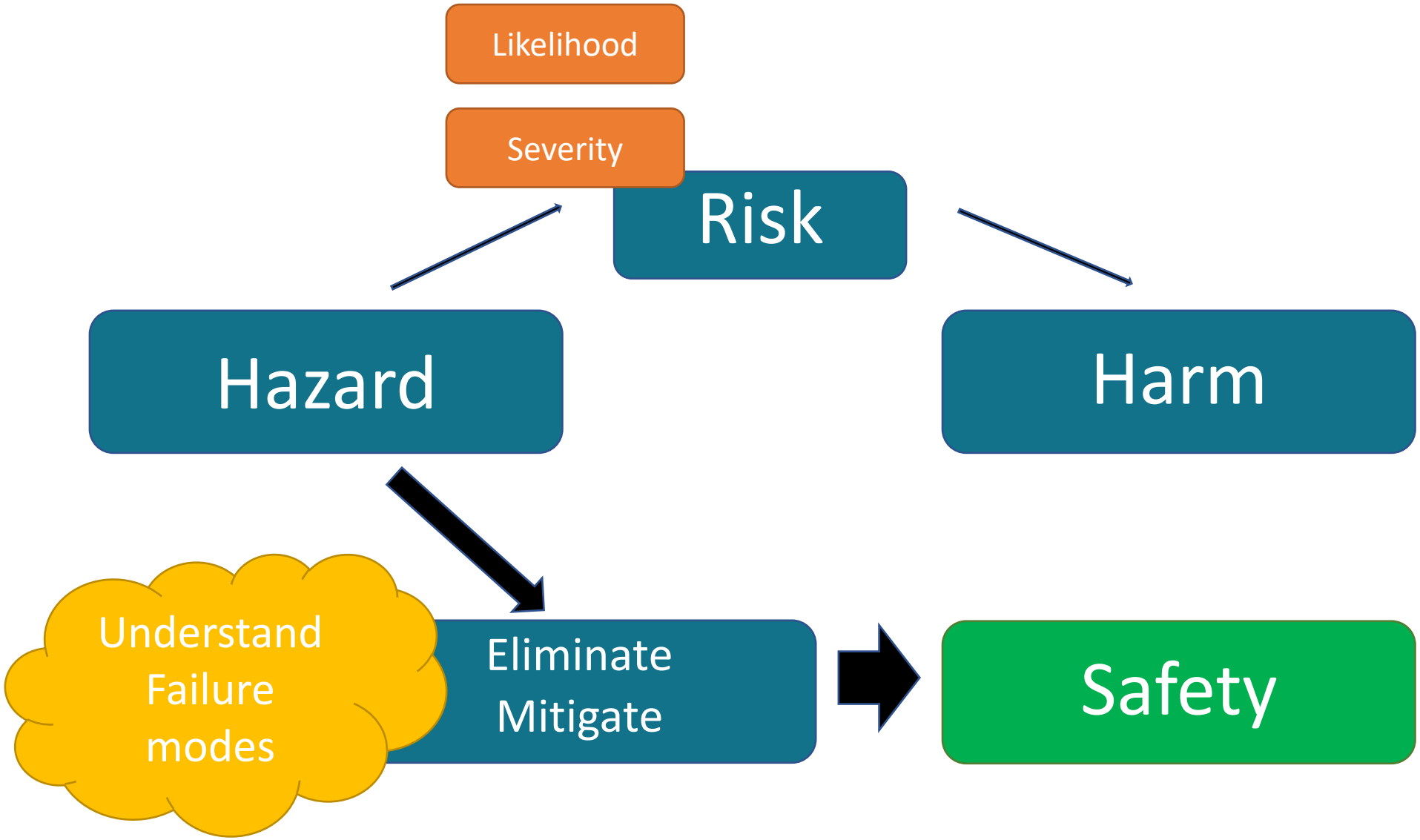

Hazard
Harm


Risk
Hazard
Harm


Likelihood
Severity
Risk
Hazard
Harm


Likelihood
Severity
Risk
Hazard
Harm
Eliminate
Mitigate


Likelihood
Severity
Risk
Hazard
Harm
Eliminate
Mitigate
Safety


Likelihood
Severity
Risk
Hazard
Harm
Understand Failure modes
Eliminate Mitigate
Safety

