



Realising patient and NHS benefits from health and care data – from policy to practice

A report on the meeting held on 22 January 2020
at the Academy of Medical Sciences, London



Collaboration for the Advancement of Sustainable Medical Innovation (CASMI)

The Collaboration for the Advancement of Sustainable Medical Innovation (CASMI), is hosted by UCL and is committed to understanding and developing better and more sustainable means of effecting medical innovation. CASMI drives interdisciplinary collaboration by facilitating networking and fostering debate, to influence policy and practice.



Health Data Research UK (HDR UK)

Health Data Research UK is the national institute for health data science. Its mission is to unite the UK's health data to make discoveries that improve people's lives. It is a not-for-profit public benefit company funded by UK Research and Innovation, the Department of Health and Social Care in England and equivalents in Northern Ireland, Wales and Scotland, and leading medical research charities. www.hdruk.ac.uk



The Academy of Medical Sciences

The Academy of Medical Sciences is the independent body in the UK representing the diversity of medical science. Our mission is to promote medical science and its translation into benefits for society. The Academy's elected Fellows are the United Kingdom's leading medical scientists from hospitals, academia, industry and the public service. We work with them to promote excellence, influence policy to improve health and wealth, nurture the next generation of medical researchers, link academia, industry and the NHS, seize international opportunities and encourage dialogue about the medical sciences.

Opinions expressed in this report do not necessarily represent the views of all participants at the event, the Academy of Medical Sciences, or its Fellows, CASMI or HDR UK.

All web references were accessed in February 2020.

Executive summary

The UK National Health Service (NHS), which provides care at the point of need funded from general taxation to 65 million people, is uniquely positioned to become a world leader in the use of electronic health records and innovative health data science for public and patient benefit. This has tremendous potential to improve patient outcomes and safety and the health of the public, facilitate health service change and new models of care, and contribute economic benefits through fostering life science industries. However, there is a risk that this potential may not be realised, if public concerns around the use of patient data, including by commercial partners, are not fully addressed.

The Collaboration for the Advancement of Sustainable Medical Innovation (CASMI), the Academy of Medical Sciences and Health Data Research UK (HDR UK) held a joint meeting on 22 January 2020 attended by key stakeholders, including from the NHS, academia, industry, charities, learned societies, patient groups and policymakers. The purpose was to share and understand perspectives and experience, and to consider the practical steps that NHS and other health data controllers, their appointed data processors, and those providing research services need to take to realise these anticipated benefits in a fair, transparent, trustworthy and accountable manner.

The following key themes emerged from the meeting:

1. Maintaining public trust in the NHS is essential; public support and partnership in using data about patients for research is a fundamental prerequisite to fully realising its potential. These uses need to be co-produced in partnerships that engage with, and give agency to, patients, the public, and healthcare professionals at all phases of decision-making. While requiring time and investment, this will be essential if we are to develop a trustworthy and continuously improving data governance system that fully incorporates the perspectives of the public and patients, including those from hard-to-reach or seldom-heard groups, as well as those of health and care practitioners. Clear communication using language that is meaningful and accessible to these groups is key and should be a continuing focus, as exemplified by the work of Understanding Patient Data.¹
2. The use of health and care data about patients for direct patient care and for research is generally well accepted and supported by the public. Nonetheless, experience from other sectors and recent controversies regarding sharing of patient data indicate that public mistrust and uncertainty about some uses remain, along with a concern that public scrutiny and decision-making on some uses has not been, or will not be, possible. It will be crucial to develop

¹ <https://understandingpatientdata.org.uk/>



approaches that maintain trust while enabling the important innovations that such research can deliver.

3. Several further challenges will need to be overcome before the promise of health data science can be realised, including:
 - The need for collaboration across organisations, disciplines, regions and sectors.
 - Providing access to clinical data at scale.
 - Addressing the fragmented state of data in the NHS, as well as the variability in data quality and the digital maturity of health systems.
 - Understanding how health data can be used effectively in real-world practice and the support health and care professionals require to do so.
 - Overcoming the complexity of driving change in a healthcare system under increasing service pressure.
 - The need to recognise the different sorts of value and benefits that can be created by the use of health and care data and ensure its distribution is fair and aligned to the ethos of the NHS.

Initiatives by organisations, such as Health Data Research UK, the Office for Life Sciences, NHSX, NHS England, the Accelerated Access Collaborative and the Professional Record Standards Body, among others, are already underway to address these important challenges.^{2,3,4,5,6,7}

4. Addressing these challenges will require continued focus, and an agile and collaborative approach that learns from experience as new issues emerge. In particular, approaches to *risk*-sharing as well as benefit-sharing will be needed (for example where responsibility lies for new risks

² <https://www.hdruk.ac.uk/>

³ <https://www.gov.uk/government/organisations/office-for-life-sciences>

⁴ <https://www.nhsx.nhs.uk/>

⁵ <https://www.england.nhs.uk/>

⁶ <https://www.england.nhs.uk/aac/>

⁷ <https://theprsb.org/>

emerging after an agreement between the NHS and commercial collaborators has been established), alongside strategies for sharing financial value (i.e. the balance of value for individual institutions and value for the NHS as a whole), with fair return reflecting the contribution and risk taken by the organisations involved at its core.

