Response to the Department for Digital, Culture, Media & Sport consultation document - "Data: A new direction"

Response from use MY data

19 November 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

Background

The consultation "Data: A new direction" was published on 10 September 2021 by the Department for Digital, Culture, Media & Sport (DCMS) to consult on reforms to create an ambitious, pro-growth and innovation-friendly data protection regime that underpins the trustworthy use of data.

The consultation presents proposals that build on the key elements of the current UK General Data Protection Regulation (UK GDPR), such as its data processing principles, its data rights for citizens, and its mechanisms for supervision and enforcement.

We highlighted the consultation to our Members on 21 October 2021 seeking their views. We also consulted our Advisory Group for their views.

Below is a summary of the points which they raised, which is drawn directly from individual Member's submissions.

Some comments are shown in quotations, directly as submitted by Members, which we hope you will find useful.

Our overall assessment

Overarching comments

We agree with the idea of standardising and hopefully simplifying the rules for data-driven research across multiple domains as exemplified in the Ministerial statement.

It is essential that Data Controllers and researchers have clarity on what is and is not allowed for data release and usage. One set of rules would be a big step for that clarity and overcome the conservatism used in applying the access rules. Where there is confusion as to which set of rules apply, some organisations are applying all of them.

Fragmentation (whether existing or not) of data controllership of multiple elements of healthcare data, when the NHS is working in the opposite direction on integration of healthcare data, does not appear to make sense.

The length (146 pages) of the document means only people in the industry will devote sufficient time to it. Could you not have done or maybe still do a document which pulls out the key issues for public response? We see this as a major omission which could be easily rectified and would encourage you to do so.

We would like to sound a strong warning note, observing that it is difficult for the Information Commissioner's Office (ICO) to be truly independent if the appointment is the responsibility of Ministers. This is a serious concern.

What's missing?

We seem to be slowly moving towards an integrated health record, added to, used and shared by multiple parties. As a result, we think that the current roles and responsibilities of multiple Data Controllers across the record will become blurred.

The issue of whether there should be more centralisation of the Data Controllership role needs consideration. The current model relates better to when individual health providers kept their own paper records or later held them on their own IT systems.

This issue of multiple data controllers in the new era of shared health records was raised by several Members. This is an issue which needs addressing.

We think the document has missed out a critical section with respect to healthcare, which was raised by several Members. At the moment many AI Tools get stuck at the stage of 'proven in the lab' and do not move to the stage of 'this is the way we do things round here' let alone improving health at national or global levels. There urgently needs to be:

- A clear process which any tool must pass to move from the first stage to the second and third. It must be practical, reliable and predictable.

- A clear understanding of who is accountable if an approved tool leads to bad consequences. Who is liable if the clinician follows the instructions on the box? The developer, the supplier, the approvals body, the clinician, the clinician's organisation?

- Clarity that liability needs to be insurable, so the insurance industry needs to be involved in the thinking behind the process.

One Member specifically noted "Sadly, from a methodologist's perspective, in practice 'proven in the lab' i.e., research published in a reputable journal etc. is no guarantee of the rigour or validity of the research. AI and related clinical research papers often reveal poor methodology which renders findings vulnerable to bias etc. I am aware of a growing number of really good academics both at KCL and internationally who are concerned about the low-quality thresholds for publishing even for 'good quality' journals."

We would also point you to David Spiegelhalter's presentation 'Be prepared to show your workings' from which the **use MY data** definition of transparency was derived. One of our Members has been working with a group at Oxford led by Dr Baptiste Vasey & Prof. Peter McCulloch on developing a Core Information Set for publishing AI development in healthcare (currently in pre-publication) which could help raise standards. We can supply email details if needed.

We are glad that this work is being done and thank DCMS for taking a lead. However, we hope that other Departments use this work rather than deciding that they need to do the same thing again, and this might be made more explicit.

Our detailed comments

Q1.2.2 P13 Certainly agree the benefit of pulling together the rules for researchers using data into a single rule book which can be applied across domains (but, if absolutely necessary, a small number of domain specific rules on top of the common base).

Q1.2.8 and following. Agree that subjects should be able to give permission for researchers to use their data in a broad area rather than just for a specific research topic. Good research always creates new questions which might be able to use the same data. As one Member noted, "I would be happy for them to continue without asking me again".

