



Accelerating effective and safe adoption of artificial intelligence in the healthcare system

FORUM workshop on Friday 17 March 2023

Jointly hosted by the Academy of Medical Sciences and the Royal Academy of Engineering



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Executive Summary

Artificial intelligence (AI) – algorithms with the ability to perform tasks that would normally require human intelligence – has great potential to improve health outcomes, reduce health inequalities, and improve the efficiency of the healthcare system, as shown by examples of early adoption of AI-based technologies in health and care. However, technical, regulatory, and cultural challenges mean that the adoption and scale-up of AI-based healthcare technologies is currently slow, piecemeal, and variable across the UK. To realise the benefits of AI in health and care more widely, a more streamlined, end-to-end pathway for safe and effective adoption of AI in the healthcare system needs to be developed, with the aim of overcoming these challenges.

In March 2023, the Academy of Medical Sciences' FORUM and the Royal Academy of Engineering co-hosted a meeting to explore the barriers and enablers to adoption of AI in the UK healthcare system and propose potential solutions. Discussions particularly focused on lessons learned from the experiences of early adopters of AI in the healthcare system, particularly for decision support. The meeting was part of the Academy of Medical Sciences' FORUM programme of events, bringing together representatives from academia, industry, and health and social care along with patients, regulators, and other relevant stakeholders. The following four key themes emerged from workshop discussions:

1. Improving confidence and trust of end-users

A lack of confidence amongst end-users (including healthcare practitioners (HCPs) and patients) in AI-based health technologies is a barrier to adoption. This may be caused by **aversion to perceived risk** (e.g. of trying a new technology), concerns about health data privacy and cyber security, and/or a lack of analysis of the limitations of the existing standard of care, which are often caused by shortages of skilled staff.

Participants suggested the following activities to help overcome the lack of confidence and trust of end-users in AI:

- Early and continued engagement with end-users to help ensure AI-based health
 technologies developed are useful, relevant, and effective. This should include meaningful
 patient involvement and engagement in technology development where relevant. Early
 end-user engagement can also help foster early adopters, who with support can act
 as ambassadors for the use of AI by the healthcare workforce.
- **Training** HCPs to improve their digital literacy, data skills and understanding of the benefits and limitations of AI.

- Communicating clearly and accessibly about how an AI-based health technology
 functions and particularly communicating the evidence of its effectiveness in real-world
 settings. Using informational material co-developed by end-users and case studies,
 early adopters, and organisations that represent 'trusted voices' can make this
 communication more effective.
- **Building a trusted system** for the regulation of AI-based health technologies. In particular, more clarity is needed about where **accountability and liability** lie regarding the use of AI-based health technologies.
- Having **informed dialogue with the wider public about AI** by, for example, setting up a national forum and/or citizen panel(s).

2. Enhancing the capacity and capability of the healthcare system to adopt AI

Cultural, workforce and infrastructure challenges are preventing widescale adoption of AI-based health technologies in the healthcare system. Participants suggested:

- Providing capital investment and financial incentives to improve the digital infrastructure of healthcare bodies.
- Standardising digital systems and data collection to improve interoperability and make scale-up of AI-based health technologies across different healthcare settings easier.
- **Developing high-quality, diverse datasets** on which to train AI-based health technologies. The introduction of **standards for data quality, collection and metadata** would help ensure the utility of the datasets.
- Ensuring HCPs have the training and capacity (in terms of time and resources) to adopt
 and use AI-based health technologies for decision support. Appointing digital
 innovation teams and creating career pathways for experts in use of AI in health in
 the healthcare system would help ensure the healthcare system has the capability to
 adopt AI.
- **Fostering a culture of useful and usable innovation** in the healthcare system (e.g. by introducing an innovation mandate for healthcare bodies).

3. Better defining the governance of AI in health, including evaluation, reimbursement, regulation, and standards

For any technology in the healthcare system, evaluation of effectiveness and costeffectiveness is essential. This is a particular challenge for AI. Participants highlighted that:

- The effect of AI can be **context specific** so comparators to judge effectiveness should be chosen with particular care.
- The performance of AI-based health technologies can change over time due to changes in the target population. Robust mechanisms for **post-market surveillance** that include a clear procedure for responding where AI-based health technologies are not or are no longer performing as intended will be important, including potentially withdrawing the technology. Evidence from such surveillance mechanisms can be used to improve the performance of an AI-based health technology, as well as monitoring and maintaining it. **Collaboration between regulators and developers** will be important to ensure surveillance mechanisms are robust yet risk-proportionate for different kinds of AI.
- Economic models that capture and quantify the value of any system-wide effects of AI-based health technologies need to be developed. Communicating the systemic value proposition to commissioners and central government will be important to ensure support for the technology is sustained.
- It would be useful to raise awareness of the guidance provided by the AI and Digital

- **Regulations Service** for developers (and adopters in due course).
- **Standards** for the adoption of AI-based health technologies in the healthcare system could help ensure consistency of performance.

4. Building a system ready for AI adoption

Due to the potentially system-wide effects of AI-based health technologies, it is important to take a systems approach to adoption and scale-up to realise their potential benefits and avoid unintended consequences. **A systems approach** involves taking into account the relationships between a broad range of relevant stakeholders and sub-systems. Participants noted that using this approach to gain awareness of any bias in the system can help **turn a risk of exacerbating health inequalities into an opportunity to address them**. Fragmentation in the healthcare system can lead to inefficiencies. Participants suggested mechanisms to improve the collaboration and coordination of the healthcare system's approach to adoption of AI:

- A consistent commercial architecture could allow 'smarter' commissioning and help avoid duplicative commissioning of AI-based health technologies between healthcare bodies or between multiple NHS Trusts.
- High-level strategic direction, resource and infrastructure would help facilitate
 adoption of AI-based health technologies, particularly to capitalise on potential systemwide benefits and ensure interoperability. This could include the development of a data
 and AI strategic roadmap by government working with partners across the healthcare
 system.
- **Demand signalling from the healthcare system** at a local, regional, and national level would be useful to enable developers to design technologies that address key problems in the healthcare system.

The complex and potentially wide-ranging impacts of AI-based health technologies on healthcare mean that **coordination and cross-sector collaboration** will be essential in developing principles for safe and effective adoption that are broadly applicable while being useful in specific contexts.

Introduction

Artificial intelligence (AI) – algorithms with the ability to perform tasks that would normally require human intelligence – is set to transform healthcare across the world. Currently, the potential to embed AI within healthcare systems raises significant opportunities as well as risks that require thoughtful consideration for development. AI-based technologies in healthcare systems range in their functionality from therapeutic and/or diagnostic capabilities to AI-enabled operational software (technology that improves operational efficiency, 1 such as triaging and productivity tools). The potential benefits of safely and effectively adopting these AI-based health technologies include: improved patient stratification, risk prediction, and methods of healthcare delivery, with positive impact on patient outcomes; faster, more efficient clinical trials; improved efficiency of patient flow through healthcare systems; improved workforce capacity; among others.

There is a window of opportunity for the UK to become a world leader in AI-based healthcare to the benefit of patients, while also generating revenue through spin-off companies and the export of AI tools worldwide. The resulting potential diversity of AI-based health technologies in terms of characteristics, risk and function poses numerous challenges for regulators, purchasers, and end-users. Some such technologies are starting to be adopted in the healthcare system, particularly those that act as decision aids to HCPs. Enhancing the pathway to the safe and effective adoption and scale-up of AI-based technologies could help ensure timely benefits are realised to patients and healthcare systems whilst avoiding unintentional harm.

This workshop on 'accelerating effective and safe adoption of artificial intelligence in the healthcare system: learning by doing' was hosted jointly by the Academy of Medical Sciences' (AMS) FORUM programme and the Royal Academy of Engineering (RAEng). The workshop was chaired by **Professor Jackie Hunter CBE FMedSci**, Board Director, OI Pharma Partners Ltd, and **Professor Lionel Tarassenko CBE FREng FMedSci**, Professor of Electrical Engineering, University of Oxford. Participants were drawn from a broad range of interests, including regulators, developers, researchers, the healthcare system, and end-users (including healthcare practitioners and patients). The aim of the workshop was to consider the ongoing adoption of AI-based health technologies in the healthcare system and potential solutions to adoption challenges, as well as how to scale up existing enablers, from multiple perspectives.

Workshop discussions focused on AI-based technologies currently being designed for, and implemented in, healthcare systems in the UK, particularly tools to support clinical decision-

 $^{^{1}}$ Joshi, I & Cushnan, D (2020). A buyer's guide to AI in health and care. NHS England - Transformation Directorate.

 $https://transform.england.nhs.uk/media/documents/NHSX_A_Buyers_Guide_to_AI_in_Health_and_Care.pdf $2 The Academy of Medical Sciences (2019). {\it Artificial intelligence and health.} https://acmedsci.ac.uk/file-download/77652269.$

making and operational software (e.g. to help with triaging). They also focused on lessons learned from real-world examples of adoption. As they are not currently deployed within the healthcare system, the following applications of AI were not explicitly discussed, though the lessons that came out of workshop discussions may be applicable: health and wellbeing products with in-built AI systems that are marketed directly to the general public, AI identification of novel drug targets or new areas for biomedical research, and AI-based health technologies as autonomous decision makers. Issues related to the deployment of autonomous AI-based systems in healthcare are discussed in a separate report by the Royal Academy of Engineering titled 'Towards autonomous systems in healthcare'.³

This report summarises the scene-setting presentations, case studies, and the following breakout group discussions that considered the major challenges and potential responses to accelerating the safe and effective adoption of AI in the healthcare system. The workshop agenda, attendee list and a glossary can be found in Annexes 1, 2 and 3 respectively.

