

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 6 July 2017

Members: Sarah Baalham, Joanne Bailey (items 1 – 2.6), Jon Fistein (items 1 – 2.7 [left partway through item 2.7]), Eve Sariyannidou, James Wilson

In attendance: Garry Coleman, Louise Dunn, Frances Hancox, Louise Hill, Dickie Langley, Stuart Richardson, Vicki Williams

Apologies: Anomika Bedi, Chris Carrigan, Nicola Fear, Kirsty Irvine

1	<p>It was agreed that Sarah Baalham would act as chair for this meeting as Chris Carrigan had to leave due to unforeseen circumstances.</p> <p>Declaration of interests</p> <p>James Wilson declared a conflict of interest in the University College London application (NIC-346693-F2X1G) due to his employment by that organisation as well as particular work connections with the specific staff involved in the study. It was agreed he would not participate in the consideration of that application.</p> <p>Review of previous minutes and actions</p> <p>The minutes of the 29 June 2017 IGARD meeting were reviewed and agreed as an accurate record of the meeting.</p> <p>Due to time pressures, action updates were not given at this meeting. Open actions are listed in Appendix A.</p> <p>Out of committee recommendations</p> <p>An out of committee report was provided (see Appendix B).</p>
2 2.4	<p>Data applications</p> <p><u>National Audit Office (Presenter: Dickie Langley) NIC-382334-Y2B1C</u></p> <p>Application: This application was to renew the applicant's existing data sharing agreement for the receipt of pseudonymised Secondary Uses Service (SUS), Hospital Episode Statistics (HES) and mental health data, and to amend the agreement to include the additional receipt of Office for National Statistics (ONS) mortality data (including date of death) and Improving Access to Psychological Therapies (IAPT) data. The previous version of this application had been considered at the 24 February 2015 DAAG meeting when IGARD had not reached a recommendation to approve, but the dissemination of data had been subsequently approved by NHS Digital.</p> <p>Discussion: Some queries were raised regarding process and the fact that this renewal application had been brought to IGARD despite the fact that NHS Digital had previously made the decision to disseminate data without a DAAG recommendation to do so. A further query was raised about the type of agreement currently in place and it was explained that the National Audit Office did not hold a Data Sharing Framework Contract as other applicants would be expected to, but that the terms and conditions of that Contract had been included in their data sharing agreement.</p>

2.1	<p>IGARD discussed the legal basis for this use of data and noted that while the application referred to the National Audit Act 1983, it was unclear how NHS Digital considered that Act to cover the provision of healthcare data and in particular to this amount of health datasets. It was agreed that a clearer explanation of the legal basis should be provided, possibly through the use of a briefing paper.</p> <p>IGARD queried whether this data was considered anonymised in context, given the amount of different datasets that would be disseminated and the possibility of linkage to other datasets; it was agreed the application should more clearly explain this with a clear commitment that the data provided by NHS Digital would not be linked to other record level data. IGARD advised that the applicant should consider how they made information about this use of data available to the general public, such as through a privacy notice. It was noted that the wording in the application to explain why patient objections had not been applied did not appear to be the standard wording and IGARD suggested this should be amended.</p> <p>There was a discussion about the controls that would be in place around access to the data and IGARD agreed that the application should provide more information about the use of controls such as role based access control, or whether data access would be limited to specific teams or types of staff. It was suggested that the updated wording around 'substantive employees' could be incorporated into the application.</p> <p>Data minimisation was discussed and it was agreed that the application should provide a clearer justification for why this amount of data was required and proportionate to the purposes for which it would be used. IGARD noted that it would likely not be reasonable for the National Audit Office to make a new application for each separate use of data but it was agreed that this application should more clearly state the justification for the amount of data requested.</p> <p>Outcome: Recommendation deferred, pending:</p> <ul style="list-style-type: none"> • The application should more clearly describe the legal basis for the NAO to require this data and how the powers under the National Audit Act 1983 apply to the dissemination of health data in general and specifically to this amount of health data. • The application should include a clearer explanation of why this amount of data is considered to be proportionate to the applicant's requirements. • Providing a clearer justification of why the data is considered to be anonymised in context, with a clearer statement that the data will not be linked with other datasets. • Providing additional information about the role based access controls that will be in place to ensure data will only be accessed for the purposes set out in this application. <p>References to the data sharing framework contract, data sharing agreement or data reuse agreement should be amended to consistently describe the type of agreement that is in place, and the explanation of why patient objections would not be applied should be updated to use standard wording.</p> <p><u>Group of 4 CCGs¹ (Presenter: Stuart Richardson)</u></p> <p>Application: This application requested an amendment for the four CCGs to share pseudonymised local flows of Service Level Agreement Monitoring (SLAM) data only between the four CCGs, for the purpose of commissioning. The application stated that the CCGs would act as data controllers in common.</p> <p>Discussion: IGARD requested more information about the controls in place for the data shared between CCGs, as it was noted that only a very brief Information Sharing Protocol was provided and this was not in line with the type of assurances provided by other CCGs</p>
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¹ NHS Bury CCG, NHS Heywood, Middleton and Rochdale CCG, NHS Manchester CCG, NHS Oldham CCG NIC-120758-L4C3B; NIC-120774-Y8L7S; NIC-120770-V1H9H; NIC-120805-F9Q4D

