

Response ID ANON-BFCS-3RRC-R

Submitted to **The roles and functions of the National Data Guardian for Health and Social Care**
Submitted on **2015-12-17 09:12:16**

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4 Are you responding:

As a member of the public, as a health or social care professional, on behalf of an organisation:

On behalf of an organisation

5 If you are responding as an individual, what is your gender?

If you are responding as an individual, what is your gender?:

6 If you are responding as an individual, what is your age?

If you are responding as an individual, what is your age?:

7 If you are responding as an individual, what is your ethnic group?

what is your ethnic group?:

8 If you are responding as a member of the public, please supply the following details, are you:

Are you a patient, service user, carer, family member, interested member of the public, a retired professional, other?:

9 If you are responding as a health or social care professional, what is your area of work?

If you are responding as a health or social care professional, what is your area of work?:

10 If you are responding on behalf of an organisation, please supply details:

If you are responding on behalf of an organisation, please supply details::

BCS PHCSG

(British Computer Society Primary Healthcare Specialist Group)

Consultation questions

11 1) The Government proposes that: the remit of the National Data Guardian for Health and Social Care role should follow the health and care data.

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

The PHCSG agrees with this, but the remit should be the data rather than named organisations and must be very clear.

We believe that the remit of the NDG should include the processing of all English personal confidential health & adult social care data, where "processing" includes its collection, processing, sharing and publication, generated during the provision of public and privately funded care to patients, and any subsequent processing of it for secondary purposes by any organisation or individual, whether by NHS, academe, charities or commercial organisations. The guidance should apply wherever the processing occurs, including outside the UK/EU.

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

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

Although Children's Social Care falls under a different legislative and regulatory framework, there is overlap with their healthcare as child healthcare data would be covered by the proposed remit of the National Data Guardian..

PHCSG suggests that the relationship between children's social care and healthcare should be further studied with a view to incorporating the advice and guidance given by the NDG on the management of health & social care personal data into children's social care in the future, but that until there has been further evaluation of the situation, no firm decisions should be made at present, and establishing the role of the NDG vis a vis adult health and social care data should not be delayed on this account.

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

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

PHCSG support the NDG giving guidance to all organisations holding personal confidential health and/or social care data, wherever the data goes. However, giving detailed advice on the implementation of the guidance to many different organisations would overburden the NDG and probably overlap the functions of other organisations.

In regulated organisations there needs to be clarity on who provides detailed advice, in order to prevent confusion.

Clarity on the government's thinking on this would be welcome: if the NDG is to provide detailed advice to numerous organisations, this would create a risk of her strategic functions becoming sidelined, and would require much more in the way of resources.

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

Any regulators with a responsibility for overseeing organisations which routinely hold, use and share health and care data, should consult the National Data Guardian on the criteria they use to assess an organisation's use of data.:

The NDG should issue guidance on the criteria regulators and other organisations (such as Monitor/Trust Authority/successor body, NHS England and HSCIC) use to assess the processing of data by regulated organisations and elsewhere, including the release of such data from the regulated organisations, and this guidance, whether the data is for direct patient care or "secondary uses" needs to be consistent and comply with statutory requirements and the guidance issued by ICO.

The guidance needs to be in the public domain and consistent for different organisations in the interests of transparency and to ensure consistency in the demands placed on regulated organisations and regulators.

Consultation with the ICO is desirable.

Regulators should demonstrate, in their and the NDG's Annual Reports how they are conforming to the advice and guidance issued by the NDG and to any concerns she has expressed.

There may be slightly different guidance where the data is shared for direct patient care, where it is to be shared for management of the NHS and/or social care, and where it is released for innovation or research

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

Organisations holding health and care data which could be used to identify individuals should be required to publish all materials demonstrating how they have responded to advice from the National Data Guardian.:

Organisations holding health and care information which could be used to identify (or re-identify) individuals should publish details of how they are incorporating guidance issued by the NDG and include this in their annual reports.

Organisations holding health and care information which identifies, or could be used to identify individuals should publish on their website, in a timely fashion - and as directed by the NDG - any advice received from the NDG and their response to such advice, , and refer to it in their annual reports.

The opportunity should be taken to highlight good practice as well as responses to criticism.

"all materials" is a vague term and requires clarification.

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

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

The PHCSG suggests that advice given and responses to such advice should be published on the NDG website in a timely fashion and only summarised in her Annual Report.

The Annual Report should include an overview of progress (or otherwise) and any trends identified, and also highlight identified good & bad practice.

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

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

The relationship between the roles and accountabilities of the NDG and other bodies including the CQC and ICO need to be clear both to the organisations involved and the public. This includes but is not limited to the role of the NDG in referring to other bodies, and the response required from them.

