

Guidance document issued by the Department for Health and Social Care (DHSC)

“Creating the right framework to realise the benefits for patients and the NHS where data underpins innovation”

Published 15 July 2019

Response from [use MY data](#)

07 August 2019

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 of these views are included in our response. We believe that there is strength in presenting a complete range of views.

We have previously responded to consultations on Artificial Intelligence, the Centre for Data Ethics, the National Data Guardian’s work and the National Data Strategy. We note the positive commitment that the guidance will align with these other national policies.

Contact details and follow-up

Our members are keen to engage with the DHSC or NHSX teams and are happy for use MY data’s response to be 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

Once submitted, this document, will be published on our website - www.useMYdata.org.uk

Section 1: Purpose

We recognise that the stated purpose of the document is to provide an update on the development of government policy to:

- establish guiding principles and a framework to help the NHS realise benefits for patients and the public where the NHS shares data with researchers
- establish a National Centre of Expertise to provide specialist advice and guidance to the NHS on agreements for use of data

“...guiding principles”

It is not clear whether the guidance is compulsory? If so, should it be policy rather than guidance?

“...shares data with researchers”

This purpose explicitly says that the guidance is for where the NHS shares data with researchers. How does this differ from existing structures and processes which govern and manage existing data flows for research, such as those from NHS Digital and Public Health England?

From a patient perspective the question of sharing data with researchers is different to the sharing of data with commercial companies, so the purpose about its scope should be clearer.

Section 2: Introduction

“Our starting point is that the government wants NHS partnerships to flourish within the strictest parameters of transparency and accountability.”

We would absolutely endorse this fundamental principle. But work has shown that “transparency” means different things to different people. We would be keen to work with you to help bring more clarity to this area.

“It must be done so in a way which is safe, ethical, evidenced and transparent”

We would also add “...and is what patients and the public would reasonably expect to happen, based on communications and dialogue...”.

“...and that their privacy and rights are safeguarded”

There is still confusion over exactly what “rights” you have in how your data is used. We regularly see groups such as MedConfidential highlighting that, even when patients have opted out of their data being used for research and planning, the data is still released under certain provisions. We need a much clearer dialogue and communication about this, to either reassure or change practice.

Section 3: Guiding Principles

Principle 1: The change to reflect that the use of data is not just about drug discovery is positive.

The focus change from being the UK to the NHS more accurately reflects that this is about England, but the relationship between this policy document and the devolved nations is unclear.

Wording around the restriction on use of datasets which are in the public domain has been removed - in reality such restrictions are virtually impossible anyway, so this is a sensible change.

Principle 2: Data is now being talked about as a resource rather than an asset. Language is important when communicating, so we need consistency. We have not specifically discussed the relative merits of the term “asset” versus “resource” with our members, but we could if that would help.

The term “mutually beneficial” has been removed. The focus on the NHS rather than just local has been strengthened, which is welcome. The need to safeguard any resources which are generated by any agreement has been included, which is positive.

Principle 3: The phrase “commercial arrangement” has changed to just “arrangement”, though it is not clear why.

The term “for raw data” has been added. It is not clear why this has been done, and we are somewhat unclear whether the term “raw data” has been clearly defined or understood in this context. This requires some explanation, perhaps with examples.

Emphasis has been added to make sure commercial arrangements do not restrict the free flow of data within health and social care. This would seem to be sensible and positive.

Principle 4: The term “commercial arrangements” has been changed to just “arrangements” (see Principle 3 comments).

The wording around public trust has changed from “not undermine public trust”, to “to support public trust”. The slight change in emphasis is welcome, as it is more about improving trust and less about just not doing damage. However, this is easy to say, and much more difficult to do. High quality communication and increased transparency will be absolutely crucial if this is to improve.

Principle 5: The term “commercial arrangements” has been changed to just “arrangements” (see Principle 3 comments).

The requirement to adhere to the GDPR and the Common Law has been added. Whilst this was probably implied in the original text, it makes sense to add this to the wording for clarity.

Section 4: Scope and application of the principles

“...by all NHS organisations”

We welcome the clear statement that the principles apply across the breadth of organisations responsible for our health and care, and not just focused on a hospital setting.

The principles are designed to apply to agreements which include a commercial partner or where the outputs could be commercialised, regardless of the type of organisation the NHS is partnering with

How does this tally with the original statement about being for researchers?

Section 5: Centre of expertise

“...to develop the concept of a National Centre of Expertise (the ‘Centre’)”
“...enable the Centre to commence operations as soon as possible this year”

The document is somewhat unclear on how far this has progressed and moves from developing a concept to recruiting a Director and establishing the Centre in 2019. It would be better just to state what is happening when, to avoid confusion.

“The Centre will sit in [NHSX](#)”

There is still a large degree of confusion over the role of NHSX.

Further questions have arisen, for which explanations are needed:

- How will the Centre adopt the principles of transparency in practice?
- Who will the Centre report to, and how will that reporting take place?
- Will the Centre publish its discussions and findings?
- Will the operational aspects be an open process?
- How is the patient voice involved in the Centre, given that it is dealing with the uses of patient data?
- Production of the legal advice - how will this work in relation to similar roles and functions which currently sit with the Health Research Authority, NHS Digital and Public Health England?
- How will the Centre interact or utilise existing independent advisory groups such as IGARD and Public Health England's independent advisory group, which already have different levels of legal expertise and opinion?

“...assessing the value of different partnership models to the NHS.”

How will this assessment take place, and will the details of the assessment be made open, or published?

“...signposting”

The document indicates a role for the Centre in providing a signposting service, so that advice and assistance can be provided and relevant questions can be routed to appropriate organisations. This looks like a sensible approach, but the process for deciding where the signposting goes to is not yet clear.

“...engagement and understanding the landscape”

How does the Centre see this taking place?

“...setting clear and robust standards on transparency and reporting to underpin and support public trust”

Having clear practices in these areas would be helpful, but this should be developed with other partners who already operate in this space. The role of the Centre could be in the coordination of the existing work, representing this out to wider stakeholders.

“We will explore what additional functions, or nuancing of these functions, would be useful ahead of publishing the full policy framework document later this year”

We welcome this commitment and look forward to exploring this with the Centre as it develops.

Section 6: Next steps and further commitments

“We plan to publish the next iteration of the principles in a policy framework later this year”

We would stress the urgency to move forwards with the establishment of the Centre. There is a lack of certainty over the timescales and deliverables, and this should be addressed.

There is a potential risk of inertia if existing research is delayed until the Centre is established. Additionally, the longer it takes to establish the Centre the higher the risks that something ill-advised will happen and undermine future prospects for good uses of the data.

About use MY data

use MY data is a movement of patients, carers and relatives

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.

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.

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.

What we do

- ❖ We promote the benefits of sharing and using data to improve patient outcomes with sensible safeguards against misuse.
- ❖ 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 workshops for patients and the public, focussing on topics related to patient data
 - a library of resources of data security, consent
 - narratives from individuals about how collecting, storing and using data can help patients.
- ❖ 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.

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