

The logo for the National Data Guardian, consisting of the letters 'NDG' in a bold, purple, sans-serif font.

**National
Data Guardian**
for health and social care

National Data Guardian for Health and Care: consultation response

Response to the comments and feedback on
the NDG's proposed work priorities

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Introduction and overview

The National Data Guardian role

The role of the National Data Guardian (NDG) is to help ensure that the public can trust that health and care information is securely safeguarded and used appropriately.

The position was established in November 2014, when Dame Fiona Caldicott was appointed as the first postholder. In 2015 the Government committed to enshrining the role in law to enhance the NDG's authority as the independent champion of patients and the public. In December 2018 Parliament passed a law to achieve this¹, which was enacted on 1 April 2019. Dame Fiona has been appointed as the first statutory NDG for a term of 18 months.

The new law means that the NDG will be able to issue guidance about the processing of health and adult social care data. Public bodies such as hospitals, GPs, care homes and service planners and commissioners, will have to take note of guidance that is relevant to them. So will organisations such as private companies or charities which are delivering services for the NHS or publicly funded adult social care.

The theme of trust has always been at the very centre of the NDG's role, with a focus on what can be done to help people be aware of, and more actively engaged in, decisions about how patient data is used and protected. The NDG's work is carried out working with other

organisations and groups which have a role to play in the use of patient data.

Dame Fiona and her panel of advisors² decided that this change presented a good opportunity to consult about what the NDG's key priorities should be as the role was moved to the new statutory footing. A public consultation³ ran from 18 February to 22 March 2019, proposing four broad priorities for the NDG and potential areas of work within each of those priorities. This document reports back on the responses we received to that consultation.

The NDG's revised priorities

In response to the consultation feedback we have refined our plans and the NDG will now be pursuing three refocussed priorities. We have also adjusted some of the areas of work beneath the three new priorities.

Later sections of this document summarise the feedback we received and how we have taken this into account to form three new NDG priorities:

Supporting public understanding and knowledge

- We will work with the relevant bodies to explore the barriers to improving patient access to their records and to information about how data about them has been used.
- We will continue to champion the NDG's long-standing principle that

¹ <https://services.parliament.uk/Bills/2017-19/healthandsocialcare/nationaldataguardian.html>

² https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/754822/874_-_NDG_Panel_short_biographies_v4.0_FINAL_06.11.18.pdf

³ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/779530/NDG_priorities_consultation.pdf

those using and sharing data must be transparent and that they must engage with the public and patients so that the case for data sharing is made.

- We will examine what additional public engagement would be most useful on the subject of the benefits from the use of health and care data.
- We will continue to support the work to develop a framework to realise the benefits for patients and the NHS where health and care data is being used to underpin innovation.

Encouraging information sharing for individual care

- We will work with others to develop advice and guidance for health and care staff with the aim of improving information sharing for individual care. This will include work to address the interplay between the requirements of common law and statutory data protection law. We will work with relevant bodies to do this, in particular the Information Commissioner's Office (ICO).
- We will work with training and education bodies to ensure advice and guidance about information sharing is embedded into their programmes where possible.

Safeguarding a confidential health and care system

- We will progress the concept of reasonable expectations and provide an update on our next steps.
- We will continue other work under the broad 'safeguarding confidentiality' theme. This will include work to ensure confidential patient information is not inappropriately linked with other types of data and/or

used for non-healthcare purposes in a manner that could undermine public trust and, potentially, discourage individuals from seeking healthcare.

As we made clear in our original consultation document, the NDG does not expect to deliver priorities alone, but rather in partnership with many other organisations and individuals. These priorities and work areas will not be the only things that the NDG will do. She will also continue to respond to the requests for advice and guidance that she receives from members of the public, government and its agencies, health and social care organisations, researchers, professional bodies and others.

The consultation feedback

The remainder of this report lists the four priorities and areas of interest originally proposed in our consultation document, summarises the feedback we received, outlines our response to the feedback and how we have taken this into account.

Some of the consultation questions asked for a yes/no response and in reporting on these, we have been able to provide numbers who support or did not support them being one of the NDG's top priorities.

Most of the consultation questions were open questions, to which respondents provided free text, for instance to suggest what particular activities they would like the NDG to undertake or what alternative priorities they would like her to pursue. Where possible, this report summarises which themes, concerns or points were raised by a relatively high number of respondents in comparison to others.

Respondents were invited to comment on the four proposed priorities and to say whether they thought each should be one of the NDG's top priorities, and whether

they thought the areas of work outlined were the right ones for the NDG and what they would like to see the NDG doing in them.

Respondents were encouraged to say if there were other areas they thought the NDG should be looking at under the priorities or if others were better placed to do the work. The consultation also gave respondents the chance to say whether they would change or remove any of our priorities, and to give any other feedback to the NDG and her team.

There were 118 responses to the consultation, with 77 being submitted via an online form and a further 41 by email. Around half were submitted by organisations and half by individuals. Some of the individuals identified themselves as members of the public. Others were health and care professionals or employees of stakeholder organisations that were not submitting an organisational response. The list of organisations which responded is listed in Annex A. Individual respondents are not named.

All responses were carefully reviewed and assessed. In general, they were supportive of the priority themes, with a majority of respondents indicating that the four proposed priorities and the outlined areas of interest were appropriate for the NDG. Some respondents suggested additional areas of work that they would like to see the

NDG take up, and others suggested alternatives.

