

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

### Minutes of meeting held 13<sup>th</sup> February 2020

**In attendance (IGARD Members):** Maria Clark, Nicola Fear, Kirsty Irvine (Chair), Eve Sariyiannidou.

**In attendance (NHS Digital):** Victoria Byrne-Watts (Item 3), Stuart Blake, Nicola Bootland, Cher Cartwright, Garry Coleman (item 4.1), Dave Cronin, Dan Goodwin (Item 3), Karen Myers, Alyson Whitmarsh, Vicki Williams.

**Not in attendance (IGARD Members):** Sarah Baalham, Anomika Bedi, Geoffrey Schrecker, Maurice Smith.

**Observers:** Imran Khan.

1	<p><b>Declaration of interests:</b></p> <p>There were no declarations of interest.</p> <p><b>Out of committee recommendations:</b></p> <p>An out of committee report was received (see Appendix A).</p>
2	<p><b>Data applications</b></p>
2.1	<p><u>NHS GP Workforce Statistics Briefing Paper (Presenters: Nicola Bootland / Alyson Whitmarsh)</u></p> <p>The briefing paper was to inform IGARD about the General Practice (GP) Workforce data set, which contains data on individual staff members providing services at a General Practice in England. The Department for Health and Social Care (DHSC) and other Arms-Length Bodies (ALBs) use the data for policy formulation and workforce planning.</p> <p>The General Practice (GP) Workforce Data Set is currently being onboarded into NHS Digital's Data Access Request Service (DARS) at the request of stakeholders. This data has been collected by NHS Digital via the National Workforce Reporting System (NWRS), formally known as the Primary Care Web Tool, since Sept 2015. Prior to that, an annual GP workforce census used information provided by National Health Applications and Infrastructure Services (NHAIS).</p> <p>This briefing paper was previously presented to IGARD on the 7<sup>th</sup> November 2019, where IGARD made a number of comments and suggested amendments.</p> <p>IGARD welcomed the updated draft briefing paper and thanked NHS Digital for the effort in updating the paper and looked forward to receiving the updated briefing note as a supporting document with an application at a future meeting.</p> <p>IGARD provided the following additional comments for inclusion in the briefing paper:</p> <ol style="list-style-type: none"><li>1. As part of the "Transparency" section that was created, to clearly address the rights of the data subject under the General Data Protection Regulation (GDPR).</li><li>2. To provide further clarity on the right to opt-out for the data subjects involved and address in terms of transparency.</li></ol>
2.2	<p><u>Liverpool Heart and Chest Hospital NHS Foundation Trust: RIPCORDER 2 Trial: HES data for outcome analyses (Presenters: Dave Cronin) NIC-303379-H4C8H</u></p> <p><b>Application:</b> This was a new revised application for identifiable Diagnostic Imaging Dataset (DIDs), Hospital Episode Statistic (HES and Civil Registrations data for a study designed to</p>

assess the feasibility and management impact of routine assessment of fractional flow reserve (FFR) in patients undergoing angiography for diagnosis and management of stable chest pain.

This application previously came to IGARD on the 15<sup>th</sup> August 2019 for advice on the consent related materials and in particular the compatibility of the consent participants had given and the applicant's request for data for the purposes outlined within section 5 of the application; where IGARD made a number of observations and suggestions for further consideration.

**Discussion:** IGARD noted that the application had been revised following the 15<sup>th</sup> August 2019 meeting where IGARD had provided advice.

IGARD noted the information provided in section 1 (Abstract) that stated the application and dataset was a one-off and asked that for clarification this was also replicated in section 5(a) (Objective for Processing).

IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD asked that NHS Digital satisfy itself and provide written confirmation to IGARD that both Data Controllers, Liverpool Heart and Chest Hospital NHS Foundation Trust and the University Hospital Southampton NHS Foundation Trust, had published revised Privacy Notices, ensuring that they were compliant with the notice requirements under the General Data Protection Regulation (GDPR) and met NHS Digital's published 10a Transparency Standard, and before data could flow.

