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AI: A Use Case for Global Health

RESEARCH

DIVYA SRIVASTAVA

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ABSTRACT

Artificial intelligence (AI) has many potential applications in health care. With the growing demand for and supply of AI applications, AI policies and regulations have become a higher policy priority across governments and geographies. Alongside this, increased international collaboration aims to support decision-making, underpinned by cross-country learning and a growing evidence base. This paper summarises current challenges with respect to AI in health care, evidence generation of AI, policy development with regards to AI and proposes priority areas to support AI research and policy development. As policymakers grapple with the question of how to regulate AI health technologies, there is a clear need for international collaboration founded on robust research.

CORRESPONDING AUTHOR:
Divya Srivastava
Visiting Senior Fellow, Department of Health Policy, London School of Economics and Political Science, UK; Assistant Professor/Lecturer in Research Methods, Lead, AI and Digital Health Lab (Centre for Healthcare Innovation Research), City St.George's, University of London, UK
d.srivastava@lse.ac.uk

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INTRODUCTION

Digital health technologies have become an important part of health care systems across the world. Their rise in popularity reflects rapid advances in wireless technology and in computing power as well as increasing interest in the application of artificial intelligence and machine learning in health care (1). The World Health Organization (WHO) in their guidelines on the use of digital health interventions refer to a broad umbrella term encompassing eHealth, including mHealth or mobile wireless technologies for health, as well as emerging areas, such as the use of advanced computing sciences in 'big data', genomics and artificial intelligence (2).

In the UK, the National Institute for Health and Care Excellence (NICE) has spearheaded health technology assessment in digital health. NICE offers a similar definition to WHO, and includes applications (apps), programmes and software used in the health and care system, which may be operated as a standalone entity or be combined with other products, such as medical devices or diagnostic tests, including artificial intelligence (3).

Digital health technologies can be designed for patients, health care professionals, health system managers, and data services. They include the use of apps, programmes, software and AI in public health interventions and for specific procedures or therapeutic purposes (2). Alongside this, they can be used for administrative and operational support systems, and can be used in isolation or in combination with other products, such as medical devices and diagnostic tests. AI in particular is commonly used for diagnosis and screening, with 132 different products (medical devices and diagnostic tests) used in diagnosis or screening covering 70 different conditions (4). So far, AI has been used across the medical field, used to diagnose or screen diseases and illnesses that include cancer, heart disease, and eye disease (1).

EVIDENCE OF DIGITAL HEALTH AND AI

AI uses clinical evidence (e.g. imaging, patient histories) to assist health providers in diagnosing and optimising treatment for patients and is already saving lives (5). For instance, in radiology, AI can be used in the preliminary steps following image acquisition. Its use in image-based tasks supports diagnosis, and assists in the process of detection, characterisation and monitoring, reporting and integrated diagnostics (4). About one third of medical errors due to miscommunication could be reduced with the help of AI (6).

Most AI applications now use generative/adaptive/deep learning algorithms which learn from the data without the need for prior definitions from human experts. In particular, deep learning uses a set of techniques similar to biological neural networks, and has already proven its capacity, with algorithms in radiology improving diagnoses and clinical decision-making. Studies have shown better performance for adaptive algorithms compared with fixed (static or locked algorithms which do not change over time) in the diagnosing and treating lung and breast cancer (7, 8). These algorithms perform equally well as radiologists in the performance for detection in ultrasonography (9). But the accuracy is mixed for PET-CT in the classification of tasks of lymph node metastasis (10).

Generating evidence on how well digital health technologies work is an ongoing area of research in need of advancement. For example, only 1% of apps have an evidence base and some mental health apps for depression, low mood and anxiety show that they are efficacious only in research settings (11).

