Response ID ANON-Y7XR-JT1G-G

Submitted on 2015-08-31 14:35:13.599608

About You

1 If you are responding to the HSCIC letter, please state your name and organisation:

My name is::
Dr Mary Hawking

My organisation is::
BCS PHCSG (Primary HealthCare Specialist Group)

2 If you are not responding to the HSCIC letter, please tell us about yourself:

Not Answered

Organisation name::

3 What type of organisation do you work for?

Not Answered

Other::

4 What kind of role do you have?

Not Answered

Other::

Scope and Purpose of IGARD

5 Please indicate your level of agreement with the following statements:

IGARD's primary purpose is appropriate:
Not Answered

IGARD's secondary purpose is appropriate:
Not Answered

Please provide any comments you may have about the above text and/or statements::
1. IGARD will consider data being released from the HSCIC: it appears from the TOR that it will not consider data requests when the data is to be processed within the HSCIC to produce new datasets e.g. by linkage of existing datasets held by the HSCIC, linkage of HSCIC datasets with datasets held by others or creation of new data collections for linkage. Will this lie within the remit of IGARD, and if not, who will scrutinise such requests?
2. under "primary purpose" there is no mention of any action to be taken following the consideration of the data release request. We would suggest clarification, including whether IGARD will suggest conditions or considerations (the GPES IAG could make three kinds of recommendations – proceed ;proceed with considerations; make major changes or reconsiderations – each of which could have detailed considerations attached) and if so, where and how the final recommendation will be recorded including whether the recommendations were accepted by the HSCIC and action taken; and if not, the reasons for the rejection.
3. Under "secondary purposes" it is not clear whether the "processes, policies and procedures" will be established during the planning of IGARD, or whether IGARD itself will develop them after it is formed.
4. Could "transparency measures such as registers" be clarified? If public confidence is to be earned, the public will need to be able to see what data has been requested, , the purpose for which it was requested (and how this is in the Public Interest) and how it will be managed to minimise any risk of the data falling into the wrong hands, be used for other than the stated purposes, and to prevent the risk of re-identification. This is not currently available for applications approved by DAAG.
5. Separation of the dissemination and collection parts of the process may lead to difficulties in assessing the validity of the consent under which the data was originally collected, and the limitations on use in the original consent, as well as leading to difficulties in 'fair processing' when the ultimate use of the data is unknown – or may be expected to be retrospectively altered – at the time of data collection: how will this be addressed?

Membership

6 Please indicate your level of agreement with the following statements:

An independent chair is appropriate:
Not Answered

It is correct that the independent chair be recommended by the National Data Guardian:
Not Answered

The proposed observer positions are appropriate:
Not Answered

The proposed balance of individual members and HSCIC staff members is appropriate:
Not Answered

The members of IGARD will be drawn from a suitably wide range of backgrounds and interests:
Not Answered

Please provide any comments you may have about the above text and/or statements::
1. The membership does not include any public or lay representation: public or patient representation would be essential to encourage public confidence.
2. The 'independent members' will be recruited for a. expertise in particular fields and b. "with an interest in the domain" ("domain" is unspecified: is it the Health and Social Care system, use of data, information governance, privacy or something else?) Clarification would be useful
3. Seeing the expertise required for the independent members, the field for recruitment is likely to be limited. More detail on how potential members will be identified and recruited is essential. Would working for either organisations with an interest in data acquisition or HSCIC/NHS England be a barrier?
4. The time commitments will be considerable: at present DAAG meets every two weeks and it seems probable that the workload will increase rather than decrease. This is also likely to limit the pool of potential applicants and increases the risk that successful applicants and/or their employing organisations will have some interest in the outcomes of applications considered.
5. The Independent members terms and conditions have not yet been written. We would suggest that the posts will require remuneration and funding for back-fill: without this the membership will be limited to those who can afford to donate considerable time – i.e. retired or with independent means and interests in the work - or who work for an organisation prepared to allow them to donate work-time to IGARD: both situations would tend to risk bias in the membership.
6. In what way will the HSCIC members function as "subject matter experts" (unless "subject matter" is defined as knowledge of the data held within the HSCIC and how it could be manipulated e.g. by linkage)? The data requested is likely to be for wide and varied purposes, and it is unlikely that the HSCIC Caldicott Guardians will have the necessary detailed knowledge for all of the data applications. If detailed expertise/knowledge is required, how will it be provided?