Several respondents emphasised the importance of the NDG's focus remaining on the most pressing challenges and where there is the most need – and potential – to improve the way that health and adult social care data is used. Some wanted more detailed descriptions of exactly what the NDG would do under the priority. Several wanted the NDG to set an order for the priorities, which was not done in the original consultation document. Some respondents wanted to reduce the number of priorities or outlined areas of interest.

The NDG listened carefully to the feedback and acknowledges the importance of setting well-defined priorities where she can make the most impact. It is important that the work is deliverable in partnership with other bodies, and on the modest budget available to support the activities of the NDG, her panel members, and her small team of office staff.

The sections that follow look at each of the original priorities set out in the consultation document and explain why the feedback has persuaded the NDG to make changes. This explains why the four original priorities have been reconfigured into the three refined priorities which the NDG will pursue during 2019-20.

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

What the consultation document said

The consultation document stated that the essential building blocks of a trustworthy system for health and care data included enabling individuals to see what data about them is held, how it is used, by whom, for what purpose and empowering people to make choices about its use.

It looked back to recommendations that Dame Fiona made in her 2013 Information Governance Review⁴ that people should have the “*fullest possible access to all the electronic care records about them and should be able to see an audit trail that details anyone and everyone who has accessed a patient’s record*”. The consultation document also noted the significant step towards enabling more patient control that was made through the launch of the National Data Opt-out⁵ service in 2018.

The consultation document set out three potential areas of interest for the NDG under this theme:

- Encouraging greater /easier access for patients to see their health and care records and who has viewed them
- Greater transparency for patients to see tailored information showing how data about them has been used for reasons other than their own

individual care, for example how it has been used to improve health, care and services through research and planning

- Exploring models for greater patient control over data

Responses to the consultation

Of the 118 respondents to the survey, 117 answered the question about whether this should be one of the NDG’s top priorities. Of these respondents, 88 (75 per cent) said it should be, 14 (12 per cent) said it shouldn’t and 15 (12 per cent) didn’t know. Three respondents volunteered that they thought it should be *the* top priority.

Respondents highlighted the alignment of this priority with wider national policy such as the NHS Long Term Plan⁶; existing health and care data initiatives such as Local Health and Care Records Exemplars⁷, the NHS App⁸ and online GP services; and the ambitions and objectives of other bodies and organisations.

Among the 102 who gave a view on whether this should be a top priority for the NDG, 14 respondents (12 per cent) thought it should not. The key reasons given were that this should be considered a longer-term piece of work or that it

⁴ <https://www.gov.uk/government/publications/the-information-governance-review>

⁵ <https://digital.nhs.uk/services/national-data-opt-out-programme>

⁶ <https://www.england.nhs.uk/long-term-plan/>

⁷ <https://www.england.nhs.uk/publication/local-health-and-care-record-exemplars/>

⁸ <https://digital.nhs.uk/services/nhs-app>

might disproportionately benefit patients who are digitally literate.

The consultation asked whether the three areas of interest that it outlined were right and 96 respondents answered this question: with 75 (78 per cent) said they were; 7 (7 per cent) said they were not; 15 (15 per cent) said they didn't know.

There was strong support for the concept of providing individuals with fuller access to their records. The view was expressed that allowing people to see more of what is in their record and offering the option to contribute to it, could empower patients to better manage their own health: "Patients must have greater and easier access to their record; this has been established as a key principle of patient empowerment and choice".

However, some expressed concerns that a greater focus on online access to empower patients could inadvertently disempower others, such as those with certain protected characteristics or who are digitally disenfranchised: "It is essential that patients have easy and equitable access to health services and that a move to more digital interactions does not exacerbate or add barriers to seeking help."

Respondents raised issues under this theme that they hoped the NDG could work with others to examine: who might be able to feed into the record; how people could contribute their own information (e.g. adding their own notes and comments or data from wearable devices such as heart rate monitors); whether and how patients can correct information or request corrections; whether there should be exclusions to what patients can view (e.g. information about third parties, doctors' notes or items that may negatively impact patients); what support people might

need to help them understand or cope with the information in their records; clarity on who can have access (i.e. parents, carers etc); and how the public would be communicated with about these. People pointed out issues and risks that may accompany the provision of greater access, and other areas that need careful consideration, such as safeguarding concerns about individuals being coerced to let others see their data; poor data quality or records leaving patients dissatisfied; burden on health and care staff from increased queries about records.

Some respondents anticipated positive results from the proposal that the NDG should pursue greater transparency for patients to see tailored information showing how data about them has been used for reasons other than their own individual care. The most frequently mentioned benefit was reduction of mistrust in data sharing: "*Transparency and openness are vital in maintaining public trust in the health and social care system. This, in turn, is vital if we are to realise the full public benefit that can be obtained through the appropriate and effective use of data for individual care and for secondary uses such as research, service management and in ensuring high standards of safety and quality of health and social care.*" There was interest, particularly among respondents from the research community, in enabling patients to see where their data has been used: "*Medical research charities support the idea of providing more tailored information on how patients' data has been used in ways outside of their individual care e.g. for research.*" But some thought that this might be difficult to implement. It was suggested that: "*The NDG could convene stakeholders to define technical and practical limits to patients' access to information about how data from their records is used, looking at the type of data it is feasible*

to track and what capacity there is to enable useful, useable audit trails for patients.”

