ABHI Response to Scottish Consultation on "Data Strategy for health and social care"

Submitted 12th August 2022

Part 3: Empowering Industry, Innovators and Researchers

We have an ambition to ensure opportunities for innovation, industry and research are driven by high quality data. This in turn will support the delivery of outstanding health and social care services that are able to integrate the findings of innovation and research.

Access to data for research and innovation

Our experience is that worthwhile projects often require large volumes of data and/or the joining of multiple datasets. However, identifiable personal information is not required for most research and innovation purposes. We know that by collaborating with industry, innovators, and academia we can create not only economic value for Scotland. We can also take advantage of opportunities to significantly improve our health and social care services with innovative technologies and approaches.

Engagement with professionals working in health and social care innovation, industry and academia has so far told us that Scotland's health and social care data should be recognised as a national asset. The value of this data to Scottish society and its economy is being examined and debated. We heard from industry and innovators that there is support for a 'Once for Scotland' approach to information governance, reducing the need for the work to be duplicated, therefore speeding up the time it takes to access data in a timely manner. That is why our Strategy will outline how we will work with the newly formed organisation, Research Data Scotland, to improve access to Scotland's health and social care data for research, whilst building on some of the truly world-class data-enabled research initiatives in Scotland such as EAVE II.

Our engagement also told us that there is widespread public support for harnessing data for public benefit (such as creating new drugs to combat Covid-19). However we also heard that there is less certainty over the sharing of data for some purposes, such as marketing, financial gain for others, or activity that could be perceived as amounting to 'privatisation' of health and social care services. We recognise these concerns and aspire to further develop a system which allows seamless and efficient access to data for research with well understood outcomes and benefits for people. One that is completely transparent and builds trust by people in the way innovators and researchers use health and social care data for the public good.

Infrastructure

To facilitate appropriate access to health and social care data for research, we must create the right infrastructure that enables access in a manner that is both timely but also safe and secure. Engagement has told us that this is a precursor to greater innovation and use of data. The outcome of engagement sessions so far has shown that there is a strong appetite for real-time data sets (meaning data that is available for use immediately or shortly after

being generated) for research and innovation use. Use of real-time data has the potential to benefit the ability to continuously improve services. We have heard that initial ambitions for the Strategy should be to create an infrastructure that allows researchers to access structured, and in some cases, real-time national health and social care data.

Innovative technologies

One area of innovation the Scottish Government wants to capitalise on is the use of Artificial Intelligence (AI), as set out in Scotland's AI strategy. AI techniques such as machine learning solutions are transforming the way healthcare is being delivered. The Data Strategy's focus on trust, ethics and inclusion will inform its position on use of AI in health and social care. Health and social care services have accumulated vast data sets in the form of health records and images, population data and clinical trial data. AI technologies are well suited to analyse this data and uncover patterns and insights that humans could not find on their own. With deep learning from AI, healthcare organisations can use algorithms to help professionals make better business and clinical decisions and improve the quality of health and social care services in Scotland. However, for this technology to be effective, the data must first be of a high quality, or its use risks having a detrimental impact on our services, both operationally and ethically – potentially increasing inequalities. Crucial to adopting these technologies is that their use is transparent, explainable, and justifiable to the recipients of health and social care services. We want to seek your views on this technology and understand what it means to you.

Sharing Scottish data with the rest of the UK

Occasionally there is also a need to share data out with Scotland (and for data from out with Scotland to be shared with us). This frequently arises when individuals move from Scotland to elsewhere in the UK. The response to Covid-19 has shown the benefits of sharing certain data across the UK, for example – including public health surveillance data to help model the impact of Covid-19 and vaccine information to help understand the impact on people with certain clinical conditions. Some sharing also relates to the regulatory nature of healthcare at a UK level, including in the regulation of healthcare professionals, medicines, and medical devices. Sharing Scotland's health and social care data and collaborating with our partners across the four nations of the United Kingdom we can better understand how to improve health and social care services and improve outcomes for individuals across the United Kingdom. We want to ensure we can continue to collaborate on shared endeavours with the rest of the United Kingdom in a safe and ethical way.

12. When considering the ethics of accessing health and social care data for commercial, development and research purposes:

12A. How do you think health and social care data should be used by industry and innovators to improve health and social care outcomes?

