Current regulatory challenges to support the spread of digital health technologies

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Abstract

The application of digital technology to healthcare applications has produced a torrent of digital innovations, which are spread across every area of healthcare. The number and range of these innovations creates a huge challenge for regulators whose procedures and expertise are geared to more conventional applications of technology. This paper examines the current regulatory environment in the United Kingdom with a focus on England relating to digital health technologies and sets out the key issues and opportunities to support the spread of digital health technologies at scale. The paper first describes that there have been a number of policy-making bodies in the regulatory space working in silos without clear central steer. This arrangement has led to unclear messaging for innovators on what is required to bring a digital health technology to market. Second, while recent initiatives are under way towards increased coordination on development, it remains to be seen whether this improves coordination and spread of such innovations. Third, there remains a lack of policy focus on downstream deployment. This will require a collaborative model with new ways of working for regulators, policy-makers, heath care professionals, patients and health service researchers to address these challenges at pace.

Keywords: regulation, digital health technologies, health care innovation, artificial intelligence

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1. Introduction

Digital health technologies is a growing global market. An industry study for the Office of Life Sciences found that the UK digital health market was worth GBP 2 billion in 2014.[2] But the market continues to grow, in part due to major advances in wireless technology, and computing power, particularly the interest in the application of artificial intelligence (AI) in health systems and service delivery.[3] In 2017, it was estimated there were over 318,000 health apps available on the main app stores worldwide with more than 200 health apps being added each day and in 2019, 2.5 billion people owned a smartphone.[4,5] In 2019, 10,000 mental health related apps were available for download on top app stores.[6] By 2025, the UK digital health market is projected to be worth USD 28 billion and globally USD 500 billion.[7]

In this paper, digital health technologies refers to health technologies as defined by the National Institute for Health and Care Excellence (NICE). This definition includes apps, programmes and software used in the health and care system, which may be standalone or combined with other products such as medical devices or diagnostic tests.[8] This is a similar in scope taken at the international level: the World Health Organization recently produced guidelines on the use of digital health interventions, as "a broad umbrella term encompassing eHealth (which includes mHealth or mobile wireless technologies for health), as well as emerging areas, such as the use of advanced computing sciences in 'big data', genomics and artificial intelligence."[9]

Digital health technologies could be used in a number of ways for patients, providers, health system managers and data services;[10] from public health interventions to specific medical procedures such as diagnostic or therapeutic purposes. AI in particular, is used across medical specialities such as ophthalmology, skin cancer, breast cancer, cardiovascular risk, neuroscience (autism, dementia), radiology (pulmonary hypertension).[11] Diagnosis and screening are the most common uses of AI, with 132 different products used in diagnosis or screening covering 70 different conditions[12]. The

[2] Deloitte. (2015). *Digital Health in the UK An industry study for the Office of Life Sciences.* London: Deloitte.
[3] Loh, E. (2018). Medicine and the rise of robots: a qualitative review of recent advances of artificial intelligence in health. *BMJ Leader*, 59-63.
[4] IQVIA. (2017). *The growing value of digital health.* Durham: IQVIA.
[5] Taylor, K. &. (2019). *Smartphone ownership is growing rapidly around the world, but not always equally* . Washington DC: Pew Research Centre.
[6] Rodriguez-Villa, E., & Torous, J. (2019). Regulating digital health technologies with transparency: the case for dynamic and multi-stakeholder evaluation. *BMC Medicine, 17*(226).
[7] Insights, G. M. (2019). Retrieved from https://www.prnewswire.com/news-releases/worldwide-digital-health-market-to-hit-504-4-billion-by-2025-global-market-insights-inc-300807027.html
[8] NICE. (2019). *Evidence Standards Framework for Digital Health Technologies.* London: NICE.
[9] WHO. (2019). *Recommendations on digital health interventions.* Geneva: WHO.
[10] WHO. (2018). *Classification of Digital Health Interventions.* Geneva: WHO
[11] Loh, E. (2018). Medicine and the rise of robots: a qualitative review of recent advances of artificial intelligence in health. *BMJ Leader*, 59-63.
[12] NHSX. (2019). *Artificial Intelligence how to get it right.* London: NHSX.

