

NHSE's Value-Sharing Framework: How our personal health data is to be marketed

Keep Our NHS Public Briefing (February 2024)

INTRODUCTION

The Government says there should be no 'unnecessary' impediments to the secondary use of NHS data that will limit innovation and economic growth.¹ This means it is now policy to facilitate access to patients' personal data for researchers and external organisations (including commercial companies) "as default".²

The primary route of access will be the expanding network of Secure Data Environments (SDEs).³ However, NHS organisations, such as GP Practices and hospital Trusts, will apparently retain oversight of patients' data that they contribute to SDEs, along with decision-making powers about who may have access, and for what purposes.⁴ This will take place mainly through data-sharing partnerships⁵ in line with guidance - specifically, the *Value Sharing Framework for NHS data partnerships (VSF)* – published by NHS England (NHSE).⁶ Innovations from partnerships may be commercialised and sold in national or international markets.⁷

While recognising the value of data for research in the interests of the public, **KONP is deeply concerned about the move towards data access as default**, and especially what this may mean if increased access is granted to the private sector. This briefing provides information about the way patients' data is to be 'shared' (Part One) and, in Part Two, looks at potential implications of such data sharing.

PART ONE

The government's Life Sciences Industrial Strategy⁸ wanted to see "active NHS engagement with commercial innovators" to transform the way healthcare is delivered in the UK" (p50). It therefore called for the creation of a forum for engagement between industry, the NHS and arm's-length bodies to agree commercial access agreements. This led to the birth of the Centre for Improving Data Collaboration (part of NHS England), which in turn produced the *Value Sharing Framework*.

The Centre for Improving Data Collaboration (CIDC)

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https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1022315/Data_Reform_Consultation_Document_Accessible_.pdf

2 <https://www.gov.uk/government/consultations/data-access-policy-update-proposed-draft/data-access-policy-update-proposed-draft>

3 SDEs give approved users access to health data for analysis, without them (necessarily) receiving a copy. NHS SDEs are still in development but it seems that, unlike Trusted Research Environments, SDEs may allow some data to be removed. (see *The Goldacre Review: Trusted Research Environments and NHS data*.)

<https://keepournhspublic.com/health-data-working-group/>

4 <https://www.gov.uk/government/consultations/data-access-policy-update-proposed-draft/data-access-policy-update-proposed-draft>

5 A data partnership is an agreement between an NHS organisation and an external organisation that allows the external partner to access health and care knowledge assets for a specific purpose."

<https://transform.england.nhs.uk/key-tools-and-info/centre-improving-data-collaboration/guide-to-effective-nhs-data-partnerships/>

6 <https://transform.england.nhs.uk/key-tools-and-info/centre-improving-data-collaboration/value-sharing-framework-for-nhs-data-partnerships/>

7 <https://transform.england.nhs.uk/key-tools-and-info/centre-improving-data-collaboration/guide-to-effective-nhs-data-partnerships/>

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https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/650447/Life_SciencesIndustrialStrategy_acc2.pdf

The CIDC works with national bodies, NHS organisations, Health Data Research hubs and other data holders to provide resources, such as specialist commercial and legal advice on data sharing agreements to those wanting to set up ‘partnerships’ with industry. This includes support with contract negotiations, help with the valuation of data as part of Intellectual Property (IP) negotiations, and the development of reimbursement models.

The aims of the CIDC, as stated in a 2020 webinar,⁹ are to “deliver value back to patients and the NHS”, ensuring that financial returns cover costs and creating revenue “where desired”. There is no mention of ‘selling’ data as such, but options for commercial return include free or discounted products; payments for access to data; royalty shares; equity shares, and Intellectual Property (IP) ownership in a new product.

The Value Sharing Framework and its principles

The *Value Sharing Framework (VSF)*, developed by the CIDC to facilitate data sharing agreements (informally referred to as ‘deals’ by the CIDC), is essentially a set of principles¹⁰ expected to simplify and accelerate negotiations between NHS and external partners. These principles apply to agreements with a commercial partner, or where the outcomes of an agreement might be commercialised, regardless of the type of partner.¹¹ The principles are:

Principle 1. Cost of access should not prevent good use of data:

The costs of access to data should not be prohibitive. Protracted negotiations risk delaying or even preventing the NHS from delivering benefits for the public. A consistent approach is preferred to optimising each individual negotiation.

