



Department
of Health

Roles and Functions of the National Data Guardian for Health and Care

A summary of consultation responses and
Government conclusions

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A summary of consultation responses and Government conclusions

Prepared by the Department of Health

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1. Executive Summary

- 1.1. To a very significant extent, the delivery of high quality health and care services has always depended on a relationship of trust between patients and service users and those who are providing their care. This relationship also depends on the unimpeded flow of information, and, as increasing volumes of personal confidential data are held across the health and social care system, it is more important than ever that people have a clear understanding about how and when information about them will be shared, how they can make an informed choice about what data is shared, and how they can opt-out, how their privacy will be protected, and who will act to safeguard their rights.
- 1.2. The Secretary of State for Health, Jeremy Hunt, appointed Dame Fiona Caldicott as the first National Data Guardian (NDG) for Health and Care in November 2014. Following her appointment, Dame Fiona has used her considerable experience to continue to build trust and confidence among members of the public about the way in which their personal confidential data is used across health and social care.
- 1.3. As National Data Guardian, Dame Fiona is guided by three main principles -
 - Encouraging clinicians and other care providers to share data to support the provision of joined-up care, better diagnosis and treatment;
 - Ensuring that people have a clear understanding about how their health and care data is being used, and that they understand the choices open to them in terms of consent and opt-out; and
 - Building a continuing dialogue with the public about how data should be used for the benefit of individuals and wider society, and how the purposes of data sharing may legitimately and safely extend beyond the limits of direct care.
- 1.4. In creating the role of National Data Guardian for Health and Care, the Government made clear its intention to provide a firm legal basis at the earliest opportunity. The Government consulted on the "Roles and Functions of the National Data Guardian for Health and Care between September and December 2015. The consultation received 73 responses from approximately 100 different organisations and individuals. Questions included a number of key areas:
 - What legislative framework would be needed;
 - What formal powers would be needed to advise health and care organisations, and what would the reciprocal duty for organisations to act on such advice look like;
 - Are there any limitations in terms of the extent/scope of data that the occupant of the role can scrutinise;
 - How should the National Data Guardian work with existing regulators such as the Care Quality Commission and the General Medical Council; and
 - How best can the role prioritise the concerns of patients and service users.
- 1.5. On the basis of the responses received, the Government has concluded that:
 - The remit for the role will be based on data collected within the health and care system, but will also allow for scrutiny and challenge in cases where such data is shared beyond the health and care sector.

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- Although children's social care data is not part of the health and care system, robust protections and safeguards still need to be in place to guard against inappropriate use. We believe that the National Data Guardian should have a role in ensuring that this happens and will work with the Department for Education to determine how best this contribution can be made.
 - The role of the National Data Guardian should include formal advice giving powers; organisations in receipt of this advice will be required to show how they have responded.
 - Relevant regulators will work with the National Data Guardian to determine criteria by which they might assess the performance of an organisation in relation to information and data, as part of their regulatory functions.
 - The National Data Guardian will be required within legislation to publish an Annual Report setting out key issues that have arisen over a 12 month period, report on progress, set out priorities for the coming year and demonstrate how the concerns of patients and service users have been recorded and acted upon.
 - The National Data Guardian will agree and publish Memoranda of Understanding with key regulators and stakeholders, which will include clarification of their respective roles in relation to information and data and a referral mechanism by which the NDG can refer any concerns or issues for consideration and action by the relevant body.
 - The National Data Guardian will not have the power to issue or enforce sanctions of its own, for example in terms of financial penalties, but will instead work with relevant regulators to ensure that the sanction making powers of those organisations are utilised in the most effective way.
- 1.6. The Government is actively considering the legislation that will be required, and will work with health and care organisations and regulators to implement changes as early as practically possible.

2. Introduction

The consultation proposals

- 2.1. The consultation on “Roles and Functions of the National Data Guardian for Health and Care” explained that greater public trust is needed in order to maximise the benefits and opportunities offered by new technology and innovative approaches to improving health outcomes for the population.
- 2.2. The role of the National Data Guardian (NDG) for Health and Social Care is a key element in building public Trust in the health and care sector and has already made a strong impact in this area. For example, in September 2015, the Secretary of State for Health commissioned the NDG to lead an independent review into data security and to propose a new model for consent/opt-out in relation to the use of health and care data.
- 2.3. The Government believes that formalising the NDG role would increase accountability across health and social care organisations, which in turn would lead to increased public trust, and to better lawful and appropriate use of this kind of information in accordance with the Caldicott Principles.
- 2.4. The consultation focussed on testing proposals and seeking views on areas that should be within the remit of the role, examples of which were:
 - **What was the scope of the data that the National Data Guardian for Health and care should have scrutiny over?** The consultation proposed that the role should have a remit over all health and care data collected within the health and care system, including the right to continue to scrutinise the use of that information wherever it is used, including outside of these settings;
 - **What do we need to consider in terms of factors and issues when considering whether children’s social care data should be included within the role’s remit?** The consultation pointed out that children’s social care data is covered via a different legislative framework than adult social care and, as such, it was important to understand fully the issues and factors that need to be taken into account when deciding whether the National Data Guardian for Health and Care should have a remit to scrutinise how this data is held and used;
 - **How can the National Data Guardian demonstrate that it really is the independent and authoritative voice of the patient and service user when it comes to health and care data?** The consultation acknowledged that the NDG needs to have the confidence of the public, and set out initial thoughts and proposals this might be achieved;
 - **Working with other key organisations** The consultation placed significant emphasis on the importance of the NDG having strong working relationships with others, including the ability to refer concerns to relevant regulators where appropriate. Examples of these organisations included the Care Quality Commission, the Information Commissioners Office (ICO) and HealthWatch. The consultation also made clear how important it was for all parties (whether the subjects of the data, or those who seek to use it in order to fulfil their functions), to understand the clear distinction between the respective roles of the NDG and other organisations who might be regarded as working in the same area of expertise or influence; and
 - **Transparency of response to advice given by the National Data Guardian.** The consultation stressed the importance of organisations being required to

