Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

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

For public consultation

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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 the Minister for Children, Equality, Disability, Integration and Youth, 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.

- **Monitoring services** — Monitoring the safety and quality of permanent international protection accommodation service centres, health services and children's social services against the national standards. Where necessary, HIQA investigates serious concerns about the health and welfare of people who use health services and children's social services.

- **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.

- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.

- **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.

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Members of the Health Information and Standards Directorate:

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Conflicts of Interest

None reported.

Note: This document is structured in two sections. The first is an introductory section to raise awareness of and educate management and staff in health and social care services about developments in the area of AI and what it will mean for them in their work. The first section contains information to help management and staff understand what AI is, examples of its use in health and social care services, the legal and regulatory landscape and where the guidance fits in the national context. The second section is the draft guidance, which has been developed to promote awareness and build good practice around the use of AI among people that are accountable and responsible for managing services, and the staff working in those services.

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

For the purpose 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. A glossary of key terms used throughout this document is included in section 3.

Please note the final national guidance document will be professionally designed so the current format is only indicative.

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1. Introduction

1.1 What is AI?

Artificial Intelligence (AI) is a machine-based system capable of operating autonomously and producing outputs like predictions, recommendations, or decisions based on input data.[1] AI has the potential to deliver a wide range of benefits in all aspects of Irish society – commercially, environmentally and within the healthcare sector.[2,3] AI already plays a key role in day-to-day life, for example, it is used to generate personalised recommendations on streaming services and it analyses traffic patterns to provide the most optimal route in navigation apps.

1.2 What are the different types of AI that are used in health and social care?

There is a broad spectrum of AI tools*. Different AI tools are designed to vary in their levels of autonomy and adaptiveness after deployment. The safeguards, checks and balances that need to be in place will vary depending on the type of AI tool and how it is being used. Examples of different sub-types of AI tools and how they can be used in health and social care are set out in table 1 below.

Table 1. Sub-types of AI in health and social care

Sub-type of AI	How it works	Example in a health and social care service
Machine learning	Used to develop tools that are able to learn and adapt without following explicit instructions, imitating the way that humans learn. These tools gradually improving their accuracy by using algorithms and statistical models to analyse and draw inferences from patterns in data.[4,5]	Machine learning can be used in health and social care services, for example to predict the risk of sepsis.
Deep learning	Uses multi-layered artificial neural networks to learn patterns within datasets with multiple layers of abstraction.[6,7]	Deep learning can be used in image processing and analysis of Magnetic Resonance Imagining (MRI) to predict Alzheimer's disease.

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

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.[5,8]	Generative AI can be used to assist with drafting standardised documents such as discharge summaries or referral letters.
Natural Language Processing	Helps computers to understand, interpret and use human language.[5,9]	Natural language processing can be used in healthcare to generate a summary of a person's medical history or to flag drug interactions.

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

The health and social care landscape is rapidly changing both nationally and internationally.[10] The health and social care system is facing rising costs, increased demand due to an aging population, increased prevalence of chronic and complex conditions and a shortage of healthcare staff to meet the demand. Innovative solutions are needed, and AI is a promising tool that can be integrated into the delivery of health and social care services to help address some of these challenges.

While the benefits of AI integration in health and social care services are clear, services must ensure that robust governance and proportionate controls are in place. Accountability is the foundation for the responsible and safe use of AI. The use of AI tools must be guided by appropriate safeguards and be in compliance with legal obligations including those set out in the EU Artificial Intelligence Act[11] to ensure that it is used in a safe and responsible way.[12] Different types and uses of AI in health and social care fall into different risk categories under the Act. It is essential that services understand the purpose and intended use of each AI tool and assess its risk classification to adopt a risk-based approach, as appropriate, in line with existing organisational arrangements.

AI is currently being used in a number of ways across health and social care services in Ireland and its use will continue to evolve and expand over time. Key applications across the care pathway are likely to include assisting with streamlining administrative tasks such as scheduling appointments or transcribing information discussed during appointments, supporting with diagnostics by highlighting and flagging patterns in scans and aiding the prediction of medical outcomes to support implementation of preventative measures, for example, risk of hospital readmission. Some more detailed examples of the positive impact AI can have are set out below.

Improved diagnosis: AI tools can help clinicians to detect illness earlier and more accurately. They can support staff by highlighting and flagging patterns in scans and lab results. This expedites diagnosis and can improve outcomes for people who use services. AI can be used to enhance radiological procedures, including Computed Tomography (CT) and MRI scans, improving image clarity and minimising radiation exposure. Research suggests that AI-powered diagnostic tools can potentially enhance diagnostics in conditions such as inflammatory rheumatic disease and certain cancers.[13,14]

Operational benefits: AI tools can assist staff in streamlining operational tasks. Enterprise systems that underpin the delivery of health and social care services, including human resource, finance, national schemes and services, communications, administrative services, legal and procurement, and service management, can be enriched with AI to predict demand, prioritise tasks, and flag anomalies. AI can also be used to support administrative tasks for those providing care, thereby increasing time for direct care. For example, ambient AI scribes can be used in healthcare consultations to support clinical note taking enabling clinicians to have more time to focus directly on the patient during the consultation.[15] AI has been applied to streamline processes in adult social care by using transcribed audio recordings to automate the completion of needs assessment forms.[16]

Enhancing more personalised medicine: AI tools can be used to support staff when they are managing personalised medicine and tailored treatments for patients. Evidence has suggested that AI can select a particular treatment pathway based on a person's genetic and clinical profile, improving outcomes for people who use services, particularly in areas such as oncology.[17]

Enhancing prediction: AI can assist with predicting medical outcomes. AI has been applied in social care services to support staff to identify individual needs such as falls risk, carer stress, or loneliness, and to provide tailored advice, sign-posting, or referral to a service.[18] The rise of wearable devices equipped with AI algorithms has been trialled and is found to be effective for supporting continuous remote monitoring. This can be particularly useful for individuals living with a health condition in the community.[19] These tools can provide alerts to both people who use services and healthcare providers if patterns indicate an elevated risk of complications, enabling timely medical intervention.[20]

Supporting research and innovation: AI can support advancements in healthcare research. AI has been found to be effective in supporting the generation of novel research questions or study designs, and it can be used to optimise clinical trials by streamlining the enrolment of people who use services.[21,22]

1.4 What is happening at a European level?

The legal and regulatory landscape regarding the use of AI in health and social care within Ireland is shaped by a number of EU Acts and regulations. These directly or indirectly set out specific requirements relating to the development, deployment and use of AI. The EU AI Act sets out additional legislative responsibilities when using AI and should be read in conjunction with other relevant legislation at EU level, such as Medical Device Regulations[23,24] and General Data Protection Regulation.[25] Each of these have significant bearing on the uses of AI in healthcare; further detail is set out below. Requirements will continue to evolve in line with the Digital Omnibus Package, published by the European Commission in November 2025, which includes targeted simplification measures to ensure timely, smooth, and proportionate implementation of certain provisions of the EU AI Act. Further detail on the Digital Omnibus Package is provided in Appendix B.[26,27]