Opinions expressed in this report do not necessarily represent the views of all participants at the event, the Academy of Medical Sciences, or the Royal Academy of Engineering.

³ Royal Academy of Engineering (2023). *Towards autonomous systems in healthcare*. https://nepc.raeng.org.uk/media/mmfbmnp0/towards_autonomous_systems_healthcare_report.pdf

Using AI-based health technologies in the healthcare system: learning from experience

Pioneering use of AI-based health technologies in the healthcare system shows the great potential of AI to improve health outcomes and the efficiency of the healthcare system. However, these experiences also highlight some of the system-wide challenges of regulating and adopting AI-based health technologies, as discussed in the opening talks.

Challenges of adopting an integrated AI-based technology into the UK healthcare system

Dr Indra Joshi, Director (Health, Research & AI) at Palantir Technologies, highlighted data infrastructure as one of the key challenges to adopting AI-based health technologies in the healthcare system in the UK. She noted that the UK data landscape is currently siloed, but that, if used optimally, more connected data could be used by AI and other digital tools to improve health outcomes. The formation of integrated care systems in England might help address this.

Dr Joshi noted that AI can be built into powerful cross-sectoral operational tools, as demonstrated by the work carried out on Palantir's software platform, Foundry, during the COVID-19 pandemic. The operationalisation of the AI models within the platform enabled policymakers to act on information such as vaccine or personal protective equipment distribution. However, in part due to current infrastructure of the system (the healthcare system) in which they are being implemented, AI-based health technologies are increasingly being used as point solutions, which address only one defined problem in one part of a care pathway. While use as a point solution can be impactful, Dr Joshi argued this both underutilises AI and leaves those technologies vulnerable at points of the AI lifecycle (e.g. in the way data is captured or changes to the model code).

Dr Joshi concluded by asking how the healthcare sector can operationalise AI, creating an end-to-end pathway to make use of AI 'business as usual', as has been done in other industries, such as manufacturing. She noted the need to move past conversations about data access, the need for practical solutions, and the need to develop an end-to-end pathway from development to adoption and implementation.

Reflections from a regulatory perspective

The regulatory system in the UK is streamlining processes to better regulate and enable adoption of AI-based health technologies in the healthcare system. **Clíodhna Ní Ghuidhir,** Principal Scientific Advisor for AI, National Institute for Health and Care Excellence (NICE), described the role of the recently established AI and Digital Regulations Service.

The aim of the Service is to develop a clear framework with a streamlined and trusted regulatory pathway to support developers and end-users in the adoption of safe and effective AI and digital health technologies that provide meaningful, user-centred benefits. Their website provides a central platform (www.digitalregulations.innovation.nhs.uk) to communicate the regulatory and access pathway to both developers and adopters of AI and respond to any queries from those groups as well. This is a multi-agency collaboration between NICE, the Medicines and Healthcare products Regulatory Agency (MHRA), the Health Research Authority (HRA), and the Care Quality Commission (CQC). The advice provided by the site is developed in collaboration, considering the remits and requirements of stakeholders across the entire pathway.

The regulatory system for AI-based health technologies in the UK is complex. The AI and Digital Regulations Service has identified five 'pillars' important for the safe and effective adoption of AI-based health technologies:

- Product regulation.
- Data and research governance.
- Service provision regulation.
- Professional regulation.
- Clinical and cost effectiveness.

Ms Ní Ghuidhir also highlighted laws and the activities of existing organisations that underpin these pillars to protect and define human rights, public sector equalities, good practice, and policy. These include the Equality Act 2010 and the Human Rights Act 1998, and NHS Digital Clinical Safety Team, the National Data Guardian, the General Medical Council, and the UK National Screening Committees. Ms Ní Ghuidhir noted that the Service operates within this larger landscape rather than trying to replace it.

There is still a large scope for improvement and further streamlining of the pathway. Ms Ní Ghuidhir concluded by reflecting on key issues and opportunities that could be considered by participants and the wider sector to further refine the pathway for adoption of AI-based health technologies. These included:

- Determining how issues with an AI-based health technology can be identified and addressed.
- Considering the impact of end-user perspectives of AI on adoption.
- How real-world outcomes data can be used to demonstrate value (both clinical and economic) and identify issues.
- Privacy-enhancing technologies.
- Local fine-tuning of AI models for clinical services.
- Health economic frameworks for AI.

Both Dr Joshi and Ms Ní Ghuidhir highlighted the complexity of the adoption pathway, with various and diverse stakeholders, which presents a significant challenge for the successful adoption and integration of AI technologies into the UK healthcare system. However, despite the challenges, some AI-based technologies have already been adopted into parts of the UK healthcare system. Three examples of AI-based health technologies that have been or are being adopted (case studies 1-3) were presented, each highlighting the barriers and enablers along the pathway to adoption and beyond.

Case Study 1: Using an AI deployment engine to enable faster and easier adoption of medical AI apps in hospitals

Mr Haris Shuaib, Consultant Physicist & Head of Clinical Scientific Computing, Guy's & St Thomas' NHS Foundation Trust, identified some of the key challenges and requirements for the deployment of AI in the hospital environment, including that:

- Deployment of AI-based health technologies is complex and takes a long time. This often leads to the prioritisation of faster delivery over perfect technical specification, resulting in technical debt. This means mechanisms to iterate and improve AI-based technologies after they have been adopted should ideally be built in.
- Interoperability is a particular challenge for healthcare due to heterogeneity in clinical systems, patient data models and language used.
- Evidence generation (including the infrastructure to test and provide feedback in a realworld environment) needs to be at the centre of the design, since many deployments of AI still require research and analysis of their performance.
- The lack of comprehensive information available to clinicians responsible for buying AI tools, which limits uptake.

Mr Shuaib described how AI deployment platforms can help overcome some of these challenges and support adoption of AI-based health technologies. An example of this is AIDE, which Mr Shuaib and colleagues developed within the healthcare system. AIDE is a medical AI operating system for hospitals that provides a single streamlined platform to allow the efficient deployment of AI-based tools to the relevant clinicians and seeks to address some of these challenges. The AIDE platform integrates AI models into clinical workflows and provides for their scalable adoption in the healthcare system, acting as an "orchestrator" of AI solutions to simplify the end-user experience. AIDE enables enhancement of existing systems and aims to shorten the timeframe from identification of a problem to development of an AI solution from 18 months to a few months. AIDE also provides a clinical review system (by a human user), which allows HCPs to send data on errors back to developers. Currently installed in King's College Hospital, AIDE will be rolled out across 10 NHS hospital trusts by September 2023.

From a broader perspective, Mr Shuaib pointed out that the lack of digital infrastructure in the UK healthcare system is at odds with that in people's everyday lives. He highlighted some potential reasons for the lack of digital maturity, including a lack of national policy, platforms, skilled people and proven value.

Case Study 2: An AI solution to support over-stretched skin cancer diagnostic pathways

Dr Dan Mullarkey, Medical Director, Skin Analytics & NHS General Practitioner, Hetherington Group Practice, outlined the complexities facing dermatology services in the NHS. Despite a greater than 200% increase in referrals for potential skin cancers in the last 10 years, the number and capacity of dermatologists has not seen a corresponding increase, with 24% of consultant dermatology posts unfilled and over 10% of patients waiting over 4 weeks for a dermatology appointment.

Skin Analytics has developed an AI solution, DERM, that can screen and triage potentially

cancerous skin lesions through the capture of images from a medical device by healthcare assistants or photographers, thereby addressing the bottleneck for consultant dermatology appointments.⁴ DERM has been deployed by eight NHS partners since 2020. Initial evaluations show: over 2,200 cancers were identified, exceeding the 95% sensitivity targets originally set, found with 100% specificity for skin cancer and 72.9% sensitivity for benign lesions, and as of January 2023, over 22,000 unnecessary face-to-face appointments avoided. Earlier cancer diagnosis and treatment is generally associated with better health outcomes for patients. Reducing unnecessary appointments saves time for both patients and stretched dermatology services and allows resources to be focused on the patients who need it most.

DERM could be used both as a point solution when integrated into current primary or secondary care pathways and/or as a disruptive solution when introduced into the community to create a new care pathway.

Dr Mullarkey acknowledged the support received through grants and accelerators as significant enablers to the development and adoption of DERM in healthcare settings. He also identified some key challenges in developing and deploying the system:

- Status quo bias: at present, there is no quantification of the risk of continuing with current practices and the impact this would have on skin cancer incidence and prognosis. This information is needed to evaluate the need for improvements, such as those that could be afforded by the widespread adoption of AI tools. Mechanisms used to generate this evidence should also be suitable to monitor the effectiveness of AI-based health technologies through post-market surveillance.
- A lack of clear ownership of the problem and collaboration between relevant stakeholders, sitting across primary and secondary care, has been a point of friction for the adoption of AI technology. The formation of integrated care systems (ICSs) presents an opportunity to coordinate, clarify and communicate the benefits of the technology.
- Variable and limited support for change development throughout the NHS. The adoption of new technologies, pathways and ways of working takes time, effort, and resources.

