

National Data Guardian for Health and Social Care: a consultation about priorities

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About the National Data Guardian for Health and Social Care (NDG)

The National Data Guardian's role is to help to 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 so as to enhance the NDG's authority as the independent champion of patients and the public in relation to how health and adult social care data is used.

In December 2018 Parliament passed a law to achieve this. 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, planners and commissioners of services, 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 role, with a focus on what can be done to help people to be aware of and more actively engaged in important decisions about how patient data is used and protected. The NDG's work is carried out working with other organisations and groups which influence and take an interest in the use of patient data.

The NDG priorities: a consultation

The National Data Guardian and her panel of advisors have been thinking about what the key priorities should be for the NDG as the role moves onto a statutory footing. This consultation sets out four proposed priorities (in no particular order) and potential areas of interest for the NDG within each of these.

We should make clear that the NDG cannot deliver these alone. These are broad and ambitious priorities which will be ongoing work in the coming years for many organisations working together. And we should add that these are not the only things the NDG will do; we will also continue to respond to the many requests that we receive for advice and guidance.

We now want to receive feedback from patients, the public and stakeholders on these priorities. Tell us what you think. Have we got this right? What have we missed? What should we be doing and who should we be working with to progress these priorities?

You can respond to the consultation [online here](#) or by emailing the ndgoffice@nhs.net by **Friday March 22**. Your response will be most useful if it is framed in direct response to the questions posed, though further comments and evidence are also welcome.

We will also be holding an event on March 11 in central London to celebrate the new statutory footing of the NDG and discuss the proposed priorities. If you'd like to come, please [reserve your place via Eventbrite](#). Tickets are subject to availability.

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

Dame Fiona has long championed the principles that there should be no surprises for individuals about how their health and care data is used and that they should be able to express preferences about how it is used. Essential building blocks of a trustworthy system include: 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 the use of their data.

Dame Fiona's 2013 review recommended: *“People must have the fullest possible access to all the electronic care records about them, across the whole health and social care system, without charge. An audit trail that details anyone and everyone who has accessed a patient's record should be made available in a suitable form to patients via their personal health and care record.”* Half a decade on, that benchmark of access is still not a reality for most individuals, even though data protection law also has requirements in this area.

We are pleased to see a number of projects, most notably the NHS App, taking forward plans to improve patient access to records. Given a growing acceptance among health and care professionals that individuals should become more active partners in managing their well-being, enabling patients to access and interact with information about themselves is more important than ever. Some patients may want to contribute information and to ask for corrections or amendments. The move towards a partnership approach over the management of records may require more active conversations about what is in a record and how it is maintained and protected so that it supports safe, high-quality care.

A significant step in enabling more patient control over data was taken in 2018 with the launch of the [National Data Opt-out](#). The NDG looks forward to the continuation of work to implement the opt-out. More proactive models have also been suggested under which patients who have access to data about their own health can make more decisions about sharing this information.

NDG areas of interest

- 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

Consultation questions

1. Should *giving people access and control of health and care data* be one of the NDG's top priorities?

Yes, provided there are caveats for the safeguards which must be built into all patient access models. These are set out in data protection legislation, namely that access can be denied when:

- it would be likely to cause serious harm to the data subject or another individual; and/or

- it gives information about a third party (other than a health professional involved in the care of the patient) unless the third party consents or it is reasonable in the circumstances to disclose without the third party's consent.

We would add a note of caution relating to the issue of the erasure of information from medical records. Under GDPR there are very limited rights for patients to erase or remove information from medical records where that information is clinically relevant. There are also sound patient safety and medico-legal reasons for non-erasure of relevant information. This does not, however, prevent doctors from receiving requests to remove clinically relevant information (for example where patients feel information might disadvantage them in insurance or mortgage application). In exploring attempts to provide patients with greater control over their data care must be taken to ensure patients are aware of the limitations on the right to erasure to avoid promoting false expectations.

Clearly patients (and all citizens) have the right to have factually inaccurate information corrected. Particular care needs to be taken when patients transition from one gender to another.

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

Yes

(Please tell us if there are other areas we should be looking at under this theme or if you think others are better placed to do this work)

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

We have nothing further to add.

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

Innovative uses of data which bring benefits for individuals and society are to be welcomed. The 2016 NDG review recommended “*The case for data sharing still needs to be made to the public, and all health, social care, research and public organisations should share responsibility for making that case*”.

Many of the new technologies which offer exciting prospects are data-driven, with patient data required for their development and implementation, sometimes in large volumes. In other areas, such as genomics, data may need to be pooled in a way that requires a degree of data reciprocity between individuals so that a wider group may benefit. We are seeing a growth in the use of digital devices away from care settings, in people’s own homes, which raises issues of data security and transparency. And there is also increasing interest in linking health and care information with other sources of data to support more intelligent, joined-up care and service provision. The involvement of commercial interests raises a layer of complexity to the safeguards that are necessary.