ABHI represents manufacturers to medical devices, diagnostics and digital health solutions. Increasingly the technologies being developed are data-driven, in that they either utilise data to support their function and/or they generate data to enable a wholistic view of patient condition.

These technologies Data is a vital element in achieving the Life Sciences Strategy for Scotland 2025 Vision: to make Scotland the location of choice for businesses, researchers, healthcare professionals and investors, while increasing Life Sciences contribution to Scotland's economic growth.

Accessible, usable and interoperable NHS and care data that respects citizen confidentiality could help to develop a globally competitive offer for Scotland which supports Research & Innovation in the Life Sciences sector, creates jobs and introduces new treatments and solutions into the health and care services. Scotland needs to ensure that its data infrastructure supports interoperability between datasets in accordance with internationally accepted harmonized standards, enabling the use of advanced analytical tools which will be key to unlocking the promise of health and care data.

Collaboration between Government, the NHS, social care and Industry to optimise the collection, use and application of Real-World Evidence (RWE) will be key to harnessing benefits for Scotland's citizens, the NHS and researchers including, but not limited to:

- Stratifying and selecting the right patients for clinical trials to develop new treatments and interventions
- Supporting delivery of precision diagnostics and therapeutics for the right patients
- Assessing the performance and cost effectiveness of medicines, health and wellbeing technologies in routine clinical practice, and identifying indicators of variable response
- Analysing and refining patient pathways to ensure the best outcomes for different patient groups, and to support equality of access to these pathways
- Research, development and access to better medical devices
- Creating opportunities for early intervention and prevention in health and care to avoid unnecessary deterioration and costly upstream interventions

We support efforts to better utilise health and care data in clinical research, which should be delivered at pace to help mitigate the pandemic's impact on research & innovation capacity within the NHS and social care.

When deciding on suitable locations to run clinical trials or research programmes, the number one priority for industry funders and sponsors is that location's ability to reliably set up the study and recruit the required number of participants within a competitive timescale. In turn, the speed and reliability of study set-up and delivery are key determinants of the performance and competitiveness in clinical trials and research.

Accessible, quality data plays a vital role in achieving this performance. For example, population health data can be used to estimate how many participants a site could recruit to a clinical trial or research programme, which can inform where the trial is based and the chances it will meet recruitment targets to schedule. Therefore, better utilisation of health and care data would enhance the performance of UK clinical research, and its benefits to the NHS – for example, in 2018/19 alone, commercial clinical research generated an estimated income of £355 million and an estimated cost saving of £28.6 million for the NHS1. In addition, the NHS was able to access innovative treatments and interventions for its patients.

[1] Association of the British Pharmaceutical Industry. Clinical research in the UK: an opportunity for growth [Internet]. 2021. Available from: https://www.abpi.org.uk/r-d-manufacturing/clinical-research/clinical-research-in-the-uk-an-opportunity-for-growth/

There is also potential for data to be used to support the assessment and implementation of innovative and flexible outcomes-based pricing models for Scotland. This would support quicker adoption and create efficiencies in patient/disease management.

12B. How can industry and innovators maintain the trust and confidence of the people of Scotland when using their health and social care data for research purposes?

Industry should adhere to the required regulatory and compliance standards. The current regulatory landscape for medical technologies (CE/MDD and CE-IVD) /IVDR) already addresses many of the regulatory standards from a technical safety and compliance perspective.

A national approach to information governance, that is informed by and understood by citizens, should be at the centre of demonstrating a trustworthy system. There should be a clear policy, and a single standard and process for users to access data for research, commercialisation and innovation across Scotland that is mandated for NHS Scotland and National Care Scotland and adopted by all public national, regional, and local bodies.

Excellent work is already being progressed with individual regional Data Safe Havens and eDRIS in Scotland on the sharing of data for research and innovation, but significant additional benefit could be secured by Scotland if the current system was more easily accessed, better joined up and expanded. The existing infrastructure of the national and regional Data Safe Havens should be built upon with a mandate that all public national, regional and local bodies share public data for research and innovation with their regional Safe Haven and through the agreed methodology with the National Safe Haven (eDRIS).

The national approach needs to include transparency arrangements with clear and accessible records of data access and use. This should be in conjunction with consistent contracting and access arrangements,

In the significant majority of use cases, industry will not need access to citizen identifiable data. Industry will rarely use datasets other than key-coded or pseudonymised datasets for scientific research purposes, however full anonymisation may not in all instances be an option, as datasets may lose their scientific value when very intrusive anonymisation techniques are applied. It should be noted that part of the problem contributing to the situation of legal unclarity, is the lack of international consensus on appropriate de-identification standards for health data for research purposes.

