GLOBAL DIGITAL HEALTH
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AI for healthcare:

Creating an international approach together

December 2020

Acknowledgements

About the Global Digital Health Partnership and the NHS AI Lab

The Global Digital Health Partnership (GDHP) is a collaboration of governments and territories, government agencies, and the World Health Organization, formed to support the effective implementation of digital health services. Established in February 2018, the GDHP provides an opportunity for transformational engagement between its participants, who are striving to learn and share best practice and policy that can support their digital health systems. In addition, the GDHP provides an international platform for global collaboration and sharing of evidence to guide the delivery of better digital health services within participant countries.

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The National Health Service (NHS) Artificial Intelligence (AI) Lab, established in August 2019 (1), was set-up to streamline the development and deployment of practical applications of data-driven technologies in the NHS in the United Kingdom. The NHS AI Lab will enable the acceleration of adoption of data driven technologies, with an initial focus on: simplifying the path to regulation in partnership with regulators; seed funding and supporting the development of evidence for promising AI innovation, and creating an ecosystem for the safe deployment of AI-based data driven technologies.

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Note from the GDHP Policy Work Stream Chair and Director of the NHS AI Lab

The potential for data driven technologies to revolutionise the delivery of healthcare has been much discussed over the past few years. However, delivering on this potential at scale, across health systems is arguably still to be realised. New developments in the field of artificial intelligence (AI) represent not only an opportunity, but also a significant challenge for policymakers. Their task is to look for appropriate ways to incorporate these technologies into the delivery of care. At the same time they need to ensure the challenges presented, such as patient safety, information governance and data security are adequately addressed and resolved.

Harnessing this potential requires robust, evidence-based policymaking that can keep pace with this rapidly growing field. This report endeavors to synthesise and present accurate and contemporary information, as well as outlining current practices across a range of countries. The paper also outlines a unique opportunity for the international community to come together to develop harmonised, interoperable policies for the use of AI in healthcare.

Given the increasing role that AI is expected to play in the future, this promise extends to an opportunity for international coordination on healthcare governance and the report sets out a potential framework through which this can be achieved.

We hope that you will find the insights presented here useful for policy application in the context of your own healthcare system.

Executive summary

The use of artificial intelligence (AI) in health systems has accelerated globally with different applications being tested and put into practice across diverse areas of health system design and delivery. The COVID-19 pandemic has led to additional deployment of AI-based data driven technologies (referred to as AI-driven technologies hereafter) in health at both national and local levels. While there is information and guidance on developing AI models for medical tasks, there is comparatively less information and guidance on supporting development and implementation of AI models within digital health technologies from a policy and regulatory perspective.

This report is a step towards providing such policy guidance to the international health community. Building upon rapid literature and policy reviews, interviews with GDHP member countries, and a focus group with experts in digital health, this report provides a set of policy recommendations on how best to support and facilitate the use of AI-driven technologies within health systems. The policy recommendations are presented at a high level, so to be applicable regardless of a country's digital health maturity level. Through this, the authors hope the policy recommendations can provide a basis for the international health community to use as they develop national and regional approaches to developing and utilising AI-driven technologies in their healthcare system.

The report has four categories of policy recommendations and tracks policy issues raised throughout the life cycle of designing, developing and implementing AI into a health system:

1 **Leadership and oversight** is necessary to ensure that countries take a 'needs-based' approach to AI-driven technology development and use within their health systems and to ensure that AI-driven technology use creates maximal benefit when it comes to health outcomes. This vision of AI-driven technology use should direct oversight across all stages of the AI life cycle, along with supporting activities such as research, funding, and workforce development.

2 Policies should focus on the entire **ecosystem** of AI research and development rather than focusing on just one aspect of the life cycle. This requires measures to aggregate and link data, public-private initiatives to address skills and funding gaps, and a robust research to deployment pipeline.

3 National **standards and regulatory processes** should ensure interoperability, safety, and efficacy of AI-driven technologies in health settings. Regulation should recognise the distinct nature of AI within digital technologies, and should also be transparent and shared publicly to build a trustworthy environment.

4 **Engagement** with stakeholders such as patients, healthcare practitioners, and industry should be proactively pursued through highlighting the demonstrable benefits of specific uses of AI-driven technologies in health systems. A focus on building trust around specific uses of AI-driven technologies will ensure that AI-driven technology development and use is informed by purposeful and educated conversations with stakeholders. Working with healthcare professionals and the higher education sector to update medical education and accreditation for AI-driven technologies, as well as to co-design future AI-driven technologies, will help ensure a frictionless deployment of AI-driven technologies that complements healthcare professional workflows.

Introduction

Background

The idea that computer science techniques falling under the umbrella term of "Artificial Intelligence (AI)" could be used to provide clinical decision support is not new. The first paper conceptualising the idea was published in 1959 (2) followed by the first technical paper in 1971 (3). While clinical decision support software has been used at scale since the 1980s, it is only in recent years that the true potential for AI for healthcare has become apparent due to advances in techniques - mostly those categorised as Machine Learning (ML) (4) - and the greater availability of healthcare data in digital form.

The research community has demonstrated the potential of AI techniques to achieve the triple aim of improved health outcomes, improved experience of care, and reduced cost. It follows that healthcare systems across the world have started investing in the research, deployment and governance of AI for healthcare.

In the context of this paper, the term "AI" is an umbrella term for a range of techniques that are used to make machines complete tasks in a way that would be considered intelligent if they were completed by a human (5). The authors have employed the term "AI-based data driven technologies," abbreviated as "AI-driven technologies," to recognise that AI is rarely deployed in isolation when implemented into a healthcare system and is instead embedded into other digital technologies, products or services.

This definition of AI-driven technologies helps makes clear the possibilities for healthcare as it highlights the potential to use AI techniques to augment existing clinical capabilities in diagnosis (6-8), drug discovery (9-10), epidemiology (11), personalised medicine (6 -8), and operational efficiency (12-13). Current use cases for AI in healthcare include: decision tree techniques to diagnose breast cancer tumours (14); Support Vector Machine techniques to classify genes (15) and diagnose Diabetes Type I (16); ensemble learning methods that can predict outcomes for cancer patients (17); and neural networks for recognising human movement (18). The use of AI-driven technologies in healthcare, therefore, needs to be carefully governed through the introduction of policies, standards and regulations to ensure that their use is safe, effective and ethically viable. These governance mechanisms need to be proportionate and balance patient safety and clinician interests with promoting and nurturing innovation.

The COVID-19 pandemic, and the associated need to change the way healthcare is being delivered to halt the spread of COVID-19, has driven an uptake in the use of digital technologies to deliver and/or augment health services. Digital health and AI-driven technologies deployed so far include telemedicine for virtual consultations (19), remote monitoring of vital signs (20), AI-enabled detection of COVID-19 symptoms using chest-imaging (19), hospital resource management and load prediction using AI techniques (21), crowd temperature screening (21), and AI-accelerated diagnostic kit production (19). These applications have been deployed both at the national level as well as independently in the local contexts of particular hospitals, communities, and states. As a result of this, the uptake in AI-driven technology, especially in local contexts, has further widened the gap between development and implementation of AI-driven technologies and the policies, standards, and regulations necessary for its governance.

Problem statement

A rapid review of the literature shows that there are currently no internationally recognised policies or frameworks for the development of AI-driven technologies within healthcare. Two United Nations agencies, the World Health Organization (WHO) and the International Telecommunication Union (ITU), established a Focus Group on Artificial Intelligence for Health (FG-AI4H) in July 2018. FG-AI4H is developing a benchmarking process for health AI models that can act as an international, independent, and standardised evaluation framework, through the testing of AI models on non-publicly available test data collated and curated by the group. So far, they have started this process for 12 AI application areas (with eight additional areas lined up), including cardiovascular disease management, psychiatry, and neurological disorders (22).

