

# Independent Group Advising on the Release of Data (IGARD)

## Minutes of meeting held 18 January 2018

**Members:** Anomika Bedi, Chris Carrigan (Chair), Nicola Fear, Kirsty Irvine, Eve Sariyiannidou.

**In attendance:** Gaynor Dalton, Dickie Langley, Terry, Hill (observer), James Humphries Hart, Matilda Koroveshi (observer), Stuart Richardson, Kimberley Watson, Steve Webster, Vicki Williams.

**Apologies:** Sarah Baalham, Joanne Bailey, Jon Fistein.

1	<p><b>Welcome and introduction</b></p> <p>The Chair welcomed Matilda Koroveshi and Terry Hill to the meeting as an observers.</p> <p><b>Declaration of interests</b></p> <p>Nicola Fear noted her professional links NIC-159399-K2M6H National Centre for Social Research, however members agreed that Nicola should be allowed to observe the discussion but would not be able to comment nor vote.</p> <p><b>Review of previous minutes and actions</b></p> <p>The minutes of the 11 January IGARD meeting were reviewed and subject to a number of minor changes were agreed as an accurate record of the meeting.</p> <p>Action updates were provided (see Appendix A).</p> <p><b>Out of committee recommendations</b></p> <p>An out of committee report was received (see Appendix B).</p>
2	<p><b>Data applications</b></p>
2.1	<p><u>Public Health England (PHE) – Daily emergency department attendance data extract from SUS CDS Type 011 Emergency Care Data Set (Presenter: Helen Buckles) NIC-149923-V5H4V</u></p> <p><b>Application:</b> This was a new application to request an extract of Pseudonymised Emergency Care Data Set (ECDS) data. PHE coordinate a number of real-time syndromic surveillance systems, which monitor pseudonymised health data from a number of different sources, including emergency departments, general practitioners and NHS 111. As part of this function the Emergency Department Syndromic Surveillance System (EDSSS) was established in preparation for the London 2012 Olympics and has continued as a legacy of the Games. The new Emergency Care Data Set (ECDS) has created an opportunity for EDSSS to be developed on a truly national scale.</p> <p>Helen Buckles noted that ECDS was a new data set and that data would not flow until the data had been onboarded to the DARS system. It was also noted the storage location of the library in Kidderminster was correct and PHE owned secure office space at the library location.</p> <p><b>Discussion:</b> IGARD asked for clarification under which Direction the ECDS data was being collected and it was explained that a briefing note and application had previously been presented to IGARD. The relevant Direction entitled: <i>The Health &amp; Social Care Information Centre (Establishment of Information Systems for NHS Services: Emergency Care Data Set Collection) Directions 2017</i> and was provided during the course of the meeting.</p> <p>IGARD noted that it was unclear if small numbers would be suppressed when the outputs were extracted from the secure storage and stored with the excel spreadsheet and IGARD asked for further clarification within section 5 of the application that small numbers will be suppressed.</p> <p>It was noted that IGARD had previously raised an action for NHS Digital to consider how the data processing role of an organisations with this type of arrangement should be reflected</p>

