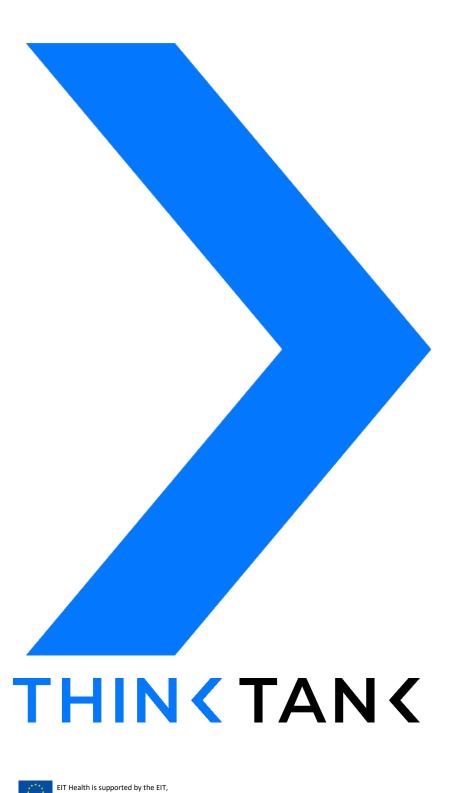
Healthcare
Workforce and
Organisational
Transformation with
AI – Enacting Change

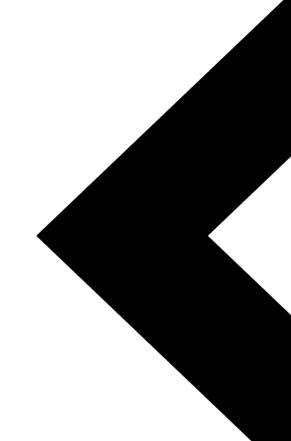


Round Table Series Meeting Proceedings

> Ireland 01.10.20



a body of the European Union





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Context for the selection of the 2020 Round Table Series Topic

In March 2020, a joint report between EIT Health and McKinsey & Company 'Transforming healthcare with AI: the impact on the workforce and organisations' was launched which aims to contribute to the debate surrounding Artificial Intelligence (AI) in healthcare but going a step further in helping to define the impact of AI on healthcare practitioners, and the implications of introducing and scaling AI for healthcare organisations and healthcare systems across Europe.

With AI in healthcare being a fast-moving field, the report provides a unique vantage point from the frontline of healthcare delivery and innovation today, and the latest view from a wide array of stakeholders on AI's potential, the real state of play today, and what is holding us back from widespread uptake and adoption.

As the report takes a broad pan-European perspective, identifying levers for change at the personnel, infrastructural and environmental levels, further exploration of how these findings and recommendations could be translated at a national level is warranted.

Through this Round Table Series, national-level decision makers representing key stakeholders that play a role in developing and implementing Al approaches at scale within existing national healthcare systems were identified to provide opinion and potential solutions that could be applied to support practitioners and providers to fully embrace the potential of Al.



Objectives of the National Round Table Meetings

In each of our seven locations, by reviewing the national infrastructural context, educational and health systemic structure, we aim to:

- > Validate the relevant barriers and enablers, as indicated within the report, for the successful adoption of AI at the Member State (MS) level, whilst also identifying similarities and differences between countries.
- > Identify how to improve 'on the ground' impact of AI by specifying obstacles to overcome and opportunities to maximise within the defined domains.
- > Outline a national (MS level) 'plan-of-action', indicating individuals, organisations, bodies or other relevant vehicles to accelerate and expedite integration of AI to drive workforce capability and organisational receptivity.

In addition, it will be useful to look at the role the EU could play in encouraging greater adoption of AI in healthcare.



Agenda and participants: Irish Round Table

Hosted by EIT Health UK/Ireland

Moderated by: Mark Kelly, Director & Chief Customer Officer, Alldus International Consulting Ltd, Dublin, Ireland

Other participants: A full list of meeting participants can be found in Appendix 1.

2020 Round Table Series Co-Chairs:

- > Charlotte Stix former Coordinator for the European Commission's High-Level Expert Group on Artificial Intelligence
- > Zineb Nouns Physician, Medical Education Specialist and HR Manager
- > Farzana Rahman CEO, London Imaging Network

Discussion topics

The agenda for the Round Tables was developed following a review of the EIT Health and McKinsey & Company report 'Transforming healthcare with AI: the impact on the workforce and organisations' and with the input and advice of the 2020 Think Tank Round Table Co-Chairs.

