

**HSE Artificial Intelligence (AI) Interim Guidance**

February 2025

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# Introduction

## Overview

Digital for Care 2030 is Ireland’s strategic plan to modernise health and social care through digital innovation, led by the Department of Health (DoH) and the Health Service Executive (HSE). This initiative aims to improve health outcomes and patient well-being by leveraging technology, data, and artificial intelligence (AI). The DoH's "Digital for Care – A Digital Health Framework" sets out a vision for a digitally enabled health service, focusing on enhancing patient-centred care through innovation, data-driven decision-making, and the integration of advanced technologies. Complementing this, the HSE's "Digital Health Strategic Implementation Roadmap" provides practical steps to reach digital maturity, with a strong emphasis on the role of AI and automation in driving improvements across clinical, operational, and administrative functions.

AI is rapidly transforming health and social care, offering opportunities to improve patient outcomes, optimise operations, and enhance service delivery. It is crucial that all HSE staff understand the potential of AI, how it aligns with HSE strategic objectives, and the requirement for responsible, ethical, and safe use of AI technologies. AI adoption within the HSE represents a fundamental shift in how health and social care services can be delivered and supported, including supporting clinical decision-making and introducing efficiencies into administrative processes.

## Purpose

This guidance is the first in a suite of supports designed to equip all HSE staff with the knowledge and confidence to engage with AI initiatives, while ensuring that these initiatives align with organisational goals and meet the existing and evolving needs of patients.

It provides foundational knowledge so that all staff can understand what AI is, its capabilities and then key considerations required to ensure best practices for AI usage assuring compliance with ethical and regulatory standards while simultaneously fostering a culture of innovation that supports the HSE’s strategic priorities.

# What is Artificial Intelligence

AI enables machines to perform activities that mimic human decision-making, particularly in pattern recognition and large-scale data processing. AI excels in tasks such as reasoning, decision-making, object detection, image recognition, and solving complex problems. However, it lacks true creativity and cannot replicate human tacit knowledge, which is crucial in fields like healthcare. To maximise efficiency, AI tools should be integrated within a human-in-the-loop approach, ensuring that human expertise guides critical decision-making**.**

Examples of AI include:

Figure 1 Examples of AI

AI can be envisioned as an assistant to which workload can be delegated to or shared with, to streamline processes, enhance accuracy, reduce errors and increase capacity. It is designed to augment the capabilities of human workers, allowing staff to work more efficiently in our journey towards a patient-centred, digitally enabled health and social care environment.

## Applications and Benefits of AI

The implementation of AI has the potential to bring significant benefits to both clinical and non-clinical areas within the HSE. These include:

* **Improving the quality of care:** AI can support clinical decision-making, enhance diagnostics, and enable personalised treatment.
* **Transforming health service delivery:** AI can modernise and streamline processes, improving patient access and the overall delivery of care.
* **Enhancing operational efficiency:** AI can improve resource management, augment staff capabilities, and provide decision support, leading to better resource allocation and reduced operational costs.
* **Supporting a skilled workforce:** AI can help staff by freeing up time from routine tasks and providing tools to boost job satisfaction, productivity and decision-making.

The table below provides some examples of how AI can be applied to enable associated benefits to be achieved.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Clinical** | Business Growth outline | **Improving Diagnostics:** AI tools can assist in early detection of diseases, providing faster and more accurate diagnoses in areas such as radiology and pathology. |
| Care outline | **Enhancing Personalised Care:** By analysing patient data, AI can recommend tailored treatment plans, ensuring better patient outcomes. |
| Bar chart outline | **Supporting Predictive Analytics:** AI enables the prediction of patient deterioration, re-admissions and other risks, allowing for proactive interventions. |
|  | **Operational** | Customer review outline | **Streamlining Resource Management:** AI can optimise staff scheduling, inventory management and equipment usage, reducing waste and improving efficiency. |
|  | **Reducing Administrative Burdens:** Automating repetitive tasks such file management, data entry and scheduling reduces errors, improves efficiency and frees staff to focus on patient care. |
|  | **Improving Patient Access:** AI-powered chatbots and virtual assistants can handle routine enquiries, delivering better user experience and expanding access to care. |
|  | **People** | Bar graph with upward trend outline | **Enhancing Productivity:** By automating time-consuming tasks, AI allows staff to focus on higher value activities, enhancing overall efficiency. |
|  | **Supporting Decision-Making:** Tools like decision-support systems provide real-time insights, enabling staff to make informed decisions quickly. |
|  | **Reducing Burnout:** AI helps to alleviate workload pressures, improving staff satisfaction and wellbeing. |

Table 1 Examples of applications and benefits

# Key Considerations for Adoption of Artificial Intelligence (AI)

When adopting an AI solution or integrating AI components into a solution, the standard process for selecting, procuring, and implementing ICT solutions must still be followed. This includes all existing approval and stage gates steps.