	<p>within applications and that it be updated to clarify that PHE are listed as a Data Controller and that they are processing data, but they are not a Data Processor.</p> <p>IGARD suggested working with senior Information Governance staff to ensure that the correct legal basis for data disseminations was listed within section 3 of the application.</p> <p><b>Outcome:</b> Recommendation to approve subject to the following condition:</p> <ul style="list-style-type: none"> <li>Clarifying in section five of the application that small numbers will be suppressed before inclusion in the Microsoft Excel spreadsheet</li> </ul> <p>The following amendments were requested:</p> <ul style="list-style-type: none"> <li>The applicant should work with DARS IG staff to ensure the correct legal basis for data dissemination is listed within the application.</li> <li>The application should be updated to clarify that Public Health England are listed as a Data Controller and that they are processing data, however they are not a Data Processor.</li> </ul> <p>It was agreed that the condition be approved OOC by the IGARD Chair</p>
2.2	<p><u>Cardiff University – building blocks trial, data archive (Presenter: Jen Donald) NIC-313754-G6X4Z – FOR ADVICE</u></p> <p><b>Application:</b> This was a new application to retain data already disseminated for 5 years for storage and back up purposes only, with no further data being requested, which will allow studies to comply with good clinical practice and regulations on retaining data for periods of time to allow for scrutiny of the findings and in some cases future research.</p> <p>Jen Donald noted that this type of application will create a template for future applications of this nature and was submitted for advice. Jen Donald noted that typos within the application had been updated</p> <p><b>Discussion:</b> IGARD welcomed the approach to build a template for future applications for the purpose of archiving.</p> <p>IGARD noted that archiving constitutes further processing and a separate purpose of data processing and that the briefing note and application be updated to reflect that fact, as well as the legal, policy and common practice framework that regulates data retention. Reference was made to earlier Department of Health guidance in the context of clinical trials which had been circulated to members.</p> <p>IGARD discussed whether archiving would be appropriate if original consent would not additionally allow this type of processing. It was noted that, under the GDPR, processing data for archiving purposes for scientific or historical research would be deemed compatible with the original purpose of the research and would not generally raise issues around consent. To offset any concerns and to comply with the principles of data integrity and confidentiality, accountability and privacy by design and default, applicants may be required, where appropriate, to pseudonymise the data before archiving, adopt appropriate security measures and practice a DPIA. It was confirmed that such requirements may only apply to data provided by NHS Digital but should be reflected in the application template, including references to data linkage.</p> <p>IGARD queried what researchers had told study participants about data retention and storage. It was noted that researchers must ensure that continued processing is fair and accounted for by providing updated fair processing information to study participants. It was also noted that when an application for the purpose of archiving would come to DARS, applicants would be expected to meet their fair processing obligations and would be subject to audit.</p> <p><b>Outcome:</b> IGARD welcomed the approach and noted their desire to work with NHS Digital to build an appropriate application template for future applications. IGARD offered their advice and further support without prejudice to the consideration of future applications.</p>
2.3	<p><u>Optum Health Solutions Ltd – bespoke extract request for producing benchmarks within products (Presenter: Jen Donald) NIC-277499-D3D0X</u></p>

	<p><b>Application:</b> This was a renewal and amendment application to retain pseudonymised 2013/14 Hospital Episode Statistics (HES) data and amend pseudonymised 2014/15 to 2017/18 Secondary Use Service (SUS) data in order to hold 4 years' worth of data for the purpose of benchmarking for NHS Clients.</p> <p>The amendment to get SUS data in place of HES data is to ensure that the applicant has the most up to date data for their NHS clients to base decisions around improving patient outcomes and making efficiency savings.</p> <p>Jen Donald noted that typos within the application had been updated including an amendment to retention wording.</p> <p><b>Discussion:</b> IGARD noted that the applicant and NHS Digital had explored data minimisation and welcomed this approach.</p> <p>IGARD queried references to HES within section 5 of the application and it was confirmed that the applicant would retain HES data until they had 4 years of SUS data and IGARD suggested that it should be explicit that the applicant is retaining HES for a period of time after which the HES data will be destroyed.</p> <p>IGARD queried if the applicant could access SUS datasets remotely and it was confirmed that they could not.</p> <p>It was noted that no yielded benefits had been included within section 5 of the application and IGARD noted that at renewal they would expect to see further information with regard to yielded benefits.</p> <p>IGARD noted that wording within the summary of the application be added to the published section 5 with regard to clarifying that the applicant is limited providing a service to NHS clients or organisations that work with the NHS.</p> <p><b>Outcome:</b> Recommendation to approve.</p> <p>The following amendments were requested:</p> <ul style="list-style-type: none"> <li>• To correct typos and remove reference to 'we' and 'our' within the application.</li> <li>• To clarify that the applicant is retaining HES for a period of time, after which the HES data will be destroyed.</li> <li>• To clarify in section 5 processing activities that the applicant is limited to providing a service to NHS clients or organisations that work with the NHS.</li> </ul> <p>IGARD noted that on renewal, IGARD would expect to see further information with regard to yielded benefits.</p>
2.4	<p><u>University College London – the relationship between education and health outcomes for children and young people across England: the value of using linked administrative data (Presenter: Dickie Langley) NIC-27404-D5Z3F</u></p> <p><b>Application:</b> This application had been considered by IGARD on the 14 December 2017 when IGARD had deferred making a recommendation pending the application and briefing note provided be updated to explicitly address the legal basis, especially with regard to the flow of identifiers from the Department of Education to NHS Digital, to provide clear evidence of the legal basis for the dissemination of ONS data and to update the fair processing for the Department of Education.</p> <p>Dickie Langley noted that typos within the application had been updated and that an ethical question had been raised with the Caldicott Guardian with regard to data being anonymised in line with ICO code of practice and Type 2 opt outs.</p> <p><b>Discussion:</b> IGARD acknowledged the updated briefing note and application provided.</p> <p>IGARD noted that the data was pseudonymised and that Type 2 objections did not apply but noted the ethical question raised by the Caldicott Guardian with regard to NHS Digital receiving identifiable data, processing that identifiable data and not applying opt outs before NHS Digital forwarded pseudonymised data to the UCL.</p>

