

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 3 October 2019

In attendance (IGARD Members): Sarah Baalham, Anomika Bedi, Nicola Fear, Kirsty Irvine (Chair).

In attendance (NHS Digital): Dave Cronin, James Humphries-Hart, Dickie Langley, Karen Myers, Kimberley Watson, Vicki Williams.

Not in attendance (IGARD Members): Maria Clark, Priscilla McGuire, Eve Sariyiannidou, Geoffrey Schrecker, Maurice Smith.

1	<p>Declaration of interests:</p> <p>Nicola Fear noted a professional link with the team at University of Oxford (NIC-315419-F3W7K) but noted no specific connections with the application or staff involved and it was agreed that this was not a conflict of interest.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 26th September 2019 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record the meeting.</p> <p>Out of committee recommendations:</p> <p>An out of committee report was received (see Appendix B).</p>
2	Data applications
2.1	<p><u>The Health Foundation: Use of secondary care in England by international immigrants (Presenter: Kimberley Watson) NIC-114819-K5Z6Q</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) Outpatient, HES Critical Care, HES Accident and Emergency, HES Admitted Patient Care, Medical Research Information Service (MRIS) and Civil Registration (death) data.</p> <p>The Health Foundation are requesting that NHS Digital create a cohort of international migrants for patients who are aged 15 years and over linked to HES A&E / OP / APC and mortality data to compare the utilisation of secondary care in England by international migrants in comparison to the 'non-migrant' population, as well as estimating the cost of utilisation for migrants for each year of registration, from 2004 onwards.</p> <p>Discussion: IGARD discussed the application which came for advice on the feasibility of the creation of a cohort for a study by NHS Digital for the applicant. IGARD made a number of observations and suggestions for further consideration, without prejudice to any additional issues that may arise if the application is fully reviewed.</p> <p>IGARD noted that Article 6(1)(f) and Legitimate Interests were being relied upon under the General Data Protection Regulation (GDPR) and advised that further justification would need to be provided as to how the Legitimate Interest Assessment (LIA) had been assessed and deemed satisfactory; and how the Data Protection Act 2018, in particular the principle of using accurate data and the Human Rights Act 1998 had been addressed.</p> <p>IGARD also suggested that the application be updated to expand upon the basis on which special category data would be processed.</p> <p>IGARD noted the proposal to disseminate data under s261(1) and s261(2)(b)(ii) under the Health and Social Care Act 2012 and suggested that further specific analyses was provided.</p>

	<p>IGARD noted that similar research with a smaller cohort had been previously undertaken and queried the purpose of this research. IGARD asked what benefits had flowed from the previous research undertaken. IGARD suggested that the purpose of the proposed research was clearly defined, including clarification of how the outputs derived from the data requested would benefit the health and social care system and how this fell into the category of “medical research”.</p> <p>IGARD noted the references throughout the application to “migrants” and “international migrants” and suggested that the application was updated with a clear and consistent definition, including how the data requested would allow the application to identify a migrant or non-migrant cohort.</p> <p>IGARD queried the amount of data being requested and how the historical HES data would support commissioning and asked for further clarification on this point.</p> <p>IGARD queried the age range of the cohort and why this age group had been specifically selected (15 years and above) and suggested this was clarified. IGARD also advised that given some of the proposed cohort were ‘children’ that the necessary protection measures were considered, including appropriate transparency arrangements which were written in a language suitable for a lay audience.</p> <p>IGARD noted reference within the application to a patient participation group and asked for further information of the work undertaken with this group and how feedback from the group informed the application.</p> <p>IGARD queried the secondment opportunity offered by NHS Digital to an analyst within the Health Foundation and asked for further clarity of how this would work in practical terms, for example, who would have supervisory responsibility, what would they have access to, who would be the Data Controller in respect of the work undertaken by the secondee and what would be the legal basis for the work undertaken.</p> <p>IGARD also suggested that NHS Digital seek further guidance on this application from NHS Digital’s Caldicott Guardian.</p> <p>Outcome Summary: IGARD discussed the application which came for advice on the feasibility of the creation of a cohort for a study by NHS Digital for the applicant. IGARD made a number of observations and suggestions for further consideration, without prejudice to any additional issues that may arise if the application is fully reviewed.</p>
2.2	<p><u>University Hospital Southampton NHS Foundation Trust: Mortality and HES data at 12 months for patients in the CHARIOT study (BMJ 2019;364:l729) (Presenter: Louise Dunn) NIC-287601-K4P2V</u></p> <p>Application: This was a new application for identifiable Hospital Episode Statistics (HES) Admitted Patient Care and Civil Registration (death) data from 2017/18 and 2018/19 for a one-year follow-up to the ‘Current THreshold for Diagnosis of “Abnormality”, including Non ST Elevation Myocardial Infarction, using Raised Highly Sensitive Troponin Appropriate for a HospiTal Population’ (CHARIOT) study.</p> <p>A blood test called troponin forms a key part of the diagnosis of a heart attack and refers to a group of proteins that help regulate the contractions of the heart and skeletal muscles; high troponin levels can indicate a problem with the heart. The aim of the study is to assess whether there is an association between high-sensitivity troponin levels and one-year outcomes.</p> <p>Discussion: IGARD noted that the abstract should be amended to make clear that the applicant is a Foundation Trust and the relevant Article 6 of the General Data Protection</p>