On the topic of models for greater patient control over data, there were some concerns about this happening while public awareness about the uses and benefits of data for research and secondary purposes remained as low as it currently is. Some of these respondents were worried that this could jeopardise research and public health work: *“Population health management and research may be undermined by models based on full individual control of all aspects of data use (due to low public understanding of benefits).”* It was suggested that first must come a greater public understanding of the value of data and how using patient data can make a difference. *“Meaningful engagement with the public is vital, with real world examples on the benefits of sharing for research. Without this, there is a risk that a lack of understanding will result in patients opting out of sharing for research.”*

It was suggested that the NDG should lead a debate on the balance that should exist between patient rights and ‘the common good’ that data sharing brings: *“The balance of advice and public perception is all about restriction of data access, and not about the beneficial uses of data.”* To redress this imbalance, it was proposed that the NDG should work with organisations which collect and use data to find ways to increase public understanding of how their data is used for purposes beyond their care, and the value this brings to society. It was also put forward that the NDG could work with others to define the parameters of ‘control’, looking at what control a person

might feasibly and legally be able to have over their own data, and whether this marries with what the public might expect and want: *“There is some difficulty in understanding what is meant by control - sovereignty is likely to be more appropriate. Clarification around the terms and what a patient/citizen can expect is important.”*

It was also suggested that the NDG should continue to monitor the existing National Data Opt-out and provide guidance when appropriate.

NDG response

It was welcome that so many support or share the NDG’s ambition that patients should have improved access to their records. She agrees that this could increase public understanding of how patient data is used and empower individuals to become more involved in their own care. Respondents highlighted improvements that have been made over recent years that the NDG also welcomes, for instance the development of GP online services and the NHS App. She agrees that for further progress to be made in this area, many different organisations will need to work together, and it will be important to work through policy points, issues and barriers highlighted in responses to our consultation.

In addition to seeking views in the consultation, the NDG has also conducted polling in this area to test public appetite for greater access to records.⁹ It found strong support for access to a fuller online GP record than is usually available currently. Nearly two thirds of those polled (65 per cent) said that this was important to them, with a

⁹ The polling was conducted by research company Kantar; key findings and full statistical tables are available here: <https://www.gov.uk/government/news/ndg-poll-findings-public-attitudes-to-organisations-innovating-with-nhs-data>

third (32 per cent) saying it was very important. Among those who already have access to a basic GP record, there was a greater proportion saying that full access is important to them (78 per cent).

The correlation between already having basic access and believing that full access is important is not surprising. It might be taken as a further reason to pay attention to the risk that some respondents to our consultation raised; that digital empowerment is unlikely to benefit all patients equally and that attention must be paid to ensuring that this does not create or exacerbate health inequalities.

It was welcome to find so much support for increased transparency for individuals about how data relating to them has been used beyond their own individual care. The NDG noted the implementation challenges raised.

A strong message from the consultation was that greater public understanding of the value of data must come before the introduction of more sophisticated control models. There were fears that greater control for individuals would lead to less data being available for research and planning. There are difficult balances to be struck here. The NDG believes that caution should be applied to arguments which could tend to restrict individuals' choices "for the greater good". But she nonetheless agrees that the best way to support individuals to make choices is by ensuring they are able to do this in an informed way. The evidence from the implementation of the National Data Opt-out strongly indicates that where the public is presented with clear information about the benefits, the vast majority will choose to allow their data to be used for research and planning to improve health and care.

The NDG agrees that the current level of public understanding about how health and care data is used is low. Her position remains that the case for data sharing needs to be made and that all health and social care, research and public organisations should share responsibility for making that case. It may be that this is such a "given" for the NDG, that it was not stated clearly enough in the consultation document.

What the NDG will do

In response to feedback across each of the consultation priorities, the NDG has decided to place more explicit emphasis on supporting the development of public understanding about how data may be used and making the case for data sharing. The title of this priority has been amended to encompass this work.

It is important to note that the NDG cannot – and should not – be undertaking the work of informing the public herself. The NDG is not resourced to do this and it is important that those who are collecting, using and sharing data retain responsibility for being transparent about what they are doing. The NDG's role in this area is to listen to the public, convene, advise and lead in the development of good practice.

The work programme for this priority has been expanded to include public engagement; the rationale for this is explained in the next section of the consultation response.

In response to the consultation, the title of this priority has become: **Supporting public knowledge and understanding.**

The expanded work programme for the NDG and her team is as follows:

What the NDG will do

- We will work with the relevant bodies to explore the barriers to improving patient access to their records and to provide information about how data about them has been used.
- We will continue to champion the NDG's long-standing principle that those using and sharing data must be transparent and that they must engage with the public and patients so that the case for data sharing is made.
- We will examine what additional public engagement would be most useful on the subject of the benefits from the use of health and care data.

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

What the consultation document said

The consultation document outlined that a diverse range of technologies is emerging. Many of these innovations have the potential to improve patient care and many require the use of patient data for their development and implementation. It acknowledged that public engagement undertaken by a range of organisations, including the NDG, has tended to show that most individuals will support the use of patient data where there is a clear public benefit and there are appropriate safeguards in place. It also noted that dialogue with the public about data use has not grown at the same speed as the capacity of technology and the related various uses of data.