	<p>IGARD queried if NHS Digital should be classed as the 'prescribed person' to receive the identifiable data from the Department for Education but it was confirmed that due to the complexities involved that analysis would cover linkage processes and that NHS Digital, along with UCL, would be classed as prescribed person.</p> <p><b>Outcome:</b> Recommendation to approve</p>
2.5	<p><u>Wilmington Healthcare – Niemann Pick Type C Patient Finder (Presenter: Kimberley Watson) NIC-34538-M7R3H</u></p> <p><b>Application:</b> This was a new application requesting Hospital Episode Statistics (HES) data to identify episodes within the HES datasets which have been coded with combinations of ICD-10 codes that suggest clinical features compatible with a diagnosis of Niemann-Pick Type C (NPC).</p> <p>Kimberley Watson noted that typos within the application and data flow diagram had been updated.</p> <p><b>Discussion:</b> IGARD welcomed the application and the positive research being undertaken to understand the impact on the cohort, their family and friends.</p> <p>IGARD queried references to Wilmington Healthcare as the Data Controller for this application and were not clear why the University College London Hospitals NHS Foundation Trust (UCLH) had not been listed as the Data Controller. It was noted that Wilmington Healthcare has worked with the Niemann-Pick Charity, but it was clear in the supporting documents that the Chief Investigator was an employee of the UCLH and that the UCLH had designed and developed the study.</p> <p>IGARD noted that within the HRA CAG letters it was not clear if the applicant had addressed the conditions previously raised as no evidence was provided. HRA CAG had queried the project's exit strategy and whether the project would end when the letter was sent to the GP as, at this point, it was up to the GP to decide whether they wished to contact the patient in the context of direct care. A number of queries were raised and clarification sought as to whether the applicant had amended the information provided to clinicians to reflect all the points outlined by CAG; when support to process information under this support will cease; whether follow up data is required and if this will be taking place under the consent obtained by the clinician.</p> <p>IGARD noted that the fair processing notice did not adequately describe the project and should be updated to accurately describe all the organisations involved, what their role was and the full scope of the processing activities and purposes of the project in order to meet NHS Digital's nine minimum criteria.</p> <p>IGARD noted that the cohort size had increased from up to 300 to approximately 400 following analysis of the data. IGARD also noted that data previously disseminated had been retained but not further processed.</p> <p>IGARD queried the role of Actelion Pharmaceuticals PLC, noting that the protocol stated that they were funders but the application did not reference this. IGARD noted that Actelion had been involved in the development of the algorithm used to search HES but would not have access to the data, and the Pharmaceutical company were referenced on the footer of the physician letter supporting documentation. It was not clear what Actelion's role in the project was and IGARD asked for clarification as to their role in the project and that they be added to the application as a funder.</p> <p>IGARD noted that although the diagnostic tool was referenced within the application, section 5 of the application should include a more detailed description of the diagnostic tool and how the tool is used to identify the cohort.</p> <p>IGARD noted that although this appeared to be in the public interest, it still raised ethical issues and asked that the application should contain references of how such issues had been addressed and that only active patients would be contacted.</p> <p><b>Outcome:</b> Unable to recommend for approval</p>