Case Study 3: Using AI to understand human behaviour, create efficient services, and challenge health inequality

Mr David Hanbury, Founder & Co-Chief Executive Officer, Deep Medical, noted that there are 8 million hospital appointments missed every year, with an absolute cost of £1.2 billion and a wider health cost to the 7 million people on an NHS waiting list. 'Did Not Attends' (DNAs) can be due to many reasons, many of which are based on underlying inequalities, such as single parents or carers struggling to find childcare so they can attend appointments and elderly people unable to travel without assistance. Missing two hospital appointments/year has been associated with an eight-fold increase in mortality in people with mental health issues. Mr Hanbury noted that non-attendance at a hospital appointment could be considered a risk marker for increased mortality and morbidity, making it an attractive prospect for investment to find a solution.

⁴ Phillips M, et al. Assessment of Accuracy of an Artificial Intelligence Algorithm to Detect Melanoma in Images of Skin Lesions. JAMA Netw Open. 2019 Oct 2;**2(10)**:e1913436. doi:10.1001/jamanetworkopen.2019.13436 ⁵ McQueenie R, et al. Morbidity, mortality and missed appointments in healthcare: a national retrospective data linkage study. BMC Med **17**, **2** (2019). https://doi.org/10.1186/s12916-018-1234-0

DM Schedules is an AI tool to identify patients at high risk of missing a hospital appointment and provides suggestions on how to improve attendance, such as prompts from medical receptionists, assistance with travel, and/or more convenient appointments. The tool also makes suggestions to fill appointments that would otherwise have been left vacant. The AI tool has been developed using historical data points and a variety of practical, local data, such as weather and road conditions. Crucially, Mr Hanbury emphasised, the model does not use sensitive health data or personally identifiable information.

Mr Hanbury highlighted the importance of performance management for AI-based health technologies. He discussed the mechanisms they have in place to allow live feedback from users and to account for data drift.

He also addressed the need for the engagement of both individual specialties and grass root support to drive the success of any AI-based system that can save money due to missed appointments.

Barriers and enablers to rapid, effective and safe adoption of artificial intelligence in the healthcare system

AI-based health technologies have the potential to enhance healthcare delivery. However, at present, their adoption and use in the healthcare system is slow, piecemeal, and variable across the UK.

Meeting participants agreed that the safe and effective adoption of AI-based health technologies in appropriate scenarios presents significant opportunities to healthcare systems. These include:

- Improving health outcomes, for example by supplementing healthcare practitioner (HCP) expertise and/or reducing variation sometimes observed between different HCPs.
- Reducing pressure on the healthcare workforce, for example by saving HCPs' time spent on routine tasks, enabling them to spend more time with patients.
- Improving the efficiency of the healthcare systems, for example by reducing missed appointments.
- Reducing health inequalities, for example by targeting interventions to those that need them most.
- Addressing particular priorities that would benefit from system-wide analysis, for example public health and preventive healthcare.
- Creating jobs, for example related to use of digital technologies in healthcare settings.

However, there are many challenges to the adoption of AI-based health technologies in healthcare systems. During the meeting, participants used a systems approach to consider the challenges to the safe and effective adoption of AI.^{6,7} To do so, they first identified the wide range of stakeholders involved, their level of interest and influence regarding adoption of AI-based health technologies, as well as their needs and motivations. This exercise enabled participants to consider the challenges through a complex web of perspectives, and combined with the perspectives from the case study talks of early adopters, informed discussions of barriers and enablers, and proposed next steps to make progress in this area. The following four key themes, explored in more detail below, emerged from the discussions:

⁶ Royal Academy of Engineering (2017). *Engineering better care: a systems approach to health and care design and continuous improvement.* https://raeng.org.uk/media/wwko2fs4/final-report-engineering-better-care-version-for-website.pdf

⁷ The workshop used some resources and approaches included in the University of Cambridge's toolkit: Clarkson, J (2022). *Improving Improvement: a toolkit for Engineering Better Care*. https://www.iitoolkit.com/Improving Improvement 1-28.pdf

- Improving confidence and trust of end-users.
- Enhancing the capacity and capability of the healthcare system to adopt AI.
- Better defining the governance of AI in health, including evaluation, reimbursement, regulation, and standards.
- Building a system ready for AI adoption.

Improving confidence and trust of end-users

Participants highlighted that a lack of confidence in using AI-based health technologies, particularly amongst end-users and decision-makers, was a main barrier to adoption of these technologies in the healthcare system. This lack of confidence can lead to a lack of trust in the effectiveness of AI. End-users in this case often include HCPs, patients, and healthcare administrators (e.g. medical receptionists), depending on the technology in question. Others involved in the deployment of an AI-based health technology can also be considered end-users (e.g. hospital IT teams, commissioners). Adding to the complexity, participants noted that each stakeholder group is likely to be heterogeneous, with differing needs, motivations, and drivers, partly depending on the type of AI-based health technology. For example, some patients might find the way an AI-based technology diagnoses their potentially cancerous skin lesion as highly salient and of interest, but they may have fewer concerns about the operating system a hospital uses to manage digital applications. For others, this prioritisation might be reversed. Therefore, care needs to be taken to consider a wide range of perspectives when exploring barriers and enablers to improving end-user confidence and trust in using AI-based health technologies.

Aversion to perceived risk

Risk aversion was highlighted by participants as one reason for a lack of confidence in AI-based health technologies, including amongst HCPs. Both a low tolerance of the risk of trying a new technology ('active risk') and concerns about risks to health data privacy and the impact of potential cyber attacks were raised. In both cases, meeting participants noted that there was a lack of awareness or consideration of the consequence of doing nothing or continuing with suboptimal routine practices ('passive risk') – also known as **a bias for the status quo**. In some cases, as illustrated in Case Study 2, preference for the status quo rather than implementing a new technology could result in sub-optimal health outcomes persisting.

Meeting participants also highlighted that a lack of digital literacy and data skills in the healthcare workforce could be contributing to a lack of confidence in using AI-based health technologies. This is further discussed in the section below on 'building a healthcare system ready to adopt AI'.

Involving end-users early in innovation

Early end-user involvement in the development of AI-based health technologies was emphasised as a powerful way of building confidence and trust in a product, as well as improving its relevance and usability. Without the meaningful involvement of relevant end-users early in development, time and money can be wasted developing products that are not relevant or useful; for example, involving clinicians but not the nurses or medical receptionists that will be using the product, or developing a product with an interface in English that would not be suitable for portions of the target population for whom English may not be their first language. Efforts should be made to engage with a variety of target endusers to ensure their needs (e.g. accessibility needs) are built into the design of a product. This should include any groups who are involved in the deployment and use of the product, which is often a broader group than those, such as patients and HCPs, who directly interface with it – for example, in addition to the HCP that uses the technology in their practice, the hospital IT team who might be responsible for installing and maintaining the technology

should also be involved. Participants suggested that case studies demonstrating best practice for collaboration between developers, end-users, and other stakeholders would be useful.

Some meeting participants also highlighted the opportunity for building confidence and trust by enabling patients and the public to have increased **agency** over their health data and the research it is used for, including projects to develop and train AI-based health technologies. Firstly, it was felt that feeding back information about what their data has been used for to patients who have provided data will reinforce trust and engagement. Participants suggested that a mechanism for communicating with patients about how their health data is being used in research, that allows patients to opt in and out on a case-by-case basis, should be developed. Other suggestions included mechanisms to allow publicly driven innovation using that data and applying AI algorithms, e.g. to solve local problems within civic innovation clusters. For example, the Liverpool City Region Civic Data Cooperative is a data governance project that aims to create an environment where data can be accessed, linked and analysed securely for the benefit of society, and provide guidance to researchers, industry experts, and the public in relation to data use. Some noted that these initiatives could be particularly effective to achieve buy-in at a local level.

Accessible and open communication

Clear communication from developers about how AI-based health technologies work is important to help overcome the risk aversion described above. Such clear communication is also important to allow end-users to understand how a technology works in their setting, its limitations, and how to use it effectively. AI-based health technology developers have a responsibility to communicate the salient details about their technology to decision-makers and end-users. Meeting participants recommended **intelligent openness** – explaining how an AI-based technology has been developed, how it works, and how data is used by it in such a way that includes salient information in an understandable and accessible manner. Some meeting participants highlighted that the level of technical knowledge communicated should be balanced with the salience of the detail provided. It was noted that the **involvement of end-users** (e.g. patients and HCPs) in the development of information leaflets and user manuals was an effective way of ensuring information is clear, concise and relevant. Some participants proposed that a standard framework for explainability, monitoring and communicating information to users would be useful for developers.

Intelligent and open communication of **the value proposition** (i.e. the evidence of effectiveness of AI-based health technologies in real-world settings, both in terms of improving health outcomes and/or system efficiencies compared to existing practice) is also important to build confidence and overcome lack of adoption, particularly among time-poor HCPs. Meeting participants discussed useful modes of this communication, including developing case studies. The advocacy of early adopters of effective technologies – explaining their experience with the tool – can also help build confidence amongst colleagues and overcome any resistance or uncertainty around adopting new technologies and thereby help to allay concerns where appropriate. Some participants noted that the voices of early adopters, alongside AI developers, have been important to encourage the acceptance of AI-

⁸ https://civicdatacooperative.com/

⁹ Liu, X et al. (2020). Reporting guidelines for clinical trial reports for interventions involving artificial intelligence: the CONSORT-AI extension. Nature Medicine 26, 1364–1374. https://doi.org/10.1038/s41591-020-1034-x

based technologies in radiology. **Support to enable early adopters at different levels in teams to share their experiences** or build their experiences into business cases could help accelerate the adoption of particular AI-based health technologies. The support could come in many forms and is currently often provided on an ad hoc basis by AI developers. Early adopters would particularly benefit from time and resource for innovation and sharing their experiences. Rewards and prizes could also be used to incentivise innovation, perhaps as a national programme. Participants noted that Royal Colleges would be well placed to encourage early adopters.

