ABHI
DIGITAL HEALTH

DATA ACCESS AND USE: DISCUSSION DOCUMENT

CONTENTS

EXECUTIVE SUMMARY

Access to well curated and trusted health data is a vital resource for the HealthTech industry to partner with others in the healthcare ecosystem to develop innovations that can save lives, manage the burden of disease, and support the efficient use of health resources.

Whilst the UK already performs well in the secondary use of data[1]. A national health and care data strategy that delivers a trusted data community between patients, clinicians, healthcare providers and HealthTech companies would support even greater use of data in a manner that engenders trust from users and citizens. Without this the UK could miss the opportunity to become a world leader in ethical data use and medical discovery, losing the associated economic growth, jobs, and clinical breakthroughs. There are some key principles we believe need to be included in the delivery of health data policy and practice:

- Protecting patient privacy must be the number one priority.
- Transparency and clarity in rules, usage and communication regarding patient data.
- Focus on appropriate, risk based standards and governance.
- A standard approach to the application and interpretation of data sharing rules.
- The regulatory system should be a central pillar of the governance programme.
- Utilise sector specific regulation where appropriate UK as an attractive investment and launch market.

Patients and Public

Patient data is a national asset with a potential value of nearly £10bn per annum[2] and patients, the NHS and the UK taxpayer should have a stake in the value of the scientific insights it creates. The form of how this occurs needs debate and should look broadly at how value is delivered to UK economy and society rather than a narrow view of returning value to patients or the NHS specifically.

There is widespread support for harnessing data for public benefit, however there is less certainty over the sharing of data with private companies[3,4]. Without access to data many innovations may never become readily accessible to NHS patients. Communications from the Government and the NHS need to highlight the role of industry in supporting the NHS and delivering new breakthroughs in prevention, diagnosis and treatment.

Governance

Governance of NHS data sits within the UK General Data Protection Regulation (GDPR), the common law duty of confidentiality and, when used within Digital Health Technologies, the regulation of medical devices. These regulations are not consistent and the Wade-Gery report[5] acknowledges the "friction for the sharing of data" within the system. For commercial organisations this is most visible in the local governance rules on data sharing from NHS Trusts, Integrated Care Systems or Health Boards. Local variances in interpretation of information governance rules vary widely and impede the routine flow and analysis of health data.

The Health Data Strategy[6] made a commitment to "share anonymous data for the benefit of the system as a whole". This commitment should also extend to sharing with industry/researchers for a broad range of applications, under correct governance framework. This needs to go beyond formal clinical studies to include research using real-world evidence, secondary use of clinical trials data and support the legal obligation of medical technology companies to engage in pre- and post-market clinical investigations and studies.

Data Infrastructure

The UK is lagging behind several jurisdictions in the quality, completeness, interoperability and accessibility of its national data[7]. This gap could be closed by building a robust infrastructure for data storage and sharing and implementing a national electronic health record (EHR) network and addressing interoperability challenges. As recommended within the Wade-Gery review[8], Trusts and Health Boards should receive and allocate funding to ensure they have the capacity and infrastructure in place to collect and analyse data.

The National Data Strategy[9] highlighted that barriers to accessing data represent a significant limitation on research. The life sciences industry has identified a number of systemic barriers that limit access to data[10], including time taken to access data, access constraints for commercial users, the effort to identify and assess the quality of datasets and, most notably, the cost of the data access itself.

Some of the issues HealthTech companies face have their origin in the lack of certainty around the appropriate legal basis and conditions for data processing, and that UK GDPR requirements are not always consistent with medical device regulations.

Before the benefit of utilising anonymised patient data for clinical research can be fully realised, some of the barriers to interoperability and standardisation need to be overcome, this includes addressing the issues caused by the deployment of a wide range of EHR platforms[11]. Data portability and interoperability would be further supported by common standards and templates for data collection.

As a first step, the UK needs to improve the aggregation and curation of NHS data. The cost of aggregating and curating patient records for data driven research and innovation is estimated at £2-3bn[12]. This would generate a revenue stream for the NHS, reduce operational costs and increase the speed of clinical research, benefiting patients. It would also make the UK a more attractive location for foreign direct investment, creating 17,000 jobs and delivering £5bn in annual revenue[13].

Security measures like pseudonymisation or de-identification are important elements to safeguard data flows, although further work is required to clearly define and explain the terminology and potential use cases. Pseudonymisation and anonymisation are not the only privacy-friendly ways to harness the potential of data, and the use of privacy-enhancing technologies, such as federated learning and synthetic data generation open new opportunities whilst mitigating data protection risks. We support the creation of Trusted Research Environments (TREs) to provide timely and secure access to health and care data. It is crucial that industry has access to such environments and can use the TREs to import their own algorithms, tools and platforms. Using a federated model to store and access information has been shown to work in multiple countries[14].