The United States (US) Food and Drug Administration (FDA) has recently acknowledged that a different, more flexible approach to regulatory oversight and clinical evaluation is needed for those medical devices that utilise continuous learning and have recently published a discussion paper (23) for a proposed framework (see Case Study 3: The USA and Japan's AI-specific regulatory updates for adaptive AI for more information). The United Kingdom (UK), whilst working on adapting its medical device regulation, has developed a wider policy base for AI-driven technologies, publishing a *Code of conduct for data-driven technologies in health and care* (24), and also establishing a central programme (NHS AI Lab) for accelerating the deployment and adoption of AI-driven technologies in the NHS (25).

Given these and other recent developments, the GDHP AI Policy Work Stream Chair was tasked to look across member countries to understand where the policy frameworks existed, what they were and where the gaps lie – with a vision of developing a universal policy framework across members.

In October 2019, the UK surveyed members of the GDHP to identify who had developed (or were developing) a specific AI policy framework, either generic or specific to health, to understand approaches to regulating AI-driven technologies in healthcare, and to uncover case studies of AI-driven technology use in healthcare. This survey revealed that, internationally, research into and the development of AI-driven technologies is already outpacing the creation of supporting policy frameworks and there is significant variability in international approaches to policy and regulation (26).

Aim of research

The aims of this research were to:

- Review activity and progress in AI-driven technologies for healthcare, and associated policy mechanisms, across the GDHP member countries since the survey in October 2019;

- Identify changes in the use of AI-driven technologies that occurred during the COVID-19 pandemic; and

- Understand reasoning behind policies at play and identify gaps.

The outputs from this research inform policy recommendations for the development, deployment and implementation of AI-driven technologies that could be adopted and trialled by the international health community.

Methodology

This research included:

1. a rapid review of the academic literature;

2. an analysis of policy documents published by selected GDHP member countries;

3. semi-structured interviews exploring selected individual countries' experience of developing and using AI-driven technologies in healthcare; and

4. a focus group with professionals working in international health and technology to discuss the themes and proposed policy recommendations that arose in activities 1-3.

Papers were included in the rapid literature review following a search in Scopus, PubMed, and Google Scholar, using the search terms (1) "AI" and "policy" and (2) "AI" and "regulation," looking through results from the years 2015 to present. From the search results, 260 papers were shortlisted for abstract review, with 32 papers selected for inclusion in the literature review.
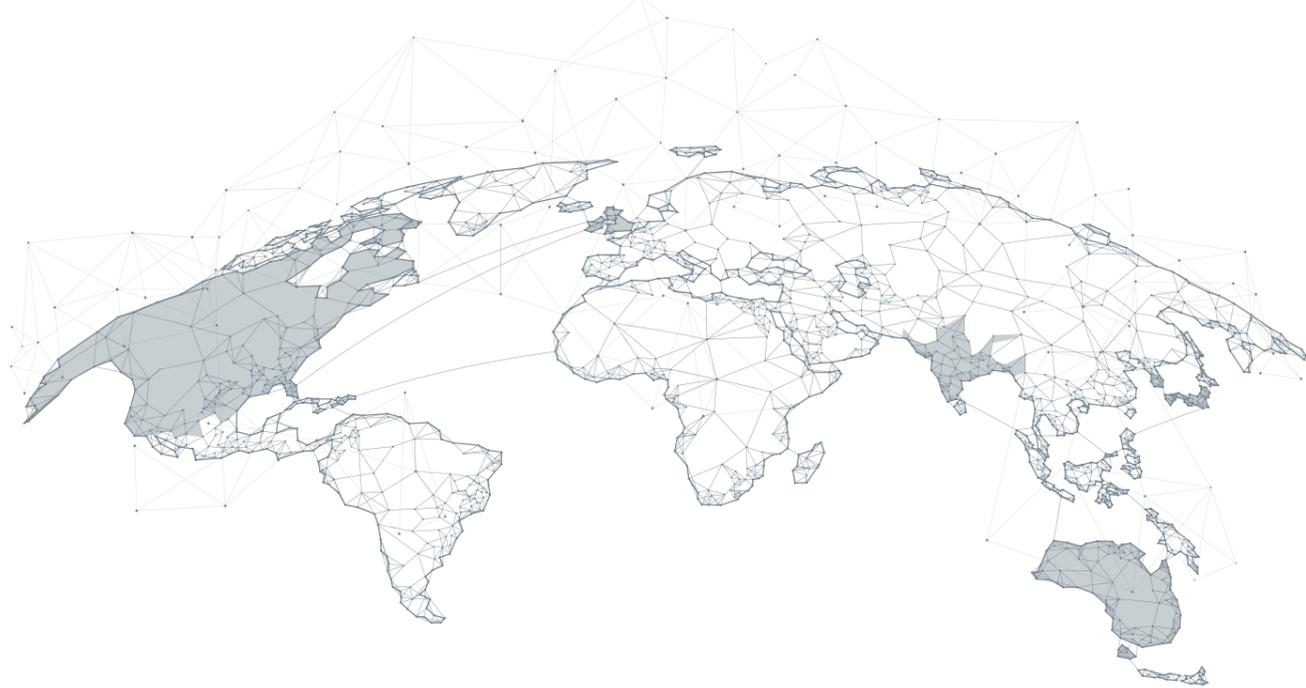
The countries included in the policy analysis were Australia, Canada, India, Japan, Republic of Korea, Singapore, the UK and the United States of America (USA). These countries were selected due to (1) having had their participation confirmed, or anticipated, for semi-structured interview, and (2) based on an informal shortlist of the most active countries within GDHP. Documents were identified following:

- a Google search, using: "[country] health AI"; "[country] health AI policy"; "[country] health AI regulation"; "[country] covid artificial intelligence", and

- exploration of available documents from a country's main institutions including health ministry, digital health agency, medical device regulators and other bodies that produce standards related to digital health technology.

16 GDHP member countries were approached to be interviewed for this research. The list of interviewees was compiled based on the original survey responses (completed October 2019), with the intention to achieve equitable distribution across the globe. 10 countries were available for an interview. Interviews were carried out by two researchers, one principal and one supporting, with interpretation services provided where requested (utilised by Uruguay and Republic of Korea). The discussion questionnaire used is available in Appendix A. Interviews were recorded and transcribed by an independent contractor.

A focus group was conducted with 10 participants following the interviews. Participants were selected based on their expertise in and/or experience working for international health and technology organisations. Some GDHP member countries unable to participate in interviews

were also invited to attend, in an attempt to ensure maximum possible representation from the GDHP. A total of six participants attended the focus group and were split into two discussion groups each facilitated by two members of the research team. Discussions were framed around four thematic areas, identified through inductive coding of the semi-structured interview transcripts.

Each interview script was coded against a tailored framework (comprising six thematic areas with associated sub-themes, available in Appendix B) developed a priori, based on the findings of the rapid literature and policy review. Each script was coded independently by two researchers followed by a thematic synthesis of the coding. The script from the focus group was also coded and synthesised against the same tailored framework.

All members of the research team analysed the synthesis activities and selected the policy areas where recommendations would be of value. Once selected, recommendations for each policy area were developed based on the aggregated research findings.

Significance for policymakers

Digital health, including AI-driven technologies, is a growing, dynamic and fast-paced industry. It is, therefore, important that comprehensive information is gathered and shared on the state of progress of research into AI and the implementation of AI-driven technologies both nationally and internationally. Additionally, it is important that decisions about the use of AI-driven technologies in health systems are aligned with the evidence, and that policymakers have the capabilities and confidence to not fall foul of the hype surrounding AI.

In order to realise the potential of AI-driven technologies, national guidelines, laws, regulations and policies, along with a culture of critical engagement, are needed to effectively govern their use in health systems. As data and AI-driven technologies are already, and will increasingly, be crossing national borders, international cooperation and consensus is required.