HCPs may have concerns about the impact of AI on their livelihoods, including a feeling of devaluing clinical expertise and even concern about losing their job. Transparent communication about the personal benefits (e.g. in terms of time saved) could assuage some of these concerns, particularly from colleagues who are early adopters.

A trusted system

As discussed in the section on 'better defining the governance of AI in health, including evaluation, reimbursement, regulation, and standards', **creating a robust and resilient system for the evaluation and communication of the effectiveness** of AI-based health technologies in real-world settings is important to build the confidence and trust needed to encourage adoption and scale-up. This should include mechanisms for post-market surveillance to evaluate impact and ongoing effectiveness. Such mechanisms would need to be coupled with robust regulatory processes to identify if an AI-based health technology is not operating effectively and withdrawing the technology (either locally or nationally) if necessary. Involvement of patients and the public at different stages of the system (e.g. on research ethics committees), and improving the visibility of that, was considered an effective way to improve confidence and trust. Raising awareness with developers and researchers of the regulations and guidance already in place and in development was also considered to be important.

Participants highlighted that **more clarity is needed about where accountability and liability** lie regarding use of AI-based health technologies and a process to address if harm is caused, for both HCPs and developers. They noted that accountability may look different for different types of AI-based health technology and that the current lack of precedence in case law reinforces this uncertainty.

Building meaningful public dialogue about AI

As suppliers of health data used to train AI and end-users of AI-based technology, patients and the public are key stakeholders. Participants reflected that AI is complex and is generally poorly understood by members of the public, even though nearly all have experience with using apps on smart devices, many of which use AI. This was thought to undermine their confidence and trust in these technologies. It was felt that giving people access to their own health data via electronic health records and agency over how it is used for research, as discussed above, would help build health literacy (which is at a low average level in the UK). ¹⁰ Improving health literacy is an important step to engaging people about how AI can contribute to improving their health. Engagement with the public about the potential benefits

¹⁰ Based on a report commissioned by Public Health England: Roberts, J. (2015). <u>Local action on health inequalities: Improving health literacy to reduce health inequalities.</u>

 $https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/460709/4a_Health_Literacy-Full.pdf$

and limitations of AI in healthcare will be required to build trust in these tools. The role of the media in shaping public opinion about AI was acknowledged: there is a need to engage with the media in an open and accessible manner about the opportunities and limitations of AI in healthcare. It was noted that such engagement could go beyond traditional media outlets to include social media and creative media industries (e.g. film).

The **need for 'trusted voices'** to communicate with end-users and the public about AI in healthcare was frequently raised at the meeting, although there was a lack of clarity on how this could be provided. It was suggested that 'impartial bodies', such as the Alan Turing Institute and NICE, could form the foundation of a coalition of 'trusted voices'. Non-governmental organisations that advocate and engage with people were felt to have the potential to be powerful enablers of the adoption of AI-based health technologies. Other suggestions to facilitate informed discussion with patients and the public about AI included the creation of a national forum and/or citizen panel(s) for engaging with patient and members of the public about AI in healthcare. Organisations such as Understanding Patient Data, Health Data Research UK (HDRUK) and relevant charities would be well placed to convene this.

Proposed next steps discussed at the meeting to improve confidence and trust of end users:

- 1.1 Developers should work with end-users early during the development of their products and in the development of understandable, accessible, transparent informational material about their products.
- 1.2 Mechanisms to allow patients and the public to understand and have agency over how their health data is used should be established.
- 1.3 Support and incentives should be provided to early adopters of AI-based health technologies to share their personal experiences with technologies. The Royal Colleges would be well placed to encourage early adopters.
- 1.4 Case studies of well-documented success stories of AI adoption in healthcare should be developed, which communicate the value in terms of health outcomes, efficiency, and cost-effectiveness. These case studies should also highlight examples of successful collaborations between developers, end-users and other stakeholders during the development and adoption of AI-based health technologies.
- 1.5 Organisations that are seen as independent and trustworthy have a role in brokering debate between the public, developers and researchers, and the wider media, to build a better understanding of technology capacity and user needs. Such organisations could make use of such case studies as those mentioned above, to help build trust, confidence and demonstrate cost-effectiveness.
- 1.6 A supportive framework to clarify accountability and liability should be established to support HCPs using different types of AI-based health technologies and to provide clarity to developers.
- 1.7 Effective methods to involve and engage with patients and members of the public about AI in healthcare on a national scale should be identified, drawing on existing initiatives where relevant. This may include a national

forum and/or one or more citizens' panels. Organisations such as Understanding Patient Data and Health Data Research UK would be well placed to convene this on a national scale.

Enhancing capacity and capability of the healthcare system to adopt AI

Currently, there are cultural, workforce, and infrastructure challenges preventing wider scale adoption of AI-based health technologies in the healthcare system.

Developing the necessary digital infrastructure

The most significant challenge highlighted by participants to the adoption of AI-based health technologies is the continuing lack of basic digital infrastructure in the healthcare systems of the UK. For example, it was highlighted that many healthcare settings still use paper notes. This is despite the recommendations of the 2016 report on 'Making IT work' from the National Advisory Group on Health Information Technology in England, which anticipated that the entire NHS would be digitised by 2023. In addition to the lack of infrastructure to adopt AI-based health technologies, healthcare settings that have not implemented electronic health records are unlikely to have local datasets with which to train AI-based health algorithms. There was strong support for capital investment and financial incentives (e.g. clear budgets for the subsequent adoption of safe and effective AI solutions) to continue the improvement of digital infrastructure in the healthcare system, with a suggestion that holding healthcare bodies responsible for their progress should be considered.

Meeting participants also noted that digital systems used where digital maturity has been achieved are often not compatible, limiting interoperability and the ability to transfer data between different systems. This increases the cost and effort of any planned scale-up for adopters and developers alike. Digital infrastructure should be introduced in such a way as to enable scale-up of new AI-based health technologies. There was suggestion of standardising digital systems across similar healthcare settings; interoperability could be considered as a key procurement criterion. It was noted that a consistent interface for HCPs would also be useful, to prevent the need for retraining.

Introducing tools and infrastructure to choose between, evaluate, feedback and, if necessary, de-implement digital products will be particularly important for the safe and effective adoption of AI-based health technologies. Participants stressed that developers of AI-based health technologies need access to diverse and representative datasets to train and evaluate AI algorithms;¹² this will be important to ensure effectiveness across different populations

¹¹ Wachter R. et al. (2016). Making IT work: Harnessing the power of health information technology to improve care in England.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/550866/W achter_Review_Accessible.pdf. While relevant to discussions of the participants, this report was not explicitly mentioned in the meeting itself.

¹² Since the workshop in March 2023, we have been made aware of the STANDING (STANdards for data Diversity, INclusivity and Generalisability) Together programme. STANDING Together has now published its green paper, with full standards due in September 2023. This provides guidance on what data curators and data users should be doing to ensure transparency about the level of diversity of the training and test data. https://www.datadiversity.org/

and to avoid introducing inequity into the system. There is currently a lack of joined-up data across healthcare bodies and between specialties to train AI algorithms for healthcare applications. Furthermore, differences in quality and accuracy of data collected and inconsistencies in the clinical language used between healthcare organisations can pose a challenge when trying to develop AI algorithms that can be deployed in multiple healthcare settings. Therefore robust, secure data collection and sharing protocols and processes are essential for the development of effective AI-based health technologies. The development of standards to ensure data quality and the collection of sufficient metadata was proposed. Such protocols and standards are also important to help maintain public trust and agency about whether and how their data is used, and how representative data being used to train AI algorithms are of different populations.

Developing a workforce with the relevant skills and capacity

To engage with digital tools, including AI

As mentioned in the section on 'improving confidence and trust of end-users', meeting participants highlighted a **lack of digital literacy and data skills in the healthcare workforce**, which undermines confidence to adopt AI-based health technologies. This included a lack of understanding about factors to consider when looking for a digital product; a lack of skills for the curation of high-quality, accurate data to train AI algorithms for healthcare; and a lack of understanding of the benefits and limitations of AI specifically. Training is needed for all relevant HCPs. The linkage of training programmes with the adoption of specific new technologies would allow immediate application and reinforcement of new skills and knowledge, and improve efficiency. The national NHS Learning Hub could be a useful platform for sharing relevant training resources.¹³

It was suggested that eWIN – the NHS workforce information network designed to enable improvements in workforce development, efficiency, and productivity¹⁴ could be further leveraged to provide resources to support the development of a healthcare workforce with the skills and confidence needed to engage with AI-based health technologies.

To innovate and adopt novel technologies

Even if a change in practice will realise efficiency savings in the future, the current lack of capacity in the healthcare system for change is a significant barrier to the adoption of innovations, including of AI-based health technologies. Participants suggested that there is a need to build digital capabilities into the healthcare workforce (e.g. digital innovation teams), to provide support to existing HCPs and healthcare staff (e.g. dedicated staff time), and give them the confidence to adopt AI-based health technologies. Furthermore, it was suggested that career pathways should be created in the healthcare system for people with in-depth knowledge of AI. This could include fellowships for HCPs to work to solve clinical problems with AI, building on the current Topol Digital Fellowships.¹⁵ Tools to streamline the adoption process, such as AI deployment platforms (see Case Study 1), can also relieve the burden of innovation on short term capacity.