	<p>Regulation (GDPR) be updated to reflect the public task for a Foundation Trust. IGARD also discussed the data storage and data retention.</p> <p>IGARD queried the reference in section 1 and section 5(a) (Objective for Processing) that stated “<i>The upper limit of normal for this test is determined by the manufacturer...</i>”, and were advised by NHS Digital that this was the “<i>manufacturer of the test</i>”, IGARD asked that the relevant sections were updated accordingly to explicitly state this.</p> <p>IGARD noted that the information provided in section 5(b) (Processing Activities) did not reflect the information in supporting document 1, the data flow diagram; and were advised by NHS Digital that section 5(b) was correct and that the data flow diagram should be updated to reflect this. IGARD also asked that once the updates had been made to the data flow diagram that NHS Digital’s Customer Relationship Management (CRM) system was updated with the latest version of the document.</p> <p>IGARD noted the applicant had a compliant Fair Processing Notice, however noted reference to a number of technical phrases and words and suggested that it be updated to ensure the use of technical jargon was used only where necessary and that it was written in a language suitable for a lay reader, in light of the target audience.</p> <p>Outcome Summary: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update the abstract section on Article 6 with the correct public task wording for a Foundation Trust. 2. To explicitly state in section 1 and section 5(a) that when referencing the “<i>manufacturer</i>” this is the “<i>manufacture of the test</i>”. 3. To update the data flow diagram to reflect the processing activities in section 5(b) and update the CRM holder with the updated version. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested that the applicant may wish to revise their (compliant) Fair Processing Notice to ensure the use of technical jargon was used only where necessary and that it was written in a language suitable for a lay reader in light of the target audience.
2.3	<p><u>University of Oxford: Epidemiological and health services research using routine NHS data: work programme of the Unit of Health-Care Epidemiology, Oxford University (Presenter: Dave Cronin) NIC-315419-F3W7K</u></p> <p>Application: This was a renewal and extension application for pseudonymised Hospital Episode Statistics (HES) Admitted Patient Care and Civil Registration (death) data to support a number of work projects, which include; trends in admission rates in hospital specialties; trends in admission rates for individual diseases and operations; geographical variation in hospital admission rates across England; mortality rates for each diagnosis and operation; studies of disease associations and multi morbidity; and maternal, obstetric and perinatal factors and subsequent disease.</p> <p>Discussion: IGARD noted the important work carried out by this Unit and noted the unique resource offered through the use of this data in combination with historic data.</p> <p>NHS Digital and IGARD noted the education sessions referenced in the application and that the applicant was using HES data for these teaching courses. IGARD queried if these sessions would only be using aggregated data, not pseudonymised record level, and asked that further</p>