interpretation of images in screening mammography, retinal imaging, X-Ray, cardiac monitoring and head CT appear to be the areas with the greatest development activity.[13]

With the exponential growth in supply and demand for digital health technologies, there is now an increased policy focus in this area, with particular attention given to artificial intelligence due to the depth and breadth of the applicability of this technology in the health sector. Recent policy initiatives are taking place in the UK, the United States and internationally.[14,15,16]

The focus of this paper is to map out the regulatory challenges and issues around digital health technologies in the United Kingdom with particular focus on England. More specifically the paper sets out to answer the following questions in relation to digital health technologies: a) who are the key regulatory bodies? b) what are the main regulatory issues and challenges?

This paper notes that there have been a number policy-making bodies working in silos without clear central steer and coordination. This has created confusion for innovators to understand what the requirements are to bring a product to market. A number of activities are now underway to improve the regulatory environment at the initial product development stage.[17] The current move towards better regulatory coordination is welcome, but greater central steer is needed. This paper argues that, equally important, is to ensure appropriate downstream regulatory requirements are in place not only to support the spread of innovation at scale but to build in feedback mechanisms to support regulatory activities at the upstream stage. A robust system that incorporates a post market surveillance with feedback mechanisms will require a new collaborative model for regulators, policy-makers, health care professionals, patients and health service researchers to meet these challenges at pace.

The rest of the paper is structured as follows. Section 2 reviews the key bodies involved in policy-making and maps out the key regulatory issues relating to the spread of digital health technologies in the NHS. Section 3 assesses current initiatives underway at the regulatory level to support spread of innovation at scale both in the UK and internationally. Section 4 provides concluding remarks.

2. Regulatory environment for digital health technologies in England

2.1 Regulatory map of key stakeholders

There are a number of policy-making bodies involved in digital health technologies with no one authority having complete oversight.

[14] NHSX. (2019). *Artificial Intelligence how to get it right.* London: NHSX
[15] FDA. (2020). *Digital Health Innovation Action Plan.* Washington DC: FDA.
[16] OECD. (2020). *OECD AI Observatory*. Retrieved from https://oecd.ai/
[17] NHSX. (2019). *Artificial Intelligence how to get it right.* London: NHSX.

In England, there are six regulators involved directly in the regulation of digital health technologies: the Care Quality Commission, the Information Commissioner's Office, the General Medical Council, the Health Research Authority,the Medicines and Healthcare products Regulatory Agency and the British Standards Institution and five statutory bodies the National Data Guardians, NHS Digital, NHS England & Improvement, the National Institute for Health and Care Excellence and Public Health England along with other key stakeholder groups. The role of each body is summarised in Table 2.0.

Recently created key stakeholders include the National Data Guardian established in 2014 to be an independent voice for patients and the public that advocates confidentiality of information and that such information is shared when appropriate.[18] In 2016, the Health and Social Care Information Centre was replaced with NHS Digital to further the government's agenda to use digital technology to transform the NHS and social care. NHSX is the most recently created unit within the Department of Health and Social Care, established in 2019. Its brief is to lead the digital transformation agenda in the NHS, allowing patients and staff to benefit from the latest digital systems and technology.[19] And although there are a number of bodies and key stakeholders involved both in the developmental phase but also in the implementation phase, it is noteworthy that no one regulatory authority has complete oversight of the entire process.

Table 2.0 shows that, across the system, a number of bodies are involved at various stages not only in the development of a digital health technology but also in deployment. Some key areas of policy making involve more than one organisation, bringing together a range of perspectives such as the development of ethical guidance, evidence standards and commissioning standards. In other areas such as safety, and information governance and privacy a number of recent activities are underway. In the area of safety, the MHRA is working with NHS Digital to develop standards for algorithms because currently none exist. The CQC is developing principles for digital innovation assessments. In this space, NHSX is working with a number of stakeholders to ensure safety is core element of the digital innovation agenda.

