Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte



National Guidance for the Responsible and Safe Use of Artificial Intelligence in Health and Social Care Services

July 2026

Supporting National Standards



About the Health Information and Quality Authority (HIQA)

The Health Information and Quality Authority (HIQA) is an independent statutory body established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

Reporting to the Minister for Health and engaging with relevant government Ministers and departments, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector of Social Services within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services** — Regulating medical exposure to ionising radiation.
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- **Health technology assessment** — Evaluating the clinical and cost effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
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- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health and social care services, with the Department of Health and the HSE.

Visit www.hiqa.ie for more information.

Acknowledgements

HIQA would like to thank all the individuals and organisations who provided their time, advice and information in support of the development of this guidance.

Particular thanks are due to the project Steering Group and the Co-production Working Group members (see Appendix A). We would also like to thank individuals who contributed to the scoping consultation, the focus groups, individual stakeholder meetings and the public consultation. Their input was valuable in informing the development of the national guidance. We would also like to thank the Health Products Regulatory Authority (HPRA) for their input in particular, regarding the regulation of AI as a medical device.

Members of the Health Information and Standards Directorate

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Conflicts of Interest

None reported.

Note:

This is a guidance document, intended to support services by outlining good practice in relation to the responsible and safe use of Artificial Intelligence (AI) in health and social care services.

This document is also designed to educate and empower people who use services with knowledge about the responsible and safe use of AI in their care.

HIQA recognises that this is an evolving area, and the guidance has been developed at a point in time. The guidance has been written to be future-proofed in so far as is possible.

For the purpose of this document, the term 'AI tools' is used to cover the broad range of types and applications of AI in health and social care services.

This document is structured in three sections:

The **first section** is an introduction. It aims to raise awareness and educate management and staff in health and social care services about developments in AI and what it means for them in their work. It contains information to help management and staff understand what AI is, examples of its use in health and social care services, and where the guidance fits in the wider context.

The **second section** is the national guidance. The guidance has been developed to promote awareness and build good practice in the use of AI among the people who are accountable and responsible for managing services, and the staff working in those services. The guidance is structured using HIQA's framework for person-centred care and support under the principles of accountability, a human rights-based approach, safety and wellbeing and responsiveness. Under each principle the guidance includes examples of how a service and staff can uphold the principle in the context of the responsible and safe use of AI, what it means for people using services and a case study for illustrative purposes. Key considerations regarding the structures, processes and procedures that services have in place to support the responsible and safe use of AI should be proportionate to the size, complexity and function of the service. The scope and purpose of the AI tools in use and the care context where other statutory duties may be relevant should also be considered.

The **third section** of the document includes a glossary of key terms used throughout the document along with an overview of some commonly used AI core concepts and terminology to provide additional context.

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Introduction



1. Introduction

1.1 What is AI?

While there is no global definition of Artificial Intelligence (AI), AI is often referred to as a machine-based system capable of operating autonomously and producing outputs like predictions, recommendations, or decisions based on input data.[1] AI is an umbrella term encompassing a range of techniques, including machine learning, deep learning and computer vision. Each has distinct characteristics and applications (see Section 3.2 AI core concepts and terminology for definitions of AI concepts and sub-types). There is a broad spectrum of AI tools. Different AI tools* are designed to vary in their levels of autonomy and adaptiveness after deployment.

AI has the potential to deliver a wide range of benefits in all aspects of Irish society – commercially, environmentally and within the health and social care sector.[2-4] AI already plays a role in day-to-day life. For example, it can generate personalised recommendations on streaming services or analyse traffic patterns to provide the most optimal route in navigation applications. However, there are potential risks associated with AI. It is important that the use of AI is guided by appropriate safeguards, that outputs are monitored and that human oversight is maintained.

1.2 What are the different applications of AI in health and social care?

AI is currently being used in a range of ways across health and social care services in Ireland and its use will continue to evolve and expand over time. There are a number of ways in which the applications of AI in health and social care services can be grouped and classified. For the purpose of this guidance, AI applications are classified across four domains, with national and international examples of its use outlined in Table 1.



*'AI systems' typically combine a number of AI tools.

Table 1. Examples of the applications of AI in health and social care services

Domain	Applications	Examples
Care delivery	*Decision support*	■ For radiological procedures, including Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) scans, AI can improve image clarity, help to detect abnormalities and minimise radiation exposure. This is currently one of the most mature and widely researched areas of AI in health.[5] ■ In social care, an AI-powered Dynamic Tasks tool can be used by care workers during home visits to assist with decisions about tasks to be completed and to ensure consistency in the care provided.[6]
	Precision medicine	■ In oncology, AI can be used to tailor treatment based on a tumour's genomic characteristics and a person's reaction to treatment.[7] ■ In physiotherapy, AI can be used to support the development and adaption of tailored rehabilitation programmes based on a person's characteristics and specific needs.[8,9]
	Patient support tools	■ When interacting with services, AI powered virtual assistants and chatbots can provide immediate health information.[5] ■ In diabetes care, AI can support continuous glucose monitoring, predict blood sugar fluctuations, and detect early signs of complications.[10]
Operational efficiency	*Resource allocation*	■ AI can enhance the forecasting of hospital admissions and bed occupancy, enabling more proactive resource planning.[11] ■ AI-driven dynamic scheduling approaches can help to match service demand to health and social care provider supply.[5] ■ In social care, predictive risk modelling can be used to help child welfare agencies to identify children at risk of maltreatment and to better target system responses to these children and their families.[12]
	Automating routine tasks	■ Ambient AI scribes can be used in health and social care consultations to support note taking so that the clinician can focus directly on the person during consultations.[13] ■ Operating theatre efficiency can be improved through AI-supported scheduling, reducing cancellations and ensuring essential equipment availability.[2]
Public health and health policy	*Understanding and forecasting population health*	■ AI has the potential to enhance the processing of population health data to predict and mitigate health risks and develop insights about the wider determinants of health.[14]
	Population health screening programmes	■ AI can be embedded in national screening programmes to analyse vast medical data and identify subtle abnormalities, thus improving accuracy, early detection, and efficiency.[2,15]
Research and innovation	*Research and innovation*	■ AI can match individuals with specific clinical trial criteria and can predict patient eligibility and potential outcomes, improving clinical trial success rates.[16,17]

1.3 What are the benefits and potential risks of using AI in health and social care?

The health and social care landscape is rapidly changing both nationally and internationally.[18] The health and social care system is facing rising costs, increased demand due to an ageing population, increased prevalence of chronic and complex conditions and a shortage of health and social care staff to meet the demand. AI is a promising tool that can be integrated into the delivery of health and social care services to support staff and help address some of these challenges. Recent advancements in AI are expanding the possibilities for innovation in health and social care. AI can support the provision of more personalised care, reduce the duplication of care, assist with decision-making, streamline access to care in the community, improve workflows and increase operational efficiencies.[2]

While the potential benefits of integrating AI tools in health and social care services are significant, there must always be balanced consideration of such benefits against potential risks and downstream impacts to ensure AI tools are used responsibly and safely. Examples of potential risks include the use of data without people's consent, unintentional breaches of people's personal data, staff uncritically accepting AI outputs without human oversight, staff misinterpreting unreliable recommendations from unvalidated or biased AI tools, and deskilling of staff due to overreliance on AI tools. It is important that services identify and understand any potential risks associated with the use of AI tools and put mitigation measures in place. Section 2 provides further examples of the types of potential risks that must be minimised to ensure safer, better care for people using services.

Accountability is the foundation for the responsible and safe use of AI. Services must ensure accountability by establishing robust governance arrangements and proportionate controls around the use of AI within the service.



While the potential benefits of integrating AI tools in health and social care services are significant, there must always be balanced consideration of potential risks.

1.4 What is the legal context for the use of AI in health and social care services?

It is important that there is clear accountability within services, with effective arrangements and governance structures in place to ensure compliance with relevant Irish and European legislation. Services need to be responsive to evolving legislation, policies, and directives that progress alongside the advancement of AI, and understand what it means for them.

The legal landscape regarding the use of AI in health and social care in Ireland is evolving. It is shaped by a number of EU Acts and regulations. The use of AI tools in health and social care services must be guided by appropriate safeguards and be in compliance with legal obligations including those set out in the EU Artificial Intelligence Act[19] along with other relevant legislation such as Medical Device Regulations[20,21] and the General Data Protection Regulation[22] to ensure AI is used in a safe and responsible way.[23] This is not an exhaustive list of relevant regulations and there are other requirements in relation to safety, data privacy, cybersecurity, and human rights† that should also be considered.[24-34] This guidance provides a high-level overview of some relevant legislation to assist services and staff in understanding the legal context and their obligations for the responsible and safe use of AI.

The EU Artificial Intelligence Act

The EU AI Act (Regulation (EU) 2024/1689),[19] a framework for governing AI systems, was published in July 2024 and entered into force in August 2024. Its obligations apply in stages between 2025 and 2027.‡ It addresses risks associated with the design, deployment, and use of AI systems. The Irish Government is developing forthcoming legislation that will provide for the full implementation of the EU AI Act across all sectors at a national level. The EU AI Act requires each EU Member State to establish or designate at least one notifying authority and one market surveillance authority for AI oversight. Ireland is adopting a distributed model of competent authorities and plans are underway to establish a National AI Office in 2026, that will act as the central coordinating authority for the AI Act in Ireland.

The EU AI Act provides the following definition:

> An 'AI system' means a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments.[19]

†Under the Public Sector Human Rights and Equality Duty, public sector bodies have specific obligations including the need to eliminate discrimination, uphold equality of opportunity and protect human rights in relation to the design, roll out and review of AI in public services.

‡Requirements will continue to evolve in line with the Digital Omnibus AI Regulation Proposal, published by the European Commission in November 2025. This is part of the Commission's broader simplification agenda under the wider Digital Omnibus Package. The measures set out in the Digital Omnibus on AI Proposals, which were still under consideration and in the EU legislative process at the time this guidance was published, will continue to inform the progression of the implementation of the AI Act nationally.[35,36]

What does the EU Artificial Intelligence Act mean for health and social care services?