	<p>clarity was provided within section 5 (Purpose / Methods / Outputs); and that if this was not the case that any reference to the education sessions should be removed from the application.</p> <p>IGARD queried the reference in section 5(b) (Processing Activities) to “...individuals holding a contract with the University of Oxford...” and asked that this was updated to explicitly state that the individuals accessing the data were either substantive employees of the University of Oxford or students of the University of Oxford; and that any related contradictory statements within the application were removed.</p> <p>It was noted the information provided in supporting document 2.1, the Unit of Health Care Epidemiology (UHCE) Publications Policy did not accurately reflect the main purposes and suggested that this was updated to replicate the information provided in section 5(c) (Specific Outputs Expected) as additional criteria for identifying the projects.</p> <p>IGARD queried if the dissemination of the full date of death materially increased the likelihood of re-identification and asked that section 1 (Abstract) was amended to make clear that NHS Digital have assessed the data sets held/to be held by the applicant, and processing as set out in the application, and consider that sufficient technical, practical and contractual controls were in place to ensure that dissemination of the full date of death did not materially increase the likelihood of re-identification (and accordingly constitute data owed a duty of confidentiality).</p> <p>ACTION: IGARD noted that the NHS Health Research Authority (HRA) Integrated Research Authority System (IRAS) form does not deem research using pseudonymised data as requiring ethical approval and that NHS Digital undertook to provide further background information on this point at a future IGARD Meeting.</p> <p>Outcome Summary: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 1) To clarify within the application that the education sessions referred to in the application will only use aggregated data, and that should this not be the case that reference to using data for education sessions be removed from the application. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1) To clarify within section 5(b) that the individuals accessing the data are substantive employees of the University of Oxford and that “students” are only students of the University of Oxford; and that any related contradictory statements within the application and supporting documents are removed. 2) To update supporting document 2.1 (the UHCE Publications Policy) to replicate the information in section 5(c) (outlining the purposes of the application) as additional criteria for identifying the projects. 3) To amend section 1 to make clear that NHS Digital have assessed the data sets held/to be held by the applicant, and processing as set out in the application, and consider that sufficient technical, practical and contractual controls are in place to ensure that dissemination of the full date of death does not materially increase the likelihood of re-identification (and accordingly constitute data owed a duty of confidentiality). <p>It was agreed the condition would be approved Out of Committee (OOC) by the IGARD Chair.</p>
2.4	<p><u>University of Oxford: An evaluation of knee arthroplasty fixation in an evolving challenging population (Presenter: Dave Cronin) NIC-316443-V5Z4Y</u></p> <p>Application: This was a new application for identifiable Hospital Episode Statistics (HES) Admitted Patient Care, pseudonymised Civil Registration (death) data and Patient Reported Outcome Measures (PROMs) data for the purpose of an evaluation of knee arthroplasty fixation in an evolving challenging population.</p>

<p>The study team are aiming to help deliver more patient specific care and improve outcomes, and also guide surgical provision for healthcare provider and help patients make more informed decisions.</p> <p>NHS Digital advised IGARD that the correct legal basis for the National Joint Registry (NJR) to flow data to NHS Digital had been removed from section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) and that this information would be reinstated. NHS Digital noted that no data would flow until they had received confirmation that the NJR approvals had been given.</p> <p>NHS Digital noted that there was a reference in section 5(a) (Objective for Processing) to “HES episodes” under the ‘Data Required’ heading and advised that the “episodes” reference would need removing.</p> <p>NHS Digital noted that the standard wording in relation to data retention had not been added to section 8 (Period and Funding) and that this would need updating to include this.</p> <p>NHS Digital advised IGARD that information had been included in the application on the applicant’s data minimisation efforts and that this had been endorsed by NHS Digital.</p> <p>Discussion: IGARD noted and supported the updates from NHS Digital on the amendments to the application in relation to reinstating the correct legal basis to section 1 and section 5; to removing the reference to (HES) “episodes” in section 5(a) and adding the data retention standard wording to section 8.</p> <p>There was an extensive discussion on the applicant’s data minimisation efforts and how this research differed from other NJR applications presented to IGARD and, noting the update from NHS Digital on the data minimisation efforts by the applicant and their endorsement of this were satisfied with the data minimisation efforts undertaken by the applicant and NHS Digital.</p> <p>IGARD queried information in section 5(a) that stated “<i>Once data is received the University of Oxford become data controllers for the data received.</i>” and asked that this was updated to make it explicitly clear that the University of Oxford was the Data Controller for the identifiers that flowed to NHS Digital.</p> <p>IGARD noted the helpful information provided in section 1 on the EQ-5D score, which is a ‘standardised measure of health status to provide a simple, generic measure of health for clinical and economical appraisal’, and asked that this was replicated in section 5(a).</p> <p>IGARD noted reference to a number of acronyms and technical phrases / words within section 5 (Purpose / Methods / Outputs) and suggested that it be updated to ensure the use of technical language was used only where necessary and that it was written in a language suitable for a lay reader.</p> <p>IGARD noted that section 5(a) should be updated to include clearer examples for processing and how the applicant has been using the data. IGARD also suggested that the applicant provide further details of pathways for disseminating the outputs of the study to patients and the public including specific examples of public / patient engagement.</p> <p>Outcome Summary: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To reinstate in section 1 and section 5 the correct legal basis for NJR to flow data to NHS Digital. 2. To update section 5(a) to make it explicitly clear that the University of Oxford is the Data Controller for the identifiers that flow to NHS Digital. 3. To update section 5(a) to replicate the information provided in section 1 on the EQ-5D score.