There is a need for development of a clear and consistently applied process for research and innovation access to data, including support for fair / standardised commercial usage to support Scotland's economy that allows for effective access to data for industry, subject to compliance with recognized safeguards.

A national approach supports easier access to data for research and innovation while also supporting clear and consistent communication on use of data to citizens. Public trust is vital to fully harness the unique potential of Scottish health and care data. Industry representatives are keen to work with appropriate teams within the Scottish Government/the NHS on the development of materials and resources which support public dialogue and understanding. This could include examples of how industry already works collaboratively with partners across the life sciences ecosystem to deliver improved citizen outcomes,

including the use of health data to support the development of new medicines and treatments, and how population-wide data can be harnessed to develop targeted and better-informed health and care interventions which can reduce health inequalities and save lives.

As companies in the HealthTech sector typically only has access to pseudonymised data, it may not be possible to provide traditional notice directly to data subjects. There may be other ways to ensure that the public understands how researchers are using such data, as well as the benefits of such data use and the safeguards that are in place. This could, for example, be done through public education and awareness campaigns, where the public and regulators are made aware of the general data uses being undertaken by the organisation, as well as the benefits to such research. This can be done by the research entity alone or through industry organisations. Such efforts can be done to also contribute to the larger ethical and sociocultural conversations on the topic. This should not be seen as a way to discourage the distribution of notice where possible but should serve to augment such efforts and replace it where notice is not possible. This is currently conducted to varying degrees across the research ecosystem. The research community (incl. academia, charities & industry) Government and the NHS need to work together to further improve practice in this space and consider how to best embed an effective approach across the system.

12C. What do you believe would be unacceptable usage of Scotland's health and social care data by industry, innovators, and researchers?

It has been shown that the majority of the public are in favour of health and care data being used by commercial organisations as long as there is a clear public benefit and appropriate safeguards are in place.[2] A clear public benefit is often seen to be, for example, something with a clear medical aim, such as developing treatments and, in some cases, improving health and care services. The same report highlighted that resistance to insurance and direct marketing companies receiving health data was very strong.

There should be a clear health and/or societal benefit as the key deciding factor for acceptable use.

12D. How should industry, innovators and researchers be transparent about their purposes in accessing, and the benefits of using, health and social care data?

As companies in the MedTech sector typically only has access to pseudonymised data, it may not be possible to provide traditional notice directly to data subjects. There may be other ways to ensure that the public understands how researchers are using such data, as well as the benefits of such data use and the safeguards that are in place. This could, for example, be done through public education and awareness campaigns, where the public and regulators are made aware of the general data uses being undertaken by the organisation, as well as the benefits to such research. This can be done by the research entity alone or through industry organisations. Such efforts can be done to also contribute to the larger ethical and sociocultural conversations on the topic. This should not be seen as a way to

[2] Commercial access to health data | Ipsos

discourage the distribution of notice where possible but should serve to augment such efforts and replace it where notice is not possible.

There are already existing mechanisms for granting industry access to data held within Safe Havens, and we believe these provide adequate protection and transparency. However, as noted above, a streamlined national approach would further enhance Scotland as a destination for commercial research and innovation.

13. We want to create an infrastructure that supports access to data for research and innovation in a safe, secure, and transparent way:

13A. How should the Scottish Government seek to store and share health and social care data for research in order that it can best facilitate easier access that is still safe and secure?

Having one source of well curated data would be ideal, Scottish Government should mandate that all public national, regional and local health and care bodies should share public data for research and innovation with their regional Safe Haven and through the agreed methodology with the National Safe Haven (eDRIS). The Safe Havens should be the default mechanism for access to large scale datasets. However, there may still be requirements to access data at a hospital or Health Board level for specialist purposes, so whilst Safe Havens should be the main, national route it should not be the only route.

Data should be organized, classified, and prepared for further usage and international standards utilised to ensure interoperability, particularly harnessing the potential of the CHI number. Outside of the EU, it is important that Scotland takes an approach which ensures that data sets are scalable across countries. Commercial partners will gravitate to data sets which are pan-country scalable

We note that the issue of data collection is not addressed with this question, we would urge a consistent approach to the coding and collection of data, as this will improve the quality of the data and reduce the resources required to curate it.