publically set out how they have addressed the issues raised by the NDG, and set out proposals on how this might be delivered in a proportionate way.

Your responses to the consultation proposals

- 2.5. The ambitions and proposals as set out in the consultation were broadly supported by respondents (as detailed in sections 3 and 4). Responses to this consultation were carefully considered and the conclusions reached as a result will inform the development of the subsequent legislative proposals.
- 2.6. This document draws on a number of direct quotes from responses to the consultation, to summarise and illustrate the issues raised. The views expressed below are examples of comments made. These highlight support for the principles set out in the consultation document, as well as highlighting areas where further thought needs to be given.
- “We are supportive of the role of the National Data Guardian to provide guidance, advice and ensure that data is shared in a responsible and secure way” *Joint LGA and ADASS*
 - “The GPHC supports the proposed National Data Guardian initiative as an additional safeguarding mechanism for health and care data. However, we suggest that the National Data Guardian’s roles and responsibilities are clearly defined and publicised to avoid confusion with other organisations with similar roles” *General Pharmaceutical Council*
 - “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”. *Wellcome Trust/Medical Research Council/Economic and Social Research Council*
 - The National Data Guardian will have a crucial role to play in ensuring people’s fears are not realised. It should ensure that the correct organisational culture and good practice are in place across health and care so that data is handled properly” *Healthwatch*
 - The Council welcomes, in the establishment of law of the role of the National Data Guardian, the recognition that an opportunity for missing or underrepresented voices in the governance of data is needed. Though the National Data Guardian cannot be expected to represent “the voice of the public” they should have sufficient powers and resources to broaden participation and provide the opportunity for a wider range of interests to be represented” *Nuffield Council on Bioethics*
 - “We support the placing of the National Data Guardian (NDG) on a statutory footing. However, the landscape is characterised by a burgeoning of groups advising on information governance matters and a lack of clarity on their status, powers and inter-relationships” *Association of Medical Research Charities*
 - “We welcome the establishment of the NDG. We have already seen the benefit of the National Data Guardian’s role in influencing improvements in information sharing to improve outcomes for people, while protecting against its inappropriate use”. *NHS England*

3. The consultation process

- 3.1. The consultation on the “Roles and Functions of the National Data Guardian for Health and Care” took place over a 3 month period, beginning on 18 September and ending on 17 December 2015.
- 3.2. The consultation sought views on 16 specific questions and proposals on the role and functions of the NDG. One clear purpose has been to give the NDG the appropriate authority to hold the health and social care system to account when it comes to the sharing of patient information.
- 3.3. The consultation document and feedback form was made available on the gov.uk website at <https://www.gov.uk/government/consultations/the-role-of-the-national-data-guardian-for-health-and-social-care>. The questions and proposals within the consultation are included as an Annex to this document.
- 3.4. In order to promote participation, a set of slides and Q&A were developed and shared with key stakeholders, representing a wide spectrum of interests, including;
 - organisations which either required data and information to fulfil their functions, or represented those that did, such as NHS England and the Association of Directors for Adult Social Services;
 - regulators which need to have an effective relationship with the NDG, such as the Care Quality Commission and the Information Commissioners Office and;
 - bodies which seek to represent the voice of patients and service users, such as National Voices and Healthwatch.
- 3.5. This group of organisations was also asked to promote awareness among their wider stakeholder groups, where those organisations have an interest in health and care data.
- 3.6. In addition, the Department of Health hosted an event on the 25 November 2015, bringing together a range of stakeholders to provide views on four key issues:
 - the potential role, if any, that the NDG should have in relation to children's social care data and information;
 - how best to maximise the effectiveness of existing regulatory mechanisms that the NDG role may be able to draw upon;
 - how the NDG can demonstrate that its priorities and activity reflect patient and service users interests and concerns; and
 - the success measures that should be used to assess the impact of the NDG.
- 3.7. The notes of this event were consolidated and included as a formal response to the consultation.
- 3.8. In addition, social media was used to promote the consultation by the Department of Health, and to promote messages from others by retweeting.

Details of consultation responses received

- 3.9. There were 73 responses to the consultation, although some of these represented joint submissions on behalf of a number of organisations, for example the Association of Medical Research Charities are an umbrella body for 13 organisations.