With respect to information governance and privacy, the ICO is working with the Alan Turning Institute on guidance development to assist organisations with explaining artificial intelligence (AI) decisions to the individuals affected. The HRA provides guidance on how research should be conducted to ensure that information governance and privacy concerns are upheld. NHS Digital considers how these issues are addressed with respect to making information systems interoperable and agile. HDRUK is supporting research in areas of data access, including interoperability. While the National Data Guardian and patient groups support guidance development to maintain a balance between encouraging information sharing for individual care while safeguarding the confidential nature of data in the health care system.

[18] NHSX. (2019). *Artificial Intelligence how to get it right.* London: NHSX

[19] https://www.gov.uk/government/news/nhsx-new-joint-organisation-for-digital-data-and-technology

Table 2.0 – Role of main stakeholders relating to key areas of policy making for digital health technologies (Source: Adapted from NHSX, 2019)

	Safety	**Information governance and privacy**	**Ethical guidance**	**Evidence standards**	**Commissioning standards**
Regulator	MHRA Guidance on apps and standalone software. CQC Ensures health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage them to improve. British Standards Institution is the national standards body of the UK. BIS produces technical standards on a wide range of products and services and also supplies certification and standards-related services to business.	ICO Upholds information rights in the public interest, promoting openness by public bodies and data privacy for individuals. HRA Protects and promotes the interest of patients and the public in health and social care research	GMC For doctors to be equipped to take advantage of the technological and digital innovations set to transform healthcare including relating to ethical guidance. HRA Protects and promotes the interest of patients and the public in health and social care research		

Table 2.0 - contd.

	Safety	Information governance and privacy	Ethical guidance	Evidence standards	Commissioning standards
Statutory bodies And Arm's Length Bodies (ALBs)	NHS Digital National information and technology partner to the health and care system including technical design, interoperability, information governance and privacy	NHS Digital National information and technology partner to the health and care system including technical design, interoperability, information governance and privacy National Data Guardian (NDG) Advises and challenges the health and care system to help ensure that citizens' confidential information is safeguarded securely and used properly.		NICE Guidance on evidence standards required for digital health technologies to show effectiveness and economic budget impact NHSEI To better support the NHS and help improve care for patients. PHE is the public health agency for England and informs the NICE evidence standards relating to public health	NHSEI To better support the NHS and help improve care for patients PHE is the public health agency for England and sets outs commissioning standards relating to public health

Table 2.0 - contd.

	Safety	Information governance and privacy	Ethical guidance	Evidence standards	Commissioning standards
Other stakeholders	NHSX Policy making for a supportive environment to develop and deploy digital health technologies with a particular focus and investment in AI	HDRUK Alliance of leading health, care and research organisations united to establish best practice to enable the ethical use of UK health data for research and innovation at scale Patient groups Advocate patient safety, and patient experience of NHS services	HDRUK Alliance of leading health, care and research organisations united to establish best practice to enable the ethical use of UK health data for research and innovation at scale	Patient groups Advocate patient safety, and patient experience of NHS services	Commissioners commission services for the population they are responsible for and can include primary, secondary and tertiary care services

2.2 Regulatory challenges

Lack of central steer and oversight has led to unclear messaging for innovators on what is required to bring a digital health technology to market

The number of regulators, statutory bodies, ALBs and stakeholders involved at various stages has led to confusion and lack of clarity over roles and responsibilities.[20] Currently, no one body has complete oversight throughout the entire process which makes policy coordination a challenge. All digital health technologies must navigate regulatory processes such as accessing data, following guidance relating to information governance and ethics. The NICE framework provides a useful starting point but these standards need to be further tested on their appropriateness. Both in development and deployment, the regulatory challenges also depend in part on the evidence requirements of the digital health technology in question.

