

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

### Minutes of meeting held 15 August 2019

**In attendance (IGARD Members):** Sarah Baalham, Anomika Bedi, Eve Sariyiannidou, Geoffrey Schrecker (Deputy Chair), Maurice Smith.

**In attendance (NHS Digital):** Dave Cronin, Frances Hancox (Item 2.3), James Humphries-Hart, Karen Myers, Kimberley Watson, Vicki Williams.

**Not in attendance (IGARD Members):** Maria Clark, Nicola Fear, Kirsty Irvine (Chair), Priscilla McGuire.

1	<p><b>Declaration of interests:</b></p> <p>Maurice Smith noted professional links to NHS Liverpool CCG [NIC-303379-H4C8H Liverpool Heart and Chest Hospital NHS Foundation Trust] but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.</p> <p>Maurice Smith noted a professional link with NHS Liverpool CCG [NIC-19237-R3T6S University of Liverpool] and would not be part of the discussion. It was agreed that Maurice would not remain in the room for the discussion of that application.</p> <p>Eve Sariyiannidou noted professional links to HQIP [NIC-120105-F0K2L University of Leicester] but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.</p> <p><b>Review of previous minutes and actions:</b></p> <p>The minutes of the 8<sup>th</sup> August 2019 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting.</p> <p><b>Out of committee recommendations:</b></p> <p>An out of committee report was received (see Appendix B).</p>
2	<b>Data applications</b>
2.1	<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 application for identifiable Diagnostic Imaging Dataset (DIDs), Hospital Episode Statistic (HES), Mental Health Services Data Set (MHSDS) and Civil Registrations data for a study designed to 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.</p> <p><b>Discussion:</b> IGARD welcomed the application which came 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</p> <p>IGARD noted that within the consent materials provided it stated "<i>Once you have been discharged from hospital you will be contacted once, 12 months after your angiogram</i>" and advised that if the applicant made the decision to contact the patients again, they would need to be clear that they were re-consenting; and advised that using supporting document 3.2, the General Data Protection Regulation (GDPR) participant Information Sheet (PIS) document would not be sufficient, since it was clear in the documentation provided that contact could only be made once.</p>

IGARD asked for further consideration to be given to minimising the data requested, such that it would be compatible with consent, if the data provided was only relevant to the cardiac condition for which the angiogram had been performed.

IGARD advised that if the applicant required additional data that was not covered by the consent materials that the applicant may wish to consider applying for s251 support as an alternative.

IGARD noted that it was not clear within supporting document 1.0, the protocol, that the study was only looking at the outcomes for the condition specified and that this did not cover other health outcomes; and suggested that the protocol was updated to clearly state this.

IGARD noted that it was clearly stated within the consent materials that patient names would not be shared but that currently proposals were to share identifiers back to NHS Digital, which were not covered by consent.

IGARD noted that the PIS advised that the information was being sought for corroboration; but that it did not state that this also contained information provided by the patient and asked that this was updated to reflect this information.

IGARD queried if the ethics approval outlined in the protocol covered this wider application for the data requested and suggested that this was clarified.

IGARD noted that further justification was required to clearly outline why the University of Southampton wanted to hold the data for a period of 25 years (as stated in section 1), noting that this was not stated specifically in the consent materials.

IGARD advised that they had been unable to directly access some of the information via the web links provided in the application and suggested that the links were tested to ensure they worked correctly and that they accessed the appropriate information.

**Outcome Summary:** IGARD welcomed the application which came for advice on the consent materials and without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD advised that consent is not compatible with the application as it stands and that the applicant may wish to consider s251 support since the consent provides no grounds to contact this cohort.

2.2

University of Liverpool: MR1298: UK Lung Cancer Screening (UKLS) Trial Lung Cancer Registry and Mortality data for consented individuals (Presenter: Dave Cronin) NIC-19237-R3T6S

**Application:** This was an amendment and renewal application for identifiable Medical Research Information Service (MRIS) for a study of lung cancer screening in the UK, with the aim of providing the information required for an informed decision about the introduction of population screening for lung cancer.

The application had previously been presented to IGARD on the 25<sup>th</sup> July 2019 where IGARD had recommended for approval subject to the following conditions in respect of the continuation of the work that is being undertaken to hold and process the existing data flows to produce outputs for the UK National Screening Committee: to clarify why The Royal Liverpool and Broadgreen University Hospitals NHS Trust are not considered joint Data Controllers and to clarify why the other collaborators named in the protocol are not considered joint Data Controllers or Data Processors. IGARD had been unable to recommend for approval any aspect relating to the sharing of data or data linkage: the sharing of derived data only is not reflected within the application which makes numerous references to the sharing of pseudonymised or record level data; it is not clear within the application what the data linkage is, what datasets will be linked and the purpose of any data linkage

**Discussion:** IGARD noted that the application had been updated to reflect most of the comments previously made.

IGARD queried the involvement of The Royal Liverpool and Broadgreen University Hospitals NHS Trust (“the Hospital”) and were advised by NHS Digital that they were no longer involved in the follow-up study; IGARD asked that section 5 (Purpose / Methods / Outputs) was updated to clearly state that the Hospital were no longer involved in the study.