> Session I

Validate the relevant barriers and enablers as indicated within the report for the successful adoption of AI at the Member State level, whilst also identifying similarities and differences between regions

> Session II-V:

Identify how to improve 'on the ground' impact of AI by specifying obstacles to overcome and opportunities to maximise within these six domains:

- 1. Clinical leadership
- 2. Rethinking education and skills and investment in new roles and talent
- 3. Regulation and policy making
- 4. Funding and reimbursement
- 5. Strengthening data quality, governance, security and interoperability
- 6. Liability and managing risk

Outline a national (MS level) 'plan of action' to accelerate and expedite integration of AI to drive workforce capability and organisational receptivity



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Session I: Validate the relevant barriers and enablers for the successful adoption of AI at the Member State level

Synopsis of participant survey results

A survey was sent to all participants prior to the Round Table meeting to gather feedback on the situation in Ireland regarding AI and healthcare in relation to the six domains identified in the joint EIT Health and McKinsey & Company report.

Domain coverage Participants agreed that the six domains identified in the report were the ones likely to have the most importance regarding meaningful change or improvement in adoption of Al into the Irish healthcare system. They were asked to rank the six domains in order of priority regarding the most urgent need for change within the national infrastructure to facilitate wider utility and adoption of Al in Ireland (1 = highest, 6 = lowest) – see Table.

Drivers of change Participants were also asked comment on what the likely drivers of meaningful change would be and whether change should be driven at a national Member State level or at an EU level – see Table.

Feedback from survey respondents

Priority ranking	Drivers of change
1	Strengthening data quality, governance, security and interoperability
	> Drivers of change: Ensuring data interoperability is key, but achieving this is unlikely to happen in the short term. There is currently a lack of good quality clinical data that can be used for Al projects. Advances in the processing of unstructured data and private sector efforts are likely to improve this.
	Member State or EU level: Primarily at an EU level. A unified framework developed at an EU levels will facilitate a more straightforward approach at the Member State level.
2	Clinical leadership
	> Drivers of change: Adapting clinical leadership to include people who are positive about using Al and understand its benefits to the healthcare system. They can be the drivers to push for change and can help facilitate the adoption process within organisations.
	> Member State or EU level: Mostly at a Member State level, but EU support will be key to assure a consistent approach.



3 Regulation and policy making Drivers of change: The push to use AI within healthcare is what drives regulatory changes, provided it is supported by clinical stakeholders. Member State or EU level: Primarily at an EU level as there are collective challenges that will benefit from collective thinking. 4 Rethinking education and skills and investment in new roles and talent Drivers of change: Similar to other AI fields (e.g. the financial services sector with automation of fraud detection; the car industry with self-driving cars) that require new approaches to education to fulfil the need for new skills. > Member State or EU level: Both, but it will vary as each country faces its own challenges. 5 Funding and reimbursement Drivers of change: These will be aligned with the transition to value-based incentives in healthcare, but need to be recognized as a priority by policy makers. > Member State or EU level: Both, but the EU can provide support in terms of the transparency of the process. 6 Liability and managing risk Drivers of change: Ethics and explainable AI are now essential for any innovation in the healthcare field. Member State or EU level: Primarily at an EU level as there is a need for consistency across Member States.

- > **Stakeholder priorities** The priority of each individual domain for different stakeholders (industry, academia, healthcare providers) showed variability as the relative importance is shaped by individual challenges and therefore reflects each stakeholder's most immediate current concerns and their level of experience with Al in practice. In general, stakeholders were interested in the use of Al in healthcare, but progress was limited beyond the research phase. IT systems are not yet ready to scale to the level required for Al adoption.
- > **National Healthcare System readiness** Participants considered that the Irish healthcare system was not yet ready for adoption of AI. This is due in part of lack of access, both historically and currently, to data, which will take time to change.
- > **International Best Practice examples** Finland, Estonia, Canada and the UK were recognised as examples of best practice in adoption of AI into their healthcare systems.
- > **Post-pandemic adoption impact** As a result of the COVID-19 pandemic, there has been an Increased interest in AI, alongside greater availability of data, which has fuelled new AI initiatives.
- > **Key challenge** A key challenge identified in Ireland was getting access to data that can be used to develop AI models and algorithms due to the sensitivity of personal health data.



Sessions II–IV: How to improve 'on the ground' impact of AI

For each of the six domains, Round Table participants discussed and developed a list of actionable recommendations. They identified the people who need to be involved and proposed the actions that need to be taken, in order for these to be realised.

1. Clinical leadership

Challenges and barriers: What is not working/what needs to change in this domain?

