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medConfidential response to the Consultation on the draft IGARD Terms of Reference

Dear HSCIC,

medConfidential welcomes the intent to replace DAAG and to upgrade the governance of HSCIC data disseminations, following serious issues revealed by the Partridge Report in 2014.

We would also like to take this opportunity to publicly recognise the work of Dr Alan Hassey, the interim Chair of DAAG, and others in improvements made during the course of the last year to the composition, transparency and procedures of DAAG as it is currently constituted.

Preamble

The Consultation on the draft IGARD Terms of Reference states:

> *One of the roles of the Health and Social Care Information Centre (HSCIC) is to ensure a systematic and coherent approach to the scrutiny of requests for data releases.*

Proper scrutiny of data dissemination ("releases") is a vitally important role, both to help secure the important research and service improvement benefits that the secondary use of NHS patient data in various forms can bring, but also to help ensure ongoing public confidence in HSCIC's governance, processes and procedures.

If HSCIC is to remain the 'institutional memory' of the NHS and become the trusted 'heart' of data handling within the health and social care system, it must - to borrow the framing of Baroness O'Neill[1] - show that it is *trustworthy* by continually demonstrating its competence, its honesty and its reliability.

Though we have reservations about the splitting of scrutiny over data collection and data extraction from data dissemination, we believe IGARD can make a significant contribution towards HSCIC achieving this necessary trustworthiness. Public trust, we hope, will follow.

With regard to the split between extractions and dissemination, as mentioned in the Introduction to the draft ToR, which refers to the abolition of GPES IAG and transfer of its (primary) advisory role[2] on the extraction of GP-held patient information to SCCI; while we welcome this consultation on

[1] https://www.ted.com/talks/onora_o_neill_what_we_don_t_understand_about_trust/transcript?language=en

[2] As detailed in "CAG, DAAG, GPES IAG – now and tomorrow" HSCIC's 2015 internal review of its IG Advisory Structures: https://www.whatdotheyknow.com/request/274729/response/670573/attach/3/CAG%20DAAG%20and%20GPES%20IAG%20Now%20and%20tomorrow.pdf

IGARD's draft ToR, we are extremely concerned that there is no equivalent public consultation on SCCI and its composition, procedures, oversight and transparency. This is a serious oversight, though clearly not within HSCIC's remit.

However, in approving the abolition of GPES IAG and proposing the IGARD / SCCI split, HSCIC has in effect surrendered a significant responsibility for scrutiny of primary care data extractions. In its current form, SCCI is neither independent - indeed, it is comprised mainly of bodies which are 'customers' for patient data - nor transparent; the membership of its obscure "independent standards assurance service"[3] (which we note is staffed by HSCIC officials) is unpublished, as is evidence of ISAS's considerations and recommendations.

We appreciate that, as just one member of SCCI (a sub-committee of the Department of Health's National Information Board) HSCIC cannot by itself *require* that an equivalent public consultation on SCCI's ToR is held. However, given that this significant redistribution of responsibilities is at its suggestion, we urge HSCIC to do everything it can to ensure such a consultation takes place at the earliest opportunity.

If this 'simplification' is going to work, it must be seen to work.

As a public test of this, we recommend that the GP code set for the care.data programme - a massive, significant and highly controversial ongoing data extraction, for which an Information Standards Notice must be issued - be put through the new SCCI / IGARD system from start to finish. This would be necessary in any case, when any significant changes[4] are made to the GP code set.

HSCIC should furthermore commit to reviewing the IGARD Terms of Reference should any of the necessary requirements on SCCI / ISAS fail to be met.

Response to Consultation

The Introduction to the Consultation states:

> *The proposals for the establishment of IGARD are designed to improve transparency, accountability, quality, and consistency of decision-making and to significantly enhance the public reputation of HSCIC.*

We shall address each aspect in turn.

Transparency

While section 7 of the ToR requires that IGARD applications be published on the IGARD website within ten working days of the next meeting, IGARD should also require that the relevant (SCCI[5],

[3] See "Critical appraisal" section: http://www.hscic.gov.uk/isce/role-hscic/qa

[4] By "significant", we would include any changes to the code set other than routine updates to code definitions or corrections to errors within the existing specification.

[5] While IGARD will deal with dissemination, the Second Data Protection Principle, "Personal data shall be obtained only for one or more specified and lawful purposes", requires that the specified purposes for which the

CAG and IGARD) case numbers for each decision be included in HSCIC's quarterly Data Release Register.

While IGARD may approve a data dissemination request just once, that decision can result in a number of data releases over a period of time - multiple quarters or years of HES, for example. Should a later inquiry begin at the Data Release Register (or a Personalised Data Usage Report[6]) it must be simple and straightforward for someone to 'click through' to review the specific SCCI / IGARD / CAG papers relevant to the approval of that release.

In addition, given the stated right of external observers to request to attend any particular meeting of IGARD at a minimum of 5 days' notice (section 6), it must be the case that the agenda for each meeting - including a sufficient description of any and all applications received for consideration at that meeting - be published at least 10 days in advance of the meeting. If this were not the case, how are external observers expected to be able to determine which meetings to attend?

