

National Data Guardian for Health and Social Care: a consultation about priorities 18th February 2019

This note provides evidence from the Royal Statistical Society (RSS) to the consultation into the priorities of the new National Data Guardian (NDG), under the first statutory office holder, Dame Fiona Caldicott. This submission is based on contributions from members of the RSS Medical Statistics Section and we are very grateful for their input.

The RSS is a learned society and professional body for statisticians and data analysts. We have around 10,000 members worldwide, but the majority of our membership is UK-based.

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

Since the publication of our Data Manifesto in 2014, increasing access to data for all users, including personal data, has been one of the RSS's priorities. We will continue to support steps to improve the accessibility of data and welcome the NDG's recognition of the importance of access to personal health data.

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

The RSS, principally, welcomes the NDG ensuring people have 'access' and 'control' of their own health and well-being, in the form of data. There is some difficulty, however, in fully understanding what is meant by 'control'; 'sovereignty' is likely to be more appropriate, in this context. Further clarification of the terms used is important and would allow patients and other individuals to fully understand the NDG's priorities and what outcomes are to be expected as a result.

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

The Society broadly agrees that the priorities outlined are the correct ones. However, we recommend that the NDG implements a preceding step, to help achieve the outlined areas of interest.

This step should explore how the set areas of interest are to be implemented on a small-scale. This would help to determine the potential impact on a larger scale. For example, pilot projects managed by Connected Health Cities show what the UK can achieve. Connected Health Cities' North West Coast pilot has implemented new consent systems that allow health professionals to use data to improve the care that patients receive, as well as using data linking to continuously update and improve this system. The importance of local clinical engagement is highlighted through these projects. They have also taken steps to encourage public involvement and trust in health data. This could act as a basis which the NDG can build upon.

The transparency of tailored information, including how it has been used and by whom, is crucial and should have structured levels of detail, including links to relevant technical and academic publications. Former RSS President, Sir David Spiegelhalter, outlined a view that for data to be transparent it must have the following four features: the data must be accessible, assessable, intelligible and usable. All tailored information should have these features incorporated to a sufficient level of detail to ensure that data is truly transparent for the user.

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

The focus of Priority 1 on individuals, given the requirements of data protection laws, is necessary. In a growing era of Big Data innovation, however, a common good approach to data should be included in all NDG activities; a partnership approach should include treating individual members of the public as also being responsible members of a community.

The NDG should seek to engage local clinical groups across the country to meet a high national standard for data access, in the long-term. We believe that this approach would champion the sharing of good practice and clear advocacy of patient expectations. An example of data sharing standards is the GUILD standard, now adopted by Office for Statistics Regulation and the Government Statistical Service in terms of information linkage for research.¹ Other good practice can be seen in the plain language summary required on the research uses of data, approved by Managing Ethico-social, Technical and Administrative issues in Data Access (METADAC).

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

The RSS recognises the value of public engagement and ensuring the public are informed and involved in decisions. However, creating a dialogue with experts, who use the data first-hand, including statisticians and data scientists, should not be overlooked as crucial stage. When setting the boundaries for data uses, the RSS acknowledges that a balance must be struck between public engagement in the decisions that are made and ensuring the NDG is well-informed with the expertise required.

¹ R. Gilbert, *et. al.* (2017), 'GUILD: GUIDance for Information about Linking Data sets', *Journal of Public Health*, 40:1.
<https://academic.oup.com/jpubhealth/article/40/1/191/3091693>



It is important to recognise that 'reality' is complex and constantly changing. This is especially true in the current political climate in the UK; as a result, the data are behaving in much the same way. We recommend the NDG, first, opens a dialogue with experts/researchers, before approaching the public. This would allow the NDG to develop a better understanding of 'reality' in order to have a well-informed dialogue with the public in the future. The NDG should aim to give a realistic view of what can be achieved and the time-frame in which the public can expect these changes to be implemented. It is somewhat unrealistic to assume that we will be able to fully 'match reality' to public expectations and a compromise may have to be sought.

4) Should 'use of patient data in innovation' be one the NDG's top priorities?