Consequently, there is an obvious need to regulate AI in the application of diagnosis and treatment. So far, the challenges have proven significant, with policy-makers grappling with them in most advanced economies (12). For example, the vast scope of adaptive AI applications in radiology brings key regulatory challenges with them. Some of these relate to standards, data access and privacy, ethics and real-time data requirements to demonstrate effectiveness. While there is current guidance for fixed algorithms used in radiology, there is no equivalent guidance for the use of adaptive algorithms. These 'deep-learning' AI applications are more difficult to regulate, as we do not fully understand how the inner layers of these applications work. This makes it a challenge not only for clinicians to interpret but also for policymakers to set out standards that assess and regulate the technology. In the U.S., the FDA does not focus on the technical components or indicated use but on the function of the technology itself –

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which means their regulatory focus is on what AI does – diagnosis or screening, for example (13).

Large patient data sets are necessary to train AI applications. But the data used in these applications can lead to unintentional biases in the results. For instance, certain groups may be absent, raising the question as to how the data relates to certain population-sub-groups, and thereby raising questions of whether the results are appropriate or valuable in all instances (14).

Developers require access to data in the development phase. The challenge for policymakers is how to permit the use of such large amounts of data while also safeguarding patient privacy. There is evidence in breast cancer of using de-identified data to circumvent some of these concerns, while others are in the exploratory stage such as the possibility of blockchains (14, 15). A jointly issued European and North American statement on the ethics of AI in radiology calls on the community to develop and adhere to a uniform code of ethics so as to provide a reliable ethical framework (16).

Data use brings with it questions of ownership of the data and raises a key legal question of responsibility when something goes wrong. The FDA approved the first device (IDx-Dr, a software program assessing the progression of diabetic retinopathy based on fundoscopic images) authorised to provide a screening decision independent of physician confirmation, where the company takes full responsibility of the ownership of the technology (17). This is currently an open question for AI applications more broadly.

These types of technologies require high quality evidence to make the case for deployment. Furthermore, NICE's recent guidance on economic impact requires that the evaluation increase in complexity if the AI carries a high financial commitment. NICE's evidence thresholds are recent and require testing to ensure these are appropriate with piloting work currently underway.

The rapid advance of digital health means that countries' strategies for digital health and to regulate the technology and systems are still in their infancy. Much of the initial thinking has failed to address the rapid adoption of digital health technologies, while it has also tended to operate in silos, with privacy authorities thinking about data concerns independently from health authorities focusing on safety, quality and efficacy. One country comparative review on health apps concluded that there is the need for governments to make quality standards visible and clear, and to create an accessible common reference for developers, users, and those who pay for their use (e.g., governments, health care providers, health insurers, patients) (18).

In the UK, the number of regulators, statutory bodies, and key stakeholders involved at various stages has led to confusion and lack of clarity over roles and responsibilities (19). No single body has complete oversight throughout the entire process, which makes policy coordination a challenge. There are core processes that all digital health technologies must complete, including data access, information governance, and ethics (21). However, these standards need to be further tested on their appropriateness, and to take into account the specific requirements of the digital health technology in question (20).

A MORE PROACTIVE APPROACH

Fragmented decision-making remains a challenge, but the growing interest in the intersection between AI and health care means there has been a shift in the decision-making landscape. First, globally, many countries are taking a proactive approach towards AI that is government-wide, bringing key institutions and stakeholders together across the health system. For example, Finland's government has brought together a range of stakeholders to work with the government on a long-term basis in constructing a digital health strategy (21). Working alongside the Ministry of Health are organisations and institutions including the data collection authority, the well-being services counties (formally the regional associations), patient organisations, and health care provider organisations. Long-term coordination and cooperation like this means that health systems are then well positioned to have their institutions work in concord to build an AI strategy.

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A study reviewing the policies of 10 European countries found that regulation of AI includes a baseline regulatory framework around data, technology, innovation, and health and human rights policy (22). In the EU, its AI Act has constructed a regulatory framework oriented around safety, innovation and the safe, protected use of data and is a helpful starting point on which to base and structure policy discussions in the region.

Third, at the international level, the Organisation for Economic Cooperation and Development (OECD) and the WHO are actively informing this policy debate, creating a space for decision-makers to come together. For example, the OECD proposes a programme of work on AI and health including policy guidance and toolkits to review and share practices across OECD countries building on its existing work on AI (5) (Box 1). The OECD AI expert group in health is an international collaborative platform to build on existing understanding across countries working on AI and bringing in the health specific requirements to support a pro-active policy space informed by evidence and underpinned by cross-country learnings (23).

