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IGARD Secretariat
Health and Social Care Information Centre

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HSCIC: Consultation on the draft Terms of Reference for the proposed *Independent Group Advising on the Release of Data (IGARD)*.

Joint response by the Academy of Medical Sciences, Arthritis Research UK, Association of Medical Research Charities, British Heart Foundation, Cancer Research UK, Economic and Social Research Council, Genetic Alliance UK, Medical Research Council, Pelican Cancer Foundation and the Wellcome Trust

28 August 2015

Key Points

- We welcome the HSCIC's efforts to improve its decision-making processes for access to health and adult social care data. We believe that safe, transparent data access for legitimate research purposes through a robust governance framework has enormous potential to benefit health, healthcare and biomedical research.
- A number of policy and governance issues remain unresolved (for example, the relation between IGARD and the SCCI¹, HRA CAG² and other data controllers). These urgently need to be clarified if IGARD's governance processes are to provide assurances to the public and the research community that data access is being appropriately managed.
- Stakeholder representation on the proposed IGARD would be substantially improved by the inclusion of representation from the patient community, and by ensuring academic representation includes expert understanding of the data needs of research communities.
- It is not possible to specify whether the IGARD draft terms of reference will enable the HSCIC to fulfil its aims of increasing transparency, accountability, participation, quality and consistency, unless and until the key queries raised in this response are answered.

¹ Standardisation Committee for Care Information

² Health Research Authority Confidentiality Advisory Group

Introduction

1. Between the organisations contributing to this response we provide significant funding for clinical, biomedical, health and social research in the UK, much of which makes use of health and social care information, and support for patients and their families. **We believe that the responsible use and sharing of data is vitally important for research and the development of an evidence based healthcare system.** We are pleased to have the opportunity to respond to the HSCIC's consultation on the 'Draft terms of reference for the proposed new *Independent Group Advising on the Release of Data (IGARD)*'. Although the consultation requested a response via an online survey, we have elected to provide more detailed comments than the survey response format permitted.
2. Research uses make up a significant proportion of requests to access data from HSCIC and we would like to see this explicitly acknowledged, in addition to the services HSCIC and IGARD provide for NHS commissioners, clinicians and analysts. We consider that bringing research uses to prominence will help IGARD to be perceived as an enabler of positive, beneficial data uses that have the potential to transform health and social care.

Comments on the proposals

3. **We broadly welcome the consultation as an opportunity for HSCIC to review its approach to data access** and are pleased that the remit of the GPES IAG³ will be incorporated into IGARD. A single decision-making process for data access, streamlined with HRA and CAG approvals, will be more straightforward and efficient than the current fragmented and inconsistent approach that is delaying research, costing public resource and diminishing opportunities to use data for health and care improvements. However, the consultation indicates that there will be a separate committee for overseeing all data extractions, the SCCI. If there is to be consistency and transparency in the processes governing the uses of health and social care data, clarity is required on the how SCCI's processes and decisions will affect IGARD's decision-making. There is a need for joined-up working between these two groups, which could be achieved through cross representation.
4. **We believe the wholly appropriate concern to safeguard patient confidentiality needs to be equally matched by a commitment to use data to improve health outcomes.** HSCIC's decision-making, particularly over the past 18 months, has been disproportionately risk averse. It has not recognised the benefits and value of appropriate, legitimate data access by members of our communities to conduct research aimed at better understanding disease, the safety and efficacy of medical interventions, and health outcomes. The creation of IGARD presents an opportunity to deliver the right balance and these principles should be enshrined in the terms of reference.

Scope and purpose of IGARD

5. In section 3 ("Purpose"), it is stated that IGARD will achieve its primary purpose by "*considering all requests for data, where devolution to HSCIC Officers is felt on a risk basis or CAG advice not to be systemically desirable, or practically feasible, or publicly defensible.*" Although difficult to interpret clearly, we take this to indicate a risk-based approach to decision-making will be adopted and that not all applications will be assessed by IGARD. If this is indeed the case, we welcome this development if it will enable applications to be assessed more efficiently. Nonetheless, it will be necessary for there to be clarity for applicants regarding: how the decision will be made as to whether to process an application via IGARD or through HSCIC Officers; where advice from CAG would enter into this process; and what the criteria and timescales for different routes to approval would be. **If a triaging system is to be introduced, it is essential this is explained clearly to applicants if this change is to improve upon the current access process.**