So there is an exciting, complex and diverse range of technologies and new uses of data emerging. 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 safeguards in place. Dialogue with the public about data use has not grown at the same speed as the capacity of technology. Where there is a gap between expectations and reality, anxiety may grow about the use of patient data to support innovation.

NDG areas of interest

- 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?

Consultation questions

4. Should *Use of patient data in innovation* be one of the NDG’s top priorities?

Yes. The collaboration between the Royal Free and *DeepMind* to develop the ‘Streams’ app is an example where developments in technology have led to an emergence of new ways of sharing patient information which had not previously been envisaged – with the added complexity of commercial involvement. We are aware that the challenges raised by ‘Streams’ are already a focus for the NDG and therefore do not need to be covered in this submission. It is, however, worth noting the recent announcement that the *DeepMind* Streams team would be absorbed by Google despite previous assurances that NHS patient data held by Streams would not be linked to Google products or services. The NDG will no doubt be aware of this development which reinforces the importance of this priority.

There needs to be increased public dialogue about what a patient might be signing-up to when accessing health services, with a focus on the difference between direct patient care and indirect care (or secondary uses of data). For example, automatic profiling based on flows of health data is something which patients are protected against under GDPR. However, we are concerned this is exactly what many of the new population health management tools are offering i.e. profiling patients into cohort groups. Where this leads to improvements in care this might be acceptable to patients (provided they know about it and there is a legal basis for this use). However, where such profiling is a cost-saving exercise with little or no benefit to patient care (or at times adverse effects on patients) it is likely that an increasingly data-driven world will fail to win patients' confidence and trust.

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

(Please tell us if there are other areas we should be looking at under this theme, or if you think others would be better placed to do the work)

We think the NDG could contribute to public debate about the benefits of participation in research. It is important that the public has a good general understanding of how research can be used for the continuing improvement of healthcare, public health and are supportive of such work (with the right safeguards in place).

The NDG could also contribute to public debate about genomics and genetics, including data sharing and the degree of control that individuals have over how data are used and shared.

The use of health Apps is another area which requires more public debate – specifically, the question as to whether patients know and understand what happens to their data when they use such apps.

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

It would be helpful for NHS trusts to have guidance on their legal obligations – both under GDPR and the common law – when approached by technology companies who are looking for access to patient data for the development or testing of their products. The NDG could provide – or commission – guidance in this area. It might be useful if this work could be a joint enterprise with the Information Commissioner's Office.

The BMA is currently involved in discussions about a replacement framework for the General Practice Extraction System (GPES). We are unsure if the NDG is involved in these discussions. We support a single framework or 'one stop shop' which organisations can use to access datasets. This would remove the burden from health providers from dealing with numerous requests. It also provides for a consistent approach which can ensure the appropriate safeguards and 'checks and balances' are in place for access to confidential data.

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

Meanwhile, in spite of the improvements that more sophisticated technologies are bringing and will bring, it is also too often the case that data is not good enough, available enough, joined-up enough or shared enough to support individuals' care.

There is a range of factors contributing to this situation. It is disappointing to observe that some of them persist in spite of having been identified in Dame Fiona's 2013 [Information Governance Review](#): lack of sharing across organisational boundaries; lack of confidence among those working in the system about their responsibilities; and uncertainty about sharing with non-regulated staff providing care, particularly within social care.

Nonetheless, it is encouraging that there is a range of initiatives being taken forward across the system to encourage appropriate sharing in line with the seventh Caldicott Principle introduced in 2013: *"The duty to share information can be as important as the duty to protect patient confidentiality."*

NDG areas of interest

- 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

Consultation questions

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

Yes. In relation to the point about working with bodies leading on education we would recommend that guidance is written in collaboration with regulators and indemnity bodies and then made widely available.

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

(Please tell us if there are other areas we should be looking at under this theme, or if you think others would be better placed to do the work)

Yes.

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

We hope that the NDG will be involved in the development and implementation of Local Health and Care Records (LHCRs). We hope that LHCRs can bring increased co-ordination to sharing for direct care whilst operating within the boundaries of implied consent and 'no surprises' for patients about who has access to their medical record. One of the key issues in this debate is recognising the difference between making medical records on patient populations accessible across geographical

(or organisational) boundaries without a legitimate relationship (LR) being established compared with making a record accessible only when a LR has been established for an individual patient. In our view, if a LR has not been established the patient's consent for their record to become accessible across an organisational or geographical boundary cannot be implied (with the exception of local out of hours services).