This policy paper outlines four strategic categories and associated policy recommendations to support policymakers to implement AI-driven technologies into their health system. All recommendations are derived from in-depth research with GDHP members and are grounded in what the authors assess as feasible for policymakers to take forward.

Policy recommendations

It is clear to the authors that any policy recommendations or frameworks for the use of AI-driven technologies in healthcare need to cover the whole AI life cycle. As shown in the simplified illustration of the AI life cycle below, the development of AI-driven technologies is an iterative process involving scoping, designing and building, then deploying the AI-driven technology with continuous monitoring, followed by improvement as and when the need arises.

In order to implement AI-driven technologies successfully within a health system, countries need to consider and support each step in the AI life cycle. This support must include: leadership and oversight; development of an enabling technical infrastructure; appropriate frameworks for sharing data; plans to build workforce capability; accepted standards and clear regulatory requirements, and engagement and collaboration with those both involved in and impacted by the development of AI-driven technologies.

Business and use-case development

Design phase

Monitoring

AI
life cycle

Deployment

Training and test data procurement

Testing and validation

Building
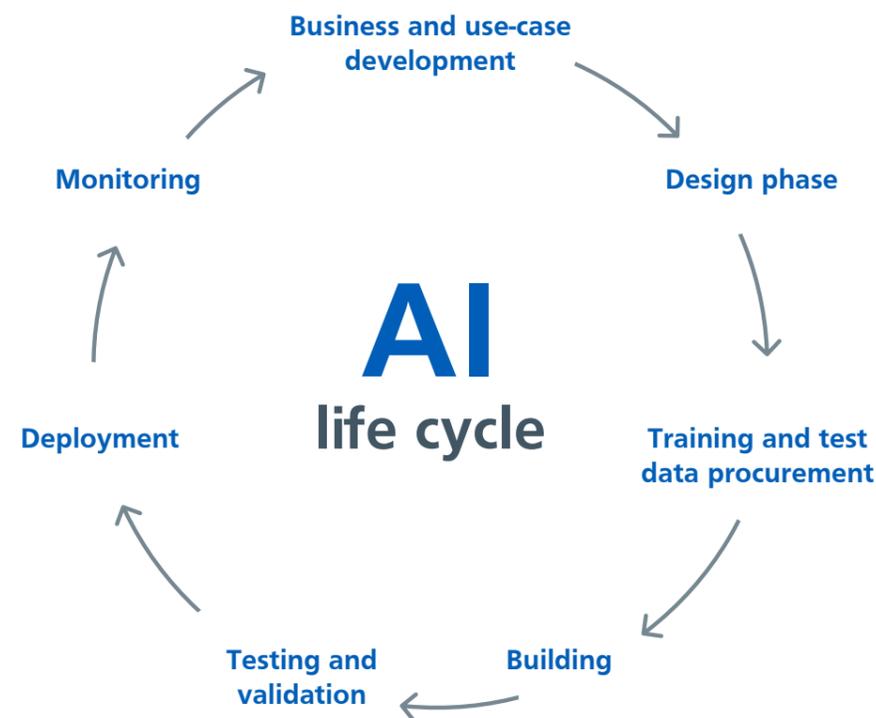
Example of a simplified AI product life cycle. Image based on and reproduced with permission from the UK's Information Commissioner's Office (27).

Leadership and oversight

The successful implementation of AI-driven technologies into health systems requires leaders who understand and appreciate the AI life cycle, the importance of defining clear use cases to justify the long term investment in AI research and development, and the required digital maturity of their health system, regulatory environment and workforce to make the most of AI techniques and products.

Policy recommendations

- **Define the need:** Countries need to take a "needs-based" approach to setting the vision and direction for the use of AI-driven technologies within their health system. A country's use of AI should be based on the problems and opportunities in the health system where AI-driven technologies could have the most impact to improve people's health outcomes.

- **End-to-end oversight:** Oversight of AI-driven technologies within a health system needs to cover the whole AI life cycle, alongside other supporting activities such as research, funding, and workforce development.

- **Provide regulatory clarity:** Regulatory clarity is required both within and between countries to enable AI developers to understand and manage the risk of introducing AI-driven technologies into a health system.

Define the need

Several countries, along with the focus group, highlighted the need for a cultural shift at the political level to bring strategic direction and drive to AI-driven technology implementation in health systems. The success of AI-driven technologies hinges on being able to demonstrate their value, effectiveness and safety in a clinical setting and across the wider health system. From interviews with GDHP member countries it was apparent that the best way to do this was to set a vision for the use of AI in the health system at a national, rather than state or provincial, level with room for local interpretation and implementation. This high-level strategic vision should be based on clearly identified areas within a country's health system where AI-

driven technologies have the potential to bring the greatest benefit to population health. As alluded to above, there should also be enough flexibility in the national vision to allow for regional interpretation and adaptation for the purposes of accuracy and context-specific implementation. This would bring a clear focus to the energies and funding for AI-driven technologies in a health system and go a long way to overcoming barriers currently experienced by developers in translating AI research into practice (discussed further within the Ecosystem section of this report).

The use of AI-driven technologies in the COVID-19 pandemic is a great example of how a needs-based approach to setting the vision and direction of AI use within a health system accelerates the translation of AI research into practice. The need to understand the impact of COVID-19 on people's lungs drove a focus on medical imaging to develop early warning systems for severe illness. As described by several countries, the potential for AI-driven technologies to meet these needs led to an improved provision in funding, access to and aggregation of health data, and political and public will for large scale deployment. As a result, there has been a significant change in the development and use of AI for medical imaging that a number of GDHP members are able to capitalise on to support ongoing understanding and management of the COVID-19 pandemic (see Case Study 1: National COVID-19 Chest Imaging Database).

National COVID-19 Chest Imaging Database

COVID-19 has accelerated the use of digital health products and services globally, often due to the ability to make up for resource gaps in diagnosis and care delivery. It has also acted as a focal point, and generated defined needs, for the health system to tackle. The National COVID-19 Chest Imaging Database (NCCID), started in England, is a centralised database containing X-ray, CT and MRI images from hospital patients across the UK. The NCCID is a NHSX (England) led programme working with the other countries in the UK for data linkages to their imaging data sets.

Within the NCCID chest-imaging data (both from individuals with COVID-19 as well as without) is aggregated so that researchers can build AI models that provide rich insights for the diagnosis, treatment and management of the disease. The approach used to develop NCCID has three main functions :

1 Acquire relevant data, including chest imaging data from PACS as well as accompanying PCR-test results, from various hospitals and care settings across the country. This data is de-identified, combined at a patient-level, and then stored in the NCCID data warehouse where it is split into a training dataset and a validation dataset.

2 Provide access to the training dataset to researchers such as universities, startups, commercial companies as well as other AI developers. These developers use the data provided to build AI models. The performance of these models is evaluated by testing them against the validation dataset (that developers are unable to access), which allows for an independent testing procedure.

3 Select and deploy the best-performing models back into clinical settings, to provide front-line aid for the COVID-19 pandemic response.

At the time of publication over 40,000 chest images collated from over 100 sites and 20,000 patients had been added to the NCCID, with an increasing number of data access requests handled. To further facilitate deployment of AI models into practice, data from NCCID is provided to developers for free. To ensure benefit to the NHS and, by extension the public, this commercial arrangement requires developers using NCCID to provide their AI model for free to the NHS for use during the pandemic. It is hoped this approach will enable faster patient assessment in clinical settings, increasing the safety and consistency of care across the UK, and allow for more efficient load handling in clinical settings.

End-to-end oversight

The oversight of and strategic vision for AI-driven technologies in health systems varied from country to country. While all countries have an organisation or body responsible for digital health, and by extension AI integration into digital health technologies, there is little consistency in how these bodies are organised, their role or responsibilities. Remit ranges from facilitating research, overseeing procurement, setting strategy, regulation, deployment of technologies, or a combination of these areas. The use of statutory powers also varies from being used to act in an advisory capacity to actually influencing legislation and standards.