Failure Modes

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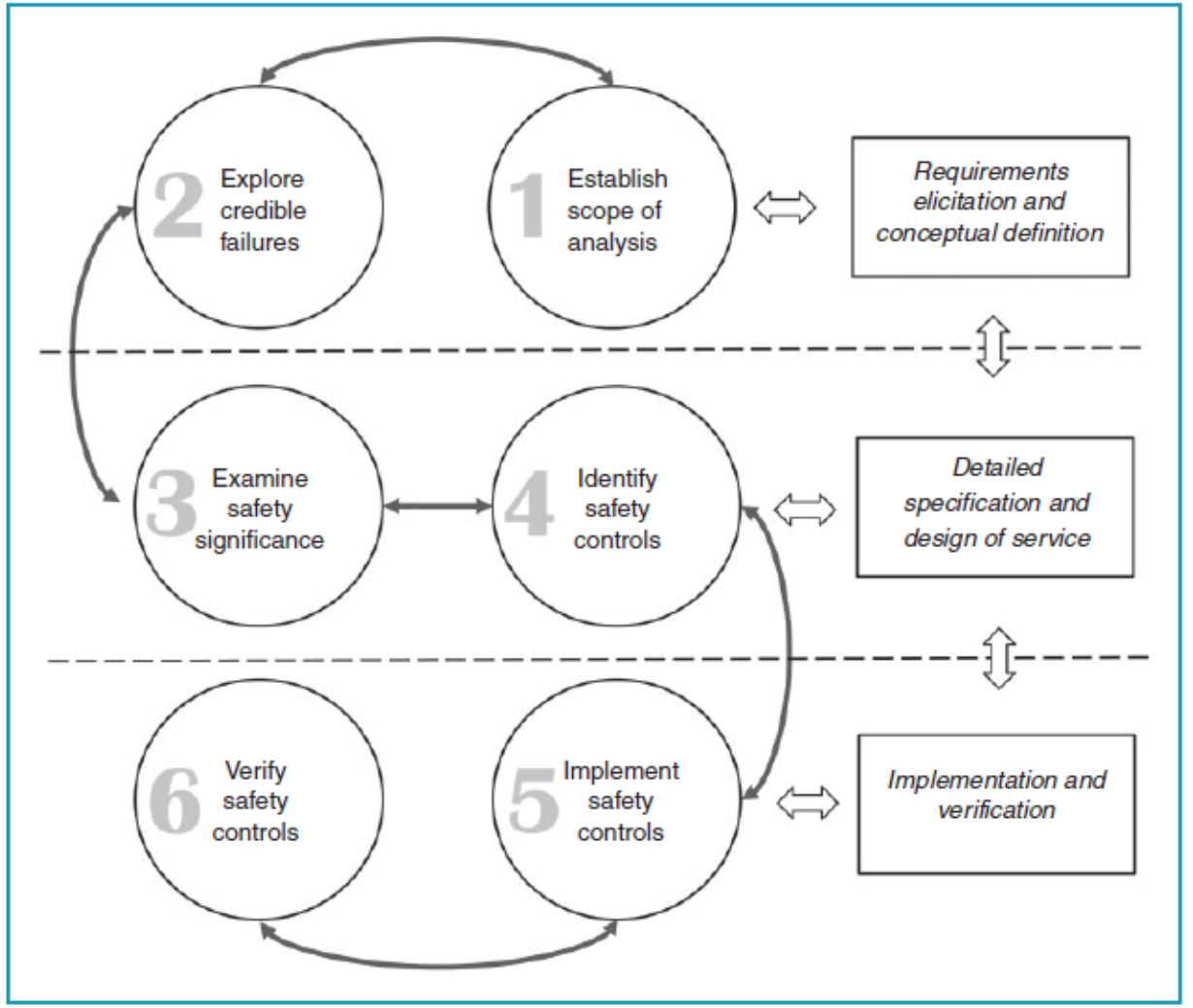
Guideword	Interpretation	Guideword	Interpretation
Omission	Something missing when expected	Commission	Something present when not expected
Early	Something happening earlier than expected	Late	Something happening later than expected
Sequence	Something happening out of sequence (when it matters)	Value	Wrong value in a piece of information
Lapse	A person not doing something that they were supposed to	Slip	A person doing something wrong accidentally
Mistake	A person doing something wrong intentionally (unaware that it is wrong – i.e. not malicious)	Access	Someone or something have unintended access to resources or data
More	Unintended increment in the quantity of an attribute of a system element (N.B. needs description of the attribute and its scale)	Less	Unintended decrement in the quantity of an attribute of a system element (N.B. needs description of the attribute and its scale)
Overload	Overloading a system or person (can also be thought of as a specific case of 'more')	Other	Generic guideword to encourage free discussion about something going wrong but not covered by the suggested guidewords
Wrong	A generic guideword capturing something wrong happening in the system	Violation	

Overview


2 Explore credible failures
1 Establish scope of analysis
Requirements elicitation and conceptual definition
3 Examine safety significance
4 Identify safety controls
Detailed specification and design of service
6 Verify safety controls
5 Implement safety controls
Implementation and verification

References

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Slide 15: Adapted Hierarchy of Controls
Slide 23, 24: Despotou G, Ryan M, Arvanitis TN, Rae AJ, White S, Kelly T, Jones RW. A framework for synthesis of safety justification for digitally enabled healthcare services. Digit Health. 2017 Apr 24;3:2055207617704271. doi: 10.1177/2055207617704271. PMID: 29942592; PMCID: PMC6001195.