³ General Practice Extraction Service Independent Advisory Group

6. Although it is inevitably difficult to clarify the relation the HRA CAG will bear to IGARD given that the CAG Regulations have still not been published, accountability and transparency require that it is made clear how CAG and IGARD interact and where each sit in relation to the processing of applications. **We call for a clear explanation of how CAG and the IGARD will work together in practice** and what the process of decision-making will look like for each: we are not satisfied that the draft terms of reference are sufficiently clear on this crucial matter. Confusion may arise from the terms of reference because, for example, the quotation above (paragraph 5) indicates that CAG may take a view on applications before IGARD, but section 3.2.g in the draft terms of reference indicates that IGARD can refer applications to CAG where necessary. Additionally, s.251 applications are submitted through IRAS, the HRA's application system, and not to the HSCIC. It will therefore be important that IGARD's coordination with CAG is clear and understandable, providing a consistent, streamlined and proportionate process for decision-making. The terms of this relationship should also be made public as soon as is feasible.
7. We recognise that the policy landscape is constantly shifting and that the framework under which HSCIC operates has not yet been completely established (e.g., there remains uncertainty over how patient objections will be handled). Nonetheless, there are strong reasons for seeking to harmonise data access processes for major data controllers such as NIHR, PHE, HSCIC and CPRD. Fragmented approaches lead to duplication of effort for data users in some instances, and inconsistencies or contradictions in what data users can do in others – all of which delay much-needed, valuable research uses of data and create opacity for the public. **If IGARD is to be the model for HSCIC, it is imperative that its approach is joined-up with those of other controllers of health and social care data.**
8. Getting the details of these relations right is crucially important if the system of data access is going to be trustworthy, and also for researchers wishing to apply for access who need to know what the decision-making process involves at each stage. **We strongly encourage HSCIC to produce a diagram or description of information flows and processes**, with key decision-making points and different decision-making bodies at each stage, which would help achieve both of these aims. Exemplars or case studies of different applications types that would flow through different routes would also greatly assist the research community and provide much-needed transparency.
9. **We welcome efforts to clarify how IGARD will make its decisions and to detail its remit.** Given the difficulties faced with data access over the past 18 months, we believe that greater emphasis should be placed on the need for efficiency of process and implementing Service Level Agreements in a timely manner, together with a sense of how IGARD will respond if the process becomes inefficient and creates unnecessary delays. IGARD's decision criteria should reflect those used by HSCIC Officers in handling applications so that there is clarity and consistency throughout the process. This would reduce the resource waste and frustrations that have occurred when applicants have received advice from HSCIC staff that has not been in line with DAAG's decision-making.
10. In the draft terms of reference, it is indicated that IGARD will need *"to ensure the related benefits are understood and justify such processing"*. The requirement to demonstrate "related benefits" does not come from legislation; indeed, the Explanatory Notes to the Care Act 2014 refer to *"a wide range of health and care related purposes – including for the commissioning of those services, and the epidemiological research that is needed at the earlier stages of developing new treatments"* (s.122, note 741). **We are concerned that the "related benefits" requirement may be interpreted narrowly, leading to wasted effort and delay for applicants.** Research proposals go through several stages of detailed scrutiny, through funding committees, and in many instances Research Ethics Committee approval. These often require justifications to be made in the form of impact statements, and we suggest that the deliberations of IGARD acknowledge these justifications rather than requiring bespoke, additional explanations of the potential benefits of data access applications.
11. The draft terms of reference state that IGARD has a secondary purpose of providing general recommendations and observations to HSCIC about its processes, policies and procedures, and a

commitment that it will produce an annual report. These are potentially very valuable functions, but it is not clear how IGARD will fulfil this secondary purpose and what resource would be required for it. For example, will IGARD actively review certain HSCIC processes, policies and procedures, or will its observations and recommendations be made on a purely *ad hoc* basis? **Further detail should be provided within the terms of reference about IGARD's secondary purpose** and how it will be fulfilled in practice as it is underspecified in the current draft.

12. Further to this, section 11 ("Function") indicates that IGARD will self-monitor and report back to the HSCIC board on an annual basis. In the interests of the championed values of participation, quality and consistency, **this reporting function should be expanded to allow data users a formal opportunity to feed back to HSCIC about what is working with the system and what isn't.** This would enable IGARD to respond to evolving needs and requirements of the data user community whilst ensuring the right protections are in place for the data over time.
13. We consider that for footnote 11, it is not acceptable that the definition of "sensitive data" is "to be confirmed". **Understanding what constitutes sensitive data and what risks and benefits access to these kinds of data creates should be at the very heart of IGARD's functions and not merely an afterthought.** The term needs to be clearly signposted as having the same definition as under data protection law, notably under s.2 of the Data Protection Act (1998). This would ensure the definition is consistent with legal and regulatory frameworks and the use of the term by other organisations. If the term "sensitive data" is not intended to have this meaning, a different term with a clear definition should be used to avoid confusion with the legislative definition.

