

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 2 March 2017

Members: Sarah Baalham, Chris Carrigan (Chair), Jon Fistein, Kirsty Irvine, Eve Sariyiannidou, James Wilson

In attendance: Jen Donald, Frances Hancox, Alan Hassey (observer), Louise Hill, Terry Hill, Dickie Langley, Stuart Richardson, Joanne Treddenick (observer), Kimberley Watson (observer), Vicki Williams

Apologies: Joanne Bailey, Debby Lennard, Anomika Bedi, Nicola Fear

1	<p>Declaration of interests</p> <p>James Wilson declared a potential conflict regarding the University College London application (NIC-49826-T0J7C) due to his employment by that organisation, but confirmed that he had no particular involvement with this study or the applicants.</p> <p>Review of previous minutes and actions</p> <p>The minutes of the 23 February IGARD meeting were reviewed and agreed as an accurate record of the meeting.</p> <p>Action updates were provided (see Appendix A).</p> <p>Out of committee recommendations</p> <p>An out of committee report was received (see Appendix B).</p> <p>A query was raised regarding the Private Healthcare Information Network (PHIN) application (NIC-13906-G0F3F) that had been signed off by IAO and Director; it was confirmed that this was a continuation of a previous application and was not related to the PHIN application on this meeting's agenda.</p>
2 2.1	<p>Data applications</p> <p><u>Guy's and St Thomas' NHS Foundation Trust (SLaM NHS Foundation Trust) - HES data for the analysis of alcohol related frequent attenders to hospitals (Presenter: Jen Donald) NIC-44383-L6C0X</u></p> <p>Application: This application for pseudonymised Hospital Episode Statistics (HES) data had previously been considered at the 9 February 2017 IGARD meeting, when IGARD had deferred making a recommendation pending a commitment from the substantive employer and confirmation of whether Guy's and St Thomas' NHS Foundation Trust should be considered a data controller in addition to South London and Maudsley NHS Foundation Trust. Clarification had now been provided about the roles and responsibilities including confirmation from Guy's and St Thomas' NHS Foundation Trust about the actions that would be taken in the event of a data breach.</p> <p>Discussion: IGARD noted the potential benefits of this work and agreed that they were content with the responses provided to previous queries. It was suggested that NHS Digital should update section five of the application to incorporate the special condition regarding data linkage, so that this would be visible when information about the application was later published in the data release register.</p>