<p>2.2</p>	<p>undertaking this type of data sharing. Confirmation was requested that appropriate contractual arrangements were in place between the CCGs.</p> <p>It was noted that the application included special condition wording around privacy notices that reflected an earlier version of IGARD's advice wording, and it was agreed that this should be updated to use the current standard wording. In addition IGARD noted that section five of the application should be amended to more clearly reflect that data would be used by multiple CCGs rather than disseminated to a single CCG.</p> <p>Outcome: Recommendation to approve, subject to condition:</p> <ul style="list-style-type: none"> • Providing an appropriate and signed data sharing contract between the four CCGs in line with the type of documentation provided for similar recent applications. <p>The special condition wording set out in the summary section regarding privacy notices should be updated to reflect IGARD's current standard advice wording. Section five of the application should be amended to more clearly describe that data will be shared between multiple CCGs. It was agreed that the above condition would be reviewed out of committee by IGARD.</p> <p><u>Group of 5 CCGs² (Presenter: Stuart Richardson)</u></p> <p>Application: This application was to extend the existing data flows and to additionally request identifiable SUS data for invoice validation, as well as changing the data processor for commissioning purposes from South East CSU to South Central and West CSU. It was noted that North East London CSU would continue to act as a data processor for the purpose of risk stratification.</p> <p>Discussion: IGARD noted a reference to Interxion and queried whether the standard special condition wording about their security arrangements should be included.</p> <p>A query was raised about the data destruction process for North East London CSU as that organisation would no longer act as a data processor for commissioning purposes. It was agreed that the CSU should be required to provide a data destruction certificate for the data that had previously been processed on behalf of these CCGs for commissioning purposes, but that a one month overlap might be required between the new data processor commencing and the former data processor destroying data.</p> <p>Concerns were raised regarding the privacy notices for all CCGs except Coastal West Sussex CCG; for example one inaccurately described the level of data collected by NHS Digital, and one was difficult to locate on the website. It was agreed the CCGs should review their privacy notices to ensure they would meet NHS Digital's nine review criteria.</p> <p>IGARD noted that the legal basis for dissemination listed in the application should be amended to also refer to section 261(2)(b)(ii) of the Health and Social Care Act 2012, and IGARD emphasised the importance of ensuring that section five of the application would be understandable to a lay audience when published within the data release register.</p> <p>Outcome: Recommendation to approve, subject to condition:</p> <ul style="list-style-type: none"> • The CCGs (with the exception of Coastal West Sussex CCG) should update their privacy notices appropriately to meet the nine point criteria. <p>A special condition should be added that North East London CSU should provide a data destruction certificate for the data that they will no longer process on behalf of the CCGs, allowing for a one month overlap with the new data processor.</p> <p>The special condition wording set out in the summary section regarding privacy notices should</p>
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² NHS Coastal West Sussex CCG NIC-91799-G0T9X; NHS East Surrey CCG NIC-91865-Y2L1H; NHS Eastbourne, Hailsham and Seaford CCG NIC-91866-V4R5J; NHS Hastings & Rother CCG NIC-91825-W4M1H; NHS High Weald Lewes Havens CCG NIC-91827-P6J6X