Some countries had large scale research programmes related to AI, but some described a frustration in not being able to translate this research into actual deployment in clinical and operational pathways. Reasons for this include lack of funding, lack of skills, and poorly defined processes and regulation. From the interviews with GDHP member countries it appeared to the authors that there is no gold standard for the structure or format of oversight of AI in a health system, as long as the whole AI life cycle is overseen and supported to ensure safe, effective operationalisation of AI-driven technologies.

The authors recommend that countries ensure they have a responsible body or bodies that oversee each phase of the AI life cycle with clearly delineated scope and responsibilities. Countries should also place importance on identifying and putting in place the infrastructure (i.e. data storage, data sharing arrangements), skills and capabilities, and funding for each phase of the AI life cycle. This is discussed further in the Ecosystem policy recommendations.

Provide regulatory clarity

It is recommended that countries ensure regulatory clarity nationally and internationally to enable faster deployment of AI-driven technologies into health systems. In the 2019 survey, 81% of GDHP members stated that the national or regional body responsible for regulating digital health was not currently regulating adaptive algorithms in a clinical setting and none were regulating adaptive algorithms in a back-office setting. While countries are looking to change the remit of their regulatory bodies and adapt regulations to make them fit-for-purpose with regards to AI-driven technologies, this process continues to lag behind the development of AI-driven technologies.

Ecosystem

The development of AI-driven technologies requires an environment that enables innovation to be directed, catalysed and scaled, with collaboration across silos and provision of adequate resources and infrastructure.

Policy recommendations

- **Aligning innovation with healthcare need:** Setting of research priorities for AI, and associated allocation of funding, should be based on the needs of patients and the health system.

- **Access to quality data:** Countries should work to aggregate and link data from across their health and social care system, to create high quality repositories for analysis by accredited researchers, with provision of secure analytics environments and/or with appropriate mechanisms for data extraction in place.

- **Deployment pipeline:** The translation of AI research into digital healthcare applications should be supported by a robust deployment pipeline.

- **Working across sectors:** There should be exploration of public-private partnerships to address relevant skills and funding gaps that are preventing and stalling AI-driven technology development, while safeguarding the interests of patients and the health system.

Aligning innovation with healthcare need

Previous research has highlighted that lack of alignment of innovation areas and the needs of clinicians and the health system is a barrier to adoption and scaled deployment of technology (28). The research for this report confirmed that such alignment is not currently happening in the domain of AI for health, presenting a barrier - along with siloed working and a lack of funding - to translation of research from algorithmic development to clinical deployment.

Thus the need for national strategic vision outlined above should encompass AI research and development priorities, and be clearly communicated to the innovation community, to allow for prioritisation of resource allocation and alignment of funding streams.

Access to quality data
The development of effective algorithms is dependent on the data used to train and validate them. Data of sufficient quality, adequate size and representative of the intended population is required to create AI-driven technologies that work across diverse communities. Therefore, the first step in developing successful AI-driven technologies in healthcare is to ensure that quality health and health system operational data is available at scale for analysis. In order to aggregate the data available nationally, countries need to first ensure that they have the appropriate legislative and policy frameworks in place to share and link data across disparate systems. There also needs to be an appropriately secure environment for storing this data, and agreed processes in place on how data will be extracted from and/or analysed within this. Creating such national (or regional where more appropriate) data stores also allows for alignment of health data with non-personal data relevant to the wider determinants of health, such as on air quality or agriculture, providing opportunities for developing AI solutions for epidemiological and other population health issues.

There was consensus across the literature, interviews and focus group that once an AI algorithm is developed, there needs to be an agreed process to validate it. Once it has been validated and, where required, incorporated into a medical device or digital technology, an evaluation process should be undertaken. Countries may want to consider providing a validation and/or evaluation service or supporting infrastructure, including access to expertise, provision of synthetic datasets and test beds. This would not only facilitate advancement of research beyond initial stages, but bring consistent application of standards and opportunities to identify AI-driven technologies for scaling. Such a certification process would provide healthcare settings with the confidence that an AI-driven technology is safe to trial or even adopt, and could be of particular use when importing AI-driven technologies that have been developed internationally. See Case Study 2: Hong Kong's health data consolidation for AI research for an example of how access to quality data can be achieved.

## Hong Kong's health data consolidation for AI research

The importance of high quality, diverse, and aggregated medical data available for AI research and development cannot be overstated. Equally important is a means to translate AI applications that are developed from such data repositories into clinical practice. Hong Kong's Data Collaboration Laboratory, operated by the Hospital Authority, is an excellent example of an initiative that achieves both these requirements.

Hong Kong's early investments to develop and consolidate health data infrastructure in the 1990s has paid off with both comprehensive (covering a large section of their population) and deep (covering patient history over the past few decades) repositories of clinical information. To ensure that this data is leveraged for AI model training and development, the Hospital Authority in Hong Kong have established the Hospital Authority Data Collaboration Laboratory (HADCL). The HADCL has the following features:

- It anonymizes and stores a large sub-set of the data collected by the Hospital Authority – this includes demographic, diagnostic, test, radiological, and other categories of clinical data (38). This data is stored on-premise in a physical location, and is currently only accessible on-site.

- The on-site infrastructure includes a big data computational platform (and sufficient levels of compute) for state-of-the-art data storage, processing, access, governance, security, and operations (39).

Researchers can apply to access the data on-site, and will have sufficient computational resources to run analyses and develop AI models. Further, the 'research environment' model, as compared to one where data is released out of the environment, ensures that data security is prioritised.

Finally, the data sharing agreements are structured so as to ensure that HADCL has rights of use if the AI models developed are clinically useful. This ensures that a path to procurement and impact exists for models developed within this environment. Previous models, such as an AI model scanning hip X-rays for fractures, are being considered for wider clinical deployment.
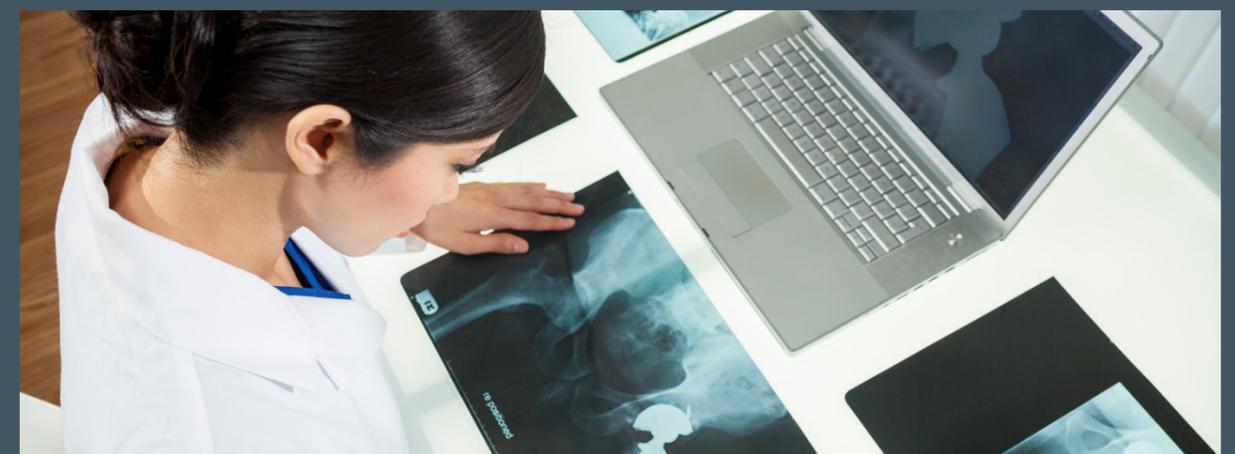
Deployment pipeline

Collaboration between policymakers, technologists, academics and healthcare professionals is required to ensure appropriate expertise is available throughout the AI life cycle. Supporting such research collaborations on a local level, e.g. within a specific hospital or city, would allow these projects to be used as examples for how AI research can be developed and translated, as opposed to relying on top down direction. This collaborative approach would facilitate progression of analytics and algorithm development into clinical practice, providing opportunities to continuously iterate and carry out 'real world' testing. This could also address the issue of AI technology developers struggling to engage and scale within health systems, while further aligning research and innovation with the needs of the local population.