For example, using the tier system from NICE's new framework, a wearable would fall into tier 2 where the evidence requirements are less (denoted "Middle" in Table 2.1) than those which require real-time data to inform preventive behaviour or diagnosis in tier 3a or 3b (denoted "Significant"). There is an obvious need to regulate AI in the application of diagnosis and treatment (tier 3b), but there are challenges that policy-makers are currently grappling with not only in the UK but also in other country settings like the U.S. (see Box 2).[21]

Table 2.1– Level of regulatory challenge for digital health technologies (Source: Authors' analysis)

	Tier of function according to NICE	List of functions	Data access, ethics and governance	Real-time data requirement	Effectiveness evidence threshold
	1	System services	Middle	Low	Middle
	2	Inform Simple monitoring; Communicate	Middle	Middle	Middle
	3a	Preventive behaviour; Self-manage	Significant	Significant	Significant
	3b	Treat; Active monitoring Calculate Diagnose	Significant	Significant	Significant

[20] Mathews, S., McShea, M., & Casey, L. (2019). Digital health: a path to validation. *NPJ Digital Medicine, 2*(38).
[21] Parikh et al. (2019). Regulation of predictive analytics in medicine Algorithms must meet regulatory standards of clinical benefit. Science, 363:6429, pp. 810-812.

Box 2 – Policy-making for AI adaptive algorithms is in its infancy

AI diagnostics in radiology are used in a number of clinical areas relating to medical imaging.[22] Within the pathway of clinical radiology AI applications can be applied in preprocessing steps following image acquisition; image-based tasks that support diagnosis and include the process of detection, characterisation and monitoring of change, followed by reporting and integrated diagnostics.[23] The growing area of AI applications use 'adaptive' algorithms which learn from the data without the need for prior definitions from human experts. In particular, deep learning uses a set of techniques that is similar to biological neural networks. Already adaptive algorithms in radiology offer the potential for improvements in diagnosis and clinical decision-making. Studies have shown better performance for adaptive algorithms compared with fixed in the area of lung and breast cancer.[24,25] Adaptive algorithms perform equally well as radiologists in the performance for detection in ultrasonography.[26] While adaptive algorithms have shown higher sensitivities than radiologists in the classification of tasks of lymph node metastasis in PET-CT, they score lower in specificities.[27]

The vast scope of adaptive AI applications in radiology bring along key regulatory challenges. Some of these relate to standards, data access, ethics, real-time data requirements, to demonstrate effectiveness and governance:

- Standards needed - it's a black-box: While there is current guidance for fixed algorithms used in radiology, there is currently no guidance for adaptive algorithms that are used in radiology. Deep-learning AI applications, have been referred to as a "black-box" because it is not necessarily clear how the inner layers of these applications work. This makes it a challenge not only for clinicians to interpret but also for policy-makers on setting out standards to assess the technology. In the U.S., the FDA does not focus on the technical components or indicated use but on the function of the technology itself.[28] The adaptive algorithms currently have no standards or benchmarking for reporting in the UK but work is underway to develop standards.[29]
- Data, data and more data:
    - Reliability: Large patient data sets are necessary to train AI applications. But the data used in these applications can unintentionally lead to biases in the results such as lack of applicability to certain population-sub-groups, and thereby raising questions of whether the results are appropriate.[30]

[22] Some examples of radiology in oncology include: thoracic imaging, abdominal and pelvic imaging, colonoscopy, mammography, brain imaging, and radiation oncology.(Hosny et al. (2018). Artificial intelligence in radiology, Nat Rev Cancer, 18(8): pp. 500 -510.)
[23] Hosny et al. (2018). Artificial intelligence in radiology, Nat Rev Cancer, 18(8): pp. 500 -510.)
[24] Paul R et al. (2016). Deep feature transfer learning in combination with traditional features predicts survival among patients with lung adenocarcinoma. Tomography 2, pp. 388–395..
[25] Cheng J-Z et al. (2016). Computer-aided diagnosis with deep learning architecture: applications to breast lesions in US images and pulmonary nodules in CT scans. Sci. Rep 6, 24454.
[26] Chen H, et al. (2016), Medical Image Computing and Computer-Assisted Intervention — MICCAI, pp. 487–495.
[27] Wang H et al. (2017). Comparison of machine learning methods for classifying mediastinal lymph node metastasis of non-small cell lung cancer, from 18F-FDG PET/CT images. EJNMMI Res. 7, 11.
[28] Harvey HB and Gowda V. (2020). How the FDA Regulates AI, Academic Radiology, 27(1), P58-61.
[29] NHSX. (2019). *Artificial Intelligence how to get it right.* London: NHSX.
[30] Buolamwini J and Gebru T. (2018). Gender Shades: Intersectional Accuracy Disparities in Commercial Gender Classification, Proceedings of Machine Learning Research 81:77-91.

