

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

### Minutes of meeting held 1 August 2019

**In attendance (IGARD Members):** Sarah Baalham, Kirsty Irvine (Chair), Priscilla McGuire, Eve Sariyannidou, Geoffrey Schrecker.

**In attendance (NHS Digital):** Victoria Byrne-Watts, Duncan Easton, Tom Foley (2.5-3), James Humphries-Hart, Dickie Langley, David Morris (2.5), Denise Pine (2.2-2.3), Tracy Taylor (2.2-2.3), Kimberley Watson, Vicki Williams.

**Not in attendance (IGARD Members):** Anomika Bedi, Maria Clark, Nicola Fear, Maurice Smith.

1	<p><b>Declaration of interests:</b></p> <p>There were no declarations of interest.</p> <p><b>Review of previous minutes and actions:</b></p> <p>The minutes of the 25<sup>th</sup> July 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	<p><b>Data applications</b></p>
2.1	<p><u>University of Hull: Examining the characteristics and predictors of alcohol withdrawal readmissions and emergency department attendances (Presenter: Victoria Byrne-Watts) NIC-226185-B6C2J</u></p> <p><b>Application:</b> This was a new application for pseudonymised Hospital Episode Statistics (HES) data for a study aiming to examine routine hospital data to look at characteristics and predictors of alcohol withdrawal in relation to admissions and Accident and Emergency (A &amp; E) attendances in England. Patients experiencing wholly attributable alcohol diagnosis often present with acute clinical presentations related to alcohol use or secondary clinical conditions. With over 1 million alcohol-related hospital admissions the burden and unmet needs of excessive alcohol consumption and related conditions remain a priority under the NHS 10-year plan and for Public Health England.</p> <p>The application was been previously considered on the 13<sup>th</sup> June 2019 when IGARD had been unable to recommend for approval as the relevant supporting documents, essential to IGARD's review, were not available: to provide a copy of the protocol or further information which clearly defines the scope of the project in sufficient detail to allow an assessment of, inter alia, data minimisation efforts and the necessity of the data for the specific research project; to provide a further explanation of the involvement of other parties outlined now, and in the future, and to provide further detail on the project, if this is part of a wider project and how it is linked to the earlier research undertaken at Kings College London.</p> <p>NHS Digital noted that an explanatory paragraph from section 5(a) (Objective for Processing) should be also included in section 5(b) (Processing Activities)</p> <p>NHS Digital noted a number of typos and grammatical errors throughout section 5 (Purpose / Methods / Outputs) which would be corrected and, in addition, to correctly reference the University of Kent when referencing "statistical support"</p> <p><b>Discussion:</b> IGARD noted the update from NHS Digital with regard to typos and grammatical errors within Section 5 and the inclusion of the University of Kent when referencing 'statistical</p>

	<p>support'. IGARD also noted that the paragraph in section 5(a) starting "<i>Data will be shared with the collaborator...</i>" should be replicated in section 5(b).</p> <p>It was also suggested that the explanatory paragraph in section 1 (Abstract) detailing how the original PhD study differed from this study and the roles of the different organisations, be included within section 5(a).</p> <p>There was a lengthy discussion with regard to supporting document 2, study protocol, provided as part of the review which stated that "...<i>ethics exemption and permission to use anonymised/non-identifiable routine data will be sought via the Faculty of Health Sciences Ethics Committee, University of Hull on receipt of the data and prior to analysis</i>". However, IGARD noted that permissions would usually be in place before release of data by NHS Digital and suggested that written confirmation from the internal ethics committee or its authorised representative be provided confirming that ethics exemption had been granted and that permission to use pseudonymised data has been given.</p> <p><b>Outcome Summary:</b> recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> <li>1. To provide written confirmation from the Faculty of Health Sciences Ethics Committee, University of Hull (or an authorised representative of that committee) that an ethics exemption has been granted and that permission to use the pseudonymised data has been given.</li> </ol> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1 To move relevant explanatory paragraphs from section 1 to section 5a.</li> <li>2 To replicate the paragraph in section 5(a) starting "<i>Data will be shared with the collaborator...</i>" to section 5(b)</li> </ol> <p>It was agreed the condition would be approved OOC by the IGARD Chair.</p>
2.2	<p><u>Moorfields Eye Hospital NHS Foundation Trust: Detecting Dementia in the Retina: a Big Data Machine Learning Approach (Presenter: Dave Cronin) NIC-116883-L8W9Q</u></p> <p><b>Application:</b> This was an amendment application for pseudonymised Hospital Episode Statistics (HES) Admitted Patient Care (APC) data, in addition to HES Accident &amp; Emergency (A&amp;E) and Outpatient data already held under NIC-116883-L8W9Q.</p> <p>The study aims to investigate the association between changes in the appearance of the retina, as measured using retinal photography and scans, with the onset of dementia and will focus on how retinal morphology evolves with time for the purpose of medical research.</p> <p><b>Discussion:</b> IGARD queried the suite of subsets under HES and if NHS Digital were content with the s251 support in place for the generic use of HES. NHS Digital noted that it was rare for s251 support to specify a particular part of HES and confirmed that the applicant had requested APC in addition to A&amp;E and Outpatient already disseminated, since HES APC and primary care data had already been demonstrated in multiple previous studies evaluating dementia coding. IGARD suggested that for transparency, the three subsets of HES requested under this application, APC, A&amp;E and Outpatients, be clearly listed as part of the sentence starting "<i>This research project requires access to HES data...</i>" with section 5(b) (Processing Activities) and suggested that if the applicant requested additional data or another subset of HES that the application be brought back to IGARD for review.</p> <p>IGARD suggested that section 4 (Privacy Notice) be updated to pluralise 'privacy notice' and suggested that the Data Controllers, University College London and Moorfields Eye Hospital NHS Foundation Trust, ensure their published privacy notices are updated and accessible.</p>