The EU Artificial Intelligence Act (Regulation (EU) 2024/1689)[11] is a framework for governing AI systems[†] and addresses risks associated with their design, deployment, and use. The EU AI Act defines AI as follows:

> 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.[11]

The Act adopts a risk-based approach to regulation, based on four risk categories – minimal risk, limited risk, high risk and unacceptable risk – in order to ensure that measures to manage the use of AI are targeted and proportionate. For practices that are not defined as prohibited in the EU AI Act, the Act categorises AI systems into different risk levels, based on their intended purpose, risk of harm to the fundamental rights of people, the severity of the possible harm and probability of occurrence. The different risk levels are subject to different rules while ensuring safety, transparency, and fairness. 'Providers' (who create and develop AI systems) must determine the intended purpose of the AI system and classify it into one of the four risk categories.

Each risk category is subject to different compliance rules and responsibilities for 'providers' and 'deployers' (who use AI systems in their professional activities) of AI. Many uses of AI in health and social care services will fall under the high-risk category, which includes AI in medical devices. Given that health and social care

[†] AI systems' typically combine a number of AI tools.

services and staff working in these services will be primarily using AI systems rather than developing them, requirements for 'deployers' are most relevant and particularly important with regard to any high-risk use of AI as defined in the Act. However, it is important to note that medical device software (including AI-based medical device software) might be developed by hospitals or health services themselves, and in this case the hospital or health service would need to meet obligations outlined for 'providers' under the EU AI Act and the obligations of a manufacturer under the Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Device Regulation (IVDR), as applicable.

The national oversight arrangements for the EU AI Act in Ireland are currently being considered (see Section 1.5 and Appendix B). It is important that services have appropriate governance structures and risk management arrangements in place to determine and manage the level of risk associated with each AI tool or system in line with obligations under the EU AI Act and related regulations.

Medical Device Regulation (Regulation (EU) 2017/745 - MDR)[23] and In Vitro Diagnostic Medical Device Regulation (Regulation (EU) 2017/746 – IVDR)[24] Since 2017, medical devices and in vitro diagnostic medical devices are regulated in Europe by the MDR and IVDR respectively and must meet all applicable requirements outlined in these legislations prior to being placed on the European market. The MDR and IVDR apply to all medical devices and in vitro diagnostic medical devices (IVD), including AI-based software devices that meet the definition of medical device or IVDs and that may be used by healthcare professionals in hospital settings or by lay users, for example, as mobile applications on smartphones. It is important to note that 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 prior to being placed on the market. 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. Where compliance with the relevant requirements has been demonstrated following the applicable procedure (as per the risk class of the device) the CE marking of conformity is affixed (as outlined in Article 20 of the MDR/ Article 18 of the IVDR) and where relevant, it is accompanied by the identification number of the Notified Body that approved the device. Medical devices and IVDs must be appropriately CE marked before they can be placed on the EU market or used in a healthcare setting.

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. The HPRA also carries out market surveillance activities to assess the safety and compliance of medical devices and IVDs once they have been placed on the market. They also operate a vigilance system for reporting of serious incidents with respect to the use of medical devices and IVDs.

General Data Protection Regulation (GDPR) 2018[25] governs data protection and privacy. For services deploying AI in healthcare, GDPR compliance is critical, particularly in managing sensitive health data, ensuring lawful processing and addressing principles such as data minimisation and purpose limitation.

This is not an exhaustive list of relevant regulations and there are other requirements in relation to safety, data privacy, cyber security, and human rights[‡] that should also be considered.[28-36] Further detail is provided in Appendix B.

It is important that services have effective arrangements and governance structures in place to ensure compliance with relevant Irish and European legislation and have a process in place for identifying and addressing potential gaps in compliance with existing and forthcoming legislation. Services need to be responsive to evolving legislative acts, policies, and directives that progress alongside the advancement of AI, and what it means for them.

1.5 How will the EU AI Act be implemented in Ireland?

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. Key areas of note include:

- Plans are underway to establish a National AI Office that will act as the central coordinating authority for the AI Act in Ireland. The National AI Office will be responsible for co-ordinating the competent authorities' activities to ensure consistent implementation of the EU AI Act.
- 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.
- To date, 15 competent authorities which will be responsible for enforcement of the EU AI Act in Ireland have been designated across all sectors. In

[‡] 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 and roll out and review of AI in public services.

healthcare, the HSE and the HPRA§ have been named as competent authorities. There is work ongoing as part of the national implementation of the EU AI Act to determine what their role will entail and how responsibilities will be assigned nationally.

- The EU AI Act also sets out that national public authorities that supervise or enforce compliance with obligations under EU law protecting fundamental rights, for example the Irish Human Rights and Equality Commission, will be given additional powers to facilitate them carrying out their current mandates in circumstances involving the use of AI systems.

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

The use of AI in health and social care services is evolving. A system-wide approach to supporting the responsible and safe use of AI in health and social care is needed. The Department of Health, the Health Service Executive (HSE) and the Health Information and Quality Authority (HIQA) are developing separate but related programmes of work in line with their organisational remits.

The draft 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 developed to support the development, deployment and implementation of AI tools across sectors of Irish society including in health and social care. Key documents are set out in table 2.

Table 2. Existing strategies and frameworks published regarding the use of AI tools in Ireland

Name of publication	High level description
AI – Here for Good: National Artificial Intelligence Strategy for Ireland[**(2,3)]:**	The strategy was developed in the context of relevant AI policy and governance processes at the EU, the United Nations, and the Organisation for Economic Cooperation and Development. The National Strategy serves as a roadmap for how Ireland can leverage the potential of AI through a people-centred, ethical approach to AI development, adoption and use.

§ As noted in 1.4 above, since 2017 the HPRA is the national competent authority for medical devices and IVD in Ireland

** The Department of Enterprise, Trade and Employment. Artificial Intelligence – Here for Good A National Artificial Intelligence Strategy for Ireland was first published in 2021. A refreshed version of this strategy was published at the end of 2024.

Guidelines for the Responsible Use of Artificial Intelligence in the Public Service[1]:	The purpose of the guidance is to empower public servants to use AI in the delivery of public services while prioritising public trust in how the government uses AI.
AI for Care – The Artificial Intelligence Strategy for Healthcare in Ireland:	The Department of Health and the HSE are developing an AI in health strategy to promote and support innovation and digital transformation in health. The Strategy 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 (2025-2030).
AI HSE Implementation Framework:	An AI implementation framework has been created that 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 the responsible and efficient AI deployment in healthcare.