IGARD noted the key conditions outlined in the specification, including reference to the sharing of derived data in accordance with the specification and restrictions with regard to data linkage, and asked that these were replicated in section 6 (Special Conditions) as special conditions.

IGARD noted the information provided in section 1 (Abstract) that stated *“The data linkages by the University of Liverpool will directly link NHS Digital data under this Agreement with ‘subject data’ (defined as: “data that has been provided by the participants as part of the trial”). No other linkages of NHS Digital data will take place. The findings from analyses of NHS Digital data will be combined with the findings from analyses of the NELSON study and reanalysed as part of a larger dataset. This will be aggregated data only.”* and asked that this was also replicated as a special condition in section 6 (Special Conditions).

IGARD queried the references within the application to “anonymised” data and asked that these were removed and that record level data was clearly described as well as further information on how the data had been derived and what the derived data actually included.

IGARD noted reference to ‘lung cancer incidence’ and suggested that this terminology be updated to ‘lung cancer mortality’ with reference to the use of cause of death data.

IGARD noted the reference in section 5(a) (Processing Activities) to *“No data covered by this Agreement will be shared with any third parties”* and asked that this was amended to state *“No data **provided by NHS Digital...**”*.

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

1. To clearly state in section 5 that The Royal Liverpool and Broadgreen University Hospitals NHS Trust is no longer involved in the follow-up study.
2. To replicate the key conditions outlined in the specification as special conditions in section 6.
3. To replicate the data linkage restrictions as outlined in section 1 as a special condition in section 6.
4. Any reference to anonymised data should be removed and record level data should be clearly described as well as how the data has been derived.

The following amendments were requested:

1. To update the application to amend the references from “cancer incidence” to “cancer mortality”.
2. To amend the sentence in section 5(a) to state that *“No data **provided by NHS Digital** covered by this Agreement will be shared with any third parties.”*

It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members

**2.3** University of Leicester: Critically ill children and young people: do national Differences in access to Emergency Paediatric Intensive Care and care during Transport affect clinical outcomes and patient experience? The DEPICT study (Presenter: Kimberley Watson) NIC- 120105-F0K2L

**Application:** This was an extension to the Data Sharing Agreement (DSA) and amendment application for pseudonymised Civil Registration and Hospital Episode Statistics (HES) data to add an additional purpose (work stream C) and add two individuals under honorary contract who will apply particular health economics expertise to analysis the data for work stream C.

Critically ill children who are admitted to district general hospitals can require specialist transport to a paediatric intensive care unit (PICU), this study is looking at the association between timelines of access to paediatric intensive care and 30-day mortality. The amendment is to add an additional purpose, Workstream C – economic analysis; and to add two individuals under honorary contracts who will apply particular health economics expertise to analyse the data for Workstream C.

**Discussion:** IGARD noted the other organisations listed in supporting document 5.2, the protocol and supporting document 8, the collaboration agreement and queried why these organisations were not also considered joint Data Controllers. They asked for a clear explanation as to why these organisations were not regarded as joint data controllers for the study and suggested that for each project a list of all members of the study team be reviewed (to identify which organisation they were associated with) which may help evidence who should be considered a Data Controller; it was noted that the protocol and other supporting documentation did not appear to specify which organisations were involved in which workstream(s) of the study and this made it more difficult to understand who was involved with certain areas and not with other areas. IGARD requested that involvement of the various organisations should be updated within section 5 (purpose, methods, outputs).

IGARD queried if the two individuals who were carrying out the health economics analysis were substantive employees with the appropriate honorary contracts in place and suggested that an appropriate clause was included that the substantive employer of the individuals under the honorary contract would take appropriate action against the individuals in the event of a data protection or confidentiality breach; and asked that written evidence of this was provided.

IGARD noted that s251 documentation had been provided as supporting documentation, however it was not clear if the original s251 support was ongoing and asked that evidence of this was provided.

IGARD noted the information provided in section 3(c) (Patient Objections) that stated that **no** patient objections had been applied and queried if they had applied in the previous iteration of the application and asked that section 1 (Abstract) was updated to include the historical information on patient objections.