5. Policy makers, NHS bodies and academic organisations across the UK, including the Office for Life Sciences, NHSX, the Institute of Global Health Innovation at Imperial College and the Academy of Medical Sciences, among others, are seeking to define guidelines and best practice as to how the use of health data can be optimised to increase its impact on the health and wealth of the UK. For example, NHSX is committed to hosting a Centre of Expertise, which will provide specialist commercial and legal advice to NHS organisations entering data agreements.⁸ The body of evidence on the public views of commercial access to health data continues to be strengthened, with new insights emerging from deliberative public dialogues, including those commissioned by Understanding Patient Data and NHS England, and the OneLondon Local Health and Care Record Exemplar.^{9,10}
6. Participants agreed that practical interpretations of the policies and principles intended to guide the use of health data for research are needed so that all involved know what to do (and what not to do), how to do it, and why and how decisions are made. Public scrutiny, transparency and accountability regarding what happens in practice is critical to ensure practice aligns with agreed principles and to enable policies and principles to evolve over time in the light of unanticipated issues.
7. The Digital Innovation Hub programme – led by HDR UK and consisting of the UK Health Data Research Alliance, the Health Data Research Innovation Gateway, and the Health Data Research Hubs – is a timely development that can serve as a practical national exemplar.¹¹ As the programme develops, with transparency at its core, it will provide the opportunity for shared learning to help identify the attributes of successful models that can maintain public trust while addressing the challenges in realising the huge public health and economic benefits that health data science has the potential to deliver.
8. The proposed HDR UK commercial framework – consisting of two use-based and two outcome-based elements – was considered as comprising helpful attributes, being comprehensive but flexible enough to be adapted for different needs and responsive to emerging guidance from other organisations. The framework as proposed will allow each Hub to develop a suitable model aligned to its focus, emphasising different elements of the framework. It will be important for these arrangements to be agreed through public and patient involvement in decision-making and to be made transparent on the Gateway. It was recognised that careful contextualisation of the framework will be required to emphasise the importance of non-monetary values and that financial benefit is not regarded as the only or most important form of value to be derived from data. The outcome-based elements will also require careful management, particularly to encourage behaviours that are aligned with the public good, and it was agreed that it would be useful to have a suite of model agreements which address risk and benefit sharing.

⁸ Office for Life Sciences (2020). *Life Sciences Industrial Strategy Update*
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/857348/Life_sciences_industrial_strategy_update.pdf

⁹ <https://understandingpatientdata.org.uk/news/NHS-company-partnerships>

¹⁰ <https://www.digitalhealth.net/2019/08/one-london-to-begin-deliberative-dialogue-on-data-use-privacy-and-consent/>

¹¹ <https://www.hdruk.ac.uk/infrastructure/>

Discussions at the meeting highlighted that organisations and others across the sector should continue to collaborate and:

- Work with NHSX, the Office for Life Sciences, and other key bodies in England and the devolved nations to develop and share best practice, striving for clear alignment of frameworks and principles on the use of health and care data in research.
- Work with others across the sector to ensure that the key messages around public and patient involvement and engagement reach NHS and other organisations not included in the Health Data Research Alliance.
- Work with others to further identify gaps in public understanding and encourage the testing of context specific uses with the public as they are developed.

As an outcome of this meeting, the Health Data Research Hubs, HDR UK and the UK Health Data Research Alliance will:

- Use the framework and feedback from the meeting to develop the Hub business models, with engagement and involvement of members of the public, patients and practitioners throughout, and inclusion of lay representatives in their decision-making.
- Publish the Hub commercial arrangements via the Innovation Gateway with progress reviewed and reported through the UK Health Data Research Alliance.
- Consider the use of standardised model terms and contract templates.
- Maintain, with partners across the life sciences sector, a continued focus on the challenges highlighted at the meeting and establish explicit mechanisms to tackle these and monitor progress moving forwards.
- Provide an update on progress and lessons learned at the second symposium of the UK Health Data Research Alliance at the end of 2020.

Introduction

The rapid digitisation of the NHS health and social care systems, combined with the increasing scale and complexity of data collected about patients in the course of their healthcare and associated research, is creating unprecedented opportunities for transforming direct patient care and health systems and accelerating medical innovation.

This can deliver better care, better patient and population health outcomes, advance our knowledge of the underlying causes of diseases and their prevention, and foster an even more vibrant life sciences sector with attendant economic benefits. It requires high quality data that is effectively curated, is managed ethically and in line with public expectations, and that can be accessed safely and securely. These are key priorities for the health service, researchers and policy makers, alongside a recognition that it is crucial to involve patients, the public, healthcare professionals, and other stakeholders to gain their perspectives on the appropriate uses of health data for research and fair distribution of the benefits that accrue from data use.

“In the last 5 years, we have accumulated more health data than in the whole of human history.”

Baroness Dido Harding, Chair of NHS Improvement



One component of using health data for research are the models by which the NHS and other health data custodians can derive benefit or value from access to the data it controls and in which it has considerable expertise. These models are guided and informed by principles and guidelines such as those set out in the Department for Health and Social Care’s ‘Code of conduct for data-driven health and care technology’ and those outlined in the Office for Life Sciences’ Life Sciences Sector Deal 2.^{12,13} They are also guided and informed by recent and ongoing public dialogues, such as those conducted on behalf of Wellcome and the Academy of Medical Sciences, and upcoming dialogues commissioned by NHS England and Understanding Patient Data, and the OneLondon Local Health and Care Record Exemplar, which are due to report later in 2020.^{14,15,16,17}

While each UK jurisdiction has systems to authorise and provide access to some health data, access to more detailed and complex clinical data remains a challenge. Health Data Research UK has recently funded and established seven Health Data Research Hubs that provide a timely opportunity to address this challenge.¹⁸ These Hubs are developing sustainable business models that will enable them to continuously improve the range and quality of data available to researchers for fair and ethical use.

On 22 January 2020, the Collaboration for the Advancement of Sustainable Medical Innovation (CASMI), the Academy of Medical Sciences and Health Data Research UK (HDR UK) hosted a joint workshop: ‘Realising patient and NHS benefits from health and care data – from policy to practice.’

The purpose of this workshop was to share best practice and perspectives, reflect on experience to date and get sector wide views and perspectives on the emerging governance, commercial frameworks, and priorities for the Hubs and the wider sector. In particular, it provided an opportunity to critique and assess the sustainability models that might be used by the Hubs and by organisations that are NHS data controllers and data processors. Ninety-six people attended the event in person, 96 watched the live stream and there are 183 views of the recordings of the event, which are available on HDR UK’s YouTube channel¹⁹.