Box 2 – contd.

- Ethical frameworks needed
  - Protecting privacy: Developers require access to data in the development phase. The challenge for policy-makers is how to permit the use of such large amounts of data while also safeguarding patient privacy. There is evidence in breast cancer of using de-identified data to circumvent some of these concerns relating to ethics and potential bias in data referred to as "unsupervised learning[31], while others are in the exploratory stage such as the possibility of blockchains.[32] A jointly issued European and North American statement on the ethics of AI in radiology calls on the community to develop and adhere to a uniform code of ethics so as to provide a reliable ethical framework as the technology rapidly advances.[33]
  - Who is responsible? Data use brings with it questions of ownership of the data and raises a key legal question of responsibility when something goes wrong. The FDA approved the first device (IDx-Dr, a software program assessing the progression of diabetic retinopathy based on fundoscopic images) authorised to provide a screening decision independent of physician confirmation, where the company takes full responsibility of the ownership of the technology.[34] This is currently an open question for AI applications in radiology.
- Governance:
  - Demonstrating effectiveness: These types of technologies require high quality evidence to make the case for deployment. Furthermore, NICE's recent guidance economic impact requires that the evaluation increase in complexity if the AI used in radiology carries a high financial commitment. NICE's evidence thresholds are recent and require testing to ensure these are appropriate with piloting work currently underway.
- Ongoing monitoring necessary:
  - Once deployed, however, developers should continue to evidence the effectiveness of their technology in the real-world so policy-makers can better understand their functionality. The FDA last year has moved towards a total product lifecycle (TPLC) approach.35 This means once the technology is on the market, the FDA's focus is to know how the adaptive algorithms operate in the real-world. This puts emphasis on the need for a robust regulatory environment to monitor and benchmark these technologies as they continually evolve.

[31] M. Kallenberg, K. Petersen, M. Nielsen, A.Y. Ng, D. Pengfei, C. Igel, et al. Unsupervised deep learning applied to breast density segmentation and mammographic risk scoring IEEE Trans. Med. Imaging, 35 (5) (2016), pp. 1322-1331.
[32] Zerka, F., Barakat, S., Walsh, S., Bogowicz, M., Leijenaar, R., Jochems, A., Miraglio, B., Townend, D., & Lambin, P. (2020). Systematic Review of Privacy-Preserving Distributed Machine Learning From Federated Databases in Health Care. JCO clinical cancer informatics, 4, 184–200. https://doi.org/10.1200/CCI.19.00047
[33] Geis JR et al. (2019), Ethics of Artificial Intelligence in Radiology: Summary of the Joint European and North American Multisociety Statement, Radiology, 293(2), pp. 436-440.
[34] Abràmoff M.D., Lavin P.T., Birch M et al. (2018). Pivotal trial of an autonomous AI-based diagnostic system for detection of diabetic retinopathy in primary care offices, NPJ Dig Med, 28, pp. 1-39.
[35] Harvey HB and Gowda V. (2020). How the FDA Regulates AI, Academic Radiology, 27(1), P58-61.

While there is widespread interest and use of digital technologies as seen in other industries, the health sector has been slower to adopt.[36] Key reasons the author notes relate to the challenges highlighted in this paper such as well coordinated policy-making bodies, effective process to review technologies to assess safety, governance and privacy, ethical standards, and evidence standards. Once deployed, policy functions for ongoing monitoring and review are necessary to inform changes to existing policy guidance relating to the technology in question.