As part of the AOB discussion that took place later in the meeting, IGARD additionally noted the following in respect of this application. IGARD noted that there was evidence that the applicant had entered into a contract with HQIP for the supply of data and that the University of Leeds appeared to be acting under the instructions of the applicant to provide audit data to NHS Digital. The assumption was made that the University of Leicester had satisfied itself as to the lawful basis under which it receives personal data from HQIP. Therefore the data controller for the PICANet and ICNARC case mix programme data is the University of Leicester and the application was amended to reflect this and to provide the appropriate GDPR legal basis.

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

1. To clearly explain why the other organisations listed in the protocol and the collaboration agreement are not regarded joint data controllers for the study, as the study protocol and other supporting documentation do not specify which organisations are involved in each workstream of the study.

2. To provide written evidence that appropriate honorary contracts are in place for the individuals who will carry out the health economics analysis, which will include a clause that the substantive employer of the person under the honorary contract will take disciplinary action in the event of a data protection or confidentiality breach.
3. To provide evidence that the original s251 support is ongoing.

The following amendments were requested:

1. To update section 1 with the historical information on patient objections.
2. With regard to the two flows of data into NHS Digital, to amend the abstract and section 5 to clearly state the correct Data Controller for the PICANet and ICNARC for the case mix programme data, and to provide the appropriate legal bases under the GDPR

It was agreed the conditions would be approved OOC by IGARD members

2.4

NHS South, Central and West CSU: DSfC - Berkshire West ICS and Frimley Health and Care ICS - Commissioning (Presenter: James Humphries-Hart) NIC-299082-H4R7S

**Application:** This was a new application for pseudonymised Mental Health Services Data Set (MHSDS), Improving Access to Psychological Therapies Data Set (IAPT), Maternity Services Data Set (MSDS), Community Services Data Set (CSDS), (Diagnostic Imaging Dataset (DIDs), National Cancer Waiting Times Monitoring DataSet (CWT), Civil Registration, National Diabetes Audit (NDA), Patient Reported Outcome Measures (PROMs) and Secondary Use Service (SUS) for Commissioners for the purpose of commissioning.

The objective is to process data for two Integrated Care Systems (ICS's) on one joint platform to provide one consistent, single source of data that can be used by all stakeholders across the ICS's regardless of the organisation, for the provision of their information and analysis needs, the aim being to provide one single source of truth. The ICS's also aims to develop the skills of their information analysts and architects to provide closer support to decision makers.

**Discussion:** IGARD welcomed the application and noted that this was the first of its type to be presented.

IGARD noted similarities to Sustainability and Transformation Partnership's (STPs) and Vanguard, however queried the governance structure of the ICS since it was not clear and asked that the application was reviewed to clearly outline the structure, including (but not limited to) how this may impact on the data controllership; and to confirm whether people from outside the CCG involved in the commissioning process had honorary contracts with that CCG for that work; and what the content of these were.

IGARD were advised by NHS Digital that the CCGs hold the data already under previous Data Sharing Agreements (DSAs) and asked for clarification as to whether this application would replace prior applications by the same CCGs for the same data, either individually or as part of other groups, for example the STPs.

IGARD asked that section 1 (Abstract) was updated to clearly outline what data each CCG currently held under those DSAs and how this related to what they do already. IGARD also asked for clarification as to whether the work outlined in this application could be addressed by amending existing applications / DSAs and if not, to provide further information to outline why not.

NHS Digital noted that they had sought advice from NHS Digital's Security Advisors on Cloud storage and that section 1 would be updated to reference this.

IGARD queried if automated decision-making around patient stratification and predicted modelling was being undertaken; and asked that this was considered.

IGARD noted the special conditions included in section 6 (Special Conditions) and asked that these were reviewed to ensure they are meaningful and relevant.

IGARD noted reference to a number of technical phrases and words throughout the application 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.

IGARD queried the inclusion of the historical CCG Information Governance Toolkit (IGT) in section 1 and asked that this was removed as it was not relevant.

IGARD noted that there were references within the application to 'CCG' when referring to the four CCGs and asked that the terminology was clearly pluralised throughout.

IGARD suggested that NHS Digital consider whether the Public Interest Test has been met for the dissemination of data under the Health and Social Care Act section 261(2)(b)(ii).