The issue of research translation to deployment of AI-driven technologies described by GDHP countries during the interviews is reflected in the available peer reviewed research, with a predominance of pre clinical, early stage validation seen (29). There has been an emergence of clinical trials related to health AI evaluation, with concerns raised about potentially flawed design and inadequate reporting (29). To address this, the Consolidated Standards of Reporting Trial (CONSORT)-AI and Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)-AI Steering Group have developed AI-specific extensions to the CONSORT and SPIRIT statements. These extensions focus specifically on clinical trials in which the interventions include a machine learning or other AI component, and they are intended to function as internationally accepted standards (29, 30). Additionally, open reporting of research findings and algorithmic code will help build collective intelligence across the national and international AI communities, and could catalyse further collaboration.

The design of trials for AI-driven technology will also ensure that trial protocols account for assessment metrics across both technological considerations and human factors. Beyond assessment of direct efficacy, such a multidisciplinary approach brings opportunities to expand evaluation of AI-driven technologies to include assessment of comparative benefit and cost effectiveness. Being able to show the value of using AI-driven technologies in healthcare over or in conjunction with conventional methods is key for countries to garner further support for their development and use. As one of our focus group participants told us:

> "Most of the research we see when we think about Artificial Intelligence is, at best, you have a dataset, you derive a model, you test it in an external dataset. Now, that's not comparative efficacy and it's not cost effectiveness. Those are the things that change practice. That's what changes guidelines."

Working across sectors

This level of multidisciplinary working is not possible without the attraction and retention of talent to address current and emerging skill requirements across the AI life cycle. It was also noted by participants in our interviews and focus group that health systems need to develop an 'in house' technology workforce and/or ways to collaborate meaningfully with relevant industries. Such skills integration will provide the continuous access to the expertise required to develop, and make decisions about, AI-driven technologies. While some GDHP countries interviewed expressed hesitance in engaging in public-private partnerships with the technology and life sciences sectors, consideration should be given to how such partnerships could be established in a way that brings value to health systems and access to beneficial AI-driven technologies. Countries should have robust mechanisms in place to set up and oversee such partnerships, bringing appropriate scrutiny to the sharing of patient data, securing fair commercial terms and upholding the interests of their health system.

Standards and regulation

Ensuring the safety and quality of AI-driven technologies requires the development of rigorous standards that facilitate comprehensive regulation and are coherent across the international landscape.

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Policy recommendations

- **Clear and comprehensive AI standards:** There is a need for national standards to set minimum evidence and expectations for the entire AI life cycle, which should, where possible, be co-created with relevant disciplines and industries.
- **International standards for benchmarking:** International standards should be developed to promote collaboration, with guidance for adaptation to national contexts and accounting for socioeconomic and cultural nuances.
- **Robust regulation of AI throughout the life cycle:** Countries need to create robust regulatory processes that have a clearly defined scope and intention, recognising the distinct nature of AI-driven technologies within regulatory models and delineating responsibility for each stage of the AI life cycle. These processes need to be transparent, proactive and flexible.

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Clear and comprehensive AI standards

Clear standards should be provided for AI-driven technologies to be assessed against, allowing technology to be built towards optimal safety and quality standards rather than retrofitted at the end of the development process. Countries, therefore, need to have nationally agreed open standards for each step in the AI life cycle, with flexibility for regional and/or local implementation approaches as required. Where possible, these standards should be co-created with those who will be using them, to ensure they are comprehensive, feasible, and applicable to the relevant design and/or deployment context (31).

These standards should be treated as part of the same continuous work stream, with recognition of the interdependencies between each stage of the AI life cycle. Several countries described a disconnect between how they develop policies and standards for data and for AI-driven technologies, resulting in disharmony in both their underlying principles and implementation. Not only can this lead to stagnation of innovation in AI, but presents a risk to stringent regulation and associated risk management.

Ethical considerations and application of accepted norms should be carried throughout the AI life cycle, and metrics for inclusion integrated into AI-driven technology evaluation and regulatory processes. Very few of the countries in this research had established (or are currently developing) ethical standards specifically for the use of AI in healthcare, although several mentioned including ethical considerations in relation to data sharing and working with commercial partners in research and development. There is, as detailed in the findings of our rapid literature review, a need to distinguish AI ethics as a distinct area that requires rigorous independent standards, which are complementary to governance and regulation (32).

AI life cycle stage	Example standards and guidance to be considered
Business and use-case development	• Guidance for performing a needs assessment for health technology intervention, evaluating patient/public outcomes and/or health system need • Framework for financing of AI-driven technology development and deployment, with remuneration for its use where needed
Design phase	• Co-production and user engagement guidance
Training and test data procurement	• Human rights and data rights frameworks and/or international agreements • Data access and governance standards
Building	• Data quality standards for analysis and machine learning • Interoperability standards for IT systems
Testing and validation	• Standards for training and validation of AI algorithms, covering data and process requirements • Evaluation framework for AI-driven technologies, including the assessment of adaptive algorithms
Deployment	• Governance frameworks for utilisation of AI within healthcare setting • Cybersecurity standards
Monitoring	• Regulatory standards and assessment processes • Post market adaptation and surveillance standards

Examples of the types of standards and guidance that should be considered across the simplified AI life cycle. Please note, this list is not exhaustive.

International standards for benchmarking

There are international bodies and consortia that have been working to develop or update standards for development and deployment of AI-driven technologies in healthcare. The International Organization for Standardisation (ISO) subcommittee for AI has developed a number of frameworks for AI systems, with their use cases covering healthcare applications. While ISO standards are already used by many GDHP members, interview participants highlighted some gaps that they wish to see addressed, particularly for the implementation of AI in real world health settings. For example, we heard from Singapore:

> "I really wish that one fine day we can have ISO standards for AI...practical way, in terms that we for use and apply AI now, and explore the use of that in real life, clinical workflow, we have no choice, because it's now a necessity that we have to create a framework ourselves."
> - Singapore

Standards for deployment of health AI would need to encompass a very broad range of healthcare settings and behaviours. While this complexity presents a challenge to international level agreement, there are areas of AI deployment, in particular safety and technical aspects, that could be considered for standards development. Where standards are not the appropriate tool, policy and/or governance frameworks may suffice to provide international support for national approaches.

Additionally, the ITU and the WHO have established an "AI for Health" Focus Group (FG-AI4H), working to develop assessment standards across data (including on acquisition, annotation and storage), AI assessment and regulatory considerations for international benchmarking (33). While this initiative may not include representatives from every GDHP member country, it is a unique example of international cooperation around pressing and emerging issues related to the use of AI in healthcare, so its outputs should be considered for use. The FG-AI4H and ISO subcommittee have been liaising to ensure cohesion across content and approaches, and their standards should be accompanied with the necessary guidance and capability building for successful implementation.

There was recognition across the interviewed GDHP members that such international alignment is crucial for bringing coherence across the digital health system, while catalysing opportunities for international collaboration. This was reflected in the research findings, particularly with regards to the COVID-19 pandemic response where previous technical, regulatory and even cultural barriers were overcome to allow international collaboration. Such international co-operation is vital for the benefit of international standards to be truly realised, as without global buy-in their value is limited and there is risk of countries developing conflicting frameworks in parallel.