Developers are unclear to know what is required at each stage of the process to have their technology adopted and implemented in the NHS.[37] This has adversely affected the number of digital health technologies coming to market. NHSX reports results from the State of the Nation survey and the NIHR horizon scanning exercise conducted in 2019 that while 90 of the 132 products addressed priorities in the Long-Term Plan, 40 had European market authorisation; and two-thirds of AI developers reported that their product would not be ready for deployment at scale in one year.[38]

Development stage challenges have a knock-on effect on the deployment stage

Both the development and deployment phase have regulatory challenges that are to some extent interdependent. In particular, these relate to data, ethics, governance, and evidence requirements. An important implication for the existing guidance is to be as clear as possible to inform developers on what is required for deployment, otherwise there is a continued risk of confusion and ambiguity that could affect processes in the deployment stage.

The State of Nation Survey and the NIHR horizon scanning exercise highlight where some of these issues crop up. There was a 50/50 split on whether developers sought ethical approval. One third were not developing in line with Code of Conduct for Data-Driven Health and Care Technology. Most developers reported that they were unaware of the commercial arrangement they had in place to gain access to the data. Furthermore, no one specific body has oversight to prevent bias in algorithmic tools which raises concerns about the quality of the data used in algorithms.[39]

A second area requires clarity around the classification of a digital health technology. This may require CE marking, and whether it is classified as research or not. At the development stage, MHRA sets outs out guidance for obtaining CE marking and NICE has published evidence standards for a digital health technology requiring CE marking. CE marking is a product certification mark that the product conforms with health, safety, and environmental protection standards for products sold within the European Economic Area and those sold outside the EEA that have been manufactured to EEA standards. In the development phase, a distinction must be made on whether the product is involved in direct patient

[36] Loh, E. (2018). Medicine and the rise of robots: a qualitative review of recent advances of artificial intelligence in health. *BMJ Leader*, 59-63.

[37] NHSX. (2019). *Artificial Intelligence how to get it right.* London: NHSX.

[38] NHSX. (2019). *Artificial Intelligence how to get it right.* London: NHSX.

[39] NHSX. (2019). *Artificial Intelligence how to get it right.* London: NHSX.

care or secondary use. For example, a software that is used to support a medical device is considered secondary use and should be classified as research. In this case, the developer is required to obtain approval from HRA to be classed as research. For products not undergoing CE marking, the regulatory processes and requirements are not clear and the evidence requirements for those not needing CE marking need to be developed and tested. Indeed, confusion exists as NHSX reports that 50% of developers were not seeking CE market classification to become certified as a medical device as it was not applicable. Greater clarity will be needed as current guidance does not consider 'algorithms' as medical devices but new regulations coming into force include the terms algorithms and mobile computing platforms.[40] The main term used to regulate is 'software', but the definition of what constitutes software is not yet defined.[41]

In the deployment phase, there are regulatory challenges that also include data access, ethics and governance coming from real-time data and evidence requirements. These issues will affect both CE marked and non-CE marked products. For developers, accessing data and reporting activity of the products once deployed need a clear steer around their reporting requirements. Policy-makers involved in the deployment phase oversee important areas to monitor activity and assess quality and take action if required. A robust system of understanding activity once digital health technologies are in the market will not only inform how well they are spreading but also provide an opportunity to feedback information in the development phase. Such information is necessary to inform data registries, but also for CQC inspection requirements, ICO investigations, and the MHRA Yellow Card Scheme. This scheme is a voluntary reporting system in the UK for providers and patients. It collects and monitors information on safety concerns or incidents involving medicines and medical devices.

