

# **Building trust in data access through public involvement in governance**

**Survey findings and recommendations from HDR UK's Public Advisory Board**

**June 2021**

## Summary

While people may be content to share their de-identified data for planning and research if they are sure their privacy will be protected and it will not be used for marketing or insurance purposes, they want reassurance about users' motivations for requesting access to the data and their competence to protect it. This requires an approach to data access requests that is fully transparent, open to public scrutiny and regularly reviewed. Patient and public involvement in the committees tasked with making these decisions should be standard practice and information on assessment procedures and approved uses of the data should be publicly available and accessible.

Building on a survey of UK Health Data Research Alliance members, we make a number of **Recommendations** on how public and patient understanding of, and involvement in, data governance procedures should be improved in order to develop and maintain public trust.

## Introduction

This paper builds on findings of a recent survey of Alliance members initiated by HDR UK's Public Advisory Board (PAB) to gather information about patient and public involvement in the assessment of data access requests and monitoring of data use. The survey, which was sent to individuals in 45 Alliance member organisations during February/March 2021, revealed a wide range of approaches from full public involvement in decisions about data access to none.

The survey revealed many missed opportunities to inform and involve the public about policies in relation to health data use and only a few examples of excellence in public involvement and transparency. There was a lack of consistency in how data access requests are assessed and publicised. It was apparent that most information about data access procedures is produced for researchers, not for the public.

**We are concerned that opaque or exclusive data access processes will have a negative effect on public trust, with damaging consequences.** We recognise that many data custodians are at an early stage in the development of robust data governance procedures and experience of involving lay people in these is limited. We have therefore included a number of suggestions on how progress might be achieved. This window of opportunity is time limited, and public sentiment can harden if sub-optimal practice is identified in one or more well-known organisations.

The survey also revealed some good practice, and we are seeking the Alliance Board's support to pilot a shared learning workshop bringing together relevant organisations to identify good practice and opportunities for peer support. The event could also provide an opportunity to articulate the importance of openness and public involvement to engender and maintain public trust.

The full survey report can be accessed [here](#). Below we outline the rationale for the survey and a summary of the main findings.

## 1. Rationale for the survey

Building and maintaining public trust through transparent data access procedures is a key priority for HDR UK and for the UK Health Data Research Alliance. A report from the National Data Guardian underlined the crucial importance of transparency throughout the data life cycle (collection, storage, assessment and use) and of engaging a wide range of people in all aspects of governance, including reviewing data access requests.<sup>1</sup> Other recent studies have reinforced this, highlighting five governance principles (transparent, mutually beneficial, sustainable, responsive, legally compliant) that the public expects to see underpinning data governance.<sup>2 3</sup> The importance of transparency, accountability and public involvement to demonstrate trustworthiness has recently been reiterated in debates about plans for replacing the General Practice Extraction Service (GPES) with an upgraded system.<sup>4 5</sup> The negative headlines this has generated underscore the urgent need to ensure that all data controllers tackle this issue now.

PAB members who attended a number of workshops on data access over the last year noted a lack of consistency in relation to public and patient involvement in procedures for governing access to data. At our December 2020 Public Advisory Board meeting we agreed to survey Alliance members about their current and future plans for involving lay people in data access approval procedures. The survey achieved 22 responses from 20 of the 45 Alliance member organisations (less than half of those organisations surveyed).

The questionnaire covered three main topics:

- Patient/public involvement in data access committees
- Criteria for assessing data access requests
- Publication and monitoring of data access approvals

## 2. Patient/public involvement in data access committees (DACs)

The majority of those who responded indicated that their organisation has a DAC (defined as a committee or an equivalent body that is involved in assessing access requests and overseeing the management and administration of data access). Those who did not have a DAC or equivalent were currently planning to establish one. The majority of these committees are empowered to make decisions about who should receive access to data and for what purpose, and most committees review all eligible data access requests.

Only 9 of 22 respondents indicated that patient/public representatives are fully involved in reviewing data access requests in their organisation. Others described various functions performed by public advisory bodies that did not include direct input to decisions about data access.