The creation of unified international standards would mean that developers of AI-driven technologies would not have to develop different products for different markets, potentially driving access to innovation. It would also allow countries to carry out benchmarking and 'counter checking' of any AI-driven technology already approved internationally against their own country and deployment context. Yet, there is a danger that by pushing for international agreement standards and associated regulation, these standards could end up based on the lowest common denominator (34).

This research also found that there is a continuing need for the international community to capitalise on the sharing of learning, data and methods to tackle COVID-19, and work towards interoperable data standards for AI-driven technologies in healthcare to bring benefit across global health issues. The GDHP has previously released a [white paper on interoperability](#), which outlines best practice and the most pertinent barriers to be addressed to achieve this (35). It recommends development of a Global Interoperability Maturity Model (GIMM), which can be used to assess a product's, organisation's or health system's interoperability maturity level.

As AI-driven technologies in the healthcare context will have a great impact on society, there is a need to consider even stronger forms of cooperation that address policy and governance challenges beyond specific regulatory and technological issues (36), such as upholding a population's data rights. For example, while ethical frameworks need to account for countries' cultural and social norms, their underlying principles can be set at an international level for consistency and transparency.

Robust regulation of AI throughout the life cycle

Regulation of AI and AI-driven technologies in healthcare varies between countries. It was found in both this research and the previous survey that GDHP member countries were grappling with its scope and delegation of responsibility across existing regulatory bodies and frameworks. For example, our policy review showed that when it comes to regulation of AI as a medical device, most countries whose documents we analysed have not updated their medical device standards to account for the nuances of AI. Countries also need to determine which aspects of regulation should be mandated at a national level and where local flexibility should be allowed e.g. processes such as algorithmic auditing and managing algorithmic drift should be overseen by national regulation, but carried out locally in a manner consistent with underlying risks. This all raises concern of, and at times has resulted in, aspects of regulation not being carried out fully or even of duplication of process by different entities, and possibly with variance in assessment criteria.

The previous survey of GDHP member countries delivered by the UK in 2019 also found that over 81% of countries' national or regional body(s) responsible for regulating digital health are not currently regulating adaptive algorithms in a clinical setting, with none regulating adaptive algorithms used in back-office settings (26). This means that AI-driven technologies' quality and safety assurance will degrade during its deployment. While there is no definitive approach to carrying out such proactive regulation, there are several methods currently being trialed by member countries e.g. specifying the nature of future updates from real-world learning before the model goes to market, so that if the updates match pre-approved criteria no further evaluation is needed.

It was also found that 75% of countries surveyed highlighted that their national or regional regulatory body were looking to change their remit and adapt regulations appropriately (26), with evidence from Japan and the USA of steps taken to lay the groundwork for a fundamental change of their regulatory process in order to be responsive to the challenges of AI deployment (for more information see Case Study 3: The USA and Japan's AI-specific regulatory updates for adaptive AI). This, along with the potential gaps in regulatory coverage described above, presents an opportunity for a precedent to be set on an international level that countries can align their national processes to. Countries should also work to balance regulatory rigour with flexibility that will support deployment at scale. While patient safety is of paramount importance, regulatory systems should not delay or prevent access to innovation.

The USA and Japan's AI-specific regulatory updates for adaptive AI

As more AI-driven technologies are used, it becomes increasingly important to match the cadence of the regulatory process to that of the development and improvement of AI models. This forms part of the policy recommendation outlined above, to recognise the distinct nature of AI-driven technologies within regulatory models. Two countries that are updating their overall regulatory workflows for medical devices to address this are the USA and Japan.

With the release of the FDA's discussion paper on regulatory framework modifications (23) and the Japanese Ministry of Health, Labour, and Welfare's updates on medical device regulation (40) over the last year, both countries are considering workflow changes for adaptive AI models. Adaptive algorithms, unlike 'locked' algorithms, are able to learn continuously and change their performance even after market rollout, for instance to improve overall performance or adapt to new use conditions. A continuous learning feature holds great potential for the ability of AI-driven technologies to truly transform healthcare delivery, by enabling deployed models to perform better as time passes and new information is received. However, given the novelty of this feature, existing regulation approaches are not optimised to regulate adaptive AI with most performance changes requiring the AI model to be re-evaluated entirely.

The American and Japanese approach to workflow modification gives AI developers the opportunity to articulate prospective future changes to an algorithm through a "predetermined change control plan". Such a predetermined change control plan would include information about the types of intended modifications (e.g. changes to the performance of the model, input data, intended use) as well as how they would be implemented. This predetermined change control plan would be evaluated by the regulator as part of standard pre-market evaluation of the AI-driven technology. It is intended then that subsequent changes to the AI model after market deployment can then be evaluated against the change control plan that has already been approved, and also that modifications that have been pre-approved can be unproblematically implemented.

The FDA discussion paper labels this strategy part of a "Total Product Life Cycle" (TPLC) regulatory approach, which is particularly suited for AI-driven technologies. Another aspect of the TPLC approach evaluates the manufacturers of such AI-driven technologies to ensure that they have an established quality system and abide by "good machine learning practices", which govern data acquisition, model training, tuning, and testing, and the transparency of the model (such a broad approach is also being practised in other countries, such as Republic of Korea). Such a TPLC approach is a good example of a regulatory approach that recognises the distinct nature of AI-driven technologies and starts to optimise regulatory workflows to be suited to this distinct nature.

From the research it was demonstrated that many countries are bringing in changes to regulation of AI-driven technologies in healthcare in response to the COVID-19 pandemic, including procedures for exemptions and to increase the pace of deployment. While some of these changes may be beneficial, they should still be assessed for ethical and risk impacts, and be accompanied by sunset conditions, which allow automatic termination, to prevent uncritical acceptance after the need that has arisen from the COVID-19 pandemic passes. In particular, there is a balance to be struck between realising the benefits of improved data accessibility and safeguarding data privacy. As we heard during the focus group:

> "There's been accountability commissions – and quite a few countries have set them up – saying that it's very important that systems are sunsetted and data is deleted. And then the research community said, 'No, please don't do that. We really would like that data to be able to do research on it. We don't want any identity information. We just want to be able to at least have availability for a period to be able to look at that data.'"

The focus group also raised that there is a lack of skills, capabilities and knowledge within the regulatory workforce to understand and regulate AI-driven technologies in healthcare (37),

confounding the lack of clarity on scope and oversight. This discrepancy in capability could potentially be addressed by utilising an international network for regulation, allowing countries to reach out to the network for addressing issues and refining approaches in regulation, rather than taking it all on themselves.

Whatever form a country's AI regulatory process takes, it should be created and carried out transparently. The evidence and rationale for certifying an algorithm or AI-driven technology should be publicly available, and decision making clearly communicated to patients and the health system. This is key for facilitating adoption, as we heard from Canada during our research that:

> "We don't have a proper certification process for AI and so there's a little bit of hesitancy in actually using AI in decision making, in decision support, because nobody really knows whether it really works and people are not willing to necessarily take the risk."
> - Wales

Such transparency would also serve to catalyse innovation, as uncertainty around regulation can impede the development beyond analytic models while developers seek clear guidance before building AI-based digital health products.

Engagement

The value derived from engaging the public, healthcare professionals (HCPs), industry and other stakeholders in conversations about the use and impact of AI in healthcare can be enhanced through focused engagement on how AI-driven technologies are meeting needs and engendering trust within a health system.

Policy recommendations

- **Design with users:** The patient, HCPs and relevant stakeholders need to be involved in the design of AI-driven technologies from the start to ensure the resultant product or service meets clinical, user and professional needs and complements existing workflows and experiences.

- **Demonstrable benefit:** Countries should focus on engaging and generating trust with the public, HCPs, industry, and other stakeholders through delivering AI-driven technologies that are concentrated on meeting a need(s) within the health system. Doing so moves the conversation about the public acceptability of AI away from the theoretical to one of showing the benefit and value AI-driven technologies bring to the health system.