The consultation highlighted two areas of interest for the NDG under this theme, asking:

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

Responses to the consultation

Of the 118 respondents to the survey, 116 gave a view on whether this should be a key priority for the NDG with 87 (75 per cent) saying it should, 18 (nearly 16 per cent) saying it should not and 11 (9 per cent) saying they did not know. A small

number of respondents (three) volunteered that it should be *the* top priority.

A key reason given for supporting the inclusion of this priority was the potential benefits that innovation using data can bring to patient care. Some respondents wanted the NDG to act as a champion for the increased use of data and technology. Some respondents expressed impatience to see these benefits, advocating for data use and access to be made simpler so that advances in technology could be made available sooner. A number of respondents voiced a concern that a greater pace of progress in other countries could mean that the UK is in danger of becoming a “laggard” and losing out on job creation and the opportunity to lead innovation.

There were also concerns that the speed of advances in technology is already out of kilter with the slower pace at which the public and patients are informed and engaged. The theme of public trust was raised: *“Data-driven and emerging technologies hold the potential to improve patient outcomes and care. However, these technologies are complex and the ways in which data are shared often opaque. This means there is a significant risk to building trust and confidence with these technologies.”*

Respondents were asked to say whether the consultation document had identified the right areas of interest for the NDG under this priority and 81 respondents answered this question, with 55 (68 per cent) thinking that we had. A further 12 (15 per cent) thought we had not and 14 (17 per cent) said they didn’t know. Some agreed that the NDG should explore the question of whether there is a reciprocal relationship whereby those receiving care allow the usage of their data to facilitate improvements in health and care.

However, more had reservations about this concept being developed further while public understanding of the way that health and care data is used remains low.

Another recurrent theme was access to data by commercial entities and how the resulting benefits of this should be distributed and managed: *“We believe that the National Data Guardian should give particular attention to the commercialisation of the national data asset. Whilst we have some discomfort with the use of the term “commercialisation”, we believe that this needs to be undertaken in a way which produces benefit both to patients and financial or other benefits to the NHS, all being tangible and transparent. We should not be blindly driven by dogma (either for or against) on this point but take a sensible, well-considered view. We see the National Data Guardian as having a role in this.”*

Among those who argued against this being one of the NDG’s priorities, the most common reason given was that the NDG should not focus on innovation and technology per se, but instead on the wider issues of how patient data may be used, whether it is to support ‘new’ technology or not. There was not much support for the suggestion in the consultation document that the NDG might look at how far public expectations of data usage match reality in NHS apps and non-NHS health apps. But there was a clear message of support throughout the consultation for the broader importance of understanding what the public would expect and accept in relation to the use of data.

Some respondents expressed the view that public benefit is critical to understanding what the public would expect and accept. Some felt that more should be done to define public benefit:

“Data generated by a public healthcare system should be used for public benefit. We need a much stronger narrative on what it is ok to share for the national good, and how to do it.” Another respondent urged the NDG to: *“Encourage active and ongoing collaboration between patients and service providers to reach mutual understanding on benefits and future plans.”*

Many respondents raised the need for better communication and engagement with the public and patients. Some respondents expected the NDG to be undertaking work to engage and inform, others wanted her to advise and work with others to achieve this. Further related topics raised by several respondents as being important were the potential for digital inequalities to cause or exacerbate health inequalities and the linking of health and care data with other types of data.

Respondents cited other organisations with whom the NDG could work on this topic such as the Information Commissioner’s Office, the Medicines & Healthcare Products Regulatory Agency, the Care Quality Commission, the Health Research Agency, the Centre for Data Ethics and Innovation, the Ada Lovelace Institute, the Office for Life Sciences and Understanding Patient Data.

NDG response

It was encouraging to find that respondents almost without exception acknowledged the importance of ensuring that there is transparency for patients and public about how data may be used. Many respondents wrote that they agreed with the NDG’s belief that dialogue with the public about data use has not grown at the same speed as the capacity of technology, and that the resulting knowledge gap that has

resulted could prove a threat to both public trust and their support for those technologies. There was a clear sense of urgency around this topic; respondents felt that better guidance was needed soon to help health and care providers to take decisions about how data they hold may be used so that this is in line with the law and with public expectations.

In addition to asking questions about this in the consultation, the NDG has also conducted polling to examine public attitudes towards NHS organisations collaborating with partner universities or private companies to use patient data to develop new medicines and technologies to improve health¹⁰. The polling found strong agreement that it is fair that the NHS and patients should benefit when partnerships between the NHS and universities or private companies lead to valuable new discoveries; benefits such as access to new technologies at a reduced cost and improved patient care were very popular with around seven in ten supporting this.

Around half of those surveyed agreed that it is fair for a profit to be made in these circumstances by a partner private company (51 per cent) and or a partner university (49 per cent). Among those who said they were aware that such partnership working already takes place, there was markedly stronger agreement with the idea that partners and the NHS should be benefitting financially where valuable discoveries are made. There were sizeable minorities who neither agreed nor disagreed to the polling questions. This might be because respondents did not feel knowledgeable or because people remain undecided on

these questions. Alongside the feedback to the consultation, the polling results confirmed that these issues need more exploration and discussion with patients.