The role of the NDG as a guardian, as opposed to an industry regulator, provides an opportunity to harness the use of data in innovation. With this as a top priority, the NDG can further encourage new innovation. Gaining a better understanding of a patient's journey by using a host of technological innovation should be a priority at both a national and a local level. However, a priority such as this will need to have a clear strategy to determine how the data is processed and to whom it is accessible, especially in light of the Cambridge Analytica scandal. The NDG should look to establish a governance role in data innovation. Once the boundaries for the uses of the data have been set, through expert and public dialogue, the governance role would encourage continued good practice.

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

Health applications and similar technology represent only one aspect of innovation. The RSS believes that the NDG requires a broader understanding of innovation, to include aspects such as the efficiency of service provisions, as part of data linkage work to establish where links in routine data have greater potential benefits, and where existing systems are creating potential obstructions.

In addition, the Society recommends the NDG continue to closely follow and contribute to empirical studies that identify the public opinions on the use of data, as these opinions are likely to be dynamic in nature, in line with the big data era, rather than static.

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

One of NDG's interests in this area is posed as a question - 'is there understood to be a reciprocal relationship, whereby those receiving care should allow data usage?' This is an ethical question of considerable complexity; the question must be addressed by working together with a wide range of disciplines and stakeholders to avoid a lack of coordination and potential derogation of aspirational ethics standards.



It is unclear what is meant by 'reciprocal relationship'; the notion of 'reciprocity' can be termed 'solidarity'. In our view, 'solidarity' is much more relevant to the use of data in the health sector, where a single person's data is not of interest. The NDG needs to shift its focus from the benefits to individuals to focusing on delivering specific services, such as health apps. Statistical use of data in innovation is about to become diffuse with potential health benefits across populations. We have noted that this has not been featured in public conversations to date. The NDG should address this as a national issue, working with partners such as the Faculty of Public Health. At a local level, organisations could request support directly from the NDG.

Proposal 3: Getting the basics right – information sharing for individual care

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

Guiding organisations to look at the overall picture of a patient's journey, beyond the organisation's own data, is crucial to improving the public's confidence in the handling of data in those organisations.

Much like the NDG's 'data in innovation' priority, in practice it likely that the NDG will need to play a governance role. Low-level interventions to ensure that organisations are using, and interpreting, data correctly is important to properly safeguard patient data. This would be another opportunity to promote and share good practice. The pathfinder project, the Great North Care Record, is a fantastic example of where this is working well. It allows clinicians and trusts to share data and good practice across the North East and North Cumbria. Sharing good practice is much more likely to drive improvements than top-down interventions. Higher-level interventions to ensure managers and directors have sufficient education and knowledge of the benefits and risks of data sharing may be necessary, if the Chief Clinical Information Officers (CCIO) Network has not taken on this role.

The NDG should focus its efforts on the governance of the growing system for data sharing. The evaluation of the barriers to sharing data for individual care should be a part of any review of the Caldicott guidelines that the NDG undertakes. There needs to be clarification on specific areas of the guidelines, as highlighted throughout our response. However, the Society believes it is not necessary for a full review of the Caldicott guidelines to be a 'top' priority, at present. The NDG should first focus its efforts on establishing continued good practice nationwide and consider reviewing the guidelines as a lesser priority.

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

The NDG, as part of its endeavour to promote good practice, should seek to train the existing workforce, at all levels, on the handling and sharing of data. Within this, simplification of technical language should be a focus to ensure the accessibility and usability of both the training and the data itself.



There is a risk, also, that increasing data sharing between organisations would put additional strain and increase the workload of NHS staff. The NDG should be aware of this risk and look to address any concerns over staff workloads. It would also be useful for the NDG to clarify other implications that this may have on the workforce.

Finally, the seventh Caldicott guideline states ‘the duty to share information can be as important as the duty to protect patient confidentiality’. This guideline must be differentiated to consider not only sharing individual data, but also the sharing of big data in relation to individual patients.

Priority 4: Safeguarding a confidential health and care system

10) Should ‘safeguarding a confidential health and care system’ be one of the NDG top priorities?

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. It is important to have reasonable expectations for organisations to uphold. However, these expectations should be reasoned with a positive or desired outcome for the data in mind, as opposed to imposing arbitrary procedures. It is also important for the NDG to continuously converse with other organisations responsible for safeguarding health data, such as NHS Digital, Public Health England and the Health Research Authority, to ensure coherence across the sector.