AI will play an integral part in providing health and social care services, with its use expected to increase over time. 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 and HSE have developed a national strategy; the implementation of this, through the associated implementation framework, will be crucial. To support workforce readiness for AI, an integrated and overarching approach to training is required at a national level with more tailored and product-specific training provided at a service level.

1.7 How does this guidance interact with other national standards developed by HIQA?

HIQA develops national standards based on evidence and international best practice, to improve the quality, safety and reliability of health and social care services across Ireland. National standards provide a common language to describe what high-quality, safe, person-centred care looks like and to assist people using services to understand what they should expect from a health or social care service. Two examples of such national standards include the National Standards for Safer Better Healthcare[37] and the National Standards for Information Management in Health and

Social Care.[38] Aligned with national standards developed by HIQA, this national guidance provides detail on the use of AI for health and social care services and staff.

With the evolving role of AI in health and social care services, national standards developed by HIQA will need to consider the role of AI and how it can be used in a responsible and safe way. As HIQA updates existing standards and develops new standards, the role of digital technologies including AI will be further considered and 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.

1.8 How does the guidance interact with the requirements of my professional regulatory body?

Professional regulatory bodies, for example the Medical Council of Ireland, the Nursing and Midwifery Board of Ireland and CORU, regulate the competence and performance of individual professional practitioners. Some services and staff working in health and social care services may be in a position that other existing and future standards or guidance from their professional body regarding the responsible and safe use of AI are also relevant to them.

2. Guidance

2.1 Purpose of the Guidance

The 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.

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 will also be of use to people using services by educating and empowering them on what their expectations should be in respect of how AI can be used safely and responsibly while engaging with 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 3 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. 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 and complexity of the service.

Table 3. 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, community hospitals, district hospitals, health centres, dental clinics, GP surgeries and home care.	The draft guidance provides examples of the arrangements that people who are accountable and responsible for managing services, make decisions about AI technologies and have responsibility for their use within health and social care 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.
Staff	The people who work in health and social care	The draft guidance is designed to support staff to understand their role and

	services, including clinical and non-clinical staff.	to make decisions that ensure the responsible and safe use of AI when it is used as a tool to support 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.	The draft 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 draft national guidance was developed

HIQA has adopted an evidence-based and collaborative approach to develop the draft National Guidance, undertaking research and conducting stakeholder engagement throughout the process. This involved:

- A public scoping consultation was undertaken to gather initial key insights to inform the development of the draft guidance.
- An evidence review was conducted to understand good practice regarding the responsible and safe use of AI in health and social care services.
- A Steering Group was convened to provide support and advice on the development of the draft guidance, to ensure that the guidance aligns with national policies, legislation and operational level initiatives.
- A Co-production Working Group, comprising of a diverse range of interested and informed parties, was convened to participate in the development the draft guidance providing input, support and advice at key stages of the project.
- Focus groups and individual interviews with key stakeholders were undertaken to develop a more stakeholder-informed version of the draft guidance from a broad range of perspectives.
- The HPRA were engaged with to obtain subject matter expertise, in particular regarding the regulation of AI as a medical device.

The next stage is to undertake a public consultation on the draft guidance.

2.4 How the draft guidance is structured

HIQA develops standards and guidance that are underpinned by the principles of accountability, a human rights-based approach, safety and wellbeing, and

responsiveness. These 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. The adaptions are based on information gathered through an evidence review and stakeholder engagement undertaken as part of the development of this draft guidance.

While it is useful to understand and consider each principle individually (as demonstrated in this draft guidance), it is important to recognise that the four principles are interdependent and have to be balanced in order to work together to 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 will be discussed under that principle, however, it may apply to other principles also. For example, training of staff will be 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 is reflective of 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 draft guidance is structured

A brief explanation of the principle	To describe how the principle applies in the context of the responsible and safe use of AI in health and social care and the areas to consider.
Examples of how a service can uphold this principle in practice	To help people that are accountable and responsible for managing services to understand the governance structures and evaluation procedures needed in order to uphold this 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	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.
Examples of what this means for you as a person using a service when this principle is upheld	To help people using health and social care services to understand what to expect when this principle is being upheld.
A short case study of the principle in practice	To provide an example of what the responsible and safe use of AI may look like in a health and social care service. The case studies are for illustrative purposes, services will have various arrangements in place for approval of AI products depending on the size and type of the organisation, and it is important to be familiar with such arrangements.

Principle 1: Accountability

Overview

The principle of accountability means that health and social care services have appropriate governance structures in place to provide high-quality care and support that is consistent, coordinated, and focused on achieving the best outcomes for people using services. The principle of accountability is the foundation for the responsible and safe use of AI 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.

In an accountable service, there are formalised governance arrangements in place, including clear lines of accountability at the individual, team and service levels. Everyone is aware of their roles and responsibilities about the use of AI including decisions regarding the integration of AI tools, their deployment in the service, continuous monitoring while in use, and retirement of tools. These roles and responsibilities are embedded within existing structures, for example in relation to risk management, data quality and data security. Clinical governance, where the service is accountable for continuously improving the quality of clinical practice and safeguarding high standards of care, is also important for the effective integration of AI. An accountable service has effective arrangements in place to ensure compliance with relevant Irish and EU legislation and codes of practice for the use of AI. There are processes in place to identify and address any areas of interaction, overlap, or gaps between current practices and existing and forthcoming legislation.[23-25,28-36] Human oversight should be in place, with the use of AI tools in health and social care services augmenting, rather than replacing, human judgement and clinical decision-making. The service clearly outlines management and organisational arrangements to support and empower staff to exercise their professional and personal judgement in overseeing outputs from AI and to report any concerns. 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.

Accountability in the context of the responsible and safe use of AI in health and social care comprises a number of sub-themes:

Have robust governance and oversight: Health and social care services using AI tools 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. The service has robust quality control and assurance practices in place to ensure the safe and responsible use of AI tools.

Ensure compliance with legislation: The use of AI tools in health and social care services complies with national and international regulations, including but not limited to deployer[††] requirements outlined in the EU AI Act and data privacy, consumer law, cybersecurity, and medical device regulations. It is important to note that medical device software (including AI-based medical device software) might be developed by hospitals or health services themselves, and in this case the hospital or health service would need to meet obligations outlined for providers under the EU AI Act and the obligations of a manufacturer under the MDR/IVDR, as applicable. Current professional obligations and requirements, including legal obligations of staff and codes of conduct that promote the safe and responsible delivery of care, guide the use of AI tools in health and social care services. Services have regular assurance reporting in place so that management can be assured that the use of appropriate AI tools is in compliance with legal requirements in the EU AI Act and other related legislation.