The consultation process

3.10. The breakdown of responses by type is shown below.

• Healthcare (commissioner and providers):	17
• Suppliers:	4
• Local Government:	9
• Charitable/Voluntary Organisations:	24
• Professional Bodies:	9
• Research:	17
• Regulators:	4
• Patients & service users (including individuals):	12
• Privacy organisations:	2
• Others:	5

4. Responses to consultation questions

This chapter provides a summary of the feedback to the 16 questions included in the consultation document.

Question 1: The Government proposes that: the remit of the National Data Guardian role should follow the health and care data

- 4.1. The majority of the 73 respondents answered this question. There was broad support for this proposal as public concern was often driven by the perception that health and care data was being held and used inappropriately in settings outside of the health and care system.
- 4.2. There were also many comments about the importance of defining which data is within the scope of the NDG. Suggestions were also made around influencing change by working with relevant regulators inside the health and care sector, and also with wider remits, including sectors such as research or finance.
- 4.3. The quotes from respondents below, reflect these points:
 - “We agree with the Government’s proposal about the remit of the National Data Guardian and that data should cover data generated within the health and care sector, including when it has been passed on to organisations outside of the sector” *Information Commissioner’s Office*
 - “Public Health England supports this proposal. Organisations working across the health and care system have a responsibility – not just in law but also from an ethical, patient focussed service delivery perspective – to build public trust in the ways that personal data is used and protected”. Public Health England
 - “While it is sensible and appropriate for the role to follow the data, it is important to recognise that diverse and potentially very different governance regimes might be in place as between different sectors” *The Farr Institute of Health Informatics Research*
 - “Clear guidelines required to determine what is Health and Social Care data” *London Borough of Havering*
 - “Agree. It should apply to non-health NHS/health services in the same way as it applies to the health and care sector” Member of the public
 - “The HSCIC agrees with this proposal. The role and remit needs to be set out in a way that is easily digestible for the public and for those organisations with which the NDG has a relationship. Describing this in terms of following the data is reasonable but it requires some further explanation” *HSCIC*

Question 2: The Government is seeking your views on: what are the key factors and issues that need to be considered when determining whether children’s social care should be part of the National Data Guardian remit and where the National Data Guardian could make a positive contribution to care services for children and young people?

- 4.4. The majority of the responses were clear that the NDG had an important contribution to make to ensure that children's social care data has robust protections in place in terms of how it can be held and used. Building on these views the Department of Health, working with the Department for Education and the wider children's social care sector, will consider and agree how best that the NDG can contribute to this element of data.

4.5. The quotes from respondents below, reflect these points:

- “ADCS members feel it is sensible to bring information governance in both adult and children’s services in line. This reflects the approach being taken in a significant number of local authorities in terms of organising services.” *Association of Directors of Children’s Services*
- “LGA/ADASS welcomes that consideration is being given to children’s services as part of the National Data Guardian remit. Historically, as the consultation indicates, children’s social care data has not been traditionally in scope of arrangements for health and care services. We believe that Children’s Social Care should be included as part of the remit of the National Data Guardian” *LGA/ADASS*
- “We are starting to realise that we need joined up services, with joined up organisations and single identifiers (NHS number). If and when the NHS number becomes the principle way of identifying clients and patients across health and social care, this will impact adults and children alike. Therefore, we have to be consistent to begin with and I feel it should be part of the programme” *Health and social care professional*
- “If Children’s Care is not included, they won’t be the NDG for health and care” *Leeds City Council*
- “It would be utterly perverse for those who are at the most risk of data being used inappropriately to have the least protection from the National Data Guardian.” *MedConfidential*

Question 3: The Government proposes that: the National Data Guardian should be able to provide advice to all organisations that hold health and care data which could be used to identify individuals.

4.6. The majority of respondents who answered this question were in support of the proposal and felt it was an important part of ensuring the NDG is recognised as the independent and authoritative voice of the patient and service user. Some respondents also noted the need for any advice to be evidence-based, and to not add confusion by conflicting with other trusted guidance being used by the health and care system. This fed into a wider point made by some about the need to reduce the current fragmented guidance that exists in this area, not add to it.

4.7. The quotes from respondents below, reflect these points:

- “The NDG should be able to provide advice to all organisations that hold health and care data which could be used to identify individuals, recognising, however, that identification risk is a function of the environment in which the data are contained” *Association of Medical Research Charities*
- “It is important that the National Data Guardian is able to provide advice to organisations holding and using health and care data both in identified and de-identified formats” *NHS England*
- “The IGA would like confirmation of the separate roles of IGA and the National Data Guardian in respect of advice and guidance” *Information Governance Alliance*
- The nature of this advice should cover all topics referring to correct information management ranging from data storage, to objection and consent as well as data sharing with third parties and data destruction in line with Caldicott Reports “ *Healthwatch*
- “We strongly support the proposal that the NDG should be able to provide advice to a range of organisations and note this ability will only be effective if the NDG’s

office is sufficiently resourced to do so. Nevertheless we believe that a scope of 2data [sic] which could be used to identify individuals potentially misses a number of uses of data that have important consequences for privacy” *Nuffield Council on Bioethics*

Question 4: The Government proposes that: any regulators with a responsibility for overseeing organisations which routinely hold, use and share health and care data, should consult the National Data Guardian on the criteria they use to assess an organisation’s use of data.