	<ol style="list-style-type: none"> 4. To remove the reference to HES “<i>episodes</i>” in section 5(a) under the ‘Data Required’ heading. 5. To update section 5 to ensure the use of acronyms and technical jargon is used only where necessary; and where it is necessary, to be also written in language suitable for a lay reader. 6. To update section 8 with the standard wording relating to data retention. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested on renewal that further details of pathways of dissemination of the outputs be provided, including examples of public / patient engagement.
2.5	<p><u>University College London: LAUNCHES QI: Linking AUdit and National datasets in Congenital Heart Services for Quality Improvement. (Presenter: James Humphries-Hart) NIC-234297-P4M5G</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) Admitted Patient Care, HES Outpatient, HES Accident & Emergency and Civil Registration (death) data.</p> <p>LAUNCHES QI is a dataset analysis of five linked audit and national datasets which will include up to approximately 144,000 patients with congenital heart disease that have been captured by the National Congenital Heart Disease Audit (NCHDA) since 2000, the core dataset defining the study CHD population. The study aims to indirectly improve services for congenital heart disease (CHD) by providing the first description of how CHD patients interact with the NHS acute sector and where variation in outcomes or service use exist. This information is the first crucial step in supporting service improvement by building the evidence base on which aspects of the current service offer the most potential for improvement programmes.</p> <p>NHS Digital noted there had been a change to the requested derived fields since submission to IGARD and that that admission / discharge data had been removed and a year and month of birth included, to be consistent with the data received by PIACnet and ICNARC. Both section 1 (Abstract) and section 5(b) had been updated to remove the reference to admission / discharge data and replaced with the month and year of date.</p> <p>Discussion: IGARD noted and supported the update to the application in relation to the derived fields.</p> <p>IGARD noted that it expected the applicant to have undertaken appropriate due diligence and to have reassured itself as to the lawful basis under which data from the Healthcare Quality Improvement Partnership (HQIP) was provided.</p> <p>IGARD queried if funding was ongoing and asked that section 5 (purpose / methods / outputs) of the application be updated to state that the funder would not have influence on the outcomes nor suppress any of the findings of the research / study.</p> <p>IGARD noted inconsistencies with the cohort numbers, the application stated them as being approximately 144,00 and supporting document 3.1, the CAG register (detailing the s251 support) stated 122,267; and asked that the application was amended throughout with the correct cohort figure or that an explanation was provided with regard the inconsistencies between the two figures provided.</p> <p>IGARD queried the end date listed within the application which stated March 2017, however the end dates provided in supporting document 3.1 and supporting document 1.0, the protocol was March 2018. IGARD asked that clarification was provided with regard the</p>

	<p>discrepancies between the end dates listed or that the application was amended throughout to ensure consistency with the supporting documents provided.</p> <p>IGARD noted the helpful information provided in section 5(a) (Objective for Processing) that outlined the description of the data linkage, and asked that for consistency this was also replicated in section 1 (Abstract).</p> <p>Outcome Summary: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To confirm within section 5 that the funder will not have influence on the design of the study, the outcomes nor suppress any of the findings of the research. 2. To amend the application throughout or to provide an explanation on the inconsistencies of the cohort numbers between the application and the s251 support. 3. To provide clarification on the discrepancies between the end dates listed in the application, s251 and protocol; or to amend the application throughout to be consistent with the s251 support and protocol. 4. To amend section 1 to replicate the information provided in section 5(a) outlining the description of the data linkage.
2.6	<p><u>NHS Rotherham CCG: DSfC - NHS Rotherham CCG - Comm, RS & IV (Presenter: James Humphries-Hart) NIC-174557-H6J6Y</u></p> <p>Application: This was a renewal application for pseudonymised Secondary Uses Service (SUS+), Local Provider Flows, Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registries Data (CRD), National Diabetes Audit (NDA) and Patient Reported Outcome Measures (PROMs); and an amendment to add Liaison Financial Services and Microsoft UK as Data Processors; to update the processing and storage locations of North of England Commissioning Support Unit and to add Attain Health Management Services (previously labelled as NHS Sheffield CCG) to the application.</p> <p>The purpose is for Invoice Validation (IV) which is part of a process by which providers of care or services are paid for the work they do, Risk Stratification (RS) which is a tool for identifying and predicting which patients are at high risk or likely to be at high risk and prioritising the management of their care and to provide intelligence to support the commissioning of health services.</p> <p>NHS Digital advised IGARD that a query had been submitted to NHS England who had confirmed that the proposed activity within the application came under the s251 support for Invoice Validation.</p> <p>NHS Digital advised that they had received written confirmation from NHS Rotherham CCG that they had authorised Liaison Financial Services to undertake the activity outlined in the application on their behalf.</p> <p>Discussion: IGARD noted the update from NHS Digital on the confirmation received from NHS England that the proposed activity comes under the s251 support for Invoice Validation; and that confirmation had been received by NHS Digital from NHS Rotherham CCG authorising Liaison Financial Services to undertake the activity outlined in the application.</p> <p>IGARD noted that Liaison Financial Services was listed on NHS England's website as an approved 'controlled environment for finance' and asked that a special condition was included</p>