All versions of Memoranda of Understanding should be clear, in the public domain, dated and any planned review dates published.

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

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

This would appear to add a policing role, i.e. the management of individual offences, to its primary task of providing strategic advice.

There are already many channels for management of data breaches or misuse by individuals, and making the NDG responsible for this would lead to further confusion and duplication of existing management of data breaches by individuals.

It is also not clear from this whether the government would expect the referral from the NDG to take precedence over the normal requirements and procedures of the professional regulator(s) or to create offences which are additional to normal professional requirements.

In view of the existing pathways and the NDG resources required to do this task, PHCSG suggest that this is not an appropriate role for the NDG.

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

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

The role of the NDG is to provide guidance and advice on the collection, sharing, release and use of personal confidential data to organisations.

This question is not clear: is it expected that the NDG will be charged with regulating or advising individuals - as opposed to organisations - on the management of health and care data?

Many professionals - e.g. in management and IT - are not statutorily required to be registered with a professional body, and if the NDG is to issue binding advice to such individuals - as opposed to the organisations in which they are employed - it is hard to see what sanctions could be legally applied to ensure conformity. We would suggest that, as with question 8, the role of the NDG might include guidance but that the resources of the NDG and her supporting organisation should not be stretched by dealing with individuals.

If the government wishes to involve the NDG with monitoring individuals, there would be considerable organisational and workload - and therefore funding - implications which should be examined before any decision about it is made.

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

How the National Data Guardian and regulators can maximise the appropriate use of existing sanctions and fines. :

The role of the NDG is to provide guidance on good practice and that of the regulators to ensure the guidance is followed, and where it is not to apply any sanctions that are appropriate.

Having to apply fines or sanctions suggests a failure in the system - although the existence of fines and sanctions is necessary - as is the expectation that they will be applied and enforced.

Sanctions need to be available, and to be applied consistently to ensure the deterrence of data misuse.. For example what sanctions exist for breach of the conditions in a s251 notice issued by CAG, how should they be enforced, and who should enforce them?

It is not clear from this question whether the government expects the role of the NDG to include disciplining organisations failing to follow her guidance, but as this is already the role of the regulators and ICO, more clarity on the government's thinking on this would be welcome.

The consultation document only refers to the CQC and ICO: we feel that Monitor and the Trust Authority (or their successors) should also be included.

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

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

In principle, the NDG and support team should not be housed in any organisation expected to receive advice from (or be called to account by) the NDG.

This would include among others NHS England, the HSCIC, CQC, Monitor/Trust Authority or their successor bodies.

As the Secretary of State for Health has the power under the Health & Social Care Act to direct the collection and dissemination of personally identifiable information, it would seem logical to have the NDG and her office report directly to Parliament (or the Chief Medical Officer) rather than to the Secretary of State for Health or the Department of Health. Therefore establishment as an Advisory Non-Departmental Public Body seems the most appropriate option.

In order to maintain the independence of the NDG, consideration should be given to plans for future appointments, lines of accountability and the management of the support team and secretariat. None of these should be under the direct or indirect control of any organisation falling under the remit of the NDG

22 12) The Government proposes that: the National Data Guardian's annual report should include a section demonstrating how the National Data Guardian has sought and gathered the views of the public and how those views will inform work in the future.

The National Data Guardian's annual report should include a section demonstrating how the National Data Guardian has sought and gathered the views of the public and how those views will inform work in the future.:

This proposal raises significant questions that need answering before the PHCSG can respond fully to it:

(a) Why is an annual public consultation needed?

(b) If the function of the NDG is to provide advice and guidance to organisations sharing and/or processing personal confidential health and care data and their regulators while providing protection for the individuals to whom the data relates, how would this be improved by gathering the views of the public by unspecified means on an annual basis?

(c) How will the topics for public consultation be decided? Will they vary from year to year?

(d) What measures will be taken to ensure that the conclusions of any consultation are representative of the public as a whole?

(e) An annual public consultation giving representative (and so worthwhile) results will be expensive. Where will the funds come from?.

There should be a means for the individuals and organisations to communicate with the NDG, but it is unlikely (and generally undesirable) that her strategic guidance would or should be altered by them. However periodic and representative sampling of stakeholder opinion (including the subjects and controllers of the data concerned) could be used by the NDG to make proposals for changes to the legislation and/or standards governing the processing of personal confidential

health and social care data.

If the remit of the NDG were to be revised annually in response to public input from organisations, there is a risk that the views of parties with an interest in acquiring health and social care data will be over-represented - and given more weight - than the views of those wishing to protect the data from potential misuse and/or re-identification. We would welcome clarification of the government's thinking on this, including how lobbying from interested parties would be addressed. In the interests of transparency, all public opinion collected and communications from individuals and bodies should be published, with appropriate steps taken to conceal the identity of individuals (but not organisations) if they request it.