4.8. This question, where nearly all 73 respondents expressed a view, generated widespread support. The proposal was seen as an opportunity to address some of the different advice and guidance on similar issues, which are currently a real barrier to progress. Respondents felt that it should be compulsory that regulators act on input from the NDG.

4.9. The quotes from respondents below, reflect these points:

- “We agree with this proposal, and expect that the joint work currently being undertaken by the Office of the NDG and the Care Quality Commission regarding information and security policies will set a baseline for this aspect of the role of the NDG” *HSCIC*
- “Data security is a key public concern (Royal Statistical Society/IPSOS Mori 2014) and therefore ensuring the NDG has oversight of the standards to which organisations handling data will be held to account on this is welcome. Oversight by the NDG would be particularly helpful where it could bring alignment and simplification to the system” *Richmond Group of Charities*
- “If the role of the NDG evolves to encompass development of standards and policy, then it follows that those bodies assessing the use of data takes account of the criteria set out by the NDG. That is not to say, however, that the NDG criteria should be the only criteria used: data security and data use are fast moving areas of public policy and it should be expected that measures over and above the criteria set by the NDG will need to be used to ensure standards are maintained at all times” *Care Quality Commission*
- “As a regulator will we be expected to consult the NDG on those criteria we use to assess an FT’s use of data? We would like to understand in those cases where the NDG raises concerns or provides advice to an FT or aspirant FT –will we be compelled to ensure that the advice is implemented.” *Monitor*

Question 5: The Government proposes that: organisations holding health and care data which could be used to identify individuals should be required to publish all materials demonstrating how they have responded to advice from the National Data Guardian.

4.10. Responses were supportive of the proposal that the NDG should be given formal advice giving powers. Consequently, the responses to this proposal tended to be supportive of mandating a need for those bodies receiving advice to be required to act upon it. This was regarded as being crucial to demonstrating that the NDG had real authority, and would act as an independent voice of the patient and service user in relation to health and care data.

4.11. The level of transparency proposed in the consultation, by which bodies would be required to publish material setting out how they have responded, was also welcomed. There was some divergence of views in terms of how quickly organisations should be required to show how they had addressed the advice, with some feeling that it should be rapid, and others being concerned about creating additional burdens on organisations.

4.12. The quotes from respondents below, reflect these points:

- “Absolutely, but also set a timetable for publication. In the past they have delayed by up to a year, and large parts redacted when they do come out” *Member of the public*
- NHS England agrees with this proposal. It is important for the public to understand what guidance the National Data Guardian has provided and what action the organisation has taken in response to enable them to make an informed judgement and raise challenges if they perceive an organisation has not done enough to protect their personal data.” *NHS England*
- In order to develop public trust and accountability, organisations holding health and care data should publish all materials demonstrating how they have responded to the advice of the National Data Guardian. In order to reduce the bureaucratic burden of publically responding to the advice from the National Data Guardian, the organisations receiving the advice should be able to respond to this advice on an annual basis on their annual reports” *Healthwatch*
- “LGA and ADASS are in agreement with this proposal but only in so far as it is proportionate to the case being considered by the National Data Guardian. We would caution against an industry of publishing information for the sake of publishing information and instead focus on what is being done to actively put things right rather than risking the creation of a blame culture” *LGA/ADASS*
- “We agree that the public needs to be confident that an organisation has taken action to address advice given by the NDG. Noting that the suggested mechanism to achieve this is via an annual publication, which could mean that patients are waiting many months to be reassured, could consideration be given to allow a more timely notification that the advice is being acted upon?” *British Medical Association*
- “We are very keen that the introduction of the NDG should not result in an excessive extension of the bureaucratic burden on our members” *NHS Confederation*

Question 6: The Government proposes that: the National Data Guardian should be required to publish an annual report which should include a report of all the advice provided in the relevant year and an overview of how the relevant organisations responded to it.

4.13. Most respondents answered this question and, although many were supportive of it in principle, there was a divergence of views on the level of detail required and the level of additional administration required.

4.14. Responses to the consultation suggested that it would be useful to have one place where people and organisations could go to see the advice issued by the NDG alongside the responses. It was also felt to be important that the NDG would have to be adequately resourced to fulfil this requirement.

4.15. The quotes from respondents below, reflect these points:

- “We also agree that the NDG should publish details of the advice that is issued” *HSCIC*
- “Publication of an annual report assists with both transparency and accountability” *Information Commissioner’s Office*
- “All the remit of one person. Too much time spent on admin means less done on the actual work. The Guardian needs a team, then this would be an excellent idea”. *Retired health/social care professional*

- A requirement stating that all advice is published has a potential to be excessive, if a relatively high level of detail is required. Themed summaries of the advice provided would be more feasible and more useful to the public and other organisations” *Cancer Research UK*

Question 7: The Government proposes that: the referral role of the National Data Guardian with the CQC and ICO should be set out in a Memorandum of Understanding.