	<p>be updated to reflect IGARD's current standard advice wording. The application should also be amended to include the standard wording regarding Interxion security controls. The legal basis listed in section 3 should be updated to refer to section 261(2)(b)(ii) of the Health and Social Care Act 2012.</p> <p>It was agreed that the above condition would be reviewed out of committee by IGARD.</p> <p>Stuart Richardson raised a query regarding the updated standard application wording around substantive employees. It was agreed this would be discussed out of committee.</p> <p>Action: Stuart Richardson to circulate a suggested change to the updated 'substantive employees' wording for discussion out of committee.</p>
2.3	<p><u>NIC-91808 Brighton & Hove CCG (Presenter: Stuart Richardson) NIC-91808-P5Z1F</u></p> <p>This application was withdrawn by the presenter prior to the meeting.</p>
2.5	<p><u>Queen Mary University of London / Barts Health NHS Trust - International Surgical Outcomes Study (Presenter: Louise Dunn) NIC-68740-X7R2N</u></p> <p>Application: This application was to receive linked pseudonymised HES and ONS mortality data, including date of death, for a cohort of patients enrolled in the International Surgical Outcomes Study (ISOC). IGARD were informed that only approximately 10% of the total available HES fields had been requested. In addition it was noted that all data would be stored and processed at Barts Health NHS Trust, with only Barts Health NHS Trust employees accessing data with the exception of one individual working on an honorary contract.</p> <p>Discussion: IGARD noted that the patient information materials stated that participants' health status would be followed up for one year, and queried whether the data provided would only include one year of data for each individual participant.</p> <p>Queries were raised about whether the participant consent was considered to include data linkage, as it was noted that the patient information leaflet provided referred to linkage between HES and ONS but the protocol provided (which appeared to be dated more recently) referred to consent for linkage to national databases or registries and the consent form itself did not refer to linkage. Clarification was requested of this apparent inconsistency. IGARD noted that the consent materials did not clearly describe that patient identifiable data would be sent to NHS Digital, although this was described in the protocol.</p> <p>It was suggested that section five of the application should be amended to more clearly state that data would not be shared with any third party organisations. IGARD noted that the honorary contract addendum did not appear to be dated and confirmation of the date was requested. A query was raised about time period for the study funding, as the letter provided was dated 2014 and no period was specified. In addition IGARD suggested that the application should more clearly describe the dissemination plan for outputs and how this would help provide healthcare benefits, and how outputs would be made available to relevant patient groups or the general public.</p> <p>Outcome: Not recommended for approval.</p> <ul style="list-style-type: none"> • Clarification was needed regarding inconsistencies in how consent for data linkage is described in the protocol and the consent materials provided. • Confirmation of whether only a single year of data will be provided for each individual participant, as the consent only allows for a one year follow up. • Confirmation was requested of the date for the honorary contract addendum provided.