- **Invest in education:** Countries need to invest in wider public, professional and industry education on what is classed as AI, how AI-driven technologies are currently used in the health system and other industry, and what the benefit is to the end user especially compared to conventional methods.

Design with users
It is the authors' opinion that designing AI-driven technologies for healthcare should not be treated differently to designing any other digital health intervention or technology for use by people. It is crucial that the intended recipients and people involved in the eventual delivery and maintenance of an AI-driven technology are involved in its design, development and implementation. Doing so not only builds trust and facilitates adoption, but can also improve efficacy and help identify opportunities for further growth.

Some GDHP members shared how they work closely with HCPs, ranging from clinicians to nurses to pharmacists, in their digital delivery organisations to both identify opportunities for AI (at a high level) and also to inform digital health development and delivery. Other countries have embedded understanding users, their needs, and context in best practice guidance to technology developers. A good example is the English Department of Health and Social Care's *Code of conduct for data-driven health and care technologies* that highlights the importance of considering clinical, practical and emotional factors that can impact on an AI-driven technologies uptake and ongoing use (24).

Demonstrable benefit
There was variety in who and how GDHP member countries engaged in conversations about the use of AI-driven technologies in health systems. Relevant stakeholders GDHP member countries have engaged with include patients, the broader public, HCPs, academia, industry and governmental actors. Engagement methods ranged from formal consultations to research with specific user groups to direct product feedback. How insights from these engagement activities fed into countries' national policies, standards and the actual development of AI-driven technologies also varied. Australia, for example, described the use of public engagement in the development of legislation and other countries engaged the public for local policy testing.

There was a variety of opinions on the value of the public engagement, with some countries recognising that it is often limited by the heterogeneity of the population and there is a risk of the most vocal and/or digitally literate groups monopolising the conversation, as shared by Canada:

> "… it's a fairly small portion of the population that can meaningfully contribute to a conversation like that so, frankly, a lot of that engagement ends up being sort of the loudest voices or even the folks that are sort of regularly around the table."
>
> - Canada

Another issue faced when engaging stakeholders is a clear and common understanding of what AI actually is and what that means when applied to AI-driven technologies. Examples of misconceptions, as put forward by the focus group, include AI being autonomous (instead of existing, for example, as a decision-support system), AI only being used in medical imaging, and other confusion on how much data is needed.

These misconceptions and engagement as a whole would benefit from shifting the focus from theoretical and exploratory conversations on AI for healthcare to tangible examples and/or use cases for how AI-driven technologies are actually already being used in health systems. Furthermore, as outlined in the Leadership and Oversight policy recommendations, use cases of AI-driven technology in health systems are more powerful when they demonstrate the value of AI-driven technologies to meet unmet needs in the system, improve user experience, and improve health outcomes compared to alternative methods and/or technologies.

A related recurring theme when speaking with GDHP countries was providing HCPs with opportunities to understand the value of AI integration into healthcare delivery as a means of augmenting their work and as a way to improve patient outcomes. A few countries (Italy, Uruguay) shared examples of the opportunity afforded by the COVID-19 pandemic for technology developers to show the value and usefulness of AI-driven technologies when they were deployed to meet the immediate needs of the pandemic.

Invest in education
There is consensus across GDHP countries that more education of the public on AI and its uses in healthcare is needed to accelerate trust and drive adoption. There was discussion that education on AI should also include HCPs, regulators, policymakers, industry and other stakeholders involved at different points and levels in the AI life cycle to improve their ability to use and/or make decisions about the use of AI-driven technologies in health systems.

Five GDHP member countries highlighted the apprehension and even skepticism amongst the clinical community towards the use of AI-driven technologies. Some countries believe this apprehension is driven by a concern for data quality and privacy, while others believe it to be due to a lack of understanding of AI and concern that HCPs will be replaced by AI ("robot doctors") (4).

"From what I know, I think there's some scepticism and nervousness from patients and clinicians, about the inherent risks that come with algorithms to inform decisions. So there's a lot more work to do, to engage with patients and wider clinical colleagues about how AI can help… "
- Wales

The apprehension of the clinical community for supporting the development and adoption of AI-driven technologies was also raised by the focus group. The focus group cited fear of redundancy and fear of extra work as AI-driven technologies disrupt existing workflows as contributing to this apprehension.

It is, therefore, recommended by the authors that countries consider investing in education that covers:

- What is AI including scope and example technologies;

- How AI is and could be used in digital health technologies and/or other industry products and services;

- Where AI-driven technologies are currently used in healthcare including clinical and operational pathways; and

- Why AI-driven technologies are used, including the benefits to the end user and health system compared to conventional methods.

The authors recognise that countries will have: differing access to resources, funding and time to invest in education about AI; different approaches to engaging the stakeholders as described above, and also different priorities in this space. Countries are encouraged to explore online courses and information about AI that, once vetted for quality and validity, can be signposted and/or adapted for use in-country, and may ease some of the burden of starting from scratch when investing in education.

It is also recommended, based on research with the focus group, that countries explore how to update and/or supplement their medical education programmes to help incoming HCPs be more confident and comfortable with the use of AI-driven technologies. Again, the use of tangible examples of AI-driven technologies, such as hospital resource management and load prediction using AI (21), will go a long way to demonstrating the value of AI-driven technologies to a HCPs practice and, by extension, their patients. Furthermore, building the knowledge and confidence in adopting AI-driven technologies amongst HCPs will contribute to establishing trust in the use of these technologies with patients, their families, and the wider healthcare sector. Building knowledge and confidence with HCPs can be done in a number of ways, including involving them in the evaluation of AI-driven technologies, as described by the Kingdom of Saudi Arabia:

> "The main challenge with professionals was they were feeling that AI would substitute their services. However, when we involved the physicians to evaluate a [private company decision-making health symptom checker product], they found that AI would actually augment their services. This augmentation means that the practitioner will do more, in less time and more accuracy."

Next steps

The authors recommend that this line of research is continued by the GDHP, in collaboration with other international health bodies including the WHO and ITU, to co-develop an international policy approach for AI-driven technologies in healthcare. The breadth and variation of issues and responses from GDHP countries who participated in the research indicates that more discussion and understanding is needed to refine and expand the policy recommendations outlined in this paper.

These policy recommendations could be, for example, tested with all members of the GDHP, to ensure maximum representation of differing global views, or tested by members of the GDHP in their own country with the implementation monitored and evaluated. Further research could be conducted focused on aspects of the AI life cycle not delved into here, or an even deeper look taken at some of the specific pain points outlined. From this extended research, the authors believe a core set of "universal" policy recommendations orientated around the AI life cycle could be developed and endorsed by the GDHP.

The authors encourage the GDHP to ensure this work continues to align with the work carried out by the FG-AI4H led by the ITU. It is also recommended that the GDHP continue to look to use cases in specific member countries that exemplify best practice, as highlighted in the three case studies within this paper, and to countries that are making steps towards what would be considered best practice at different stages of the AI life cycle.

The authors recognise the importance of reflecting on and learning from the rapid adoption of, investment in and use of digital health technology, including AI-driven technologies, during the COVID-19 pandemic. In particular, the digital health response to the COVID-19 pandemic highlighted further the potential for AI-driven technologies to fundamentally change how healthcare is designed and delivered, and to contribute to the delivery of safe, effective and high quality care for patients and the public.

Appendix A - Interview discussion guide

Interviews with GDHP member countries were semi-structured covering the use of AI-driven technologies in the country's health system, how AI-driven technologies are developed and regulated, and how the COVID-19 pandemic has impacted the use of this type of technology.

As the interviews were semi-structured, below are the primary questions, which are not an exhaustive list of questions asked of interview participants.

