

# Written evidence submitted by the National Data Guardian for Health and Care (GEN0026)

## About the National Data Guardian for Health and Care

1. The National Data Guardian (NDG) advises and challenges the health and care system to help ensure that citizens' confidential information is safeguarded securely and used properly.
2. Dame Fiona Caldicott was appointed as the first NDG by the Secretary of State for Health, Jeremy Hunt, in November 2014.

## Priorities

3. The NDG believes it is important to build trust in the use of data across health and social care and is guided by three main principles:
  - encouraging clinicians and other members of care teams to share information to enable joined-up care, better diagnosis and treatment
  - ensuring there are no surprises to the citizen about how their health and care data is being used and that they are given a choice about this
  - building a dialogue with the public about how we all wish information to be used, to include a range of voices including commercial companies providing drugs and services to the NHS, researchers discovering new connections that transform treatments, and those managing the services
4. Although sponsored by the Department of Health, the NDG operates independently, representing the interests of patients and the public. The NDG also appoints an independent group of experts – the NDG panel – to advise and support this work.
5. More information is available on the NDG webpages on GOV.UK:  
<https://www.gov.uk/government/organisations/national-data-guardian/about>

## NDG interest in the inquiry

6. The National Data Guardian, supported by members of her independent advisory panel, has over the past six months been undertaking work to look at the way that genomic and genetic data is currently shared to support care, how it may be shared in the future as this area of medicine continues to develop and become mainstreamed into the NHS, and how patient expectations might be informed with regard the way information about them is used.
7. In order to inform this work we held an evidence session in October 2016 jointly with the PHG Foundation and the Association for Clinical Genetic Science (ACGS) to explore developing a consensus on data sharing to support NHS clinical genetics and genomics services.
8. The key aim was to explore whether the provision of advice from the NDG or a further process involving the NDG might help to address concerns about the legitimacy of genomic data sharing, which contributes to variance in practice.

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9. Following that session the NDG, her independent advisory panel and office have conducted further conversations with stakeholders and have identified a number of recommended next steps which will be published in due course.
10. Key areas of NDG interest are around the way that genomic and genetic data relating to individuals are used and shared, questions of appropriate consents, and the importance of engagement with the public.

### **Executive summary of response**

11. Genomics offers huge potential for personalised medicine to improve the effectiveness of healthcare while reducing or eliminating side-effects.
12. The NDG welcomes the significant amount of work that has gone into developing Genomics England's consent model.
13. The NDG believes that as we anticipate genetic and genomic medicine increasingly becoming part of mainstream NHS care, it would be useful to examine how information about patients should be used and shared in the future to support and improve care and what sort of consent model and information provision would be appropriate to underpin this.
14. The NDG Review of Data Security, Consent and Opt-Outs published last year makes a number of recommendations to strengthen the security of health and care information and to help people make informed choices about how their data is used.

### **Key points**

15. Genomics offers huge potential for personalised medicine to improve the effectiveness of healthcare while reducing or eliminating side-effects.
16. This is an area of medicine where there are particularly complex considerations with regards to maintaining confidentiality and the management of consent. This is largely because the lines between direct care and research uses data are blurred: interpreting the clinical significance of an individual's genomic variants is reliant on the data of larger cohort of patients with similar disorders.
17. The National Data Guardian welcomes the significant amount of work that has gone into developing Genomics England's consent model and the care that has been taken to ensure that participants are enabled to make informed decisions about the implications of their agreeing to genomic sequencing.
18. The NDG believes that as we anticipate genetic and genomic medicine increasingly becoming part of mainstream NHS care, it would be useful to examine how information about patients should be used and shared in the future to support and improve care and what sort of consent model and information provision would be appropriate to underpin this. It will be important that any model is developed with a sound understanding of the reasonable expectations that patients have about how their data might be used and what information would be required properly to inform those expectations.

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19. More generally, with regard to data security, consent and opt-out, the NDG last year published a Review of Data Security, Consent and Opt-Outs, which was commissioned by the Secretary of State for Health.
20. In that she recommends that the case for data sharing still needs to be made to the public, and all health, social care, research and public organisations should share responsibility for making that case. Dame Fiona also recommended that there should be a new opt-out model to allow people to opt out of their personal confidential data being used for purposes beyond their direct care. She also recommended ten new data security standards to apply to all organisations that hold health or care information.
21. The Government has conducted a public consultation on the recommendations and will publish its response in due course.
22. The NDG welcomes the decision of the Science and Technology Committee to launch this inquiry. Dame Fiona believes there should be an ongoing conversation with the public about how data is used and what choices people can make. Such engagement is vital in areas of scientific and medical innovation in order to build public trust.

*January 2017*