- 4.16. Most respondents submitted a contribution to this question and were supportive of the proposal.
- 4.17. It was felt that a Memorandum of Understanding had merit and could demonstrate that even where the NDG role was not taking any direct action; it did have the reach and ability to hold organisations to account. Respondents also felt that this could be a good way of providing clarity between the functions of the NDG and other organisations.
- 4.18. Some responses also made the point that whilst the Care Quality Commission and the Information Commissioner’s Office were natural candidates for agreeing a Memorandum of Understanding, there may be other organisations where it would make equal sense for the NDG to establish similar formal ways of working together.
- 4.19. The quotes from respondents below, reflect these points:
- “We welcome the proposals in the consultation for Memorandum of Understanding to be developed between the NDG and the use of formal reference mechanisms to formalise and clarify their relationships and respective responsibilities” *NHS Confederation*
 - “PHE supports this proposal. It is important that the demarcations of responsibility between the NDG and statutory regulators are made clear from the outset, and that the independence of the NDG to provide advice is not constrained by being tied to regulatory functions that are grounded in narrow and specific statutory responsibilities” *Public Health England*
 - “The Memorandum of Understanding between the ICO and the National Data Guardian has already been agreed. This will be reviewed and updated where necessary when the National Data Guardian is established on a statutory basis.” *ICO*
 - “We fully support an MOU between us (CQC) and the NDG, we are working on it at present” *CQC*
 - The BMA supports the NDG’s referral role in relation to the ICO and the Care Quality Commission and notes that the NDG will be able to rely on their powers in bringing organisations back into compliance, including the application of sanctions where appropriate” *BMA*

Question 8: The Government proposes that: the National Data Guardian should have power to refer actions by an individual to the appropriate regulator for the profession concerned.

- 4.20. Mirroring the previous proposal, the consultation sought views on how best the NDG could respond to the actions of an individual professional who may raise concerns, as opposed to an organisation.
- 4.21. There was largely support among those who responded for the NDG to be able to refer actions by an individual to the relevant professional regulator, although a couple of respondents expressed the view that this area should be the territory of the NDG.

Responses to consultation questions

- 4.22. A couple of respondents made the point that the NDG will need to be able to ensure action was taken where health and care data has left the health and care system or is being handled by unregulated individuals.
- 4.23. The quotes from respondents below, reflect these points:
- “It is already open to the National Data Guardian, if she has serious concerns about the way that a doctor has obtained, used or shared health and care data to raise those concerns with the GMC as the professional regulator for doctors. As part of putting the National Data Guardian’s role on a statutory footing, we agree that he or she should have a formal power to make referrals to us” *General Medical Council*
 - “We entirely agree, but while covering regulated professionals is necessary, it is insufficient as it ignores the largest area of concern, which is unregulated professionals” *MedConfidential*
 - “It would be useful to allow the National Data Guardian to refer actions by an individual to the proper regulator for the profession concerned. This will ensure the use of existing synergies as well as a more harmonised way in which information is managed across the health and care system” *HealthWatch*
 - “The Council support the proposal. However, the Council thought this was more about the NDG being able to insist on a response rather than being able to make a referral” *UK Council of Caldicott Guardians*
 - “This is sensible and will avoid a duplication of regulation” *General Pharmaceutical Council*
 - “The strict role of a regulator is compliance rather than improvement. Therefore, while the regulator will be able to take actions against an individual if they fail to comply with professional standards, it is not best placed to provide the training and support needed to improve data handling behaviours. It is not clear from the consultation document where Government sees the responsibility for this falling across the relevant sectors, but we do not see this as being the role of regulatory bodies or the NDG”. *Richmond Group of charities*
 - “NHS England has concerns about this proposal and is hesitant to agree to the proposal to establish specific powers to refer an individual to the appropriate professional regulator.” *NHS England*

Question 9: Please also provide any other comments on how the National Data Guardian might advise and challenge professionals working outside the regulated professions or organisations.

- 4.24. Most respondents provided comments responding to this question.
- 4.25. Many respondents highlighted that data leaving the health and care system had the greatest potential to damage public trust. It was therefore essential that the NDG was able to influence good practice and compliance. Suggestions were also made on how the NDG could best work in this space. In particular, researchers were concerned about how lack of public trust could restrict their access to data.
- 4.26. The quotes from respondents below, reflect these points:
- “It makes it important that the National Data Guardian is able to follow the data, irrespective of what has been done with it and by whom. There are likely to be models around Government for this, the Faculty of Public Health offers one, there are others in social work, each with their own approaches”. *Med Confidential*
 - “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 diversity and ensure that the requirements on academic institutions using health and social care data are proportionate” *Association of Medical Research Charities*

- “For those organisations who are data generators or data holders and that share information with organisations outside regulated professions and organisations, the National Data Guardian should be able to provide information and guidance as to how to share information with non-regulated organisations” *HealthWatch*
- “The IGA SME’s suggest that if the NDG is given power to refer actions by an individual to professional regulators, then for those unregulated professionals who work in a profession with a voluntary registers (such as operated by PSA) the NDG could refer those professionals to the organisation operating the register. This could also include the informatics professions and care provider managers who are registered with the CQC” *IGA*
- “Co-ordinated work with the ICO and other regulators to promote awareness. Link information across websites. Make reference to each other’s organisation in advice and information. Hold joint conferences and workshops to promote the work of organisations and promote best practices” *London Borough of Havering*

Question 10: Please also provide any other comments on how the National Data Guardian and regulators can maximise the appropriate use of existing sanctions and fines.