AI

There are specific concerns around the use of AI, not just as regards the use of data to develop, train and deploy such systems, but in their decision-making role within a care pathway or intervention. A report by PWC[15] highlighted that the UK was consistently less willing than other countries to utilise AI within its health care regime. Further clarification is needed around the fundamental regulation principles for AI in particularly accountability, transparency, fairness, and security

A risk-based and sector-specific approach to regulation and guidance is the best means to address issues related to the use of AI in medical devices, because it addresses patient risk in the context of where those solutions are deployed. This could provide legal certainty on how those fundamental principles apply to specific, already well-regulated sectors such as medical devices. This should build on the existing regulatory framework and future work programmes established to develop guidance for AI as a Medical Device or Diagnostic[16].

Commercial Partnerships

The Health Technology industry has a range of skills, resources and tools that could support the NHS to deliver significant clinical and system efficiency insights. Policy and practice should encourage and facilitate public-private partnerships to help the NHS realise the full potential of the data asset. We recognise that when it comes to data sharing, there needs to be an exchange of value – it is important that health services see a benefit, not least to inspire public confidence in data sharing. There should also be consideration given to ensure that it is not detrimental to, but enhances the UK as a favoured location for economic investment and growth.

We welcome the current approach from UK Government, based on recent consultations, to recognise the importance of cross-border data flows and take a risk-based approach to international data transfers, governed by pragmatism and effectiveness. The UK should continue to promote strong privacy safeguards and international data flows as pillars of the data economy when negotiating trade deals, helping UK businesses to have a streamlined regulatory approach that supports growth for companies seeking to expand their business outside the UK.

The non-rivalrous nature of data means it can be difficult to establish the rights to develop intellectual property from data, therefore we need a sophisticated approach that encourages innovation and competition whilst maintaining public trust and ensuring that the NHS and the public see the benefits of data driven innovation.

RECOMMENDATIONS SUMMARY

- The UK should invest to improve the aggregation and curation of health and care data to generate revenue, reduce NHS operational costs, and make the UK a more attractive location for investment.
- Government and NHS patient communication needs to consistently highlight the value of data sharing and the vital role of commercial companies in supporting the health and care system and delivering new breakthroughs in prevention, diagnosis and treatment.
- Reduce the friction for the sharing of data by simplifying and aligning regulation and providing easily accessible and usable guidance, particularly in data regulation and lawful grounds for processing.
- A common regulatory and governance framework, processes and templates should be centrally arranged and deployment enabled at national, regional or local level.
- Extend the definition of 'research' under UK GDPR to encompass pre and post-market clinical investigations, post market surveillance and impact modelling.
- Remove inconsistencies between UK GDPR requirements and medical device regulations.
- The Government should continue to support the Health Data Research Innovation Gateway as part of the HDRUK and encourage greater completeness and quality of its datasets.
- NHS E/I should implement the recommendation Wade-Gery review[17] to reprioritise spend to lift the share devoted to digitally enabled system transformation from the current estimate of circa 2% to the suggested target of 5%.
- Address the fragmentation of the data infrastructure, including:
    i. Develop a target data architecture for health and social care to support interoperability with standardised provision for data sharing, storage and access.
    ii. Progress towards creating at-scale data assets that bring together the different types of health data to develop new tools for prevention, diagnostics and clinical decision-support.
    iii. Development of open, non-proprietary standards and APIs for data, data access, and interoperability.
- Establish TREs with industry access and ability to import their own algorithms and tools. Results of any analysis should reside with industry.
- Provide clarity on the terminology and potential use cases regarding "anonymisation", "anonymous data", "de-identified data" and "secondary use".
- We recommend that there is further clarification of the fundamental principles for AI in regulation, especially in relation to requirements around accountability, transparency, fairness, and security in AI.
- Adopt a risk-based and sector-specific approach to regulation and guidance for AI building on existing MHRA requirements for SaMD.
- Implement, in legislation, proposals from the Taskforce on Innovation, Growth and Regulatory Reform (TIGRR) independent report[18] and consultation "Data: A New Direction" to remove Art.22 of UK GDPR, establish a list legitimate interests for which no balancing test would be required and enable private companies, processing personal data for a public body to be permitted to rely on that body's lawful ground for processing.
- When assessing the value of data partnerships consideration should be given to the overall value of any partnership to the advancement of healthcare and the broad economic impact.
- The Health Data Strategy[19] made a commitment to "share anonymous data for the benefit of the system as a whole". This commitment should extend to sharing with industry/ researchers.
- The Centre for Improving Data Collaboration should support data sharing partnerships between NHS Trusts and commercial entities and ensure conditions and fees for data use are non-discriminatory, proportionate, objectively justified and do not restrict competition.
- The UK should look at international alignment on data use and regulation to support UK trade and investment and hence economic growth and employment, becoming an exemplar for global data usage, security and sharing
- Implement proposals in the consultation from the ICO on International Data Transfers[20], particularly:
    i. Establish an International Data Transfer Agreement, that is flexible and easy to use.
    ii. Adoption of model data transfer agreements issued in other jurisdictions.
    iii. The inclusion of the draft addendum to the EU Standard Contractual Clauses (SCC's) so the clauses can be used for data transfers from the U.K.