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 are defined by the service and clearly understood by staff. Management within a service holds responsibility for decisions relating to the use and monitoring 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 service users. People using services understand where responsibilities rest within the service and there is a culture of continuous quality improvement in relation to the use of AI which is informed by audits, incidents and feedback from staff and service users.

Maintain human agency: The use of AI tools in health and social care services augment, rather than replace, human judgement and clinical decision-making to ensure that AI supplements clinical expertise while maintaining the quality, empathy, and personal connection that underpin effective care. AI tools used in health and social care services must be 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 ("human in the loop") in real time or allowing the system to operate autonomously with the ability to be overridden by a human as needed ("human on the loop"). Accountable services that use AI tools

[††] 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".(11)

have arrangements in place to ensure human agency and control, and staff have the option to override an output from an AI tool.

Be transparent: Transparency refers to informing 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 impacts they might have on the care, safety, security, and privacy of people using the service. Transparency also relates to the need for AI tools used in health and social care services to be explainable so that staff understand how an AI tool produces an output, as well as appropriate uses and limitations so that they can trust and have confidence in the tool that they are using. Traceability mechanisms embedded within a service can also support transparency. Clear documentation demonstrates due diligence and enables swift action if something goes wrong and also facilitates audit. Accountable services that use AI tools have arrangements in place to ensure the service is transparent about what AI tools are in use, the scope and appropriate use of AI tools in use and the maintenance of clear documentation regarding the AI tools to facilitate explainability, traceability and auditability.

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, and the service is clear where there may be interactions with other existing or forthcoming legislation, for example relating to data governance, quality assurance and risk management.
- There is clarity with regard to the use of AI in the service. For example, a list of authorised AI tools is maintained by the service. The service provides staff with a list of authorised AI tools in use by the service.
- Prior to the initial use of an AI tool in a service, its governance structures are assured of the following:
    - Legal and regulatory expertise and guidance are consulted. This includes expertise on ethical and cyber security impacts of the tool and EU AI Act requirements.
    - Appropriate quality control measures and assurance practices for the use of AI tools are developed and implemented.
    - Fundamental rights impact assessments[‡‡] are conducted for high-risk tools as per the EU AI Act.

[‡‡]A fundamental rights 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. The assessment involves identifying risks to fundamental rights, proposing mitigations, engage with stakeholders to protect rights such as privacy, non-discrimination and setting a plan for risk management.

- Processes are in place to identify potential gaps with existing and forthcoming legislation related to the use of AI and flexibility to adapt to a changing AI landscape is maintained.
- 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, for example in relation to consent.
- 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 is assigned responsibility for compiling and maintaining an inventory for AI tools in use in the service. This process is in line with legal and regulatory requirements and also facilitates ongoing monitoring and accountability of AI tools.
- Risk assessments are conducted on AI tools used within the service in line with existing risk management procedures.
- 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, incidents, feedback, concerns from staff and complaints from people using the service. It is also important to note that there are specific legal obligations on reporting for deployers of AI tools under the EU AI Act.
- AI tools used within the service are explainable and product-specific information and training is made available to staff so they can understand how a tool produces an output.
- 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.
- Complaints in relation to an AI tool are managed in line with the service's 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.
- An audit trail is in place to ensure outputs from an AI tool are traceable.

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.

- Adhere to established corporate and clinical governance arrangements in line with their roles and areas of responsibility.
- Understand their individual and collective responsibilities when an AI tool is integrated to support clinical or administrative tasks.
- Interpret outputs produced by an AI tool through a critical lens based on their professional knowledge and experience and understand how to manage conflicts of opinion with outputs from an AI tool.
- Be vigilant and regularly monitor and evaluate AI tools 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 to support the delivery of care.

Examples of what it means for people using services when this 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 know where responsibility lies if I have any concerns about the use of an AI tool in my care.
- I am aware of the process for making a complaint about the use of AI in my care and how it 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, medical physicists, IT, quality and safety, hospital management, and the Data Protection Officer to evaluate the tool. Following a three-month pilot study, 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, the roles and responsibilities of staff using the AI tool, and updated patient information to explain about 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 asked all radiologists to ensure that they cross check a small sample of the AI-enhanced MRI image against the original each week to ensure that the tool is working as it should 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 images. She also had received positive feedback from patients 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 products that is dependent on the size and type of the organisation, and it is important to be familiar with such arrangements.

Principle 2: A human rights-based approach

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.[28,39-43] A human rights-based approach advocates for the dignity, autonomy, and equality of individuals to be at the centre of technological advances. FREDA[44] is an internationally recognised framework through which human rights can be considered under the following five principles: Fairness, Respect, Equality, Dignity and Autonomy. In the context of the responsible and safe use of AI, a human rights-based approach means that people who use services are viewed as equal partners in planning, developing and monitoring the use of AI and that their needs and preferences are taken into consideration. Services upholding a human rights-based approach promote an inclusive, sensitive, equitable and fair approach to the use of AI tools, where people's rights are protected and staff are supported to facilitate this.

In order to ensure that a service takes a human rights-based approach for the use of AI, there needs to be good governance processes established in the service. This ensures that decisions relating to the use of AI protect and promote the fundamental rights of people and align with relevant legal frameworks and human rights treaties. There are clear lines of accountability, as well as processes and procedures in place to protect and promote the rights of people when AI is used in their care, for example, designated individuals are responsible for categorising the risk of AI tools and it is mandatory to undertake a Fundamental Rights Impact Assessment (FRIA) for high-risk tools (as defined in the EU AI Act). This assessment is carried out prior to the first use of the tool to evaluate the potential impact of the tool on the rights of people using the service, and to identify and outline mitigation measures (including collecting feedback on the impact of the tool).

A human rights-based approach in the context of the responsible and safe use of AI in health and social care comprises a number of sub-themes:

Ensure inclusivity and non-discrimination: AI tools that are used in health and social care services are implemented in a way that is fair, equitable and accessible and do not discriminate against any individual or group. In order to support this, there needs to be accountability, good governance, and clear and effective decision-making. Arrangements are in place within the service to ensure AI tools align with relevant human rights legal frameworks, national policies, best practice guidelines, and regulatory and statutory requirements. Ongoing and active partnership with stakeholders, including with people who use services and staff, informs decision-

making about the implementation of AI. This is important to ensure that the AI tools which are implemented meet the needs of the service and the needs of people who use the service.

When AI tools are being developed, bias can be caused by training data that reflects existing systemic biases or data that is not representative of the population that the AI tool will be used for, and this must be minimised to prevent discrimination. Services using AI tools have measures in place to avoid discrimination, including seeking assurances from the AI developer to ensure the AI tool was developed on diverse data and regularly monitoring and evaluating AI tools to identify disproportionate effects on any groups or individuals. Services take steps to monitor the performance of an AI tool and to monitor any outputs through an equality, diversity and inclusion lens to assess and address the risk of bias.