	<p>in section 6 (Special Conditions) stating that should they lose this status that NHS Digital would be immediately informed.</p> <p>IGARD queried the amount of data that Liaison Financial Services would be receiving and asked that the application was amended throughout to make it clear that they would only receive a subset of SUS data to enable them to conduct historical invoice validation and that NHS Rotherham CCG received SUS data for the day to day and future invoice validation.</p> <p>IGARD noted that the list of Data Processors in section 1 (Abstract) did not include Microsoft UK and asked that this was updated to reflect this.</p> <p>Outcome Summary: recommendation to approve</p> <ol style="list-style-type: none"> 1. To update section 6 to include a special condition stating that Liaison Financial Services is an approved 'controlled environment for finance' and should they lose this status NHS Digital must be informed immediately. 2. To amend the application throughout to make clear that Liaison Financial Services will only receive a subset of SUS data to conduct historical invoice validation and that NHS Rotherham CCG receives SUS data for day to day and future invoice validation. 3. To update section 1 to include Microsoft UK in the list of Data Processors.
3	<p><u>Returning Application - NIC-156411-42L16 Institute of Cancer Research</u></p> <p>IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital.</p> <p>IGARD welcomed the application as part of their oversight and assurance role and noted a number of comments to NHS Digital and suggested that further information and comments be provided in an IGARD Oversight & Assurance Report which will be published separately to the minutes of the meetings, for transparency of process, and on a quarterly basis.</p>
4 4.1	<p>AOB:</p> <p><u>Invoice Validation Briefing Paper</u></p> <p>Liaison Financial Services are a Data Processor who are working across several CCGs to conduct Invoice Validation on historical data to ensure any missed invoices and payments can be addressed. There are up to 90 CCGs that will be working with Liaison Financial Services and therefore potentially up to 90 amendments to be made to existing application to include Liaison Financial Services as a Data Processor.</p> <p>The purpose of the briefing paper was to request that IGARD consider that these applications were taken through the IAO and Director route rather than through the IGARD recommendation route based on set criteria, to avoid a large volume of applications of the same type being presented to IGARD.</p> <p>IGARD welcomed the briefing paper and asked that any applications that would be impacted by this amendment should make it clear that any Invoice Validation that is to be carried out by Liaison Financial Services was historical only and that a special condition was included in section 6 (Special Conditions) of the application stating that Liaison Financial Services is an approved 'controlled environment for finance' and should they lose this status NHS Digital must be informed immediately.</p> <p><u>Cancer Waiting Times (CWT) Briefing Paper</u></p>

<p>4.2</p>	<p>NHS Digital brought the CWT briefing paper to IGARD to advise that IG responsibilities for the CWT system had now transferred to NHS Digital and to highlight an issue with the new system that enabled a CCG to view record level data of other patients that are not part of their commissioning area.</p> <p>The situation has been considered by NHS Digital's Data Protection Office and Information Governance colleagues, who had confirmed that they were content that the risk should be highlighted within the Data Protection Impact Assessment (DPIA) and had suggested that the data sharing agreements could be clearer to highlight the issue to applicants.</p> <p>IGARD welcomed the briefing paper and noted the proposed contractual solution, however queried the technical fix and the steps undertaken and suggested that NHS Digital's Information Asset Owner attend a future IGARD meeting to discuss further.</p> <p>There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.</p>
<p>4.3</p>	

Independent Group Advising on Releases of Data (IGARD): Out of committee report 27/09/19

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)
NIC-91871-D2W1N -	NHS Horsham and Mid Sussex CCG	12/09/2019	1. To revise section 5(c) and section 5(d) to outline the specific expected outputs and benefits flowing directly from the addition of the Mental Health Services Data Set.	IGARD Members	Quorum of IGARD members	

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

- None