	<p>IGARD noted that within section 3(c) (Patient Objectives) that the answer to the question 'patient objections applied' was 'no' and suggested this be updated to 'yes' since legal basis was s251 support.</p> <p><b>Outcome Summary:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To amend section 4 to reflect two data controllers (eg 'privacy notices' (plural)).</li> <li>2. To amend section 5(b) to specifically note the three HES subsets requested under this application (APC, A&amp;E and Outpatients).</li> <li>3. To update section 3(c) to answer 'yes' to the question 'Patient Objections Applied'.</li> </ol> <p>The following advice was given:</p> <ol style="list-style-type: none"> <li>1. IGARD advised that should the applicant request additional data, including additional HES products, they would wish to review this application again.</li> <li>2. IGARD advised that the Data Controllers should ensure their updated privacy notices are published forthwith.</li> </ol>
2.3	<p><u>The University of Manchester: Neighbourhoods and Dementia (Presenter: Kimberley Watson) NIC-33318-X4Q1B</u></p> <p><b>Application:</b> This was an amendment application to add Lancaster University as a joint Data Controller. Pseudonymised Hospital Episode Statistics (HES) Accident &amp; Emergency (A&amp;E), Outpatient and Admitted Patient Care (APC) data was approved to be disseminated under the previous agreement.</p> <p>The Economic and Social Research Council (ESRC) have funded the Universities of Manchester and Lancaster to investigate the impact of hospital staff training in best care for patients with dementia, on key hospital outcomes for patients with dementia. This objective is part of a larger 5-year programme of ESRC-funded research aimed at improving the lived experience of people with dementia across many areas of their lives.</p> <p><b>Discussion:</b> IGARD noted the helpful summary within section 1 (Abstract) which clearly articulated the analysis undertaken by NHS Digital with the applicant to establish that Lancaster University was a joint Data Controller alongside the University of Manchester for this application.</p> <p><b>Outcome Summary:</b> recommendation to approve</p>
2.4	<p><u>Barts Health NHS Trust: MR1486 - International Surgical Outcomes Study: Long-term survival (Presenter: James Humphries-Hart) NIC-68740-X7R2N</u></p> <p><b>Application:</b> This was a new application for identifiable Medical Research Information Service (MRIS) Cause of Death Report and MRIS Flagging Current Status Report data.</p> <p>The study is a key part of a wider International Surgical Outcomes Study (ISOS) that was completed in 2014 and identified that patients suffering complications were far more likely to die than those who didn't. The aim is to complete studies related to the ISOS UK Cohort and the mortality data being used to answer what the long-term survival is following surgery and how this differs for those suffering complications.</p> <p><b>Discussion:</b> IGARD noted that NIC-68740-X7R2N had been previously presented to IGARD on 6 June 2017 when Queen Mary University of London had been the applicant and Data Controller.</p> <p>It was noted that the chief investigator was a substantive employee of Queen Mary University of London (QMUL) with a honorary contract with Barts Health NHS Trust and</p>

since QMUL was listed as a Data Controller on the previous iteration of the application presented to IGARD in June 2017, that NHS Digital may wish to assure itself that the application referenced the same organisation as the Data Controller instead of Barts Health NHS Trust which could only exercise control under an honorary contract, as noted in supporting document 8.1, honorary contract addendum letter.

It was noted that the European Surgical Outcome Study had been completed in 2014 but that the ISOS was a follow up and according to supporting documentation provided was still ongoing. It was suggested that this be clarified in section 5(a) (Objective for Processing) including clarification as to how the UK arm of the study fitted within the ISOS.

IGARD suggested that when referring to the GDPR legal basis for Foundation Trusts in the application, the following should also be included in section 1 (Abstract): *"The NHS Act 2006 section 43(5) which described the functions of authorised NHS Foundation Trusts states that 'the authorisation must authorise and may require the NHS Foundation Trust (a) to carry out research in connection with the provision of health care (b) to make facilities and staff available or the purposes of education, training or research carried out by others'."*

IGARD noted that within section 3(c) (Patient Objectives) that the answer to the question 'patient objections applied' was 'yes' and suggested this be updated to 'mixed' since legal basis was consent for year 1 and s251 support for years 2 and 3 of data disseminated under this application.