However, AI-specific solutions require additional rigour to comply with the EU AI Act and other emerging and related frameworks. This means that, alongside the standard evaluation and return-on-investment assessments, extra measures must be taken to meet such regulatory requirements.

These processes are designed to maintain continuous human oversight, ensuring that human judgement and expertise remain central from development through to deployment and ongoing monitoring. By following these steps, we ensure that AI solutions are not only compliant with regulations but also uphold the highest standards of ethical and responsible AI deployment.

The following table provides key considerations for the adoption of AI within the HSE, providing an interim framework to guide staff and clinicians as they explore AI solutions. While not an exhaustive list, these factors — such as patient safety, compliance, ethics, data privacy, and scalability — are important to consider when thinking about AI opportunities. Future updates will be informed by the ongoing work being progressed by the HSE and HIQA.

The AI & Automation Centre of Excellence (CoE) will be available to support you through the process, helping to enable AI initiatives aligned with organisational goals and regulatory requirements. To ensure consistency, all proposed AI solutions must be assessed using an assessment tool provided by the AI and Automation CoE.

Further details can be found on the Technology and Transformation website URL TBC.

|  |  |  |  |
| --- | --- | --- | --- |
| **Theme & Definition** | **Viable If…** | **Conditional if…** | **Not Viable If…** |
| **Benefits to Service Delivery -** Identifying a clear problem or opportunity where AI can deliver measurable benefits  | **●** AI addresses a clear problem or opportunity with defined goals | **⚠** The problem statement is vague, and it’s unclear if AI is the right solution | **X** No clear opportunity exists, or AI doesn’t add value |
| **Patient Safety -** Ensuring AI applications do not harm patients and contribute to safer outcomes | **●** AI is expected to maintain or improve safety without increased risk | **⚠** There are unclear or minor risks that need further investigation | **X** AI poses serious risks to patient safety with no clear mitigation plan |
| **Compliance -** Adherence to legal, regulatory, and organisational policies, including GDPR, EU AI Act and HSE standards | **●** AI **does** meet GDPR, EU Act and HSE standards | **⚠** Compliance with regulations is uncertain or needs clarification | **X** AI breaches legal, regulatory, or organisational policies |
| **Ethics -** Upholding principles of fairness, transparency, and equity while avoiding bias and harm | **●** The use of AI ensures fairness, equity, and minimise ethical concerns | **⚠** Ethical risks exist but could be managed with further assessment | **X** AI presents significant ethical risks, such as bias or inequity |
| **Data Protection & Security -** Protecting sensitive health data and ensuring it is used in compliance with privacy laws | **●** Data is to be handled securely and comply with privacy laws | **⚠** Data security or privacy measures are unclear or need strengthening | **X** AI risks breaching data privacy laws or fails to secure sensitive data |
| **Risk Assessment -** Evaluating potential risks (safety, technical, operational and liability) and ensuring mitigation strategies | **●** Risks are identified and manageable | **⚠** Risks are only partially addressed or require more planning | **X** Risks are high, unaddressed, or make AI unfeasible |
| **Patient Engagement & Consent -** Ensuring patients are informed, engaged, and give consent for AI use in their care | **●** There is a mechanism for patients to be informed and recorded | **⚠** Processes for patient engagement or consent are unclear or insufficient | **X** Patients cannot give consent, or trust is at risk |
| **Data Availability and Governance -** Ensuring sufficient, high-quality data is accessible and usable for AI purposes | **●** High-quality data is available and usable for AI | **⚠** Data quality or availability is inconsistent and needs improvement | **X** Data is missing, inaccessible, or non-compliant |
| **Scalability -** Potential for AI solutions to be expanded across departments, health regions or nationally in a cost-effective and sustainable manner | **●** AI is expected to scale well across teams or services | **⚠** Scaling is costly or has unclear benefits | **X** AI cannot scale or becomes too expensive to sustain |
| **Productivity Improvements -** Potential for AI to enhance efficiency, save time, and optimise workflows | **●** AI is expected to save time and improve workflows | **⚠** The impact on productivity is unclear or uncertain | **X** AI is unlikely to improve workflows and might create inefficiencies |
| **Evidence Base –** Evidence base showing reliability, validity, and effectiveness of an AI solution for the intended purpose | **●** AI has robust evidence base with demonstrable output relevant to the intended purpose  | **⚠** The evidence base is unclear or uncertain | **X** AI cannot provide sufficient evidence of key metrics for the intended purpose |

