

NUFFIELD COUNCIL ON BIOETHICS

Response to the National Data Guardian for Health and Social Care
consultation about priorities

March 2019

Introduction

The [Nuffield Council on Bioethics](#) is an independent body that examines and reports on the ethical issues in biology and medicine. Our response to this consultation is drawn from the approach and principles set out in our 2015 report [The collection, linking and use of data in biomedical research and health care: ethical issues](#).

General comments

The Nuffield Council on Bioethics remains very supportive of the work of the National Data Guardian and we were pleased to see this role placed on a statutory footing in December 2018. We welcome the opportunity to comment on the priority areas set out in this consultation and to any further opportunities that may arise in future to support and inform your work from an ethical perspective.

We are pleased to see some of the core principles for data management we outlined in our report - and in an earlier [consultation response](#) in 2016 - are reflected in the four priority areas set out in this consultation. We support these four priority areas and below we set out some more specific comments in answer to your questions. We have answered only the questions to which our report conclusions and recommendations are most relevant.

Priority 1: Encouraging access and control: individuals and their health and care data

NDG areas of interest

- *Encouraging greater /easier access for patients to see their health and care records and who has viewed them*
- *Greater transparency for patients to see tailored information showing how data about them has been used for reasons other than their own individual care, for example how it has been used to improve health, care and services through research and planning*
- *Exploring models for greater patient control over data*

Consultation questions

1. *Should giving people access and control of health and care data be one of the NDG's top priorities?*

Yes, *one of the top priorities*, although if the numbering of the priorities indicates a ranking system, we would suggest that good governance (as discussed further in priority 4, for example) is equally, if not more so, important.

2. *Are the outlined areas of NDG interest the right ones for the NDG?*

Yes, it reflects our view that the NDG should create opportunities for those with relevant interests to find out about, engage with and influence how data are used.

'Access' for patients to their records must be meaningful, and an important consideration is exactly what recorded information people will have access to. Being able to see who has viewed patient data is a key component of accountability, so the ability to see tailored information showing how data has been used for reasons other than individual care would be strongly welcomed.

Priority 2: Using patient data in innovation: a dialogue with the public

NDG areas of interest

- *How do patients want and expect data about them to be used within health technology? Is there understood to be a reciprocal relationship, whereby those receiving care allow data usage to facilitate improvements? What are the boundaries that people would put around this?*
- *How far do public expectations of data usage match reality, for instance in NHS apps and non-NHS health apps? What should be done to ensure expectation and reality are brought closer together?*

Consultation questions

4. *Should use of patient data in innovation be one of the NDG's top priorities?*

Yes, both promoting and governing it are important here.

5. *Are the outlined areas of NDG interest the right ones for the NDG under this priority? (Please tell us if there are other areas we should be looking at under this theme, or if you think others would be better placed to do the work)*

Yes. The questions set out here are excellent, covering the right areas. This approach to patient involvement accords with our general recommendation from our report that the set of expectations about how data will be used (or re-used) in a data initiative, and the appropriate measures and procedures for ensuring that those expectations are met, should be determined with the participation of people with morally relevant interests.

6. *What would you like to see the NDG do in this area?*

One suggestion would be integrating patient panels into the governance processes.

Priority 3: Getting the basics right: information sharing for individual care

NDG areas of interest

- *Working with bodies leading on education and training to ensure that those working within the health and care system are equipped to handle and share data with confidence*
- *Encouraging better sharing for individual care across boundaries, particularly between health and social care*
- *Reviewing existing Caldicott guidelines with a view to giving further clarity or guidance which would support appropriate sharing*

Consultation questions

7. *Should Getting the basics right: information sharing for individual care be one of the NDG's top priorities?*

Yes. (We don't have any further specific comments on this priority).

Priority 4: Safeguarding a confidential health and care system

NDG areas of interest

- *Clarifying the interplay between the requirements of common law and data protection law with an aim of finding a way to explain this that clinicians and patients can understand*
- *Progressing the concept of reasonable expectations as an important aspect to shape the boundaries of information sharing*

Consultation questions

10. *Should Safeguarding a confidential health and care system be one of the NDG's top priorities?*

Yes, absolutely. We suggested the concept of "morally reasonable expectations" in our report so we are pleased to see this wording reflected here. The NDG will need sufficient powers to ensure this is fully developed.

11. *Are the outlined areas of NDG interest the right ones for the NDG under this priority?*

Whilst we welcome the clarification of the relevant laws regarding data protection, we would also point out that merely acting in accordance with the law (for example complying with the terms of consent) is not, in itself, enough. Those who use data have moral duties towards all those who have relevant interests in the data, whether they are people from whom the data were initially collected or the people who stand to be affected by their use. So, the second area of interest, on reasonable expectations, is vital. We therefore need a proper process of establishing what these expectations are. Public involvement is a crucial part of this both in establishing what are 'reasonable expectations' and in monitoring through governance arrangements.

12. What would you like to see the NDG do in this area?

As we have said in our report, the use of data in biomedical research and health care should be in accordance with a publicly stateable (by which we mean articulated in a way that is meaningful, and understandable to those with interests at stake) set of morally reasonable expectations and subject to appropriate governance.

We would like to see the NDG enforcing accountability measures such as mandatory publication of data sharing agreements, along with the findings of periodic independent audits of compliance those agreements.