Furthermore, we would recommend that Public Health Scotland and Research Data Scotland complete a review of all current public health and care data repositories to identify the source and quality of data - capturing the flow of data, incentives and barriers (at a local, regional and national basis) to inform data infrastructure requirements. An associated workplan and timelines for this should be published.

Appropriate Privacy Enhancing Technologies, such as cloud based federated datasets, could be deployed to ensure safe and secure access and enhance security and trust.

The infrastructure should be set up in such a way that it allows for the anonymously linking of multiple disparate data sets together at the patient level, providing data requesters with the most comprehensive view of the patient (in accordance with the requester's documented data needs) while maintaining a minimum risk of re-identification.

Finally, ABHI suggests that the Scottish Government considers becoming an authorized participant in the European Health Data Space (see art. 52, par. 5, EHDS Act). This may come with expectations of compliance including with standards for secure processing but open up additional opportunities for data requesters in Scotland to access additional health data.

13B. What do you believe are the key data needs and gaps that are faced by industry, innovators, and researchers when it comes to Scotland's health and social care data?

The HealthTech industry's key data needs relate to medical and diagnostic data. They need to be complemented with demographic data such as age, gender, country, ethnic origin, and ideally family history (to consider genetic issues) which may help also to personalised digital medicine/medical device. To arrive at better health outcomes, socio-economic issues are relevant including, cultural influences, food, lifestyle (i.e. mobility, sporting, recreational, alcohol consumption, etc.), employment (i.e. chemicals exposure, sedentariness, stress levels at work), or the environment. Having full relevant data sets then allows irregularities and outliers to be identified. It is important to have complete, longitudinal records for patients and citizens, rather than disconnected, partial data sets or separate data sets for different analyses.

There is a need for better access to big data sets related to the durability claims of medical and pharmaceutical equipment, including EHR data, disease state registry data, patient quality registry data etc. However, it can be technically challenging to bring together disperse data sets and linked, longitudinal data are often not easily available. This provides an opportunity for greater research activity if Scotland can address such issues.

The HealthTech industry is also interested in data associated with cost and effectiveness of care, (i.e. billing data), so it can be subject of a health-economic analysis and provide better transparency on cost versus benefits.

Whilst industry recognises that significant improvements have been made to mechanisms for access to health and care data, there remain significant challenges. These include:

- A continuing lack of transparency about what data are available, at what scale and at what quality, due to the plethora of custodians and an unknown number of potential datasets within the NHS and social care. Potential users need more help (perhaps through directories of datasets), as well as hands-on support from custodians to navigate data libraries. More effective signposting of what is available would enable researchers to make better use of data and enable Scotland to attract more research and innovation activity.
- Consistency of access arrangements – efforts must continue in Scotland to ensure there is no variability in access across health boards to data as variances produce a complex environment for industry, innovators and researchers to navigate and potentially create unnecessary barriers which prevent the efficient & effective access to, and use of, datasets. The inconsistency also includes access to data experts with the Health and Social care system.
- There remains poor access to secondary care data and poor linkage of social, primary and secondary care data, and this has been identified as a major barrier. Access to primary care data, has been acknowledged as a strength of the UK system, but that there is a huge unmet need in secondary care data collection and access, particularly data from outpatient and A&E settings. Because of this, industry has in some cases needed to directly contract data collection on a board-by-board basis. Examples like this bring additional complexity with potentially different interpretations for access by different trust data custodians.

Access to social care data is even more complex, with a very fragmented landscape. This requires to be integrated with the regional and national Safe Havens approach.

- The Health and Social Care Data Strategy should be ambitious in seeking to link health and care data from a range of sources – especially primary and secondary care data at scale, along with other valuable datasets such as prescribing information, genomic laboratory hubs, social care and tertiary care. In addition, the ultimate aim to achieve maximum scale is to be able to horizontally link datasets nationally across the NHS for each disease and patient sub-group, and to link data which informs other social determinants of health. This should be accompanied by improved data curation at source (with the necessary resource, digital infrastructure and training), and a reduced lag time between the collection of data and access to it.