## Key Considerations for AI Solutions

Table 2 Key Considerations for the Adoption of AI

# Human Centred Approach

AI should not replace human oversight and human interventions. This is crucial in both clinical and non-clinical settings to ensure the responsible, effective and trustworthy use of AI within the HSE.

In clinical practice, clinicians must review AI-driven recommendations to ensure they align with established clinical protocols and patient safety standards. Their expertise ensures that AI tools are used appropriately in decision-making, with adjustments made when necessary to prevent errors or misinterpretations that could affect patient outcomes.

In non-clinical functions, human oversight ensures that AI systems support operational and administrative processes. Staff must monitor AI outputs to ensure they comply with regulatory requirements and ethical standards while improving efficiency. By maintaining human involvement in the oversight process, the HSE ensures that AI remains a tool to assist, rather than replace, human judgment, promoting accountability and contributing to positive outcomes.

**Accountability**

AI systems can process vast amounts of data efficiently, but they lack the ability to properly assess ethical considerations. Humans ensure that AI decisions align with societal values and ethical standards, preventing biases and discrimination.

Human oversight promotes transparency and accountability in AI systems. By overseeing the development, deployment, and maintenance of AI, humans can identify and rectify biases, building trust between technology and society.

**Ethical Decision Making**

**Ethical Decision Making**



**The Importance of Human Oversight**



**Patient Safety & Mitigating Errors**

Human oversight ensures that AI recommendations prioritise patient safety. **Clinicians** can validate AI outputs, preventing potential harm from incorrect diagnoses or treatment plans.

AI systems can struggle with dynamic situations and the subtle nuances of human interactions. Humans can adapt to new circumstances, leverage contextual knowledge, and make informed judgments that AI might miss.

**Adaptability**



**Continuous Improvement**

Humans play a vital role in the continuous learning and improvement of AI systems. By providing feedback and making adjustments, they help AI systems evolve and improve over time.

Figure 2 Importance of Human Oversight

# Regulatory requirements

The EU AI Act is an EU regulation that came into force in August 2024. This Act, along with the General Data Protection Regulation (GDPR) and the Medical Device Regulation (MDR) creates a robust legal structure for the responsible use of AI in health and social care. The key details of each regulation are as follows:

* **EU AI Act:** Establishes a framework for categorising AI systems by risk level, ensuring AI is used in a transparent, accountable, and human-centric manner.
* **General Data Protection Regulation (GDPR):** Ensures the protection of personal data, which is crucial when AI systems handle sensitive health information.
* **Medical Device Regulation (MDR):** Governs the safety and performance of medical devices, including software as a medical device and AI technologies used in health and social care.

It is essential that HSE staff understand the clear guidelines that the AI Act outlines for the development, deployment and use of AI systems, to ensure that they are safe, transparent, and accountable. Below are the risk categories from the EU AI Act to consider when exploring AI opportunities.

E.g.
Workforce scheduling, fitness apps

**Minimal Risk -** AI systems with **negligible or no impact** on **safety** or **rights**. These systems are encouraged to adhere to ethical guidelines but **require no specific regulatory compliance**. AI systems that pose a clear threat to safety, rights, or fundamental values are banned under this category.

E.g.
AI chatbots, AI powered appointment scheduling

E.g.
Social Scoring, Facial recognition

E.g. Diagnostic tools, clinical decision support

**High Risk -** AI systems that have a significant impact on **safety** or **fundamental rights**, requiring strict compliance with **safety**, **transparency**, and **accountability standards**.

**Limited Risk -** AI systems with moderate impact, requiring transparency but not as strict oversight. These systems might not directly endanger health but still require **accountability**.

AI systems that pose a clear threat to safety, rights, or fundamental values are banned under this category.

**Unacceptable Risk -** AI systems that pose a clear threat to **safety**, **rights**, or **fundamental values** are banned under this category.