- The European Union has introduced rules about the development and use of AI tools. These rules, which will apply on a phased basis, have been introduced to protect the health, safety and fundamental rights of people.
- The EU AI Act takes a risk-based approach based on four risk levels – minimal risk, limited risk, high risk and unacceptable risk. AI tools that are categorised as 'high risk'[§] have stricter rules than AI tools that are categorised as 'limited risk' or 'minimal risk'.
- 'Providers' (who create and develop AI tools) must determine the intended purpose of the AI tool, classify it into one of the four risk levels and register it as appropriate in line with the requirements in the Act.
- Each risk level is subject to different compliance rules and responsibilities for 'providers' (who create and develop AI tools) and 'deployers' (who use AI tools in their professional activities) of AI. A deployer can also be classified as a provider in certain circumstances, for example, if the deployer substantially modifies a high-risk tool or modifies the intended purpose of an AI tool.
- Many uses of AI in health and social care services will fall under the high-risk category, which includes AI in medical devices.
- The EU AI Act is designed to exist and apply alongside other legislation (including but not limited to medical device regulation and data protection regulation).
- Health and social care services that use AI tools need to have measures in place to ensure they follow all the rules that are outlined in the EU AI Act and other relevant related legislation.

[§]AI tools which pose significant risks to the health, safety, or fundamental rights of individuals are categorised as high risk.

Medical Device Regulation and In Vitro Diagnostic Medical Device Regulation

Since 2017, medical devices and in vitro diagnostic medical devices are regulated in Europe by the Medical Device Regulation (MDR) (Regulation (EU) 2017/745 - MDR)[20] and In Vitro Diagnostic Regulation (IVDR) (Regulation (EU) 2017/746 – IVDR)[21] respectively and must meet all applicable requirements outlined in these regulations prior to being placed on the European market. This includes AI-based software devices that meet the definition of a medical device or In Vitro Diagnostics (IVD) and that may be used by healthcare professionals in hospital settings or by lay users, for example, as mobile applications on smartphones. Most AI-based medical device and IVD software will also meet the definition of a high-risk AI system under the EU AI Act.

Medical devices and IVDs need to be appropriately certified and CE marked before they can be placed on the EU market or used in a healthcare setting. For higher-risk medical devices and IVDs, this typically includes assessment by an independent assessment body known as a Notified Body. This assessment verifies that all relevant technical specifications and clinical requirements in relation to the safety, functioning and use of the medical device or IVD have been demonstrated through relevant testing and validation prior to the device being approved by the Notified Body.

The Health Products Regulatory Authority (HPRA) is the national competent authority for medical devices and IVDs in Ireland. The HPRA designates and oversees Notified Bodies in Ireland that are responsible for certifying medical devices and IVDs as outlined above.

General Data Protection Regulation

The General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679)[22] governs data protection and privacy and regulates how personal data is collected, used, stored and shared. It applies to any processing of personal data, including in an AI tool. For services deploying AI tools in health and social care, GDPR compliance is critical, particularly in managing personal sensitive data including special category personal data, ensuring lawful processing and addressing principles such as transparency, consent, data minimisation and storage limitation, accuracy and individuals' rights (access, erasure and objection to processing). In the health and social care context, the lawful basis for processing personal data or special category personal data may vary depending on the purpose of processing the data. Under the GDPR, a Data Protection Impact Assessment** is mandatory where data processing "is likely to result in a high risk to the rights and freedoms of natural persons". This is particularly relevant when a new data processing technology is being introduced.[37] GDPR applies directly in Ireland (and across the EU), along with further national rules set out in the Irish Data Protection Act 2018.[38]

**A Data Protection Impact Assessment is a process designed to identify risks arising out of the processing of personal data and to minimise these risks as far and as early as possible.

1.5 What is happening at a national level around the use of AI in health and social care?

AI is already playing a part in the provision of health and social care services in Ireland, with its use expected to further increase over time. A system-wide approach to supporting the responsible and safe use of AI in health and social care is being adopted. It is important that there are strong and effective governance arrangements in place at national, regional and local service-delivery level to support the safe and responsible use of AI in health and social care services. The Department of Health, the Health Service Executive (HSE) and HIQA are developing separate but related programmes of work in line with their organisational remits:

- **AI for Care – The Artificial Intelligence Strategy for Healthcare in Ireland 2026-2030** describes the vision for AI in healthcare and the opportunity areas that will be considered for AI deployment in the Irish health service over the next five years. This strategy was developed by the Department of Health and the HSE and is underpinned by the vision in **Digital for Care: A Digital Health Framework for Ireland 2024-2030** to digitally transform health and social care services in Ireland.
- The **HSE's AI Implementation Framework** outlines how to implement AI for Care and provides a toolkit for implementing AI projects across the HSE. The intention of the framework is to ensure robust governance, regulatory adherence specifically to the EU AI Act, innovation, AI knowledge and enablement, and high-level project instruction to ensure responsible and efficient AI deployment in healthcare.
- The **National Guidance for the Responsible and Safe Use of Artificial Intelligence in Health and Social Care Services,** developed by HIQA, outlines good practice for services and staff in relation to the responsible and safe use of AI in health and social care services.

The National Guidance for the Responsible and Safe Use of Artificial Intelligence in Health and Social Care Services complements existing strategies and frameworks that have been published to support the development, deployment and implementation of AI tools across all sectors of Irish society including in health and social care including **Digital Ireland – Connecting our People, Securing our Future**[39] and **Guidelines for the Responsible Use of Artificial Intelligence in the Public Service**.[1]

1.6 Why has HIQA developed this guidance?

Under the Health Act 2007, HIQA has a role to promote safety and quality in the provision of health and personal social services for the benefit of the health and welfare of the public. HIQA also has a mandate to develop national standards for health and social care services and to monitor compliance with these standards. HIQA develops tools to assist services and staff to implement the national standards in their setting, or as a guide to making improvements in a particular area.

This national guidance is intended to support the implementation of national standards in practice, including, for example, the National Standards for Safer Better Healthcare[40] and the National Standards for Information Management in Health and Social Care.[41] Other HIQA guidance documents that may be relevant to consider alongside this guidance include:

- National Guidance on Good Communication in Health and Social Care: Using Plain Language.[42]
- National Guidance on a Human Rights-based Approach in Health and Social Care Services.[43]
- National Guidance on a Data Quality Framework for Health and Social Care.[44]

As HIQA updates existing standards and develops new standards, the role of digital technologies including AI will be further strengthened. The standards will be enhanced to identify good practice to support person-centred care when digital technologies are used in the delivery of health and social care.

1.7 How do the requirements of professional regulatory bodies apply?

Professional regulatory bodies in Ireland, for example the Medical Council, the Nursing and Midwifery Board of Ireland, the Pharmaceutical Society of Ireland and CORU, regulate the competence and performance of individual professional practitioners. They have professional codes of conduct and ethics which set out values and principles underpinning good practice in areas including informed consent and patient safety. These principles apply across all areas of practice. Regulatory bodies may issue additional or more detailed requirements or guidance for their registrants in relation to the responsible and safe use of AI, for example in areas such as AI literacy, competence, supervision and scope of practice.

Guidance



2. Guidance

2.1 Purpose of the guidance

This national guidance aims to support services to promote and drive a responsible and safe approach to the use of AI in the health and social care sector in Ireland. HIQA adopted an evidence-based and collaborative approach to develop the national guidance and there was engagement with a wide range of stakeholders including clinicians, people who use services, staff involved in the management and administration of services and a variety of organisations including representative bodies, professional unions and advocacy groups. See Appendix B for further details on the process undertaken to develop the guidance.

The main purpose of this guidance is to promote awareness and build good practice among services and staff about the responsible and safe use of AI in their services. The guidance provides examples of the arrangements that services need to have in place to promote robust governance, transparency, and public engagement in order to support the responsible and safe use of AI.

The guidance can also be used by people using services to educate and empower them on what their expectations should be regarding the responsible and safe use of AI in health and social care services.

2.2 Scope of the guidance

The guidance is intended for use by all services and organisations that provide health and social care in Ireland (see Table 2 for further detail). The expectation is that all services can use the guidance to develop and embed good practice to ensure safer, better care for people using health and social care services.

- Key considerations regarding the structures, processes and procedures that services have in place to support the responsible and safe use of AI should be proportionate and context specific.
- The size, complexity and function of the service, the scope and the purpose of the AI tools in use and the care context and setting in which they are used will inform what is appropriate.

Table 2. Overview of who the guidance is relevant for and how it is relevant

	Who the guidance is relevant for	How the guidance is relevant
Services	Anywhere health or social care is provided. Examples include but are not limited to acute hospitals, pre-hospital emergency care, rehabilitation services, hospice, community care, dental clinics, primary care services, general practice, pharmacies, residential care for older people, people with disabilities, and home support services.	The guidance provides examples for people who are accountable and responsible for managing services, make decisions about AI tools and have responsibility for their use within health and social care services. It outlines the arrangements they need to have in place to promote robust governance, transparency, and public engagement in order to support the responsible and safe use of AI.
Staff	People who work in health and social care services, including clinical and non-clinical staff.	The guidance is designed to support staff to understand their role and to make decisions that ensure the responsible and safe use of AI as a tool to support the operation of services and the delivery of care and support.
People who use services	People who use health and or social care services (service users), their parents, legal guardians, carers, family members or nominated advocates or representatives.	The guidance is designed to help people to understand what some of their expectations should be when AI is used in their care in a safe and responsible way.

2.3 How the guidance is structured

HIQA develops standards and guidance that are underpinned by its principles-based framework. The framework is informed by evidence and stakeholder input and consists of four key principles of accountability, a human rights-based approach, safety and wellbeing, and responsiveness.[45] The principles work together to achieve person-centred care and support as set out in Figure 1 below.

The definition of each principle has been adapted and tailored to reflect what it means in the context of the responsible and safe use of AI in health and social care services. It also incorporates the broader range of principles cited in other AI-related guidance and framework documents.

While it is useful to understand and consider each principle individually (as demonstrated in this guidance), it is important to recognise that the four principles are interdependent. They must be balanced to work together and collectively ensure the provision of person-centred, safe, high-quality care. Therefore, examples presented under one principle may also be relevant to other principles. It is not intended for the principles to be read in isolation; where a theme is considered most relevant to one principle, it is discussed under that principle, however, it may apply to other principles also. For example, training of staff is discussed under the principle of responsiveness, but it is an important facet of all four principles.