Knowledge and experience

Introducing new innovations, including AI applications, into healthcare systems is often met with resistance as people can be reluctant to change familiar practices and may only have a basic knowledge or limited experience of the use of AI. In addition, AI is often wrongly perceived as something that will 'take over' existing jobs so it is important to change the cultural mindset and raise awareness that AI can actually be of great value and can benefit a range of healthcare roles, freeing up valuable time for direct patient care.

To drive these changes within healthcare organisations in Ireland will require clinical leadership teams who have experience of AI and a clear understanding of its benefits, which currently is often lacking. Clinical leaders who will champion AI applications are needed in each hospital. This might be improved by creating cross-functional teams, led by clinicians but including experienced data scientists and other stakeholders with AI insight who are driven by research interests. Funding will be required to build such teams and ensure they have the appropriate skills to drive AI initiatives forward. This multidisciplinary structure might also facilitate a more open-minded approach to AI and reduce some of the bureaucracy related to data access.

There may be opportunities to make links with the HSE's <u>National Doctors Training and Planning programme</u> and include Al information within professional development courses. This would also offer a good opportunity for networking.

Collaboration between innovators and practitioners

Greater collaboration between AI application innovators and clinical teams is needed both to generate new ideas and solutions, and to move those ideas forward. Innovation hubs are useful in this respect but often people don't know where to go to make the right connections. Innovation hubs therefore need more visibility to ensure good AI innovations are realised. Similarly, a greater understanding of how all the different stakeholders operate – hospitals, universities, industry, etc. – is also needed so that the correct and most appropriate connections can be made. Participants agreed on the importance of being able to connect people and engage in communication, but these opportunities need to be clear, simple and accessible. Immersion of AI



innovators into in the clinical setting to see first-hand what the challenges are to help them understand the unmet need is an approach that has been shown to be valuable.

Public—private partnerships are important for innovation creation and development but require considerable resources to be successful. More effective partnerships need to be developed reflecting the multidimensional nature of healthcare organisations. For example, in Sweden, many regional hospitals take the lead, and this has worked well. Currently, within healthcare organisations significant efforts and finances are being invested in maintaining legacy technology which is not the most efficient way forward.

Organisational culture

Organisations need to develop a more positive culture and defined strategy for Al innovation so that all stakeholders understand its importance – a more entrepreneurial mindset. There has often been conflict in this regard as health is about avoiding risk, while entrepreneurship is about taking risk.

Integrating AI offerings into existing workflows

Participants suggested that an incremental rather than an all-at-once approach is best when integrating Al applications into existing workflows as healthcare systems are notoriously slow to change. Al applications should be built in parallel with existing systems and then find the right intersection point that will benefit the business process.

Drivers for change

Participants considered that any change in AI adoption should be driven from the top down within healthcare organisations – from a CEO level – and with support from the HSE centrally. This might require incentivisation to drive change, but the example was given of hospitals that are given financial incentives by the HSE for patient outcomes such as smoking cessation.

EU versus Member State level

Both were considered necessary drivers of change. Although national initiatives are important, Ireland is more likely to move forward if the EU is pushing for change, particularly if funding is available. The EU has an important role when it comes to standards and regulation as solutions need to work across Member States. Large EU organisations, such as the International Organisation for Standardisation (ISO) and the World Wide Web Consortium (W3C), may be good sources of information regarding implementation of standards.

What is working well and best practices identified in this domain

Existing successful projects and positive experiences

> A good example of a positive organisational culture can be seen at the University of Limerick which has an initiative driven by research nurses to put forward their ideas for technology-assisted projects via a platform accessible through a mobile phone app.

Best practice examples

> In the Nordic region, many regional hospitals take the lead in terms of building successful public–private partnerships to drive AI innovation. Good examples are Karolinska Institutet in Sweden and Helsinki University in Finland.



- > As an example of top-down investment and a centralised approach, Norway's Directorate of eHealth has developed a <u>national digital health records system</u> with Accenture, which has significantly improved information sharing and access to data.
- > In Spain, private healthcare companies now use a data platform rather than EMR.

Key points

- > Clinical Leadership currently lacks the knowledge, expertise and skills to drive Al adoption.
- > Clinical staff lack a clear pathway to communicate with Clinical Leaders in order to develop innovative ideas for AI projects.
- > The realities of everyday work and reluctance to embrace change can be a barrier to clinical staff engaging with AI applications.
- > There is a need to communicate with clinical teams regarding how AI can help them in their work and free up valuable time.