Crucially, an increasing problem is the confidentiality of patient data being broken internally by healthcare staff. This is reported by the media in major cases, or where the patient is well known in the public domain; however, it is almost certainly a wider problem than indicated by these cases alone. If such cases become increasingly common, the problem represents the kind of issue that Priority 1 suggests will be avoided. The NDG needs to be vigilant and review systems that monitor inappropriate access internally. However, to avoid pre-existing procedures being seen as sacrosanct by healthcare professionals, the NDG should also be careful not to penalise simple mistakes or, in contrast, penalise over-vigilance too harshly.

11) Are the outlined areas of NDG interests the right ones for the NDG under this priority?

As stated above, this priority is especially relevant to NDG’s remit as a guardian. Further clarity would be welcomed on specific tasks the NDG would look to undertake in the future.



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

Based on the seventh Caldicott guideline - 'the duty to share information can be as important as the duty to protect patient confidentiality' - the NDG should aim to include the sharing of big datasets under a protection framework. Work needs to be done on implicit consent, waivers of consent and the possible applicability of community assent models regarding population or population strata level 'big data'.

Anything implemented for use by the NDG should be simple to use or follow and have a significant level of transparency, for both patients and professionals.

The NDG also needs to ensure that researchers understand the concerns and expectations of patients and oversee a realistic compromise and alignment of the research with what patients are willing to accept.

Additional consultation questions

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

Whilst the NDG is not a regulator, the regulatory landscape for data is at risk from becoming overcrowded. Alongside coordination with other bodies on 'safeguarding health data', the NDG should coordinate with organisations within the regulatory landscape, such as the Centre for Data Ethics and Innovation, to avoid duplication and promote further sharing of good practice.

The new Ada Lovelace Institute provides an exciting opportunity for the NDG to pass on some concerns and open the debate on a deeper, more public level. The RSS believes that data has the ability to transform our future and have a positive impact on our society. However, there is work to be done to improve the way in which data are currently presented. This requires human interventions to ensure that current good practice is reflected and implemented across multiple sectors and domains. Health data are already artificially separated from other data. The NDG should make conscious efforts to close this gap; without this, the NDG risks exacerbating the situation.

The RSS would encourage the NDG to clarify a position, in the future, on the following areas:

- a) There are ongoing discussions surrounding the concept of 'big data' and how it should be classified. There are also intrinsically linked discussions that are aiming to establish whether 'ownership' of data is an appropriate term or whether 'stewardship' might be better suited. This debate discusses, among other issues, whether 'big data' and other data sources should be considered an asset, a resource or a public common good, *et cetera*.



- b) The NDG should aim to base all its future activity on a transparent, accessible statement of its position on the crucial data ethics questions: under what circumstances should state agencies provide public data to commercial enterprises and how should this information be disseminated?

- c) Big data is increasingly becoming a starting point for health research. Innovative methodologies start from large data sets that are then analysed to identify individuals. Thus, predictive big data is becoming increasingly individualised; even 'anonymised' data should have a set of specified sensitivities. A central distinction has been made within data guidance and legislation between personal and non-personal data. Personal data demands a higher level of ethical oversight and regulation than non-personal data. There is no question that this distinction is ethically relevant, but the distinction will need to be revisited as data technologies evolve. The NDG should engage with these questions and those involved in beginning to answer these crucial questions; this will continue to be an increasingly important issue.

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

Priority 2 seems to be primarily focused on directly attributable services and benefits that could, in practice, stifle the innovation that Priority 2 actually seeks to bring about. Our concerns around the simplicity of the NDG's understanding of data in technological innovation should be addressed and Priority 2 needs to be rewritten to reflect broader innovation ideas, as opposed to focusing exclusively on health apps and related technology.

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

Studies and in-depth evaluations would need to be carried out before the implementation of new system integrations or other changes. Researchers and experts could play a valuable role in assisting this evaluation. Undergoing these evaluations will help to identify potential flaws in a system before it is implemented on a large-scale, establish lessons to be learnt and, critically, ensure that patient data and its users are protected to the best possible standard, whilst maintaining accessibility.

