National Framework for the Responsible and Safe Use of AI in Health and Social Care Services

Scoping Consultation Feedback Form
April 2025

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. HIQA has a responsibility to develop standards, recommendations and guidance to support the Irish digital health and health information landscape to ensure safer, better care for people using health and social care services. HIQA has been requested by the Department of Health to develop a national framework to promote and drive the responsible and safe use of Artificial Intelligence (AI) in health and social care services to ensure safer, better care for people using health and social care services. The framework will provide an overarching set of principles to drive and promote a safe and responsible approach to the use of AI in the health and social care sector in Ireland.

This scoping consultation gives stakeholders an opportunity to identify the key areas that this framework should address, to identify what will support the implementation of the framework, as well as an opportunity to provide examples around good practice from their experience. The scoping consultation will also aid in identifying additional stakeholders to be engaged with further as part of the process.

HIQA will carefully assess all feedback received and use it, along with other available evidence, to develop the draft National Framework for the responsible and safe use of AI in health and social care. Before you complete this consultation feedback form, please read the accompanying **brief** available on www.hiqa.ie and the instructions for submitting feedback on the next page.

The closing date for the scoping consultation is Friday 2 May 2025.

Instructions for submitting feedback

- When completing this form online, please ensure you scroll down the webpage and complete the form in full.
- If you are commenting on behalf of a service or organisation, please combine all feedback from your organisation into one submission form and include the details of the service or organisation.
- Please do not paste other tables into the boxes already provided — type directly into the box as the box expands.
- Please spell out any abbreviations that you use.

Data Protection and Freedom of Information

This consultation is being conducted in accordance with data protection law, including the GDPR and Data Protection Act 2018.

HIQA will only collect and store personal information during this consultation for the purposes of verifying your feedback or where you have indicated that you would like to be contacted to participate in future focus groups.
For further information on how HIQA uses personal information, please see our Privacy Notice available here. If you have any concerns regarding your personal information, please contact HIQA's Data Protection Officer on dpo@hiqa.ie.

Following the consultation, we will publish a Statement of Outcomes document summarising the responses received, which will include the names and types of organisations that submitted feedback to us. For that reason, it would be helpful if you could explain to us if you regard the information you have provided us as being confidential or commercially sensitive.

If we receive a request for disclosure of the information under FOI, we will take full account of your explanation, but we cannot give you an assurance that confidentiality can be maintained in all circumstances.

1. About you

The feedback in your consultation form will only be used to help develop the draft framework for the responsible and safe use of AI in health and social care services in Ireland, for research purposes and to inform further reports. Any information you provide will be held securely, in accordance with data protection law and Freedom of Information (FOI) Act 2014.

Please tick as appropriate:

Question 1: Are you providing feedback as:

☐ an individual

☒ on behalf of an organisation

If answering on behalf of an organisation, please provide the name of the organisation and a name and phone number for a contact person within the organisation:

Name of the organisation: Irish Medical Organisation

Name and phone number for a contact person within the organisation:

Vanessa Hetherington, Assistant Director, Policy and International Affairs

01 676 7273

Please tick as appropriate

Question 2: Are you commenting as:

☐a person who has used, is currently using or may in the future, use health and social care services

☐a staff member or other person working in a health and or social care service *Please specify your role*:

☒other *Please specify*:

The Irish Medical Organisation (IMO) is the trade union and representative body for all doctors in Ireland.

2. Feedback to inform the draft guidance

In this section, we would like to hear what you think are the key areas that the framework should address, examples of good practice, who we should engage with further during the development process, and what will support the implementation of the National Framework for the responsible and safe use of AI in health and social care services.

Question 3: What are the key areas that the framework should address? (Please indicate why they are important)

- **Human-rights & equity** – Bias detection/mitigation, accessible design, applicability to the intended setting should be openly sought, discovered and published in advance of deployment.
- A particular challenge in the Irish context is the significant number of sites of relatively small size and with differing local structures and operational guidance.
- Minority groups , where present in small numbers are particularly at risk from erroneous outputs from A.I systems. In small volume use, error detection may be difficult to detect given low relative frequency/signal strength. Post deployment, patient subset study should be strategically deployed to minimise the risk of same.
- Care should be emphasised in the area of output ranking where probability based decision outputs are ranked separately to medical utility and ethical value based outputs. Risk of probabilistic weighting drowning out medical utility and ethical value outputs should be minimised.
- **Clinical safety & effectiveness** – Deployment of AI technologies within the healthcare setting must be subject to high quality clinical and real-world evaluation to avoid the deployment of ineffective technologies, poor use of limited healthcare resources and risks to patient safety from bias, errors and unforeseen consequences. Pre-market evidence plus continuous post-deployment monitoring should be utilised – as above, noting particularly the increased risk in situations where patient / data set is less than perfectly matched to the training data set.
- **Where *distribution shift* occurs – ie real world inputs deviate from training data, 'wild-type' outputs may emerge – outputs that are**

potentially highly variable in both their number and magnitude of inaccuracy. These outputs may not have been identified or foreseen under training conditions.