Q1.4 and following. Agree with the concept of a list of uses which would always be considered legitimate but the possible list in Q1.4.2 felt uncomfortable. That area needs more justification. This is an area where the privacy campaigners might have a field day and undermine the whole set of changes envisaged.

Q1.5 and following. Fairness in AI. Agree that there is a plethora of organisations (some official, some merely interested) putting forward their definitions of fairness which makes it difficult for researchers to be sure they are using data fairly and causes data controllers to be ultra conservative in allowing their data to be used because of the competing and conflicting rules and guidance. We must move towards a single definition and a single process through the approval. This would not only allow the rules to be applied consistently but also give clarity to researchers and data controllers on what is fair and save taxpayer money in that we can stop multiple bodies re-inventing slightly but irritatingly different wheels.

Q1.5.10, 11, 12. Strongly agree.

Paras 96 to 100. We do not think there is sufficient focus on 'explainability'. For 'explainability', we see two dimensions in health:

1. The logic as to how a recommendation has been reached must be understandable, explainable and agreed at the expert level.

2. The clinician or whoever is communicating the recommendation to the patient must be able to explain the reason why, in comprehensible terms to the individual concerned. Thus, the clinician must have sufficient understanding of how the recommendation was developed which presents a real challenge.

For making decisions regarding members of the public, it is absolutely necessary that individuals are given or can obtain an understandable explanation of why the decision was taken. One Member highlighted this by saying "To take an exaggerated absurd health example to make my point – if I report earache and the computer says my leg should be chopped off, I want to know why, I don't just want to be told that's what the computer says".

Q1.5.17 Related to the previous paragraph, we think that in deciding the circumstances where purely automated decision making is ok, due regard must be given to the potential consequences of the decision to the individual impacted.

Q1.5.18, 19, 20 Use of profiling in AI and fairness. Clearly critical but the preceding discussion, whilst exemplifying the problem, is very woolly and vague on what is being proposed. It's a critical area (and again getting it wrong could undermine the overall proposals) and a lot more thought needs to go into the proposals and making them clear. One Member summarised saying "I like the thought of an Algorithmic Risk Assessment but what is it in practice and how would it work?"

Q1.6.1, 2, 3, 4 Strongly agree need clearer definition of what is anonymous or pseudonymised. We are asked to choose between two different rule books, but the ICO is currently studying the issue. We think it would be best to wait for the ICO analysis and recommendations rather than pre-judge by jumping for one of the two.

Q1.7 etc. There is a role for responsible data sharing within health facilitated by intermediaries. It should include not just the normal NHS Data Controllers but also social care and private healthcare as part of the move to a National Health Record. We were not sure whether in the text you are looking at something that goes beyond this?

Q2.2.1 and following. Support the development of a clearer/simpler privacy management programme In health. In particular, the measures that require Trusts to have a Data Protection Officer, an Information Governance Manager and a Caldicott Guardian operating in the same domain but applying different controls on how data is collected, used and shared, produce added bureaucracy, confusion, conservatism and costs. There should be a radical rethink of this regime to create greater clarity. This is not in the interests of patients.

Chapter 3 – We did not think this chapter was as relevant to health, so no comments provided.

Chapter 4 - Q4.3.3 4.4.1 Strongly agree.

Chapter 5 generally. We would add that if we clarify and strengthen the ICO's role we should consider what further value the Office of the National Data Guardian adds and whether it would be better to combine the roles.

Q5.2.1 Strongly agree.

Q5.2.2 Very, very strongly agree.

Q5.3.2 - The appointments process for the Information Commissioner raised concerns with Members.

One Member usefully summarised, saying “I was only alerted to this issue by hearing the current Information Commissioner on Radio 4 last week. She was concerned that the Government's proposals would change the appointment from one made by Parliament to one made by Ministers”

Specifically, paragraph 359 in the document talks about the appointments process being done under the existing governance code on Public Appointments. This all sounds very reasonable, but the clue is in the statement in para 359 about appointments being a responsibility of Ministers accountable to parliament. What this means in practice, and we have seen it happen in various arm’s length bodies, is that Ministers can (and do) ignore the appointments panel recommendation and appoint whoever they like.

We would like to sound a strong warning note, observing that it is difficult for the ICO to be truly independent if the appointment is the responsibility of Ministers. This is a serious concern.

We strongly emphasise the need to keep the ICO independent from Ministers.

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.