At the meeting, a range of stakeholders presented and discussed their perspectives and experience (see Annex 1 for the meeting agenda) and, following this, participants were invited to consider and discuss HDR UK’s draft commercial framework for the Hubs. This comprised four elements – two use-based and two outcome-based. This framework enables each Hub to develop a model appropriate to its focus, emphasising different elements of the framework, with these arrangements agreed through public and patient involvement in decision-making and made transparent on the Gateway. Feedback was sought on the framework and involvement and engagement of the public, patients and practitioners in its ongoing development and delivery.

¹² Department of Health and Social Care (2018). *Code of conduct for data-driven health and care technology*
<https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology/initial-code-of-conduct-for-data-driven-health-and-care-technology>

¹³ Office for Life Sciences (2018). *Life Sciences Sector Deal 2*
<https://www.gov.uk/government/publications/life-sciences-sector-deal/life-sciences-sector-deal-2-2018>

¹⁴ Ipsos MORI (2016). *The One-Way Mirror: Public attitudes to commercial access to health data*
<https://wellcome.ac.uk/sites/default/files/public-attitudes-to-commercial-access-to-health-data-wellcome-mar16.pdf>

¹⁵ Ipsos MORI (2018). *Future data-driven technologies and the implications for use of patient data*
<http://www.acmedsci.ac.uk/datadialogue>

¹⁶ <https://understandingpatientdata.org.uk/news/NHS-company-partnerships>

¹⁷ <https://www.digitalhealth.net/2019/08/one-london-to-begin-deliberative-dialogue-on-data-use-privacy-and-consent/>

¹⁸ <https://www.hdruk.ac.uk/infrastructure/the-hubs/>

¹⁹ <https://www.youtube.com/playlist?list=PLBI5k9SgYrItRqFrzOSfOZb2jN7rG-Erz>

This report constitutes a summary of presentations, discussions and views that were expressed at the workshop. For a full record of the event, please refer to the video recordings that are available on HDR UK's YouTube channel.²⁰



²⁰ <https://www.youtube.com/playlist?list=PLBI5k9SgYritRqFrzOSfOZb2iN7rG-Erz>

From policy to practice

The opportunity

Data and technology are creating a new era with immense potential for benefit in healthcare. The rate of change in health data science is exponential, disruptive, and is leading to the convergence of care with research. This helps realise the possibility of Leroy Hood's vision of 'P4 medicine' that is predictive, pre-emptive, personalised and participatory.²¹

The UK is positioned to be a leader in this space. The NHS, which provides 'cradle to grave' healthcare at the point of need, holds the longitudinal health and care records of around 65 million people living in the UK collected in the course of their care. The UK boasts outstanding strengths in scientific and medical innovation in the NHS as well as in the academic and private sectors. If we are to leverage the full potential of these resources for public and patient benefit, then, first and foremost, health data science must operate in ways that maintain existing public trust and support for the NHS.



Earning and maintaining trust

Trust takes time to earn, but can be lost in an instant. For health and other forms of data, failure to respect public expectations of trust and privacy poses substantial risks to its continued use for innovation and progress. It is therefore the collective responsibility of the sector to work together with the public, patients and healthcare professionals and to act responsibly, transparently and accountably and in a trustworthy manner.

²¹ Hood L and Flores M. (2012). *A personal view on systems medicine and the emergence of proactive P4 medicine: predictive, preventive, personalized and participatory* New Biotechnology. **29 (6)**: 613–624.

Earning and maintaining trust is an ongoing process that requires commitment and openness, including the willingness to be honest about things that go wrong, and to learn from them. Views expressed at the meeting indicated that while the potential of health data science has not always been well communicated with members of the public, where this is managed effectively the public recognise the benefits for individual healthcare and the NHS as a whole, particularly where tangible benefits are demonstrated. It was noted that the public expresses consistent concerns about data security; the impact of inaccurate or biased data; the potential to create or exacerbate inequity between individuals or between organisations, or to undermine the NHS and its ethos; financial and reputational risks; as well as its desire to be actively involved in governance and decision-making. These concerns, and efforts to allay them, will need to be carefully considered to develop trustworthy data governance systems.

Other challenges

Beyond the responsibility of generating a trustworthy data system to earn and maintain public trust, other challenges must be overcome in order to realise the benefits of health data science. It is the responsibility of this generation of health leaders to resolve them.

- This is a hugely complex area, which cannot be addressed by any one organisation – partnerships are required across organisations, disciplines, regions and sectors, with low barriers to participation and a level playing field for involvement.
- The scale required to achieve the full benefit of data is enormous – this is a truly international challenge.
- Data quality and the digital maturity of health systems varies widely at present, and is often insufficient for direct patient care or for meaningful health data science research and analysis.
- The NHS is a huge, complex system with hundreds of organisations – change cannot be imposed from the centre but needs to be driven by securing full engagement of practitioners, direction-setting, guidance, access to appropriate training and standard-setting.
- Health and care data are fragmented across NHS organisations, biobanks, registries, charities and other government organisations. Creating longitudinal records for direct care, research and innovation requires a transformational change in digital maturity, actively supported by NHSX and equivalent bodies in the devolved administrations. In addition, the UK requires robust, safe, digital infrastructure and systems to enable authorised access to this data.
- Combining the power of NHS data with the innovation of the NHS, academia and the private sector requires a fair deal for everyone that sustains public trust in the use of data. The draft guiding principles set out by the Office of Life Sciences' 'Creating the right framework to realise benefits for patients and the NHS where data underpins innovation' and the Health Data Research UK Principles for Participation²² provide useful frameworks, but the challenge will come in how these principles are applied and by whom.²³

²² Health Data Research UK (2019). *Digital Innovation Hub Programme Prospectus Appendix: Principles for Participation* <https://www.hdruk.ac.uk/wp-content/uploads/2019/07/Digital-Innovation-Hub-Programme-Prospectus-Appendix-Principles-for-Participation.pdf>

²³ Department of Health and Social Care (2019). *Creating the right framework to realise the benefits for patients and the NHS where data underpins innovation* <https://www.gov.uk/government/publications/creating-the-right-framework-to-realise-the-benefits-of-health-data/creating-the-right-framework-to-realise-the-benefits-for-patients-and-the-nhs-where-data-underpins-innovation>