- 4.27. Virtually all of those who responded agreed with the proposal that the NDG should not have the power to issue sanctions. There are already a comprehensive set of organisations with powers in this area and respondents felt that to add another would be unhelpful. Instead, the NDG should focus on maximising the use of existing regulators and their ability to apply sanctions and fines.
- 4.28. Respondents felt that the NDG role should potentially focus more on helping organisations ‘get it right first time’ rather than simply holding them to account when things go wrong.
- 4.29. A number of respondents expressed a view that the sanctions and penalties currently available to regulators were not sufficiently “tough” to ensure compliance.
- 4.30. The quotes from respondents below, reflect these points:
- “NHS England does not consider it necessary to establish new or additional regulatory mechanisms to levy fines or apply conditions to an organisation or individual’s registration process. The National Data Guardian should be able to rely on existing regulators powers to apply sanctions and fines., in particular the CQC and ICO” *NHS England*
 - We agree that the Government should not be considering the creation of new sanctions and fines but should rely on those currently in place and ensure that the National Data Guardian works with those organisations that have enforcement powers” *LGA/ADASS*
 - Our only comment relates to the need for consistency across all organisations and care settings. It would be regrettable, though, if the focus of the NDG were to be only associated with “sticks”. It is also important that there is a focus on positive levers, influencers, enablers and support which are commensurate with the importance of this agenda” *HSCIC*
 - “If sanctions and enforcement mechanisms are to rely on existing current regulatory powers through the ICO and CQC, we suggest that these sanctions

need to be more consistently applied, better explained and publicised” *Wellcome Trust/Medical Research Council/Economic and Social Research Council*

- “Without the ability to hand down custodial sentences the current sentencing regime lacks teeth this is something that will continue with or without the National Data Guardian” *Big Brother Watch*.
- “The Association would welcome the introduction of custodial penalties for those who deliberately abuse confidential data. We believe that custodial penalties would be a far more effective deterrent than the current fiscal sanctions”. *British Medical Association*

Question 11: The Government is seeking views on the most suitable long-term location for the National Data Guardian.

- 4.31. Less than half of the 73 respondents contributed on this question.
- 4.32. Those who did respond did not suggest specific locations for the NDG, but felt it was important that the location promotes rather than undermines the independence of the role. For example, respondents felt that basing the role within an organisation which might then be the subject of the NDG’s concerns would be wholly inappropriate.
- 4.33. The quotes from respondents below, reflect these points:
- “A new ALB is probably the best option as all other orgs have some interest in either collecting data or seeing it used in particular ways” *Cancer Research UK*
 - It is important, however, that the National Data Guardian is recognised as independent from both the Government and regulatory bodies. The location selected should not compromise that view” *Information Commissioners Office*
 - One of the key strengths and assurances that the role of the National Data Guardian can provide to members of the public stands in its independence. The independence of the National Data Guardian should be reflected to where the Guardian will sit” *Healthwatch*
 - It is essential that the NDG is independent in operation and therefore should sit outside all existing organisations” *Member of public*
 - “We strongly support the proposal for the National Data Guardian to remain independent. This is fundamental to ensure her recommendations and referrals are objective. For that reason, the most suitable long-term location would be a truly independent regulator, such as the National Audit Office” *techUK*.

Question 12: The National Data Guardian’s annual report should include a section demonstrating how the National Data Guardian has sought and gathered the views of the public and how these views will inform work in the future

- 4.34. The majority of respondents contributed on this proposal and expressed strong support. Respondents felt that as the NDG role is to be the voice of patients and service users it was essential to be able to demonstrate that the NDG was listening and acting on the public’s concerns.
- 4.35. Reinforcing this point, a couple of respondents expressed a view that the role has already achieved a lot of visibility with organisations holding and using data in the health and care system - but that the role currently has less visibility with the wider public.
- 4.36. The quotes from respondents below, reflect these points:
- “We agree with and support this proposal. The principle of participation (along with the principle of accounting for decisions) is a core concept of the Council’s Report. The views of the public and participants should be at the centre of any data collection and sharing initiatives” *Nuffield Council on Bioethics*

- “We welcome the suggestion that the National Data Guardian reports the views of the members of the public in its Annual Report and use these in defining the priorities of future areas of work” *Healthwatch*
- “We agree. The views of the public in this area are critically important. Such activity has the potential to helpfully explore public views with respect to the use of personal data in health and care research”. *Health Research Authority*
- “During our review of arrangements for data security across the NHS, we found examples where even senior staff in some large providers were less aware of the NDG and the roles and responsibilities of their Caldicott Guardian than they should have been. This does not bode well for the level of awareness which might be found among the general public, yet it is the general public that the NDG serves” *Care Quality Commission*