Provide public education and information to support informed decisions: People using services have a right to information and to be fully informed about the use of AI tools in their care. Improving the knowledge of people using services on the use of AI encourages confidence and trust and supports them to exercise their rights. This information should be clear, succinct, comprehensive, and in an accessible format to enable them to fully understand how the AI tool will potentially be used as part of their care. Steps are taken to educate people using services and the public on risks, benefits, how their information will be used and how to evaluate the use of an AI tool so that they are empowered to make an informed decision regarding the use of AI in their care.

Protect privacy and confidentiality: The privacy and confidentiality of people's personal information is maintained 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. Privacy also refers to an individual's right to know if information is being collected about them, and to know how their personal data is collected, shared, and used, including the right to access, amend, or refuse data use. It is the duty of those entrusted with the data to ensure that the person's right to confidentiality is upheld, and services and staff have a responsibility to safeguard the data of people using the service. The use of personal data in AI tools must comply with privacy and security laws including GDPR and other EU and national legislation. For example, a Data Protection Impact Assessment[***] needs to be conducted if the AI tool processes any health-related data.

Promote human connection: Care remains person-centred and the duty to uphold standards of care when interacting with and treating people who use services is upheld. People who use services are supported to make the best decision for their

[***] 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, this is a requirement under GDPR.

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, there is an option to revert to interacting directly with a human.

Examples of how a service can uphold this 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 about what AI tools are used and integrated within the service in a way that is 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.
- For AI tools categorised as high-risk as per the EU AI Act, a designated individual is responsible for conducting a Fundamental Rights Impact Assessment[†††] prior to initial use of the tool[‡‡‡]. The individual(s) responsible may differ based on the type and size of the service.
- Roles and responsibilities in relation to protecting and promoting human rights when AI is used are clearly outlined and 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 user feedback is incorporated to refine and enhance the use of AI tools. This can be done, for example, through a pre-existing service user forum.
- The service is assured and is 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 regarding what information is gathered about a person by an AI tool, the purpose of collecting this information and the rationale for retaining the data, ensuring 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.

[†††] A fundamental rights 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. The assessment involves identifying risks to fundamental rights, proposing mitigations, engaging with stakeholders to protect rights such as privacy, non-discrimination and setting a plan for risk management.
[‡‡‡] As per the EU AI Act, a high-risk AI tool is defined as an AI tool that poses significant risk to health, safety or other fundamental rights and is subject to stringent regulatory obligations.
[§§§] 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, this is a requirement under GDPR.

- Data used in AI tools is securely stored, and when accessed and transmitted, it is 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 and avoid the use of technical language when engaging with people using services about the use of AI tools in their care.
- Signpost people to further information about the use of AI within the service as required.
- When using an AI tool to inform a clinical decision, critically evaluate any outputs to mitigate any 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 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.

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

- I can easily find information on how the service uses AI tools in my care in a format and medium suited to my needs. I understand how AI is used in the delivery of my care.
- I know what AI tools are used in my care and I understand the risks and benefits associated with these tools. I am able to make informed decisions about the use of AI in my care based on these risks and benefits.
- I received 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 am confident that my privacy is protected and any information about me stored by an AI tool will be kept secure.
- I have had an opportunity to ask questions and to seek clarity on anything I am concerned about in relation to the use of AI in my care.
- I am assured that my care remains person centred and any decision about my care is not solely informed based on an output from an AI tool.

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

Background:

The ageing of the population, in particular the increasing frailty of older people, is an important public health issue and a concern due to the associated increased risk of adverse health outcomes. A Regional Population Health Management Steering Group has recently procured an AI tool for use with regional health datasets to support population health management; initially this tool will focus on frailty management. The AI tool will use regional health datasets to segment and risk-stratify the population in order to identify older people who may benefit from a more personalised, proactive and preventative approach to their health needs.

Dr Habib's story

Dr Habib is a Consultant Geriatrician in St Peter's Hospital. She has recently started using the AI tool which uses regional health datasets to provide a more personalised and preventative approach to addressing her patient's health needs. The use of the tool in hospitals in the region was recently approved following a stringent procurement process by the Regional Population Health Management Steering Group[****]. The procurement of the tool was initially delayed because the Steering Group was concerned that tool could be biased, as it had been developed outside of Ireland and there could be challenges with the representativeness of the population groups used to build the tool. The Group noted that in line with public sector duty there was a need to assess equality and human rights issues and wanted assurances that the outcome from the tool was representative for all regardless of ability or disability and was not biased. In order to address some of the challenges noted by the group, a Fundamental Rights Impact Assessment was conducted to understand and mitigate risks to fundamental rights. The issue of bias in AI tools for population health management was explored by the Steering Group and assurances were sought from the developer to ensure the AI tool was developed using a diverse dataset that is reflective of the Irish population. When the tool had been procured, existing monitoring and evaluation frameworks for population health management were utilised so that measures were in place to assess the equity impact. Clinicians using the tool were asked to monitor and assess for any potential bias in the outcomes of the tool so that it could be identified and

[****]The case studies are for illustrative purposes, services will have various arrangements in place for approval of AI products that is dependent on the size and type of the organisation, and it is important to be familiar with such arrangements.

managed early in implementation. Carlos, one of Dr Habib's patients, has recently benefited from the use of the tool. Dr Habib was able to use the AI tool to identify more targeted support for Carlos, for example, loneliness was identified as a potential risk for frailty given his characteristics and circumstances. Acting on this, Dr Habib linked him with a public health nurse suggesting referral to relevant community support services.

Principle 3: Safety and wellbeing

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. Services have a responsibility to be alert to the safety and wellbeing of people who use the service and to respond to any concerns in a person-centred way and in line with legislation, regulations, national policy, standards and guidelines. Providing health and social care can never be completely risk free. A service that is focused on safe care is continuously looking for ways to provide a reliable service and to improve the quality-of-service delivery. In relation to the use of AI in services, AI is optimised to enhance safety and wellbeing in the delivery of care. Similar to other digital health technologies, services review and monitor AI tools to ensure their safe operation, security of information and technical robustness.

