

DHSC Data Access Policy Update: Proposed Draft

22 June 2023

Introduction

On 26 May 2023 the [Data access policy update: proposed draft](#) was published on the website of the Department of Health & Social Care. It describes the implementation of secure data environments across the NHS in England, with a set of ten draft proposals.

This is a significant document and of interest to Members of use MY data. The Secretariat sought the views of Members of use MY data and their direct views have been collated into this summary response.

The response has been sent to dataaccesspolicy@dhsc.gov.uk.

Summary from use MY data

The development of Secure Data Environments (SDEs) brings the potential for more robust, auditable and accessible means for appropriate uses of health data, for patient and public benefit. It is essential that the development takes place with significantly improved inclusion and transparency, then has been the case for some national patient data developments.

We see significant confusion about the overall plans for national health data infrastructure. The relationships between national SDEs, regional SDEs and the Federated Data Platform are poorly and/or barely described. Without simple clarity about how patient data will be used, it is not possible to engender public interest, support or trust. This is a serious omission.

It is unclear how multiple SDEs will be kept in step, nor how they will be kept definitionally consistent. Who is responsible for the required national consistency? Can a mandate apply, or is that seen as stifling innovation?

Finally, there is no detail about dates and delivery for much of the national work which is being proposed.

Responses on the ten points in the Policy Update

We have listed each of the ten points in the DHSC update ([shown in blue](#)), together with responses we received from our Members (shown below each point).

1. Secure data environments (SDEs) will become the default route for accessing NHS data for research and external uses. Instances of disseminating NHS data outside of an SDE for research and external uses will be extremely limited.

We note the slight shift to recognise that some data will still be disseminated and that SDEs won't be the solution for everyone. Our questions are around how these exceptions are managed, who decides, how are these made public and what audits will be implemented to check the data is being used appropriately.

Our other point of the benefit of an SDE approach is that it will be easier to describe all the SDE uses that are being made and making the anticipated benefits of each piece of work more widely available and publicised - this in the current Data Release Register but remains largely hidden.

These should all be good news stories which should be actively communicated to build public understanding.

2. NHS platforms exclusively used for operational purposes, including for commissioning directly by the NHS, are currently out of scope for data access policy. This includes operational instances of the 'Federated Data Platform' procured by the Chief Data and Analytics Office of NHS England (NHSE). This is because these platforms do not provide access to NHS data to third parties or for research. NHSE remains committed to implementing data access as default, as part of a holistic set of controls in line with the 'Five Safes', for operational purposes.

This seems to say that this Data Access Policy Update does not apply to "2. NHS platforms exclusively used for operational purposes, including for commissioning directly by the NHS". Our question is, what does apply to those uses? What scrutiny and transparency will apply to the Federated Data Platform uses?

3. The NHS Research SDE Network will become the primary way to access NHS data for research and external uses, alongside the small number of existing local (for example, NHS trust specific) SDEs for research. There will be a small number of defined exceptions to data access policy (see point 10, below).

We have seen some mention of the term 'NHS Research SDE Network' but it is difficult to obtain clarity about what it actually is. Could we improve the transparency about this please.

4. We expect NHS organisations to have oversight over data held in SDEs and have decision-making powers about which users may access datasets, for which projects. NHS controlled SDEs may use commercial or academic technical solutions, where it is more efficient than the NHS providing this itself. However, apart from for defined exception use cases (outlined in point 10, below), we do not expect that commercial and/or academic controlled SDEs will continue to host NHS data or make it available for research. We encourage partnership between academic organisations and their subnational SDE to maximise funding efficiencies and expertise.

It is unclear who actually decides on access. Are these decision groups defined and do they include patients? How will the decisions be made public for transparency and scrutiny. Will this include approved and not-approved requests?

If there are to be no academic controlled SDEs, what is the role of HDR Digital Hubs?

5. The cut off date for data sharing for research and external uses of NHS data has not yet been set, but by the end of 2023 we will provide clarity on when we expect this to take place. 'Data sharing' refers to the process where data is provided from the NHS to an external researcher or organisation. We expect that there will be a period of dual operating (data sharing and data access) while the change is embedded across the system, but ultimately there will only be a very small number of defined exceptions to the policy.

Our feeling is that the end of 2023 might be ambitious, given the current changes inside NHS England, as a result of the merger with NHS Digital.

Is there any detail about what the exceptions might be? Do use-cases exist to demonstrate the need for these exceptions?

6. Initially, from a researcher perspective there will be a single Data Access Committee to apply to for each NHS funded SDE in operation. These committees will have harmonised data application processes to ensure consistency and efficiency of decision making. Over time we will explore the possibility of delegated authority across data access committees. All data access committees will include patient and public representatives.

We are concerned about a single committee for each SDE. In reality, how will we maintain consistency of approach and decisions? How will the harmonisation happen - is someone leading this?

7. SDEs will be expected to uphold high standards of transparency about how data is used and who accesses it:
 - all NHS controlled SDEs will uphold high levels of transparency over how decisions are made
 - all NHS controlled SDEs will uphold high levels of transparency over who is accessing data, for which purposes, and the outcomes
 - all NHS controlled SDEs will conduct patient and public involvement and engagement in designing processes and making decisions, as well as engaging and informing people about how their data is used and the benefits

The phrase “High levels of transparency” is easy to say, but what does this mean in reality?