Ways of Working

7 Please indicate your level of agreement with the following statements:

The proposed ways of working are appropriate:
Not Answered

The proposed transparency arrangements for sharing applications / minutes are appropriate:
Not Answered

It is appropriate to use the Chatham House Rule:
Not Answered

Please provide any comments you may have about the above text and/or statements::
1. Attendance of Observers. These may be invited by the Chair or Deputy Chair, and External Observers must register their wish to attend at least 5 working days before the meeting. Does this mean that the agenda and papers for the meeting will be publicly available at least 5 days before the meeting? If not, how will potential external observers know that the applications in which they have an interest will be considered at that particular meeting?
2. "To ensure transparency, applications received into IGARD and minutes from the meetings will be available on the HSCIC website not more than ten working days after the meeting date." This commitment is very welcome – but how will matters which may be commercially confidential be recorded for the public and in the interests of transparency?
Publications if applications should include all the information provided by the applicants to IGRAD, including a full list of the data types and structures required by them. Commercial secrecy should not be allowed to turn what is published into meaningless gabble:. The minutes must include the detailed recommendations made by IGARD, and ultimately the acceptance or otherwise (including why) of the recommendations to the HSCIC.

3. How will data applications not considered to need IGARD scrutiny be published?
4. ". In some instances the Chair or Deputy Chair may ask members to consider cases outside formal meetings on behalf of IGARD where certain criteria apply; for example when cases are straightforward or very similar to those where a precedent has previously been established; or, where a specific follow up action has been completed following a full IGARD meeting; or, where there are particular urgent circumstances which might apply." This would benefit from clarification: how will the criteria be developed, by whom and under what general principles? E.g. in the case of "straightforward applications" who decides on this status and whether the data applied for will, in fact, be sufficient but not excessive for the stated purposes in the application?

General Principles

8 Please indicate your level of agreement with the following statements:

IGARD will enable increased transparency of decision-making:
Partially Disagree

IGARD will enable increased quality in decision-making:
Partially Disagree

IGARD will enable increased accountability in decision-making:
Disagree

IGARD will enable increased participation in decision-making:
Disagree

IGARD will introduce greater levels of independent advice into decision-making:
Disagree

IGARD will enable improved consistency of decision-making:
Partially Disagree

IGARD will contribute to the increased reputation of the HSCIC:
Disagree

Please provide any comments you may have about the above statements::
The consultation rightly recognises the need to strengthen public confidence in the HSCIC, and we believe that having IGARD advise the HSCIC in its dissemination of patient data that is identifiable or carries a significant risk of being so is a significant step in the right direction, particularly if the suggestions made in our response are implemented. However there is an equally pressing need to build clinician confidence in the handling of confidential patient data by the HSCIC, and for a mechanism similar to IGARD to advise the HSCIC on its collection of confidential patient data.
Prior to June 2015, part of this remit – the collection of patient data from general practice – was carried out by GPES IAG. Amongst other things, it provided the only (if partial) check on the operation of Directions enabled by the HaSC Act 2012 to collect confidential patient data. GPES IAG was seen (as the HSCIC has acknowledged) to be a sound model patient information governance mechanism, and anticipated the form that IGARD would take but with much greater clinical and public representation and a more transparent modus operandi. Its abolition has badly damaged confidence in the information governance operations of the HSCIC, particularly as the mechanism planned to replace it has not been the subject of a consultation and as currently envisaged does not appear to be transparent in its operation.
In the light of this, we believe the creation of IGARD modified as we suggest is necessary but not sufficient to create the public and clinician trust appropriate to the operations of the HSCIC. For this to occur it is necessary to introduce a mechanism similar to GPES IAG (and to IGARD revised as we suggest) to advise on all collections of confidential patient data by the HSCIC. The best start to creating such a body would be a public consultation of on the form that it should take."
1. transparency This could be increased if - and only if - there is full publication of all the relevant applications and decisions as well as the minutes of the meetings at which the applications were considered in an accessible form (such as the pages, now removed, where GPES IAG responses to Customer Requirements for data from GP records were summarised by topic).
If an application has been approved, details of what has been approved should be published in full.
2. accountability. IGARD is an advisory body, and the independent members are there as individuals with specific interests/expertise, and specifically not accountable to or representing any other organisation. Independent external scrutiny is valuable - but the response of the HSCIC to IGARD recommendations need to be published if the accountability is to the public.
3. participation. Absence of public representation among the members, and lack of detail on the terms for members suggests that the pool of possible members is limited, and insufficient attention has been given to means of recruitment and selection as yet. See previous comments.
4. quality in decision making. The interim DAAG appears to be functioning well, apart from lack of publication of the applications: GPES IAG has been told repeatedly that their work was exemplary: without knowledge of the other bodies being replaced it is hard to tell whether quality in decision making (or advice) will be improved, maintained or decreased.
5. consistency. probably - once the new members have been trained in this type of decision making, and provided their recommendations are accepted by HSCIC.