	<ul style="list-style-type: none"> • Confirmation of the funding period, with the provision of a contract if this is in place. • Further information was requested on how outputs will be disseminated to help ensure healthcare benefits, including making outputs available to the general public. <p>Section 5 of the application should be amended to state that data will not be shared with third party organisations.</p>
2.6	<p><u>Device Access UK Ltd (Presenter: Jen Donald) NIC-05429-H7X6R</u></p> <p>Application: This application was to renew the flow of pseudonymised HES data and also to request additional HES data. The application had most recently been discussed at the 8 June 2017 meeting when IGARD had not recommended approval, with more information requested about the commercial nature of the work and how the purposes for which data could be used would be limited. Additional supporting information had now been provided about the purposes and potential benefits of this use of data, and the purpose section of the application had been rewritten to improve clarity.</p> <p>Discussion: Some concerns were raised that the purposes described for which data could be used with clients were not sufficiently detailed in a way that would be transparent to a general public audience. IGARD agreed that the applicant should further explore the criteria used to determine which projects this data could be used to support, and consider whether it would be appropriate to include oversight of this process by an independent group. It was agreed that the data sharing agreement should be limited to six months only at this point in time, with an updated application to be expected in six months that should provide further detail on these points. It was also agreed that the updated application would be expected to provide more specific details about the individual projects for which data had been used and the specific data required for each project. IGARD also suggested that the renewal application would be expected to state what efforts the applicant had made to increase their NHS client base for this work.</p> <p>In addition some concerns were raised about how the Device Access UK website currently described the use of health data to help target sales, and it was noted that this application stated that the outputs provided to clients should not be used for sales or marketing.</p> <p>Outcome: Recommendation to approve for a period of six months only. The renewal application in six months should include more information about the principles used to determine what data can be used for which projects and the governance arrangements in place to decide this, potentially including the use of independent oversight; and more specific information about the projects for which data is being used and each project's specific data requirements. In addition IGARD would expect the renewal application to include more information about what efforts had been made to increase their NHS client base.</p> <p>It was the view of IGARD that this application would not be appropriate for renewal via the IAO and Director delegated authority route.</p> <p>Given that the Device Access website currently described that could enable customers to use health data to 'precisely target your sales effort', IGARD suggested that NHS Digital might wish to consider auditing the organisation.</p>
2.7	<p><u>University College London – Whitehall II (Presenter: Jen Donald) NIC-346693-F2X1G</u></p> <p>Application: This application was for the applicant to continue to receive HES, mental health data, ONS mortality data and cancer registration data for the Whitehall II study, as well as to additionally receive Diagnostic Imaging Dataset (DIDs) data. It was noted that this was a long-running study of a specific cohort with section 251 support in place as well as Approved Researcher and Microdata Release Panel approval for the use of ONS data. IGARD were informed that any references in the application to sharing data with third party researchers</p>

referred to the self-reported data, with the NHS Digital data only being used to verify the self-reported data. The applicant had committed to update the information for participants provided on their website and to provide updated information to participants as part of an upcoming survey.

Discussion: IGARD discussed the applicant's commitment to provide updated fair processing information for participants, and agreed the importance of making these updates promptly. It was noted that the information sheet should more clearly explain the level of data that would be processed and what data would be shared with researchers. IGARD were informed that the study would issue updated information with the participant survey that would be sent out within the next few months, and it was noted that as the study continued to have a high response rate it was likely that the majority of participants would have sight of this updated information. It was agreed that the special condition wording in the application around fair processing updates should be amended to be clear that appropriate updates would need to be provided as part of the next wave of questionnaires.

IGARD noted that the study's section 251 support seemed to have been due for renewal within the last few months and queried whether this renewal had been submitted and approved by HRA CAG. It was agreed this would need to be confirmed.

A query was raised about the funding in place from European Commission Horizon 2020, and it was noted that the application referred to limitations on data sharing as part of the EU-funded LIFEPAATH project. It was agreed the application should be amended to be clear that these limitations, which included not sharing record level data with funders or project partners and that the funders would not influence the outcomes of the study, would also apply to any other future EU funding or similar projects. In addition it was agreed that the application wording around 'making pseudonymised data available to the scientific community for use in UCL-approved research studies' should be amended to be clearer that this would not include sharing pseudonymised NHS Digital data with researchers such as partners to EU funded projects.

IGARD discussed the way that NHS Digital data would be used to verify self-reported data, and queried whether the data shared with researchers would include any episodes from HES that an individual had self-reported. It was confirmed that if the self-reported data had not included an episode that was reported in HES, then that information would not be shared with researchers and therefore only things that had been self-reported would be shared.

IGARD noted that the legal basis for dissemination listed in section five of the application currently only referred to section 261(7) of the Health and Social Care Act 2012 for some of the data, and that this should also refer to the study's section 251 support.

By this point of the meeting, not enough IGARD members were present to have a quorum; it was therefore agreed that a provisional recommendation should be given, with this to be ratified out of committee by the two IGARD members who had planned to be present for this agenda item but due to unforeseen circumstances had been unable to stay for the full agenda.