It is welcome that since the consultation was launched there has been progress in the area which was most often cited as needing urgent attention – guidance for health and care organisations engaging with private sector organisations to use data to innovate. The Office for Life Sciences (OLS) has been engaging with a range of bodies, including the NDG, to support the development a framework to realise benefits for patients and the NHS where data underpins innovation¹¹. The NDG has been pleased to work with OLS and to see that public engagement will be taking place on this issue¹² and will continue to support this work.

She has also noted the interesting public engagement work that Genomics England has undertaken and published recently, testing views on the idea of a ‘social contract’ in relation to genomic medicine. The NDG has taken an interest in the area of genomics for some years now. In many ways this branch of medicine challenges conventional understandings of medical confidentiality because of the way that data about many patients may be needed so that the best diagnoses and care can be provided to individuals. Patients in this area will in many cases be highly motivated to allow their data to be shared for the benefit of others and more informed about the potential uses of data. She will watch with interest the work that Genomics England is taking forward in this area and consider if it has lessons to be more broadly applied.

¹⁰ Polling was undertaken by Kantar and the full set of tables and an accompanying press release can be found here: <https://www.gov.uk/government/news/ndg-poll-findings-public-attitudes-to-organisations-innovating-with-nhs-data>

¹¹ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/768570/life-sciences-sector-deal-2-web-ready-update.pdf

¹² <https://understandingpatientdata.org.uk/news/NHS-company-partnerships>

In relation to this priority area, it is accepted that the NDG should not focus on particular types of technology or their novelty. The most important issues at stake are whether data is being used in ways that the public expect and accept – this is the case whether the data techniques are new or commonplace.

Given the feedback from the consultation, the NDG has decided not to pursue this theme as a separate priority. Instead she will take forward action to address points identified by respondents as most important under two other redrafted priorities.

What the NDG will do

- We will continue to support the work to develop a framework to realise the benefits for patients and the NHS where health and care data is being used to underpin innovation. This will come under our priority: **Supporting public understanding and knowledge**
- We will address respondents' calls for the NDG to support the use of data in innovation which can improve care. This will now come under the priority **Supporting public understanding and knowledge.**
- We will examine what additional public engagement would be most useful on the subject of the benefits from the use of health and care data. This will now be addressed as a new area of work under the priority: **Supporting public understanding and knowledge.**
- We will amend our priority for **Safeguarding a confidential health and care system** to reference work looking at the linking of health and care data with other types of information.

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

What the consultation document said

The consultation document noted that it is too often the case that data is not good enough, available enough, joined-up enough, or shared enough to support individuals' care. The document remarked that it was disappointing that some of the barriers identified in Dame Fiona's 2013 Information Governance Review¹³ are still preventing appropriate sharing.

The document outlined three potential areas of interest for the NDG:

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

Responses to the consultation

Of the 118 respondents to the consultation, 86 gave a view on whether this should be one of the NDG's top priorities, with 81 respondents (94 per cent) saying it should be, three (3 per cent) saying it should not and two (2 per cent) saying they didn't know. Among the

86 who answered this question, 12 respondents (14 per cent) also volunteered that they thought it should be *the* top priority.

The role that improved (increased) appropriate data sharing can play in improving individual care and outcomes was recurrently cited as the reason that respondents supported this priority.

Enduring problems with sharing data across geographical and organisational boundaries were confirmed: "The sharing of patient data across boundaries is especially important, particularly for the small proportion of patients who have multiple long-term conditions. These patients utilise multiple health and social services. Inadequate sharing of data results in unwarranted variability in care and exacerbates the high costs associated with this small subset of patients." The "data sharing black hole" between the health and social care sectors was highlighted by many as a persistent problem. It was suggested that the most problematic flow tends to be from health to social care.

Respondents agreed that a fear persists among health and social care staff about sharing data and that this is in spite of patient expectation that information about them will be readily available to those involved in their care: "*In our experience, fear of being criticised for inappropriate sharing is the greatest barrier to appropriate information sharing.*" Respondents also nominated

¹³ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/192572/2900774_InfoGovernance_accv2.pdf

inadequate technology as a barrier to good data sharing.

While there was a strong message that the result of the NDG's work in this area should be to enable data sharing, respondents still emphasised that a legal and ethical framework is important: *"Doctors' roles are continuing to evolve and change and that it is likely to be more challenging to make sure there is a legal and ethical basis for using patient information in this complex health and social care environment."*

The small number of respondents who did not support this being one of the NDG's top priorities were generally advocating for other priorities in the consultation to be advanced ahead of this.

Looking at the areas of interest outlined in the consultation document, 79 respondents gave an answer to the question of whether these were the right ones for the NDG. Of the 79, 66 (84 per cent) thought that they were, eight (10 per cent) thought that they were not and five (six per cent) did not know.

There was strong support for the NDG to be working with bodies leading on education and training to ensure that those working within the health and care system are equipped to handle and share data with confidence. Respondents called on the NDG to work with others to better embed information governance training into professional training and development. The need to ensure any NDG action is complementary to the Topol Review¹⁴ recommendations and implementation was referenced by several respondents, as was liaison with the Royal Colleges, the Information

Commissioner's Office, the Local Health and Care Exemplar programme, the UK Caldicott Guardian Council, the NHS Digital Academy, data scientists, academics, and other bodies. There were also valid points made to the effect that the scale of the challenge should not be underestimated: *"The lack of awareness and confidence of staff at all levels and specialities within health and social care shouldn't be ignored or underestimated."*

Respondents were also supportive of the second area of interest named in the consultation document - encouraging better sharing for individual care across boundaries, particularly between health and social care. Some respondents believed that this would be a consequence of progress being made in the first area of interest.