The Hubs: a national exemplar

Efforts are underway by organisations in the UK and internationally to address the challenges described above. Examples of such initiatives include work by NHSX, NHS England, the Accelerated Access Collaborative, the Professional Record Standards Body, the Centre for Data Ethics and Innovation, and the Ada Lovelace Institute, among others.^{24,25,26,27,28,29}

Another major initiative is the Digital Innovation Hub programme led by HDR UK, which has been designed and developed after extensive engagement with stakeholders across the health data sector and guided by HDR UK's Public Advisory Board.^{30,31} This programme is designed to be scalable, sustainable, interoperable, and involves all four nations of the UK. Twenty-seven national bodies, charities, NHS trusts and research cohorts have so far joined together as the UK Health Data Research Alliance. An Innovation Gateway³² is under construction to provide streamlined access to data, with the Minimum Viable Product now live, including metadata covering over 400 datasets. In parallel, seven Health Data Research Hubs have also been launched to provide well curated data, spanning 110 organisations across the four nations of the UK, including industry, charities, NHS and



academic partners. All the organisations involved in the programme have signed up to the Principles for Participation that include commitments to public and patient involvement and engagement, an ethical framework based on the '5 safes' (safe projects, safe people, safe data, safe places, safe outputs,) and non-preferential access to data.³³

The Digital Innovation Hub programme will serve as a national exemplar for accessible, research-ready data sets. As it develops, with transparency at its core, it will provide the opportunity for shared learning to demonstrate trustworthiness to the public and engage with the other challenges in realising the huge health and care benefits that data and technology can deliver.

²⁴ <https://www.nhsx.nhs.uk/>

²⁵ <https://www.england.nhs.uk/>

²⁶ <https://www.england.nhs.uk/aac/>

²⁷ <https://theprsb.org/>

²⁸ <https://www.gov.uk/government/organisations/centre-for-data-ethics-and-innovation>

²⁹ <https://www.adalovelaceinstitute.org/>

³⁰ <https://www.hdruk.ac.uk/infrastructure/>

³¹ <https://www.hdruk.ac.uk/about/people/public-advisory-board/>

³² <https://healthdatagateway.org/>

³³ Health Data Research UK (2019). *Digital Innovation Hub Programme Prospectus Appendix: Principles for Participation* <https://www.hdruk.ac.uk/wp-content/uploads/2019/07/Digital-Innovation-Hub-Programme-Prospectus-Appendix-Principles-for-Participation.pdf>

Upholding the ethos of the NHS: the purposes, benefits and values of using health data

Patient, public and healthcare professional involvement and engagement (PPIE) are a vital part of building a trusted system through understanding the public wants, needs and concerns, and acting on these. It was explored how health data can be used for research in the context of public dialogues, and the overarching ethos that the NHS should act in the public interest when considering how it uses patient data.

These dialogues, including the citizen's jury run by Connected Health Cities³⁴, have shown that in the right contexts and with appropriate privacy, security and transparency, people are generally supportive of health data being used for research that provides real benefits, including commercial companies. However, this does not mean that approaches to commercial access to health data can assume sanction and acceptance of the public. As such, PPIE needs to be ongoing, meaningful and context specific. There is an expectation on the NHS and the organisations it works with to uphold the social contract that embodies fairness, equity and social solidarity when using health data.

Agency and trust

Current evidence suggests that a partnership with the public is needed to achieve the best outcomes, and that the public expects to be involved in the decision-making at all stages about the uses to which data are put and by whom. The public and patients have valuable insights and perspectives on what constitutes fair access to data, the values that inform its uses, and how any resulting benefits should be shared. The public dividend of commercial involvement needs to be demonstrated, and tangible health outcomes, and their potential impact on equity and social values of the NHS, considered as a basis from which the public can reach informed conclusions on what access should be authorised.

The scope of public benefit – now and for the future – needs to be clearly articulated. People need to see that the data agenda will reinforce the core NHS values of universality, equity and reciprocity and will also benefit them in what they are currently doing: for clinicians, providing better care more efficiently; for patients, having a better experience of being looked after; and for the public, safeguarding the NHS and its social ethos and values. The interdependence of academia and life science industries in driving medical innovation and resultant public benefit also needs to be better communicated and confidence in this relationship fostered by profound public engagement.

³⁴ *Connected Health Cities Citizens Jury Report, 2017*: https://www.connectedhealthcities.org/wp-content/uploads/2016/08/CHC-juries-report-Feb-2017_2.pdf

Some choices constrain others, and as such, transparency is key, not only about decisions, but about the reasons for decisions. Potential risks as well as benefits need to be exposed, mistakes and data breaches acknowledged, and the boundaries and safeguards in the system demonstrated, so people can increase their insights into the trade-offs involved in the light of experience to date and in the future.

Co-producing innovation

People are interested in how data can be used to provide benefit but also in equity: both how the use of data can help reduce inequities, and the risk that it may exacerbate inequity. They are concerned not only with individual harms but also the possibility of social harm. There is concern over 'exploitation' of assets: despite the fact that there is suspicion of the commercial sector, evidence suggests that the public does not consider it intrinsically wrong to work with the commercial sector; rather, wrong to do so when this increases inequity, leads to discrimination or bias, or results in the NHS failing to have its fair share in the resulting benefits.

Co-production with the public and patients has been shown to enrich understanding of the potential benefits, and risks, of using health data for research. By extension this means that the innovations and advances developed from research are more likely to be relevant, more effective and to better address the unmet needs both for patients and the health and social care system. Bringing these benefits to fruition will require a concerted and dedicated effort by the entire community of researchers, health and social care organisations, companies and policymakers to embed public dialogue, engagement and involvement as a routine and valued component of research and development using health data.