The OECD AI Classification Framework was published in 2022. This framework is the product of cross-country learnings and discussions across OECD countries on how to systematically classify AI and proposed five dimensions:

- People & Planet,
- Economic Context
- Data & Input
- AI model
- Task & Output.

The framework focuses on risks that are typical of AI, such as bias, explainability and robustness,. It offers an approach to develop policies and regulations, guided by AI system characteristics that influence the technical and procedural measures they need for implementation. The dimensions of the OECD Framework for the Classification of AI Systems can also refer to stages of the AI system lifecycle to identify a dimension's relevant AI actors, which is relevant to accountability and decision-making.

Box 1 International work on AI regulation

Source: OECD (2022), "OECD Framework for the Classification of AI systems", OECD Digital Economy Papers, No. 323, OECD Publishing, Paris, https://doi.org/10.1787/cb6d9eca-en.

MOVING FORWARD ON AI IN HEALTH TOGETHER

With all the potential opportunities of AI in health care, the fundamental question of whether it is a force for good remains. Any attempt to answer this question requires grounding in the following principles to support knowledge and evidence on the use of responsible AI.

First, policymakers should understand the risk and functionality of AI technologies. For example, low-risk could relate to basic functionality such as monitoring and relatively higher risk could be around functionality that supports diagnosis and clinical decisions (24). Understanding the risks and functionality of the AI could be supported with a range of activities such as academic research, industry and academic collaboration, data privacy, governance and public engagement.

Second, countries should have evidence standards for AI technologies in place. Researchers should be encouraged, if not required, to meet certain standards when reporting how well an AI technology works. Health care economic evaluation provides methods to assess and evaluate the costs and benefits of medicines and medical technologies. In individual countries, health technology assessment bodies apply these methods to inform decisions around their use, adoption, pricing and reimbursement. For example, NICE updated its Evidence Standards Framework to include the evidence requirements for AI solutions (3) (Box 2). This work resulted in a collaborative approach, with a range of experts to reach consensus on evidence requirements.

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United Kingdom: The National Institute for Health and Care Excellence (NICE) in the United Kingdom updated their evidence standards framework (ESF) for digital health technologies to include evidence requirements for artificial intelligence (AI) and data-driven technologies with adaptive algorithms (3). The ESF consists of twenty-one standards, mapped to the phases of the digital health technology product lifecycle: design factors, describe value, demonstrating performance, delivering value and deployment considerations. A consistent framework provides structure and predictability for innovators to be able to develop solutions that will be interoperable with the UK's digital health ecosystem.

Box 2 UK case study

Third countries should monitor AI models. We examined current national efforts and future opportunities to systematically use large amounts of data and evidence in decision-making in five countries (Estonia, Finland, Germany, Italy and the United Kingdom) (25). The findings include a framework for systematic use of large data underpinned by the agreement for a robust regulatory environment to monitor and benchmark these technologies as they continually evolve. Countries have in the past already established post-market surveillance systems for medicines and medical devices to monitor their safety and quality (26). We propose the notion of 'digital health technology vigilance' to be established in countries which would build on these existing systems. We argue that adopting a total product lifecycle (TPLC) approach may better align the data needs and requirements for decision-makers in policy and regulatory circles, manufacturers, providers and patients because it adopts a wholistic approach as the technology evolves. For example, at proof of concept, certain evidence requirements could be established and then once the AI is on the market, appropriate evidence requirements could be set out for monitoring (Figure 1). Developers should be encouraged to continue to evidence the effectiveness of their technology in the real-world so policymakers can better understand what they do (Figure 2) (13).