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<sup>1</sup> Hopkins Van Mil: Putting Good into Practice. National Data Guardian, Understanding Patient Data, Sciencewise, UK Research and Innovation, April 2021

<sup>2</sup> Foundations of fairness: views on uses of NHS patients' data and NHS operational data Feb 2020

<sup>3</sup> <https://www.gov.uk/government/publications/cdei-publishes-its-first-report-on-public-sector-data-sharing/addressing-trust-in-public-sector-data-use>

<sup>4</sup> NHS Digital. General Practice Data for Planning and Research, 2021

<sup>5</sup> Coulter A. Patient trust in plans to share primary care data. *BMJ* 2021;373:n1413 <https://doi.org/10.1136/bmj.n1413>

Of those organisations that do include patient/public members on their DAC, five respondents said that more than 2 lay members were involved, two had 2 lay members and two had just 1.

Respondents reported using a range of techniques to ensure input is obtained from a diverse range of population groups, including targeted recruitment, rotating membership, and training.

### 3. Criteria for assessing data access requests

Respondents were asked what criteria they use to assess SAFE use of data (Safe Projects, Safe People, Safe Data, Safe Settings, Safe Outputs) when assessing data access requests and whether these criteria are made available on a publicly accessible website.<sup>6</sup>

Eleven respondents (50%) provided links to websites where this information could be found. Others outlined criteria used to assess the acceptability or otherwise of data requests, but these were not available on their websites. While some respondents provided detailed information on their review processes and the ways in which they involve patients/public, others did not. Some of those organisations that had not yet published their criteria for reviewing data access requests indicated that they had active plans to put the information on a website in the near future.

### 4. Publication and monitoring of approved data access requests

The survey asked respondents to indicate whether they keep a publicly accessible register of approved requests. Twelve respondents answered 'yes' to this question and eight provided links, but subsequent responses indicated a degree of confusion about what is meant by a publicly-available data use register. Other respondents said they do keep records of approved requests, but these are not yet publicly available, though most planned to make them available in the near future. More detailed analysis of Data Use Registers has been undertaken by the Alliance secretariat showing that just under half of Alliance members had a publicly accessible register, but these are often incomplete, updated infrequently and not written in plain English<sup>7</sup>.

In response to a question about monitoring, audit and follow-up of approved data uses, 11 respondents described specific processes ranging from publication in annual reports to more detailed compliance checks. Thirteen respondents described sanctions that would be applied if a breach of data use conditions were detected. Some stated that they did not have a monitoring process or agreed sanctions in place as yet.

### 5. Key points and examples of good practice

Fewer than half of the organisations that responded routinely include patient and/or public representatives in decisions about data access. There is little consistency across organisations in how data access requests are assessed, including differences in the criteria applied, how compliance with conditions of usage is monitored, and how any breaches are detected and dealt with.

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<sup>6</sup> Desai T, Ritchie F, Welpton R. Five Safes: designing data access for research. 2016. <https://www2.uwe.ac.uk/faculties/bbs/Documents/1601.pdf>.

<sup>7</sup> Karrar N, Khan S, Manohar S, Quattroni P et al. Analysis of Data Use Registers published by health data custodians in the UK [preprint] <https://www.medrxiv.org/content/10.1101/2021.05.25.21257785v1>

Some respondents provided useful detail on their procedures that could be helpful for those organisations that are addressing these issues for the first time. For example:

- One organisation described how, after an initial sift by staff, applications are forwarded to a Data Trust Committee, an independent group of patients and lay people whose recommendations are considered binding. All requests are listed on their website, including those that have been declined and the committee's reasons for refusing access.
- Another listed numerous criteria used to assess requests, including the following: Is the proposal clinically appropriate? Will the research be of value to healthcare and in the public interest? Is the organisation requesting access working in the public interest? Is the researcher from a reputable institution? If pseudonymised and/or identifiable data are requested, are specified consent processes required? If not, are there alternative legal bases in place? Do the researchers/research organisations have bona fide credentials? How will the requestors access the data? What security policies are in place? Are there contracts and commercial arrangements in place to support or prevent the data sharing proposed? Are there any concerns noted by the patient stakeholder(s)? Is the request likely to raise trust or reputational issues?
- Another organisation provided a link to a list of data access approvals on a publicly accessible website, presented in a clear and accessible form, including study titles, date of approval, lay summary, technical summary, list of health outcomes to be measured, and names of those requesting data.