Relevance

Despite the wealth of understanding that deliberative public involvement can provide, it is clear that the contexts, scopes and multi-factorial nature of health data research mean that there is no 'one-size-fits-all' approach. This therefore strengthens the case for working with patients and the public in decision-making across different health data research programmes, regardless of their intended use or scale. For example, it is likely that some contexts for use may provide significant benefits on a local level but, when translated to a national programme may require adjustments or changes – these will need to be informed by context specific input from the public and patients. Similarly, applying national, top-down programmes at a local level will require bespoke local solutions developed with patients and the public as partners.

Language and communication

Engagement, involvement and communication with the public presents a significant opportunity in terms of building trust and support. However, miscommunication or a lack of transparency may foster distrust rather than allay it, even when intentions are good. For the public to appreciate the benefits of health data research in a fair way, the uncertainty of the benefits of research must be communicated transparently, with no false claims or promises. Conversely, to help communicate that there may indeed be real and tangible benefits to health data research, there must be demonstrable and evidenced case studies and exemplars, developed and communicated on an



ongoing basis as they are implemented. Understanding Patient Data has collated a range of case studies available on its website for the community to use.³⁵

Similarly, communication around the ‘ownership’ of data must be made carefully – data, while controlled and protected by the NHS, are a product of relationships between patients, their healthcare professionals and the healthcare system, and none of these parties should be classified as the outright owner of the data. Health data is ‘about patients’ rather than ‘owned by patients’.

Finally, given the sensitivities around the use of health data by commercial organisations, communicating different commercial models must be done with great care. For example, the distinctions between ‘licensing’ and ‘selling’ data might be clear to the data science community, but may not be to the wider public.

³⁵ <https://understandingpatientdata.org.uk/case-studies>

What it takes to do this effectively

Meaningful public and patient involvement and engagement is a process that requires the building of a relationship and a constant and considered dialogue over time. This necessitates investment of time and money.

It can take courage for policy makers and leaders in the system to trust the public, especially where the issues and ideas are not yet fully formed, or where divergent views and debate may be seen by some as delaying innovation. It is essential to continuously emphasise the importance of public and patient involvement and engagement and to do this we need to empower our health system leaders to listen and engage with the public, and to act on the outcomes of public consultations and views.

Charities and healthcare professionals can play a key role in communicating with patients and the public, and it is essential that there is a co-owned endorsement of the practical way forward involving these groups. It is important also to access young people, perhaps through specific consultations or panels, both to gain their perspectives and ensure their voices are heard on issues that concern their future.

Remaining gaps in understanding of public views

Although a significant amount of research into the views of the public and patients has been carried out, gaps remain. This is especially true for specific use cases for commercial access, as opposed to more generalised discussions around attitudes to commercial use of data. There is a need for research that considers the benefits and risks alongside each other in a way that allows risk-benefit scenarios that are important to the public and patients to be understood. This will give a clearer view of not only 'red line scenarios', but will also directly inform real world examples where the benefits and risks are more subtle. Similarly, there are clear gaps in understanding of the views of certain groups, including children and young people, vulnerable or marginalised groups, or those from disadvantaged backgrounds.



Practical interpretations and learning from experience

Starting point

NHS organisations have variable digital maturity and, although there is a large volume of NHS data, much of the data are fragmented and siloed, and there are differences in quality and curation. Nonetheless, there are strong exemplars of practical approaches being pioneered. These include University College London Hospitals NHS Foundation Trust recent deployment of an Epic electronic health record system to increase its digital maturity for its patients.³⁶ It has also used its dataset of brain MRI scans to develop diagnostic algorithms. Another example is Moorfields Eye Hospital NHS Foundation Trust's collaboration with Google Health (formerly Deepmind Health) to apply AI to anonymised optical coherence tomography (OCT) eye scans, to search for signs of eye disease.^{37,38} In doing so, the partners had to address questions ranging from data quality and technical considerations, to ethical and governance issues. Nevertheless, it succeeded in showing proof-of-concept that the system performs on par with experts for over 50 different retinal diseases³⁹. There are other exemplars from across the UK and, going forward, it will be important to document such case studies.

Value

Value is created from high quality, linked, readable, longitudinal datasets. However, value is contextual and varies, even for the same data, based on purpose of use and the perspective from which it is viewed: it can be financial or non-monetary, taking the form of improved efficiency, patient satisfaction, health outcomes, among others. Financial value can be shared with the NHS in various forms. For example, in the Moorfields Eye Hospital partnership with Google Health, the hospital has free use of the algorithm for research purposes, and if a commercial product is developed, it will have free use of it for direct patient care. Moorfields Eye Hospital has also gained reputational value as a result of the collaboration, attracting international research fellows and funding, and the learning achieved in the collaboration has been considerable.

Investment

In order to realise benefits from health and care data, they need to be gathered, curated, made accessible and readable. This requires investment in the right capabilities, both in terms of skill sets and technology infrastructure, by organisations that are data controllers, including NHS Trusts and general practice. Additionally, the right commercial and legal skill sets are required within these organisations for contractual negotiations to ensure the NHS gets a fair return on the investment that created these resources. However, once these are in place, additional projects using the same infrastructure and staff will have increased expertise and capacity to process applications and

³⁶ <https://www.uclh.nhs.uk/News/Pages/UCLHpartnerswithEpicdesignandbuildnewEHR.aspx>

³⁷ <https://www.moorfields.nhs.uk/content/latest-updates-deepmind-health>

³⁸ Ronneburger O. et al. (2018). *Clinically applicable deep learning for diagnosis and referral in retinal disease* Nature Medicine, **24**, 1342–1350

³⁹ <https://www.nature.com/articles/s41591-018-0107-6>

contracts at a relatively lower cost. For example, Moorfields Eye Hospital has been able to build on the initial project with Google Health and has linked three million scans with Hospital Episodes Statistics (HES) data to derive insights about comorbidities at very modest cost.