IGARD queried information provided in section 5(a) that outlined the data minimisation efforts undertaken and asked that this was expanded further to provide a justification for the DIDs data that had been requested; along with a further justification to the specific HES fields that had been requested.

IGARD also asked that the table in section 3(b) (Additional Data Access Requested) was amended to clarify the cohort numbers, the fields required and any other data minimisation efforts that had been undertaken.

IGARD noted that the data transferred by Liverpool Heart and Chest Hospital NHS Foundation Trust to NHS Digital, would not include patient names; and asked that for the avoidance of doubt, this was also clarified in section 5(a) and that patient names would not flow to NHS Digital.

IGARD queried if the "*12-month follow-up period*" referenced within the application started from the date of recruitment to the study **or** the date of the angiogram; and asked that this was confirmed in section 5(a) and, if applicable throughout the application.

IGARD noted that within section 1, the legal basis for processing the data had been provided for the University Hospital Southampton NHS Foundation Trust but had not been provided for the Liverpool Heart and Chest Hospital NHS Foundation Trust; and asked that section 1 was updated to confirm the legal basis for both Data Controllers; or that if the same legal basis was being relied upon for both, that this was clearly stated.

IGARD noted that the consent materials did not confirm the time for which the data would be held and therefore suggested that in the absence of this information and because this was a clinical trial, the five years as recommended in the UK Medicines for Human Use Regulation 2004 (as amended) should be applicable, not 25 years as previously indicated with the application, noting the applicant must comply with the law.

IGARD advised that they would wish to review this application again when it comes up for renewal (for any reason).

**Outcome Summary:** recommendation to approve subject to the following conditions:

	<ol style="list-style-type: none"> <li>1. To further expand on the data minimisation information provided in section 5(a), which includes a justification for the nature of the DIDs data requested along with further justification to the request for the HES fields requested.</li> <li>2. NHS Digital to satisfy itself and provide written confirmation to IGARD that both Data Controllers have published revised Privacy Notices, ensuring that they are compliant with the notice requirements under the GDPR and meets NHS Digital's published 10a Transparency Standard.</li> </ol> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To clarify in section 5(a), for the avoidance of doubt, that patient names will not flow to NHS Digital.</li> <li>2. To update section 5(a) and, if applicable, throughout the application, to confirm if the 12-month follow-up period starts from the date of recruitment <b>or</b> the date of the angiogram.</li> <li>3. To amend the table in section 3(b) to clarify the cohort numbers, fields required and any other data minimisation efforts undertaken.</li> <li>4. To replicate the information from section 1 into section 5(a) stating that this is a one-off application and dataset.</li> <li>5. To update section 1 to confirm the legal basis for both Data Controllers; or if the same legal basis is being relied upon for both Data Controllers, to clearly state this.</li> </ol> <p>The following advice was given:</p> <ol style="list-style-type: none"> <li>1. IGARD suggested that, noting the consent materials do not confirm the time for which the data will be held for, that the five years recommended in the UK Medicines for Human Use Regulation 2004 (as amended) should be applicable.</li> <li>2. IGARD advised that they would wish to review this application again when it comes up for renewal (for any reason).</li> </ol> <p>It was agreed the condition would be approved Out of Committee (OOC) by IGARD members.</p>
2.3	<p><u>Group Application 4 CCG's<sup>1</sup>: DSfC - Joint DC Commissioning application - North Yorkshire (Presenter: James Humphries-Hart) NIC-325899-B0C9B</u></p> <p><b>Application:</b> This was a new application for 4 CCG's to receive 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). The purpose of the application is to provide intelligence to support the commissioning of health services.</p> <p><b>Discussion:</b> IGARD noted and endorsed NHS Digital's review that the four CCG's did <b>not</b> meet NHS Digital's Standard for privacy notices.</p> <p>IGARD queried the references throughout the application to "<i>consented data</i>" and asked that an explanation of this was provided; or if this was not relevant to this application, that these references were removed.</p> <p><b>Outcome Summary:</b> recommendation to approve subject to the following condition:</p>