Proposed actions and recommendations

Clinical leadership		
Action	Target Stakeholder(s)	
Facilitate more opportunities for collaboration between innovators, researchers and clinical teams – improve the visibility of innovation hubs and identify key stakeholders within healthcare organisations.	HSE; Health Innovation Hub, Ireland; clinical training programmes	
Use platforms such as <u>Skillnet Ireland</u> as a starting point for Clinical Leaders and other personnel to learn about AI and its benefits to healthcare with the aim of developing champions for AI within each organisation.	HSE; Clinical training programmes	
Develop clear communication channels within healthcare organisations for clinical staff at all levels to propose ideas for Al projects to the Clinical Leadership.	HSE; Healthcare organisations	

2. Education and skills

Challenges and barriers: What is not working/what needs to change in this domain?

Learning from others' experience

Adoption of AI into healthcare systems will require re-education of the workforce and preparation for new roles with different skillsets. Participants suggested that Ireland could help fast-track this process by learning from the experience of countries such and Finland and Estonia where successful adoption of AI in health is relatively advanced.



Centralised roles

Future roles will undoubtedly require good data scientists, but it was suggested that their function should be centralised to avoid having silos of individual experts in each hospital who do not communicate with each other, thereby repeating the mistakes of the past. Cross-functional training of data scientists and clinicians would be of benefit.

Education at all levels

Participants considered that there were significant advantages to educating healthcare personnel at all levels about AI and data science, from the administrative staff up to the Clinical Leadership. Data science and digital health should be incorporated into professional educational curricula for anyone entering the healthcare sector so that they can become educated users of AI and understand its benefits to healthcare systems, patients and citizens.

Undergraduate courses generally include informatics, methods of clinical research, data and biostatistics but should also incorporate AI as a part of the study of data analysis. For those who have a particular interest further courses could be developed at a postgraduate level. The HSE's National Doctors Training and Planning programme has recently appointed National Fellows for Innovation and Change as part of their Spark Innovation programme which might provide opportunities to promote AI education.

It was recognised that universities can be slow to change so this process could take several years. There is often a reluctance to change already intensive medical school curricula, however the advent of COVID-19 and the move to online learning may be an opportunity to accelerate this change.

Educational opportunities should be made accessible for all people joining healthcare organisations so they can build their understanding and interest. It is important to make the process easy and time efficient, so there should be options to take individual modules and undertake 'learning by doing', rather than signing up for long-term courses.

Greater collaboration between industry and the healthcare sector would also be of value in improving knowledge and skills, for example via <u>Health Innovation Hub Ireland</u>. Organisations such as <u>Skillnet Ireland</u>, a business support agency of the Government of Ireland, may be able to provide a partnership approach to upskilling and re-skilling of workforces.

Generation of ideas

Clinical Leadership in healthcare organisations need to allow engagement and cross-fertilisation of innovative AI ideas between the different levels. Anyone within the healthcare team needs an accessible route to be able to put forward and execute good ideas. As an example, the COVID-19 pandemic has resulted in more remote monitoring or patients, and one effect of this has been that nurses are often the ones enthusiastically driving the development of apps as they are the ones working most closely with patients.

Attracting people to careers

The term 'Al' often has a mystique – and sometime a fear – about it, so the right type of communication is important when attracting people to work in this sector or to use Al applications in their role. The focus and language of any communications should not be on the



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technology itself but on the challenges that it can help solve for the benefit of people's health and making job roles easier.

EU versus Member State level

It was agreed that education and skills initiatives need to be executed at a national level however EU support and funding was essential. The EU can provide frameworks and guidance on implementation and the correct sequence of activities.

What is working well and best practices identified in this domain

Existing successful projects and positive experiences

- > The University of Limerick has developed and implemented an online <u>Masters course in Al</u> in under a year. This is sponsored by <u>Skillnet Ireland</u>.
- > The <u>ADAPT Centre</u> in Dublin, a research centre for digital media technology, runs education programmes involving collaboration between data scientists and clinicians.

Best practice example

> Imperial College and Great Ormond Street Hospital in London both have programmes where data scientists doing PhDs can work in tandem clinical teams.

Key points

- > Academic institutions need to take the lead in terms of incorporation of AI and data science modules into educational curricula, however but financial investment from the EU is likely to be necessary to support this.
- > Courses should be made more accessible to people who do not have a data science background.
- > The current trend towards digital learning lends itself to rapid adoption of new courses.

Proposed actions and recommendations

Education and skills	
Action	Target Stakeholder(s)
Professional education institutions (medical, nursing etc) should embed AI and data science modules into their courses.	EIT Health could facilitate
The EU could provide financial incentives to Member States for education in AI and data science.	Universities; HSE; innovation hubs to help delivery training; EIT Health could facilitate



3. Regulation and policy making

Challenges and barriers: What is not working/what needs to change in this domain?