Figure 3 EU AI Act risk categories

Note: It is a mandatory requirement for organisations that all use of AI solutions must be registered in an AI inventory. The AI and Automation CoE will maintain this central repository on behalf of the HSE.

Further details can be found on the Technology and Transformation website URL TBC.

# Conclusion

AI offers transformative potential for the HSE, enhancing both clinical outcomes and operational efficiency. By adopting AI responsibly and aligning it with national strategies, HSE staff can contribute to a health and social care system that is more patient-centred, efficient, and innovative.

For further information or support, please contact the HSE AI & Automation Centre of Excellence (CoE) at **AIandAutomationCoE@hse.ie**

# Glossary

|  |  |
| --- | --- |
| Term | Definition |
| Advanced Analytics | Refers to the use of sophisticated techniques and tools, such as machine learning and predictive modelling, to analyse data and extract deeper insights. These methods go beyond basic data analysis to uncover patterns, trends, and relationships that can inform decision-making and drive strategic actions. |
| Artificial Intelligence (AI) | Refers to the ability of machines or systems to mimic human intelligence, enabling them to think, learn, and solve problems. |
| **Algorithm** | An algorithm is a set of step-by-step instructions that a computer follows to solve a problem or complete a task. |
| **Bias** | In AI, bias means that the AI system has a preference or unfair tendency in its decisions or predictions. This could happen if the data used to train the AI is not balanced or representative, leading the AI to favour certain outcomes over others. |
| **Chatbot** | A chatbot is a computer program designed to talk with people. It can answer questions, provide information, or help with tasks by having a conversation, just like chatting with a real person. |
| **Computer Vision** | Computer vision is a field of AI that enables computers to see and understand images and videos. It's like giving a computer the ability to recognize and interpret what it "sees", similar to how humans do. |
| **Data Mining** | Data mining is the process of examining large datasets to identify useful patterns or information. It involves analysing extensive information to uncover insights that can support decision-making. |
| **Data Quality** | Data quality refers to the degree to which data is reliable and valuable. High-quality data is characterized by its accuracy, completeness, and utility, whereas low-quality data may be inaccurate or lack essential information. |
| **EU AI Act** | The EU AI Act is a set of rules created by the European Union to regulate artificial intelligence (AI). It aims to ensure that AI systems are safe, trustworthy, and respect people's rights. |
| **Forecasting** | Forecasting is the process of predicting what will happen in the future based on current data and trends. It's like making an educated guess about future events by looking at what is happening now and what has happened in the past. |
| **GDPR** | The GDPR (General Data Protection Regulation) is a law in the European Union that protects people's personal data. It gives individuals control over their data and requires organisations to handle this data responsibly and transparently. |
| **GenAI** | GenAI (Generative AI) is a type of artificial intelligence that can create new content, such as text, images, or videos, based on what it has learned from existing data. |
| **Human Oversight** | Human oversight in AI means that people are involved in monitoring and guiding AI systems to ensure they work correctly and ethically. |
| **Machine Learning** | Machine learning (ML) is a type of artificial intelligence where computers learn from data and improve their performance over time without being explicitly programmed.  |
| **Medical Device Regulation** | The Medical Device Regulation (MDR) is a set of rules in the European Union that ensures medical devices are safe and effective for use. It requires manufacturers to meet high standards for quality and safety before their devices can be sold in the EU. |
| **Natural Language Processing** | Natural Language Processing (NLP) is a field of AI that helps computers understand and work with human language. It enables computers to read, write, and interpret text or speech in a way that makes sense to people. |
| **Pathology** | Pathology is the study of diseases, including their causes, development, and effects on the body. It helps doctors understand how diseases work and how to diagnose and treat them. |
| **Predictive Modelling** | Predictive modelling is 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 the data. |
| **Radiology** | Radiology is a medical field that uses imaging techniques, like X-rays, MRIs, and CT scans, to see inside the body. It helps doctors diagnose and treat diseases by providing detailed pictures of bones, organs, and tissues. |
| **Scalability** | Scalability in relation to AI systems means the ability of the system to handle increasing amounts of work or data without losing performance. It ensures that the AI can grow and adapt as the demands on it increase. |
| **Statistical Analysis** | Statistical analysis is the process of collecting, examining, and interpreting data to find patterns and trends. It helps make sense of numbers and data to draw meaningful conclusions and make informed decisions. |
| **Virtual Assistant** | A virtual assistant is a computer program that uses artificial intelligence to help people with tasks through voice or text commands. It can answer questions, manage schedules, control smart devices, and perform various other tasks to make life easier. |

Table 3 Glossary of terms

# Appendix

## Frequently Asked Question (FAQs)

1. **What is the purpose of the HSE AI Interim Guidelines?**

The guidelines aim to support HSE staff with the knowledge and confidence to engage with AI initiatives, ensuring these initiatives align with organisational goals, meet patient needs, and comply with ethical and regulatory standards.