Industry perspective

The consensus at the meeting was that there is enthusiasm from industry about the potentially transformative impact of health and care data on innovation. The goal of this transformation is first and foremost about outcomes for patients and the efficiency of the NHS, and that this needs to be driven based on public trust and trustworthy governance. The widespread experience in industry of working with data, as well as with the NHS and academia, will enable industry to support the development of UK health data infrastructure, delivering datasets that have the necessary scale, depth and duration to support research and development. A number of pharmaceutical companies have taken the lead in making accessible the data underpinning the results of clinical trials, thereby recognising and responding to the need for openness in reporting of data, while safeguarding patient privacy and confidentiality.⁴⁰ If the aspiration of HDR UK is delivered, the UK will have not only a world class health data infrastructure, but it will also be a global leader in the application of data-driven technologies to healthcare at scale.

The Health Data Research Hubs

The Digital Innovation Hub programme led by HDR UK includes seven Hubs providing expert services and curated data in: cancer (Data-CAN); primary care, mental health and social care for real world evidence (Discover NOW); respiratory health (BREATHE); inflammatory bowel disease (Gut Reaction); eye health (INSIGHT); datasets to make clinical trials quicker and cheaper (NHS DigiTrial); and acute care (Pioneer).⁴¹ Information about the initial datasets (metadata) is available and discoverable on the Innovation Gateway.⁴² These datasets and expert services will support numerous case studies ranging from feasibility studies for clinical trials and real world measurement of treatment impact, to identification of predictive factors for treatment response and development of algorithms to improve patient care. Public and patient involvement and engagement is central to all the Hubs, including developing relationships with data controllers that, in some cases, number in the hundreds. They aim to provide, or support access to, well-curated data in their specialist domains, but also to sharing experience and best practice that can be of value to others in the NHS and more widely.

⁴⁰ House of Commons Science and Technology Committee (2018). *Research integrity: clinical trials transparency*
<https://publications.parliament.uk/pa/cm201719/cmselect/cmsctech/1480/1480.pdf>

⁴¹ <https://www.hdruk.ac.uk/infrastructure/the-hubs/>

⁴² <https://healthdatagateway.org/>

Building a framework – interactive session

Proposed commercial framework

The primary objective of the use of health and care data is to provide benefit to patients in the form of new or improved medicines, diagnostics, devices and services, or to the population in terms of the health of the public. In order to achieve this, the Health Data Research Hubs need sustainable business models that enable them to continuously improve the range and quality of data available to researchers for fair and ethical use.

At the meeting, HDR UK proposed a commercial framework for the Hubs which consists of four elements, two of which are use-based and two of which are outcome-based, as shown below:

| Use-based | | Outcome-based | |
|--|--|--|---|
| Data Access | Data Service | Share of cost saving | Share of revenue |
| Description | | | |
| Fee for accessing data and data products | Charge for specific data services required to fulfil the user's request | Agreed proportion of cost savings attributable to use of the data shared with data custodian | Agreed proportion of revenue in product or company shared with data custodian |
| Variants | | | |
| <ul style="list-style-type: none"> • Frequency of payment: one-off, yearly, other • Free or discounted services for a defined or unlimited period e.g., basic level of service • Fee stratified by dataset quality level • Fee stratified by type of data user or data use | <ul style="list-style-type: none"> • Charge per service type • Charge per time required to provide service • Charge stratified by type of data user or data use | <ul style="list-style-type: none"> • Proportion of cost savings realised by partner • Discounted services for the data custodian / NHS for products developed using the data | <ul style="list-style-type: none"> • Multiple one-off fees linked to product sales / milestones • Royalty/ revenue share from products developed using the data • Profit share: portion of the profits generated by partner • IP ownership share • Equity share/Golden share |

Figure 1: Proposed Commercial Framework

Based on this proposed framework, each Hub may develop a different model, emphasising different elements of the framework and/or setting charges for access at different levels than other Hubs. Hubs may also use different combinations of the elements of the framework for different user types or project types. Furthermore, Hubs, working with their data access committees, may choose to discount or waive financial charges in favour of other forms of public benefit derived from the use of data. The arrangements that the Hubs develop will be published on the Gateway.

Nature of the interactive session

Participants at the meeting joined one of five facilitated breakout groups and were asked to focus on two questions:

1. Given the types of use cases that the hubs are envisaging, what are the benefits and risks associated with the proposed Commercial Framework and are any important elements missing?
2. How should members of the public, patients and practitioners be involved and engaged in the ongoing development and delivery of this approach?

The feedback on these two questions is summarised below.

1. Benefits, risks and missing elements in the commercial framework

The proposed commercial framework is useful and transparency on the Innovation Gateway will be important. The framework was considered to be comprehensive in its hybrid approach of use- and outcome-based elements which provides flexibility through the opportunity to blend the different components in different ways. It provides a common language, and – if accompanied by standardised model terms and contract templates – might level the playing field for small and medium enterprises by reducing their legal and other professional costs, and support NHS data controllers in their decision-making. The outcome-based elements might also encourage a partnership mindset rather than a purely transactional relationship and allow the commercial benefits of products and services to be tracked, which is an advantage with regulatory and commissioning implications.



However, since the framework is concerned only with the commercial arrangements between the Hubs and data users, it does not communicate public benefit, other elements of value created by the use of data or approaches for involving patients and the public. It does not provide guidance on the way financial benefit may be shared with data controllers and the NHS either. The framework therefore needs to be implemented alongside mechanisms that incorporate these considerations to maintain public trust and agency. Care also needs to be taken to ensure that the application of and language used to describe the framework is inclusive and readily understandable by all sectors of society.

The hybrid approach of use- and outcome-based elements could create complexity. In particular, the use of outcome-based elements would need to be managed carefully since tracking outcomes may be difficult. In addition, it will be necessary to ensure that such arrangements encourage behaviours aligned with the public good. Communicating outcome-based models to the public may also be challenging.

The framework could include a subscription model as one of its variants, which may help recover upfront setup costs. For example, consideration could be given to commercial members of the Alliance subscribing to services in a manner commensurate with their size/turnover allowing discounted access in return for helping establish the necessary digital infrastructure.