Implementing regulations

The General data Protection Regulation (GDPR) was a mandated directive and is a good example of the strength of the EU in implementing legislation when it's needed. Something similar is needed for the regulation of AI applications in healthcare. A suitable case needs to be built to obtain a directive which will require collaboration between stakeholders. Advocacy groups need to champion it at an EU level and get buy-in, which can take time to develop, then escalate to the EU parliament level (where Ireland has elected MEPs).

While Members States do require a certain degree of flexibility in terms of implementation of Al applications into healthcare systems, it is important that there are champions to drive this and clear directives regarding regulation.

Regulatory requirements and assessment of risk

The regulations for AI initiatives, in particular what specifically applies to them, are currently very unclear. In the USA, AI is assessed through a similar process to medical devices. In the EU, it was suggested that AI applications should be considered under the Medical Device Regulation (MDR).

In terms of data regulation, France seems to be leading the way and has created a national Health Data Hub, a single platform for all citizens' health data that is subject to strict data protection rules. In addition, the French data protection authority (CNIL) has adopted standards for health sector data relating to the processing and retention of personal data, including that used for research, study, and analysis in the health sector.

A hands-on practical workshop for risk assessment/regulation in Al would be beneficial. Regulation in Al should form part of education and training initiatives.

Creating an 'enabling' regulatory environment

Ideally, a national body should be formed who have appropriate expertise and can act as the guardian of health data and who can coordinate the various needs of different stakeholders: hospital, researchers, patients and citizens, etc.

Regulatory environments for AI in Estonia and Finland should be looked at as examples that are working well. In Finland, <u>SITRA</u> has the oversight of health data nationally. Due to the potential risk of data breaches and legal repercussions, it was suggested that data oversight was something that needed to be government led and be within the framework of the existing constitution of Ireland.

What is working well and best practices identified in this domain

Existing successful projects and positive experiences

> The MDR (Medical Devices Regulation) has been well adopted and understood, so it would be beneficial if Al falls under the MDR for regulation. Ireland would be well positioned to



enable/advise in this regard. Key opinion leaders for the EU regulations in this space are based at Dundalk Institute of Technology.

Best practice examples

- > The French <u>Health Data Hub</u> is a single platform for all citizens' health data, and facilitates the use of these data for research projects, by both private and public entities.
- > The French data protection authority (CNIL) has adopted standards for health sector data relating to the processing and retention of personal data, including that used for research, study, and analysis in the health sector.
- > Regulatory environments for AI in Estonia and Finland are good examples of where this is working well.

Key points

- > There is a lack of understanding regarding where AI fits into the regulations or even how to conduct a risk assessment for AI application, which is hampering progress and causing some projects to fail.
- > Al algorithms should fall under the EU Medical Device Regulation.
- > Ireland lacks a national regulatory body with a mandate and expertise in the field of Al and data science.

Proposed actions and recommendations

Regulation and policy making	
Action	Target Stakeholder(s)
Form an advocacy/lobbying group to call for a GDPR-style directive at the EU level.	Multi-disciplinary consortia
	EIT could possibly contribute to this
Obtain a clear directive from the EU as to where AI fits in terms of regulation – does it fall under the MDR?	MEPs who are engaged with the MDR
Implement a hands-on workshop to provide guidance on how to navigate the regulations for Al applications.	EIT Health could facilitate
Create a national body in Ireland to act as the guardian of health data.	HIQA; HSA



4. Funding and reimbursement

Challenges and barriers: What is not working/what needs to change in this domain?

Demonstrating value

As discussed in relation to Clinical Leadership, participants considered that adoption of AI is more likely to succeed if it is incentivised, so funding is an important issue.

Demonstrating the value of an Al application is crucial to attracting further investment. This is likely to be easier if it relates to operational efficiencies (e.g. reducing footfall in an outpatients department due to the use of a remote monitoring application), rather than if it relates to clinical needs and outcomes. Many clinical decision-support applications are still in the research phase rather than being used in clinical practice as they require full testing in clinical trials to determine if they make a clinically significant difference. However, moving forward it will be important that the business case and long-term value of Al applications is captured and communicated to stakeholders.

Organisations may be interested in AI applications, which then undergo proof of concept testing (pilot, then full operationalisation), however, the financial value that the solution can bring (in revenue and costs savings) is often not completely clear upfront, making it hard to develop good public—private partnerships and move forward with the initiative.

Investors need to have a good understanding of AI and know the expected financial return of a new AI application in order to decide appropriate investment. Not every project will generate high revenue immediately, some will generate income or savings over time, but this needs to be clear at the start. Participants highlighted that often quantifying return on investment (ROI) is difficult as the data generated by AI application has a value in itself and should be considered when calculating ROI.

