UK Health Data Research Alliance: feedback on a data use registers Green Paper

Response from use MY data

22 July 2021

Introductory Note

This response has been coordinated by the Secretariat of **use MY data**, on behalf of members.

As with all the responses we collate on behalf of **use MY data**, these may contain contrasting views from members. It is inevitable that we receive a range of views from members, and all these views are included in our response. We believe that there is strength in presenting a complete range of views.

Contact details and follow-up

Our members are happy for **use MY data**'s response to be used or shared without restriction.

If you would like to follow-up with **use MY data**, or ask any questions about our response, please contact the Coordinator, Alison Stone - alison@useMYdata.org.uk

Our comments are provided below and follow the online template for submission of responses, as detailed at https://www.hdruk.ac.uk/news/uk-health-data-research-alliance-seeks-feedback-on-a-data-use-registers-green-paper/.

Background

As with other consultations, we contacted the **use MY data** Advisory Group Members asking for comments on the areas identified in the Green Paper and the attached list of proposed items to be included in release registers.

We collated the responses into this single document, showing the survey questions first, followed by our response.

We used the contents of this document to complete the online form.

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 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.
- 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.

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.

Recommendation 1: All data custodians and controllers responsible for the collection, storage and sharing of data for the purpose of research, innovation and service evaluation should publish a public record (data use register) of approved research studies, projects and other data uses.

Are you supportive of this recommendation?

- Very supportive
- Somewhat supportive
- Neutral
- Not supportive

Comments

No comments

Recommendation 2: Data use registers should, as far as possible, be populated in near real time directly from information provided through the Data Access Request process to improve timeliness and accuracy of entries.

Are you supportive of this recommendation?

- Very supportive
- Somewhat supportive
- Neutral
- Not supportive

Comments

Where processes allow this, we would support this point in principle. However, the term "near real time" is very subjective. We would need some measurable timescale. Implementing a truly real-time solution may be costly, and not the best use of limited NHS resource. There needs to be a balance.

Recommendation 3: Data use registers should be made available in both human readable and machine-readable formats.

Are you supportive of this recommendation?

- Very supportive
- Somewhat supportive
- Neutral
- Not supportive

Comments

No comments

Recommendation 4: Data use registers should have a consistency of format and content based on the Five Safes framework and an agreed specification to enable ease of understanding and aggregation of registers.

Are you supportive of this recommendation?

- Very supportive
- Somewhat supportive
- Neutral
- Not supportive

Comments

A consistent format is needed for the machine-readable version. Online, user friendly formats should be developed with users, rather than just technologists. If registers are all machine-readable, and to a consistent format, we should also move to a single viewing portal.

We would also note that if register content is based solely on the 5 safes, it misses the point about benefits. Data sharing is also strongly about patient and societal benefit.

Recommendation 5: Researchers, data custodians and funders should use data use registers to close the loop on the impact of data use by including links to research findings and other outputs as these become available.

Are you supportive of this recommendation?

- Very Supportive
- Somewhat supportive
- Neutral
- Not supportive

Comments

We very much support this principle, though also recognise that there may be a burden on research teams to put this in place robustly. We suggest a joint piece of work involving patients and researchers to define what might be possible, with what effort and impact.

We would also point out that data-users are not always researchers. Others, such as data companies, CCGs and others should be similarly expected to highlight benefits and findings.

There should be a time limit from the date of publication and reminder that negative findings can be just as valuable as positive findings

Feedback on specification: Do you have any advice on the recommended content, format and frequency of updates to data use registers? Please refer to Table 1 in Green Paper or download the specification spreadsheet from GitHub.

On the question about frequency, for a manually dependent process we would suggest a minimum of every three months, with an ideal of monthly. If systems are in place to automate the process, we would suggest this be best done overnight or weekly, with a minimum monthly.

We would like to go further to be transparent around areas of public concern if we really want to build public trust – at the moment the Green Paper seems to have a strong technical/scientific bias to it - we note that public trust is the final aim noted, not the first.

Any glossary has to be understandable to lay readers.

We need clarity about whether registers are for release or access, or both. We think both.

There should also be something about promoting the existence of data release registers. Making them easy to use is good, but that's passive and a more active approach is needed. The public and patients need to know they are there, especially if the Green Paper is to achieve its laudable aims of trust, transparency etc. We may not want to find or use them, but we need to know they are there.

On the list of suggested fields:

There needs to be a heading which names the accountable organisation that is making the release, the date the register was released and the dates for which it covers all approvals and all releases. We would also like to see the date that the next register will be released.