INTRODUCTION

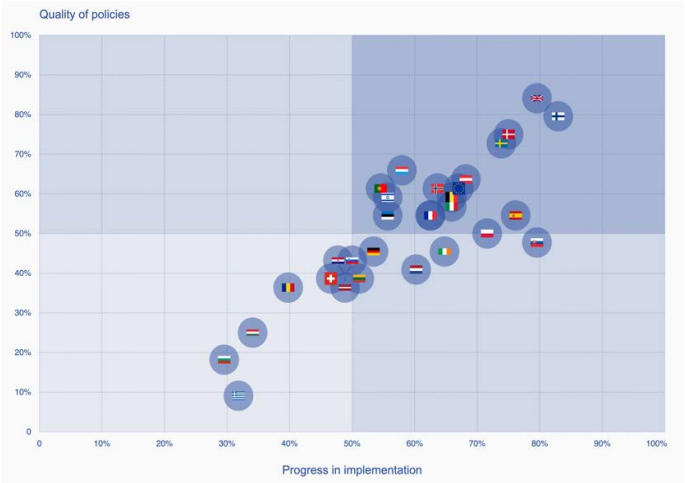
Access to well curated and trusted health data is a vital resource for the Life Science industry to develop innovations that can save lives, manage the burden of disease and support the efficient use of scarce health resources.

"The value of the curated NHS data set could be as much as £5bn per annum and deliver around £4.6bn of benefit to patients per annum — generated through NHS operational savings, enhanced patient outcomes and creation of wider economic benefits to the UK, generated through 'big data', artificial intelligence and personalised medicine."

Realising the value of health care data: a framework for the future, EY, 2019

Even before the pandemic, there was an urgent need to optimise healthcare systems and manage limited resources more effectively, not least to meet the needs of growing, and often ageing, populations. The Pandemic has both heightened that need, but also shown us a way forward. This discussion document aims to highlight the steps that can be taken to support the creation of a set of ambitious recommendations from industry.

A report from the Open Data Institute on Secondary Use of Health Data in Europe[21] ranked the UK highest across Europe, so we are starting from a strong position, yet we know there is more that can be done to support greater use of data. It should flow through the system seamlessly, to deliver better patient outcomes and experience and support innovation but, critically, to do so in a manner that engenders trust from users and citizens. Despite the excellent overall performance, the UK score for innovation was weaker than our overall score, based on the recognition of the unrealised opportunity of secondary use of health data and investment in EHR systems and very low on ethics, i.e. the level of trust in healthcare systems and the ethical and accountability framework.



This is reinforced by a recent evidence session held by the Digital Health APPG which highlighted that respondents consistently highlighted the "siloed" nature of data and that regulations around information governance were described as "impenetrable", "confusing" and "stifling".

The National Data Strategy[22] highlighted that barriers to accessing data represent a significant limitation on research that must be addressed if the UK is to remain at the forefront of science and research. This report will outline some of the barriers, and recommendations that will help maximise the impact of data sharing with industry to support the UK economy and delivery of innovation to the NHS to deliver improved clinical and financial outcomes. We will look broadly at the policy changes required, the processes that need adaptation and, importantly, the cultural and societal issues associated with data. This is an unusual area, in that some of the legislation and certainly some of the cultural norms are dictated by organisations and factors well outside of health. This means that in some cases it is about how the health sector and industry need to adapt to factors outside of our control rather than the amendment of heath policy or practice.

The UK has the opportunity to become a world leader in ethical data analysis and medical discovery and we cannot afford to let this opportunity slip through our grasp. The risk is that value, jobs, and clinical breakthroughs will be commercialised outside of the UK. We need a national health and care data strategy that embraces a partnership model to ensure public trust in the use of patient data and that the UK does not lose its competitive advantage.

