

Consultation response: A consultation about priorities

Submitted to

National Data Guardian for Health
and Social Care

Submitted by

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The PHG Foundation is pleased to see that the position of National Data Guardian has now been enshrined in statute, and welcomes the questions posed by this consultation

Q1: Should giving people access and control of health and care data be one of the NDG's top priorities?

The PHG Foundation has long championed more systematic and robust data sharing within and across the NHS. This is vital to facilitate prompt diagnosis and guide treatment and management for patients receiving screening, care and treatment in the NHS. Whilst we are supportive of the general principle of people being given access to their health and care data, this can be problematic in some contexts.

The challenges associated with providing individual access to certain types of sensitive data (such as human or pathogen genetic/genomic data) have been well described in the academic literature and in applicable professional guidance. Providing patients with access to their genome sequence data and in some cases genetic/genomic test results may not only convey information about the patient but also about their relatives. Thus providing access to these data could also breach confidential relationships between patients and their health care professionals.

Genomic/genetic data could also convey information about social relationships between family members (e.g. evidence of consanguinity or misattributed paternity) that might be potentially harmful to disclose. The disclosure of pathogen genomic data could show transmission chains for infection that could lead to claims of blame and responsibility.

In summary, we believe that there should be a more nuanced approach to giving people access and control of health and care data. Providing access and control can also give the illusion of 'data ownership' without the legal rights.



We have some reservations about how the National Data Opt-Out might have a negative impact on other aspects of health and wellbeing

Providing access to health and care data could undermine confidential relationships between people and their health professionals. For this reason we believe that some of the other strands of work that have been identified should be prioritised over this work.

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

We have some reservations about how the National Data Opt-Out might have a negative impact on other aspects of health and wellbeing, particularly on public health and on those types of research that are reliant on comprehensive population coverage (e.g. some types of epidemiology). We think that it is important, going forward, that the NDG commission formal evaluation of the impact of the National Data Opt-out on public health research. It also is important that more is understood about the characteristics of those people who opt-out of sharing their data for secondary use, so that there is clarity about the possible impact of the National Data Opt-Out on datasets that are used for health and public health. It might be helpful for the National Data Guardian to build close collaborations with Public Health England and their Registration services if these do not already exist.

Q.3: What would you like to see the NDG do in this area?

See below.

Q.4: Should Use of patient data in innovation be one of the NDG's top priorities?

Building a reciprocal relationship between those receiving care and health systems

The idea of fostering a reciprocal relationship between those receiving care and health systems is not new. It has been proposed on numerous occasions over the last decade, most recently as part of the NHS Constitution agenda and through the Chief Medical Officer's Generation Genome work. For data sharing to work well, there needs to be transparency about how data is used, and an expectation that infrastructure, systems and users are trustworthy. However, we would go further and suggest that a learning healthcare system model in which a virtuous circle of data capture, evaluation and use – should underpin the development of health systems over the next two decades.

We are supportive of such a model provided that this can be done in ways which are not coercive. For example, we would not wish to see instances of people being denied care because they refuse to share their data.

Citizen generated data

Prevention is high on the health system agenda and with it potential to develop innovations around predictive prevention strategies. Development of such strategies will require not only data from patients but also data from citizens who are not yet patients. Consideration needs to be given as to how citizens could interact with and share their data with the health system and/or technology developers with the appropriate safeguards in place. Once any developed predictive prevention strategies are in place, a longer-term

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consideration is how healthy citizens can access and control their data to contribute to their future care (if they choose).

Grow digital literacy around data usage

The growing use of citizen data to inform health care is likely to become increasingly important in the future as the rate and nature of personalised health care and prevention gains pace. This is likely to involve greater data integration from diverse sources which seems likely to result in a variety of proprietary claims over data. For this reason there is increasing need to enhance transparency about the scale and nature of data sharing across all sectors. Initiatives such as 'Understanding Patient Data' are important in developing positive narratives around data sharing and use.

Q.5: Are the outlined areas of NDG interest the right ones for the NDG under this priority?

Our view is that it will become increasingly difficult to maintain a clear distinction between NHS and non-NHS health apps as the blurring between health and wellbeing increases through personalised approaches.

Apps for health and wellbeing

There has been an exponential growth in the development of apps for health and wellbeing. Only a small fraction of these have been through sufficiently robust scrutiny. Outsourcing this scrutiny to companies like [Orcha](#) might offer some reassurance to consumers in the short-term. In the longer term, more work needs to be done to clarify the appropriate regulatory pathways for health and wellbeing apps. We support the NDG working with regulatory bodies such as the MHRA and CQC to develop guidance on app development for these different sectors (which – respectively - regard apps as devices and apps as services).

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

We would like to see more emphasis placed on app providers being transparent about how personal data is used and shared.