Any Additional Comments

9 You now have the opportunity to provide any further comments you may have about the proposed establishment of IGARD:

Any further comments you may have about the proposed establishment of IGARD:
The decision to close DAAG and replace it with the new IGARD is stated that it is to "ensure a systematic and coherent approach to the scrutiny of requests for data releases": when the functions of assessing and approving requests for data is separated from decisions to release the data, it is not clear how such consistency will be achieved.

This raises major issues about the provision of fair processing information where the information concerned is considered identifiable under the DPA 1998, which is not mentioned at all in the consultation.
Will IGARD also deal with requests that involve creating new datasets by:-
(a) linking data that the HSCIC already holds and/or
(b) by linking data that HSCIC holds to data held by others, and
(c) data that HSCIC will have to collect de novo from one or more external source

One of the stated functions of the new IGARD is to replace part of the functions of the GPES IAG.
The main function of the GPES IAG was to consider requests for data which was to be extracted from GP electronic records using GPES as the mechanism. (data is also extracted using Apollo). .The only commonality between the two is that both GPES IAG and IGARD look at the intended users and uses of the data involved in order to determine the legality and ethicality of the collection before making recommendations.
It is not clear whether any applications to IGARD will implicitly or explicitly involve the dissemination of data that is not already held by HSCIC (and if they do, whether such collections have already been approved by whatever mechanism replaces GPES IAG).
The mechanisms proposed for linking the decision to extract or collect data for a specific purpose and the decision to disseminate that data needs to be made clear if public confidence in the secondary use of medical data – and confidence in the bodies holding and managing that data including the HSCIC – is to be established and/or maintained.

The current “Interim” DAAG (which is significantly different from the DAAG established in 2010) publishes its minutes but does not appear to publish the applications presented to it in full – nor any of the supporting documents taken into consideration (unlike the GPES IAG): if the intention is to increase Transparency, the full documentation as well as the decision – and caveats – should be published in an easily available place and format, preferably with comments/caveats clearly listed (as in the original GPES IAG pages on the HSCIC website), so that requests which are being considered for a second time can be clearly identified and the narrative followed.

If the recommendations made by IGARD are to be accepted – or not accepted – by the SIRO – who should be identified – such decisions should be published with, in the event that they are not accepted, reasons for the non-acceptance.

We would recommend adopting the format used by the GPES IAG in its original form, with individual applications - such as care,data - being assembled on a single page, detailing recommendations and the actions taken to address them, for clarity & transparency. The current archive of the GPES IAG documents, consisting only of undated documents (Customer Requirements, Benefits and IG Assesments) and Minutes has reduced rather than enhanced Transparency.

Regarding quality and consistency, it would be useful to have a reference guide – along the lines of the GPES Information Governance Principles and the GPES IAG Public Interest paper - to which both the public and members of IGARD could refer.

If the intention of establishing IGARD is to increase public confidence in and the reputation of the HSCIC and promote Transparency, IGARD cannot be considered in isolation.
Although the role of the SCCI lies outside this consultation, if public confidence is to be maintained or established, the relationship between SCCI (approving data collections and any public benefits from these) and IGARD (releasing data) needs to be included in the TOR for IGARD.
There will, apparently, be no public consultation on the SCCI’s increased and changed role – or the changes in the composition and function of the SCCI needed to address its changed responsibilities – as there has been no consultation on the abolition of the GPES IAG which was designed to provide assurance to GPs and their patients that their data would be used responsibly and ethically.
Clarity on this would be welcome