Outcome: *This provisional recommendation was made in committee and then was ratified out of committee by the IGARD Chair and one other IGARD member to reach a quorum.*

Recommendation to approve, subject to a condition:

- Confirmation from HRA CAG of whether the study's section 251 support has been renewed.

The application should be amended so that the special condition regarding patient information states that the applicant must appropriately update the information that will be provided to participants as part of the next wave questionnaires to refer to pseudonymised data rather than anonymous data.

A reference in section five to "Making pseudonymised data available to the scientific community" should be amended to further explain this and to be clear this does not include

	<p>sharing NHS Digital data to researchers that are partners to EU funded projects. Section five should be updated to indicate that any future funding arrangements, including EU funding, will not include sharing NHS Digital record level data with these future funders or EU project participants, or permit them to influence the results or dissemination of results. The legal basis listed in section 3 should be updated to refer to the specific legal basis that enables dissemination as well as section 261(7) of the Health and Social Care Act 2012. It was agreed that the above condition would be reviewed out of committee by IGARD.</p>
3	<p>Any other business</p> <p>During the educational session, Stuart Richardson and Garry Coleman joined the meeting to discuss the process for privacy notice reviews carried out by NHS Digital. Given current work pressure around Data Services for Commissioners applications, IGARD agreed that for a three month trial period the team could submit applications to IGARD where the CCG's privacy notice had not yet met the essential nine review criteria and that a condition would be applied to these applications that data must not be disseminated until the CCG had updated their privacy notice to the point that it met the nine review criteria. During the same three month trial period IGARD requested sight of the privacy notice review checklists for all DSfC applications submitted to IGARD for consideration to help with ongoing mutual learning. It was agreed to review at the October 2017 education session.</p> <p>Action: Stuart Richardson to ensure that privacy notice checklists are provided for all DSfC applications for a trial period of three months from 13 July IGARD meeting.</p>

Appendix A: Summary of Open Actions

Date raised	Action	Owner	Updates	Status
15/11/16	To update DAAG on the feasibility of providing random samples of data to applicants, and to ask the Production Team to provide DAAG with further information about the options for data minimisation	Garry Coleman	<p>06/12/16: This action was ongoing and it was anticipated an update would be available in mid-January. There had also been a discussion during the training session about data minimisation, with a suggestion for Peter Short to contact the Production Team for further information, and it was agreed that would be incorporated into this action.</p> <p>20/12/16: It was anticipated an update would be available in mid-January.</p> <p>10/01/17: Ongoing. It was agreed that this action would be taken forward by Alan Hassey rather than Peter Short.</p> <p>17/01/17: A number of internal discussions had taken place and it was anticipated an update would be brought to DAAG within the next few weeks.</p> <p>31/01/17: Ongoing. It was agreed the IGARD Chair would request an update on progress of this action.</p> <p>09/03/17: Ongoing. A number of internal discussions continued to take place and it was agreed the action would be taken forward by Garry Colman.</p> <p>23/03/17: Ongoing. There was a suggestion it might be helpful to discuss the type of sampling used by the Department for Work and Pensions.</p> <p>11/05/17: This action was not discussed due to time restrictions.</p> <p>18/05/17: IGARD received a verbal update on work underway to develop 'dummy data' for the purpose of developing tools and algorithms.</p> <p>15/06/17: It was agreed the IGARD Chair would contact Garry Coleman about this action and ask whether an update could be provided in the near future, or if not then agree to close the action</p>	Open