14. Used appropriately and well, technologies such as Artificial Intelligence can help to improve decision making, empower health workers and delivery higher quality health and social care services to citizens, improving how you receive health and social care services:

14A. What are your views on the benefits of using AI to improve the delivery of health and social care services?

AI is increasingly being used across the health system to support earlier and better diagnosis, triage, population health management and service efficiency through pathway redesign and enables the development of smarter medical devices. With AI algorithms, devices can go beyond tracking and reporting raw data, to better guide and inform clinicians and patients. For example, a trained AI algorithm can suggest among thousands of tissue images the areas to focus on for possible malignancies. AI solutions, including machine learning AI forms, can help diabetes patients better understand and predict their patterns and responses to nutrition and exercise, to become more proficient with their insulin pump settings and improve their "time in range" of appropriate blood glucose levels, a key indicator of effective diabetes management. This provides greater freedom to patients, more peace of mind to parents and other care providers, and helps keep patients "in range," which is central to their health in both the long and short term. AI offers great opportunity to support patient 'self-service' and patient initiated follow up as well as addressing work force shortages by enabling clinicians to operate 'at the top of their licence' by supporting processing of more routine tasks.

However, AI tools require access to high-quality data to learn from, and companies investing in AI therefore invest significantly in accessing and improving data. Having access to high quality data for algorithmic training and validation to support the development of AI it is vitally important.

14B. What safeguards do you think need to be applied when using AI?

We recommend a risk-based approach where the level of safeguards required are determined by the risk level of the AI application in the specific context of its intended and actual conditions of use. Safeguards range from transparency requirements about how the

algorithm has been designed, trained, validated and rolled out, to ongoing monitoring throughout the AI application lifecycle.

Only well validated AI technologies should be implemented, especially for AI applications that present a risk of harm to the user or recipient of the solution. But for validation the system needs to provide a safe, secure and easier path to validation of these solutions. Robust AI algorithm updates procedures also need to be put in place (as AI is used more widely the data generated can then be used to improve the AI, but the system needs to make sure the updated algorithm does not require full re-regulation.

Healthcare systems should consider how these changes in AI algorithms impact over time and establish ways of monitoring these changes and evolving operating processes. The regulatory process is treating Ai as a subset of Software as a Medical Device rather than introducing specific legislation with any Ai specific issues being addressed through guidance. We recommend this approach is also adopted within healthcare implementation.

There is a need to utilise significant data sets to ensure that AI applications are accurate and inclusive. The proposed approach to modernising Scotland's health and social care infrastructure and data curation will be crucial if Scotland is to unlock the benefits of AI and attract further research and innovation activity in this space.

Overall Reflections

15. Please use this box to provide any further information that you think would be useful, which is not already covered in your response.

ABHI welcomes the consultation on 'Data Strategy for Health and Social Care' in Scotland and the recognition that working with industry can support both economic value and deliver innovations that can benefit health and care services, and improve citizen lives and wellbeing.

We broadly support the following discussion points raised within the consultation and the aim to address the biggest challenges to adoption of information standards and increasing interoperability in health & adult social care

- Recognition of Scotland's health and care data as a national asset
- The need to better facilitate appropriate access to high quality health and care data
- Create the right infrastructure to enable timely access
- Develop a 'Once for Scotland' approach to Information Governance
- Align existing work to minimise duplication at a national level
- The need for accurate, complete and up-to-date data to support development of AI solutions
- Mandated data standards for collection, storage and accessing of data

We also feel there is opportunity to go further in the strategy to develop a globally leading environment that will support collaboration between Scotland's health and care system and the Life Science industry. Involvement in wider data sharing activities such as EHDS and

HDRUK would enhance this. In that respect we would also like to see further recognition of the international aspect of data and the need to collaborate internationally. This should be acknowledged in the implementation of internationally accepted harmonised data standards as one example.

We would specifically like to see recognition in the data strategy of the economic benefit to Scotland of providing streamlined, national access to health and care data, with the necessary protections and transparency, to support commercial Life Science organisations.

About you

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To find out how we handle your personal data, please see our privacy policy. By clicking submit you agree to our privacy policy.

What is your name?
Andrew Davies

What is your email address?
Entering your email address allows you to return to edit your consultation at any time until you submit it. You will also receive an acknowledgement email when you complete the consultation.

andrew.davies@abhi.org.iuk

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Organisation

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If responding on behalf of an organisation, please enter the organisation's name here.
Association of British HealthTech Industries

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