3. A changing regulatory landscape

Activities underway in England to make digital health technologies scalable point to efforts to improve policy coordination but absent is equal focus on downstream deployment

Two broad strategies have taken course in England to support the spread of innovation and policy coordination. The first is via the Accelerated Access Collaborative (AAC) created in 2019. This initiative aims to have a coordinated approach working with patient groups, government bodies, industry and NHS bodies. Its aim is to bring innovations sooner to patients including digital productions, medicines, diagnostics, devices, pathway changes and new workforce models.[42]

[40] Regulation 2017/745 in May 2020 and Regulation 2017/746 on in vitro diagnostic medical devices (IVDR) in May 2022. [Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745]. [Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0746]

[41] PHG. (2019). *Algorithms as medical devices.* Cambridge: PHG.

[42] https://www.england.nhs.uk/aac/

To date, the programme is working with over 350 innovators, and supporting 500 clinicians. Over 250,000 patients have accessed 26 innovations ranging from digital tools that reduce medication errors to a device that detects patients undergoing bowel cancer tests. Over 140,000 patients and 100 NHS organisations had access to the Rapid Uptake Products alone.[43] Some areas include 4,000 pregnant women accessed a blood test for pre-eclampsia; 8 new trusts accessed heart scans that reduce the need for intervention procedures; 14 new trusts accessed a minimally invasive alternative to relieve urinary tract symptoms in men; 274 multiple sclerosis patients accessed a tablet at home that helps decrease relapses.

The second strategy focusses on AI, where a number of initiatives are currently underway to bring greater clarity on relationships, role and responsibility of regulators, statutory bodies, and stakeholders. A consultation is running over the spring and summer on the tech plan for health care. In the meantime, the strategic approach targets five areas: leadership and society; skill and talent; access to data; supporting adoption and international engagement. [44]

Key activities relate to data access, governance and ethics, definition of a medical device, standards for AI algorithms including adaptive algorithms, as well as the evidence requirements for digital health technologies to be deployed and commissioned in the NHS. NHSX plans to establish a national centre for expertise to sit within NHSX to oversee the policy framework for implementation and provide specialist commercial and legal advice to NHS organisations entering data agreements.[45] An announcement of £250 million has been made available for NHSX to establish the NHS AI Lab to support and speed up adoption that is safe and ethical. Some initiatives include:[46]

- Delivery:
  - NHSX working with the Accelerated Access Collaborative and matchmaking commissioners' needs with the developers who can meet them.
  - NHSX will explore how to integrate digital tools into the NHS and care digital ecosystem, through both NHS patient-facing channels such as the NHS App, and external sources
  - CQC, is partnering with MHRA, NICE, NHSX, to improve adoption of technologies in clinical practice. The British Standards Institution (the UK National Standards Body) is being brought in as part of this specific work to consider gaps and overlaps with industry standards.[47]
  - CQC established a "Sandbox" cohort specifically for machine learning and its application to radiology, pathology, imaging and physiological measurement services to improve registration and inspection policies with industry and NHS partners.

[43] https://www.england.nhs.uk/aac/how-are-we-doing/
[44] NHSX. (2019). *Artificial Intelligence how to get it right.* London: NHSX.
[45] NHSX. (2019). *Artificial Intelligence how to get it right.* London: NHSX.
[46] NHSX. (2019). *Artificial Intelligence how to get it right.* London: NHSX.
[47] British Standards Institution (BSI) is the national standards body of the United Kingdom. BSI produces technical standards on a wide range of products and services and also supplies certification and standards-related services to businesses.

- Research:
  - NHSX to work with HDRUK via NHS AI lab from development to deployment. The Digital Innovation Hubs managed by HDRUK is a 4 year programme to create alliances, curating data sets, and making data usable.

While these activities are welcome, it remains to be seen how well increased joined up activity will translate into improved implementation. Missing is a clear central steer into learning from the products once they are on the market. An equal focus on downstream activity is necessary that builds in an element of ongoing monitoring and learning as seen in the FDA's Total Produce Lifecycle Approach for adaptive AI algorithms. Such an ecosystem requires coordination, monitoring with feedback mechanisms in place to support policy oversight once the technology is on the market but also to inform the upstream stage. One particular challenge is how to create a robust post-market surveillance system to harness effectively and efficiently use of real-time data flows. There are ethics, governance and privacy issues around the real-time data needs including feasibility of online data platforms, and databases, particularly when certain digital health technologies are available globally. This will require a new collaborative model for policy-makers, health-care professionals, patients and health services researchers. There is an urgent need to both to draw on local learnings but to learn from wider networks of learning nationally and internationally.