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

The PHG Foundation and ACGS published a report on [data sharing to support clinical genetic services in 2015](#). This highlighted the necessity of sharing genetic and genomic data across the NHS to ensure timely and safe diagnosis and treatment of people with genetic disease. This is especially true in rare genetic conditions where the cause of disease may be uncertain. Supporting appropriate sharing through further guidance is fundamental. As outlined above, in the context of rare genetic disease, this could sometimes involve sharing genetic/genomic data across the NHS.

Q.8: Are the outlined areas of NDG interest the right ones for the NDG under this priority?

Our view is that the NDG should work collaboratively with others in this area. The Topol review and Health Education England are actively involved in clarifying the educational and training competences that will be required. More cross organisational working is required to ensure that health professionals are equipped for a health system which is capable of using novel technologies.

Q.9: What would you like to see the NDG do in this area?

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

We strongly support the NDG and her panel progressing the concept of reasonable expectations to shape the boundaries of information sharing, with the caveat that the backdrop for these expectations are a generalised ignorance about the extent of existing data sharing; and a lack of digital literacy. Reasonable expectations should be regarded as one factor informing reasonable data use but not necessarily determinative.

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

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

Accessible/sector specific guidance on consent

We have observed that the narrow legal basis of consent for data processing under the GDPR often gets confused with other uses of consent in the context of health, social care and public health. Would it be helpful if the NDG worked with the ICO and HRA to produce guidance which could articulate more clearly the various contexts for these different types of consent, and what they mean for patients and clinicians.

Additional consultation questions

Q.13: Looking at all the priorities outlined, are there other areas of work that you would suggest for the NDG?

AI and transparency

Artificial intelligence and machine learning is being increasingly adopted for health applications albeit mostly in research. As the use of AI gains pace in the health sector, the NDG could bring an authoritative voice to the debate. Many other bodies that are developing guidance in this area (such as the Ada Lovelace Institute; the Alan Turing Institute; the Information Commissioners Office; and the Centre for Data Ethics) are working across sectors.

The PHG Foundation has been funded by the Wellcome Trust to explore the topic of 'Black Box Transparency' in which we are exploring the ethical and legal requirements for transparency when using AI and/or machine learning. As part of this work we will be reviewing the components of what might constitute a model explanation in health applications of AI, and will

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be holding a series of meetings with representatives across the sector to explore possible implications for clinical practice. There are some important distinctions between health applications and AI use in other sectors (such as finance or criminal law) which have not yet been properly explored.

For example, on a population level, personalised prevention is likely to involve stratifying 'at-risk' populations using multiple sources of data, to identify sub-populations at different levels of risk who can be offered tailored interventions. Whilst risk-stratification has been an established part of public health practice for many years, the prospect of carrying out such risk-stratification on an automated basis is novel. Yet such an approach could have considerable health benefits. We envisage that depending on context and application, such an activity might be justified on the basis of public interest.

A requirement for individual consent for these activities as an alternate legal ground would in our view result in some groups being systematically excluded from health benefits that risk stratification might bring. This would be inequitable and would result in some groups being marginalised from screening that has potential clinical utility.

Another application where automated decision making might play an increasing role in the future is as part of patient or citizen held devices that are used to monitor or improve the health of an individual. This could be in the context of a digital sensor that is worn by an individual to monitor blood pressure, heart rate etc. It seems possible that such data could be sent to a central repository for automated analysis, or an alert system might notify the data subject if these data fell outside normal clinical ranges. It could also be used to alert a third party clinician or, if fully automated, their designated decision support system. In contrast to the public health example described above, we envisage that such a system would be predicted on obtaining the consent of the data subject. The validity of any consent secured in such an application would rely upon the data subject understanding the reliability of the risk predictions, the extent of uncertainty, (i.e. the scientific validity and utility and the (if any) clinical validity and utility) of the device and its usual functioning. Consent would also need to address data sharing aspects, such as if personal identifiable data is sent to a central repository for analysis.

Data sharing and Brexit

The political uncertainty associated with Brexit has created alarm about how potential new political relationships might impact on healthcare. Is there a place for the NDG to create some accessible information to patients about what the foreseeable impacts will be on their care?

Q.14: Are there any priorities you would remove or change?

(Please explain why and what you would like to see the NDG doing.)

As described above, we would urge caution in encouraging a discourse around individuals 'owning data' through exploring issues of access and control.

Q.15: Please provide any other comments or feedback to the NDG and her team.

We are pleased to see that the position of National Data Guardian has now been enshrined in statute, and are pleased to have opportunities to work with the NDG's office in the past on the topic of genomic data. Please contact us if we can provide more information about our current work programme.

This response is submitted on behalf of the PHG Foundation. If you have any further questions about this submission or our work, please do not hesitate to get in touch.

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PHG Foundation is a health policy think tank with a special focus on how genomics and other emerging health technologies can provide more effective, personalised healthcare