¹³ https://learninghub.nhs.uk/

¹⁴ http://www.ewin.nhs.uk/

¹⁵ https://topol.hee.nhs.uk/digital-fellowships/

Fostering a culture of innovation

To facilitate the development of digital infrastructure and the upskilling of the healthcare workforce discussed above, a culture of innovation and adaptability should be promoted in the healthcare system. Participants suggested that this may be achieved by mechanisms to promote innovation to improve health. This might include an innovation mandate for healthcare bodies - a step-by-step process to continually generate ideas, implement them, and maximise their value to the healthcare system, based on improving healthcare, either directly or indirectly by saving resources. 16 Participants suggested that 'bottom-up' innovation and adoption activities by HCPs should be underpinned by 'top-down' support from management and leadership. The need to introduce mechanisms to monitor progress, improve processes and demonstrate impact was highlighted, to ensure that innovations introduced are effective. However, participants stressed that these metrics should be used as enabling rather than punitive tools. Awards and prizes to recognise and celebrate such impacts could also be introduced to incentivise HCPs to innovate their practice. One suggestion was the creation of a national programme of healthcare innovation champions in roles throughout the healthcare system, to encourage and help establish a culture of innovation.

Proposed next steps discussed at the meeting to enhance the capacity and capability of the healthcare system to adopt AI:

- 2.1 Efforts to improve the digital infrastructure across the healthcare systems of the UK should continue, including providing capital investment and financial incentives to support these efforts. To enable interoperability, digital systems and the end-user interface should be standardised across similar healthcare settings. NHS England and counterparts in other UK nations would be well placed to lead on this work.
- 2.2 Data standards should be developed to ensure robust, secure collection, curation and sharing of high-quality data, with sufficient metadata, that can be used to train and monitor the performance of AI-based health technologies.
- 2.3 Training should be provided to HCPs to improve digital literacy, data skills, and knowledge of the benefits and limitations of AI. Health Education England would be well placed to lead on education of those currently studying. Platforms such as the NHS Learning Hub would be well placed to provide relevant educational resources to currently practicing HCPs. Training could also be linked to the adoption of specific AI-based health technologies, with the support of developers.
- 2.4 Healthcare bodies should provide support to HCPs for the adoption of health technologies. This may include dedicated staff time or the

¹⁶ Since the meeting, England's 15 Academic Health Science Networks (AHSNs) have been relicensed under the revised badge of 'Health Innovation Networks', reflecting their key role in supporting development and spread of innovation across health services. The AHSN Network (2023). NHS and Government back AHSNs to continue to lead innovation, under new name. 26 May. https://www.ahsnnetwork.com/news/nhs-and-government-back-ahsns-to-continue-to-lead-innovation-under-new-name/

- establishment of digital innovation teams.
- 2.5 Career pathways for experts in AI should be created in the healthcare system. This could include setting up specific fellowships for HCPs to work to solve clinical problems with AI, building on current programmes such as the Topol Digital Fellowships.¹⁷
- 2.6 Mechanisms to promote useful and usable innovation to improve health, such as an innovation mandate for healthcare bodies, would be useful, supported by management and leadership.
- 2.7 Mechanisms to monitor and celebrate positive impacts would be important to build a culture that values and encourages innovation. This could include establishing a national programme of healthcare innovation champions.

Better defining the governance of AI in health, including evaluation, reimbursement, regulation and standards

For any technology in the healthcare system, evaluation of effectiveness and cost-effectiveness is essential – to help prove safety and efficacy to regulators, for commissioners to assess value, and to give decision-makers and end-users the reason to adopt the new technology and confidence in ongoing performance of the tool. AI-based health technologies can have specific challenges that make them particularly difficult to evaluate in terms of effectiveness (of improving health outcomes and/or delivering system efficiencies) and value.

Choice of comparator

One question raised by participants was how to choose a 'fair comparator' to determine the effectiveness of an AI-based health technology when use of the technology is context specific. For instance, if a diagnostic aid was to be used to help a GP decide about a patient referral to a specialist centre, then comparing its performance against that of a panel of specialist consultants would not alone capture how much the tool will improve standard of care in the real world. Furthermore, meeting participants noted that there is often variability between standard of care delivered by different HCPs in the same specialism and that this should be taken into account when choosing comparators. Relatedly, participants noted that giving HCPs AI tools could help remove some of this variability. Participants suggested that, to improve the relevance and usefulness of processes to determine effectiveness of an AI-based health technologies, comparators should be chosen that are as close to the context in which a technology will be used as possible.

A need for post-market surveillance

Another challenge is that the **performance of AI-based health technologies can change over time**. Performance is dependent on the nature and quality of the training data sets and how well these datasets continue to represent the target population over time. Significant change in the input data over time (whether from change in the characteristics of the target population, the health care setting, or the data acquisition process) may result in increasing

¹⁷ https://topol.hee.nhs.uk/digital-fellowships/

divergence from the training dataset ('drift') and consequent degradation in performance. To ensure effectiveness of an AI-based health technology is maintained after adoption despite these challenges will require **post-market surveillance** and an ability to respond efficiently, including updating models to maintain performance or even to withdraw models nationally or locally where necessary. Participants suggested that such surveillance should incorporate a process for providing rapid qualitative assessment of AI tools to generate real-world evidence that can be used to monitor effectiveness. A procedure should be put in place to respond if a system is found not to be performing as expected, particularly where there is risk of or actual harm. As also mentioned in the Regulatory Horizon Council's report on 'the regulation of artificial intelligence as a medical device', ¹⁸ this could include implementing updates to the model, or withdrawal of the technology, where withdrawal can be local or national. Meeting participants also suggested introducing a process for identifying and sharing system failures to be learned from.

Participants highlighted that monitoring and addressing issues, such as under-sampling, biased sampling, or data drift, is complex and would benefit from larger datasets that are more representative of a heterogeneous population. Participants discussed whether developers could pool datasets for this purpose to improve predictive ability. However, there were concerns that this would be particularly challenging, as a lack of companies working in the same space and unwillingness to share data in this way to protect intellectual property prevents such sharing. Clarifying how AI-based health technologies are valued and defining what functions are competitive or non-competitive would be important if **data sharing** between developers for post-market surveillance purposes were to be viable; a participant noted that currently such data sharing takes place in joint projects where it is written into the terms of the collaboration.

Some meeting participants pointed out that evaluation should go beyond post-market surveillance to prevent decline in performance, and that **real-world evidence and human feedback mechanisms could be used to iterate and continually improve the performance** of AI-based health technologies. They noted that this would be particularly important to enable these technologies to adapt to the needs of different settings and populations in different regions when adopted on a wider scale after adoption during pilot studies in specific areas. It will be important that regulatory frameworks are developed that allow for such iteration.

There were questions around what data to record, where it comes from, who it would be used by, and whether post-market surveillance would constitute an additional regulatory step. Some participants suggested that technologies should be developed with such evaluative mechanisms built in, as with Case Study 3. Some highlighted the NHS Long Term Plan: equality and health inequalities impact assessment as a useful high-level tool to help identify potential sources of bias. One suggestion was to join up and scale up existing audit tools (e.g. in radiology) to allow incorporation of evaluation of AI-based health technologies and other tools. The systemic capture and examination of edge cases – anomalous events that arise during use of an algorithm – based on patient outcomes was suggested as being of particular

¹⁸ Regulatory Horizons Council (2022). *The regulation of artificial intelligence as a medical device*. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1120503/R HC_regulation_of_AI_as_a_Medical_Device_report.pdf

interest for evaluation and improvement of AI-based health technologies.

Evaluation mechanisms for AI-based technologies could be coupled with training and support for end-users, and particularly those responsible for quality assurance, to help build their ownership as well as their confidence and trust in the system, as mentioned above.

Different types of AI face different challenges and pose different levels and kinds of risk. Although meeting participants generally agreed that post-market surveillance was necessary and useful, they noted that these differences should be taken into consideration by regulators when considering appropriate levels and mechanisms for post-market surveillance, to avoid over or under regulating certain technologies.

Building an economic model of the benefits of AI-based health technologies

As the wide-scale adoption of AI-based health technologies requires significant funding, in addition to evaluation of effectiveness, it was suggested that a standardised and transparent process to calculate real-world benefit (in terms of health economics as well as improved health outcomes) is required to inform commissioning decisions. It was noted by participants that AI can have system-wide effects – for example, the benefits to a specialist clinic and their patients of a new diagnostic aid introduced in general practice that reduces the number of referrals to the clinic, in terms of reclaimed resource and staff time. It was felt that the current regulatory or health technology assessment systems may not capture these downstream benefits at present. It was noted that this might encourage a focus on point solutions rather than technologies that can transform and improve whole care pathways or systems. Meeting participants suggested evaluating AI-based technologies using broader and more complex economic modelling that considers downstream effects on the system in addition to Quality-Adjusted Life Years, especially when they relate to system changes that release resources within the healthcare system.