Health and social care services using AI tools should always have rigorous oversight of their use through effective governance structures and evaluation procedures across the AI lifecycle. Therefore, while accountability is a standalone principle, elements of accountability are included in the other three principles as appropriate. This reflects the fact that accountability is the cornerstone of the responsible and safe use of AI, and robust governance structures and clear lines of accountability need to be embedded across all uses of AI in health and social care services.

Figure 1.

Principles that underpin the National Guidance for the Responsible and Safe Use of AI in Health and Social Care Services



Overview of how the guidance is structured

An explanation of the principle	Describes how the principle applies in the context of the responsible and safe use of AI in health and social care.
Examples of how a service can uphold the principle in practice	Aims to help people who are accountable and responsible for managing services to understand the governance structures and evaluation procedures needed in order to uphold the principle. These examples are not exhaustive and may apply in different ways depending on the size and complexity of the service.
Examples of how staff can uphold the principle in their day-to-day work	Aims to support staff working in health and social care services to be confident to use AI in an accountable, responsible and safe manner in their day-to-day work. These examples are not exhaustive and should be considered in the context of existing obligations under codes of professional conduct and ethics.
Examples of what it means for people using services when the principle is upheld	Aims to help people using health and social care services to understand what to expect when the principle is upheld.
A short case study of the principle in practice	Provides an example of what the responsible and safe use of AI may look like in a health and social care service with a focus on some of the key areas of good practice under the relevant principle. The case studies are for illustrative purposes. Services will have various arrangements in place for approval of AI tools depending on the size and type of the organisation, and it is important to be familiar with such arrangements.

Appendix C provides an overview of considerations for services using AI tools based on the examples outlined below under each of the four principles. This includes considerations across the AI lifecycle at the procurement and planning stage, the deployment, operation and monitoring stage, and the decommissioning stage.

Principle 1:
Accountability





Principle 1:

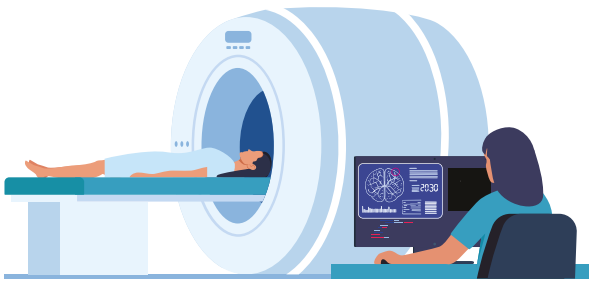
Accountability

Key points to consider under the principle of accountability:

- Governance arrangements are in place to ensure full oversight of the use of AI tools.
- AI tools are used in line with approved policies and procedures.
- The use of AI tools adheres to legal requirements and professional obligations.
- Roles and responsibilities regarding AI tools are defined and clearly understood.
- AI tools support but do not replace human judgment and decision-making.
- There is transparency about the use of AI tools, including appropriate levels of traceability and explainability.

Overview

The principle of accountability means that health and social care services have appropriate governance structures in place to provide high-quality, safe care that is consistent, coordinated, and focused on achieving the best outcomes for people using services. In the context of AI, the principle of accountability is the foundation for the responsible and safe use of AI tools to enable person-centred care and support. Corporate and clinical governance combined with effective leadership and management are essential to integrate AI tools into health and social care safely and responsibly.



The principle of accountability is the foundation for the responsible and safe use of AI tools to enable person-centred care and support.

In an accountable service, there are formalised governance arrangements in place, including clear lines of accountability. An accountable service has effective arrangements in place to ensure compliance with relevant legislation and codes of practice for the use of AI. A culture of openness and transparency within the service is promoted and it is important that the service is resourced to meet obligations regarding the safe and effective use of AI tools in the delivery of care.

In the context of the responsible and safe use of AI in health and social care, the principle of accountability includes the following sub-themes:

Have robust governance and oversight:

Health and social care services have rigorous oversight of an AI tool's use through established governance structures and evaluation procedures. Existing policies and procedures are updated, and new policies and procedures are put in place which outline the arrangements for the use of AI tools in the service and address requirements outlined in the EU AI Act and other sector-specific guidelines. Robust quality control and assurance practices are in place in the service to ensure the safe and responsible use of AI tools. A culture of continuous quality improvement is promoted. Governance arrangements are in place to ensure full oversight, including assurance of testing and validation, performance monitoring, observing the extent of automation bias or uncritical acceptance of AI outputs, periodic re-evaluation, and responsible decommissioning or withdrawal. These arrangements are adapted as new uses of AI and related risks emerge.

Ensure compliance with legislation:

Health and social care services ensure that the use of AI tools complies with national and international legislation, including but not limited to deployer[††] requirements outlined in the EU AI Act and data privacy, consumer law, accessibility, cybersecurity, and medical device regulations. There are processes in place to identify and address any areas of interaction, overlap, or gaps between current practices and existing and forthcoming legislation.[20-22,24-32] Services have regular assurance reporting in place so that management can be assured that the use of AI tools is in line with legal requirements in the EU AI Act and other related legislation. Staff adhere to current professional obligations and requirements when AI tools are used in health and social care services, including legal obligations and codes of professional conduct and ethics that promote the safe and responsible delivery of care.

[††]As per the EU AI Act, a deployer is defined as "any natural or legal person, including a public authority, agency or other body, using an AI system under its authority, except where the AI system is used in the course of a personal non-professional activity".[19] Some services may develop AI tools (including AI-based medical device software), and in this case the service must also comply with requirements for AI providers as defined under the EU AI Act (as well as requirements for manufacturers under the MDR/IVDR as applicable).

Define roles and responsibility:

To ensure the accountable use of AI tools in health and social care services, roles and responsibilities for the use of AI tools at the individual, team and service level are defined by the service and clearly understood by staff. These roles and responsibilities are embedded within existing structures, for example in relation to risk management, data quality and data security. Management are responsible for decisions about the procurement, governance, monitoring, and auditing of AI tools, while staff hold responsibility for the interpretation of AI outputs and ensuring that AI tools are used in line with their professional obligations. Clinical staff remain responsible for their clinical decisions in the treatment of people using services. Information on where responsibilities rest within the service is available to people using services.

Maintain human agency:

Accountable services that use AI tools have arrangements in place to support staff to maintain meaningful oversight over AI tools, whereby they understand, question and where necessary override AI decisions where there is conflict with their professional judgment. The use of AI tools augments, rather than replaces, human judgment and professional decision-making while the quality, empathy, and personal connection that underpin effective care are maintained. AI tools in use are part of a process that has appropriate human oversight built into it. Depending on the intended purpose and use of an AI tool, this may include a human directly overseeing decisions in real time ("human in the loop") or allowing the tool to operate autonomously with the ability to be overridden by a human as needed ("human on the loop").

Be transparent:

Accountable services that use AI tools have arrangements in place to ensure the service is transparent about what AI tools are in use and their scope and appropriate uses. Transparent services inform people using services about when, where and for what purpose AI tools are used in their care, how they are used to support decisions, and what impact they might have on the care, safety, security, and privacy of people using the service. AI tools are used in a way that allows appropriate traceability and explainability (the extent to which the reasoning behind AI outputs can be understood and interpreted). Traceability mechanisms embedded within a service support transparency, for example clear documentation facilitates monitoring and audit, demonstrates due diligence, and enables swift action if something goes wrong.



By upholding the principle of accountability, services have measures in place to minimise risks such as use of unauthorised AI tools, non-compliance with legal and professional obligations, uncritical acceptance of AI outputs, erosion of professional autonomy and unexplainable decisions.

Examples of how a service can uphold the principle in practice:

- Services understand their role in relation to the governance of AI. New or updated policies, procedures and processes are in place to address requirements outlined in legislation and sector-specific guidelines for the use of AI. These align with existing governance structures.
- Prior to the initial use of an AI tool in a service, the service's governance structures are assured of the following:
  - Legal and regulatory expertise and guidance have been consulted. This includes expertise on ethical, data protection and cybersecurity impacts of the tool and EU AI Act requirements.
  - The tool, where relevant, has gone through appropriate regulatory review and approval and there is evidence to support the safety, accuracy and efficiency of the tool.
  - Appropriate quality control measures and assurance practices for the use of AI tools are developed and implemented.
  - Fundamental Rights Impact Assessments (FRIA)[‡‡] are conducted by a designated individual for high-risk tools as required by the EU AI Act describing the intended use, affected groups, potential risks, human oversight measures, and mitigation strategies. The individual(s) responsible may differ based on the type and size of the service.
  - The environmental impact of the tool is considered and procurement is in line with existing green policies and initiatives.
- Processes are in place to identify potential gaps with existing and forthcoming legislation related to the use of AI, for example, in relation to data governance, quality assurance and risk management and there is flexibility to adapt to a changing AI landscape.
- Processes are in place to monitor that mitigation measures identified in FRIAs are in place in practice and to ensure that the FRIA is updated if key information changes while an AI tool is in use, such as how the tool is used or the groups affected.
- Pre-existing policies and processes are regularly reviewed and adapted in line with legislation and best available evidence relating to the use of AI tools in health and social care services, for example in relation to consent.

[‡‡]A fundamental rights impact assessment is a requirement of the EU AI Act and it is essential for services using high-risk AI tools to understand and mitigate risk to fundamental rights. This assessment is carried out prior to the first use of the tool and involves identifying risks to fundamental rights, proposing mitigations, engaging with stakeholders to protect rights such as privacy and non-discrimination and setting a plan for risk management. After performing the FRIA, the deployer notifies the relevant market surveillance authority of the results. The market surveillance authorities are expected to be responsible for actively monitoring and inspecting AI tools on the market.

- Staff are supported to understand their roles and responsibilities and work in line with relevant legislation, regulations and standards, as well as national and local policies and procedures.
- An individual or named function is assigned responsibility for compiling and maintaining an inventory of authorised AI tools for use in the service. This process is in line with legal and regulatory requirements and facilitates ongoing monitoring and accountability of AI tools.
- There is clarity about the use of AI tools in the service. For example, a list of authorised AI tools is maintained by the service and this is provided to staff.
- Risk assessments are conducted on AI tools used within the service in line with existing risk management procedures.
- There is a process in place for decommissioning or withdrawing an AI tool from the service, including swift and safe disengagement of a tool where necessary, which is overseen by an accountable person, is transparently justified, and adheres to policies and regulations to protect data security and privacy.
- There is a culture of continuous quality improvement in relation to the use of AI tools. This includes undertaking reviews to ensure the reliability and accuracy of tools and learning from audits and incidents. There are mechanisms for responding to and learning from feedback, concerns or complaints from staff and from people using the service.
- AI tools are used in a way that allows appropriate explainability and traceability, for example, an audit trail is in place to ensure outputs from an AI tool are traceable. Where explainability is constrained, a formal governance justification and risk mitigation plan is approved before use of the tool in the service.
- A culture of openness and accountability is promoted throughout the service so that staff exercise their responsibility to report in good faith any concerns that they have in relation to the safety and quality of an AI tool.
- The service's complaints procedure is updated to incorporate complaints related to the use of an AI tool and any complaints are managed in line with this complaints procedure, which is clear, open, transparent, and accessible to people using the service.
- Services are transparent with people using the service about how AI tools are used in the provision of their care.