- Protecting patient privacy must be the number one priority when designing any system which allows for the use of patient data.
- Ensure transparency and clarity in rules, usage and communication regarding patient data.
- Focus on appropriate, risk based standards and governance to avoid over complexity and unnecessary bureaucracy.
- Do it once, remove local divergence in the interpretation of data sharing rules, safeguards and governance.
- A robust, transparent and risk stratified regulatory system should be a central pillar of the governance programme.
- Where appropriate, utilise sector specific regulation rather than broad horizontal legislation.

PATIENTS AND PUBLIC

Patient data is a national asset and patients, the NHS and the UK taxpayer should have a stake in the value of scientific insights unlocked by combining large datasets. The form of how this occurs needs significant debate and should look broadly at how value is delivered to UK society, rather than a narrow view of returning value to patients or NHS specifically. The UK has the potential to become a world leader in health data use and medical discovery, to facilitate this we need a national health and care data strategy that embraces a partnership model that facilitates a trusted data community between patients, clinicians, healthcare providers and life science companies that is transparent, fair and effective.

As with many new forms of technology, there are questions regarding whether digital health tools have any unintended consequences, particularly for under-represented groups and those who are not digitally connected.

These are legitimate concerns that need to be addressed in the development and deployment of Digital Health Technologies (DHTs) and the consequent access, storage and use of patient data. The Health Data Strategy[23] puts great emphasis on the role of patients in controlling, accessing and understanding their own data, it also highlights the privacy and security measures in place to prioritise patient confidentiality and trust. Responses to the government's National Data Strategy consultation showed widespread support for harnessing data for public benefit, however there is less certainty over the sharing of data with private companies. A survey by Imperial College[24] has shown that only 5% of citizens would be willing to share health data with commercial entities and that when institutions are likely to use data for commercial purposes, respondents were less willing to share their data, especially in the case of 'tech' organisations, this has been backed up by previous surveys[25].

There is strong support that during a public health emergency (such as coronavirus) it is more important than usual that health data is shared with those involved in the response[26]. However at this stage there is no clear understanding on how people's attitude to data sharing with industry outside of emergency conditions may have been changed by experiences during the pandemic.

Whilst reports have highlighted the concerns of patients and the public in sharing data with industry, without access to this data many innovations may never become readily accessible to NHS patients. Communications from government and NHS needs to consistently highlight the vital role of industry in supporting the health and care system and delivering new breakthroughs in prevention, diagnosis and treatment. Specifically, there needs to be a sustained and systematic communications campaign to ensure that patients and citizens understand:

- The value of their data (when combined with many others).
- The role of commercial companies in developing innovations for use by the NHS.
- The benefit to be gained for them personally by sharing their data.
- The privacy and security standards employed on the use of the data.

There are many topics that will feed into demonstrating that there is a trustworthy system in place to manage and use patient data and these will be addressed in more depth in later sections, but include:

- Governance and Regulation.
- Privacy Enhancing Technologies (PETs)and Trusted Research Environments (TREs).
- Anonymisation and Pseudonymisation.

There appear to be specific concerns in the use of AI, not just as regards the use of data to develop, train and deploy such systems, but in their decision-making role within a care pathway or intervention. A report by PWC[27] highlighted that UK was consistently less willing than other countries to utilise AI within their health care regime.

However it is important to recognise a wider context when addressing public concerns over use of data. A recent report from the Nuffield Trust[28], looking at five European health systems, highlighted that a long history of using digital tools in many areas of public life was the "most fundamental" thing in creating a "culture of confidence" around the use of data.

GOVERNANCE AND REGULATION

Governance of NHS data sits within the wider regulatory framework of the UK General Data Protection Regulation (GDPR), the common law duty of confidentiality and the regulation of medical devices. These overlapping regulations are not consistent, and this disconnect has been highlighted as one possible reason why the NHS can be overly cautious regarding data sharing[29]. There is huge potential for regulatory guidance in this space to clarify the intersection between these regimes. Such guidance would need to involve multiple stakeholders, given the interplay of regulatory regimes, including the National Data Guardian, the Information Commissioner's Office, NHS England, the MHRA, and the Health Research Authority (HRA)[30].

The Wade-Gery report[31] acknowledges the "friction for the sharing of data" within the system. For commercial organisations this is most visible in the local governance rules on data sharing from NHS Trusts, Integrated Care Systems or Health Boards.

A clear and consistent legal and governance framework for accessing data, including governance mechanisms for primary and secondary use of health data, is needed. Whilst GDPR provides a strong foundation for secondary use of health data, governance tools are needed to enable data reuse. For example, codes of conduct, ethics committees, infrastructure for real-world data and real-world evidence, stronger data institutions, and clearer legal frameworks[32]. Consideration should be given to development of joint codes of ethics between a relevant NHS body (possibly the Centre for Improving Data Collaboration) and organisations representing user groups, including industry.