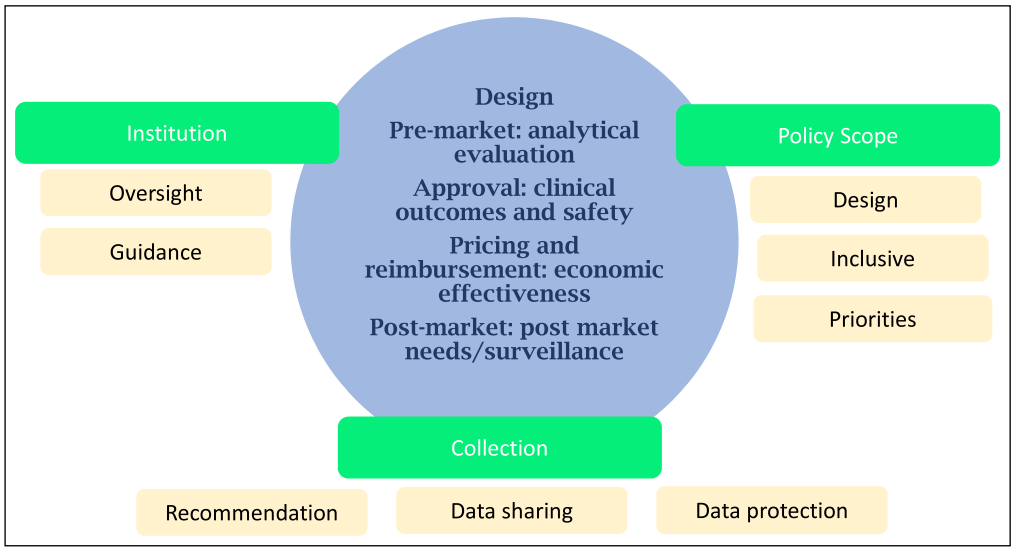

Figure 1 Building block principles to support a total product lifecycle approach.

Source: **Srivastava D, Henschke C, Virtanen L, Lotman E-M, Friebel R, Ardito V,** et al. Promoting the systematic use of real-world data and real-world evidence for digital health technologies across Europe: a consensus framework. HEPL. 2023; 18(4):395–410. DOI: https://doi.org/10.1017/S1744133123000208.

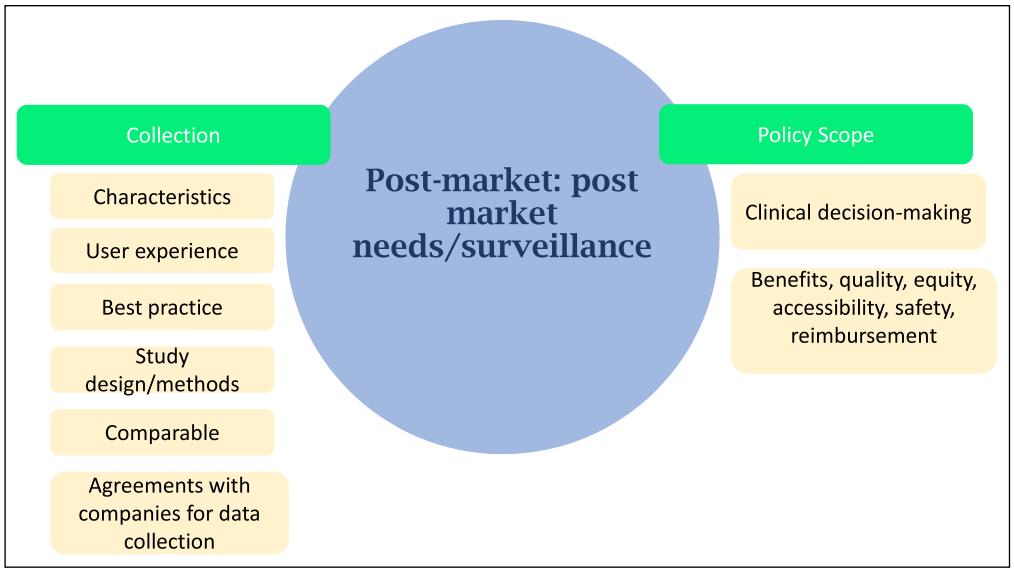

Figure 2 Principles for post-market surveillance and digital health technology vigilance.