There will be ongoing challenges that require focus, for example how to approach *risk*-sharing as well as benefit-sharing (e.g. commercial collaborators that are unable to undertake due diligence without access to the relevant data), and balancing value for individual organisations as well as the NHS more widely. Robust processes that instil confidence and trust will need to be developed, without stifling commercial activity through an overly bureaucratic approach. While applying the framework it will therefore be critical to learn and adapt as the business models of the Hubs are developed.

2. Involving and engaging the public, patients and practitioners

It will not be sufficient for commercial arrangements merely to meet legal requirements – they need to be trusted and supported by members of the public, patients and practitioners. A segmented approach may be required, with communication effectively tailored to each constituency. A breadth of engagement methods should be used, from citizens' juries to online outreach, with particular efforts to hear the voice of hard-to-reach groups. Dialogue should be broad and sustained, with a focus on engaging and involving members of the public, patients and practitioners in who is doing what, why, by and for whom and with what outcomes. Concrete use cases and demonstration of tangible benefits are important, especially those that test red lines and trade-offs. These case studies should be scrutinised by patients and the public to ensure that lessons are learnt. Investment is required to make engagement work: involvement in this kind of dialogue must be underpinned by appropriate training and support, and involvement of clinical staff may require sessions of their time to be bought or backfilled.

It is also not always clear what constitutes 'public benefit' or 'public interest', nor who is making decisions around defining this. The involvement of patients, members of the public and healthcare practitioners on data access committees might therefore ensure that what is deemed to constitute public benefit aligns with these groups' views.

Conclusions and next steps

Overview

Research using health and care data has tremendous potential to improve patient and population health, as well as deliver benefits to the NHS as a whole and economic benefits to the Nation. Despite the challenges in bringing this opportunity to fruition, these could be addressed to realise the full potential of health data science. The UK is well positioned to be a leader in this domain, with its unique innovative and world-leading NHS combined with outstanding research in academia and a vibrant industry sector.

There is also international progress in the development of large scale, usable patient datasets, which is particularly appealing to and can help attract the life science industry. Time to market is critical, and real use cases from the Hubs and other exemplars are essential to demonstrate the pace of the change that is happening. The UK risks falling behind by seeking the perfect unitary solution and being too risk averse. It needs to be agile, learn from what others are doing, and its health leaders need to take responsibility for managing risk.

Ongoing meaningful involvement and engagement of the public, patients and practitioners will continue to be paramount. The public benefit at stake will never be realised without mutual support and trust. Collaboration is required if this endeavour is to succeed. Partnerships across sectors and disciplines are needed, and the strengths of all nations and regions of the UK should be leveraged.

The systems that are developed need to be future-proofed by considering the types of data sources that might be available in the future, including from additional sources outside of the NHS. Systems also needs to be informed through involvement and engagement of groups that have been less involved in dialogue to date, such as young people and vulnerable groups.

The question of how financial value is shared is important. Individual institutions should be incentivised to participate and innovate, but the NHS as a whole also needs to receive a return for the system investment that makes that innovation possible and in accordance with the principle of fairness that is at its core. Beyond the required technology, the key to building and maintaining a trustworthy UK health data research ecosystem lies in values, fair distribution of benefit, reciprocity of respect, transparency of decision-making and the willingness constantly to listen and learn.

The proposed commercial framework

Continuing long term investment will be needed to increase digital maturity. This aligns with the work of NHSX and equivalent bodies in the devolved nations driving the digitisation of health and care services.

Overall, the proposed commercial framework was agreed to be helpful. It was thought to be comprehensive and not overly-prescriptive, enabling flexibility with a blended approach and acknowledging that learning and iteration will be required. However, the framework will need to be carefully contextualised to describe the non-monetary value and benefits of health data research. The outcome-based elements will also require careful management, particularly to encourage behaviours that are aligned with the public good. It would be useful as a next step to have a suite of

model agreements which address risk and benefit sharing and which would help level the playing field between large and small companies. This could also be extended to international access agreements.

Patient perceptions will need to be integrated in any consideration of value, as will more intangible benefits. These might include the breakdown of siloed working by increasingly sharing experience and collaborating with partners, or the continuous quality improvement that can be expected in institutions involved in data gathering and use.

Trust and public and patient involvement and engagement

Legal acceptability does not equate to social acceptability. Developments will need to continue to be tested through ongoing partnership and dialogue with members of the public, patients and practitioners, which includes their involvement in decision-making. This emerging 'social contract' needs to preserve the NHS's underpinning principle of equity, so that the benefits of data extend to all groups. Data are required to further improve and refine effective public and patient involvement and engagement. Involving members of the public in articulating the benefits of health data research will be important, as will engaging with healthcare professionals and other intermediaries that provide a trusted conduit between health data research and the public. Misunderstanding of the value of data or suspicion of commercial involvement by any of these constituencies could negatively impact on the trustworthiness of data governance systems. Use cases demonstrating tangible benefits would be helpful and the Gateway needs to provide transparency of commercial arrangements in order to sustain engagement and public trust.

Next steps

Discussions at the meeting highlighted that organisations across the sector should continue to collaborate and:

- Work with NHSX, the Office for Life Sciences and other key bodies in England and the devolved nations to develop and share best practice, striving for alignment of frameworks and principles on the use of health and care data in research.
- Work with others across the sector to ensure that the key messages around public and patient involvement and engagement reach NHS organisations that are not included in the Health Data Research Alliance.
- Work with others to further identify gaps in public understanding and encourage the testing of context specific uses with the public as they are developed.

As an outcome of this meeting, the Health Data Research Hubs, HDR UK and the UK Health Data Research Alliance will:

- Use the proposed commercial framework and feedback from the meeting to develop the Hub business models, with involvement and engagement of members of the public, patients and practitioners throughout, and inclusion of lay representatives in their decision-making.
- Publish the Hub commercial arrangements via the Innovation Gateway with progress reviewed and reported through the UK Health Data Research Alliance.
- Consider the use of standardised model terms and contract templates.
- Maintain, with partners across the life sciences sector, a continued focus on the challenges highlighted at the meeting and establish deliberate mechanisms to tackle these and monitor progress moving forwards.
- Provide an update on progress and lessons learnt at the second symposium of the UK Health Data Research Alliance at the end of 2020.