AI has the potential to improve the quality, reliability and safety of health and social care, for example by improving diagnostics or using predictive analysis to enable the early identification of illness. In order to ensure that AI is used in a safe way, it is essential that there is oversight of AI tools and adherence to good governance processes. AI tools should maintain performance under varying conditions and there should be business continuity plans in place. The service designates individuals responsible for the risk categorisation of AI tools and risk management measures throughout the AI lifecycle, including approval, performance evaluation, monitoring and, if necessary, withdrawal of an AI tool. Staff are trained and supported to use AI tools competently. AI tools augment rather than replace human judgement and staff have oversight of AI tools. Services are transparent about AI use, especially in the event of an incident. Safety and wellbeing in the context of the responsible and safe use of AI in health and social care comprises a number of sub-themes:

Maintain safe care: Services have a duty to protect the safety and wellbeing of people and to mitigate 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 a service and governance structures are provided regular assurance that the tool is working as intended. Existing safety frameworks should be updated by the service to incorporate AI. There is continuous monitoring, maintenance, and performance evaluation of AI tools in a service to ensure safety and reliability in line with risk management procedures and instructions for use. A service considering an AI tool has assurance of the following from the AI developer: rigorous testing, evidence-based evaluation and validation in real-world settings. Additionally, for AI tools that also qualify as medical devices or IVDs, compliance with the relevant requirements of the MDR or IVDR (as applicable) should be 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 resilient to errors. There are clear lines of oversight for compliance with relevant security policies and strategies, including those relating to data privacy and business continuity. Existing policies and procedures for managing data and business continuity are updated to incorporate the use of data by AI tools. To ensure that services are resilient to errors or attacks affecting AI tools, contingency plans are in place for tool failures to ensure the continual delivery of safe care. If an incident does occur from the use of an AI tool, there are steps in place to prevent reoccurrence in the future.

Examples of how a service can uphold this 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.
- 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 incident management, or digital clinical safety processes.
- The service is confident that all AI tools in use have been tested and evaluated in real-world settings and tools are initially trialled in the service to ensure their suitability for the specific setting.
- There is robust risk management within the service, including clinical risk management. A risk management policy and risk register are developed for the use of AI tools and are incorporated into existing risk management processes.
- 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 in the event that a known incident occurs from the use of an AI tool, and the incident is recorded for 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, and how data is used for secondary purposes[††††].
- Policies and procedures for managing data 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.
- Enforceable 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 as intended and as per the instructions provided.
- Apply professional judgement 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 or security of an AI tool.
- Report any incidents resulting from the use of an AI tool in line with the services' policies and procedures.
- Explain to people who use services what AI is, how it is used in their care, the risks and limitations and how these are managed so that they can make an informed decision about its use within their care.

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

- I am confident that regular checks are in place to ensure the safety of AI tools.
- 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 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.

[††††] 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.

Example of safety and wellbeing being upheld in practice

Background:

A respiratory clinic has recently started using an AI decision-support tool during consultations. The tool is a CE marked medical device. The tool has been approved for use in the hospital following a clinical safety review and data protection impact assessment.[‡‡‡‡] The clinician inputs a patient's medical notes during the consultation, and the tool helps to prepare treatment plans, including an assessment of a person's suitability for medications. When a person using the service checks into the clinic, a staff member directs them to information about the new AI tool being used during consultations.

Anna's story:

Anna has Chronic Obstructive Pulmonary Disease (COPD) and recently had an outpatient appointment with her consultant, Dr McGuire. At the start of Anna's consultation, Dr McGuire confirmed that she understood the purpose of the new AI tool and explained that he will always review, amend as appropriate, and approve the notes and any treatment plans before proceeding. He reassured Anna that although the AI tool has been shown to be safe and reliable, he does not over-rely on the tool and uses the output alongside clinical judgement. Anna asked Dr McGuire if he could clarify how her data will be protected. Dr McGuire explained that the notes are stored in line with data protection laws on a secure system like her previous notes had been. Dr McGuire checked if Anna had any more questions and if she was happy for him to proceed. Towards the end of the consultation, Dr McGuire carefully checked the treatment plan and medication recommendation generated by the AI tool, which aligned with his clinical assessment. He verified the details with Anna, who agreed with the treatment plan.

[‡‡‡‡]The case studies are for illustrative purposes, services will have various arrangements in place for approval of AI products that is dependent on the size and type of the organisation, and it is important to be familiar with such arrangements.

Principle 4: Responsiveness

Overview

The principle of responsiveness represents how a service responds to and meets the needs of people using the service, and the health and social care system as a whole. A responsive service has skilled and experienced staff who can identify and effectively address the needs of people using the service. In the context of AI, services upholding the principle of responsiveness ensure that AI is being used for the benefit of people who use health and social care services.

Responsiveness means that 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. If an AI tool is found to have a proven benefit, for example by reliably improving outcomes for people who use services, or supporting operational efficiency or cost-effectiveness, and if the improvement clearly outweighs any risks or costs, services consider the use of the tool. When introducing an AI tool, services also consider the impact and burden on staff, and a change management process is in place to support staff through the transition. AI tools that integrate within existing systems are considered, and a staged approach is taken if required to allow staff to adapt effectively. For AI tools that also qualify as medical devices or IVDs, compliance with the relevant requirements of the MDR or IVDR (as applicable) should be confirmed prior to use.

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. This facilitates adherence to obligations under the EU AI Act for services to ensure AI literacy among staff working in the service. Staff receive appropriate training to use AI in a way that minimises physical, psychological, emotional, and harm, and to protect and promote safety and wellbeing. Management ensures that staff receive ongoing training and education, so they understand how to use AI tools to provide the highest quality care and support, and to identify any potential risks to the safety of people who use the service. Services maintain a record that staff have been offered and completed necessary education and training. Staff ensure that they have knowledge and awareness of their roles and responsibilities in relation to how AI is used in their workflow.

The quality of the data underpinning AI tools is a key consideration. Specifically, it is essential that the data underpinning AI is of high quality, is broadly representative of the population and is updated during the lifecycle of the AI tool, to produce accurate results.

Responsiveness in the context of the responsible and safe use of AI in health and social care comprises a number of sub-themes:

Integrate into practice: Integration refers to services incorporating AI tools within existing clinical and operational workflows to minimise burden on staff and to reduce the impacts on service delivery. AI tools providing the most benefit for their intended purpose while being cost-effective are prioritised, for example, those with the greatest clinical impacts or that best support operational efficiencies. 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. Only tested and approved AI tools are incorporated into clinical care. Medical devices are verified as clinically useful and compliance with the relevant requirements of the MDR or IVDR (as applicable) should be confirmed prior to use.

Provide education and training to support development of staff: In line with AI literacy obligations, services have a responsibility to undertake training needs analysis and facilitate education, training and career support for staff to adapt to AI-enhanced roles. Training provides staff with skills and knowledge to use AI tools safely and responsibly, including: understanding and critically evaluating AI outputs; communicating AI-assisted decisions to people who use services; identifying biases in AI outputs and when AI may be providing inaccurate or misleading information; building confidence to override AI outputs if required; and building a working knowledge of how AI tools function and how they are evaluated. Staff understand 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, where the tool stores data, and the benefits and any potential limitations of the tool. Staff maintain their clinical skills and do not become reliant on AI tools, ensuring continuity of care in the event of an AI tool failing or being compromised.