Question 13: The National Data Guardian, CAG and the HSCIC should agree and publish a Memorandum of Understanding that sets out the National Data Guardian remit in relation to the additional safeguards that are being put in place as described at para 4.2

- 4.37. This proposal sought to provide clarity about the respective roles of the NDG in its interactions with the Confidentiality Advisory Committee (CAG) and with the Health and Social Care Information Centre (HSCIC).
- 4.38. Where comments were received on this proposal (less than half of the overall total), they were supportive of the need for clarity around the different remits and functions of organisations and, as importantly, how they could most effectively work together.
- 4.39. The quotes from respondents below, reflect these points:
- “We agree that it will be helpful to set out in the public domain details of the agreed roles, remits and relationships between these organisations” *HSCIC*
 - “PHE supports this proposal. It is important that there is a clear demarcation between the roles and responsibilities of the NDG and both the statutory regulators and other bodies with advice giving powers” *Public Health England*
 - “We agree, however, there may be more effective mechanisms for specific regulators that should be accommodated” *MedConfidential*

Question 14: The National Data Guardian should engage with the relevant regulators of organisations outside of the health and care system to ensure that they understand their obligations and responsibilities in relation to the health and care data to which they have access.

- 4.40. Some of the most significant concerns people raised were about information and data that is transferred outside of the health and care system.
- 4.41. This proposal sought views on how the NDG might best ensure that organisations and activity outside of the health and care sector meet their legal and ethical obligations when they hold and use health and care data.
- 4.42. There was a consensus that the NDG should be able to follow the data and, therefore, needed to be able to comment on how health and care data was used outside of the health and care system - and bring matters to the attention of relevant regulators.
- 4.43. This is key to increasing public trust.
- 4.44. The quotes from respondents below, reflect these points:
- “NHS England agrees with the Government’s view that it is important for the National Data guardian to engage with regulators and governance mechanisms

outside the health and care system and agree a way of working together” *NHS England*

- “It is important for the National Data Guardian to engage with relevant regulators of organisations outside of the health and care system for the purposes specified above. In addition, the National Data Guardian should make concrete steps in ensuring that regulators of organisations outside of the health and care sector can understand the importance of minimising distress for health and care users in case of possible breach of their personal records” *Healthwatch*
- This is entirely necessary: The National Data Guardian must be able to “follow the data” *MedConfidential*
- “What sanctions could be applied? But in essence, I agree” *Member of the public*
- “Further clarity is needed on which organisations outside the health and care system the Government is anticipating the NDG will engage with. As a coalition of charities the Richmond Group would support the NDG engaging with the Charity Commission, ICO and research approval bodies in order to get clear guidance to third sector organisations on the access to and protection of health and care data, where data may be used for research, service improvement and marketing purposes” *Richmond Group of Charities*
- “We agree, but suggest that this alone will not be sufficient to address public concerns about possible misuses of health data” *Nuffield Councils on Bioethics*

Question 15: Do you have any comments or views on the potential impact that these proposals have on equality between different groups and health inequalities

- 4.45. Around half of the respondents made a contribution on this request for comments and views.
- 4.46. The overwhelming response was that the role had the potential to be a positive agent in reducing inequalities. Many considered that those most vulnerable and in need were most at risk of their data and information being used inappropriately. If the NDG could achieve an independent and authoritative voice, then these groups were more likely to have their data and information appropriately protected.
- 4.47. The quotes from respondents below, reflect these points:
- “More detailed consideration should be given in regards to the role that the National Data Guardian might have in terms of protecting the rights of vulnerable people, particularly those (including children) who do not have the capacity to give informed consent” *Healthwatch*
 - “The Council believes that if these proposals are properly enacted they will have a positive impact” *UK Council of Caldicott Guardians*
 - “We believe that the potential impact that these proposals have on equality between different groups and health inequalities will be positive in relation to the provisions of the 2010 Equality Act” *Yorkshire Ambulance Service* ”
 - The Commissioner places great weight on ensuring he engages with all sections of society in performing his duties and embeds diversity issues in his decision making processes. All public bodies should adopt a similar approach” *Information Commissioner’s Office*

Question 16: Do you have any comments or views on the potential impact that these proposals have on the potential for financial or administrative burdens.