The consultation document suggested that the NDG might review the existing Caldicott principles (which were last reviewed as part of the 2013 Information Governance Review¹⁵) to give further clarity or guidance to support appropriate sharing. There was some support for this proposal: *"It might be timely to revisit the Caldicott guidelines in this respect and place added emphasis on the importance of sharing information for the provision and development of safe and effective care to reflect the statutory duty to share."* However, other respondents disagreed, saying that effective implementation of the existing principles was required, rather than revision.

There were a relatively high number of requests for the NDG to develop national guidance to support improved information sharing that could be applied

¹⁴ <https://www.hee.nhs.uk/our-work/topol-review>

¹⁵ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/192572/2900774_InfoGovernance_accv2.pdf

across the health and adult social care sector. *“We would like to see clear and consistent guidance for all health and social care organisations to follow that will avoid any misunderstandings and provide a framework that will be easy to follow for the professionals as well as the general public.”* Some suggested that this could be a code of practice for direct care services which should include definitions of direct care, guidance around consent and other relevant terms. Some respondents wanted the NDG or others to audit data use and enforce adherence or penalise lack of adherence to a framework.

Some respondents wanted to see other areas of interest pursued under this theme. It was suggested that this priority should not be focused solely on the delivery of individual care, but instead explicitly encompass the sharing of information for other purposes. Some wanted the NDG to introduce a duty to share data for research and planning. Other respondents thought that data quality and standards should be improved before greater data sharing could be improved. Several respondents raised the issue of technology, arguing that lack of interoperability between infrastructure and systems was the key barrier here and that tackling this would be best addressed by organisations other than the NDG. Some thought that the implementation of a single shared record across all of health and care should be pursued.

Many respondents to this priority expressed the view that the amount of sharing that takes places falls *below* public expectation and therefore that the focus of the NDG’s work should be directed to encouraging the health and care sector to share more: *“Healthcare organisations still lag behind public and patient expectation in the nature and extent of their data-sharing practice.”*

And: “Sharing information for direct care is not the most significant risk in terms of creating public grievance or exposing organisations to legal action and sanctions. Even where the particular aspect of sharing for direct care is not common, if the individual can see a link between the sharing and their care, there is little likelihood of them feeling aggrieved at the sharing...Indeed, the failure to share for direct care may have a greater capacity to affect public trust in the NHS’s ability to safeguard data. On this basis we think that the main priority in relation to sharing for direct care is to make sure that boundaries are not put in the way of this and the fulfilment of the statutory duty to share.” However, some respondents felt that more engagement was needed with the public about data sharing for individual care and that individuals should be given much more control over this sort of information sharing.

NDG response

The responses to our consultation emphatically endorsed the NDG’s concern that barriers to appropriate sharing still exist. The NDG’s role and statutory powers, past body of work and expertise leads her to believe that she can best support progress in this area by addressing cultural barriers to information sharing – in particular the “culture of anxiety” identified in the Information Governance Review and which responses to our consultation told us is still a problem. It will be critical to work with other bodies, in particular to address the problems of insufficient sharing between health and adult social care.

Most respondents thought that the Caldicott principles, and in particular the

7th Caldicott principle¹⁶, are already a positive tool. There was not a clear view on whether they should be reviewed to give further clarity or guidance which would support appropriate sharing.

The importance of other factors that were identified as barriers to good information sharing – in particular the need for consistent standards to promote more interoperability between systems and technology – should be acknowledged. However, as respondents pointed out, there are others who are better placed to address this.

Some respondents would have liked this priority to address the sharing of data for purposes other than individual care, such as improving services through research and planning. However, the NDG believes that she will be more effective if she focusses this work on information sharing for individual care. However, she has heard this message and is taking account of the importance of the uses of data for purposes other than individual care in other priorities. Likewise, she understands that some respondents thought that public engagement should take place to support this priority area. However, she believes that there is strong evidence that the public and patients expect sharing for individual care to already be taking place to a much greater degree than it actually is and therefore that work would be best addressing the barriers within the system that mean public expectations are not being met. This priority has been renamed in order that it sits better alongside the first renamed priority. It will now be: **Encouraging information sharing for individual care.**

What the NDG will do

- We will work with others to develop advice and guidance for health and care staff with the aim of improving information sharing for individual care. This will include work to address the interplay between the requirements of common law and statutory data protection law. We will work with relevant bodies to do this, in particular the Information Commissioner's Office (ICO).
- We will work with training and education bodies to ensure advice and guidance about information sharing is embedded into their programmes where possible.

¹⁶ The duty to share information can be as important as the duty to protect patient confidentiality

Consultation Priority 4: Safeguarding a confidential health and care system

What the consultation document said

The consultation document re-iterated the NDG's previously expressed view on why safeguarding confidentiality is so important. This is so that people using health and care services feel able to discuss sensitive matters with a doctor, nurse, social worker or other member of their care team knowing that the information they have provided will not be improperly disclosed.

It laid out that the NDG was considering two areas of interest under this theme:

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

Responses to the consultation

Of the 118 respondents to the survey, 111 gave a view on whether this should be a top priority for the NDG. Of those 111, 94 respondents (84 per cent) thought that it should, 10 (9 per cent) that it should not and 7 (6 per cent) did not know. Among these 18 (16 per cent) volunteered that they thought it should be *the* very top priority.