	<ul style="list-style-type: none"> <li>• Clarifying why University College London Hospitals NHS Foundation Trust (UCLH) is not listed as the Data Controller and why Wilmington Healthcare is not listed as the Data Processor.</li> <li>• Providing evidence that the applicant has adequately addressed the condition of the s.251 support outlined by HRA CAG to clarify as to when support to process information under this support will cease, whether follow-up data is required and whether this will be taking place under the consent obtained by the clinician.</li> <li>• Providing evidence that the applicant has adequately addressed the condition of s.251 support to amend the information provided to clinicians to reflect all the points outlined by CAG.</li> <li>• The fair processing notice be updated to accurately describe all the organisations involved, their role and the full scope of processing activities and purposes of the project to meet NHS Digital's nine minimum criteria.</li> <li>• The application be updated to identify Actelion Pharmaceutical PLC as the funder organisation, as reflected in the supporting documentation, and to clarify its role in the project.</li> <li>• Providing within section 5 a more detailed description of the tool, how it is used to identify the cohort and how the associated ethical issues have been addressed.</li> </ul>
2.6	<p><u>National Centre for Social Research - Adult Psychiatric Morbidity Survey (APMS) (Presenter: Steven Webster) NIC-159399-K2M6H</u></p> <p>Nicola Fear was an observer for this discussion.</p> <p><b>Application:</b> This application for 2014 Adult Psychiatric Morbidity Survey (APMS) had previously been considered by IGARD on the 11 January 2018 when IGARD had deferred making a recommendation pending receipt of a briefing paper to clearly explain the legal basis for receipt of data and various amendments to the application summary.</p> <p>Steve Webster noted that the application and briefing paper had been updated to clarify the legal basis for receipt of data, noting that prior to 2013 Directions did not exist but that a Memorandum of Understanding (MoU) was in place between NHS Digital and Department of Health.</p> <p><b>Discussion:</b> IGARD acknowledged the updated briefing note and application provided for consideration. IGARD also noted the importance of the APMS study providing data on the prevalence of both treated and untreated psychiatric disorder in the English adult population (aged 16 and over).</p> <p>The information provided for consideration by IGARD did not explicitly state the legal basis for collection of data and NHS Digital were unable to provide a copy of the relevant Direction, and could only provide a copy of the Commencement Order. IGARD noted that the copy of the MoU between NHS Digital and Department of Health was not provided for consideration.</p> <p>IGARD noted that they were only able to reach a recommendation based on the information it was provided for review and although they believed there was an authority to collect the data the evidence was not provided for IGARD to consider, therefore IGARD found itself in the position of not being able to make a recommendation.</p> <p><b>Outcome:</b> Unable to recommend for approval</p> <p>IGARD believe there is an authority to collect the data outlined within the application, however evidence of the legal basis was not available for IGARD to consider. IGARD recognised the importance of the work involved and that NHS Digital may choose to continue to flow data. IGARD found itself in difficult position of not being able to make a recommendation for approval.</p>

2.7	<p><u>Group application for 4 CCGs<sup>1</sup> – Out of Committee re-review (Presenter: Stuart Richardson) GA04a-AMD-NoE</u></p> <p><b>Application:</b> The application had previously been presented to IGARD on the 24 August 2017 and IGARD had recommended for approval subject to conditions: The CCGs (other than Hardwick CCG) should update their privacy notices in line with NHS Digital's nine criteria, in particular ensuring to use accessible language, be clear who data will be shared with, describe the involvement of Optum as a data processor, ensure that all website links are functioning and ensure not to conflate opting out with patient consent in a way that could be misleading. This should be confirmed by a senior member of NHS Digital staff with appropriate IG expertise.</p> <p>Stuart Richardson noted that the applicant had removed invoice validation from the application but still required risk stratification.</p> <p><b>Discussion:</b> IGARD noted that Pulsant were listed as a storage location and stated in their view that it would be more appropriate to also list this organisation as an additional data processor. It was acknowledged that there was currently an open action with NHS Digital regarding storage locations and how to reflect their role as data processors</p> <p><b>Outcome:</b> Recommendation to approve</p>
3	<p><b>Any Other Business</b></p> <p><b>3.1 Briefing notes to IGARD</b></p> <p>IGARD agreed that briefing notes which accompany first of type applications for either recommendation or advice should contain a number of key headings including:</p> <ol style="list-style-type: none"> <li>1. Explore the legal and policy and common practice guidelines from a wide variety of sources</li> <li>2. the nature and type of data requested;</li> <li>3. data flows;</li> <li>4. the context of the requirement;</li> <li>5. the legal bases for the requirement;</li> <li>6. the actors involved;</li> <li>7. the legal bases that outline the statutory functions, strictly relevant to the requirement;</li> <li>8. complies with ICO, explains its effectively anonymised &amp; if 2015 is legal basis the explanation as to why</li> </ol> <p>It was agreed that IGARD Secretariat would provide a briefing note template for NHS Digital use.</p>

<sup>1</sup> The application refers to: NIC-134337-C2C8Q NHS Erewash CCG; NIC-134460-X5B7B NHS Hardwick CCG; NIC-134486-C9C7S NHS North Derbyshire CCG; NIC-134495-Q1M6S NHS Southern Derbyshire CCG

