

Consultation on the roles and functions of the National Data Guardian for Health and Care

Joint Response by the Wellcome Trust, the Medical Research Council and the Economic and Social Research Council

17 December 2015

Key Points

- Capitalising on the tremendous potential value of health and care data will require the public and stakeholders to have trust and confidence in the system of information governance. We support placing the National Data Guardian (NDG) on a statutory footing and consider it a step towards this ambition to develop a more robust and trustworthy overarching governance framework for health and care data.
- A fragmented range of groups currently provide advice on issues of information governance, with little clarity over their lines of accountability and relationships. We urge the Government to ensure the NDG occupies a definitive leadership and oversight role in this overly complex information governance landscape.
- Health and care data do not exist within a vacuum. Although the remit of the NDG is set out only to encompass these types of data, governance frameworks must fit within a broader context of data protection, regulation around personal data and with broad social expectations over how sensitive information is handled.
- Academic research makes significant and valuable use of health and care data. Although not within the remit of professional regulators, there is established best practice with regard to research integrity, data security and robust information governance within academic research. The NDG needs to recognise the specific needs and existing best practices of the academic research sector and place proportionate requirements on academic institutions using health and care data.
- A transparent appointment process for the NDG role needs to be established, to ensure public confidence in the competence and expertise of the NDG appointee.
- The Information Commissioner's Office has a wealth of expertise in developing guidance around complex issues of data protection. Although the NDG has a role distinct from the ICO and other regulatory bodies, there is a strong need for these to work closely together and avoid developing parallel, possibly conflicting policies and guidance for data users. There is also a need for the NDG to work with relevant bodies in Wales, Northern Ireland and Scotland.

INTRODUCTION

1. The Wellcome Trust, the Medical Research Council (MRC) and the Economic and Social Research Council (ESRC) are pleased to respond to this consultation. In this response, we consider the benefits of clear, cohesive oversight of information governance for health and care data together with the need to recognise the wide range of important research uses and users of these kinds of data.

2. The National Data Guardian consultation is a welcome step towards addressing the key issues in the governance of health and care information that have badly affected public confidence in the way data is handled and protected. However, on its own it is not a panacea to address legitimate public concerns about information governance, privacy and data security, while ensuring the benefits to patients and to the health and care system, and broader wellbeing of the UK population from using data are realised.
3. The scientific research community, alongside other users of health and care data, will benefit enormously from transparency in decision-making, clear lines of accountability and consistent processes for data access across different data controllers. The role of the NDG has the potential to enable timely, valuable access to data whilst at the same time ensuring that patients' confidentiality and privacy are appropriately protected.

Proposed roles and functions of the National Data Guardian for Health and Care (NDG)

Proposals 1 & 2: Remit of the NDG

4. The proposed remit sensibly aims to ensure the NDG role is able to capture the full range of uses of health and care data, whether for commissioning, audit, health service provision, research or commercial purposes. However, it is not clear what constitutes "*health and care data generated within the health and care system*". Does this remit include data generated through social services? Does it include data collected in hospitals that is not directly about patients' health and care? Much valuable research relies on linkages between different data types, including some which would sit beyond a narrow interpretation of a "health and care system" (such as education) and it is necessary to clarify what data types do and do not fall within the NDG's oversight.
5. The complexity of relationships between organisations that may process and use health and care data means that lines of accountability are not always transparent. It is imperative that the remit of the NDG is broad enough fully to "follow the data". This would mean that anyone using data from the health and social care system must fall within the scope of the NDG's oversight.
6. We welcome the decision by the Secretary of State that the extraction of GP data for the *care.data* programme will be postponed until the NDG is satisfied with the programme's proposals and safeguards (Section 1.6). This represents a clear recognition that independent oversight is needed for such a large-scale project of national importance. We believe that any planned health data initiatives from Government should be subject to the same scrutiny by the NDG, within a comprehensive information governance framework. This would avoid the hugely negative publicity that the proposed extraction of data from GP IT systems attracted when it was requested by the Prime Minister's Challenge Fund in July this year.¹
7. The NDG remit should include children's health and social care. For research purposes, the fragmentation of legislative and data collecting frameworks that currently apply to adult and children's care make it difficult to undertake research that crosses this age divide. We suggest that the Government take into account the challenges for accurate, consistent and comprehensive data collection, use and governance afforded by a system that treats adult and child care services entirely separately.