Transparency over outcomes is fine as a concept, but when someone applies for access, they don't have any outcomes, they just have anticipated benefits. Will there be anything in place to make sure outcomes (which could be seen quite a while later) are embedded?

What actual plans are in place for the final bullet? And are there any ways to measure the success of this?

We think that PPIE (patient and public involvement & engagement) should be specifically mentioned within the context of roles on Data Access Committees - the wording is a little too vague here now.

8. While policy remains to be developed, SDEs providing access to NHS data for research and external uses already exist, for example, the NHSE SDE. These services are covered by several assurance mechanisms:
 - secure data environments must comply with existing legal frameworks to keep data safe and used correctly. This includes the provisions of the Freedom of Information Act (FOI), in relation to requests for information about the operations of the SDE, in line with existing guidance for public authorities
 - SDEs in the ‘NHS Research SDE Network’ are currently coordinated by the Data for Research and Development Programme Board. Their design and implementation will also be influenced through the Network’s Community of Practice (CoP)
 - our commitment within the data saves lives strategy to put in place robust accreditation for NHS Research SDEs remains firm, but we believe that existing security and governance measures covered above provide sufficient reassurance in the interim period
 - platforms should continue to be invested in while a fuller accreditation model is developed

Are there any published details about the “Data for Research and Development Programme Board”? (We couldn’t find any). Clear terms of reference, membership, process and decisions need to be available for transparency.

Similarly, what details are available for the “Network’s Community of Practice (CoP)”?

There is a commitment to put in place “robust accreditation” for NHS Research SDEs, but this implies that the current processes are not robust. Which areas need improvement?

What are the timescales for the development of the “fuller accreditation model”?

Who is responsible for the development? Are patients involved?

9. Development of an accreditation model:

- we are currently in the process of defining a long-term model of accreditation of SDEs, which will ensure the future credibility and quality of SDEs hosting and providing access to NHS data for research and external uses
- engagement is underway with stakeholders to determine the options for implementing an appropriate model of accreditation. Specifically, we are considering how to maximise existing frameworks while ensuring fitness for purpose for NHS data. Furthermore, we want to ensure a long-term model is sufficiently scalable and avoids unnecessary duplication
- initial testing and implementation of a model of accreditation will focus on the Data for R&D programme’s NHS Research SDE Network to ensure the suitability and tailoring of the solution

If this is “long term”, what is available now, and in the interim? How is this accreditation development including patients? Accreditation also implies a one-off process - what about audit to validate compliance?

10. The following exceptions currently apply to data access policy, this list will be reviewed regularly as part of the iterative policy development process:

- sharing of patient-level data between NHS SDEs, as well as between SDEs in other countries, will be considered on a case-by-case basis in the same way as now, and only be done where there is a legal basis to do so and adequate protections in place
- sharing of patient-level data between NHS SDEs and SDEs controlled by government departments and arms-length bodies within England will be considered on a case-by-case basis in the same way as now, and only be done where there is an existing legal basis to do so, and value is added to data held elsewhere
- consented NHS data, including clinical trial data and consented cohorts, are out of scope for data access policy

- this does not mean that consented clinical trial and cohort data cannot be stored and accessed within SDEs, where there are reasons to do so. However, data can be shared in-line with the approvals in place and consent given by participants
- where appropriate consent exists, NHSE data linked to consented cohorts or clinical trial data may be onward shared, if this is consistent with information provided to participants in the trial
- we recognise there will be exceptions beyond this and will factor these into future phases of this work

For this list of exceptions, what policies apply (if this one doesn't). For the "case by case basis", is there any scrutiny or reporting of decisions? If so, where.

What is meant when it says that clinical trial data is out of scope? The wording about what can/can't be shared isn't very clear.

Are the intra-Government sharing documented and reported? What are the decision-making processes?

Will the exceptions be documented as they arise, and how will they be dealt with?

The only independent UK movement of patients, relatives and carers
focussed on the use of patient data to save lives and improve outcomes

Our vision


Our vision is of every patient willingly giving their data to help others, knowing that effective safeguards to maintain the confidentiality and anonymity of their data are applied consistently, transparently and rigorously.

Our mission statement

- **use MY data** is a movement of patients, carers and relatives.
- **use MY data** endeavours to highlight the many benefits that appropriate usage of healthcare data can make, to save lives and improve care for all.
- **use MY data** supports and promotes the protection of individual choice, freedom and privacy in the sharing of healthcare data to improve patient treatments and outcomes.
- **use MY data** aims to educate and harness the patient voice to understand aspirations and concerns around the use of data in healthcare delivery, in service improvement and in research, aimed at improving patient decision making, treatment and experience.

What we do

- We promote the benefits of collecting and using patient data to improve patient outcomes with sensible safeguards against misuse.
 - We work to bring a patient voice to all conversations about patient data.
 - We have developed the Patient Data Citation, which acknowledges that patients are the source of the data. Details are available [here](#).
 - We act as a sounding board for patient concerns and aspirations over the sharing and using of data in healthcare and health research.
 - We provide learning resources for patient advocates on patient data issues, including:
 - Hosting events for patients and the public, focussing on patient data topics
 - a library of resources of data security, consent
 - narratives from individuals about the value of collecting and using patient data.
 - We advocate public policy that supports the effective use of patient data within appropriate frameworks of consent, security and privacy, and with the aim of providing benefit to patients and their health care services.
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