Source: **Srivastava D, Henschke C, Virtanen L, Lotman E-M, Friebel R, Ardito V,** et al. Promoting the systematic use of real-world data and real-world evidence for digital health technologies across Europe: a consensus framework. HEPL. 2023; 18(4):395–410. DOI: https://doi.org/10.1017/S1744133123000208.

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More evidence, robust studies and transparent reporting of AI are needed. Our recent work on how to establish standards in economic evaluations for AI is a step towards improving the calibre and benchmark AI related research outputs (27). The Consolidated Health Economic Evaluation Reporting Standards (CHEERS) were last updated in 2022, and our work on the evidence requirements for reporting the economic evaluation of AI technologies supplements this. The standards are a checklist for study authors to address when conducting economic evaluations. The reporting items recommend that study authors are clear about the health intervention uses of AI in the title and abstract, making the purpose clear, as well as its mechanism of action, development, and validation in terms of the implications of relevant ethical and equity considerations.

The way in which AI effects care decisions, quality, and, ultimately, health outcomes should be considered carefully and reported clearly (24). For example, costs, such as fees or ongoing subscriptions, staff training or changes in service reorganisation, should be reported because of their resource implications. As AI models learn over time, what they learn and how has implications for economic evaluations. This includes how future learning effects are measured and captured in an economic evaluation, and how future versions of models and software are implemented and paid for. All of these effects and developments are important considerations for authors to report and decision makers to consider (24).

Researchers and academics have an important role to play in evidence generation of AI technologies in health care. We have established an international platform – the Economics of Digital Health Technology Special Interest Group. This is a platform for health economists and researchers internationally in the intersection of digital health and AI and health to come together to connect, collaborate, identify and develop, research, policy relevant output and teaching curriculum based on a model of collaboration (28).

DISCUSSION AND CONCLUSION

AI in health care is an active area of ongoing learning, requiring ways to test solutions and its applications. There is increased research and policy focus in AI nationally and internationally to build resilient health systems and it is important to leverage this momentum (20). The first implication is that policy makers should have a position on how to handle large volumes of data arising from AI technologies. There is a growing consensus that monitoring AI technologies is required, and policy makers should be pro-active to support *digital health technology vigilance* with appropriate policy and regulatory systems in place.

Second, policy makers should support and encourage evidence generation of AI technologies with key stakeholders in their health systems: patients, developers, regulatory authorities, policy makers, researchers. They could fund models of collaboration, which would generate evidence and insight from a range of important perspectives. Collaboration could bring many benefits in this respect. Potential actions include listening and engaging with the public about concerns, public reporting and monitoring of AI performance, setting out rules about data control, incentivising and overseeing adherence to responsible AI principles, and monitoring solutions and applications once they are available on the market.

Third, policy makers should avoid reinventing the wheel and engage in cross-country learning. AI technologies are increasingly targeting numerous country markets, and this trend is expected to continue. International collaboration will complement national efforts. This might include a focus on operationalising policies and codes of conduct that remove the unnecessary and unhelpful barriers to responsible AI while ensuring appropriate risk classification frameworks, mitigation measures and oversight are in place. As market activity continues to grow, tracking progress with the development of AI policy will improve our knowledge (5).

International forums offer a space for sharing collective learning to identify policy responses, joint problem solving and co-ordination to mitigate barriers. AI has become the use case for ongoing collaboration and learning in global health. Indeed, this brings to the fore a notion articulated almost two decades ago around a model for continuous learning by the National Academy of Medicine – learning health systems – an approach that resonates when it comes to AI in health and is more pressing now than ever before (29).

COMPETING INTERESTS

The author has no competing interests to declare.

AUTHOR AFFILIATIONS

Divya Srivastava orcid.org/0000-0001-5135-3592
Visiting Senior Fellow, Department of Health Policy, London School of Economics and Political Science, UK; Assistant Professor/Lecturer in Research Methods, Lead, AI and Digital Health Lab (Centre for Healthcare Innovation Research), City St.George's, University of London, UK

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