2.2	<p>There was a discussion about the process to review applications where IGARD had previously deferred making a recommendation, and it was suggested that in future the application outcome should specify whether it was anticipated that an updated application would require a further full review or only review of the specific points previously raised.</p> <p>Outcome: Recommendation to approve. IGARD advised that the application should be amended to ensure that the special condition regarding linkage is adequately reflected in section five.</p> <p><u>University College of London (Centre for Longitudinal Studies) - Birth Cohort Studies Data Linkage: 1970 British Cohort Study (Presenter: Jen Donald) NIC-49826-T0J7C</u></p> <p>Application: This was a new application for pseudonymised HES data for a specific cohort who had been signed up to the study cohort in the 1970s and had recently re-consented to the use of their data for research. The data would be used to carry out data quality checks including against self-reported outcomes, to create methodological papers and to populate a research database. It was anticipated that the applicant would in future apply to share data from this research database with other third party researchers, but that was not included within the current application. The presenter drew IGARD's attention to the similarities between this and the Next Steps study application (NIC-51342-V1M5W) that had been considered at the 31 January 2017 DAAG meeting.</p> <p>IGARD were informed of some errors within the application, including that the application did not list NHS number as an identifier that would be provided to NHS Digital, and members were asked to disregard the data flow diagram. It was noted that these errors would be addressed prior to producing a data sharing agreement.</p> <p>Discussion: IGARD discussed the study consent materials and noted that while these specifically asked for consent to share name, address, sex and date of birth there was no mention of NHS number. IGARD considered that members of the study would likely not be surprised that their NHS number was shared along with these other clear identifiers, and it was noted that the fair processing information for the study website provided more information about the proposed data linkage.</p> <p>A query was raised about the timescales to publish the fair processing information, as IGARD noted that this should be published with sufficient time for individuals to view the information and consider opting out before data was disseminated. It was confirmed that the fair processing information had already been published.</p> <p>IGARD noted a reference in the participant leaflet to data about the participant's partner, and requested confirmation that the data requested as part of this application was only for the cohort. It was confirmed that only data for the cohort was requested and no data on partners would be included.</p> <p>IGARD queried a statement in the application that survey response data would not contain identifiers, as it was noted that this would include a study ID. It was suggested this wording should be updated to be clear that while the data could include indirect identifiers such as a study ID, no direct identifiers such as date of birth would be included.</p> <p>There was a discussion about the special condition to keep identifiable data for the cohort separate from the pseudonymised data provided under this application.</p> <p>Outcome: Recommendation to approve. It was noted that errors in the application would be corrected, including listing NHS number as a data item to be provided to NHS Digital. IGARD advised that the application should be</p>
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<p>2.3</p>	<p>amended to clarify a statement that the survey response data does not contain identifiers, to be clearer this refers to direct identifiers such as name or NHS number, and the application wording should be amended to ensure that special conditions are adequately reflected in section five.</p> <p><u>Health and Safety Executive - The Prospective Investigation of Pesticide Applicators' Health Study (PIPAH) (Presenter: Dickie Langley) NIC-385032-K3N9S</u></p> <p>Application: This was a new application to follow up a consented cohort, with the identifiable data requested including Personal Demographics Service (PDS) demographic data, cancer registrations and Office for National Statistics (ONS) mortality data including date and cause of death.</p> <p>Discussion: IGARD acknowledged the potential benefits of this type of work and expressed their support.</p> <p>IGARD noted a reference on the study website to processing HES data, although it was noted that HES data was not requested as part of this application. It was agreed the application should be updated to confirm that the applicant does not currently hold HES data and IGARD suggested that the applicant should consider amending their website wording to more accurately describe the data currently held. IGARD queried whether the applicant had destroyed the list cleaning data previously provided by NHS Digital but it was noted that this data would have been used to update their own records.</p> <p>A reference in the application to data being 'extracted from the database' was queried. IGARD asked for this wording to be amended to be clearer that this referred to data being processed by study staff only, and not to extracting data to share with any third parties.</p> <p>The consent and patient information materials were discussed and IGARD noted that while the website provided a clear explanation of what data would be sent to NHS Digital to enable data processing, this was not clear from the information leaflet. It was suggested the applicant should consider updating the patient information leaflet to include this information in future.</p> <p>Outcome: Recommendation to approve.</p> <p>IGARD advised that references in the application to extracting data from the database should be amended to be clearer that this refers to the use of data by HSE employees, rather than sharing data with third parties. The application should also be amended to include confirmation that the applicant does not hold HES data for this study.</p> <p>IGARD advised that the study should update their patient information leaflet to more clearly inform participants that data will be shared with NHS Digital, and update the website wording to accurately reflect the data held.</p> <p>2.4</p> <p><u>Private Healthcare Information Network (PHIN) – HES-ONS and ONS linked data in support of the Competition and Markets Authority's Private Healthcare Market Investigation Order 2014 (Presenter: Dickie Langley) NIC-28602-D7G4J</u></p> <p>Application: This application requested linkage of identifiers collected by private healthcare providers to pseudonymised HES and Office for National Statistics (ONS) mortality data, with patient consent as the legal basis for dissemination. The data would be used to produce publicly available performance indicators about private healthcare. It was noted that the PHIN consent materials had been considered for advice at the 18 October 2016 DAAG meeting.</p> <p>Discussion: IGARD queried the data that PHIN would provide to NHS Digital, as it was noted that the consent materials only stated that NHS number and postcode would be provided. It was confirmed that while other information might be provided to help linkage, those would be</p>
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<p>2.5</p>	<p>the only direct identifiers used. IGARD also queried whether the applicant could make use of aggregated data for their purposes instead of record level data, but it was thought that this would not be practical for their requirements.</p> <p>There was a discussion of the proposed consent process and IGARD expressed concerns that it was not entirely clear whether individuals would always be provided with the privacy notice information at the same time that they were asked to consent to data sharing. IGARD felt strongly that individuals should be provided with all the necessary information at the time of consent, with sufficient time to review the materials, to ensure that informed consent could be given.</p> <p>Additional concerns were raised about a statement early in the consent form that the organisation is 'required to share your personal data', as it was considered that this could lead individuals to assume that they were required to give consent and could be potentially coercive. IGARD asked for the wording to be amended to be clearer that the requirement for organisations to share data did not mean that individuals were required to give their consent. A query was raised about whether individuals who had consented using the previous version should be asked to re-consent but it was felt this would be disproportionate.</p> <p>IGARD noted that the previously considered PHIN application had included a statement that data sharing with private healthcare facilities could take place solely for the purposes of data quality and data validation. It was suggested that the same statement should be included within this application. IGARD queried the use of terminology such as 'mandate', 'mandated' or 'legally required' in the application and it was suggested this should be amended to instead just state that PHIN are required to provide data.</p> <p>There was a discussion about the process for reviewing applications that had previously been considered for advice on consent, rather than for a recommendation. It was noted that where an application was submitted for advice only, DAAG outcomes had usually included a statement that any advice was given without prejudice to the consideration of a future application, but it was acknowledged that it would be beneficial to have a level of consistency between previous DAAG advice on consent, NHS Digital views on consent and current IGARD views on consent materials. IGARD suggested that in instances where they raised any particular concerns that did not seem to have been addressed by NHS Digital review this should be discussed in more detail outside of the meeting for educational purposes.</p> <p>Outcome: Recommendation to approve, subject to conditions:</p> <ul style="list-style-type: none"> • Confirmation that providers will make the privacy notice available to patients at the same time they are provided with the consent form, and that patients are given sufficient time to consider this before giving consent. • Updating the consent form to be clearer that references to a requirement to provide this data do not mean that patients are required to give consent. <p>IGARD advised that application should be amended to replace references to PHIN being 'mandated' or 'legally required' to instead refer to them being 'required' to provide data, and that section five should be amended to include the previously agreed wording regarding data quality and data validation by private healthcare facilities.</p> <p>It was agreed that these conditions would be reviewed out of committee by the IGARD Chair.</p> <p><u>Cambridge University Hospitals NHS Foundation Trust - Evaluation of the Role of Inflammation in non-pulmonary disease manifestations in Chronic Airways (Presenter: Dickie Langley) NIC-147978-LZDFC</u></p> <p>Application: This application was to amend an existing agreement in order to permit the linkage of study cohort data to HES data. IGARD were informed that the applicant organisation was no longer in contact with the study cohort but it was intended that additional information</p>
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about data processing would be made available on the study website, in addition to the information provided when consent was obtained.