Communication to commissioners, and local and central government, of the systemic value proposition and return on investment once an AI-based health technology is adopted will be important, to ensure that support for the technology is sustained. Healthcare bodies would need support to measure impact and develop or implement metrics. It was suggested that nationally-agreed standardised formats for assessments by healthcare bodies of the impacts of AI-based health technologies and other governance tools would be useful. Furthermore, the adopters are not necessarily those who benefit from systemic efficiency benefits of AI-based health technologies, as explored in Case Study 2, meaning it can be unclear who is best placed to pay for a technology. Participants suggested that it may be appropriate to have central government funding for healthcare bodies to commission AI-based health technologies that will have system-wide benefits in all UK nations.

Regulation of AI-based health technologies

The complexity of issues and risks of AI-based health technologies, including those mentioned above, makes AI-based health technologies a particular challenge to regulate, as noted by the 2022 Regulatory Horizon Council's report on 'the regulation of artificial intelligence as a medical device' and the recently published 'pro-innovation regulation of technologies review:

digital technologies'.^{19,20} Participants noted that regulation of AI-based health technologies in the UK is currently considered to be complicated and has been difficult to understand for developers, who may not have expertise in medical regulation. It was noted that the regulatory pathway for software as a medical device provides a strong foundation on which to build regulation for AI as a medical device, though there are elements that need to be adapted, as acknowledged by the MHRA's 'software and AI as a medical device change programme – roadmap'.²¹ There was concern about the ability of the existing regulatory systems to consider the system-wide effects of AI-based health technologies. Participants were also concerned about the capacity of the UK regulatory system – for example, they noted a lack of Approved Bodies to support the MHRA in the evaluation of AI-based health technologies. Participants welcomed the introduction of the AI and Digital Regulations Service to provide clearer guidance to developers, and to analyse and improve the pathway of AI-based health technologies through the regulatory system.²² They felt more should be done to raise awareness of this Service.

Standards

Participants reflected that standards are important and can help across the development and implementation pathway. In a regulatory context, international standards provide a way for innovators/manufacturers to show that their technology is compliant with the regulator's requirements. Compliance should therefore provide health providers and patients with greater confidence regarding the performance, safety, and quality of that technology.²³ In a clinical context, many specialities may have their own standards across a range of healthcare pathways to drive quality of care delivery. It was noted that there are few existing standards/criteria for adopters about the adoption of AI-based health technologies, which has led to a variability in uptake between healthcare bodies in some cases. In a data and technical infrastructure context, participants highlighted that standards may help ensure interoperability and improve efficient sharing of data between systems, as mentioned in the section on 'enhancing the capacity and capability of the healthcare system to adopt AI'.

Proposed next steps discussed at the meeting to better define the governance of AI:

3.1 Mechanisms to enable post-market surveillance should be developed that use real-world evidence (and potentially human feedback) to monitor, maintain and improve the performance of AI-based health technologies.

¹⁹ Regulatory Horizons Council (2022). *The regulation of artificial intelligence as a medical device*. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1120503/R HC_regulation_of_AI_as_a_Medical_Device_report.pdf

²⁰ HM Government (2023). *Pro-innovation regulation of technologies review: digital technologies*. Digital_Technologies_report.pdf. Note that this review was published after the date of the workshop and was not explicitly discussed by the workshop participants.

²¹ MHRA (2021). *Software and AI as a medical device change programme – roadmap.*

https://www.gov.uk/government/publications/software-and-ai-as-a-medical-device-change-programme/software-and-ai-as-a-medical-device-change-programme-roadmap#wp-9-ai-rig-ai-rigour ²² https://www.digitalregulations.innovation.nhs.uk/

²³ https://www.iso.org/standard/72704.html

- These could be integrated with any pre-existing audit tools. Health economic analysis should be undertaken for AI-based health technologies.
- 3.2 There should be support to increase the capacity of the regulatory system to enable it to better address the specific issues and risks of regulating AI-based health technologies.
- 3.3 Efforts to raise awareness of the AI and Digital Regulations Service amongst relevant stakeholders would be useful.
- 3.4 There should be further work to explore what standards could be useful to accelerate the adoption of AI-based health technologies in the healthcare system. The British Standards Institute and the AI Standards Hub may be well placed to help take this forward.

Building a system ready for AI adoption

Healthcare systems are complex, with many interconnected and inter-dependent sub-systems and stakeholders. Furthermore, as mentioned above, the integrity and effectiveness of the system overall can affect the confidence and trust of end-users in the AI-based technologies that are implemented. It is important to take **a systems approach** to adoption of AI-based health technologies, ²⁴ which takes into consideration these relationships, to realise the transformative potential and to avoid unintended consequences. This includes considering a broad range of stakeholders involved in adoption, breaking down sub-groups to consider the impacts of more nuanced drivers, needs and motivations. One suggestion to help apply a systems approach was to build a virtual model – a digital twin – of a relevant healthcare context, such as a hospital that can be used to model the adoption and effectiveness of a new technology in silico. This could build on work to model wards in a hospital. However, some felt this would be challenging to do effectively.

Considerations for health inequalities

Meeting participants noted that, while technologies may tend to focus on improving the health outcomes of the majority, issues of equality, diversity and inclusion should be considered. Examining the needs of those in the minority who may not interact optimally with the technology will be required to ensure they are not left behind. Building technologies and systems that treat stakeholders differently based on needs and motivations may lead to bias in the system. However, it was noted that acknowledging differences will likely be necessary to deliver better service to those who are currently under-served, to help **address existing inequalities**. For example, while a lack of access to a mobile phone may limit a minority from directly accessing benefits of an AI-based appointment management system that sends text reminders, the time of the medical receptionist that is saved by the system could be used to interact with this group more regularly, provided that the system also highlights these patients for a different mode of follow-up. Thus, the introduction of such a system may have an indirect benefit. As mentioned above, **the NHS Long Term Plan: equality and health**

²⁴ Royal Academy of Engineering (2017). *Engineering better care: a systems approach to health and care design and continuous improvement.* https://raeng.org.uk/media/wwko2fs4/final-report-engineering-better-care-version-for-website.pdf

inequalities impact assessment was highlighted by some as being a useful highlevel tool to help pinpoint potential sources of bias.²⁵

Collaboration and coordination, including at a national level

The fragmentation of the healthcare system across the UK, and particularly of decisionmaking therein, presents a challenge for the adoption and scale-up of AI-based health technologies. At a local level (e.g. within a trust or between different departments in a hospital, or between the healthcare setting and developers), there is often a lack of communication between the relevant stakeholders involved in deployment of a technology. This is a particular challenge where the department that needs to adopt a technology to alleviate a pressure on the system is not the same department or service that feels that pressure, as in Case Study 2 where the challenges faced by the dermatology specialism due to the volume of patients being referred is not directly felt by general practitioners in charge of referrals. At a regional level, there is also a lack of communication between NHS Trusts once a technology has been adopted in one Trust, which both prevents learnings being shared and can result in duplicative commissioning. Tools such as AI deployment platforms can help both to connect developers with those using their products in a bidirectional way and, if adopted in multiple hospitals/trusts, to share learnings about technologies and help compare between products. Meeting participants also highlighted the Future NHS platform as a useful way of sharing best practice.²⁶

From the developers' perspective, having to deal with healthcare bodies one at a time often duplicates work, slowing down the scale-up process. Experience from the Brainomix e-Stroke system, an AI-based health technology deployed nationally,²⁷ shows that the introduction of a **consistent commercial architecture** in the healthcare system could allow 'smarter' commissioning and procurement while speeding up adoption and scale-up.

Integrated care systems (ICSs) in England and equivalent structures in other UK nations were felt by participants to be useful fora to encourage collaboration between relevant stakeholders and reduce the fragmentation of decision-making. In particular, ICSs could be used to **engage community health services** such as pharmacies and other healthcare stakeholders, such as private healthcare, which could play an important role in adopting AI-based health technologies to reduce pressures on other parts of the healthcare system whilst improving health outcomes. It was also suggested that **local system-wide partnerships to drive innovation** (such as the Civic Data Cooperative in Liverpool)²⁸ could be a powerful way of prioritising solutions to solve local problems.

Meeting participants also felt that **high-level strategic direction, resource and infrastructure** would be useful to accelerate the adoption and scale-up of AI-based health technologies, potentially including the development of a data and AI strategic roadmap that includes specific strategic priorities for AI in healthcare, drawing on examples from other countries such as Japan and Ireland.²⁹ This could include a national framework for the

NHS England (2019). <u>The NHS long term plan – equality and health inequalities impact assessment.</u> https://www.england.nhs.uk/wp-content/uploads/2019/01/ehia-long-term-plan.pdf
https://future.nhs.uk/

²⁷ https://www.gov.uk/government/news/artificial-intelligence-revolutionising-nhs-stroke-care

²⁸ https://civicdatacooperative.com/

²⁹ https://www8.cao.go.jp/cstp/ai/aistratagy2022en.pdf; https://enterprise.gov.ie/en/publications/publication-files/national-ai-strategy.pdf

implementation of AI as a medical device with a scheme similar to that used by NICE for drug approval for AI tools at a national level. Participants suggested that such a framework should have a mechanism built in to determine the impact of implementation on the system as a whole (similar to the UK National Screening Committee).³⁰

Participants highlighted a number of independent reviews and reports that should be implemented and leveraged at a national scale to help ready the system for AI adoption, including:

- The Topol review on preparing the healthcare workforce to deliver the digital future.³¹
- The Paul Nurse review of the research, development and innovation organisational landscape, and its effectiveness, sustainability and responsiveness to global challenges.³²
- The report from General Sir Gordon Messenger and Dame Linda Pollard into leadership across health and social care in England.³³

Taking a needs-based approach

The adoption and effectiveness of AI-based health technologies rely on their having clinical utility, solving a real-world problem for HCPs. Meeting participants highlighted that many developers and AI researchers start by developing an interesting piece of technology rather than beginning with a problem experienced in healthcare, meaning it may not be useful to healthcare professionals in practice. There was strong support for a needs-based approach to be taken to AI research and development (R&D) and for demand signalling from the healthcare system to guide such an approach. The prioritisation of key areas of focus at both a UK-wide level, such as the Life Science Vision missions, and regional level was felt to be useful. One suggestion was to develop a model or framework for gap assessment at a regional level that could be completed by ICSs (in England), integration joint boards (in Scotland) or regional partnership boards (in Wales) to inform needs for innovation, including AI-related innovation, in the region. Such prioritisation should feed into needs-led funding streams for AI R&D. Funding and accelerators should include mechanisms and support for the early engagement of end-users, to enable developers to consider clinical utility throughout development.