Ensure data quality: Successful development of AI tools for use in health and social care relies on high-quality data, which is used to train and validate algorithmic tools. High-quality data ensures that outputs from an AI tool are reliable and trustworthy and prevents unintended harm from the use of AI tools. Within a service, the data inputted into an AI tool needs to be of high-quality, 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.

Encourage eco-responsibility and sustainability: Eco-conscious practices are part of service delivery (for example, energy-efficient computing) and decisions about the use of AI tools in health and social care services align with environmentally sustainable and climate friendly practices.

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 and, in the case of medical devices, that the tool is clinically safe and complies with the relevant requirements for MDR or IVDR (as applicable).
- The decision to implement a tool also considers the impact on service delivery and that the tool is interoperable with other information systems that are in use.
- A robust change management process is in place to support staff through the transition when an AI tool is being integrated to an existing system, to ensure continuity of care and minimise disruption to people using services.
- 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 clinical 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 including the EU AI Act.
- Training is delivered to enable the development of a highly trained and competent workforce that can use AI in a safe and responsible way.
- Training is provided to staff based on their role and responsibilities to ensure they have the skills, competencies and knowledge to use AI safely. This training may include how AI is developed, how to recognise bias in data or outputs, how to identify when AI is providing misleading or inaccurate information, how to address and report any concerns, and how to comply with data privacy laws.
- Robust information management practices are in place to ensure the data entered into AI tools by staff is accurate and of good quality.
- Environmentally sustainable practices are considered when AI tools are introduced by a service.

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

- Undertake any available training to understand how to use AI in a safe and responsible way, including how to recognise bias or flaws in data or outputs, how to comply with data privacy laws, 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 benefits of using an AI tool compared to more traditional care options.
- Understand and be able to explain to a person who uses services how an AI tool works, the benefits and risks of the AI tool and its limitations.

- Be informed about how AI is used within the current workflow and identify who is the person responsible for overseeing clinical interpretations and recommendations when using outputs from an AI tool.

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

- I know that the use of AI in my care is based on best available national and international 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 relating to the use of AI in my care. This may include questions on the benefits of AI versus traditional care pathways and the limitations of the AI tool.
- I am confident that staff are trained and supported to use AI in a safe and responsible way in my care.

Example of responsiveness being upheld in practice

Background:

Staff in a home care 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 their temperature, blood pressure and heart rate. The AI tool, which is a CE marked medical device, monitors this information and alerts the service if a person is at risk of a health problem. This alert can prompt preventative action, helping 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 care staff regarding how the tools works, how it derives its outputs and how to identify and respond to poor performance.

Kiran's story:

Kiran is 75 years old and lives alone. After a fall three years ago, Kiran decided that home care could help him to maintain his independence and continue to live well in his own home. Kiran's home care provider John visits regularly to help with everyday tasks. John recently mentioned a new app that is being offered by

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

the home care service to help reduce health problems. 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 monitor this information and alert the home care service to respond if it identifies a risk to Kiran's health. John provided Kiran with the relevant information he needed to actively participate in the decision regarding whether to include the app as part of his home care service. As a result of the training he received, 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.

3. Glossary

A human rights-based approach: 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 receiving care and support at all times.

Accountability: The principle of accountability is the foundation for how health and social care services ensure that people receive high-quality safe care and support that is consistent, coordinated and focused on achieving good outcomes for them.

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

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

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.

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

Bias: Bias in an AI tool occurs when systematic errors in machine learning algorithms produce unfair or discriminatory outcomes.

Black box AI: An AI tool that can be viewed in terms of its inputs and outputs without any knowledge of its internal workings.

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.

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.

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.

Deep learning: A subfield of machine learning that uses multi-layered artificial neural networks to learn patterns within datasets.

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 understood and interpreted.

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.

Generative AI: A type of artificial intelligence that can create new content, such as text, images, or videos, by learning patterns and structures from large amounts of data. It differs from natural language processing in that it can create new content, not just analyse or understand existing data. Examples include chatbots such as ChatGPT.

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 system 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 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. (see Appendix B for further information)

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. These tools gradually improve their accuracy by using algorithms and statistical models to analyse and draw inferences from patterns in data.

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. (See appendix B for further information)

Narrow AI: AI tools designed for specific tasks or domains rather than general reasoning or learning across domains. For example, a voice assistant like Siri.

Natural Language Processing: A sub-field of AI that helps computers understand, interpret and use human language. It enables computers to read, write, and interpret text or speech in a way that makes sense to people. It can be used to transcribe clinician notes.

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.

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".

Responsiveness: The principle of responsiveness includes both how health and social care services are organised to deliver coordinated care and support that meets the needs of people using their service, and how people working in these services identify, assess and respond to a person's needs in day-to-day practice.

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

Safety and wellbeing: The principle of safety and wellbeing is about how health and social care services work to protect and enhance the safety and wellbeing of people who use their services.

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.

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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
Philip Dodd	Deputy Chief Medical Officer, Department of Health
Tom Laffan	Chief Data and Analytics Officer, Health Service Executive
Ronan O'Kelly	Assistant Principal Officer, Health Infrastructure Division, Department of Health
Meabh Smith	Digital Clinical Safety Lead, Health Service Executive

Project Co-production Working Group membership

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

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

Appendix B. EU legal and regulatory landscape for the use of AI in health and social care

The legal and regulatory landscape regarding the use AI in health and social care within Ireland is shaped by several EU acts and regulations which directly or indirectly address specific aspects of AI development, deployment, and use. These collectively shape key aspects such as safety, performance, data quality and interoperability, and clinical evidence. This includes cross-sector regulations and healthcare-specific regulations. An overview of some examples of the key complementary acts and legislation that are relevant and will need to be complied with to support the responsible and safe use of AI in health and social care are listed below.

EU Artificial Intelligence Act (AIA)[11]

The AIA (Regulation (EU) 2024/1689) is a cornerstone of the EU's regulatory framework for governing AI systems, addressing risks associated with their design, deployment, and use. The AIA addresses potential risks of AI to citizens' health, safety, and fundamental rights. It adopts a risk-based approach and classifies AI technologies into four risk categories (unacceptable risk, high risk, limited risk and minimal risk) based on their intended purpose, risk of harm to the fundamental rights of people, the severity of the possible harm and probability of occurrence which are subject to different rules while ensuring safety, transparency, and fairness. 'Providers' of AI systems must determine the intended purpose of the AI system and classify it into one of the four risk categories. Many healthcare AI applications, such as diagnostic tools, clinical decision support tools, and patient monitoring tools, fall under the high-risk category.