Annex 1: Meeting agenda

| 8:30am REGISTRATION & REFRESHMENTS | | |
|------------------------------------|--|--|
| 9:00am | Welcome and introduction | John Tooke, CASMI |
| Session 1 | From policy to practice: Three perspectives (Chair: Ara Darzi) | |
| Part 1: | | |
| 9:10am | Health Data Research Hubs: commercial challenges | Andrew Morris, HDR UK |
| 9:25am | From Policy to Practice: the NHS strategy for making better use of data for research | Dido Harding, NHSE & NHSI |
| 9:40am | Findings of the UPD commissioned public dialogue on commercial models for accessing NHS data | Natalie Banner, UPD |
| 9:55am | Questions & Answers | |
| Session 1 | Panel Discussion - Upholding the ethos of the NHS: the purposes, benefits and values of using health data (Chair: Carol Dezateux) | |
| Part 2: | | |
| 10:10am | <p><i>A panel to explore the public, patient and societal context for commercial access to health and care data and the acceptability criteria for commercial access to health and care data.</i></p> <ul style="list-style-type: none"> <i>How do we ensure appropriate benefit share across the health and care system from these approaches?</i> <i>How do we ensure appropriate patient and public involvement and transparency to maintain trust?</i> | <p>Natalie Banner, UPD Hilary Newiss, National Voices Aisling Burnand, AMRC Amy Darlington, Imperial College Health Partners and OneLondon's Public Engagement Programme Jonathan Montgomery, Healthcare law</p> |
| 10:50am BREAK | | |
| Session2: | Practical interpretations and learning from experience (Chair: Julie Moore) | |
| 11:05am | The value of data | Bryan Williams, UCLH BRC |
| 11:20am | Preparing NHS data sets for entering commercial partnerships | Pearse Keane, Moorfields <i>on curation for Google DeepMind partnership</i> |
| 11:35am | Pharmaceutical Industry perspective | Carole Longson, Chief Scientific Officer, ABPI |

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|---------|---|---|
| 11:50am | Panel discussion: Perspectives on sustainability opportunities across the Health Data Research Hubs | Chair: Julie Moore, Warwick University 7 health data research hub leads: Charlie Davie, DATA-CAN Axel Heitmueller, Discover-NOW Aziz Sheikh, BREATHE John Bradley & Mary Kasanicki, Gut Reaction Alastair Denniston, INSIGHT Martin Landray, NHS DigiTrial Elizabeth Sapey, PIONEER |
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12:45pm LUNCH (with hub stands)

Session 3: Building a framework – interactive session (Chair: Caroline Cake)

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|--------|---|---|
| 1:45pm | Overview of commercial framework: objectives and questions | Caroline Cake, HDR UK |
| 2:00pm | <p>Break-out workgroups <i>Review draft commercial framework (pre-reading) and hub use cases (pre-reading):</i></p> <ul style="list-style-type: none"> Given the types of use cases that the hubs are envisaging, what are the benefits and risks associated with the proposed Commercial Framework, and have we missed any important elements? How should we engage and involve members of the public, patients and practitioners in the ongoing development and delivery of this approach? | <p>Five break-out groups:</p> <ul style="list-style-type: none"> Each delegate is assigned to a group, indicated by the colour on their badge. Each group will go to a different room to discuss and reflect on discussions. Each group will have a facilitator and note-taker present to record discussion and feedback to the delegation. |
| 2:50pm | Groups return to the Council chamber | All delegates to return to the main room for the reporting back session. |
| 2:55pm | Reporting back session | Group facilitators report back key points |

3:15pm BREAK

Session 4: Feedback and closing remarks (Chair: John Tooke)

| | | |
|--------|--|--|
| 3:45pm | Review of key themes and additional discussion | <i>The co-chairs present the collated feedback from the break-out sessions and invite additional comments from the delegation.</i> |
| 4:30pm | Closing remarks | John Tooke and Andrew Morris |

4:45pm MEETING ENDS

Annex 2: Glossary

Accelerated Access Collaborative

A dedicated unit within NHS England and NHS Improvement responsible for coordinating activities across AAC partner organisations to drive forward priorities. It aims to remove barriers and accelerate the introduction of ground-breaking new treatments and diagnostics which can transform care.

Data Custodian

Responsible for the safe custody, transport and storage of the data according to agreed policy.

Data Controller

An individual or body with a legal identity (e.g. NHS Trusts, Clinical Commissioning Groups (CCGs), GP Practices, Local Authorities) that determine the purposes for which personal data will be processed and/or determine the way that the data is processed.

Digital maturity

The process of learning how to respond appropriately to the emerging digital competitive environment

Health Data Research Hubs

Centres of excellence with expertise, tools, knowledge and ways of working to maximise the insights and innovations developed from the health data.

Innovation Gateway

An application which will support researchers and innovators to discover and access data from the UK Health Data Research Alliance in a safe and responsible manner.

Local Health and Care Record Exemplars

Enable the safe and secure sharing of an individual's health and care information as they move between different parts of the NHS and social care.

Longitudinal patient record

A comprehensive clinical summary of a patient's clinical experience, as opposed to encounter-based, or provider-based records.

NHS England and NHS Improvement

NHS England and NHS Improvement have come together as a single organisation. It aims to better support the NHS and help improve care for patients.

NHSX

A new unit driving forward the digital transformation of health and social care.

Office for Life Sciences

Part of the Department of Health and Social Care and the Department for Business, Energy & Industrial Strategy. It champions research, innovation and the use of technology to transform health and care service.

Professional Record Standards Body

An organisation that was established back in 2013 to ensure that there are consistent standards for care records.

UK Health Data Research Alliance

Facilitates partnership working across NHS organisations and other health data custodians, leading to an ethical, consistent approach to the use of data and public engagement.