- Responses on many AI systems are heavily determined by input / user factors-resulting in considerable inter user variability risk. LLM systems where deployed will respond differently depending on the exact way a query is worded and how the model was trained. Outputs while confident, may be incorrect with serious consequences
- Escalation risk may present where a suboptimal output is accepted as valid and increasingly is seen as a norm when re-presented as an output. This may also lead to feedback loop generation in actions arising from the result.
- Constraints placed on the input side in an effort to homogenise input data and increase reliability of outputs may reduce the overall ability of any system to discern between clinically or socially nuanced situations. Such issues will be immediately recognised in the fields of clinical decision making and psychiatric triage/evaluation where social, demographic, age and patient personal factors may heavily weight traditional decision outputs.
- **Data quality & governance** – Provenance, interoperability (SNOMED CT, FHIR), cyber-security, system wide integration may be limited by existing architecture and software in place . Current HSE systems have multiple cross site compatibility issues and are not generally compatible with community based systems residing largely in General Practice settings – where the majority of nationally coded clinical and prescribing data resides.
- **Transparency & explainability** – Doctors should be able to to understand the internal functionality and output of the AI system allowing them to explain to third parties what the AI system does and and why, as well as question the output or decisions made. Model logic, confidence scores, patient-friendly summaries should be provided. Issues around 'black box' workings and potential inability to forecast in advance drift in results emerging from varied data set inputs in real world use across multiple user types / sites.
- **Accountability & liability** – There should be a named owner at each stage (developer, deployer, clinician). Caution must be given to avoid payor agenda driving selection of model / software that produces outputs at odds with clinical standards / best practice as deemed by responsible clinicians. A considerable liability fog exists where a user decision/action is partly or wholly based on an AI prompt.
- **Human oversight** – AI is a decision-support; final clinical judgement must stay with medical professionals. Continuous monitoring post-deployment is essential, especially in situations where similar models are deployed across multiple and differing sites – eg the deployment of a sepsis detection or early

alert A.I. system will provide varying reliability and diagnostic accuracy across different sites given local demographics, patient cohorts, levels of acuity and on the ground structures will differ. Those sites that best match the system training data can reasonably be expected to perform closest to development studies. In sites with inputs different to the original training sites, results may vary unpredictably. Should such a system underperform, given the relatively low frequency of adverse events resulting, detection and interpretation of error at single sites may be particularly unreliable. Additional issues arise from data drift on the input side as populations or systems adopting the AI evolve with time.

- **Error mitigation measures** – rigorous validation is required across sample real-world data sets and stress testing for boundary data sets, guardrails and filtering layers (especially where outputs inform clinical management), auditability and traceability, regulatory frameworks.
- **Lifecycle risk-management** – procurement, validation, upgrade/change-control, de-commissioning. Downstream consequence in terms of transfer of risk to other departments / clinicians and workload drive arising from, for example, referral decision support algorithms or discharge planning and transfer of care with AI assisted workflow / monitoring guidance attached.
- **Workforce competence** – minimum training standards, digital-clinical roles. Particular emphasis is required in educating users with regard to requirement for AI users to use systems within their own level of competence.

  Where a user receives a guidance that is incorrect, there is increased risk of harmful follow on action if the user lacks the necessary competency to critically appraise that guidance. It is best practice that any user, should not receive and act upon an output guidance that is beyond their usual scope of clinical competence or experience.

  Patient engagement & consent – Medical Professional ethics and data preoction regulations must be upheld. Equally patients must be informed and consent to the use of AI for diagnositcs and decision-making.

- Patients should have clear information, opt-out routes, and be warned where their online activity is being data harvested by third parties – eg cookies monitoring engagements and resulting in specific healthcare based advertising being deployed. Such selective deployments may include , for example, the use of sophisticated A.I. chatbots to engage the patient on their item of query and offer privately funded pathways of unmonitored quality that may ultimately lead to offers of service or drug sales of varying and often

dubious quality. Risks arising from loss of trust by individuals or groups within the broader public should be identified and mitigated.

- **Environmental impact** – Consideration must be given to energy-efficient computing, sustainable procurement.

Question 4: What are some examples of good practice around the responsible and safe use of AI in health and social care services that you are aware of?

- **Mater Misericordiae University Hospital (Dublin)** – Aidoc imaging AI flags critical findings within 2-3 minutes, >700 pathologies caught in first six months. Healthcare AI | Aidoc Always-on AI
- **National Diabetic RetinaScreen / NEC Care** – community screening programme piloting AI triage inside a robust QA pathway (>150 sites). HSE.ie
- **Galway University Hospital** – Philips Lung-Cancer Orchestrator tracks incidental nodules and automates follow-up. Pulse+IT
- **AI systems are increasingly used in General Practice settings to assist with HER generation, transcription of notes / referral letter / patient information generation .** Real time transcription, customisable templates and data privacy compliance allow for increased time efficiency, notekeeping accuracy and reduction in administrative burden. Examples include but are not limited to Heidi Health and Zirr AI medical Scribe.