Guidance should be provided to NHS organisations around the patient consent or other mechanisms for data sharing, and specifically around whether secondary use is appropriate or not. Currently interpretation and implementation can vary widely. The way the General Data Protection Regulation (GDPR) is being applied makes it difficult to move research forward and to share data. There is little or no evidence of patient data ever becoming de-anonymized during clinical research and there is a need to be able to access public databases. But the fear of personal details being released has led to overregulation, resulting in a reduction in research[33].

Local variances in interpretation of information governance rules impede the routine analysis of health data. A common regulatory and governance framework should be centrally arranged and should enable multiple deployments e.g. at regional/national level, depending on data types and intended use, and result in federated Health Data Spaces. We would recommend that there is a single template developed centrally and deployed nationally to reduce barriers and complexity.

The Health Data Strategy[34] made a commitment to "share anonymous data for the benefit of the system as a whole". This commitment should also extend to sharing with industry/ researchers, under appropriate governance, and to support this we need clear definitions and processes for the assessment of benefit, as well as clarity on governance arrangements.

There are some specific areas where further guidance or changes to regulation would support industry to appropriately utilise NHS data to deliver patient and system benefit.

Research

The phraseology of 'secondary use for research' is often used. However, it should be clear that there are a wider variety of secondary uses that could be appropriate, such as

- Prototyping, validation and verification of algorithms.
- Post market surveillance for patient safety.
- Clinical and economic impact modelling for innovations (technology, clinical or pathway).

Research is a critical area for data use within industry, and wider, however the term is not used consistently or broadly. Advancement of research in HealthTech would benefit from clarity and legal certainty that the "research" provisions of the UK GDPR apply equally to private and public research projects. We would recommend clarifying a broader meaning for the term "research" in legislation than is currently defined. It is important for the definition and scope of "research" under UK GDPR to go beyond formal clinical studies to also include research on real-world evidence and secondary use of clinical trials data. These sources and uses are increasingly important to HealthTech development, and their use both speeds and improves the quality of research. The definition and scope of "research" should also support the legal obligation of medical device companies to engage in pre- and post-market clinical investigations and studies, which requires the collection and processing of sensitive data.

Some of the issues HealthTech companies face originate in the lack of certainty around the appropriate legal basis and condition for data processing and that UK GDPR requirements are not always consistent with the medical device regulations. Work to align sector-specific regulation (UKCA mark for medical devices and invitro diagnostics) would be beneficial.

Data Processing

There are a number of scenarios where Health Technology companies will process data on behalf of a public body (usually an NHS Organisation). The proposals in the recent consultation from the Department of Culture Media and Sport (DCMS) "Data: a new direction" to enable private companies, organisations and individuals processing personal data for a public body to be permitted to rely on that body's lawful ground for processing the data would be welcome to support faster data handling. The implementation of this would, however, raise important considerations for the private sector entity regarding how it would receive assurance that the public body had themselves appropriately assessed the lawful ground and how the private sector entity would be impacted if the public body was found by ICO to have erred in its assessment.

Legitimate Interests

We also support the proposal in the DCMS consultation to establish a list of legitimate interests for which no balancing test would be required within UK GDPR. This would substantially support innovation and the development and use of HealthTech in the UK. It is critical that mechanisms exist to keep this list contemporary so as not to limit future applications. We also believe that there may be an opportunity to provide sector-specific legitimate interests, in addition to the general menu available to all. We are of the opinion that the concept of such a list should not exclude a broad framing of legitimate interest so as not to limit future applications.

DATA INFRASTRUCTURE

The UK is lagging behind several jurisdictions in the quality, completeness and interoperability of its national data. For example, whether patients consent covers the intended use of the health data, whether third parties are legally able to use the dataset in the way they intend, what the costs of access are, and how long it will take to get permission and practically access the dataset[36]. This gap could be closed by building a robust IT infrastructure for data storage and sharing, implementing a national EHR network across primary and secondary care, and addressing interoperability challenges. It is recognised that given the diversity of secondary care system, this is a long-term goal.

The establishment of the Health Data Research Innovation Gateway as part of the HDRUK Research Alliance is a positive step. However, challenges exist with the Alliance. Organisations are not required to make specific commitments to data access, and membership of the group is not comprehensive, with some relevant bodies not signed up. The Government should continue to support the Gateway and help greater completeness and transparency of quality of the data in the available datasets.