Examples of how staff can uphold the principle in their day-to-day work:

- Understand and comply with the relevant regulatory requirements, professional obligations and codes of conduct at the local, national, and international level when using AI tools.
- Only use AI tools that are authorised and supplied by the service to ensure standard technical support, maintenance, supporting infrastructure and security management are in place.
- Understand individual and collective responsibilities when an AI tool is integrated to support clinical, operational or administrative tasks.
- Adhere to established corporate and clinical governance arrangements in line with roles and areas of responsibility.
- Understand how to manage conflicts of opinion with outputs from an AI tool in line with scope of practice, skills and expertise and maintain an audit trail of decisions in line with the organisation's policies and procedures.
- Interpret outputs produced by an AI tool through a critical lens, and make decisions based on professional judgment, knowledge and experience.
- Be vigilant, regularly monitor and evaluate AI tool outputs in line with procedures outlined by the service, cease using an AI tool if it is not functioning as intended and escalate any concerns in line with the service's policies and procedures.
- Be open and transparent with people using the service about the use of AI tools to support the delivery of care.

Examples of what it means for people using services when the principle is upheld:

- I am confident that the service is governed and managed in a way that ensures AI is used in a responsible and safe way.
- I am confident that the use of AI tools in my care complies with the law.
- I trust that AI tools used in my care are carefully overseen to ensure they are safe.
- I am aware of the process for making a complaint related to the use of AI tools in my care and I understand how the complaint will be managed.

Example of accountability being upheld in practice



Background

Templeville Hospital's Radiology Department has faced increasing MRI waiting times. It has recently started using an AI-enhanced medical device during MRI scans. The AI tool supports radiologists by improving the overall MRI image quality and decreases time to review the image. The new AI tool has benefits for patients as it reduces scan times by 60%, meaning more patients can be seen quicker. In line with local governance procedures, prior to approving the AI tool's integration into the clinical workflow, the Clinical Director of Radiology established a multi-disciplinary working group consisting of radiologists, radiographers, medical physicists, IT, quality and safety, hospital management, and the Data Protection Officer to evaluate the tool. Following a three-month pilot, regulatory review (including Fundamental Rights Impact Assessment as the tool was high risk under the EU AI Act), and clinical validation, the Clinical Governance Committee approved the implementation of the tool.[§§] The hospital identified the process for ongoing monitoring of the tool during use and the roles and responsibilities of staff using the AI tool, and updated patient information to explain the purpose of the AI tool and how it is used in their care.

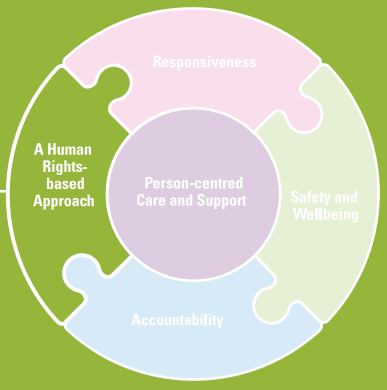
Dr Kumar's story

Dr Kumar is a Consultant Radiologist in Templeville Hospital and has recently started to use the new AI tool to enhance the quality of MRI images. Prior to using the tool, she undertook mandatory training developed by hospital management and the developer of the AI tool. The training outlined how the tool works to enhance image quality, the benefits and the risks associated with its use, and how to incorporate it into current workflows. During the training the hospital detailed the process for managing the ongoing clinical safety of the tool. The hospital instructed all radiologists to ensure that they cross check a small sample of AI-enhanced MRI images against the original each week to ensure that the tool is working as intended and to document the findings in the departmental audit log. The hospital noted that there would be a monthly department audit meeting to review the performance of the tool. In the event that the tool was not working as expected, the training outlined how this would be managed – radiologists were informed to escalate the issue via the Clinical Director who would bring the issue to the Clinical Governance Committee. The Clinical Governance Committee would then take appropriate actions which may include, suspending use of the tool, updating clinical guidelines, systematically reviewing any affected scans, and notifying patients and regulatory authorities. Dr Kumar commenced using the tool and she felt it improved her ability to review MRI scans by enhancing the quality of the images. She also received positive feedback from people using the service, who commented that they were seen quickly from the point of referral and overall the department reduced waiting lists for MRI scans.

[§§]The case studies are for illustrative purposes. Services will have various arrangements in place for approval of AI tools that are in line with the size, type and resources of the organisation, and it is important to be familiar with such arrangements.

Principle 2:

A human rights-based approach





Principle 2:

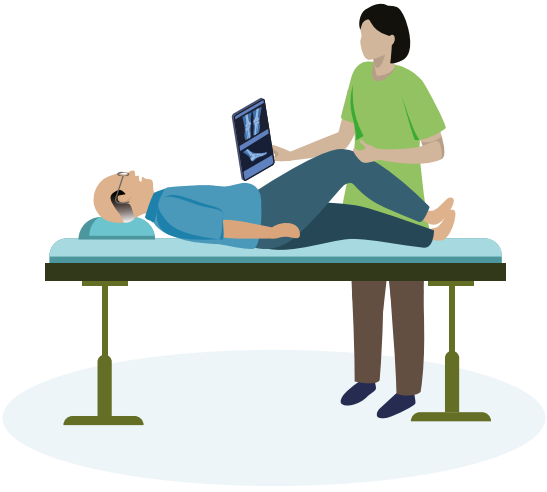
A human rights-based approach

Key points to consider under the principle of a human rights-based approach:

- AI tools are used in a way that is fair, inclusive, accessible and equitable.
- People using services are supported to make informed decisions about the use of AI tools in their care.
- The use of AI tools is in line with policies and procedures that protect privacy and confidentiality.
- Human connection is maintained and care remains person centred.

Overview

The principle of a human rights-based approach means that health and social care services respect, protect and promote the human rights of the person using the service. A human rights-based approach is underpinned by a legal framework and human rights treaties which Ireland has agreed to uphold.[24,34,46-50] A human rights-based approach promotes that the rights of individuals are at the centre of technological advances. FREDA is an internationally recognised framework through which human rights can be considered under the following five principles: Fairness, Respect, Equality, Dignity and Autonomy.[51] In the context of the responsible and safe use of AI, a human rights-based approach means that there is ongoing and active partnership with people who use services in relation to planning, developing and monitoring the use of AI tools and that their needs and preferences are taken into consideration.



A human rights-based approach means that there is ongoing and active partnership with people who use services in relation to the use of AI tools in their care.

In order to ensure that a service implements a human rights-based approach for the use of AI, there needs to be clear lines of accountability, as well as processes and procedures in place to protect, promote and uphold the rights of people when AI is used in their care. For example where relevant, these processes are in line with public sector equality and human rights duty and mitigation measures as outlined in the Fundamental Rights Impact Assessment.[19,52]

In the context of the responsible and safe use of AI in health and social care, a human rights-based approach includes the following sub-themes:

Ensure inclusivity and non-discrimination:

Health and social care services implement the use of AI tools in a way that is fair, equitable and accessible and does not discriminate against or exclude any individual or group. This includes ensuring that universal design principles have been applied during the development of the AI tool to support full and equal access for anyone impacted by the AI tool. Ongoing and active partnership with stakeholders, including with people who use services and staff, informs decision-making about the implementation of AI tools.

When AI tools are being developed, bias can be caused by training data that is not representative of the population that the AI tool will be used for or historical bias present in the training data, and this must be minimised to prevent discrimination. Services using AI tools have measures in place to monitor the performance and outputs of an AI tool through an equality, diversity and inclusion lens to assess the benefits and address the risk of bias, and to identify any disproportionate effects on any groups or individuals.

Educate the public and provide information to support informed decisions:

Health and social care services are transparent about the use of AI tools and take steps to inform people using services about the integration of AI tools as part of the delivery of their care. Improving knowledge about the use of AI among people using services encourages confidence and trust and supports them to exercise their rights. People using services have a right to information, to be fully informed, to ask questions and seek clarification and to be involved in decisions about the use of AI tools in their care. Services should provide information in a format that meets the needs of service users and that is proportionate to the nature and degree of risk posed by the AI tool. For example, AI tools used for supply chains or bed management may not require the same level of information as those used to support clinical decision-making. Services review and update consent policies and procedures to incorporate, where relevant, the use of AI tools and staff ensure to follow these procedures when delivering care.

Protect privacy and confidentiality:

Health and social care services maintain the privacy and confidentiality of people's personal information when an AI tool is used as part of their care, as well as in any secondary uses of health data, for example, processing of data in the development and testing of AI tools. It is the duty of those entrusted with the data to ensure that the person's right to privacy and confidentiality is upheld, and services and staff have a responsibility to safeguard the data of people using the service. Services must ensure that the use of personal data in AI tools complies with privacy and security laws including GDPR and other EU and national legislation.

Promote human connection:

When AI is used within health and social care services, care remains person-centred and standards of care are upheld. People who use services are supported to make the best decision for their care that aligns with their own needs and preferences. Human interactions are, where possible, maintained between staff and the people using the service when AI is used in health and social care. In circumstances where a person who uses services is engaging directly with an AI tool, for example an AI chatbot which the service has in place to provide patient support, there is an option to revert to interacting directly with a human and this is clearly signposted.



By upholding the principle of a human rights-based approach, services have measures in place to minimise risks such as biased outputs, mistrust of AI tools, privacy concerns and erosion of human connection in care.