Discussion: IGARD noted the intention to provide fair processing information via the study website but expressed some concerns that if participants had consented roughly five years ago and had not been in regular contact with the study, they might not be aware to look at the study website for updates. It was suggested that the applicant should consider what other reasonable steps might be taken to inform participants of the proposed data processing, such as providing posters for relevant clinics to display or providing updates through patient groups.

IGARD discussed the timescales for fair processing information and advised that the applicant should allow a reasonable period of time between publishing the website update and when data would be disseminated, to allow the opportunities for individuals to see the update and to withdraw their consent if they wished to do so. In addition there were some concerns that the draft website wording did not provide a clear mechanism for individuals to withdraw consent, but instead advised them to contact their GP or the hospital where they originally gave consent. It was agreed that participants should be offered a clearer explanation of how to withdraw their consent. There was a further suggestion that the website wording should more clearly explain what would happen to an individual's data if they withdrew their consent.

Outcome: Recommendation to approve, subject to conditions:

- The website wording should be updated to provide a more straightforward mechanism for individuals to withdraw consent and to specify what will happen to participants' data if an individual opts out.
- Confirmation that the website will be updated with fair processing information with sufficient time to allow individuals to withdraw consent before data is disseminated.

IGARD advised that the study should consider making fair processing information available to participants through additional routes such as providing posters for display in relevant clinics or sharing information through relevant patient groups or charities. The application should be amended to ensure that the special conditions are adequately reflected in section five.

It was agreed that these conditions would be reviewed out of committee by the IGARD Chair.

2.6

Redbridge CCG (Presenter: Stuart Richardson) NIC-81417-R1V4C

Application: This application requested pseudonymised SUS and local flows (ambulance, community and emergency care) data relating to 32 CCGs in Greater London. Data would be used to support the work of the Health London Partnership Urgent and Emergency Care Programme. Data would be processed by North East London CSU and by Chelsea and Westminster NHS Foundation Trust as the legal entity hosting the North West London CLAHRC. The application had previously been considered at the 16 February 2017 IGARD meeting and deferred pending clarification of data controllership and the role of the CLAHRC.

Discussion: IGARD noted the assurances that Redbridge CCG were leading the project on behalf of the other 32 CCGs, and would act as sole data controller. It was agreed that this clarification should be included in section five of the application, as well as in the summary section to ensure it would be appropriately included in the data sharing agreement.

Outcome: Recommendation to approve.

IGARD advised that the application should be amended to include a statement in section five as well as the summary that Redbridge CCG are acting as the lead CCG and are the sole data controller on behalf of the other CCGs.