Trusts and Health Boards should also receive funds to upgrade their IT systems and ensure they have the capacity and infrastructure in place to collect and analyse data. We endorse implementing the recommendation within the Wade-Gery review[37] to reprioritise NHSEI spend to lift the share devoted to digitally enabled system transformation from the current estimate of circa 2% to the suggested target of 5%.

The National Data Strategy[38] highlighted that barriers to accessing data represent a significant limitation on research that must be addressed if the UK is to remain at the forefront of science and research. For example, research into data use by the life sciences industry identified a number of systemic barriers that limit access to data. Most companies surveyed noted experiencing delays and uncertainties. These include time taken to access data, access constraints for commercial users, the effort to identify and assess the quality of datasets and, most notably, the cost of the accessing data itself.

Before the benefit of utilising anonymised patient data for clinical research and to improve care can be fully realised, some of the barriers to interoperability and standardisation need to be overcome. Currently, health and care data in the UK is held on multiple platforms A recent study found that of the 117 NHS trusts using EHR systems, 92 of them were using at least 21 different systems[39]. To facilitate access to data that creates intelligence about disease states and public health, whilst providing insights to designing better and more personalised therapies, this fragmentation needs to be addressed.

As a first step, the UK needs to improve the aggregation and curation of NHS data. The cost of aggregating and curating patient records for data driven research and innovation is estimated at £2-3bn[40]. Once complete, this would generate a revenue stream for the NHS, reduce costs and increase the speed of clinical research, benefiting patients. It would also make the UK a more attractive location for foreign direct investment and has the potential to create 17,000 jobs and deliver £5bn in annual revenue[41].

Anonymisation and Privacy

Regulation/Compliance has a key role to play in managing risks in relation to sufficiently anonymised data sets, whilst continuing to promote ongoing innovation. HealthTech strongly believes that balance is best achieved through risk-based and sector- specific regulation and guidance

Security measures, like pseudonymisation or de-identification are key elements to safeguard data flows. In addition, for regulated data, it would be beneficial to ensure controls on security and privacy by design are required, including encryption at rest and in transit by default, together with minimum least privileges and segregation of duties in the code. A final piece is to ensure compliance to stringent regulatory requirements and rigorous certifications such as ISO 27001.

For the data to be considered anonymous, one must not be able to identify a natural person by any means such as singling out, 'linkability' or inference. Thus, the determination of whether or not the data is anonymous is based on a risk-based evaluation and anonymisation is therefore defined as a risk threshold. The ICO provide greater clarity in their code of practice on anonymisation[42].

Further work is required to clearly define and explain the terminology and potential use cases regarding "anonymisation", "anonymous data", "de-identified data" and "secondary use" and when a dataset can be considered sufficiently anonymised so it can be used and shared for commercial scientific research by HealthTech companies. Following proposals laid out in the "Data: a new direction" consultation, the requirement to make data anonymous should be only relative to the means available to the data controller to re-identify it.

Privacy-Enhancing Technologies (PETs)

Anonymisation is not the only privacy-friendly way to harness the potential of data. The Government should explore new opportunities to promote and support privacy-enhancing technologies, such as federated learning (where the data is not shared, but instead algorithm training is done where the data is located) and synthetic data generation. These approaches could boost innovation, whilst mitigating data protection risks. In that respect, it would be beneficial if the Government and the MHRA encouraged the ICO to provide clear guidance to help organisations build confidence in the use of emerging PETs. Moreover, it should be clear when pseudonymisation or PETs are mandated, versus when they simply offer additional protection for data subjects. For example, PETs may be applied as part of a privacy-by-design approach, but it remains unclear how an organization might validate that they are sufficient. Technical standardisation could also help organisations and their suppliers to develop these approaches in partnership.

Technical platforms and trusted research environments

Greater interoperability of data can deliver improvements in clinical operations, patient outcomes and the cost of healthcare. We support the creation of Trusted Research Environments to provide timely and secure access to health and care data. It is crucial that industry has access to such environments and can use the TREs to import their own algorithms, tools and platforms.

To enable the necessary data analytics, we would recommend the following.

- To facilitate a consistent and secure use and re-use of health data, a target data architecture for health and social care should be developed, outlining how and where data will be accessed, shared and stored.
- Progress towards creating at-scale data assets that bring together the different types of health data.
- Development of open, non-proprietary standards and APIs for data, data access, and interoperability.
- Provide clarity on whether data need to be held within the NHS Health and Social Care Network or if it is acceptable for the anonymised, aggregated data to be shared outside under certain conditions.

Using a federated model to store and access information has been shown to work in multiple countries[43]. This should be supported by legislation on interoperability and data sharing requirements. A good example is Findata[44], a 'one-stop shop' set up with co-operation between the public and private sectors to make the secondary use of social welfare and healthcare data easier. Data are more available, and the system is able to promote its secure use for more extensive purposes. With new enabling legislation that came into force in May 2019, Finland became the first country to successfully enact a law on the secondary use of well-being data that met EU GDPR requirements[45].

