ABHI response to consultation on Data Access Policy Update

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ABHI

Introduction

The UK Department of Health & Social Care (DHSC) has launched a consultation on the Draft Data Access Policy. The policy update builds on previously published secure data environment policy guidelines. The aim is to provide researchers and innovators with faster access to higher quality data, whilst maintaining the highest security and ethical standards, doing so via a move to a system of 'data access as default' for the secondary uses of NHS health and social care data. The draft policy makes a number of specific recommendations while also outlining further the strategy on data access. Below we have outlined ABHI response to each recommendation as well as making some general comments on the subject.

General Comments

We generally supportive of the move to SDEs and as the default access point for data as this has the potential to create a rich data resource with streamlined access through a robust, transparent governance process. For the approach to meet its potential we must ensure that the sub national SDEs operate as a single network with a common IG process, applied once for all SDEs, that supports a single point of access to the network and enables seamless exchange of data between SDEs. International initiatives, particularly the European Health Data Space, should also be looked at with a view to alignment of standards.

As development of the SDEs continues some of the detail underpinning the recommendations below will be important to understand, such as the accreditation process, data access committees and technical infrastructure and we welcome the opportunity to input into theses as appropriate.

The issue of commercial arrangements for data access remains outstanding. Currently some access is prohibitively expensive for SMEs, and we would recommend control mechanisms are established otherwise there is a risk of limiting access to data, and associated innovation and development, to larger entities. Mechanisms such criteria-based could be considered to ensure access is not prohibited too much by cost.

Policy Recommendations

DHSC Proposal 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.

ABHI Response: We recognise the need for the NHS to ensure the privacy and security of data through mechanisms such as the SDEs. Mandating the SDEs as a default route for accessing NHS data for secondary use will enable the necessary technical and governance measures to be put in place consistently across the network. In discussions with NHS Trusts, they have outlined that they will still be working with HealthTech companies in providing data access as they will be able to provide more granularity than that contained within SDEs.

It would therefore be useful to clarify the use cases for data access via the various possible access points, e.g., NHS Trust, Sub National SDE and National SDE and the types of data that will be available through each. The interaction between the different levels will be important as we

recommend there is a mechanism to query the data sets if they seem erroneous, or something is missing, is important. Therefore, requiring some level of traceability back to the Trust/dept.
There are often studies where access to the medical records of individuals with a unique character set is required, and the ability to have additional questionnaires or blood tests or similar conducted by that person. Will the structures be able to facilitate this?

DHSC Proposal 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.
ABHI Response: Linked to the point on use cases above it would also be useful to have more clarity on those that will be dealt with via the FDP. As there is likely to be a large overlap in the data underpinning both platforms clarity on access to different modalities of data would be welcome.

DHSC Proposal 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).
ABHI Response: We welcome the development of SDEs as a mechanism to provide streamlined access to high quality NHS data for research and development by the HealthTech Industry. To ensure that the SDEs are meeting the data needs for developers it will need to ensure it has the breadth and depth of information that can currently be accessed elsewhere in the NHS either at a national or local level. See point 4 below regarding exceptions.

DHSC Proposal 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.
ABHI Response: We would welcome further clarity on the oversight of the data held within each SDE. It appears to imply that that any Trust proving data into an SDE can have a veto on use of the data within the SDE or on a particular user. This could cause significant issues if each 'supplying' organisation must have its own IG sign-off for each project. We understand the need to control access and ensure access is only granted to those entities with genuine scientific merit reasons for requiring access but would hope there is a transparent robust process in place for access control that is streamlined and transparent.
There are some well-known and well run SDEs already existing which it would seem would fall outside of the expectations of this data policy. We would welcome clarification on the exceptions that are going to be allowed and of the overall policy: is it that DHSC does not expect commercial/academic controlled SDEs or in fact do not want them?
From an industry perspective we do not see issues with commercial or academic led SDEs provide they are operating to the accreditation standards. These SDEs could provide a valuable resource where there are specific use case requirements that may be disease, data modality or use case

specific which are not catered for within the NHS SDE Network. This will continue to foster innovation and extract value from data in the UK but also respect the safeguards the NHS will set out through the Data for R&D program.

DHSC Proposal 5: The cutoff 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.
ABHI Response: Having clarity of timelines well in advance of any cut-offs will be vital, also clarity on how contractual arrangements will be dealt with in any transition of responsibilities between an existing NHS organisation and an SDE. Transitionary arrangements should be developed in advance of any cut off to avoid any cliff edges and ensure that SDEs contain all the required data.

DHSC Proposal 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.
ABHI Response: We welcome a single data access committee, however rather than applying to this committee for each SDE we would strongly recommend that there is a "once for all SDEs" approach taken to eliminate the need for multiple applications. We support the inclusion of patient and public representatives and more generally an inclusive approach to committee memberships which should also include 'customer' representatives from academia and industry.

DHSC Proposal 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

ABHI Response: Transparency is to be welcome, although raises an issue of how you measure this and how can technology help provide factual information to contribute to this, e.g. audit trail of who accessed and transformed the data at any time point

DHSC Proposal 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

ABHI Response: Industry/Companies also have internal Data Privacy and Protection frameworks which they have to adhere to. In the development of the future accreditation model could there be a universal framework which takes account of these?

DHSC Proposal 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.

ABHI Response: We welcome a consistent approach to accreditation and through that the standards that the SDEs have to meet in delivering their services. As one of the key customers of the SDEs HealthTech/Life Science Industry input into the development of the process should be considered. The accreditation should take a holistic view of the SDE including people, process and technology. As part of the accreditation process we recommend there should be a standard set of KPIs that the SDEs have to report against, including both leading indicators (such as time for access approval) and lagging (such as value of innovations derived). They should also include measures of data quality and can adopt work undertaken by HDRUK in this respect.

DHSC Proposal 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.

ABHI Response: The ability to share and aggregate data between SDEs is a critical part of the infrastructure and should be designed in by default not addressed on a case-by-case basis. While we appreciate that sharing with other countries means interacting with systems outside of NHS control and with different standards in place, we strongly urge that arrangements are put in place ensure interoperability with the European Health Data Space (where GDPR is a major consideration). This will avoid making it cumbersome to procure comprehensive datasets.
We agree that consented NHS data, including clinical trial data and consented cohorts, should be out of scope for data access policy. We would appreciate further details on how clinical trial data & cohort datasets will be made discoverable through the SDEs and what data access processes will be in place for these, given they are put of scope of this policy.

ABOUT ABHI

ABHI is the UK's leading industry association for health technology (HealthTech).
ABHI supports the HealthTech community to save and enhance lives. Members, including both multinationals and small and medium sized enterprises (SMEs), supply products from syringes and wound dressings to surgical robots and digitally enhanced technologies. We represent the industry to stakeholders, such as the government, NHS and regulators. HealthTech plays a key role in supporting delivery of healthcare and is a significant contributor to the UK's economic growth. HealthTech is the largest employer in the broader Life Sciences sector, employing 145,700 people in 4,300 companies, with a combined turnover of £30bn. The industry has enjoyed growth of around 5% in recent years. ABHI's 400 members account for approximately 80% of the sector by value.