Reasons that were recurrently cited in support of the inclusion of this among the NDG's priorities were that it was integral to her remit and to maintaining and building public trust: *"This priority is*

of crucial importance; it should be considered as the cornerstone of the entire remit of the NDG. When considering any advances in the collection of new or additional information from patients, this priority should underpin all ideas and activities." Many respondents said that clearer guidance is needed which could enable more confidence about decisions to use and share data, and more clarity to be provided to the public. Several respondents referred to the need for confidentiality to be safeguarded so that individuals felt able to seek healthcare safely. Some respondents specifically cited their concerns about previous arrangements that enabled the Home Office to receive address details of NHS patients suspected of immigration offences.¹⁷

Among those who felt that this area should not be a priority, some argued that the law and policies around confidentiality were already well-developed: *"Although safeguarding a confidential health and care system is the fundamental and essential function of NDG, it has some level of maturity now. In my personal opinion, NDG should prioritise others now although it should not be ignored or omitted at all."* Some respondents - and not just those opposed to the inclusion of this theme as a priority - expressed a concern that an over-emphasis on confidentiality prevents data being shared when it should be: *"[there is a]... need to prioritise usage and benefits alongside the area of safeguarding. We would make the point that safeguarding is essential but should not be at the expense of appropriate sharing and usage. We are concerned that in the past there has*

¹⁷ <https://www.parliament.uk/business/committees/committees-a-z/commons-select/health-committee/inquiries/parliament-2017/mou-data-sharing-nhs-digital-home-office-inquiry-17-19/>

been a ‘play it safe’ culture of obstructing data sharing to the detriment of public benefit.”

Looking at the two areas of interest outlined in the consultation document under this theme, 99 respondents gave a view on whether these were the right ones for the NDG. Of those, 84 (85 per cent) said they were right, 14 (14 per cent) said they were not or had reservations and two respondents (2 per cent) said they didn’t know.

Between the two areas of interest described in the consultation document, support was strongest for the aim of clarifying the interplay between the requirements of common law and data protection law. Among the 84 respondents commenting on the areas of interest, 26 (31 per cent) of respondents specifically named this as a concern. *“It is essential that there is clear guidance as to how common law and data protection law interact for both clinicians and the public to ensure confidence and consistency”*. There was a very small minority that sought to argue that this was not necessary work. The most commonly requested piece of work was for guidance on consent, to support the health and care system to comply with both GDPR and the duty of confidence.

Nearly a quarter (20 of the 84 respondents commenting on the areas of interest) also specifically cited support for the NDG to continue work on the theme of reasonable expectations. While there was interest in the concept and the work that the NDG has previously undertaken in this area¹⁸, some respondents felt that the term and how it might be applied needs much greater definition. For instance: *“Those who use data have moral duties towards all those*

who have relevant interests in the data, whether they are people from whom the data were initially collected or the people who stand to be affected by their use. So, the second area of interest, on reasonable expectations, is vital. We therefore need a proper process of establishing what these expectations are. Public involvement is a crucial part of this both in establishing what are ‘reasonable expectations’ and in monitoring through governance arrangements.” For some, the term was considered too ‘nebulous’ or ‘vague’ to be helpful. Greater clarity on this was requested.

There were some other suggestions for themes under this priority, although no clear, recurrent themes emerged. Suggestions included artificial intelligence and machine learning; data minimisation; sharing of health data with non-health bodies; consent and capacity to consent;

A strong theme that came through on this priority was a call for greater simplicity to help people to navigate better the complexity of laws, standards and guidance. Respondents pointed to a need for greater transparency with the public about how data is used, with some suggesting that there should be a ‘standard NHS statement’ to support this; some wanted the NDG to play a part in ensuring this happened, others expected the NDG to be leading on this.

NDG response

This theme could be said to underpin all of the NDG’s work and respondents pointed out that the proposed areas of interest were a relatively narrow focus

¹⁸ <https://www.gov.uk/government/speeches/talking-with-citizens-about-expectations-for-data-sharing-and-privacy>

under this broad heading. The responses to the consultation on the two proposed areas of interest do, however, suggest that these two pieces of work would be helpful for the health and care sector. The clearest support was for work to clarify the interplay between the requirements of common law and data protection law, particularly in regard to consent. The NDG will therefore make this the first piece of work under this theme.

She acknowledges that there is a need to ensure that work under a priority of 'safeguarding confidentiality' does not err on the side of excessive caution in data sharing, which would not be in the best interests of patients or the public. She believes that the work that she will be undertaking under the other two priorities will mitigate against this risk. She also recognises the call for work to support public understanding about how data is used and so has changed another priority to include this.

What the NDG will do

- Our first step under this theme will be to develop advice/guidance on the interplay between the requirements of common law and data protection law. This piece of work has been moved under the renamed theme: **Encouraging information sharing for individual care.**
- We will progress the concept of reasonable expectations and provide an update on our next steps.
- We will continue other work under the broad **Safeguarding confidentiality** theme. This will include work to ensure confidential patient information is not inappropriately linked with other types of data and/or used for non-healthcare purposes in a manner that could undermine public trust and, potentially, discourage individuals from seeking healthcare.