Principle 2. The NHS will always charge a fee for accessing health data:

“The NHS should seek to recover the costs of providing access to data”, including a proportionate share of overheads. Failure to do so takes money away from frontline services.

Principle 3. The cost of access should depend on how data is being used:

Charges for access to data should take into account the type of data to be accessed and how it will be used, but not the nature of partner looking for access: for example, NHS organisations should not charge commercial companies more than charities or academic institutions.

Principle 4. The NHS should share in the value created by its data:

“The NHS should expect a share of any commercial value arising from a data partnership proportionate to the NHS’s contribution to that value.” This contribution will vary by project and take into account the source data and any clinical or analytical expertise involved. Returns, particularly from commercial uses of data, “will depend on the maturity of the service offering compared to international comparators”.

PART TWO

Public opinion

Research¹² suggests that although there may be support for sharing personal data between the NHS, academic institutions and national research charities, there is ambivalence about doing so with profit-

⁹ <https://www.youtube.com/watch?v=ydQSYalwFj0&t=817s>

¹⁰ These principles overlap with those set out for data-sharing by the DHSC in 2019, but which also specified that a) the use of NHS data must have an explicit aim to improve patient health and care or the operation of the NHS, b) that NHS organisations should not enter exclusive arrangements so that data remains available for others to use, and does not undermine the wider digital infrastructure of the NHS and c) arrangements should comply with all applicable legal, regulatory, privacy and security obligations.

¹¹ NHSE has also developed commercial principles to underpin commercial access to data.

<https://transform.england.nhs.uk/key-tools-and-info/centre-improving-data-collaboration/guide-to-effective-nhs-data-partnerships/#2-successful-data-partnerships-in-a-changing-data-landscape>

¹² See, for example an on-line survey of over 29,000 UK residents. <https://bmjopen.bmj.com/content/12/4/e057579>

making companies researching treatments, and actual opposition to sharing data with other companies.^{13 14} A major reason for opposition appears to be a lack of public trust.

Patient engagement has not been a priority for NHSE. When it consults, it has tended to use organisations that are biased towards increased data access to organise engagement surveys or events. Notably, a new ‘engagement campaign’ announced by NHSE¹⁵ will seek views on patient data sharing, including about the contentious Federated Data Platform (FDP)¹⁶ - even though the engagement exercise will take place after the FDP contract has been awarded.

Ownership

The sharing of personal data raises questions about its ownership. This is increasingly the case, given the expanding field of Big Data and Analysis (BDA), the creation of ‘data lakes’, such as Secure Data Environments, and the growing number of relationships between data subjects/providers and data users.

Some argue that it is not possible to own data because it is not property in the conventional sense as it can be used repeatedly without being depleted. Others suggest that the concept of “ownership” exists to clarify rights and responsibilities concerning the ability to use (e.g. reproduce or sell) information, control the flow of that data or restrict it to preserve privacy, along with the responsibility to avoid harmful information release.¹⁷

The EU GDPR states that the data subject (i.e. the individual whose data is being processed) should be viewed as the ultimate ‘owner’ of their own personal data.^{18 19} However the rights of the data subject spelt out by the GDPR – such as the right to be informed when their data is being collected or used (i.e. not whether it can be) - do not suggest that ownership necessarily means control. There is no indication, for example, that patients will have any say about whether their data will be included in data sharing agreements, or even if they will be informed about negotiations for their data’s use.

Value

The NHS’s 55 million patient records have been given an indicative market value of several billion pounds (2019 figures).²⁰ This value is expected to increase as NHS data sets are linked with new forms of data now becoming available, such as a patient’s unique phenotypical and genomic information or data from a patient’s tissue and fluid samples (see also *Patients’ privacy’* below). Surprisingly, the CIDC appears to downplay the unique value (monetary and otherwise) of NHS data, stating that the NHS should focus on “providing data that meets user needs, rather than seeking value shares that stifle innovation.”²¹ Furthermore, it is also unclear whether NHS organisations can claim a legal basis for exchanging patients’ personal data for some kind of return.

The CIDC offers advice on negotiating contracts for data sharing but there are bound to be limits on the support they can offer. In contrast, private companies with commercial acumen, considerable resources and expertise in negotiating will be well placed to run rings around NHS organisations such as hospital Trusts. On top of which, the CIDC is charged with getting deals done quickly: the ‘value’ of data, and how this can be quantified, is a secondary consideration.