Assessment of AI applications

Tools and standards are needed in order to assess Al solutions regarding their ability to deliver value and to put forward a business care for reimbursement. A more cohesive approach is needed across the healthcare sector to address this problem. It is also important to ensure that those assessing Al innovations have adequate expertise. The Irish Medtech Association has put together a Digital Working Group which might be good to connect with.

Uptake of Digital Health technology is now high as there is a clear pathway for assessment. In Germany health technology products are allowed to be on the market for one year in order to generate real-time data of their value. This is something that could be considered for Al applications.

Securing funding

It can be difficult for SMEs to secure funding for AI/data science projects in the healthcare sector and as a result it is dominated by large companies, such as IBM and Microsoft. Better insight is needed into EU funding opportunities and the categories of funding available that could apply to operational or clinical AI use cases.



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EU versus Member State level

There was no clear consensus on whether change should be driven at the EU or national level. A notable barrier is the two-tier system of the HSE and health insurance companies.

Key points

- > From an investor's perspective, there is often no clear financial value or return on investment from AI initiatives, so it is hard to progress beyond proof of concept.
- > Funders tend to have a limited understanding of AI technology making them less likely to invest.
- > Entrepreneurs often are not aware of the different funding options available to them from the EU Microsoft employs Deloitte to navigate and map out funding options for them.
- > Private companies find it hard to find the right partnerships with public entities due to the multi-level healthcare system.
- > The Al/data science sector is a difficult space for SMEs to operate in due to the large initial costs involved and the subsequent drain on resources for a limited return it is more suited to large companies, such as Microsoft.

Proposed actions and recommendations

Funding and reimbursement	
Action	Target Stakeholder(s)
Develop strategic connections that will facilitate public/private partnerships (including projects such as the EIT Health Think Tank).	EIT Health could facilitate
Develop a comprehensive map of the EU funding options available entrepreneurs in AI and data science.	EIT Health could facilitate
Secure national funding for Al use cases to demonstrate successful application.	HSE; industry; academia

5. Strengthening data quality, governance, security and interoperability

Challenges and barriers: What is not working/what needs to change in this domain?

Data access

In common with many other countries, a key problem with health data in Ireland, is that it often exist in silos, rather than being amalgamated or joined-up, so an overall perspective of the data in



its entirety is difficult to achieve. The <u>HSE</u>, which provides all of Ireland's public health services in hospitals and communities across the country, holds the majority of its data in silos which is a primarily a reflection of the personal nature of health data and the desire to preserve data privacy and security, which is likely to be slow to change.

As a result, there are often barriers to accessing health datasets to test Al applications and the approach taken is often a slow and cautious one requiring the pathways and processes of data usage to be fully defined, in conjunction with ethics committee approval, which places limits the speed of progress. Commonly audit trails for each entry/access to data are required, that involves capturing all activity that's carried out on dataset: who, when and what it was used for, so there is full traceability.

Improving access to data will require collaboration with motivated clinical leaders who understand its benefits and who can help overcome the current barriers. Where centralised data access is a barrier, federated learning may be an alternative. This decentralised machine learning approach allows the AI model to move around and learn from a range of local datasets without the need to share data.

One factor that may have an overall impact on health data access and governance is the advent of the COVID-19 pandemic as this has meant that rapid access to up-to-date, accurate health information about individuals has become even more important for clinical teams. In addition, is some countries there is a now focus on developing a decentralised model for personal information whereby each individual has their own has digital identity.

Data quality

The type and quality of health data varies considerably. Often, this relates to how data have been input and classified, and this is reflected in GP-level data which can be poor quality and difficult to work with due to its variability, so better standardisation is needed. A key barrier to AI is how the different data sets are defined, and this needs to be standardised.

Although many hospitals and community health centres in Ireland now use electronic medical records (EMR), in some cases these still exist as handwritten paper charts. It was suggested that the Irish healthcare system should look to standardise EMR across the board but move to using the more sophisticated next-generation EMR software and tools. Another significant challenge is that of interoperability as a range of different IT systems are used across healthcare organisations, including the HSE.

Efforts are ongoing to improve metadata, data standardisation and data quality, however agreed quality standards are urgently needed. While various stakeholders in AI are keen to access and use health data, the tools to do this are currently lacking. For most AI use cases data need to be cleaned and digitised before it can be used to train an AI model.

Data security

Data security should not be an issue when used to test Al applications as tokenisation algorithms are available and data can be identified and de-identified easy for analysis.

Comparison can be made with the financial services sector which manages highly confidential data securely. The knowledge therefore exists to solve the problem of data security across different sectors, but it requires investment.