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

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

There needs to be a clear understanding of the roles of the NDG, CAG as advising the HSCIC, and the HSCIC per se, and which organisation's requirements take precedence. The HSC Act 2012 charges the HSCIC with producing a code of practice on the processing of confidential health & social care information (s263) and providing "guidance on any matter relating to the collection, analysis, publication or other dissemination of information" (s265), which seems to overlap with the responsibilities of the NDG. However s271 of the same Act permits the HSCIC to arrange for any other body to perform any of its functions, and so it would be possible for the HSCIC to ask the NDG to take over responsibility for its s263 and 265 obligations.

We would suggest that the powers of NHS England and the Secretary of State for Health to direct the HSCIC to collect and distribute personal identifiable data under the Health and Social Care Act 2012 should also be considered in this context.

Any agreement should be formalised and published, including the frequency of review if considered necessary.

The PHCSG observes that the GPES IAG (General Practice Extraction Service Independent Advisory Group) was abolished on 30th June 2015, and the proposed replacement of its functions with IGARD (Independent Group Advising on the Release of Data) and an expanded SCCI (Standardisation Committee for Care Information) to consider and approve data extractions from general practice are not yet in place. As stated in our response to Q1, we believe that collections of data from care providers (including general practice) are within the remit of the NDG. We would welcome clarification on the mechanisms by which data processing proposals - including data collections - will be subject to independent scrutiny in the future, and whether such scrutiny will be included in the remit of the NDG.

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

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

The PHCSG agree, but many bodies processing confidential patient data outside the health and care system, including large commercial organisations, SMEs and individuals developing innovative approaches to healthcare, will not fall under any regulatory regime, other than that of the ICO and the legislation under which he acts, i.e. the DPA 1998 and the common law duty of confidentiality.

Assuming that personal confidential health and social care data will be released to non-regulated organisations and individuals, the NDG should ensure that their advice and guidance makes the recipients' obligations vis-à-vis the data clear. These obligations should be stated in any data sharing agreements and legal contracts made between the discloser and receiver(s).

However, if innovation by SMEs and charities is to be encouraged, data sharing agreements and contracts should not be overly bureaucratic or costly.

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

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

The role of the NDG is to protect the public and individuals in the management of personal identifiable health and social care data, both for direct patient care and for secondary purposes, however defined.

Data sharing for direct care of individual patients has always been a professional obligation. New situations where the sharing is on a population basis - i.e. sharing the personal information of all the patients in a practice - or hospital - with all the other organisations which might be involved in care of one or more of those patients in the future is a different scenario and requires different safeguards. Patients need to have the right to refuse to having their data shared in this way.

Unfortunately, some groups are likely to exercise their rights to refuse sharing of their data for either direct care or secondary uses e.g. travellers, and this could have the impact of under-representation of such groups for secondary uses and in the provision of services.

If patient objections are to be recognised and respected (as they should be) it may be difficult to avoid the impact of such objections.

26 16) Do you have any comments or views on the potential impact that these proposals have on the potential for additional administrative and financial burdens?

Do you have any comments or views on the potential impact that these proposals have on the potential for additional administrative and financial burdens?:

The implementation of these proposals is bound to create extra administrative and financial burdens.

If this role is to be established by statute, consideration needs to be given to the manner in which future National Data Guardians will be appointed, their expected duration of service and the TOR of the NDG and supporting organisation, including how the supporting team are recruited, the appointment and funding of the secretariat, and lines of accountability.

If the role is to function properly, there will be a considerable financial and administrative burden on the office of the NDG and, most importantly, on those required to follow - and demonstrate that they have followed - the guidance of the NDG.

This might be mitigated if a clear framework were to be developed outlining the functions of all the organisations providing advice and guidance on the management of health and social care data and the regulators and organisations which have the responsibility of ensuring that the guidance and advice are

implemented and embedded in the organisational systems. The rationalisation of the bodies responsible for creating information governance guidance and advice and monitoring its implementation would help keep extra costs down

Such a framework would also have the advantage of avoiding duplication of (possibly conflicting) guidance, and - because of clarity - encouraging and enabling compliance.

In addition, if the advice and guidance given is to be observed, it will be necessary to have a clear means of ensuring that the advice has been followed, and that any sanctions available are actually applied, which will be an additional consequential cost in the system.

(e.g. CAG has standard conditions for s251 approval: however, if these are not observed, there is no mechanism for applying sanctions or rescinding the s251 consent)