¹³ https://www.adalovelaceinstitute.org/wp-content/uploads/2022/05/Who-Cares-What-the-Public-Think_April-2022_v4.pdf

¹⁴ [https://www.thelancet.com/journals/landig/article/PIIS2589-7500\(20\)30161-8/fulltext](https://www.thelancet.com/journals/landig/article/PIIS2589-7500(20)30161-8/fulltext)

¹⁵ <https://www.pulsetoday.co.uk/news/breaking-news/nhs-to-launch-new-2m-engagement-campaign-on-patient-data-sharing/>

¹⁶ The FDP will bring together data (including patients’ health data) that is currently stored in separate NHS systems in order to ‘understand patterns, solve problems and plan services for local populations’. NHS England has already awarded a £24.9m contract to US-based company Palantir to ‘transition’ existing NHS projects into the new platform. Palantir is also the frontrunner to win the overall £480m contract.

¹⁷ <https://blogs.bmj.com/bmj/2020/08/06/who-owns-patient-data-the-answer-is-not-that-simple/>

¹⁸ <https://www2.deloitte.com/uk/en/blog/risk-powers-performance/2021/data-ownership-whats-in-a-name.html>

¹⁹ We have been unable to find if this statement remains in the UK GDPR.

²⁰ EY Realising the value of data: A framework for the future. https://assets.ey.com/content/dam/ey-sites/ey-com/en_gl/topics/life-sciences/life-sciences-pdfs/ey-value-of-health-care-data-v20-final.pdf

²¹ <https://transform.england.nhs.uk/key-tools-and-info/centre-improving-data-collaboration/guide-to-effective-nhs-data-partnerships/>

Patients' privacy

Legislation²² currently passing through Parliament addresses the government's National Data Strategy's call for the "lifting of compliance burdens" imposed by existing data protections.²³ This includes extending the definition of what constitutes 'anonymous' data and placing more data beyond legal protections, while regulations principally decided by the Secretary of State may allow data to be transferred abroad or to international corporations.²⁴ In short, the move to 'data access as default' promoted by the VSF is happening in a context when protections governing the privacy of our personal data are already being undermined.

In addition, with the development of new technologies, the nature of NHS data is changing. For example, the linkage of genomic and phenotypic data with electronic patient records will create unprecedented and highly intimate detail about individuals' current and future health status that is invaluable, for example, to the growth of personalised medicine.²⁵ As the global consortium EY suggests,²⁶ more targeted treatment through personalised medicine could bring greater economic benefits, especially when data is analysed to identify commercially valuable insights. Even members of the public who are currently unconcerned about the use of their data may feel more than a little uneasy about this level of increasingly intimate and identifiable information about them becoming commercially available here and abroad.

CONCLUSION

The public are largely unaware that, without their consent, access to their personal health data is being offered to commercial companies and other third parties *as default*, to make up for NHS underfunding – or that any 'rewards' are likely to be inconsequential. We know that the public are averse to the use of their data by private companies. The risk, should they find out that this is happening, is that public trust will be undermined and increasing numbers of patients will want to 'opt out' of data sharing. This would have serious implications for the usefulness of the NHS data pool.

Instead of data sharing with private companies there should be greater public investment in the NHS and academic sector for research and innovation in the public interest. Further, the NHS should not have to rely on trading our health data with the private sector to counter the underfunding of the NHS.

Keep Our NHS Public is a non-party-political organisation campaigning against the privatisation and underfunding of the NHS. For information about its work concerning NHS data, see <https://keepournhspublic.com/health-data-working-group/>

²² The Data Protection and Digital Information Bill v2.

²³ <https://www.gov.uk/government/publications/uk-national-data-strategy/national-data-strategy>

²⁴ <https://keepournhspublic.com/wp-content/uploads/2023/04/KONP.MPsBriefing.DataProtectionBill-2.pdf>

²⁵ Personalised medicine tailors treatments to the characteristics of individual patients.

²⁶ https://assets.ey.com/content/dam/ey-sites/ey-com/en_gl/topics/life-sciences/life-sciences-pdfs/ey-value-of-health-care-data-v20-final.pdf