Internationally, there is a growing policy focus on digital health technologies

The Global Digital Health Partnership (GDHP) of governments and territories, government agencies and the World Health Organization reported that 75% of members confirm that the body (or bodies) responsible for regulating digital health technologies is currently looking to change their remit and adapt regulations appropriately.[48] The changing regulatory landscape signals a policy recognition that it is important to create an environment to test safety and efficacy, and invest in methods to apply ethics and regulatory requirements.[49] A review of practices in select OECD countries concluded that better coordination was necessary as current policy making is siloed with data protection authorities focussing on privacy and data protection issues, whereas health authorities focus on safety and efficacy considerations.[50] There is increased momentum in this space, and recently, there is policy interest to coordinate activities and also to learn from one another. The World Health Organization, the European Commission and the OECD have begun work in this area (see Box 3).

[48] NHSX. (2019). *Artificial Intelligence how to get it right.* London: NHSX.
[49] NHSX. (2019). *Artificial Intelligence how to get it right.* London: NHSX.
[50] Ferretti A, Ronchi E, Vayena. (2019). From principles to practice: benchmarking government guidance on health apps, Lancet Digital Health, 1: June.

Box 3 - International initiatives relating to digital health technologies (Source: NHSX 2019; EU 2020, OECD 2020)

WHO
The WHO has set up AI4Health focus group to establish a benchmarking framework, whereby eligibility of an AI model can be assessed, and feedback provided to improve quality.

EU
Public consultation currently underway on developing a European approach to digital technology

OECD
The Organisation for Economic Co-operation and Development (OECD) recently launched the AI Observatory as a platform for countries and others to shape policy and institutional frameworks for the development of trustworthy AI that benefits society as a whole.

4. Concluding remarks

This paper reviewed the key regulatory and decision-making bodies that oversee digital health technologies in the United Kingdom with a focus on England. This paper also noted the current policy challenges to improve the spread of innovation in England and policy implications to improve uptake.

First, a number of policy-making bodies have worked in silos with poor coordination. This has led to unclear policy messages and lack of central steer to the industry sector. Innovators are confused on what the policy requirements are not only for development but also deployment. Such barriers have led to delays in the number of technologies available on the market.

Second, a number of initiatives underway particularly in the development phase to ensure better policy coordination to support and guide innovators is a welcome step. A growing area of policy focus relates to the application of AI in the health sector in England and internationally. It remains to be seen whether increased policy coordination removes current siloed approaches to working and improves policy implementation leading to a rise in the number of digital health technologies on the market.

Challenges around data access, ethics, governance, and evidence requirements exist in the development phase but also once the digital health technology is on the market. There are implications for the deployment of digital health technologies and their scalability because these challenges are interdependent.

Third, absent is a policy focus once the digital health technology is on the market. Equal attention, therefore, is necessary to support downstream needs to ensure that digital health technologies are scalable. A robust system of monitoring the activity of digital health technologies once deployed in notable areas such as data access, ethics, governance and evidence requirements brings an opportunity to not only inform the spread of innovation but also provides an opportunity to build in feedback

mechanisms for the development stage. A key challenge is to establish a robust post-market surveillance system that harnesses the information from real-time data and takes into consideration a total product lifecycle approach.

This paper has shown that the regulatory challenges, however, are expected to be significant and require agile and more effective ways of working for regulators, policy-makers, health care professionals, patients and health service researchers to be responsive at pace. With a rapidly growing digital health technology market, pro-active policy-making responses are necessary. A collaborative model is needed and will help to identify the benefits of digital health technologies that are safe and provide value for money. The policy focus in this area is necessary and timely as it provides health service researchers a unique opportunity to be part of the debate and inform the decision-making process.