- 4.48. Around half of respondents commented on this issue.
- 4.49. The main issue raised related to the proposed requirement on organisations to respond to advice from the NDG and to transparently demonstrate that they had done so, through the publication of relevant materials.
- 4.50. The majority of those who responded expressed a view that these proposals would not create any significant financial or administrative burden. If organisations were ‘getting it right’, then their interactions with the NDG would be extremely limited and, if they did ‘get it wrong’, remedying should not be regarded as a burden.
- 4.51. The point was also made that, over time, the NDG could support potential savings, as ‘getting it right’ would be cheaper than making mistakes and having to invest time and resources to rectify them. However, some considered that publishing materials to demonstrate how organisations had addressed the advice from the NDG could potentially present a real burden.
- 4.52. The quotes from respondents below, reflect these points:
- “With regards to the financial and administrative impact within the NHS in England, it is NHS England’s belief that if an organisation is operating good information governance practice and complying with the law as a business as usual approach, then these proposals should not have any significant impact on administrative and financial burdens” *NHS England*
 - “Good data governance should already be part of good quality care – so while there may be some requirements associated with the proposed measures, we would expect that organisations are already taking steps to ensure data security as part of good governance, assurance and effective leadership” *Care Quality Commission*
 - “In our view the burden is entirely justifiable, when weighed up against the potential benefits.” *Nuffield Council on Bioethics*
 - “LGA and ADASS agree with this point in the consultation paper that although there may be some small additional burden where a formal response is required to the National Data Guardian, that this should be focussed on bringing organisations back into line with existing duties. We would however caution that any such responses, alongside the publishing of such information, are undertaken in a way which is adding value both to members of the public as well as the National Data Guardian and organisations themselves.” *LGA/ADASS*
 - “PHE advises the Department of Health that while the administrative burden of responding to NDG advice should be negligible for most organisations, the financial implications of acting on that advice may be substantial”. *Public Health England*

5. Next Steps

- 5.1. This section provides a brief overview of the proposed next steps on outstanding issues in relation to the establishment of the NDG.
- 5.2. This overview covers:
 - Clarification of the NDG's role and functions;
 - Consideration of the most appropriate legal mechanism to establish the NDG role on a statutory footing;
 - Hosting arrangements for the NDG; and
 - Identification of the most appropriate mechanism by which the role can input and advise on children's social care data

The National Data Guardian's role and functions

- 5.3. The remit for the National Data Guardian role will be based on data collected within the health and care system, but will also allow for scrutiny and challenge in cases where such data is shared beyond the health and care sector.
- 5.4. The role of the National Data Guardian will include formal advice giving powers; organisations in receipt of this advice will be required to show how they have responded.
- 5.5. Relevant regulators will work with the National Data Guardian to determine criteria by which they might assess the performance of an organisation in relation to information and data, as part of their regulatory functions.
- 5.6. The National Data Guardian will publish an Annual Report setting out key issues that have arisen over a 12 month period, report on progress, set out priorities for the coming year and demonstrate how the concerns of patients and service users have been recorded and acted upon. This requirement will be set in legislation in due course.
- 5.7. The National Data Guardian will agree and publish Memoranda of Understanding with key regulators and stakeholders, which will include clarification of their respective roles in relation to information and data and a referral mechanism by which the NDG can refer any concerns or issues for consideration and action by the relevant body.
- 5.8. The National Data Guardian will not have the power to issue or enforce sanctions of its own, for example in terms of financial penalties, but will instead work with relevant regulators to ensure that the sanction making powers of those organisations are utilised in the most effective way.

Mechanisms to establish the role on a statutory footing

- 5.9. To deliver the commitment to place the role on a statutory footing at the earliest opportunity, the Department is exploring a range of mechanisms by which this could be achieved, including through relevant primary legislation, by a Statutory Instrument, or by extending the legal remit, either of an existing Arm's Length Body or other suitable organisation, to include the functions that have been agreed for the NDG.
- 5.10. When determining the long-term hosting and location for the post-holder and their Office, the Government will ensure that it does not compromise the independence of the role. The NDG is currently hosted within the Health and Social Care Information Centre (soon to be NHS Digital), whilst maintaining absolute independence from that organisation.

Roles and Functions of the National Data Guardian for Health and Care

The Government has concluded that this arrangement remains appropriate and should continue, for the moment.

- 5.11. This work will take account of a number of factors, most notably:
- Timeliness - to establish the role to place it on a statutory footing at the earliest opportunity; and
 - Appropriateness - via a mechanism that protects the independence and integrity of the role, and is in keeping with the purpose of the role.
- 5.12. The Department will provide an update when an appropriate legislative mechanism is agreed.

Hosting of the National Data Guardian

- 5.13. We are seeking to identify a long-term and sustainable arrangement for the hosting of the NDG. The NDG is currently hosted by the Health and Social Care Information Centre (soon to be NHS Digital to reflect its central role in relation to the health and social care system), whilst remaining completely independent of that organisation.
- 5.14. The Government has considered a number of options, and has concluded that the right level of independence could not be assured or the potential for a conflict of interest be avoided, if the National Data Guardian was hosted by a regulatory body e.g. the Care Quality Commission. Neither does it seem appropriate at this time to create a separate legal organisation (e.g. Advisory non-Departmental Public Body) especially when the Government is generally seeking to reduce the number of such bodies.
- 5.15. The Government has therefore concluded that the hosting arrangement with the Health and Social Care Information Centre remains the most appropriate location for the NDG and, consequently, that this arrangement should continue, for the moment.

National Data Guardians Role on Children's Social Care Data

- 5.16. Although children's social care data is not part of the health and care system it should still be robustly protected against inappropriate use. The responses to the contribution were clear that the NDG could have an important contribution to make in ensuring that this is the case.
- 5.17. We accept this view and will undertake further work with the Department for Education to determine the most appropriate mechanism for this to be achieved.