High-risk AI tools must adhere to certain requirements. The requirements differ based on the role of deployer ("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") or provider ("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") of the AI tool. For high-risk activities, the provider's obligations include risk management, data governance, detailed documentation and human oversight measures. Deployers' obligations include conducting data protection and human rights impact assessments, using AI tools in line with instructions, human oversight, and monitoring the functioning of the tools and reporting serious incidents. The

table below summarises the AIA risk categories and includes some of the requirements for deployers of AI tools under each category.

Table 4. Risk categories as defined by the EU AI Act

Risk categories	**Description**	**Deployer obligations**[19]
Unacceptable risk (Prohibited Systems†††††)	Poses a threat to safety, rights, or livelihoods. Use of AI for these purposes is strictly prohibited, except in limited circumstances.	The placing on the market, the putting into service and the use are prohibited (Article 5).
High-risk	Poses significant risks to the health, safety, or fundamental rights of individuals are categorised as high-risk. As such, they are as treated as high-risk under the EU AI Act with obligations for developers and deployers including data protection and fundamental rights impact assessments, human oversight, monitoring the functioning of the tools and reporting serious incidents.	AI literacy measures (Article 4) Use systems in accordance with instructions (Article 26(1)) Assign human oversight to qualified natural persons (Article 26(2)) Ensure relevant and sufficiently representative input data (Article 26(4)) Monitor the functioning and inform stakeholders of serious incidents (Article 26(5) and Article 72) Keep automated logs (Article 26 (6)) Registration obligations for certain deployers (Article 26(8) and Article 49) Data protection impact assessment (Article 26(9))

††††† The term AI tool is used throughout this document – however, in legislation the term AI system is also used and therefore appears in this table

		Fundamental rights impact assessment (Article 27)
Limited risk	Presents low risks.	AI literacy measures (Article 4) Transparency obligations (Article 50)
Minimal to no risk		No requirements in the EU AIA but should follow best practice

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. While the detail has not been finalised, it is expected that the notifying authorities will be responsible for conformity assessment of AI systems. It is also expected that the notifying authorities will be responsible for designating, monitoring and overseeing "notified bodies" (independent organisations responsible for assessing whether certain AI systems comply with the requirements under the AI Act before the systems are placed on the market). The market surveillance authorities are expected to be the national enforcement body for the regulation of AI tools post entry onto the market. The market surveillance authorities are expected to be responsible for actively monitoring and inspecting AI systems on the market.

On 19 November 2025, the European Commission published the *Digital Omnibus Package*, which includes targeted simplification measures to ensure timely, smooth, and proportionate implementation of certain provisions of the AI Act. This is part of the Commission's broader simplification agenda. The Digital Omnibus proposals are an important element of the overall approach to improving competitiveness at an EU level, in line with the Draghi Report and related work. The Digital Omnibus proposals will continue to inform the progression of the implementation of the AI Act nationally.[26,27]

Medical Device Regulation (Regulation (EU) 2017/745 - MDR)[23] and In Vitro Diagnostic Medical Device Regulation (Regulation (EU) 2017/746 – IVDR)[24]

Medical devices and in vitro diagnostic medical devices are regulated in Europe by the MDR and IVDR respectively and must meet all applicable requirements outlined in these legislations prior to being placed on the European market. The MDR and IVDR apply to all medical devices and in vitro diagnostic medical devices (IVD), including AI-based software devices that meet the definition of medical device or IVDs and that may be used by healthcare professionals in hospital settings or by lay users, for example, as mobile applications on smartphones. It is important to note

that 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 prior to being placed on the market and 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. The HPRA also carries out market surveillance activities to assess the safety and compliance of medical devices and IVDs once they have been placed on the market and operates a vigilance system for reporting of serious incidents with respect to the use of medical devices and IVDs.

The General Data Protection Regulation 2018[25]

The specific rights of a person in respect of their personal data are set out in the European General Data Protection Regulation (GDPR). For organisations using AI in healthcare and social care, GDPR compliance is critical, particularly in managing sensitive health data, ensuring lawful processing, and addressing principles such as data minimisation and purpose limitation.

Other regulations that should be considered by staff working in or managing services in the context of the responsible and safe use of AI:

The **European Health Data Space (EHDS) Regulation**[34] establishes a unified and secure framework for health data exchange across EU Member States. It is expected to provide a valuable foundation that could incentivise the establishment of high-quality datasets essential for the training, performance testing, and monitoring of AI tools. The EHDS Regulation strengthens patients' rights over their electronic health data. The forthcoming Health Information Bill[45] is the first in a suite of national measures to give full effect to EHDS, ensuring greater patient access, transparency, and control over their health information.

The Product Liability Directive 2024 (PLD)[33]:
The new PLD (Directive (EU) 2024/2853), formerly Directive 85/374/EEC, is a key EU framework aimed at ensuring liability and protecting individuals who suffer harm caused by defective products. This is particularly important in healthcare, where AI tools are increasingly integrated into critical medical devices and diagnostic tools. The PLD focuses on liability for harm caused by defective products, including AI tools, regardless of fault. Recognising the dynamic nature of AI tools, the updated PLD proposes considerations for risks that may emerge over a product's lifecycle, such as those linked to learning and adaptation post-deployment.

The General Product Safety Regulation 2023 (GPSR)[32]:
This regulation sets outs the requirements and obligations for consumer products on the EU market to ensure their safety and functioning.

NIS2 Directive:[36]
The NIS2 Directive is a significant update to the EU's cybersecurity regulations aimed to strengthen and harmonise cybersecurity across the EU, and to keep-up with increased digitisation and an evolving cybersecurity threat landscape. The Directive aims to strengthen the culture of security across sectors that are vital for our economy and society and that rely heavily on ICT, such as energy, transport, water, banking, healthcare and digital infrastructure.

Critical Entities Resilience Directive 2022 (CER):[35]
The Resilience of Critical Entities Directive is part of an EU-wide effort to increase the resilience of essential services that provide vital societal functions in all Member States. The regulations will apply to the following sectors of the economy: energy, transport, banking, financial market infrastructure, health, drinking water, wastewater, digital infrastructure, public administration, space, and large-scale food production, processing, and distribution. In accordance with the requirements of the CER Directive, the Irish Government has passed legislation to assign a number of

pre-existing regulators as Competent Authorities (CA's) for the regulation of relevant service providers in their sectors. In the health sector, HIQA, the HPRA and the Department of Health have been confirmed as CAs. Under this legislation, CAs will by July 2026 identify which service providers are deemed to be Critical Entities as determined by criteria established by the Department of Defence. Once identified, these Critical Entities will be subject to additional regulatory requirements to ensure that they have adequate arrangements to ensure resilience and business continuity, including recovery measures should services be disrupted. A first step in this process will be the requirement for Critical Entities to formally submit risk assessments to CAs, such as HIQA, in 2027 outlining steps taken to ensure service resilience.

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