			and to raise the topic again at a later date. 29/06/17: Ongoing.	
23/03/17	To provide a response to previously raised IGARD queries about indemnity.	IGARD Secretariat	06/04/17: An update had been provided and the action remained open. 13/04/17: This was ongoing within NHS Digital. 01/06/17: The Caldicott Guardian had request a meeting with the IGARD Chair and others to discuss this. 08/06/17: A call had been scheduled to discuss this. 15/06/17: Ongoing pending the scheduled call. 22/06/17: This call had taken place and a note would be circulated to confirm the outcome. 29/06/17: Ongoing.	Open
20/04/17	IGARD Chair to contact key stakeholder organisations regarding the benefits of uses of data to feed into the IGARD annual report.	IGARD Chair	29/06/17: Ongoing.	Open
27/04/17	IGARD Chair to contact the NHS Digital Caldicott Guardian regarding GPs' data controller responsibilities for fair processing around risk stratification.	Arjun Dhillon	18/05/17: Ongoing. It was agreed this would be discussed with the Deputy Caldicott Guardian. 22/06/17: Ongoing; it was suggested the Deputy Caldicott Guardian should discuss this in more detail with Joanne Bailey. 29/06/17: It was noted this action would be taken forward by the Deputy Caldicott Guardian, and the action owner was updated.	Open
04/05/17	Robyn Wilson and Joanne Treddenick to agree updated wording for the PCMD application template on type two objections, ensuring that this is consistent with published NHS Digital information about exceptions to type two objections.	Robyn Wilson	11/05/17: The IG Advisor gave a verbal update with confirmation that in October 2016 NHS Digital had confirmed a decision that type two objections would not be considered to apply to this flow of data due to the specific legal gateways around ONS data sharing. Further work was planned to agree the specific application wording to describe this. 18/05/17: IGARD were informed by the Secretariat that Robyn and Joanne had agreed new draft wording, and that this would be circulated to IGARD for discussion out of committee. 25/05/17: The new draft wording had been circulated out of committee and members were reminded to provide any comments by email if they wished to do so.	Open

			<p>08/06/17: There had been a further discussion of the wording by email.</p> <p>15/06/17: IGARD had received an updated email response to the queries raised. IGARD were asked to provide any comments on this by the following week's meeting.</p> <p>22/06/17: This was currently with an IGARD member to respond.</p> <p>29/06/17: Ongoing pending a response from IGARD members.</p>	
18/05/17	Garry Coleman to provide information about different arrangements for data storage and backup locations, for consideration of whether the organisations involved would be considered to be processing data.	Garry Coleman	<p>15/06/17: IGARD had been advised by email that a paper about this would be submitted to an upcoming IGARD meeting.</p> <p>22/06/17: It was anticipated that this would be discussed at the 6 July 2017 IGARD meeting. IGARD asked for some information to be circulated by email prior to the meeting in order to inform members who would not be present at that particular meeting.</p>	Open
01/06/17	Garry Coleman to provide information about the process for applicants moving from the use of identifiable to pseudonymised data and what standard steps are taken when they opt to retain identifiable data as well as receiving new pseudonymised data.	Garry Coleman	29/06/17: Ongoing.	Open
15/06/17	NHS Digital to provide information about the standard approach to data destruction where an applicant has been provided with data for linkage, and whether the original data should be retained as well as the linked data.	Jen Donald	29/06/17: Ongoing.	Open
15/06/17	Data Services for Commissioners to work with NHS Digital IG staff to check the privacy notices for these 4 CCGs (South Kent Coast CCG; Ashford CCG; Thanet CCG; Canterbury & Coastal CCG) as part of the ongoing training, and provide a copy of the outcome of this check to IGARD for information.	Stuart Richardson	29/06/17: Ongoing. It was suggested it would be helpful to discuss this at an upcoming educational session.	Open
22/06/17	NHS Digital to ensure that in future applications using the Health and Social Care Act 2012 as a legal basis provide more detail about the applicable	Garry Coleman	29/06/17: Ongoing.	Open

	subsections, such as section 261(2)(b)(ii).			
29/06/17	Stuart Richardson to contact DARS regarding standard data destruction timescales and processes where data processing is moving from one data processor to another.	Stuart Richardson		Open
06/07/17	Stuart Richardson to circulate a suggested change to the updated 'substantive employees' wording for discussion out of committee.	Stuart Richardson		Open
06/07/17	Stuart Richardson to ensure that privacy notice checklists are provided for all DSfC applications for a trial period of three months from 13 July IGARD meeting.	Stuart Richardson		Open

Appendix B: Out of committee report (as of 30/06/17)

These applications were previously recommended for approval with conditions by IGARD, and the conditions have subsequently been agreed as met out of committee.

No conditions have been signed off out of committee since the previous report (23rd June 2017).