## Appendix A: Summary of Open Actions

Date raised	Action	Owner	Updates	Status
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	<p>14/09/17: Ongoing. It was agreed this would be discussed during the educational session.</p> <p>07/12/17: Ongoing. It was agreed to bring the first draft to January's education session.</p> <p>18/01/18: Ongoing.</p>	Open
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> <p>27/07/17: An email had been circulated requesting further information from IGARD members.</p> <p>03/08/17: Two IGARD members had responded by email and the action remained ongoing.</p> <p>10/08/17: It was anticipated that a paper on this would be brought to IGARD within the following two weeks.</p> <p>24/08/17: The paper was in the process of being updated based on recently published ICO guidance.</p> <p>14/09/17: Ongoing. IGARD noted that given the amount of time that had passed, they would consider starting to note this on relevant</p>	Open

			<p>applications where a data storage location was not listed as a data processor.</p> <p>21/09/17: Ongoing. IGARD asked for Dickie Langley to provide an update on Garry Coleman's open actions at the next meeting to help ensure timely progression.</p> <p>02/11/17: IGARD discussed this action with Garry Coleman and requested a written update in response to the points previously raised by IGARD. Some difficulties were acknowledged as this specific scenario did not seem to be addressed in existing ICO guidance; IGARD suggested that NHS Digital should seek legal advice and if necessary then contact the ICO directly.</p> <p>16/11/17: Ongoing. IGARD queried the progress made regarding this action and there was a suggestion that this should be discussed at an education session; however it was suggested that it would be necessary to receive an updated response from NHS Digital before this.</p> <p>18/01/18: Ongoing</p>	
20/07/17	Garry Coleman to provide an update within two weeks on how NHS Digital manage the risk involved in CCGs using South Central and West CSU as a data processor in light of data sharing breaches and recent audits.	Garry Coleman	<p>10/08/17: It was anticipated that a paper on this would be brought to IGARD within the following two weeks.</p> <p>24/08/17: IGARD received a verbal update on the work that had taken place following both audits and verbal assurances that NHS Digital were content with the level of risk involved in this organisation continuing to act as a data processor. IGARD welcomed this update and requested written confirmation.</p> <p>31/08/17: IGARD were notified that the requested written confirmation should be provided within one day.</p> <p>14/09/17: An email response had been circulated on 31 August, and IGARD noted that they were awaiting receipt of the post-audit report.</p>	Open



			18/01/18: Ongoing	
20/07/17	Garry Coleman to categorise different standard lengths of indicative data retention periods for general research and clinical trials, with appropriate justification.	Garry Coleman	18/01/18: Ongoing	Open
31/08/17	Garry Coleman to report back on how cancer registration data was previously described as pseudonymised PDS data within older versions of applications, and present to a future education session on changes to how MRIS reports are now shown within applications.	Garry Coleman	18/01/18: Ongoing	Open
19/10/17	Stuart Richardson to provide a briefing on the Temporary National Repository infrastructure.	Stuart Richardson	16/11/17: Stuart Richardson noted discussions were ongoing. 18/01/18: Ongoing.	Open
02/11/17	NHS Digital to consider the responses provided by an applicant (Imperial College London NIC-27085) in relation to the language and terminology used in patient information materials.	Louise Dunn	18/01/18: Ongoing.	Open
07/12/17	Dickie Langley to provide a briefing note on NHS Digital's due diligence policy and process	Dickie Langley	18/01/18: Ongoing.	Open
07/12/17	Stuart Richardson to provide a briefing note outlining NHS Digital's work with STP's to clarify the legal / access arrangements in place between CCG's to ensure responsibilities are clearly defined	Stuart Richardson	18/01/18: Ongoing.	Open

21/12/17	NHS Digital / IGARD to discuss at a future meeting the issue of consistency across applications presented.	IGARD Chair / Garry Coleman	18/01/18: Ongoing.	Open
11/01/18	Gaynor Dalton to ensure the legal basis table contained within the summary of applications clearly states the legal basis for receipt and dissemination of data	Gaynor Dalton	18/01/18: Gaynor Dalton noted that the application summary had been updated for future applications. This action can be closed and removed from the action table.	Close

## Appendix B: Out of committee report

### Independent Group Advising on Releases of Data (IGARD): Out of committee report 12/01/18

These applications were previously recommended for approval with conditions by IGARD, and since the previous Out of Committee Report the conditions have been agreed as met out of committee.

NIC reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
None			•			

In addition the following applications were not considered by IGARD but have been progressed for IAO and Director extension/renewal:

- None notified to IGARD