RCGP response: DHSC Consultation on Data access policy update

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.'***

   The RCGP has consistently highlighted the importance of trusted research environments (TREs) or SDEs. We welcome the expansion of the principle agreed at a national level with respect to the General Practice Data for Planning and Research programme, that pseudonymised data must not be disseminated and should only ever be accessed via secure SDEs.

   The RCGP Research and Surveillance Centre (RSC), one of Europe's oldest sentinel systems, is an active research and surveillance unit that collects and monitors data from over 1900 GP practices across England and Wales that volunteer to share data. Due to its extensive experience, we aim for the RSC to become an SDE pilot and a flagship demonstration site for the usability of SDEs.

   Regarding the exact wording of the data access policy, it is important that this is clear on what "external uses" might consist of beyond research, and in which "extremely limited" circumstances data might be disseminated outside of an SDE. The RCGP would suggest that data should in fact never be disseminated but only ever accessed within an SDE, and that external uses should be clearly defined, tightly limited, and closely monitored.

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.'***

   '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).'

   The RCGP also welcomes the implementation of holistic controls in line with the 'Five Safes', along with the fact that a limited number of channels-SDEs (NHS Research SDE Network and local SDEs) will become the route and default to access research data.

   However, we do have concerns about the sharing of data outside of SDEs where external companies are being commissioned to provide NHS platforms, such as is the case for the 'Federated Data Platform'. It is critical that all such organisations involved

in sharing, storing, and processing NHS data have the full confidence of the public, the profession and those responsible for data governance. It is also critical that the safeguards regarding the storage and use of data under these contracts, which may have extremely wide scopes, are carefully designed and clearly set out.

The RCGP considers migrating and building on existing NHS functionality and further exploring the support that could be offered by UK-based, trusted organisations to be a better option than commissioning large external contracts. This would help to avoid concerns about the safeguards in place, reduce the risk of vendor lock-in and the loss of control, and internal data processing capability.

We also consider it important to clarify the implications this policy will have for other initiatives and platforms such as the Clinical Practice Research Datalink (CPRD) and Biobank.

3. ***'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.'***

   The RCGP considers there is not enough information about the oversight mechanisms and safeguards described, and therefore, encourages DHSC to provide more detail in this regard. While the College supports clear oversight over which organisations can access data sets, we would suggest it is important to have clear processes in place to maintain the independence of research.

   Although the policy focuses on data access for research purposes, we would like clarification on the potential implications for GPs as data controllers of NHS organisations having oversight of data held in SDEs.

   We support a reduction in the number of organisations and SDEs holding NHS data. However, there is value in working in partnership with academic organisations, taking advantage of existing expertise and SDE provision.

4. ***'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.'***

   The RCGP believes that the cut-off for data sharing should be communicated well in advance to avoid negative repercussions to any current data extract

processes/commitments. Also, as set out above in response to point 1, we think exceptions should be extremely limited, if not none.

5. ***'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.'***

   The RCGP considers there is not enough explanation about the Data Access Committees' functioning. The College supports the inclusion of patients and public representatives within the DACs, however, it would help to know which other groups, organisations, and institutions will be represented. Where decisions are being made in relation to general practice data, there must be GP representation in these groups. Similarly, we consider it important to have an explanation of how decisions will remain consistent across the multiple DACs.

6. ***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.'***

   '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'***

   The RCGP believes the standards listed appear reassuring in terms of transparency. However, we would encourage NHSE to develop a means of robustly accrediting SDEs as soon as possible. Similarly, we request that the information about the changes in security and governance measure are made available as soon as possible.

7. *'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.'*

    As above, the RCGP is supportive of efforts to develop an SDE accreditation model. We would welcome the opportunity to provide stakeholder input into this process to provide GPs' perspectives as data controllers, and subject matter experts. In addition, we would encourage DHSC to involve primary care researchers who use this data. This would ensure the profession can have confidence in the process.

8. *'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.'*

    The RCGP is pleased to see that these exceptions are reasonably limited. Our main concerns lie around the cases where data can be shared, particularly with other government departments, as this can risk exposing sensitive information about vulnerable patients (e.g., traveller communities, homeless people, and those who could face problems with immigration). This could lead to certain groups being less likely to access the healthcare they need due to the actual or perceived risk of their records being accessed.

    The College considers there should be greater clarity on the mechanisms and guidelines by which decisions are taken to approve data access on a case-by-case basis. We would

like to have more information about the process and time required to assess these exceptions and the prioritisation that is applied after approval.

9. **Additional comment:**

Internal uses, such as health planning or informing policymaking, are apparently out of the scope of these policy updates, however, this is an area where great care is also needed, with transparency being a concern. If health data is being used for internal analyses to form policy, for instance, there should be an oversight and approval process for these analyses and the searches being run should be published.