Proposals 3 & 4: Formal advice giving powers for the NDG

8. The proposals suggest the NDG's oversight will be of those organisations that "*hold health and care data which could be used to identify individuals*". It is difficult to define what this means in practice. Individuals may be identifiable in principle through linkage with other information beyond the health and care domain even if they are not directly identifiable in the datasets under the remit of the NDG. We suggest the Government seeks the advice of the Information Commissioner's

¹ <http://www.theguardian.com/society/2015/jul/27/patient-data-must-be-safeguarded>

Office (ICO) on how best to address this issue and to recognise that identification risk is a function of the environment in which the data is contained, not solely of the data itself.

9. Although the NDG is concerned with health and care data, the use and sharing of these kinds of data do not represent qualitatively different risks to individuals than many other kinds of sensitive personal data. The ICO already has well-established, thorough guidance for undertaking assessments of how organisations handle sensitive personal data and the information governance requirements necessary to protect it. If the NDG is to develop its own set of criteria with specific regard to additional legislation (Health and Social Care Act 2012; Care Act 2014; NHS Act 2006), it needs to be very clear to data users what the additional criteria imposed on them by the NDG are, and their legislative basis, to avoid confusion and fragmentation. Any guidance should be transparently and consistently applied, developed in consultation with other regulators, and in line with other relevant guidance to ensure data users have clear and consistent expectations about their responsibilities.
10. Many biomedical and social science researchers share data between each other internationally using legally binding data access or material transfer agreements, which stipulate conditions of data security at the receiving institution. These agreements are standard practice among academic researchers. It would be a welcome reinforcement of these principles of data security if the NDG sought to emphasise these responsibilities when institutions share data.

Proposals 5 & 6: Duties on recipients to act on formal advice from the NDG

11. Transparency and accountability are key to enabling the development of trust in the governance of health and care data. The requirement for organisations to formally respond to advice from the NDG is an important part of upholding these principles.
12. A diverse range of research studies is conducted in England using health and care data, ranging in scale from involving only a handful of participants to large, long-running longitudinal studies and population-level projects. These are conducted in academic institutions, often in partnership or collaboration with other universities here and abroad, within or without the NHS, and over varied timescales. Given the wide range and scale of organisations that may hold health and care data, reporting requirements on advice from the NDG must be proportionate. The proposal for the NDG to annually report on responses it has received to advice should satisfy the accountability and transparency criteria, without placing undue burden on the academic institutions who receive such advice.

Proposal 7: Reference mechanisms to the CQC and the ICO

13. We welcome the recognition by Government that the relation between the NDG, Care Quality Commission (CQC) and ICO needs to be formalised in a Memorandum of Understanding. This will need to be robust enough to be enforceable, but should be flexible to incorporate changes in potential data users or controllers. Public trust will require clear lines of accountability in what is a complex area of regulation and oversight. The relation the NDG bears to the controllers of health and care data should also be set out in the same way. This is particularly important for organisations such as the Health and Social Care Information Centre (HSCIC), Clinical Practice Research Datalink (CPRD) and Public Health England (PHE) to ensure that the NDG can provide advice that will be consistently translated into guidance, protocols and policies for data users applying for access to data from these organisations. Setting up the role of the NDG in this way may go towards addressing the current fragmentation and inconsistency in approaches to information governance across and within controllers for health and care data, and clarify the complexity in the current system.

Proposal 10: NDG powers to apply sanctions

14. We welcome the proposal that the NDG should have the authority to impose sanctions against those who misuse data or are negligent in their responsibilities towards protecting and sharing health and care data. If sanctions and enforcement mechanisms are to rely on currently existing

regulatory powers through the ICO and CQC, we suggest that these sanctions need to be more consistently applied, better explained and publicised. They must also cover breaches of Caldicott's Principle 7, that data holding organisations are responsible for the appropriate sharing of data.

15. Strong regulations can act as both powerful deterrents and as a mechanism through which to bolster public confidence that misuse of data will be punished. They can also encourage organisations to treat their responsibilities towards data as a key organisational priority. Timely, appropriate sharing of data can still be achieved if these requirements are well understood.
16. Although we recognise the intention of Government to avoid further legislation, it is worth noting that legislation will be needed to implement the European Data Protection Regulation which is likely to come into force in 2016. This may provide an ideal opportunity to consider whether or not additional sanctions would be appropriate for the deliberate misuse of the data under the remit of the NDG.

Proposal 11: Location of the NDG

17. As the NDG will be an independent role, it should not be hosted within the HSCIC in the long term. We have no strong view on the best location of the NDG either as an Arm's Length Body, Advisory Non-Departmental Public Body or other arrangement, but note that as a vital statutory function the office of the NDG needs to be adequately and sustainably resourced to carry out its functions in full.
18. No reference is given in the consultation to the appointment process for the NDG. While we are pleased that Dame Fiona Caldicott's role is being placed on a statutory footing, we are concerned that no detail is forthcoming with regard to the process and criteria by which successors should be appointed. It is vital that the appointing process is transparent and well-run if the appointee is to enjoy the confidence of the public and health professionals in this demanding role.