Examples of how a service can uphold the principle in practice:

- Existing governance structures and processes are updated to ensure that decisions about the initial use and operation of AI tools within the service consider the impact on people's rights.
- Information is readily available, using a variety of communication methods, about what AI tools are used and integrated within the service in a way that is clear, comprehensive, accessible and appropriate to the needs and preferences of people who use the service.
- Arrangements are in place to ensure the use of AI tools aligns with relevant human rights legal frameworks, national policies, best practice guidelines, regulations and statutory requirements.
- Roles and responsibilities in relation to protecting and promoting human rights, when AI tools are used to support the delivery of care, are clearly outlined. This is communicated to, and understood by, staff at all levels.
- A co-design approach with individuals, groups and communities, including those with diverse needs, is adopted so that service users have an opportunity to give their views during all stages of the AI lifecycle to refine and enhance the use of AI tools. This can be done, for example, through a pre-existing service user forum.
- The service has inclusive mechanisms in place to capture feedback from all people who use the service. This includes ensuring that multiple communication channels are available to support different communication needs.
- The service is assured and confident that the AI tool has been developed based on representative data and the service regularly reviews outputs from an AI tool to ensure they are not biased.
- There is a clear rationale for what information is gathered about a person by an AI tool, the purpose of collecting this information and the rationale for retaining the data to ensure good information practices.
- A Data Protection Impact Assessment is conducted, if required, prior to introducing an AI tool to identify and mitigate any data protection-related risks.
- Data used in AI tools is securely stored, and when it is accessed and transmitted, this is done in line with relevant privacy and security laws including GDPR.
- The service recognises the continued importance of human interactions when AI tools are used to support the delivery of care and staff are supported to maintain these interactions.

Examples of how staff can uphold the principle in their day-to-day work:

- Listen to the needs and preferences of people who use services in relation to the use of AI in their care.
- Communicate clearly, openly and honestly in a format suited to the needs of people who use services. Avoid the use of technical language when engaging with people using services about the use of AI tools in their care.
- Provide information to people who use services on the benefits and potential risks of the AI tool, why the tool is being used, how the tool is being used, the process for monitoring the safety of the tool and how their information will be used so that they are empowered to make an informed decision about the use of AI in their care.
- Signpost people to further information about the use of AI tools within the service as required.
- When using an AI tool to inform a decision, critically evaluate outputs to mitigate any potential risks associated with bias.
- Respect the privacy of the personal information of people who use the service and manage the use of information in line with relevant legislation, national standards and the service's policies and procedures.
- Ensure appropriate and proportionate consent procedures have been followed and documented in relation to the use of an AI tool to support the delivery of care, in line with the service's policies and procedures and relevant professional codes of conduct and ethics.

Examples of what it means for people using services when the principle is upheld:

- I can easily find information about how the service uses AI tools in my care. This is in a format and medium suited to my needs.
- I know what AI tools are used in my care and I understand the benefits and potential risks as well as the consequences for my care if AI is not used. I am able to make informed decisions about the use of AI in my care based on my understanding of these benefits and risks.
- I am confident that my rights and the standard of care that I receive will not be negatively impacted when AI tools are used in my care.
- I am confident that my privacy is protected. I know what information is being collected about me, how it is being collected, shared and used and that the collection of my personal data will not be beyond what is necessary.
- I know that AI will not replace my care provider and that I will always have the option to speak to a human.

Example of a human rights-based approach being upheld in practice



Background

Richmond Physiotherapy Clinic has recently procured an AI-enabled digital rehabilitation platform to check in on progress in between physiotherapy sessions. The clinic procured the tool to support people using the service and manage their progress and recovery in between visits. The platform uses data provided by service users to generate personalised exercise programmes and assess service users remotely through a series of questions about their symptoms, level of movement and functioning since their last physiotherapy session, how frequently they are completing the exercises and if they are experiencing any difficulties with the exercises. The AI tool reviews and summarises their responses listing them in order of priority for the physiotherapist, who then decides if a follow up call or appointment is needed. The procurement of the tool was initially delayed because the clinic was concerned that the tool may be biased towards people with full mobility. The clinic noted that in line with public sector duty there was a need to assess equality and human rights issues and wanted assurances that the output from the tool is representative for all.*** The issue of bias in AI tools used in physiotherapy was explored by the clinic and assurances were sought from the developer to ensure the tool was developed using a diverse dataset that would be reflective of the users of the clinic.

Carlos's story

Carlos recently had a hip replacement and attends Richmond Physiotherapy Clinic for physiotherapy sessions. After his first physiotherapy session he was informed by his physiotherapist, Ali, that he would receive a link to an app which is linked to the clinic's digital rehabilitation platform before his next session. Ali provided Carlos with an information sheet, in plain English, which described how the app and platform work. Carlos had questions about where his private information would be stored. Ali assured him that appropriate steps had been taken to ensure the confidentiality of his information and that it would be secure. Carlos received a link to the app a few days after his physiotherapy session. When Carlos tried to access the link, he was struggling to download the app. Carlos felt frustrated and rang the physiotherapy department to complain. The receptionist offered to input his responses to the questions directly into the platform. Based on the data inputted into the digital rehabilitation platform, Ali was prompted to schedule a follow up appointment with Carlos as soon as possible. Carlos was prioritised by the AI tool based on his responses as his movement was decreasing and he was struggling with the exercises recommended. During the follow up appointment Ali provided support setting up the app and demonstrated to Carlos how to use it.

***The case studies are for illustrative purposes. Services will have various arrangements in place for approval of AI tools that are in line with the size, type and resources of the organisation, and it is important to be familiar with such arrangements.

Principle 3:

Safety and wellbeing





Principle 3:

Safety and wellbeing

Key points to consider under the principle of safety and wellbeing

- Corporate and clinical governance structures oversee the safety and quality of AI tools.
- AI tools are continuously monitored and evaluated to ensure safety, reliability and accuracy.
- Services have contingencies in place for AI tool failures and incidents are managed to prevent reoccurrence to ensure the continuous delivery of safe care.

Overview

The principle of safety and wellbeing refers to how health and social care services work to protect and promote the safety and wellbeing of people who use services. While the provision of health and social care can never be completely risk free, services have a responsibility to be alert to the safety and wellbeing of people who use the service, work to prevent harm and respond in a timely and proportionate manner to reduce risks. In the context of AI, tools are optimised to enhance safety and wellbeing in the delivery of care and are used in a way that minimises risk of harm, including physical, psychological and emotional harm. AI tools should maintain performance under varying conditions and there should be business continuity plans in place to maintain the continuous delivery of safe care.



AI tools are optimised to enhance safety and wellbeing in the delivery of care and are used in a way that minimises the risk of harm.

In the context of the responsible and safe use of AI in health and social care, safety and wellbeing includes the following sub-themes:

Maintain safe care:

Services have a duty to protect the safety and wellbeing of people and to mitigate the risk of harm when using an AI tool. The use of an AI tool, including its performance, is overseen by the corporate and clinical governance structures within services and governance structures are provided with regular assurance that the tool is working and is being operated as intended. Existing safety frameworks are updated by services to incorporate AI use. Continuous monitoring, maintenance, and performance evaluation of AI tools are in place in services to ensure safety, reliability, accuracy, integrity and robustness in line with risk management procedures and instructions for use. Any concerns about safety are responded to in a person-centred way and in line with legislation, regulations, national policy, standards and guidelines. Services considering the use of an AI tool are assured about the safety of the tool by the AI developer. Additionally, for AI tools that also qualify as medical devices or IVDs, compliance with the relevant requirements of the MDR or IVDR (as applicable) are confirmed prior to use.

Ensure technical robustness and security:

To uphold security, AI tools are secure, robust, capable of maintaining performance under varying conditions and are resilient to errors. There are clear lines of oversight for compliance with relevant security policies and strategies, including those relating to data privacy, cybersecurity and business continuity. Existing policies and procedures for managing data security and business continuity are updated to incorporate the use of data by AI tools. Contingency plans are in place for tool failures to ensure that services are resilient to errors or attacks and to maintain the continual delivery of safe care. If an incident does occur from the use of an AI tool, there are steps in place to manage the incident and prevent reoccurrence in the future.



By upholding the principle of safety and wellbeing, services have measures in place to minimise risks such as inaccurate or unreliable outputs, the use of unvalidated AI tools, changes in AI tool performance over time, data breaches, cybersecurity threats and disruption to service delivery.

Examples of how a service can uphold the principle in practice:

- Existing governance structures and processes are updated to ensure that decisions about the initial use and operation of AI tools within the service support and protect the safety and wellbeing of people using the service.
- Roles and responsibilities relating to oversight of the quality and safety of AI tools are clearly outlined.
- Existing safety frameworks used by the service are adapted for the use of AI tools, for example frameworks for digital clinical safety processes or clinical and operational safety reviews are adapted, and incident management frameworks are updated (in line with national reporting requirements, when established).
- The service has assurances of the following from the AI developer: rigorous testing, verification of conformity assessment if required, use of representative data, evidence-based evaluation and validation in real-world settings. Tools are initially trialled in the service to ensure their suitability for the specific setting and the population using the service.
- There are systems in place for continuous monitoring of AI tools, including monitoring performance to ensure robustness, monitoring data quality, changes in AI tool performance, concept drift and data drift, and reviewing feedback from staff and people using the service on an ongoing basis.
- There is robust risk management within the service, including clinical risk management. The service's risk management processes, including the risk management policy and risk register, are updated to reflect the use of AI tools.
- Services have appropriate mechanisms in place to respond to risks, including measures for suspending use of an AI tool and for notifying relevant parties in line with requirements under the EU AI Act or national reporting requirements.
- Clinical safety checks are in place to ensure that AI tools meet clinical standards and do not compromise the safety of people who use services. There are checks in place to ensure that staff are using the tool according to the instructions for use.
- The service is open, transparent and accountable and in the event that a known incident occurs from the use of an AI tool, affected individuals are informed in line with the service's open disclosure policy as appropriate. Incidents are recorded and actively reviewed to identify risk factors and support future learning and quality improvement.
- Governance structures within the organisation are provided with regular assurance that the tool is working as intended. To ensure business continuity and continuity of care, a contingency plan is in place in the event of an AI tool not working as intended.

- Strong data governance practices are in place to ensure there is oversight of how data used by AI tools is processed, where data is stored, who has access to data, how data is shared, and how data is used for secondary purposes[†††].
- Policies and procedures for managing data security and business continuity are updated to incorporate the use of data by AI tools. Staff responsible for data security, including cybersecurity, are made aware that their role now incorporates the use of data by AI tools.
- Controls are in place to prevent identifiable data being inputted into public, openly available large language models which could lead to a data security breach.

