

# Guidance on Patient Safety Hazard Assessment for Digital Health Solutions and Products

October, 2024

## Introduction

This document provides a guide to the process of managing patient safety hazards which may arise around digital health solutions.

This guidance based on HSE Risk Assessment Tool and informed by NHS Digital Clinical Safety Assessment.

The Digital Clinical Safety function in Ireland is in its infancy with the Digital Clinical Safety Strategy in development (for completion Q1, 2025), however key digital health projects should have a focus on Patient Safety, separate to project risk registers.

## About Digital Health Solutions

Digital Health is the use of information and communication technologies to improve health outcomes, healthcare services and facilitate wellness. It includes the tools and information to empower patients to better understand and manage their health. From mobile medical apps and software that support the clinical decisions doctors make every day to artificial intelligence and machine learning, digital technology has been driving a revolution in health care. Digital health tools have the vast potential to improve our ability to accurately diagnose and treat disease and to enhance the delivery of health care for the individual.

Digital health technologies use computing platforms, connectivity, software, and sensors for health care and related uses. These technologies span a wide range of uses, from applications in general wellness to applications as a medical device.

## Hazard Identification and Assessment Approach

The first step to preventing harm to patients arising from implementation, use or update of digital health tool is to ensure that as far as possible, a thorough process for hazard identification, hazard analysis and risk mitigation to ensure that any residual risks are tolerable.

Activities that should be carried out to clarify and address this potential include:

- Initial patient safety assessment carried out with input from stakeholders (clinical, technical, patient, business and operational) who are deeply embedded in project development streams;
- Production of a hazard log for the project;
- Review of the hazard log following broad consultation;
- Review of mitigation of risks as part of the development of the final Standard Operating Procedures and the implementation guidance;

- Clinical safety mitigation of the project deliverables and confirmation of risks to be passed to maintenance stages identified;
- Final draft of hazard log, standard headings and clinical safety report following final consultation;
- Drafting of safety case (approaches to mitigating the risks identified);
- Review and updating of safety case;
- HSE Digital Health Clinical Safety Case Report Review and Approval.

### The Patient Safety Risk Assessment Approach

The patient safety risk assessment approach:

- What could go wrong?
- Identify possible causes;
- Articulate the potential harm to a patient;
- Assess the risk: likelihood and consequence, as below;
- Propose and implement risk mitigation (and recommendations to improve patient safety) leading to a reduced and acceptable residual risk;
- Clarification regarding actions required a- terminate or transfer unacceptable processes, features leading to “unacceptable” risk as set out below.

### The Hazard Log

The full hazard log comprises:

- Hazard name and description;
- Potential causes;
- Potential patient safety/harm issue description;
- Initial hazard rating including likelihood and consequence – date stamped;
- Proposed mitigation;
- Actions taken – date stamped;
- Revised hazard ratings.

### Hazard Assessment

<b>RISK MATRIX</b>	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 Assessment Guidance: Impact

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 Assessment Guidance: 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

### 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 (6-10): Undesirable level of risk. Attempts should be made to eliminate or control to reduce risk to an acceptable level. This will only be acceptable when further risk reduction is impractical.

Green (3-4): Tolerable where cost of further reduction outweighs benefits gained.

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

### Support & Guidance

Further guidance will be available in Q1 2025. The Digital Health Clinical Safety lead ([Meabh.smith1@hse.ie](mailto:Meabh.smith1@hse.ie)) is also available to support projects.