

# Clinical Safety in Digital Health Glossary

TERM	DEFINITION
Alert fatigue	Desensitisation to frequent or excessive alerts, leading to slower responses, missed alerts, or errors.
Artificial Intelligence (AI) <a href="#">A common understanding: simplified AI definitions from leading standards   Digital NSW</a> ISO/IEC TR 24028:2020 (en)	<p>In general, AI is the ability of a computer system to perform tasks that would normally require human intelligence, such as learning, reasoning, and making decisions. AI encompasses various specialised domains that focus on different tasks. Examples include Machine Learning, which enables computers to learn from data; Computer Vision, allowing them to interpret visual information; and Natural Language Processing, for understanding and generating human language.</p> <p>According to the standards definition, AI is the capability of an engineered system to acquire, process and apply knowledge and skills.</p>
Business as usual (BAU)	Normal execution of standard operating activities within an organisation.
Clinical governance <a href="#">As per the NSQHS National Model Clinical Governance Framework</a>	<p>Clinical governance is the set of relationships and responsibilities established by a health service organisation between its state or territory department of health (for the public sector), governing body, executive, clinicians, patients, consumers and other stakeholders to ensure good clinical outcomes. It ensures that the community and health service organisations can be confident that systems are in place to deliver safe and high-quality health care, and continuously improve services.</p> <p>Clinical governance is an integrated component of corporate governance of health service organisations. It ensures that everyone – from frontline clinicians to managers and members of governing bodies, such as boards – is accountable to patients and the community for assuring the delivery of health services that are safe, effective, integrated, high quality and continuously improving.</p>
Clinical risk	The potential for an individual or individuals to experience harm or a negative outcome in health and care due to a hazard, taking into account both the likelihood of occurrence and the severity of the outcome.

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<b>Clinical risk in digital health</b>	A clinical risk due to a hazard associated with the design, implementation or use of digital health technologies. This encompasses risks related to the use of health IT systems, mobile health apps, telehealth, AI, electronic patient records, and other digital health tools.
<b>Clinical safety</b> Adapted from: <a href="#">WHO</a>	A framework of organised activities that creates cultures, processes, procedures, behaviours, technologies and environments in health and care that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, makes errors less likely and reduce its impact when it does occur.
<b>Clinical safety in digital health</b> Adapted from the NHS England	Clinical safety with a focus on digital health technologies that enable health and care. This includes systems, products and services that collect, use, exchange and display of health and care information.
<b>Controls</b> ISO/IEC Guide 63:2019	Process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels.
<b>Cybersecurity</b>	Cybersecurity safeguards systems to ensure information remains confidential, available and maintains integrity.
<b>Digital health hazard</b>	A 'potential source of harm, adverse outcome, or unintended consequence in digital health'. Examples of digital health hazards that can reach a person include health information that is: <ul style="list-style-type: none"> <li>• incorrect</li> <li>• incomplete</li> <li>• unclear, or</li> <li>• unavailable.</li> </ul>
<b>Digital health product</b>	Practical applications of digital health technology that meets user needs.
<b>Digital health service</b>	Combination of technology, people, process and systems that support health and care.
<b>Digital health technology</b> ISO/TR 11147:2023	System that uses computing platforms, connectivity, software, and sensors for healthcare and related uses.  Further explanation: These technologies span a wide range of uses, from applications in general wellness to applications as a medical device. They include technologies intended for use as a medical product, in a medical product, or as an adjunct to other medical products (devices, drugs, and biologics). They can also be used to develop or study medical products.

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Harm ISO/IEC Guide 51:2014	Injury or damage to the health of people, or damage to property or the environment.
Hazard ISO/IEC Guide 51:2014	Potential source of harm. Further explanation: Potential sources of harm include breach of security and reduction of effectiveness.
Health and care Adapted from definition of healthcare in ADHA resources	Provision of services and or support designed to maintain, improve or optimise health and well-being across all stages of life. Note: this definition includes provision of acute health care, longitudinal health care, and other care services such as aged care.
Health technology	Systems or products for healthcare and related uses.
Human Factors <a href="#">ACSQHC Incident Management Guide</a>	The study of how interactions between organisations, tasks, and the individual worker, impact on human behaviour and affect systems performance.
Incident <a href="#">ACSQHC Incident Management Guide</a>	An event or circumstance that resulted, or could have resulted, in unintended and/or unnecessary harm to a patient or consumer. An incident may also be a near miss and may involve complaints, loss, or damage.
Interoperability	The ability of a system or product to transfer meaning of information within and between systems or products without special effort on the part of the user.
Mitigation ISO 31000:2018	Actions or measures taken to reduce the severity, impact or likelihood of risks or adverse events.
Privacy	Privacy protects who can access personal information and respects individuals' rights to have accurate and up-to-date information.
Processes ISO 9001 ISO 31000	A set of interrelated or interacting activities that transform inputs into outputs.
Residual risk ISO 81001-1:2020	Risk remaining after risk control measures have been implemented.
Risk ISO 31000:2018	The effect of uncertainty on objectives.

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<p><b>Safety</b> ISO/IEC Guide 63:2012</p>	<p>Freedom from unacceptable risk.</p>
<p><b>System</b> ISO 9001 ISO 31000</p>	<p>A set of interrelated or interacting elements organised to achieve a specific objective.</p>
<p><b>Technology</b> Part of ISO/TR 11147:2023 definition</p>	<p>System that uses computing platforms, connectivity, software, and sensors.</p>
<p><b>Telehealth</b> ISO 13131:2021</p>	<p>Activity supported at a distance by information and communication technology service(s).</p> <p>Further explanation: It is possible that the subject of care is not directly involved in a telehealth service, e.g. in the case of tele-dermatology where one physician consults another physician who is at a distant location.</p> <p>Healthcare activities may include healthcare provider activities such as diagnosis, treatment, review or advice, and self-care activities as prescribed or recommended by a health professional, preventive (educational) advice and management of healthcare processes.</p> <p>Healthcare activities may include both synchronous (real-time) and asynchronous (delayed) interactions between actors. For example, a radiology examination can be transmitted and subsequently reported by a radiologist over a communications network. A discussion on the diagnostic findings can occur in real time over a telephone or video conferencing connection between a patient and health professionals.</p>
<p><b>Use error</b> ISO 9241-11:2018</p>	<p>User action or lack of user action while using the system, product or service that leads to a different result than that intended by the manufacturer or expected by the user.</p> <p>Further explanation: Use error includes the inability of the user to complete a task.</p> <p>Use errors can result from a mismatch between the characteristics of the user, user interface, task, or use environment.</p> <p>Users might be aware or unaware that a use error has occurred.</p> <p>A malfunction of an interactive system that causes an unexpected result is not considered a use error.</p> <p>The term use error is used in preference to user error or human error in order to avoid the implied assignment of responsibility for the error to the user.</p>