Examples of how staff can uphold the principle in their day-to-day work:

- Ensure that an AI tool is being used only as intended, within professional scope of practice, and in line with instructions for use (including, as appropriate, those provided by the developer of high-risk AI tools).
- Apply professional judgment and always exercise due care in line with clinical governance arrangements when using an AI tool to support the delivery of clinical care.
- Listen to and support people using the service if they have a concern about the safety of an AI tool or the security of their information and understand the process for recording concerns about AI tools within the service as appropriate.
- Report any incidents resulting from the use of an AI tool in line with the service's policies and procedures.
- Explain to people using the service how AI is used in their care, the potential risks and any limitations and how these are managed so that they can make an informed decision about the use of AI tools in their care.

[†††]Collection, use and sharing of health data for reasons beyond direct care such as planning and management of health services, policy-making, public health and research.

Examples of what it means for people using services when the principle is upheld:

- I am confident that regular checks are in place to ensure the safety of AI tools.
- I am assured that my care remains person centred and that staff use their professional judgment to oversee that recommendations informed by AI tools are appropriate for me.
- I know that staff will be open and honest with me if something goes wrong with an AI tool that was used in my care, and I know the service will learn from this to improve the safety of the service.
- I feel listened to and supported if I have concerns about the safety of an AI tool. I know staff will act on any concerns that I raise.
- I receive clear information about how my data will be collected, used and stored by an AI tool or within systems that are integrated with AI such as an electronic health record.
- I have an opportunity to provide feedback on the use of AI in my care so that the quality of the care I receive, and the care others receive, is continuously improved.

Example of safety and wellbeing being upheld in practice



Background

A general practice has recently started using an AI decision-support tool that supports GPs by suggesting a range of treatment options during consultations. The tool is a CE marked medical device. The tool has been approved for use in the practice following a clinical safety review and data protection impact assessment.‡‡‡ The GP inputs medical notes to the AI tool during the consultation and the AI tool suggests a range of treatment options. When a person using the service checks into the practice, a staff member directs them to information about the new AI tool being used during consultations.

Anna's story

Anna lives with Chronic Obstructive Pulmonary Disease (COPD) and a long-term kidney condition. She recently had an appointment with her GP Dr McGuire to discuss her COPD symptoms. At the start of Anna's consultation, Dr McGuire confirmed that Anna understood the purpose of the new AI tool and explained that he will always review and approve the consultation notes and treatment plan before proceeding. He reassured Anna that although the AI tool has been tested and shown to be safe and reliable, he does not over-rely on the tool and uses the suggestions alongside clinical judgment. Anna asked Dr McGuire if he could clarify how her medical information will be kept safe. Dr McGuire explained that the notes are stored in line with data protection legislation on a secure system. Dr McGuire checked if Anna had any more questions and if she was happy for him to proceed. Dr McGuire conducted the consultation as usual, supported by the AI tool. Towards the end of the consultation, Dr McGuire carefully checked the treatment options generated by the AI tool. Using his clinical judgment, knowledge of Anna and awareness of local services, Dr McGuire agreed with the suggestion to refer Anna to an occupational therapist. Dr McGuire reviewed the AI tool's suggestions about medications, factoring in information about potential interactions with Anna's kidney condition. Following discussion with Anna, he prescribed a new medication to help with her symptoms.

‡‡‡The case studies are for illustrative purposes. Services will have various arrangements in place for approval of AI tools that are in line with the size, type and resources of the organisation, and it is important to be familiar with such arrangements.

Principle 4:

Responsiveness





Principle 4:

Responsiveness

Key points to consider under the principle of responsiveness

- AI tools with the greatest benefits are incorporated within clinical and operational workflows.
- Staff are educated about AI tools and undertake appropriate training.
- Data entered into AI tools is of high quality to produce reliable and trustworthy outputs.
- The use of AI tools is in line with environmentally sustainable practices.

Overview

The principle of responsiveness refers to how a service responds to and meets the needs of people using the service, and the health and social care system as a whole. In the context of AI, responsiveness means management who are responsible and accountable make the decision to use an AI tool within a service based on best available evidence nationally and internationally, as well as local considerations such as the impact and benefit for staff. A responsive service has trained and competent staff who are aware of how to use AI tools in line with national and international best practice. The quality of the data underpinning AI tools is a key consideration for the service in order to produce accurate outputs. The use of AI tools is in line with environmentally sustainable practices.



A responsive service has trained and competent staff who are aware of how to use AI tools in a safe and responsible way.

In the context of the responsible and safe use of AI in health and social care, the principle of responsiveness includes the following sub-themes:

Integrate into practice:

Integration into practice refers to services incorporating appropriately tested and certified AI tools within new or existing clinical and operational workflows to increase efficiencies and to reduce the impact on service delivery. AI tools providing the most benefit for their intended purpose while being cost-effective, and where benefits clearly outweigh any potential risks, are prioritised, for example, those with the greatest clinical impacts or that best support operational efficiencies. Staff are engaged with and involved when decisions are made about integrating an AI tool. User-friendly AI tools that are adaptable to existing health and social care services are prioritised, and services are assured of an AI tool's interoperability with other information systems in use. There is ongoing monitoring of AI tools and services remain responsive to new information about the effectiveness, safety or accessibility of the tool.

Provide education and training to support development of staff:

Services have a responsibility to undertake a training needs analysis and facilitate education, training and career support for staff so they have the necessary knowledge to use AI safely and responsibly in their role. Staff receive appropriate ongoing training and education so they understand their roles and responsibilities regarding how AI is used to support their work. Training is ongoing to keep up with new developments in AI, it is adapted for the staff member's role and technical knowledge and is relevant to the context in which they are using AI tools. Staff understand the benefits and any potential risks or limitations of the AI tools they use, know where to access further information about an AI tool and have this information available if requested by people who use the service. This information includes the intended use of the tool, how the tool functions, and where the tool stores data. Staff maintain their professional skills and do not become reliant on AI tools, ensuring continuity of care in the event of an AI tool failing or being decommissioned and or withdrawn.

Ensure data quality:

The successful development of AI tools for use in health and social care relies on high-quality data[§§§], which is used to train and validate the algorithm. High-quality data helps to ensure outputs from an AI tool are reliable and trustworthy and minimises unintended harm from the use of AI tools. Data inputted into an AI tool needs to be of high quality and needs to be representative of the population for which it is intended. For example, if an AI tool is used to support decision-making that impacts a person's health outcomes, the information inputted into the AI tool is of sufficient quality to produce an accurate output. Staff understand data quality principles, including understanding how incomplete or inaccurate inputs may compromise AI outputs.

[§§§]Quality data refers to data that are relevant, accurate and reliable, timely and punctual, coherent and comparable, and accessible and clear.[44]

Encourage eco-responsibility and sustainability:

It is important that services recognise the environmental impact that AI tools can have and consider energy consumption, lifecycle emissions and sustainability practices when making decisions about the use of AI tools across the AI lifecycle.



By upholding the principle of responsiveness, services have measures in place to minimise risks such as incompatibility with existing systems and practices, barriers to uptake, the impact on staff, use of AI tools without appropriate training, deskilling of staff, automation bias, unreliable outputs and environmental impacts.

Examples of how a service can uphold the principle in practice:

- Existing governance structures and processes are updated to ensure that decisions about the initial use and operation of AI tools within the service consider the evidence base for the tool. This includes that tools are appropriately tested and certified, potential impacts on service delivery and the impact on staff have been considered, and that the tool is interoperable with other information systems in use.
- The service is responsive to new information that emerges about an AI tool including new published evidence about its effectiveness, internal reviews of the tool's efficacy, feedback from service users and staff or any emerging ethical concerns.
- Staff are engaged with and involved in the implementation of AI tools and a robust change management process is in place to support staff through the transition when a new AI tool is used or an AI tool is integrated into an existing system.
- Staff are provided with clear guidance on how AI integrates within existing workflows and what the lines of responsibility are for incorporating an output from an AI tool into a decision.
- There are the necessary knowledge, skills and competencies within the service to ensure that AI is used in a safe and responsible way and in compliance with relevant legislation.
- Ongoing training is provided to staff in line with their role and responsibilities to enable the development of a highly trained and competent workforce. Training may include:
  - how AI tools function and the evidence base for integrating them in a service
  - understanding and critically evaluating AI outputs
  - recognising and responding to bias in data or outputs
  - identifying when an AI tool is providing misleading or inaccurate information

  - addressing and escalating any concerns about the performance of an AI tool
  - complying with data privacy legislation, national standards and the service's policies and procedures
  - overriding AI outputs if required
  - communicating with people who use services about how AI tools are used in their care, the benefits, potential risks and any limitations
  - safely withdrawing an AI tool from the service.
- Robust information management practices are in place to ensure the data entered into AI tools by staff is of high quality.
- Environmentally sustainable practices are considered across the AI lifecycle when AI tools are used by a service.

Examples of how staff can uphold the principle in their day-to-day work:

- Undertake training relevant to their role to understand how to use AI tools in a safe and responsible way, including how to recognise bias or flaws in data or outputs, how to comply with data privacy legislation, and how to ensure the quality of the data inputted into an AI tool.
- Understand the purpose and scope of using the AI tool and be able to explain to people who use services the intended use of the AI tool, the benefits compared to more traditional care options and the potential risks and limitations.
- Be informed about how AI tools are used within current workflows and identify who is the person responsible for overseeing interpretations and recommendations when outputs from an AI tool impact people who use services.

Examples of what it means for people using services when the principle is upheld:

- I know that the use of AI in my care is based on best available evidence and is in line with what is best for my care.
- I know that staff in the service are using AI tools to improve the quality of care and that the use of AI is for my benefit.
- I can ask staff if I have any questions and seek clarity on anything I am concerned about in relation to the use of AI in my care. This may include questions about the benefits of AI compared to traditional care pathway options and any limitations of the AI tool.
- I am confident that staff are trained and supported to use AI in my care in a safe and responsible way.