2.7

Lancashire Care NHS Foundation Trust – The Innovation Agency (Presenter: Stuart Richardson) NIC-79728-X2C2X

	<p>Application: This application was for pseudonymised SUS and local provider data for residents registered within the Liverpool CCG area, to support the work of the North West Coast Connected Health Cities programme. The application had previously been considered at the 16 February 2017 IGARD meeting and deferred pending clarification of honorary contract arrangements and confirmation that data would not be shared with other partner organisations involved in the programme. This confirmation had now been received.</p> <p>Discussion: IGARD noted the updates provided and agreed that they were content the previously raised queries had now been addressed.</p> <p>Outcome: Recommendation to approve.</p>
3	<p>Any other business</p> <p>No other business was raised.</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 / Alan Hassey	<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>02/03/17: Ongoing</p>	Open
06/12/16	To query the privacy notice review process within NHS Digital.	Chris Carrigan	<p>13/12/16: This had been discussed with the Caldicott Guardian but further clarification was needed.</p> <p>20/12/16: This action was ongoing in light of developments in other areas, including the drafting of minimum criteria. It was agreed that the action would be taken forward by Dawn Foster and Noela Almeida.</p> <p>10/01/17: Ongoing, pending updated criteria.</p> <p>17/01/17: DAAG were given a brief verbal update on the work taking place.</p> <p>24/01/17: Work was ongoing following receipt of the final DAAG comments on the minimum review criteria.</p> <p>31/01/17: A meeting was scheduled to discuss this later in the</p>	Open

			<p>week.</p> <p>09/02/17: Ongoing. It was agreed this action would be taken forward by the IGARD Chair.</p> <p>16/02/17: It was noted that a meeting with the NHS Digital Caldicott Guardian was scheduled to discuss this.</p> <p>02/03/17: This had been discussed at the educational session and it was agreed the IGARD Chair would contact the Caldicott Guardian following that discussion.</p>	
10/01/17	To speak to NHS Digital colleagues regarding security assurance for HQIP.	Garry Coleman	<p>24/01/17: This had been raised with NHS Digital.</p> <p>31/01/17: This had been raised with HQIP and it was thought that work was underway to provide assurances.</p> <p>16/02/17: Ongoing. It was suggested that Jon Fistein could support this work.</p> <p>02/03/17: It was agreed the action should be taken forward by Garry Coleman.</p>	Open
17/01/17	To provide an update on the security assurances that NHS Digital would seek for applicants using contractors.	Garry Coleman	<p>24/01/17: It was anticipated this update would be provided to a meeting within the next few weeks.</p> <p>02/03/17: Ongoing.</p>	Open
31/01/17	To consider the NHS Digital process for new applicant organisations, such as due diligence and data availability for new start-ups.	Alan Hassey / Gaynor Dalton	<p>23/02/17: Information about this had been provided via email and it was noted that NHS Digital had begun work to review this process to ensure it could adequately address the queries raised by IGARD. It was agreed IGARD members would be asked to provide comments by a certain date.</p> <p>02/03/17: IGARD's comments had been shared with the appropriate staff within NHS Digital.</p>	Closed
09/02/17	To provide an update on the out of committee sign-off of NIC-69707 KPMG.	Garry Coleman	<p>23/02/17: A brief update was provided by email and IGARD requested sight of the final application.</p> <p>02/03/17: Ongoing.</p>	Open
09/02/17	To consider the use of a standard special condition for applications that do not require data linkage.	Garry Coleman	<p>23/02/17: It was agreed there would be a discussion at an upcoming educational session about special conditions versus the standard conditions included in data sharing agreements.</p> <p>02/03/17: It was agreed this should be added to the list of items for a future educational session and the action was closed.</p>	Closed

16/02/17	To contact the NHS Digital Caldicott Guardian about terminology and the use of terms such as 'anonymised' or 'pseudonymised' to describe data, particularly in relation to Data Services for Commissioners applications.	Chris Carrigan	23/02/17: Ongoing. It was noted that wider work was taking place within NHS Digital to agree standard terminology that could be used consistently, but IGARD noted the need to address this specific query regarding terminology in Data Services for Commissioners applications and data flow diagrams. 02/03/17: The IGARD Chair had discussed this specific point with the Caldicott Guardian, and it was noted that the wider work would be taken forward by NHS Digital.	Closed
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Appendix B: Out of committee report (as of 17/02/17)

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

The following application caveats or conditions have been signed off by IGARD:

- NIC-333021-B6W2C University Of Manchester (*considered at the 31/01/17 DAAG meeting*)
- NIC-24422 University of Cambridge (*considered at the 16/02/17 IGARD meeting*)

IAO and Director approvals

The following applications were not considered by DAAG or IGARD but have been progressed for IAO and Director extension/renewal only:

- NIC-389823 NHS England
- NIC-13906-G0F3F Private Healthcare Information Network (PHIN)
- NIC-348988-V6G1J HSCIC (NPID Audit)
- NIC-76968 London Borough of Ealing