³⁰ https://www.gov.uk/government/organisations/uk-national-screening-committee

³¹ https://topol.hee.nhs.uk/digital-fellowships/

³² Nurse, P (2023). Independent Review of the UK's Research, Development and Innovation Organisational Landscape.

 $https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1141484/rdi-landscape-review.pdf$

³³ Independent report for the Department of Health & Social Care: Messenger, G & Pollard, L (2022). *Leadership for a collaborative and inclusive future.* https://www.gov.uk/government/publications/health-and-social-care-review-leadership-for-a-collaborative-and-inclusive-future/leadership-for-a-collaborative-and-inclusive-future

Proposed next steps discussed at the meeting to building a system ready for AI adoption:

- 4.1 Developers and adopters should take a systems approach to designing and implementing AI-based health technologies, considering a broad range of stakeholders, and bearing in mind potential sources of bias or inequality. Better communication between stakeholders involved in the adoption and maintenance of AI-based healthcare technologies and other digital innovations should be prioritised.
- 4.2 Consistent commercial architecture should be established to allow joinedup commissioning decisions between different healthcare bodies, including different NHS Trusts.
- 4.3 There should be coordination between different parts of the health and social care at a local and regional level to develop solutions to local problems with systemic components. This could involve local system-wide partnership to drive innovation.
- 4.4 High-level strategic direction and infrastructure is needed to encourage the adoption and scale-up of AI-based health technologies. This could include developing a data and AI strategic roadmap by government working with partners across the healthcare system, with a framework for national implementation and procurement.
- 4.5 Demand signalling from the healthcare system at a local, regional, and national level would be useful to enable developers to design technologies that address key problems in the healthcare system. The development of a model or framework for gap assessment for completion by ICSs (in England), integration joint boards (in Scotland) or regional partnership boards (in Wales) could be a starting point for this.

Conclusion

AI-based health technologies have great potential to benefit the healthcare system, when purposefully implemented in response to challenges faced and evaluated for ongoing performance. Examples of early adoption demonstrate the improvements in health outcomes and system efficiencies that such technologies can bring. However, they also highlight the challenges that face those trying to implement and scale-up AI health technologies, which at present prevent the full realisation of the potential of AI in healthcare.

AI-based health technologies can have system-wide effects, but their impact can depend heavily on who is using them, how, and in what context. **A systems approach** – that considers the relationships between a broad range of stakeholders and sub-systems – will be important to avoid unintended consequences and maximise the benefits of adoption of AI-based health technologies. It was noted that coherent use of AI is needed to avoid perpetuating and even to address health inequalities.

It was clear from the meeting that **early and continued collaboration of developers with end-users** is essential, from prioritising areas where AI based health technologies are needed, to the monitoring, evaluation and improvement of performance once implemented. Such collaboration would also help to ensure confidence in and relevance of AI-based health technologies.

Participants stressed that **fora are needed to involve patients and the broader public in informed discussion** about the benefits and limitations of AI, as they are key stakeholders using the healthcare system and, increasingly, providing health data to train AI algorithms. Such fora could be used to help drive innovation using AI, giving people agency over their data, local problems, and the potential solutions.

The healthcare system was also highlighted as needing to adapt to enable the adoption of AI, including **improving digital infrastructure**, **training the workforce** to use AI-based health technologies, and giving HCPs capacity to innovate with them. To achieve this, a **culture of innovation** should be fostered, endorsed by leadership in the healthcare system and government, and underwritten by support and incentives for this activity.

Access to **high-quality health datasets** was noted as essential to train and evaluate the performance of AI-based health technologies. Furthermore, linking up and increasing the **interoperability of data infrastructure** between healthcare settings would help accelerate scale-up of AI-based health technologies. Meeting participants suggested the development of standards for the collection and sharing of health data would also be useful to facilitate the development, adoption, and monitoring of AI-based health technologies in the healthcare system.

Measuring the effectiveness and value of AI-based technologies that have system-wide and/or context-specific effects was seen as a challenge. Meeting participants urged the careful choice of comparators, and for **impacts on system efficiency as well as patient outcomes** to be

considered in assessments of value.

As the performance of AI-based health technologies can change over time, meeting participants suggested the use of **real-world evidence and human feedback mechanisms in post-market surveillance** to monitor performance. As mentioned above, meeting participants felt performance should be measured both in terms of patient outcome and system efficiency. This data can then be used to improve the technologies and their implementation, and to **develop case studies** to communicate the positive impacts of implementing these technologies.

Due to the system-wide effects and potential of many AI-based health technologies, a strong need for **collaboration between healthcare bodies and between sectors** about how to utilise AI and share learnings was identified. **A common data model and national procurement** rules would be useful to prevent duplication and aid scale-up.

Overall, **high-level strategic direction**, **infrastructure and resource** was seen as crucial to build a healthcare system ready to adopt AI going forward.

Annex 1: Agenda

Friday 17 March 2023, 9.30 – 16.00 GMT, (with one hour of networking event to 17.00)		
Time (min)	Registration	
9.15 - 9.30	Registration of workshop participants	
9.30 – 9.35	Opening remarks from Co-chairs	
	Session 1: Adopting AI-based Technology	
9.35 – 9.55	Introduction: Adopting an AI-based technology into the UK	
	healthcare system	
	Dr Indra Joshi, Director (Health, Research & AI), Palantir	
	Technologies	
9.55 - 10.05	Reflections from a regulatory perspective	
	Clíodhna Ní Ghuidhir, Principal Scientific Advisor, Head of AI Multi-Agency	
	Advice Service Secretariat, National Institute for Health and Care Excellence	
10.05 - 10:25	Case Study 1: Deploying an AI deployment engine	
	Haris Shuaib, Consultant Physicist & Head of Clinical Scientific Computing,	
	Guy's & St Thomas' NHS Foundation Trust	
10.25 - 10.45	Case Study 2: How is AI being used to support skin cancer	
	pathways?	
	Dr Dan Mullarkey, Medical Director, Skin Analytics & NHS General	
	Practitioner, Hetherington Group Practice	
10.45 - 11.05	Case Study 3: "The patient will see you now" – Predicting Patient	
	Attendance with AI	
11.05 11.05	David Hanbury, Founder & CO-Chief Executive Officer, Deep Medical	
11.05 - 11.25	Q&A	
11.25 - 11.30	Introduction to what will happen in the breakout groups	
	Professor John Clarkson FREng, Professor of Engineering Design,	
11 00 11 15	University of Cambridge & Professor of Healthcare Systems, Delft University	
11.30 - 11.45		
	Session 2: Breakout groups	
11:50 - 12.40	Breakout 1: Using stakeholder analysis to	
	explore barriers/enablers/needs for adoption of AI in the healthcare	
	system	
	For the case study assigned, identify the key stakeholders involved in	
	facilitating technological adoption. Once identified, place these stakeholders	
	into an influence vs interest map. Define the needs of the stakeholders and	
	the reasons for those. From a problem-solving and user-need perspective, consider issues such as validation/assurance, governance, and the role of	
	standards for adoption. Participants may also examine how to evaluate and	
	monitor effectiveness, including existing processes for assessing	
	technological interventions, and unique elements relevant to artificial	
	intelligence.	