Example of responsiveness being upheld in practice



Background

Staff in a home support service recently started using an AI tool during home visits. Staff members use a mobile application (app) to record information about the health and wellbeing of people using the service. This includes information on their perception of their health, loneliness, falls, self-esteem and any co-morbidities. The AI tool reviews this information and prompts the service if a person may benefit from additional supports including a fall prevention exercise class or befriending and social activities in the community. Overall, the app helps service users to continue to live well in their own home. The app was approved for use by the service's governance board following assurances that the tool was trained on high-quality representative data.**** Training was provided to home support staff regarding how the tool works, how it derives its outputs, how to identify and respond to poor performance and also how to communicate in an accessible manner with service users about the potential risks and benefits of the tool.

Kiran's story

Kiran is 75 years old and lives alone. After a fall three years ago, Kiran decided that home support could help him to maintain his independence and continue to live well in his own home. Kiran's home support provider John visits regularly to help with everyday tasks. John recently mentioned a new app that is being offered by the home support service to help identify additional supports available to him. John explained that he would use the app to regularly record information about Kiran's health and wellbeing during visits. He told Kiran that the app uses AI to review this information and prompt the home support service to respond if it identifies a risk to Kiran's health or wellbeing. John supported Kiran to make an informed decision about the use of the app as part of his home support service by providing him with all relevant information in a way that was easy for him to access and understand in line with his needs, abilities and preferences. John noted that Kiran could opt out of the use of the app and it would have no impact on the care he received. However, he noted that the app has benefits and would prompt John with a list of services that he might not be aware of. As a result of the training he receives, John felt well informed about the AI tool and was confident about using it to help identify and respond to risks to Kiran's health and wellbeing.

****The case studies are for illustrative purposes. Services will have various arrangements in place for approval of AI tools that are in line with the size, type and resources of the organisation, and it is important to be familiar with such arrangements.

Glossary and AI core concepts and terminology



3. Glossary and AI core concepts and terminology

This section includes a glossary of key terms used throughout the document. It also includes an AI core concepts and terminology section with some commonly used terms for additional context and understanding regarding AI models and system types. Information is also provided on the types of bias that may occur when an AI tool is in use.

3.1 Glossary

AI lifecycle: The series of stages an AI tool goes through, from initial design and development to deployment and monitoring and eventual decommissioning.

Algorithm: A set of instructions that a computer follows to solve a problem or complete a task.

Artificial Intelligence (AI; AI tool): A machine-based tool capable of operating autonomously and producing outputs like predictions, recommendations, or decisions based on input data. See AI core concepts and terminology section for further information.

Bias: Systematic error in an AI tool that has been designed, intentionally or not, in a way that may generate unfair decisions. Bias can be present in the algorithm of the AI tool and in the data used to train and test it. AI bias can emerge in an AI tool as a result of cultural expectations, technical limitations, or unanticipated deployment contexts. See AI core concepts and terminology section for further information.

Clinical governance: A system through which service providers are accountable for continuously improving the quality of their clinical practice and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish. This includes mechanisms for monitoring clinical quality and safety through structured programmes, for example, clinical audit.

Compliance: Adhering to relevant legal and ethical guidelines, such as the EU AI Act, MDR, IVDR and GDPR, when designing and deploying AI tools.

Conformité Européene (CE) Mark: A CE mark is a statement by a manufacturer to indicate that a product meets the requirements as set out in EU product rules. Medical devices and IVDs must be appropriately CE marked before they can be placed on the EU market or used in a healthcare setting.

Corporate governance: The system by which services direct and control their functions in order to achieve organisational objectives, manage their business processes, meet required standards of accountability, integrity and propriety and relate to external stakeholders.

Data Protection Impact Assessment (DPIA): A process designed to identify risks arising out of the processing of personal data and to minimise these risks as far and as early as possible.

Deployer: As per the AI Act, a deployer is defined as "any natural or legal person, including a public authority, agency or other body, using an AI system under its authority, except where the AI system is used in the course of a personal non-professional activity".

Deployment: A stage in the AI lifecycle where a tool is integrated into real-world environments, making it operational for users.

EU AI Act: Legislation enacted by the European Union to ensure that AI tools are used in a safe, transparent manner that is aligned with fundamental human rights. It categorises AI tools by risk levels and sets compliance principles accordingly.

Explainability: The extent to which the reasoning behind the decisions and actions of an AI tool can be understood and interpreted.

Fundamental Rights Impact Assessment (FRIA): A process that involves identifying risks to fundamental rights, proposing mitigations, engaging with stakeholders to protect rights such as privacy and non-discrimination and setting a plan for risk management. This is required for high-risk AI tools under the EU AI Act.

General Data Protection Regulation (GDPR): The GDPR is a law in the EU that protects people's personal data. It gives individuals control over their data and requires organisations to handle this data responsibly and transparently.

Governance: An integration of corporate and clinical governance; the systems, processes and behaviours by which services lead, direct and control their functions in order to achieve their objectives, including the quality and safety of services for service users. See also Clinical governance and Corporate governance above.

Human in the loop: An approach whereby a human participates in the operation, supervision and or decision-making of an AI tool.

Human on the loop: An approach whereby the AI tool operates autonomously with the ability to be overridden or stopped by a human as needed.

Human oversight: Human oversight in AI means that people are involved in monitoring an AI tool to ensure that it works correctly and ethically.

In Vitro Diagnostic Medical Device Regulation (IVDR): In vitro diagnostic medical devices are regulated in Europe by the IVDR and must meet all applicable requirements outlined in the legislation prior to being placed on the European market.

Medical Device Regulation (MDR): Medical devices are regulated in Europe by the MDR and must meet all applicable requirements outlined in the legislation prior to being placed on the European market.

Personal data and special category personal data: Personal data means any information about a living person, where that person either is identified or could be identified. Personal data can cover various types of information, such as name, date of birth, email address, phone number, address, physical characteristics, or location data. Special category personal data include data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership; genetic data; biometric data processed to uniquely identify a person; data concerning health; and data concerning a person's sex life or sexual orientation.[53]

Provider: A provider (developer) is defined as per the EU AI Act as "a natural or legal person, public authority, agency or other body that develops an AI system or a general-purpose AI model or that has an AI system or a general-purpose AI model developed and places it on the market or puts the AI system into service under its own name or trademark, whether for payment or free of charge".

Representative data: Data that accurately represents the range of characteristics, contexts and conditions relative to the real-world scenarios and people the AI tool is intended for.

Retire/Decommission: The final stage in the AI lifecycle, when the tool is discontinued or replaced.

Traceability: A feature of AI tools that indicates whether the tool allows predictions and processes to be tracked. It involves the documentation of datasets and how data is processed by AI tools.

Training data: The data required to train, or "teach", a machine learning algorithm when developing a model.

Transparency: Openness about how an AI tool was developed and how it generates outputs, including traceability and explainability, as well as the extent to which a service is upfront about the use of AI tools.

3.2 AI core concepts and terminology

This section provides some examples of AI core concepts, technical terms, models and system types and types of bias that may occur when an AI tool is in use. Due to the rapidly evolving nature of AI, this is not intended to be an exhaustive list of all concepts and terminology but rather an overview of commonly used terminology.

Artificial Intelligence (AI; AI tool): A machine-based tool capable of operating autonomously and producing outputs like predictions, recommendations, or decisions based on input data.

- AI core concepts and technical terms include:
  - **Ambient AI:** Electronic devices that are aware of and can recognise the presence of human beings, adapting accordingly. Ambient AI may be used for clinical note taking and to generate a report during an appointment.
  - **Computer vision:** A field of AI that enables computers to interpret and understand images or videos. It can be used in healthcare to analyse scans like X-rays, CT or MRI and highlight areas of concern. Computer vision encompasses tasks such as image classification, object detection and facial recognition.[5]
  - **Data drift:** A specific form of model drift where the statistical properties of input data change over time. This can lead to inaccurate predictions if the model was trained on data that no longer reflects real-world conditions. In healthcare, data drift may result from evolving patient characteristics or diagnostic protocols, and it requires regular model updates and infrastructure to detect and respond to shifts.
  - **Deep learning:** A sub-field of machine learning that uses multi-layered artificial neural networks to learn patterns within datasets (analogous to the neural networks which support the decision-making power of the human brain).
  - **Machine learning:** A sub-field of AI which focuses on the development of tools that are able to learn and adapt without following explicit instructions, imitating the way that humans learn. Machine learning learns patterns from data and applies them to new predictions.[5] Machine learning algorithms improve their accuracy by analysing and drawing inferences from patterns in data.[54,55]
  - **Model drift:** The gradual decline in an AI model's performance over time due to changes in the environment or population it operates in. In healthcare, this can happen when clinical practices or patient demographics shift, making the model's original training data less representative of current conditions. Continuous monitoring and recalibration are essential to maintain accuracy and safety.

- **Natural Language Processing:** A sub-field of AI that enables computers to process human language in the form of text or voice data. It uses deep learning and large language models to process and synthesise human language. It can be used to transcribe clinician notes.[55,56]
- **Predictive modelling:** A technique used to predict future outcomes based on current and historical data. It involves creating a model that can make forecasts or decisions by analysing patterns and trends in data.
- **Shadow AI:** The use of AI tools by staff without formal approval or oversight. If tools are used which are not authorised it can expose services to risks including data security and compliance.[57]

- AI models and system types include:
  - **Agentic AI:** AI systems capable of autonomously planning and initiating actions and interacting with other tools or systems to achieve defined objectives with limited human intervention. It is a recently emerging model that goes beyond generative AI as it can autonomously plan, initiate action and interact with other tools or systems to achieve an objective with limited human interaction.[58]
  - **Foundation models:** Large-scale, general-purpose deep learning models trained on massive datasets, which are designed to be adaptable across a wide range of tasks.[5]
  - **Generative AI:** A type of AI that can create new content, such as text, images, or videos, by learning patterns and structures from large amounts of data. Generative AI uses machine learning and deep learning techniques to learn patterns and structures from data to create new content, such as text, images or videos.[55,59] It differs from natural language processing in that it can create new content, not just analyse or understand existing data. Examples include chatbots.
  - **Large language models (LLMs):** Foundation models that have been trained on vast text datasets to understand and generate natural human language. Large multimodal models extend the capabilities of LLMs by integrating multiple types of data, such as text, images, audio and video, within a unified framework.[5]

- **Bias:** A systematic error in an AI tool that has been designed, intentionally or not, in a way that may generate unfair decisions. Bias can be present in the algorithm of the AI tool and in the data used to train and test it. AI bias can emerge in an AI tool as a result of cultural expectations, technical limitations, or unanticipated deployment contexts. Types of bias which may occur when AI is used include:
  - **Algorithmic bias:** Bias caused by a systematic error in the algorithm that leads to unfair or discriminatory outcomes. This may be the result of biased sampling data or model design flaws.
  - **Automation bias:** The tendency for users to over rely on recommendations made by automated systems, accepting their outputs without sufficient scrutiny. In healthcare, this can result in clinicians deferring to AI-generated advice even when it conflicts with clinical judgment, potentially leading to errors.
  - **Contextual bias:** Bias that occurs when an AI tool developed in one medical or social care setting does not apply to another, for example, an AI tool developed in a high-resource centre being applied in a low-resource centre.
  - **Sampling bias:** Bias that occurs when incomplete or under-representative data is used to train a model, for example that which over- or under-represents a subgroup such as a minority group, a vulnerable group, or disease subtype.