Accountability: Data Release Register

As the publication of the 'quarterly' Data Release Register is discretionary on the part of HSCIC[7], the Terms of Reference for IGARD should be modified to require that all decisions must be included in the published Register *within 3 months of the decision being made*. This would avoid the current "purdah gap" that HSCIC was still within at the time this consultation was opened - where the Register was not published in April 2015, instead being delayed until a double release in July 2015.

The Introduction to the Terms of Reference state:

> *HSCIC's key responsibilities require that it demonstrates a robust and thorough approach to information governance, underpinning its culture and practice to gain and maintain public confidence and trust. HSCIC's Information Governance (IG) approach must ensure that:*
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> - *all processing of information is appropriate, secure and confidential*
> - *all legal and regulatory information governance requirements are satisfied.*

We would expect that HSCIC's IG approach would also meet all standards of professional medical ethics and professional research ethics, and recommend that wording to this effect be added as a third bullet point.

Quality

We hope IGARD maintains the quality of the decisions made since August 2014 by the interim DAAG. It is vitally important that IGARD continues to act with independent robustness.

Section 3 proposes to require an IGARD annual report; we note the IIGOP currently produces some form of Annual Report, and we would expect similar from the National Data Guardian.

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data was originally collected be considered. Irregardless of any administrative split in responsibilities, the law requires that every decision to disseminate must attend to the flow of patient data 'end-to-end'.

[6] https://medconfidential.org/2014/what-is-a-data-usage-report/

[7] See letter from HSCIC to medConfidential, 8 June 2015.

The Terms of Reference should require the IGARD Chair to report to the National Data Guardian / IIGOP, ahead of NDG's annual report, on the "*transparency, accountability, quality, and consistency of decision- making"* of IGARD and any other appropriate related matters of interest to the National Data Guardian and NDG Panel. In practice, that will almost certainly end up being the same report as the IGARD annual report - however, timings must be required to align.

In section 9 (and possibly elsewhere) where IGARD is required to review a particularly complex or nuanced request - equivalent, for example, to GPES IAG's reviews of the various care.data applications which it found particularly lacking - the Terms of Reference must explicitly allow the Chair to request comment and have appropriate regard to comments and advice from the National Data Guardian.

Consistency: Where did the data come from? Amend section 3.2 (c)

For any data release to be approved, IGARD members must be fully and accurately informed of any constraints put on the use of data at the time of its collection[8]. There must be a genuinely independent function providing advice to the body authorising collection or extraction, and all advice and comments made regarding collection or extraction must be available to IGARD (and, where relevant, CAG) when they make decisions on dissemination: promises must be honoured.

If IGARD does not have complete and accurate information on how the data was collected, and what conditions pertain, it will not be competent to assess and judge the current criteria 3.2 (c), nor 3.2 (d) nor 3.2 (e). We therefore propose the wording of 3.2 (c) be amended (suggestions in bold):

> *To consider whether the patient consent model**, including fair processing,** provided by applicants is sufficient to cover the use of the data requested **and to consider any and all other conditions or constraints applying to the data at the point of extraction.***

It may be sensible for IGARD to formalise this working relationship with the extraction side of the process by either adding another standing observer position (section 4) for a representative of SCCI or its independent scrutiny function - when it actually has one - or by adding such a representative to the list of normal attendees in section 6. Though not required in all cases, the ToR should require that a 'SCCI representative' must be available to IGARD when needed to inform its deliberations.

Public Reputation: DH, "Collect it all", and IGARD as a recipe for broken promises

IGARD is <u>not</u> actually a replacement for GPES IAG, though it purports to be. IAG's remit covered both collection and dissemination, but its main focus was the consideration in the round of applications to extract patient data held on GP practice systems - whereas IGARD covers only dissemination.

Having split these two functions, there is no way for IGARD to be absolutely certain it keeps every promise that has been made to individuals, professionals or others at or before the time of collection.

[8] cf. 'Transparency' p2 and footnote 5.

In fact, given the structure of SCCI or whatever ends up replacing the collection advisory role of IAG for GP data and applying it to the wider health and care system, IGARD may be fundamentally incapable of doing so. Our suggested amendments in ‘Consistency’ above are an attempt to mitigate this problem.

While the Department of Health’s various bodies each move towards a “collect it all” strategy for bulk personal datasets - taking the medical records of the nation into their own internal copies for their own purposes, including further dissemination - this problem will only get worse.

Decisions by bodies other than HSCIC are clearly beyond the remit of IGARD, but when making statements to the public, the constraints and limitations on those reassuring statements must be acknowledged. And as long as other DH bodies can simply ‘route around’ IGARD, a number of the protections claimed by Ministers and officials can only be incomplete at best.

If the Department of Health wishes the public to have trust in HSCIC, it must first demonstrate that HSCIC is trusted by itself and all of its other bodies. IGARD has a vital part to play in ensuring that the processes and procedures of HSCIC remain trustworthy and transparent; this would be fatally undermined were any other statutory body to avoid or ignore the process.

For if any DH body refuses to trust HSCIC to release data appropriately, given the diverse pressures that come to bear, why should the public?

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