16.00 - 17.00 Networking

Goals: Identify all stakeholders and their level of influence and interest. Consider stakeholder needs and the reasons for them. Highlight up to 4 barriers and 4 enablers to take forward into breakout session 2. 12.40 - 13.40 Lunch 13.40 - 14.40 Breakout 2: What needs to change? Participants will discuss ways to overcome the barriers discussed in breakout group 1 and ways to scale-up/generalise the enablers identified. They may like to consider: The role AI standards could play in accelerating adoption of AI in the healthcare system. How developers and adopters can engage with different kinds of endusers, including practical considerations (e.g. necessary infrastructure) and what questions they might ask. How to evaluate and monitor effectiveness, including existing processes for assessing technological interventions, and unique elements relevant to artificial intelligence. Participants are asked first to consider this in the context of their assigned case study and then to consider whether any next steps that have been identified are generalisable to other types of AI product/use cases for that AI product. Each breakout group will be asked to propose up to four next steps (either specific or generalisable). 14.40 - 15.00 Break **Session 3: Discussion** 15.00 - 15.45 A whole delegation discussion, led by the Co-Chairs. This session included an interactive vote (using Mentimeter) and discussion of the next steps proposed in the breakout groups. 15.55 - 16.00 Closing remarks by co-chairs

Annex 2: Attendees List

Workshop co-chairs

- Professor Jackie Hunter CBE FMedSci, Board Director, OI Pharma Partners Ltd; former Board Director, BenevolentAI (Co-Chair)
- Professor Lionel Tarassenko CBE FREng FMedSci, Professor of Electrical Engineering, University of Oxford (*Co-Chair*)

Speakers

- **Dr Indra Joshi**, Founder of One HealthTech; Director (Health, Research & AI), Palantir Technologies (*Speaker*)
- Clíodhna Ní Ghuidhir, Principal Scientific Advisor for AI, Head of AI Multi-Agency Advice Service Secretariat, NICE (Speaker)
- **Haris Shuaib**, Consultant Physicist; Head of Clinical Scientific Computing, Guy's and St Thomas' NHS Foundation Trust (*Speaker*)
- Dr Dan Mullarkey, Medical Director, Skin Analytics & NHS General Practitioner, Hetherington Group Practice (Speaker)
- **David Hanbury**, Founder & Co-Chief Executive Officer, Deep Medical (**Speaker**)
- Professor John Clarkson FREng, Director of Cambridge Engineering Design Centre and Co-Director of Cambridge Public Health, University of Cambridge & Professor of Healthcare Systems, Delft University

Participants

- Daniel Bamford, Director UK Clinical Trial Partnerships, NHS England
- Dr Peter Bannister, Founder, Romilly Life Sciences
- **Professor Iain Buchan**, Chair in Public Health and Clinical Informatics; Associate Pro Vice Chancellor for Innovation Public Health, Policy & Systems, University of Liverpool
- **Dr Finneas Catling**, Clinical Research Fellow, Imperial College London
- **Dr Annamaria Carusi**, Consulting Specialist, Interchange Research
- Zina Chatzidimitriadou, Managing Associate, Sidley Austin LLP
- Dr Jennifer Dixon CBE FMedSci, Chief Executive, The Health Foundation
- Professor Dawn Dowding, Professor in Clinical Decision Making, University of Manchester
- Professor Alejandro Frangi, Diamond Jubilee Chair in Computational Medicine, University of Leeds
- Professor Fiona Gilbert FMedSci, Head of Department of Radiology, University of Cambridge
- **Dr Yan Jia**, Research Fellow, University of York
- Professor Dame Anne Johnson DBE PMedSci, President, the Academy of Medical Sciences
- **Deborah Keatley**, Patient Representative
- Dr Gita Khalili Moghaddam, UKRI Innovation Scholar, University of Cambridge
- Dr Amrita Kumar, AI Clinical Lead Consultant Radiologist, Frimley Health NHS Foundation Trust
- Dr Luis Lacerda, Policy Advisor in Engineering Science, University College London

- Professor David Lowe, Clinical Director for Health Innovation at the Scottish Health and Industry Partnership (SHIP) NHS Scotland
- Addie MacGregor, Sustainability Executive, Association for British HealthTech Industries (ABHI)
- Sarah Markham, Patient Representative
- **John Marsh**, Member of the public
- Professor John McDermid OBE FREng, Director of Assuring Autonomy International Programme, University of York
- Clive Moore-Ceaton, Patient Representative
- Dr Myura Nagendran, Clinical PhD Fellow, Imperial College London
- Amy Nelson, Senior Research Associate, University College London
- **Sam Neville**, Regional Chief Informatics Officer, Mid and South Essex Foundation Hospitals Trust
- **Simon Noel**, Chief Nurse Informatics Officer, Oxford University Hospitals NHS Foundation Trust
- Stella O'Brien, Patient Representative
- Georgios Onisiforou, Head of AI Research & Ethics, NHS
- **Dr Florian Ostmann**, Head of AI Governance and Regulatory Innovation, The Alan Turing Institute
- Dr Michalis Papadakis, CEO and Co-Founder, Brainomix Limited
- Dr Russell Pearson, AI Regulation and Policy Specialist, MHRA
- Professor Sir Keith Peters GBE FRS FMedSci, Emeritus Regius Professor of Physic, University of Cambridge
- **Reshma Punjabi**, Patient Representative
- Professor Daniel Rueckert FREng, Professor of Visual Information Processing, Imperial College London
- Sara Siegel, Head of Healthcare, Deloitte
- Dr Karen Smith, Director, Paeony Ltd
- Professor Cathie Sudlow OBE FMedSci, Professor of Neurology and Clinical Epidemiology; Director, Health Data Research UK and BHF Data Science Centre
- Dr Christopher Elliott MBE FREng, Director, Pitchill
- **Professor Shannon Vallor**, Baillie Gifford Chair in the Ethics of Data and Artificial Intelligence at the Edinburgh Futures Institute (EFI), The University of Edinburgh
- **Dr Peter Winter**, Research Associate, University of Bristol

Staff and Secretariat

- Modupe Adeagbo, Programme Officer, the Academy of Medical Science
- Dr Melissa Bovis, Public Engagement Manager, the Academy of Medical Science
- Dr Claire Cope, Head of Policy, the Academy of Medical Sciences
- **Dr Anna Hands**, FORUM Policy Manager, the Academy of Medical Sciences
- Brittany Hsieh, Senior Policy Advisor, the Royal Academy of Engineering
- Elisabeth Kamper, Policy Intern, the Academy of Medical Science
- Kate Little, FORUM Policy Officer, the Academy of Medical Sciences
- Frances Logan, Policy Officer, the Academy of Medical Science
- Dr Natasha McCarthy, Associate Director, the Royal Academy of Engineering
- Charlie Vickers, Public Engagement Officer, the Academy of Medical Science
- Hannah Webb, Policy Intern, the Academy of Medical Science

Annex 3: Glossary

This section provides definitions for some terms related to artificial intelligence technologies and the healthcare system. For a more extensive glossary, please refer to one of the following sources:

- https://appen.com/ai-glossary/
- https://www.expert.ai/glossary-of-ai-terms/
- https://www.g2.com/articles/artificial-intelligence-terms

Algorithm

A set of instructions or rules to be followed in calculations or other operations to solve problems.

Artificial intelligence (AI)

A broad area of computer science, AI broadly refers to the ability of machines to simulate human intelligence. AI technologies perform complex tasks and solve problems by learning from sets of data.

Bayes' Theorem

A famous theorem used by statisticians to describe the probability of an event based on prior knowledge of conditions that might be related to the event. Bayes Theorem is used in machine learning, a branch of AI.

Black box

A term which refers to an AI system which is so complex that the end-user does not know its decision-making process or how it produces its insights.

Bias

Inductive Bias: the set of assumptions that the learner uses when predicting outputs given inputs that have not been encountered yet.

Confirmation Bias: the tendency to search for, interpret, favour, and recall information in a way that confirms one's own beliefs or hypotheses while giving disproportionately less attention to information that contradicts it.

Chatbot

A computer programme or an AI designed to interact with human users through conversation.

Data

The most essential ingredient to all machine learning and AI projects.

Unstructured Data: raw, unprocessed data. Textual data is a perfect example of unstructured data because it is not formatted into specific features.

Structured Data: data processed in a way that it becomes ingestible by a machine learning algorithm and, if in the case of supervised machine learning, labelled data. Data augmentation: the process of adding new information derived from both internal and external sources to a data set, typically through annotation.

Database

A structured and organised collection of data which can be accessed electronically.

Dermatology

The branch of medicine which deals with the skin.

Inference

The process of making predictions by applying a trained model to new, unlabelled instances.

Informatics

The area of healthcare science responsible for developing and improving methods for the acquisition, storage, organisation, and analysis of biological data.

Machine learning

The subfield of AI that often uses statistical techniques to give computers the ability to "learn", i.e., progressively improve performance on a specific task, with data, without being explicitly programmed.

AI and Digital Regulations Service (previously the Multi-Agency Advisory Service)

A collaboration between The National Institute for Health and Care Excellence (NICE), the Medical and Healthcare products Regulatory Agency (MHRA), The Health Research Authority (HRA) and the Care Quality Commission (CQC). The AI and digital regulations service is a cross-regulatory advisory service for developers and adopters of AI and other digital technologies in health and social care.

Medical imaging

Medical imaging can refer to several different technologies which are used to produce images of the inside of the body for purposes of diagnosis and treatment.

Medicines and Healthcare products Regulatory Agency (MHRA)

The MHRA works within the government and wider health system, and regulates medicines, medical devices, and blood components for transfusion in the UK. They are involved in the regulation of AI-based health technologies.

Model

A model is an abstracted representation of what a machine learning system has learned from the training data during the training process.

AI-based operational system

A type of system which uses artificial intelligence to oversee different parts of a computer, managing hardware and software and providing common services for applications and users.

Prediction

In AI terms, the ability of a technology to predict outcomes based on existing data.

Pre-trained model

A model that has been preliminary trained, generally using another data set.

Primary care

The first point of contact in the healthcare system, including general practice, community pharmacy, dental, and optometry (eye health) services.

Radiology

The medical discipline which uses medical imaging to diagnose and treat diseases in the body.

Secondary care

Care by a specialist with expertise in the medical problem the patient has. Secondary care often happens after referral by a GP.

Tertiary care

The level of highly specialised treatment in a hospital, such as neurosurgery and transplants.

Training data

The subset of available data that a data scientist selected for the training phase of the development of a model.

Triaging system

A system used to determine which groups of patients should be prioritised to receive treatment and care services first, often in relation to the severity of their disease and available resources.

Variance

An error due to sensitivity to small fluctuations in the training dataset.



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