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Appendices



Appendix A.

Project Steering Group membership and Co-production Working Group membership

Project Steering Group membership

Name	Role
Rachel Flynn	Director of Health Information and Standards (Chair), HIQA
Meabh Smith	Digital Clinical Safety Lead, Health Service Executive
Philip Dodd	Deputy Chief Medical Officer, Department of Health
Ronan O'Kelly	Assistant Principal Officer, Health Infrastructure Division, Department of Health
Tom Laffan	Chief Data and Analytics Officer, Health Service Executive

Project Co-production Working Group membership

Name	Role
Linda Weir	Deputy Director of Health Information Standards (Chair), HIQA
Andy Phillips	Regional Executive Officer, Health Service Executive
Conor Judge	Consultant Nephrologist, Health Service Executive
Emma Kelly	Policy and Research Officer, Patient Advocacy Service
Ger Brophy	Chief Social Worker, Tusla
Ian Murphy	Public Sector Duty Manager, IHREC
Kevin Kelly	General Manager AI and Automation Centre of Excellence, Health Service Executive
Laura Brady††††	Chief Executive Officer, IPPOSI
Maeve Goggin	Chief Risk Officer Bon Secours Health System (Private Hospitals Quality and Patient Safety Committee representative)
Markus Hesseling	Chief Medical Information Officer, Children's Health Ireland
Pawel Stepala	Head of Standards, Mental Health Commission
Rebecca Keatinge	Head of Monitoring and Compliance, IHREC
Ronan O'Kelly	Assistant Principal Officer, Health Infrastructure Division, Department of Health
Sean Egan	Director of Healthcare Regulation, HIQA
Siobhán O'Sullivan	Associate Professor, RCSI
Susan Treacy	Chief Executive Officer, HealthTech Ireland

††††Replaced Laura Kavanagh, Research and Advocacy Manager IPPOSI in November 2025.

Appendix B.

How the national guidance was developed

HIQA adopted an evidence-based and collaborative approach to develop this national guidance. Research and stakeholder engagement was undertaken throughout the process as outlined below:

- A public scoping consultation was undertaken to gather initial key insights to inform the development of the guidance.
- An evidence review was conducted to understand good practice regarding the responsible and safe use of AI in health and social care services and to map key concepts and guidance identified in the literature under HIQA's principles-based framework for person-centred care and support.
- A Steering Group was convened to provide support and advice on the development of the guidance, to ensure that the guidance aligns with national policies, legislation and operational level initiatives.
- A Co-production Working Group, comprising a diverse range of interested and informed parties, was convened to participate in the development the guidance by providing input, support and advice at key stages of the project.
- Focus groups and individual interviews were undertaken with key stakeholders, including staff delivering services, people who use services, and staff involved in management and administration of services, to develop stakeholder-informed guidance incorporating a broad range of perspectives.
- A workshop was conducted with clinicians to validate the contents of the national guidance to ensure it aligns with clinical practice and can be implemented.
- The HPRA was engaged with to obtain subject matter expertise, in particular regarding the regulation of AI as a medical device.
- A six-week public consultation on a draft of the national guidance was conducted to engage a broad range of stakeholders including, but not limited to, services, staff in services, people who use services, representative bodies, professional unions, professional regulators, and advocacy services.

Appendix C.

Considerations for services using AI tools

An overview of considerations for services using AI tools is included below. This information summarises the examples of how a service can uphold each of the four principles in practice. Information is presented under key stages across the AI lifecycle including the procurement and planning stage, the deployment, operation and monitoring stage, and the decommissioning stage.

Examples of considerations during planning and procurement

Accountability

- New or updated policies, procedures and processes are in place to address requirements in legislation and sector-specific guidelines for the use of AI.
- Legal and regulatory expertise and guidance have been consulted.
- The tool, where relevant, has gone through appropriate regulatory review and approval and there is evidence to support the safety of the tool.
- Quality control measures and assurance practices for the use of AI tools are developed and implemented.
- Fundamental Rights Impact Assessments (FRIA) are conducted for high-risk tools as required by the EU AI Act.
- The environmental impact of the tool is considered and procurement is in line with existing green policies and initiatives.
- Risk assessments are conducted on AI tools for use within the service.
- Where explainability is constrained, a formal governance justification and risk mitigation plan is approved before use of an AI tool.
- An individual or named function is assigned responsibility for compiling and maintaining an inventory of authorised AI tools for use in the service.
- The service's complaints procedure is updated to incorporate complaints related to the use of an AI tool.

A human rights-based approach

- Governance structures and processes are updated to ensure decisions about the initial use and operation of AI tools consider impacts on rights.
- Roles and responsibilities in relation to protecting and promoting human rights when AI tools are used to support the delivery of care are clearly outlined.
- A co-design approach is adopted so that service users have an opportunity to give their views during all stages of the AI lifecycle.
- The service is assured and confident that the AI tool has been developed based on representative data.
- There is a clear rationale for what information is gathered about a person by an AI tool and for retaining the data.
- A Data Protection Impact Assessment is conducted, if required.

Safety and wellbeing

- Existing governance structures and processes are updated to ensure decisions about AI tools support and protect safety and wellbeing.
- Roles and responsibilities relating to oversight of the quality and safety of AI tools are clearly outlined.
- Safety frameworks are adapted for the use of AI tools.
- The service has assurances of the following from the AI developer: rigorous testing, verification of conformity assessment if required, use of representative data, evidence-based evaluation and validation in real-world settings. Tools are initially trialled in the service to ensure their suitability for the setting and population.
- Risk management processes including the risk management policy and risk register are updated to reflect the use of AI tools.
- Policies and procedures for managing data security and business continuity are updated to incorporate the use of data by AI tools.
- Staff responsible for data security, including cybersecurity, are made aware that their role now incorporates the use of data by AI tools.

Responsiveness

- Governance structures and processes are updated to ensure decisions about AI tools consider the evidence base, including appropriate testing and certification, potential impacts on service delivery and burden on staff, and interoperability with other information systems.
- Staff are engaged with and involved in the implementation of AI tools, and a robust change management process is in place.
- There are the necessary knowledge, skills and competence within the service to use AI tools safely and responsibly.

Examples of considerations during deployment, operation and monitoring

Accountability

- Processes are in place to identify potential gaps with existing and forthcoming legislation related to the use of AI and there is flexibility to adapt to a changing AI landscape.
- Processes are in place to monitor that mitigation measures identified in FRIAs are in place in practice and to ensure that the FRIA is updated if key information changes while an AI tool is in use.
- Risk assessments are conducted on AI tools used within the service.
- Staff are supported to understand their roles and responsibilities and work in line with relevant legislation, regulations and standards, and national and local policies and procedures.
- Pre-existing policies and processes are regularly reviewed and adapted in line with legislation and best available evidence.
- A list of authorised AI tools is maintained by the service, and this is provided to staff.
- There is a culture of continuous quality improvement which includes undertaking reviews to ensure the reliability and accuracy of tools and learning from audits and incidents.
- There are mechanisms for responding to and learning from feedback, concerns or complaints from staff and from people using the service.
- AI tools are used in a way that allows appropriate explainability and traceability.
- A culture of openness and accountability is promoted so that staff exercise their responsibility to report any concerns in good faith.
- Complaints in relation to an AI tool are managed in line with the service's updated complaints procedure.
- Services are transparent with people using the service about how AI tools are used.

A human rights-based approach

- Clear and accessible information is readily available about what AI tools are used and integrated within the service.
- Arrangements are in place to ensure that the use of AI tools aligns with relevant human rights legal frameworks, national policies, best practice guidelines, regulations and statutory requirements.
- Outputs from an AI tool are regularly reviewed to ensure they are not biased.
- There are inclusive mechanisms to capture feedback from all people who use services.
- Data used in AI tools is securely stored, and when it is accessed and transmitted, this is done in line with relevant privacy and security laws including GDPR.
- The continued importance of human interactions is recognised when AI tools are used, and staff are supported to maintain these interactions.

Safety and wellbeing

- There are systems in place for continuous monitoring of AI tools.
- Services have appropriate mechanisms to respond to risks, including measures for suspending use of an AI tool and for notifying relevant parties in line with requirements under the EU AI Act or national reporting requirements.
- Clinical safety checks are in place to ensure AI tools meet clinical standards and do not compromise safety. There are checks to ensure staff are using AI tools according to instructions.
- The service is open, transparent and accountable in the event that a known incident occurs from the use of an AI tool and incidents are recorded and actively reviewed to identify risk factors and support future learning and quality improvement.
- Governance structures are provided with regular assurance that the AI tool is working as intended.
- A contingency plan is in place in the event of an AI tool not working as intended.
- Strong data governance practices are in place.
- There is robust risk management within the service, including clinical risk management.
- Controls are in place to prevent identifiable data being inputted into public, openly available large language models.

Responsiveness

- The service is responsive to new information that emerges about an AI tool.
- Staff are provided with clear guidance on how AI integrates within existing workflows and what the lines of responsibility are for incorporating an output from an AI tool into a decision.
- Ongoing training is provided to staff in line with their role and responsibilities.
- Robust information management practices are in place.
- Environmentally sustainable practices are considered across the AI lifecycle when AI tools are used by a service.

Examples of considerations during retirement/decommissioning

Accountability

- There is a process in place for decommissioning or withdrawing an AI tool from the service, including swift and safe disengagement of a tool where necessary, which is overseen by an accountable person, is transparently justified, and adheres to policies and regulations to protect data security and privacy.



Health Information and Quality Authority
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Published by the Health Information and Quality Authority.

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