1. **What is Artificial Intelligence (AI)?**

AI refers to systems that mimic human intelligence to perform tasks such as data analysis, pattern recognition, and automation. It enables machines to perform activities that mimic human decision-making, particularly in pattern recognition and large-scale data processing. AI excels in tasks such as reasoning, decision-making, object detection, image recognition, and solving complex problems.

1. **How can AI benefit the HSE?**

AI can improve the quality of care, transform health service delivery, enhance operational efficiency, and support a skilled workforce by automating routine tasks and providing decision support. It can support clinical decision-making, administrative processes, and patient safety improvements.

1. **How does AI impact patient safety?**

AI enhances patient safety by reducing human error, improving diagnostic accuracy, and assisting in the early detection of medical conditions. However, AI outputs should always be reviewed by healthcare professionals.

1. **What are some examples of AI applications in healthcare?**

Examples include improving diagnostics, enhancing personalised care, supporting predictive analytics, streamlining resource management, reducing administrative burdens, and improving patient access through AI-powered chatbots and virtual assistants. AI can assist in diagnostics by analysing medical images, lab results, and clinical data. However, final diagnosis and treatment decisions must always be made by a qualified healthcare professional.

1. **What are the key considerations for adopting AI within the HSE?**

Key considerations include patient safety, compliance with regulations, ethical use, data protection and security, risk assessment, patient engagement and consent, data availability and governance, scalability, productivity improvements, and evidence base.

1. **What are the ethical considerations when using AI in healthcare?**

Ethical considerations include data privacy, bias in AI models, transparency in decision-making, and ensuring AI complements rather than replaces clinical expertise. AI solutions must comply with GDPR and HSE data protection policies. All patient data used in AI systems must be access-controlled to prevent misuse.

1. **Why is human oversight important in AI applications?**

Human oversight ensures AI recommendations align with clinical protocols and patient safety standards, promotes accountability, and helps identify and rectify biases, ensuring ethical and responsible use of AI.

1. **What are the regulatory requirements for AI in the HSE?**

The EU AI Act, GDPR, and Medical Device Regulation (MDR) outline guidelines for the development, deployment, and use of AI systems, ensuring they are safe, transparent, and accountable.

1. **How can HSE staff get support for AI initiatives?**

HSE staff can contact the HSE AI & Automation Centre of Excellence (CoE) at **AIandAutomationCoE@hse.ie**for support and guidance on AI initiatives. The CoE supports AI and automation initiatives, providing guidance, governance, and resources to ensure AI is implemented safely and effectively. Staff can submit AI ideas to the CoE, where they will be assessed for feasibility, patient safety, and alignment with HSE priorities.

1. **What is the role of the AI & Automation Centre of Excellence (CoE)?**

The CoE supports HSE staff through the process of assessing and adopting AI solutions, ensuring alignment with organisational goals and regulatory requirements, and providing a central repository for AI solutions.

1. **How does the process for adopting AI integrate with the existing ICT process?**

The process for adopting an AI solution builds upon the existing steps required for the selection, procurement, and adoption of an ICT solution. It includes additional measures to adhere to the requirements of the EU AI Act, ensuring continuous human oversight and compliance with regulatory standards. This integrated approach ensures that AI solutions meet both technological and ethical standards, enhancing the overall effectiveness and safety of AI deployment within the HSE.

1. **Will AI replace healthcare professionals?**

No, AI is designed to support healthcare professionals by automating routine tasks, providing insights, and enhancing efficiency. It will not replace human judgement or patient interactions.

1. **How can staff ensure AI is used safely and effectively?**

Staff should follow HSE guidelines, undergo training on AI applications, and always validate AI-generated recommendations before applying them in practice.

1. **What is AI literacy and why is it important?**

AI literacy refers to the understanding of AI concepts, applications, and implications. It is important for HSE staff to have a basic understanding of AI to effectively engage with AI initiatives, make informed decisions, and ensure the safe and ethical use of AI technologies in healthcare. The CoE will provide access to AI literacy training and continuous education in order to build this literacy.



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