Deciding ownership of data is also critical issue in this space and could influence the adoption of Al.

Interoperability

Interoperability and connectedness of systems is a common barrier to Al applications. Fast Healthcare Interoperability Resources (FHIR) is a free and open global industry standard that has been developed for passing healthcare data between systems. This is something that could be adopted for Al applications in Ireland, rather than developing new standards.

Public funding

Various centres across the world have large open-access datasets which are essential for machine learning. Participants were generally in favour of public-funding for the generation of large datasets in Ireland and for their structuring and cleaning to make them available for research, since the outcome is of public benefit even if the data are not necessarily publicly available.

It was recognised that due diligence was necessary here along with transparency regarding how the data will be used and how end-users can be involved. As discussed for the Regulation and Policy Making domain, a national body should be formed with appropriate expertise who can act as an overall guardian of health data.

EU versus Member State level

Change needs to be driven at both a national and EU level. At a national level, Ireland's <u>Data Protection Commission</u> as well as the <u>HSE</u> should be involved in any discussions.

What is working well and best practices identified in this domain

Best practice example

> UK (with <u>NHS Digital</u>, the national information and technology partner to the health and social care systems) and Finland (with its independent innovation fund, <u>SITRA</u>) are examples of good practice in supporting and pushing forward the adoption of Al applications in the health sector.

Key points

- > There is a lack of joined-up data within the Irish healthcare system it tends to exist in silos.
- > Being unable to access data to test Al algorithms is a significant problem to progression of applications.
- > Deciding who owns the data is also a significant issue.
- > Strategies for access and use of health data across EU Member States is fragmented (centralised versus decentralised).
- > Ireland has an issue with the ongoing use of paper health records in some healthcare organisations.



- > In the General Practice setting, while systems for health data are improving, they need to be better standardised.
- > Ireland could look to NHS Digital (UK) and SITRA (Finland) as examples of initiatives that have helped progress the adoption of AI into the national health systems of those countries.
- > The financial sector has already solved many data security problems could these solutions be applied to AI in healthcare?
- > The HSE and the Data Protection Commission need to be engaged in terms of driving the adoption of AI.

Proposed actions and recommendations

Strengthening data quality, governance, security and interoperability		
Action	Target Stakeholder(s)	
The EU to provide support and guidance around a data governance strategy (linked to MDR guidance).	MEPs	
Create a national body in Ireland to act as the guardian of health data.	HIQA; HSA	
Involve Ireland's Data Protection Commission and the HSE in discussions regarding AI adoption.	HSE	

6. Liability and managing risk

Challenges and barriers: What is not working/what needs to change in this domain?

Explainable Al

The need for 'explainable Al' in relation to healthcare – understanding how the Al application has reached its outcome or decision, as opposed to the 'black box' situation where there is little or no insight into the process – is a of considerable debate in relation to liability and risk.

In general, participants considered that if AI applications are not explainable with full data transparency, then people are less likely to trust their outcomes. In addition, from a regulatory standpoint, AI algorithms and the data pipeline need to be auditable. It was suggested that data scientists should build in 'privacy/explainability by design' from the beginning.

While these factors are undoubtedly important, the need for 'explainability' could also be considered as a barrier to Al adoption in some cases – after all, clinicians' decisions do not require to be explained as they are based on their accumulated knowledge – so maybe there is a need for greater compromise in order to move forward. Al applications in health are intended as decision support systems and the ultimate decision rests with the clinician based on that information.



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Accountability and liability

Accountability within the healthcare sector is something that is taken very seriously. As a result, when assessing potential risks, it is sometimes used as an excuse to avoid changing current practice. Hospital indemnity policies (issued by the HSE) do not cover Al applications. Generally, consultants will have their own private indemnity insurance.

It would be of value to involve indemnity providers and the HSE in future discussions regarding cover for the use of Al applications. In the case of medications, clinicians are insured provided they prescribe only licensed products. Al will probably be classed as a medical device and be covered by the EU MDR, so if an approved Al application is used for decision support it may be covered, but this needs to be clarified. This question could be put to the HSE as during the COVID-19 pandemic remote monitoring of O_2 levels was sanctioned and presumably this was covered by indemnity insurance.

There may be a role for the EU in creating a framework regarding indemnity for AI used in healthcare.

Key points

- > There is a lack of clarity and understanding regarding who assumes liability for AI applications, for example healthcare providers or algorithm trainers.
- > Indemnity providers need to be involved in any discussions about liability and risk of Al initiatives in health.