Warm up and context setting

1. Tell me a bit more about yourself, your role and your involvement in digital healthcare in your country

2. On a high level can you tell us how your country's health system is organised?

3. How are digital health technologies used in your health system?

4. How do you define AI? (with examples)

5. Walk me through if/how AI is used in healthcare in your country.

Current use of AI in healthcare

6. Who oversees and/or regulates the use of AI in your healthcare system?

7. How is AI policy created in your country?

8. How are stakeholders engaged in the development of such policies?

9. What are the barriers you face to creating national policies for AI?

10. Would you prefer to develop AI policy at a national level, or have an international standard that you can tailor to your own country's context?

Development of AI for healthcare

11. How has this landscape of AI use in your country's healthcare system developed?

12. What barriers, if any, do you face to deploying AI in healthcare? What successes, if any, have you had when deploying AI in healthcare?

13. How do you share data with:
    - Technology companies?
    - Other nations?
    - Academia?

14. How do you regulate data sharing? How do you regulate AI?

15. How have you used AI in your response to the COVID-19 pandemic?

16. Tell me about how the COVID-19 impacted your policies around:
    - Digital health
    - Data sharing
    - AI

17. Have you participated in any multinational research studies or programmes related to AI in healthcare related to COVID-19?

18. How has COVID-19 changed the use of AI in your health system?

19. Is there anything else you think we should know about AI use in your healthcare system and/or during COVID-19 that you would like to share with us?

Appendix B - Thematic analysis framework

Thematic analysis of interviews and the focus group followed the below analysis framework. The themes within the analysis framework were selected a priori following a rapid review of the relevant literature and selected policy papers from GDHP member countries.

Category	Objective	Themes / Questions
Contextual	Identifying what is already in place: • Use of AI including during the COVID-19 pandemic • Development of AI/ digital health policy/ regulation • Development of governance arrangements	- Theme 1: A, B, C, D - Theme 2: A, C, D, E, F, G - Theme 3: A, B, C, D, E, F - Theme 4: A, B, C, D - Theme 5: A, B, C
Diagnostic	Examining what exists: why has this been developed/ used, what has shaped this environment.	- Theme 1: A - Theme 3: A - Theme 5: D - Theme 6: A, B, C, D, E, F
Evaluative	Appraising the effectiveness of what exists, and what gaps are missing.	- Theme 2: B, E, F - Theme 5: D
Strategic	Identify new areas for policy intervention, and the levers for implementation. Identify practical recommendations based on challenges identified	- Theme 1: B, C, D - Theme 2: E, F - Theme 3: B, E, F - Theme 4: B, D - Theme 5: C

Theme 1: Oversight of digital health

	Sub theme	Definition
A	Structure of the health system	The way in which the health system is structured, accessed and financed, including devolution of decision making and management to a regional or local level.
B	Organisations and bodies responsible for regulating and overseeing digital health	Current and proposed bodies that oversee the development and deployment of digital health, such as government agencies, regulatory bodies etc.
C	Organisations and bodies with sole digital health delivery remit	Current and proposed bodies responsible for digital health innovation and use, such as health service bodies, government departments etc.
D	Digital health strategies and policies in place and/or in development	Strategies and policies for the use of digital health technologies, including AI, at a national or regional level. This includes those relevant to funding, deployment and data governance and security.

Theme 2: Use of AI across health systems

	Sub theme	Definition
A	Domains of AI deployment	Uses of AI across the health system including disease and disability management, service delivery and operations, clinical trials and research.
B	Barriers to AI deployment	Major barriers to the development and deployment of AI in healthcare, across all categories (including, for instance, fragmented structure of the public health system, lack of regulatory clarity, translation from research to application, etc.), and what is being considered/ deployed in response.
C	Use of AI in COVID-19 response (nationally)	The use of AI in the national pandemic response, including for direct healthcare delivery, preventative measures and strategic planning.
D	Intercountry AI collaboration (pre, during and post COVID-19)	Any collaborations that have been carried out or are ongoing with other countries in relation to the development and/or use of AI for healthcare. This also includes research collaborations being undertaken as part of the COVID-19 pandemic response.
E	Implementation of AI: technical architecture	The current technical architecture for deploying AI, and that which has been identified as a need/ priority area for further implementation.

	Sub theme	Definition
F	Implementation of AI: skills and education	The measures being taken (or being considered) to upskill the health workforce to enable AI utilisation in healthcare delivery. This includes technical upskilling more generally for AI, but also AI upskilling specific to health, alongside upskilling and readiness of healthcare practitioners to utilise AI in their workflows.
G	Consideration of biomedical ethics	The ethical issues that have been considered, and the ethical standards/ frameworks that have been upheld, when developing and deploying AI in healthcare.

Theme 3: Development of AI

	Sub theme	Definition
A	Research	Main areas of relevant research expertise, which domains are funded and how, whether it's mainly in academia or in private companies. This also includes pipelines to harness expertise and research for deployable AI.
B	Funding for AI development	Total amount of government funding for AI in health, how it has been apportioned across different AI focus areas (if available), what are the plans to top this up in the future.
C	Data access and sharing	The processes by which healthcare data can be accessed for research and innovation purposes and conditions under which data can be shared, including relevant legislation and policy instruments. This includes sharing across the health system, academia and commercial partners.
D	Consideration of data ethics	Ethical frameworks for the governance of health data that are considered and/or adhered to for the use of data in AI development.
E	Validation of AI (technical and clinical)	Validation standards and procedures for AI development in healthcare, including for software standards, data representativeness, accuracy, and clinical associations. Current and future efforts to trial/use synthetic data for validation medical AI models.

	Sub theme	Definition
F	Evaluation of AI (technical and clinical)	Evaluation standards and procedures for AI deployment in healthcare, including system and human factors. This also includes existing and future approaches to post-market surveillance for performance, safety and clinical outcomes.

Theme 4: Regulation of AI

	Sub theme	Definition
A	Responsibility and oversight of AI regulation	The major bodies that have oversight over regulating the use of AI across the health system.
B	Regulatory process	The workflows currently in place to regulate AI in healthcare, and how that is to be updated in the future. Particular attention towards unique features of AI/Software As a Medical Device as opposed to conventional medical devices and the divergence this requires from conventional regulatory processes.
C	Incentives and sanctions	Levers to enforce regulation and examples of sanction actions which may be taken if a company/individual violates regulatory process.
D	Changes in regulatory process due to COVID-19	Amendments to the regulatory processes for AI in health, including exemptions, that have been made in response to the COVID-19 pandemic.

Theme 5: Standards and interoperability

	Sub theme	Definition
A	National standards in use	National technical standards relevant to health technologies that have been developed for use.
B	International standards being use	International technical standards relevant to health technologies that are used; adhered to as a whole or tailored for the national context.
C	New standards/ changes to standards due to COVID-19	New technical standards for health technologies introduced in response to COVID-19.
D	Desire for international versus national standards	Preference amongst member countries for adherence to national versus international technical standards for health technologies.

Theme 6: Stakeholder and engagement

	Sub theme	Definition
A	Civic involvement in developing policies and process	The inclusion of insights and perspectives from patients and the public in the development of health technology policies and standards.
B	Engagement with healthcare professionals on AI development and deployment	Current and planned engagement (through consultations, etc.) with healthcare professionals on how AI is being developed and deployed in care settings, and how these approaches should be updated.
C	Engagement with academic bodies on AI development and deployment	Extent of engagement and collaboration with research and academic actors (now and planned for the future) to encourage production and deployment of health AI products, or to help shape policy.
D	Collaboration with industry	Extent of engagement and collaboration with commercial actors (current and future) to encourage production and deployment of health AI products, or to help shape policy.
E	Trust in and acceptance of AI (health system)	Current perceptions and levels of trust that actors in the broader health system associate with the use/ potential use of AI in care delivery.
F	Trust in and acceptance of AI (patients and public)	Current perceptions and levels of trust that patient and public populations associate with the use/ potential use of AI in healthcare.

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