Proposal 12: Engagement with the Public

19. The views of the public, patients and health professionals will be very influential in determining whether trust in the handling of health and care data can be re-established following the *care.data* programme postponement last year. The widespread loss of public trust in the wake of the Partridge Review and numerous media stories about poor information governance practices following *care.data* has been hugely damaging to legitimate, valuable research using health and care data. We fully support the intention to engage with the public about how their data are used and to seek their views and concerns. Engagement requires a two-way dialogue and we welcome the stipulation that the NDG's annual report mechanism will include reporting on how public, patient and service user views influence the work of the NDG. We would also propose that this engagement activity includes health and care professionals and researchers. Satisfying these commitments will require the NDG to be sufficiently resourced to undertake its own research and to partner with data providers, funders, public, patient and professional representatives over time to ensure the diversity of opinion is considered. Plans for engagement should be published to ensure transparency and the opportunity for stakeholders to contribute.

Proposals 13 & 14: Organisations outside the health and care sector

20. Clarity is needed over the nature of the relationship between the NDG, data providers (such as the HSCIC) and approvals bodies (such as the Confidentiality Advisory Group (CAG), particularly as the regulations for CAG have not yet been laid). It will be vital for public confidence that the NDG's authority, lines of information sharing and accountability are set out in a straightforward manner. We strongly recommend a simple flow diagram of information flows and decision-making to be created for the public and stakeholders to enable transparency and understanding of these relationships.
21. More generally, the current landscape of committees and bodies with a role in the information governance of health and care data is extremely messy and unclear, with a proliferation of

advisory groups and boards occupying similar roles. Although the NDG is established under the National Information Board's workstream 4, setting out the NDG's role in relation to all of these groups in addition to HSCIC and CAG (including the Ministerial Industry Strategy Group Maximising Research Through Health Data Programme; *care.data* Strategic Oversight Board; and the Office for Strategic Coordination of Health Research) would be extremely valuable for stakeholders and the public and vital in creating confidence in the system as a whole.

22. Academic researchers constitute a significant cohort of health and care data users beyond the regulated professions. We suggest that the NDG considers a system of accreditation similar to the 'approved researcher' model used by the Office of National Statistics for access to sensitive data. Accreditation should include assessment of compliance to proportionate measures, for example checking of research affiliations, academic credentials and a commitment to data security. The NDG should consider which organisation should be responsible for accreditation, for example considering the resource implications.
23. All researchers including those falling into the category of 'data users beyond the health and social care sector' must be held to high standards by their employing institutions and by research funders for their conduct with regard to data security, data protection and research integrity. Researchers' obligations and responsibilities with regard to the use and sharing of data are standardly set out in data access agreements, with institutions bearing legal responsibility for any failings. Funders also have stringent policies on research integrity^{2 3}, and intentional misuse of data, as well as potentially being unlawful, would breach these. We would expect our funded researchers to comply with advice from the NDG and would take any challenge from the NDG extremely seriously. It should be noted that a recent evidence review conducted as part of the Nuffield Council on Bioethics' report into uses of health and biological data found no evidence of data misuse in academic research⁴.
24. The issue of commercial companies accessing health and care data is contentious and difficult to navigate, particularly as there may not be an oversight or regulatory body for the NDG to engage with on matters of information governance. The Wellcome Trust is currently undertaking a major project to explore patient, public and health professionals' attitudes towards commercial organisations accessing health, medical and genetic data. We would be pleased to share the findings with the NDG and to discuss ways to take them forward when the report is published early in 2016.

Section 5: Equality and regulatory impact

25. Providing that the reporting requirements on academic institutions are proportionate and simple, we do not consider that these proposals should create additional administrative or financial burdens on data users within the research community. Indeed, the NDG may help to alleviate some of the current administrative burdens imposed by complex, fragmented approaches to data access adopted by data controllers, through providing a unifying information governance framework for access to all health and care data in England. It will be important to garner feedback on this to ensure continuous improvement of the governance framework over time.

² <http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTD002756.htm>

³ <http://www.rcuk.ac.uk/RCUK-prod/assets/documents/reviews/grc/RCUKPolicyandGuidelinesonGovernanceofGoodResearchPracticeFebruary2013.pdf>

⁴ See p.101 "A review of evidence relating to harm resulting from uses of health and biomedical data" (June 2014) <http://nuffieldbioethics.org/wp-content/uploads/A-Review-of-Evidence-Relating-to-Harms-Resulting-from-Uses-of-Health-and-Biomedical-Data-FINAL.pdf>

The Wellcome Trust

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