Type of Sponsor (Commercial Company/Not-for-profit etc -yes); where is the Sponsor legally based (e.g. UK/Europe/USA/Elsewhere); how many records supplied; has an acceptable assessment for 'Fair value' been made (Y/N); Date of last Compliance Audit post granting of access. It might be useful to indicate these fields on the register even if the data is not generally available currently, as it sets a direction and expectation with the public.

Organisation name: needs to be clearer that this organisation is completely accountable for sticking to the agreement and the rules for data usage, access, security etc. They cannot delegate any aspect of accountability to any 'here today, gone tomorrow' researchers or any third-party data processor

Funders/Sponsors/Collaborators: add sub-contractors to pick up data processors or third-party analytical companies etc.

Opt Outs: the document only mentions the National Data Opt-out. What about the cancer opt out & Type 1's?

Benefits reporting: this is the weakest but one of the most important to get right. It talks about how important this is for patients but having identified real benefits that are intended at the time of application it seems satisfied with reporting back the papers published rather than the real-world benefits that have been realised or better pinned down for realisation because of the research. The planned benefits should include a timescale for realisation and there to be a clear requirement that realisation (or not) of those benefits should be reported back against those timescales (obviously it probably won't be in terms of lives saved but it can be things like 'established that n% of people who have this also get this compared to m% in the wider population' or 'showed that this demographic group is x% more likely to get this condition than the wider population' etc). i.e. tied back to the original research objectives. The organisation applying for the data is accountable for this reporting back for the register rather than the 'here today, gone tomorrow' researchers. There should be a principle of 'if you don't report you don't get more data' at that same organisational level.

We have also provided a listing (below, also available as a spreadsheet) which shows our assessment of the "Status" of the individual fields, which has a significant focus on some fields needing to be mandatory.

Field: Organisation Name - Status: Mandatory;

Field: Funders/Sponsors/Collaborators - Status: Mandatory;

Field: Organisation Type - Status: Mandatory;

Field: Applicant Name - Status: Recommended;

Field: Accredited Researcher Status - Status: Mandatory;

Field: Publisher Name - Status: Recommended;

Field: Organisation ID - Status: Optional;

Field: Applicant ID - Status: Optional;

Field: Project Title - Status: Mandatory;

Field: Public Benefit Statement - Status: Mandatory;

Field: Approval Date - Status: Mandatory;

Field: Lay Summary - Status: Mandatory;

Field: Legal Basis for Provision of Data - Status: Mandatory;

Field: Common Law Duty of Confidentiality - Status: Mandatory;

Field: Release Date - Status: Mandatory;

Field: Project ID - Status: Highly Recommended;

Field: Technical Summary - Status: Highly Recommended;

Field: Other Approval Committees - Status: Highly Recommended;

Field: Project Start Date - Status: Highly Recommended;

Field: Project End Date - Status: Highly Recommended;

Field: Dataset(s) Name - Status: Mandatory;

Field: Data Sensitivity Level - Status: Mandatory;

Field: Request Category Type - Status: Mandatory;

Field: National Data Opt-Out Applied? - Status: Mandatory;

Field: Request Frequency - Status: Mandatory;

Field: Description of how the data will be used - Status: Mandatory;

Field: Description of Confidential Data Used - Status: Mandatory;

Field: Trusted Research Environment (TRE) or other specified location - Status: Mandatory;

Field: How has data been processed to enhance privacy? - Status: Mandatory;

Field: Link to Research Outputs - Status: Mandatory;

Do you have any suggestions how to support adoption or address barriers to adoption? Any other comments?

We recognise that there could be barriers to adoption. This is a fundamentally essential process which underpins transparency, and is what patients expect to happen.

However, we also have some overarching points:

1. Does this apply from top to bottom in the NHS? Does every organisation from GP Surgery to NHS E have to have a Register? We hope so, but note the GP Unions were not represented in the workshops
2. Does this apply to Social services?
3. Is sharing within the NHS to be included or is it just external? We believe sharing within the NHS for purposes beyond direct care should be reported
4. The paper focuses mainly on data for research but does refer briefly to internal planning etc. It should be clearer that data for planning and management is within scope
5. Will data custodians be required to publish details for all historically agreed but currently active recurring releases (i.e. those agreed before the register was instituted but still being released)? We think it should so be.
6. There needs to be a balance between creating an expensive, bureaucratic monster versus the necessary cost of gaining and retaining public support

Finally, we would reiterate a previous point which we made, that there should be active promoting of the existence of data release registers. The public and patients need to know they are there, especially if the Green Paper is to achieve its laudable aims of trust, transparency etc. We may not want to find or use them, but we need to know they are there.