Health care professionals should only view medical records when they are providing direct care, and a LR is created at this point. We are concerned about the initial lawful and ethical basis for making the record widely accessible which occurs prior to the creation of an LR. We believe that is unlikely that patients would expect their record to be accessible across numerous organisational boundaries or geographical regions unless they have an LR with the relevant organisation.

Priority 4: Safeguarding a confidential health and care system

People using health and care services must feel able to discuss sensitive matters with a doctor, nurse, social worker or other member of their care team knowing that information they have provided will not be improperly disclosed.

The importance of this expectation, and the duty of confidentiality that arises from it has been enshrined in common law and practice over many years and runs through the work of the National Data Guardian. During 2017 and 2018, the NDG and her panel considered the role that patients' reasonable expectations about the use of their data might play in shaping the boundaries of information sharing.

The new Data Protection Act 2018, along with General Data Protection Regulation (GDPR), has a positive emphasis on individual rights, on the duty of transparency and helpfully clarifies statutory legal requirements for the processing of data.

Where confidential health and care information is being used and shared, the requirements of both data protection law and the common law duty of confidentiality need to be respected. In many respects these are complementary, placing respect for the individual and the need for 'no surprises' for the individual at the centre. However, the NDG and her panel have observed some confusion about the need to respect both data protection law and common law, in particular with regard to the differing consent requirements of these areas of law.

NDG areas of interest

- 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

Consultation questions

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

Yes, we believe this priority lies at the heart of the role of the NDG.

Safeguarding the principle of a confidential health service – and being seen by the public as performing this role – is highly relevant given recent trends in national policy and the law. As the NDG will already be aware, there have been various and repeated attempts by governments and policy-makers to lower established standards of confidentiality, erode patients' rights in this area and undermine the trust relationship between doctors and patients.

We recognise that such attempts can be grounded in the laudable aim of improving health services, however, they are usually accompanied by a lack of regard for the strong public interest in maintaining a confidential health service and with little thought as to the detrimental consequences should confidentiality be undermined.

The NDG is already aware of, and has intervened in, the most recent examples where the principle of confidentiality has been threatened:

- the Memorandum of Understanding between the Department of Health and Social Care (DHSC), the Home Office and NHS Digital (MoU); and

- the current debate about the definition of ‘confidential patient information’. The BMA and others, including the NDG, are opposing attempts by government to categorise patients’ demographic information as information which does not attract a duty of confidentiality. This is contrary to professional and ethical guidance which treats names and addresses as being confidential within the health service. We believe this approach is in-line with patients’ expectations when they provide their name and address, in confidence, to their GP practice or other care setting.

It is important to remain vigilant to ensure further attempts to undermine confidentiality are challenged. We strongly welcome the role and intervention of the NDG in this area. The benefits of the independence of the NDG which enable her to challenge the government are already apparent, most obviously the interventions relating to the MoU.

The NDG has already mentioned the existence of confusion between data protection law and common law. We agree with this observation. Confusion over the interpretation of the rules of medical confidentiality exists in a number of areas and it is often the case that policy-making organisations, or those producing guidance, can themselves aid confusion - the DHSC’s recent position in classifying demographic data as non-confidential being the most obvious example. If patient and public trust is to be built and maintained it is important that organisations do not attempt to change established presumptions which are understood by both patients and healthcare professionals. This only serves to add to confusion and builds mistrust.

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

(Please tell us if there are other areas we should be looking at under this theme, or if you think others would be better placed to do the work)

The NDG has an important contribution to make to ensure the NHS Confidentiality Code of Practice is fit for purpose, in particular in relation to the confidentiality of demographic information and the controls on disclosures in the public interest. As mentioned above, the NDG must also make appropriate high profile interventions when confidentiality, privacy and trust are threatened – as has, for example, been the case under the MoU. Confidentiality is clearly vital for all patients, but we must be particularly vigilant in protecting the confidentiality of marginalised groups – immigrants, refugees, asylum-seekers, the homeless et al – else trust in the NHS, in confidentiality and in the doctor-patient relationship will be undermined, to the detriment of individual and public health.

Finally, we are awaiting consultation on regulations under the Digital Economy Act 2017. This Act set aside the common law duty of confidentiality to permit sharing of health data amongst public bodies, including NHS Digital, without consent. We assume the NDG will have a key role to play when the consultation is published. Depending on the outcome of the consultation process it will be important to provide clarity for providers on their obligations under this new legislation.

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

No further comments.

Additional consultation questions

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

No.

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

No. We believe these priorities are the correct priorities and we welcome the NDG's involvement in these areas.

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

How to respond

You can respond to the consultation [online here](#) or by emailing the ndgoffice@nhs.net by **Friday March 22**.

Your response will be most useful if it is framed in direct response to the questions posed, though further comments and evidence are also welcome.