Proposed actions and recommendations

Liability and managing risk	
Action	Target Stakeholder(s)
Engage insurance companies and the HSE in discussions regarding liability for the use of AI applications in healthcare.	HSE; insurance complies (but would need facilitation)
Create a framework for indemnity relating to AI applications in healthcare at an EU level.	MEPs
Obtain a clear directive from the EU as to where AI fits in terms of regulation – would it fall under the MDR in terms of liability?	MEPs



Session V: Driving acceptance and utility of Al in healthcare

Participants at the Irish Round Table meeting agreed that the six domains identified in the joint EIT Health and McKinsey & Company report were those most likely to have the greatest importance in bringing about meaningful change or improvement in adoption of AI into the Irish healthcare system. They considered that the three key areas that should be prioritised were: (1) strengthening data quality, governance, security and interoperability, (2) clinical leadership, and (3) regulation and policy making.

Participants considered that in the immediate short-term, the Irish healthcare system was not ready for adoption of AI and would be well advised to evaluate and learn from the processes undertaken in countries such as Finland, Estonia, Canada and the UK that have been successful in adopting AI into their healthcare systems.

Clinical leadership currently lacks the knowledge, expertise and skills to drive AI adoption, so this is something that needs to be developed so that these leaders can act as 'champions' of AI within their organisations and communicate to their teams the benefits it can bring to their everyday work, and the healthcare system as a whole. Communication channels within healthcare organisations need to be developed so that staff at all levels are able to propose innovative ideas for AI projects.

Education regarding AI is needed across the board within healthcare to help overcome some of the misconceptions about AI applications. Any educational initiatives should be accessible to all healthcare staff, even those who do not have a data science background, and easy to undertake. Academic institutions can take the lead in this by incorporating AI and data science modules into educational curricula, but financial support from the EU is likely to be necessary to achieve this.

There was agreement amongst participants that the regulatory requirements for Al initiatives and assessment of risk, in particularly what specifically applies to them, are currently very unclear and present a significant barrier to progress. Direction on this is urgently needed from the EU. Ireland would benefit from establishing a national regulatory body with expertise in the field of Al and data science who can guide the regulatory processes and act as the guardian of citizens' health data.

In order to attract funding for AI applications beyond proof of concept, it is important that value and return on investment can be demonstrated, which can be challenging – better tools are needed to assess this. Improved methods for developing strategic connections are also needed to generate successful public—private partnerships alongside clear funding pathways that will allow SMEs to compete in a sector dominated by larger corporations.

One of the key challenges identified within Ireland was getting access to high quality data that can be used to develop AI models and algorithms due to the sensitivity of personal health data and the need for security. Data tends to exist in silos within the Irish healthcare system, causing



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problems with access, data quality, and interoperability, so this is a key priority to address. It would be beneficial to Involve Ireland's Data Protection Commission and the HSE in discussions regarding AI adoption and data usage, however support and guidance around data governance is needed from the EU to facilitate progress.

Any new innovation in healthcare needs to undergo assessment of risk. Currently, there is a lack of clarity regarding who assumes liability for AI applications when used within the healthcare system, in particularly for clinical decision support. Within Ireland, insurance companies and the HSE should engage in discussions regarding liability for the use of AI applications in healthcare, however a framework for this is needed at an EU level. Linked to this, participants considered AI applications needed to be 'explainable' with full data transparency, so that people are more likely to have confidence in their outcomes.



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Appendix 1: Round Table Meeting participants

EIT Health would like to thank the following participants for their input into the Round Table Meeting:

Name	Organisation
Advisers	
Mark Kelly (moderator)	Director & Chief Customer Officer, Alldus International Consulting Ltd, Dublin, Ireland
Donal Sexton	Adjunct Assistant Professor, Clinical Medicine, Trinity College Dublin, Ireland
Liam English	CEO, Bluemetrix, Cork, Ireland
Marie Wallace	Data Strategist, IBM Watson
Niall McDonagh	Healthcare Lead for Western Europe, Microsoft
Pepijn Van de Ven	Professor in Artificial Intelligence, Limerick University, Ireland
Ricardo Simon Carbajo	Head of Innovation & Development, CeADAR, Dublin, Ireland
Aisling Dolan	Senator and Seanad Spokesperson for Education, Higher Education, Research & Innovation, Houses of the Oireachtas, Ireland
Organisers and other attendees	
Leslie Harris	Managing Director, EIT Health UK-Ireland
Paul Anglim	Partnership Development Lead, EIT Health UK- Ireland
Adam Mohamed	Communications Manager, EIT Health UK-Ireland
Ala Alenazi	Business Creation Project Manager, EIT Health UK- Ireland
Sameena Conning	Director of External Affairs, EIT Health e.V.
Mayra Marin	Think Tank Manager, EIT Health e.V.