<sup>1</sup> NIC-325899-B0C9B NHS Hambleton, Richmondshire and Whitby CCG, NHS Harrogate and Rural CCG, NHS Vale of York CCG, NHS Scarborough and Ryedale CCG

	<p>1. To provide an explanation to the references within the application to “<i>consented data</i>”, or if this is not relevant to remove this reference from the application.</p> <p>It was agreed this condition would be approved Out of Committee (OOC) by the IGARD Chair.</p>
2.4	<p><u>Group application for 3 CCG’s<sup>2</sup>: DSfC - NHS Bedfordshire CCG, NHS Luton CCG and NHS Milton Keynes CCG - Comm (Presenter: James Humphries-Hart - NIC-338789-M0T3Q</u></p> <p><b>Application:</b> This was an amendment application to 1) add pseudonymised GP Data, linked to the standard pseudonymised commissioning data set at the CSU, to be processed by Optum Health Solutions UK Ltd; and 2) to add in cloud storage by Microsoft UK. The purpose of the application is to provide intelligence to support the commissioning of health services; the first amendment serves to enhance the population health analytics.</p> <p><b>Discussion:</b> IGARD noted and endorsed NHS Digital’s review that the three CCG’s did <b>not</b> meet NHS Digital’s Standard for privacy notices.</p> <p>IGARD noted the amendment within the application to add GP and Social Care Data to the existing Data Sharing Agreement (DSA) and queried why these amendments were not also reflected in supporting document 1, the data flow diagram. NHS Digital confirmed that the reference to “social care data” was an error and was not part of this application and advised that this would need removing from the application. IGARD noted the update from NHS Digital and supported the amendment to the application to remove references “social care data”; in addition, IGARD also asked that the data flow diagram was updated to correctly reflect the updated application.</p> <p><b>Outcome Summary:</b> recommendation to approve subject to the following condition:</p> <p>1. To remove the references to “<i>social care data</i>” from the application.</p> <p>The following amendments were requested:</p> <p>1. To update the data flow diagram to reflect the updated application.</p> <p>It was agreed this condition would be approved OOC by the IGARD Chair.</p>
2.5	<p><u>St George's, University of London: MR39 - SMOKING STUDY - MEN ATTENDING BUPA MEDICAL CENTRE (Presenter: James Humphries-Hart) NIC-148331-5F2FS</u></p> <p><b>Application:</b> This was an extension application for pseudonymised Medical Research Information Service (MRIS); and an amendment application to change the Data Controller and Data Processor from the Wolfson Institute of Preventative Medicine at Queen Mary, University of London (QMUL) to Population Health Research Institute, St George's, University of London (SGUL).</p> <p>The purpose is for a study looking at the risk factors for cancer and cause specific mortality, with an emphasis on the risks of smoking; the cohort consisted of 22,000 men aged 35-64 years who attended the British United Provident Association (BUPA) medical centre in London for a comprehensive medical examination between 1975 and 1982.</p> <p><b>Discussion:</b> IGARD queried the information provided within the ‘summary’ in section 1(a) (Abstract) that stated that the reason for the amendment was to “...to add <i>Data Processor</i>”; and were advised by NHS Digital that this should note an amendment to change the Data Controller organisation. IGARD noted the clarification from NHS Digital and asked that section 1(a) was amended to reflect the amendment.</p>

<sup>2</sup> NIC-338789-M0T3Q\_NHS Bedfordshire CCG, NHS Luton CCG and NHS Milton Keynes CCG