## 6. Recommendations

We recognise that member organisations are at different stages in developing procedures to deal with data access requests. While some have long-established procedures in place, others are at a much earlier stage of development and could benefit by learning from those with more experience.

It is not within our remit to devise prescriptive guidelines, nor is it the spirit in which we seek to work. Rather we recommend to the UK Health Data Research Alliance that organisations adopt ways of working that support public involvement to demonstrate transparency and fairness in use of health data. We list below our suggestions for improved practice:

### A. Establishing a Data Access Committee (DAC)

- DACs should act independently, with oversight of the entire data lifecycle – collection, storage, access, and use. Committee chairs should support meaningful patient/public involvement in their committees.
- Patients/public should be involved in co-designing data access approval procedures. Data access procedures, policies and checklists should be published online; efforts should be made to ensure these are visible to patients and the public and written in accessible language. Rationale for processes, especially any that are specific to the DAC, should be clearly explained.

- There should be patient/public representatives on all DACs, and they should be recompensed in line with NIHR guidance.<sup>8</sup> We recommend a minimum of two patient/public members on each DAC, but ideally, they should make up at least 25% of members. The number should be proportionate and reasonable in relation to the size of the organisation and the volume of data access requests.
- Recruitment of all committee members should aim for diversity of backgrounds and experiences (e.g., ethnicity, age, gender, location) across all members of the DAC. This is important for ensuring that judgements reflect public views.
- All committee members should be offered support if required, including induction and mentoring.
- There should be fixed and/or rotating terms for all committee members.

## B. Reviewing data access requests

- Context is key. It may not be necessary for every request to be reviewed by patient/public representatives. If the volume of requests is high, some prioritisation may have to be considered and precedents that make detailed assessment unnecessary identified, but this should be subject to discussion, active agreement, and review with patient/public members.
- Patient/public representatives should always be involved in data access requests that involve personal and/or sensitive data.
- Criteria need to be clear and understood by all committee members to ensure consistent application, with any disputed decisions clearly discussed and recorded. For example, see Critical Appraisal Skills Programme (CASP) tools used for assessing research methodology: <https://casp-uk.net/>.
- The 'Five Safes' model should be adopted as it provides a good basis for assessing requests, including those issues that are of particular interest to patients/public.
- Wherever possible, data access should take place only within a Trusted Research Environment and this should be clearly explained in terms that lay people can understand.

## C. Monitoring and follow-up

- All data custodians should keep a data use register (data requests that have been approved) and make these publicly available on a website in an accessible format, as this is vital for transparency and public trust. The Innovation Gateway may offer a suitable platform for this.
- Data use registers should include any conditions imposed by the DAC, information on how access to the data will be audited on an ongoing basis, and how these conditions will be monitored.
- The custodian's conditions of data use should be prominently displayed on their website in an accessible format, including actions taken if conditions are breached.

## 7. Putting this into practice

We call on senior leaders within Alliance organisations to acknowledge the importance of patient/public involvement in data access processes and take a lead on this. Specifically, we ask the Board to:

- Enable public involvement in all data access procedures.

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<sup>8</sup> <https://www.nihr.ac.uk/documents/centre-for-engagement-and-dissemination-recognition-payments-for-public-contributors/24979>

- Standardise data access processes, as far as possible based on the Five Safes model.
- Demonstrate transparency in data access and use through a publicly available register, in line with the principles and recommendations set out above.
- Establish an Alliance forum to encourage shared learning across organisations, drawing on the views and experiences of patient/public members involved in existing approval processes, with a view to securing meaningful public involvement in all stages of the data lifecycle.

Meanwhile, the Public Advisory Board is committed to repeating the survey in 2022 to identify progress and obstacles and learn what is working well. We will also discuss with HDR UK options for supporting these efforts, possibly including provision of a shared space with links to appropriate resources and a lay members network.

We will be very interested to know what the Board considers possible in the short, medium, and longer term and look forward to hearing about the outcome at our next meeting.