AI AND MACHINE LERNING

We recommend that there is further clarification of the fundamental principles for AI in regulation, especially in relation to requirements around accountability, transparency, fairness, and security in AI.

In parallel, ABHI recommends adopting a risk-based and sector-specific approach to regulation and guidance to ensure there is legal certainty on how those fundamental principles apply to specific, already well-regulated sectors such as medical devices.

For medical devices, the existing medical device regulatory framework administered by the Medicines and Healthcare Products Regulatory Agency (MHRA) already sets out precise requirements for medical device software, and there is further work on going to establish better guidance for AI as a Medical Device or Diagnostic[46]. The MHRA regulatory framework, rather than a broad horizontal AI regulation, - is the best means to address issues related to the use of AI in medical devices, because it is contextual and would avoid potential legal confusion or lack of certainty for medical device innovators that could arise from any competing MHRA and horizontal AI legal principles.

Government should consider how sector specific guidelines could be introduced for the ethical use of AI. We would recommend that, wherever possible, broad legislation is minimised and sector specific approaches taken, in the case of medical technology through the UKCA Medical Device and diagnostics framework.

Fairness

ABHI recommends that the definition of "outcome fairness" needs to be clarified and recommends leveraging existing MHRA regulations in this regard. This existing framework is best placed to determine how the concept of "outcome fairness" applies to HealthTech that incorporates AI, and the necessary regulatory requirements.

Automated Decision-Making

We support the Taskforce on Innovation, Growth and Regulatory Reform's (TIGRR)[47] recommendation that Article 22 of UK GDPR be removed, and that the use of solely automated AI systems be permitted based on legitimate interests or public interests. Subject to appropriate sectorial regulations, as laid out in existing medical device and invitro diagnostics regulations, which already require that manufacturers of medical devices (including those AI-enabled) demonstrate the safety and performance of their devices considering their intended use.

Bias in AI

The issue of bias is a systemic issue, and not unique to AI, all medical and in vitro diagnostic devices must be developed in a manner to minimize bias. There are multiple entry points for bias to be fed into the system. The data collection process through disparities in the recruitment of research subjects, the use of data to construct algorithms may also carry prejudices and access to healthcare facilities and HealthTech suffers its own forms of inequalities[48].

This is why medical device developers, including AI as a medical device, follow design control requirements with rigorous processes related to design specifications, risk management, verification, human factors, and validation. These processes are at least partially reliant on the data that are captured, curated and made accessible from the health system. The nature of adaptative algorithms or machine learning requires that there is a shared responsibility in monitoring performance and outcomes.

ABHI shares the view outlined in the DCMS consultation[49] that making explicit consent a prerequisite for data access for use for bias detection and mitigation purposes may, in itself, risk introducing bias into the data used in an AI system, furthering the risk of introducing unwarranted bias in AI algorithms used in HealthTech. Such a use should be part of a list of legitimate interests that organisations can use without applying the balancing test.

COMMERCIAL PARTNERSHIPS

The HealthTech industry has a range of skills, resources and tools that could support the NHS, and increasingly connected and powerful devices provide data that can produce significant clinical and system efficiency insights. More use should be made of this resource and the NHS should allow the data to be analysed, processed by technology manufacturers and returned to the NHS. Policy and practice should encourage and facilitate public-private partnerships to help the NHS realise the full potential of the data asset, which will only be recognised if data is properly curated and linked at scale, rather than developed in an ad hoc way by small groups of Trusts or Health Boards.

We recognise that when it comes to data sharing, there needs to be an exchange of value. It is important that health services see a benefit, not least to inspire public confidence in data sharing. Whilst considerable weighting should be given to the value of data for the NHS and patients, there should also be consideration given to the overall value of any partnership to the advancement of healthcare and the positive economic impact of the HealthTech industry in the UK. The Health Data Strategy needs to take a broader approach to value and include a test to ensure that it is not detrimental to, but enhances the UK as a globally competitive location for economic investment and growth.

The NHS has a patient dataset with world leading potential for medical discovery and drug development. The non-rivalrous nature of data means it can be difficult to establish the rights to develop intellectual property from data, which is important for driving new discoveries. As the National Data Strategy makes clear, we need a sophisticated approach that encourages innovation and competition whilst maintaining public trust and ensuring that the NHS and the public see the benefits of health data innovation. The NHS should ensure that the implementation of the open-source approach does not damage Intellectual Property and hence make working with the NHS undesirable. IP assignment and protection should be transparent and aligned with value creation. By defining standard interfaces between applications and incentivising open-source code and library sharing, we can seek to address the challenges around IP.