	<p>IGARD noted that the server was being transferred from QMUL to SGUL, and that the controllership was changing but not the processing, and that the location would remain the same, and was in part due to the Principal Investigatory Professor retiring from QMUL; and that the only staff members with access to this data were based at SGUL. IGARD therefore asked that the application was updated to clearly state that the retired Principal Investigatory Professor would <b>not</b> have any access to the data at SGUL.</p> <p>IGARD also suggested that NHS Digital should satisfy itself that QMUL did not hold any duplicate hard or electronic copies of the data, following the change in Data Controllership.</p> <p>IGARD queried the statement in section 1(a) that MRIS data was identifiable and were advised by NHS Digital that whilst the data was sensitive, it was not identifiable; IGARD noted the update and asked that section 1 was amended to confirm that the applicant only holds pseudonymised MRIS data.</p> <p><b>Outcome Summary:</b> recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> <li>1. To clearly state within the application that the retired Principal Investigatory Professor will not have any access to the data at SGUL.</li> </ol> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To amend section 1 to confirm that the applicant has only ever held pseudonymised MRIS data.</li> <li>2. To amend the information within the 'summary' at the start of section 1(a) that the amendment is to change the 'Data Controller'.</li> </ol> <p>The following advice was given:</p> <ol style="list-style-type: none"> <li>1. IGARD suggested that NHS Digital should satisfy itself that QMUL does not hold any duplicate hard or electronic copies of the data.</li> </ol> <p>It was agreed this condition would be approved OOC by the IGARD Chair.</p>
2.6	<p><u>Clinical Registries, Databases and Audits – Briefing Paper (Presenter: James Humphries-Hart)</u></p> <p>The briefing paper was to inform IGARD about the new Clinical Registries, Databases and Audits product. In line with the Data Services for Commissioners Directions, NHS England requires defined clinical data extracts from specified Clinical Databases, Registries and Audits to be able to fulfil their statutory functions as a commissioner of NHS Services, as determined by the Health and Social Care Act 2012.</p> <p>The briefing was an 'overarching briefing' which intends to cover all relevant information to the inclusion of any clinical database or audit in the NHS England and NHS Digital Data Sharing Agreement (DSA) as all the material details in terms of legal basis for the purposes for and processing of the data flows is the same for all Clinical Database, Registry and Audit extracts.</p> <p>This briefing paper was previously presented to IGARD on the 5<sup>th</sup> December 2019, where IGARD made a number of comments and suggested amendments.</p> <p>IGARD welcomed the updated draft briefing paper and reiterated their request for:</p> <ol style="list-style-type: none"> <li>1. In respect of each of the six clinical dataset appendices, to include an abstract-level statement (i.e. the level of detail provided in applications presented to IGARD) clearly setting out the verifiable legal argument that establishes <b>why</b> the parties referenced are considered Data Controller(s) and Data Processor(s).</li> <li>2. To expand the briefing paper further to outline how the approval process (including IGARD) will flow for new clinical registries</li> </ol>