Question 5: What key organisations or individuals should we engage with when developing the framework? (We may invite them to take part in future focus groups or to comment during the consultation on the draft framework)

Insert text here

- System owners: Department of Health, HSE, Section 38/39 providers, private hospitals.
- Clinical professional representatives and regulators: IMO, Medical Council, Postgradute training faculties: RCSI, RCPI, ICGP.
- Academia & research: NUIG Digital Health, TCD ADAPT, UCC Insight, RCSI Population Health.

- Industry & vendors: Irish MedTech Assoc., start-ups and large suppliers
- Regulators & enablers: Data Protection Commission, HPRA, NSAI,
- Civil-society & patient voices

Question 6: What will support the implementation of a framework for the responsible and safe use of AI in health and social care services?

Insert text here

Supports needed for successful implementation

- Central **AI-in-Health Governance Hub** – model registry, incident-reporting, shared guidance. Clalrification re liability fog where actions arising from or partly informed by an AI system lead to harm.
- **Standard procurement clauses** – data-sharing, performance guarantees, update/change control.
- **Training & accreditation** – e-learning for frontline staff; micro-credentials in clinical AI. – Integration of AI into medical education, post gradute training and a must be balanced to preserve critical thinking skills and clinical reasoning.
- **Liability Regime** - A clear liability regime must be put in place for the use of AI in healthcare.
- **Regulatory sandbox/testbeds** with seed grants for rigorous local pilots.
- **Secure, interoperable data infrastructure** to let algorithms be validated on Irish datasets without exporting personal data.
- **Mapping tools** linking the framework to the EU AI Act and existing HIQA standards, avoiding duplication.
- **Education and regulatory measures to guard against opportunistic and target advertising arising downstream of patient engagement with HSE or other health service provide websites and APPS.** Particular emphasis is appropriate with regard to the risks posted by targeted online advertisement / canvassing of patients following on from web based engagements**.**
- For example, where a patient opens a HSE.ie article—say, "Side-effects of chemotherapy." The page contains a social-share widget such as ShareThis or a Facebook pixel. That widget quietly drops a cluster of third-party cookies (DoubleClick, Adnxs, BlueKai, etc.) and transmits the exact URL the patient is reading to dozens of ad-tech companies in real time. At this point, those firms know nothing more than "a browser at IP X just read a cancer page,". The tracker's data lands in an ad-exchange. The patients cookie ID,

IP address, device characteristics and the page context ("chemo side-effects") are broadcast to hundreds of bidders. Data brokers store a copy and tag the identifier with labels such as "likely oncology patient". From now on, any time that cookie shows up elsewhere on the web, when the patient engages with other websites, advertisers can bid to reach it and selectively deploy customised advertisements/chatbot invitations with planned downstream handoffs to sellers of remedies/pharmaceutical products etc. None of these follow on engagements are subject to regulation. In short, what starts as a single invisible pixel or cookie on a healthcare providers webpage can, through the ad-tech supply chain, morph into highly targeted canvassing aimed precisely at people with a newly inferred medical condition.

- Downstream issues arising from the above may include, Predatory or misleading outreaches, re-identification and stigma.
- For examples of tracking relation issues that might form a basis for learning **DPC 2020 cookie-sweep** – the Data Protection Commission found several public-sector sites (health included) launching third-party cookies "as soon as a user lands", and undocumented Facebook Pixels that controllers "were not aware of".
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3. Register to hear about future engagement opportunities

Question 7: Would you like to hear about opportunities to engage with us on the development of this framework, or on other future projects?

(This may include an invitation to focus groups or to comment during consultation on the future draft framework)

☒Yes ☐ No

If you answer yes to above please provide:

your name: Vanessa Hetherington, Irish Medical Organisation

email address: vhetherington@imo.ie

contact number: 01 676 7273

Thank you for taking the time to give us your views on the development of a National Framework for the responsible and safe use of AI in health and social care services in Ireland.

You can **download** a consultation feedback form at www.hiqa.ie

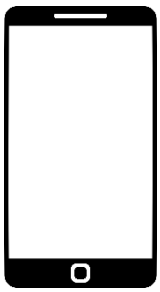
Then **email** the completed form to hist@hiqa.ie

OR

Print the consultation feedback form and post the completed form to:

Framework for the Responsible use of AI in Health and Social Care Services

Health Information and Quality Authority
George's Court
George's Lane
Smithfield
Dublin 7
DO7 E98Y



If you have any questions on this document, you can contact the HIQA Standards Team either by:

Phoning: **(01) 814 7400**

Or

Emailing: **hist@hiqa.ie**

Please ensure that you submit your form online or return it to us either by email or post by 5pm on Friday 2 May 2025