Other consultation feedback

As well as asking respondents to comment on the four individual priorities, we also asked some ‘additional questions’ - whether there were any other areas of work that respondents would suggest, whether they would remove or change priorities, and to provide any other comments or feedback to the NDG and her team.

Some respondents took the opportunity of the ‘additional questions’ to emphasise the need for more to be done to encourage data sharing – this was also a clear theme in responses to the four proposed priorities. There was a host of suggestions about the purposes for which there should be greater sharing of data and how the NDG should encourage this sharing. There were recurrent references to the seventh Caldicott principle, with multiple respondents saying that it was not being implemented sufficiently to support sharing for individual care or sharing for other purposes. Nonetheless there were some other voices arguing that too much data is shared and that patients and the public are not given sufficient choice over the use of their data, indicating again that there is a spectrum of comfort with data sharing.

Another theme that cropped up through the responses to all parts of the consultation was a call for simplicity. Respondents expressed frustration and confusion at the complexity of the laws and guidance around data sharing, providing evidence that this affects a wide range of stakeholders including researchers wanting to access data, organisations making decisions on how to handle data, frontline professionals and patients and the public. Respondents

wanted any guidance from the NDG to ameliorate the situation.

Several respondents re-iterated in their responses to the ‘additional questions’ that the NDG should work with other bodies with a remit over and interest in data, including bodies looking at a broader variety of data than ‘simply’ health and care data. Several also cautioned against the NDG taking on too many priorities, arguing that a smaller and more focused set of aims would be wiser. Although the consultation document stated that the priorities were not presented in a particular order, several respondents thought it was important to distinguish which among them was most important, pressing etc.

Some respondents wanted the NDG to do more to clarify data definitions and the boundaries between definitions. Terms and categories that were recurrently highlighted as needing this attention included ‘big data’, ‘anonymous’ and ‘pseudonymous’. Some felt that the need to revisit definitions had been prompted by GDPR, others cited the development of technology which could affect the extent to which any data can be understood to be anonymous. On the subject of definitions and boundaries, some respondents said that the definition of individual or direct care should be revisited and some said that the boundaries between individual care and research are too heavily drawn.

A few respondents wanted the NDG to do more to explore to what extent it is relevant or helpful to ask the question of who ‘owns’ data. The concept of data ‘stewardship’ was also suggested.

Some also argued that the NDG should be doing more to examine where and

how health and care data may be combined with other sorts of data, in particular data collected or held by other parts of government, and for what purposes.

A handful of respondents put forward the view said that they thought there should be patient representation on the National Data Guardian's panel of advisors.

NDG response

In reshaping the priorities and areas of interest, the NDG has taken on points made about the need to encourage more sharing of data where appropriate, more emphasis on making the case for data

sharing and the need for clear and simple guidance.

She has also taken heed of those urging us to set a smaller and more focused set of priorities. The NDG acknowledges the importance of many of the other issues that respondents would like us to look at but has carefully used the feedback to decide where there is most demand and need for NDG work.

While the number of respondents raising the issue of patient or lay representation on the National Data Guardian's panel of advisors was relatively low, this proposition will be pursued.

Annex A: list of organisations which responded to the consultation

The list of organisations which responded (and consented to being named) is listed below. Individual respondents are not named.

- Association of Anaesthetists
- Association of Medical Research Charities
- Cambridgeshire Community Services (CCS) NHS Trust
- Cancer Research UK
- Cancer Survival Group, London School of Hygiene & Tropical Medicine
- Care Quality Commission
- Clinical Practice Research Datalink (CPRD)
- Closer, University College London - (partnership including the British Library and the UK Data Service).
- Data Privacy Advisory Service
- defenddigitalme
- Dorset Care Record
- Faculty of Public Health in collaboration with the Health Statistics User Group.
- Fight for Sight
- Future Care Capital
- General Medical Council
- General Pharmaceutical Council
- Greater Manchester Combined Authority
- Hempsons Solicitors
- Hertfordshire Bedfordshire and Luton ICT Shared Services hosted by NHS East and North Hertfordshire Clinical Commissioning Group (CCG)
- HF Trust Limited
- Integrated Mental Health Research Program, University of Melbourne, Australia
- IQVIA
- King's College London
- Leeds Institute of Clinical Trials Research
- Macmillan Cancer Support
- Marie Curie
- medConfidential
- Medic Creations Ltd
- Medway NHS Foundation Trust
- MRC Clinical Trials Unit at UCL
- Mycarematters
- NHS England
- NHS North and East London Commissioning Support Unit
- NHS North Cumbria CCG
- NHS Northern, Eastern and Western Devon CCG
- NHS Resolution
- NHS South, Central and West Commissioning Support Unit
- Nuffield Council on Bioethics
- Outstanding Care Homes
- PHG Foundation
- RELX
- Royal College of Anaesthetists (RCOA)
- RCOA Lay Committee
- Royal College of Midwives
- Royal College of Nursing
- Royal College of Physicians
- Royal Statistical Society
- Strategic Information Governance Network (SIGN)
- The Confidentiality Advisory Group
- The Health Foundation
- The Health Research Authority
- The Information Commissioner's Office
- The Royal College of Radiologists
- UK Faculty of Public Health
- Understanding Patient Data
- Use MY data and their patient and carer Advisory Group
- West Suffolk NHS Foundation Trust