	<p>3. To ensure there is a robust change control process and mechanism in place, and to provide further details of how applicants access this.</p>
2.7	<p><u>NHS England: NHS England - DSfC - NCDR amendment 2019 (Presenter: James Humphries-Hart) NIC-139035-X4B7K</u></p> <p><b>Application:</b> This was an renewal application to NHS England's National Commissioning Data Repository agreement for pseudonymised Clinical Registry data; Children and Young People's Health Services (CYPHS), Secondary Use Service (SUS) for Commissioners, Local Provider Flows, Community Services Data Set (CSDS), Mental Health Learning Disability Data Set (MHLDDS), Diagnostic Imaging Data Set (DIDs), Improving Access to Psychological Therapies (IAPT), Mental Health Minimum Data Set (MHMDS), Maternity Services Data Set (MSDS), Civil Registration, Mental Health Services Data Set (MHSDS), National Cancer Waiting Times (CWT), National Diabetes Audit (NDA), Community Services Data Set (CSDS), Assuring Transformation (AT), Patient Reported Outcome Measures (PROMs).</p> <p>NHS England requires access to data collected within Clinical Registries, Databases and Audits. Part of NHS England's responsibility is to oversee the budget, planning, delivery and day-to-day operation of the commissioning side of the NHS in England as set out in the Health and Social Care Act 2012.</p> <p>The application had previously been presented to IGARD on the 12<sup>th</sup> December 2019 and IGARD had recommended for approval for a period of 2 months, in conjunction with the updated Clinical Registries Briefing Paper.</p> <p><b>Discussion:</b> IGARD noted that at the previous review on the 12<sup>th</sup> December 2019, a short-term approval period of 2 months had been recommended to allow NHS Digital to resolve some of the outstanding issues and queries that had been discussed. IGARD highlighted to NHS Digital that this revised application did not address some of the queries raised last time to allow them to form a view.</p> <p>IGARD previously requested a detailed response that clarified the Data Controllorship issues and the Data Controller and Data Processor analysis for each of the clinical registries outlined in the application (the specifics of this previously-raised request were set out in the Clinical Registries Briefing paper discussion on 5 December 2019) and asked that this be provided.</p> <p>IGARD previously queried the proposed outputs that were outlined in section 5 (Purpose / Methods / Outputs) and asked that the applicant ensured that these were realistic and achievable.</p> <p>IGARD previously suggested that a more detailed description was included in section 5 outlining how the change control processes would be undertaken following the inclusion of new clinical registry datasets, and again reiterated their request for this information.</p> <p><b>Outcome Summary:</b> IGARD were unable to make any recommendation as there was not enough information to address the previously-raised questions in order for IGARD to form a view and NHS Digital may wish to consider a short-term extension until resolved and IGARD looked forward to welcoming this application back to IGARD in due course.</p>
3	<p><u>Returning Applications</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> <ul style="list-style-type: none"> <li>• NIC-127189-R2K8F St George's, University of London</li> <li>• NIC-43771-N0W3Q University of Cambridge</li> </ul>

	<ul style="list-style-type: none"> <li>• NIC-148204-7B1XT University of Oxford</li> <li>• NIC-90019-Q8P9K The Health Foundation</li> </ul> <p>IGARD welcomed the four applications 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 and Assurance Report which would be published separately to the minutes of the meetings, for transparency of process, and on a quarterly basis.</p>
<b>4</b>	<p><u>AOB:</u></p> <p><u>Associate Director, Data Access</u></p>
<b>4.1</b>	<p>The Associate Director, Data Access attended (part of) the meeting as part of his regular catch-up with IGARD.</p>
<b>4.2</b>	<p><u>Survey Data (Presenters Stuart Blake / Cher Cartwright)</u></p> <p>As part of IGARD’s continuous learning and development, NHS Digital presented a brief overview of the surveys run by NHS Digital that cover a range of health and lifestyle areas; and are used extensively by the central government, local government, policy-makers, researchers, charities and for undergraduate and postgraduate teaching.</p> <p>IGARD welcomed and thanked NHS Digital for the briefing / discussion and noted the importance of the direction as a key action in order to enable the survey datasets to be onboarded and processed. IGARD also recognised the time given and personal details that have been provided by members of the public; and the importance of these survey’s for researchers who were waiting to access the data.</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>

## Appendix A

### Independent Group Advising on Releases of Data (IGARD): Out of committee report 07/02/20

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-08472-V9S6K	UK Biobank	16/01/2020	1. To either (i) disable the 'live links' on Biobank's website to the Access Procedures and the Material Transfer Agreement documents, or (ii) add a note on the website that these documents are 'currently under review'.	IGARD members	Quorum of IGARD members	

In addition, a number of applications were processed by NHS Digital following the Precedents approval route. IGARD carries out oversight of such approvals and further details of this process can be found in the quarterly Oversight and Assurance Report.

In addition, a number of applications were approved under class action (addition of Liaison Financial Service and Cloud storage):

None