The Centre for Improving Data Collaboration should support data sharing partnerships between NHS Trust and commercial entities and consider innovations in business models that support public/private collaborations, do not restrict use of the data, and ensure that appropriate value is return to all parties involved. True 'risk sharing' approaches, where each party puts in the required resource and is remunerated accordingly should be encouraged.

Conditions and fees for re-use of public sector data should be non-discriminatory, proportionate, objectively justified and not restrict competition. The existing work of the Centre for Improving Data Collaboration picks up on a number of these themes.

To encourage private sector to participate in data sharing and data management there needs to be certain safeguards in place, which will include:

- Commercial in confidence information should be respected.
- Provision should be made for "safe harbour" discussions on data handling.

International Trade

The UK is in a globally competitive environment and data regulation needs to be seen within an international context and other policy initiatives, such as the Life Science Vision. Legislation and practice should seek to be coherent with initiatives and legislation in other major trading blocs such as the US and EU. The UK should look at international alignment to support UK trade and investment and hence economic growth and employment, becoming an exemplar for global data usage, security and sharing. The UK should not lose sight of adequacy with the EU and align with the EU Recommendations on EHR exchange format.

We welcome the current approach from UK Government, based on recent consultations, to recognise the importance of cross-border data flows and take a risk-based approach to international data transfers, governed by pragmatism and effectiveness. At a time of rising protectionism across the world, the UK should continue to promote strong privacy safeguards and international data flows as pillars of the data economy. The UK should also be a strong voice against localisation trends and other restrictions to international data flows.

There is an opportunity within these broad principles to avoid fragmentation between international legal frameworks whilst enabling UK business to have a streamlined regulation that reduces bureaucracy and supports growth.

The incorporation of adequacy agreements as part of trade deals will be an important mechanism to support international data flows, however, there needs to be further mechanisms to support data exchange with countries where there is no trade deal or adequacy agreement in place. The proposals in the consultation from the ICO on International Data Transfers[50] are generally helpful in this regard, particularly:

- Establishing an International Data Transfer Agreement, and specifically:
    i. The tabular approach and ability to edit to make it flexible and easy to use.
    ii. 'One size fits all' approach rather than the modular structure of the EU SCCs.
    iii. Flexibility in the application of clauses based on status of parties.
    iv. Option to make the agreement multiparty and recognition that parties may have linked agreements and ability to cross-reference these.
- Adoption of model data transfer agreements issued in other jurisdictions.
- The inclusion of the draft addendum to the EU SCC's so the clauses can be used for data transfers from the U.K. It is good that the addendum is short, clear and flexible, allowing its terms to be modified so long as appropriate safeguards are maintained. This removes complexity and cost for organisations and the need for preparing different forms of language for the EU and UK transfers. The ICO should consider adopting the same approach as the Swiss Federal Data Protection and Information Commissioner in this respect of implementing the addendum.

Adopting model data transfer agreements issued in other jurisdictions is vital to help reduce fragmentation and avoid international companies needing to comply with different obligations (like potentially different sets of Standard Contractual Clauses). This in turn enables UK businesses to have a streamlined regulatory approach that reduces bureaucracy and supports growth should a company seek to expand its business outside the UK.

ABOUT ABHI AND HEALTHTECH

ABHI supports the HealthTech community to save and enhance lives. Members, including both multinationals and small and medium sized enterprises (SMEs), supply products from syringes and wound dressings to surgical robots and digitally enhanced technologies. We represent the industry to stakeholders, such as the government, NHS and regulators. HealthTech plays a key role in supporting delivery of healthcare and is a significant contributor to the UK's economic growth. HealthTech is the largest employer in the broader Life Sciences sector, employing 138,100 people in 4,140 companies, with a combined turnover of £27.6bn. The industry has enjoyed growth of around 5% in recent years. ABHI's 320 members account for approximately 80% of the sector by value.

As the most highly regarded universal healthcare system in the world, the NHS in turn is dependent on technology produced by the industry to enhance the efficiency of services and drive continuous improvement in their delivery. The NHS has grown and developed partly on the basis of the UK's historic 'can do' approach to engineering and problem solving.

HealthTech is accordingly an engineering-based industry, characterised by rapid, often iterative product design and development, and a large number of SMEs. It is one of two distinct subsectors of the broader Life Sciences. Future growth and success will mean the HealthTech sector being recognised in its own right. The sector has evidence, regulatory and adoption needs that differ significantly from those of the other, biopharmaceuticals.

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February 2022

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