Membership

14. **We believe the proposed membership of the group omits stakeholder representation from the patient community and the general public.** IGARD will be making decisions that impact patients and the public in a number of ways, and the group will also be a key component of the governance mechanisms by which the HSCIC can give assurances to the public about the transparency of its decision-making. As such, it is extremely important to consider patient and public views on how data is handled and for what purposes it can be accessed⁴. We would strongly advocate including patient representation in the membership of IGARD. This approach would be valuable both for improving transparency and for the unique expertise patient representation can bring to a decision-making process. It would match the participative approach taken by the majority of healthcare related decision-making committees and advisory groups, such as (in England) NICE, NHS England, HFEA, HTA, NIHR and PHE.
15. The draft terms of reference indicate that a "senior academic figure" will be included in the membership of IGARD. While we welcome this inclusion, it is not clear that this adequately covers the need for the IGARD to understand and support legitimate research uses of data, which are varied and can be complex. It is evident that, historically, DAAG and HSCIC staff have not had a sufficient understanding of research processes and uses of data, which has led to unnecessary delays. **We would like to seek assurance that any "senior academic figure" has the breadth and depth of expertise to be able to assist IGARD** in making informed, balanced decisions about access to data for research purposes across clinical, medical, health and social research and strongly encourage including more than one "senior academic figure" to ensure this.
16. Although we acknowledge the challenges in interpreting the complex range of legal frameworks governing access to data, and in particular, the provisions of the Care Act 2014, our research communities have indicated that HSCIC appears to have interpreted legal frameworks more

⁴Research has indicated that patients and the public wish for their data to be used to improve outcomes so long as the appropriate safeguards have been put in place, e.g. Royal Statistical Society Report "Public attitudes to the use and sharing of their data" (July 2014) <http://www.statslife.org.uk/news/1672-new-rss-research-finds-data-trust-deficit-with-lessons-for-policymakers> ; ESRC Public Dialogues www.esrc.ac.uk/public-engagement/public-dialogues.aspx

conservatively than other data handling organisations, which disadvantages both researchers and the patients who could ultimately benefit from their research. **The inclusion of a member with a legal background is therefore a welcome addition** to the group and should ensure that the decision-making is based on sound, reasonable legal interpretations.

17. **It is important to get the patient, academic and legal representation on the group right.** The proposed membership appears to be quite small, and this increases likelihood of not being quorate for all meetings, which would not, in our view, be acceptable. This could introduce delays to the processing of applications and we therefore suggest that HSCIC considers whether the membership numbers should be increased to ensure that a sufficient range of expertise is available and that access decisions can be made at every IGARD meeting.

Openness and transparency/ ways of working

18. **We have some concerns about IGARD's capacity to review data access requests in a timely manner.** The DAAG met weekly and typically discussed around 15 applications in that time. It is stated that the frequency of IGARD meetings will be "*not usually less than monthly*" which does not seem sufficient, particularly considering that IGARD will also be taking on the previous GPES IAG's data dissemination requests. Data users have already been experiencing significant delays and backlogs in assessing their applications: we believe it is likely that the planned frequency of meetings will only add to unnecessary delays. Timeliness of processing is crucial and we strongly encourage HSCIC to continue publishing metrics of time taken to make decisions as a Key Performance Indicator, as part of IGARD's monitoring and review process.

19. In relation to the frequency of IGARD meetings, it is also stated (section 8) that in some instances applications can be seen by members outside of the formal meeting. This may place an unacceptable workload on IGARD members and also generate uncertainty for applicants unless this stipulation is formalised into a standard. **It is therefore important that it is made clear when and under what circumstances an application could be "fast-tracked" or considered outside of the usual process of full application review.** Some criteria are given but not adequately specified in the draft. Again, transparency here would be beneficial both to applicants and to the public to provide assurances that similar applications are treated equally and fairly.

20. **We support the transparency arrangements for the sharing of application details and minutes of the IGARD meetings.** Our researchers have indicated that these steps would enable them to understand why their own applications had been unsuccessful, and would help them be more successful in the future. This utility is contingent on the meeting minutes being sufficiently detailed to enable researchers to understand the decision-making process within the meeting.

General principles

21. Without further specification as to: how IGARD will function in practice; who its members will be; how it relates to CAG; how its governance relates to other data controllers; the policy framework under which it will operate; and the resource commitment behind it, it is not possible to say whether the draft terms of reference will result in better decision-making and improvements in transparency, accountability, participation, quality and consistency, as asked in the consultation document.

22. The recognition that HSCIC processes need to change, and the development of this consultation, are steps in the right direction towards ensuring the HSCIC can be a trustworthy controller of data that is honest, competent and reliable. We would, however, welcome further and on-going engagement with both researcher communities and patient communities and representatives to ensure that the governance being developed is fit for purpose.

23. This response has been coordinated by the Wellcome Trust and we would be happy to discuss any of the points raised here in more detail with HSCIC.