**Action:** IGARD noted the work undertaken by CCG's and asked that NHS Digital provide a number of case studies outlining how they yielded benefits of this work including how CCG's performed their statutory duties following receipt of data for commissioning purposes, how the system benefited from the data and the work undertaken

**Outcome Summary:** Unable to recommend for approval

1. To review the application and clearly outline the governance structure of the ICS including (but not limited to) how this may impact on Data Controllership and whether people from outside the CCG involved in the commissioning process have honorary contracts with that CCG for that work; and what the content of these are.
2. To provide clarity as to whether this application will replace prior applications by the same CCGs, either individually or as part of other groups, e.g STP's.
3. To update section 1 to clearly outline what data each CCG has under those DSAs and how it relates to what they do already.
4. To clarify whether the work outlined in this application can be addressed by amending existing applications /DSAs and if not, why not.
5. To amend section 1 to reference NHS Digital's Security Advisor's advice on Cloud storage.
6. To consider whether automated decision-making is being undertaken.
7. To review the special conditions in section 6 to ensure they are meaningful and relevant.
8. To update the application throughout to ensure the use of technical jargon is used only where necessary; and where it is necessary, to be also written in language suitable for a lay reader
9. To remove from section 1 the historical IGT information.
10. To amend the application throughout to pluralise the terminology used to clearly reference the 4 CCG's.

The following advice was given:

1. IGARD suggested that NHS Digital consider whether the Public Interest Test has been met for the dissemination of data under the Health and Social Care Act section 261(2)(b)(ii).

<p>2.5</p>	<p><u>National Commissioning Data Repository: NHS England - DSfC - NCDR amendment 2019 (Presenter: James Humphries-Hart) NIC-139035-X4B7K</u></p> <p><b>Application:</b> This was an amendment application for pseudonymised Children and Young People Health Service (CYPHS), Local Provider Flows, Community Services Data Set, Mental Health and Learning Disabilities Data Set (MHLDDS), Diagnostic Imaging Dataset (DIDs), Improving Access to Psychological Therapies Data Set (IAPT), Maternity Services Data Set, Civil Registrations, Mental Health Services Data Set and Secondary Use Service (SUS) for Commissioners.</p> <p>The requested datasets are required to ensure that NHS England (NHSE) can meet its statutory duties and to meet the requirements of the Five-Year Forward View.</p> <p>NHS Digital advised that this application had been submitted to IGARD for advice on section 5 (Purpose / Methods / Outputs).</p> <p><b>Discussion:</b> IGARD welcomed the application which came for advice on section 5 of the application</p> <p>IGARD noted the content of section 5 and advised that it was a good starting point including detail about the statutory function of NHS England, what they do and why they do it, but although helpful, would need further work to bring the information together as a cohesive summary..</p> <p>IGARD thanked NHS Digital for providing NHS England’s Health and Social Care Information Centre’s Directions 2015 and asked that section 6, which outlined what was going to happen with the data was included as part of the introduction in section 5 since it provided information on the registries, audit, databases and how they were linked together.</p> <p>IGARD noted reference to a number of technical phrases and words within section 5 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.</p> <p>IGARD queried why NHS England’s Clinical Register schedule was not included as part of the supporting documents and advised that this would have been helpful when undertaking their assessment of section 5.</p> <p>IGARD noted the reference to <i>“The budget for Specialised Commissioning alone is estimated to be £16 Billion (in 2018/2019).”</i> and suggested that this figure was put into context of the NHS budget.</p> <p><b>Outcome Summary:</b> IGARD welcomed the application which came for advice on the draft wording for the inclusion of Clinical Registry data to the NCDR prior to submitting an amendment to the NCDR application and without prejudice to any additional issues that may arise when the application is fully reviewed.</p>
<p>3</p> <p>3.1</p> <p>3.2</p>	<p><b>AOB:</b></p> <p><b>Data Controllership</b></p> <p>There was a further discussion with regard to data controllership (HQIP vs University of Leicester). Please see item 2.3.</p> <p>There was no further business raised, the IGARD Deputy Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.</p>

### Independent Group Advising on Releases of Data (IGARD): Out of committee report 09/08/19

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-250100-R3W1G	Glasgow Caledonian University	25/07/2019	1. To provide written confirmation that the HRA CAG conditions of support have been met, in particular, the displaying of information posters within the relevant clinics.	OOO by IGARD Chair	OOO by IGARD Chair	
NIC-147884-R7CBN	University of York		<ol style="list-style-type: none"> <li>1 To provide confirmation within section 5 that the protocol provided is specific to this application and does not relate to the historical UKCCS study.</li> <li>2 To provide confirmation in section 5 that no other organisations are involved in any capacity with this study.</li> <li>3 To provide further justification why MRIS data already held by the applicant needs to be resupplied to the applicant again and to identify the relevant TPP issues.</li> <li>4 To confirm that there are no non-NHS sites involved in the collection of data.</li> </ol>	OOO by IGARD Members	OOO by IGARD Members	<ol style="list-style-type: none"> <li>1. To update section to clarify that there are no non-NHS sites involved</li> <li>2. To update the legal basis within the abstract.</li> </ol>

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

- None