IGARD also suggested that since s251 support only gave approval for 3 years of data from date of consent, that the NHS Digital ensure only 3 years of data was disseminated under this application and this should align with the date consent was given. It was suggested that should the applicant require additional data years, that they would need to submit an amendment application to the Health Research Authority Confidentiality Advisory Group (HRA CAG). In addition the data years in table in section 3(b) (Additional Data Access Required) should be updated to ensure that only 3 years of follow up data was provided to the applicant and from the date of consent and reference to 'deceased individuals' be removed from the legal basis column since it would not be known if individuals were deceased.

IGARD suggested that the sentence in 5(a) referencing "...patients suffering from complications were fare more like to die than those who didn't" be amended to include "in the short to medium term" as referenced in the study protocol, provided as a supporting document. IGARD also suggested that reference to "...no moral or ethical issues" be removed since it was not necessary.

**Outcome Summary:** recommendation to approve for three years follow up data and from date consent was given.

The following amendments were requested:

1. To include the following when referring to the GDPR legal basis *"The NHS Act 2006 section 43(5) which described the functions of authorised NHS Foundation Trusts states that 'the authorisation must authorise and may require the NHS Foundation Trust (a) to carry out research in connection with the provision of health care (b) to make facilities and staff available or the purposes of education, training or research carried out by others'."*
2. To amend section 3(b) to delete *"latest available"* and ensure that only three years follow up data is provided to the applicant, from the date of consent.
3. To update section 3(c) to answer 'mixed' to the question 'Patient Objections Applied'.
4. To clarify in section 5(a) that the study that was completed in 2014 was the European Surgical Outcome Study and to clearly state that the International Surgical Outcome

	<p>Study is a follow up study and ongoing; in addition to clarify how the UK arm of this study fits within the international study.</p> <p>5. To remove from section 5(a) reference to '<i>there are no moral or ethical issues</i>'.</p> <p>The following advice was given.</p> <ol style="list-style-type: none"> <li>1. IGARD drew to NHS Digital's attention that the chief investigator is a substantive employee of Queen Mary University of London, which was named as Data Controller in the earlier iteration of the same application presented to IGARD on 6 July 2017. Accordingly, IGARD suggested that NHS Digital may wish to consider whether this application should reference that same organisation as the Data Controller, instead of an organisation which can only exercise control over the chief investigator under an honorary contract.</li> <li>2. For the avoidance of doubt, IGARD noted that should the applicant wish to have additional years of data (beyond a three year follow up), the applicant would need to submit an amendment application to HRA CAG..</li> </ol>
2.5	<p><u>NHS Scarborough and Ryedale CCG: Cancer Alliance access to National Cancer Waiting Times Monitoring Data Set (NCWTMDS) from the Cancer Wait Times (CWT) System (Presenter: Duncan Easton) NIC-204531-P5L8G</u></p> <p><b>Application:</b> This was a new application for pseudonymised National Cancer Waiting Times Monitoring Dataset (CWT) to both monitor and improve performance against the Cancer Waiting Time standards and to inform wider cancer pathway improvements.</p> <p>NHS Digital noted that this Cancer Alliance application was different to ones previously seen as it reference two Data Controllers: NHS East Riding of Yorkshire CCG and NHS Scarborough &amp; Ryedale CCG</p> <p><b>Discussion:</b> IGARD noted that since the original briefing note with regard to Cancer Alliances had been presented to IGARD in March 2018 then updated in August 2018, the arrangements in place appeared to have significantly changed including Data Controller / Data Processor arrangements. IGARD suggested that NHS Digital provide an updated briefing note to IGARD reflecting current arrangements including the Data Controller / Data Processors, the decision making undertaken and how is making those decisions, the products being produced, the degree of automation undertaken and the different variations of cancer alliances across England.</p> <p><b>Action:</b> NHS Digital to provide an updated briefing paper on the Cancer Alliances.</p> <p>NHS Digital noted that under this application both Data Controllers were accessing the data, through the Clinical Alliance Staff who were mainly hosted by NHS East Riding of Yorkshire CCG and a smaller Clinical Network Team based at NHS Scarborough &amp; Ryedale CCG, on behalf of the Humber, Coast and Vale Cancer Alliance, with a population of approximately 1.4 million people. IGARD noted that since the other Data Processors listed within section 1(c) (Data Processors) were also part of the Cancer Alliance, that NHS Digital confirm via a written analysis why no other member of the alliance should be considered a joint Data Controller in addition to those already listed.</p> <p>IGARD noted that this was templated wording, however suggested that application be updated to pluralise the terminology used to clearly reference the two lead organisations and Data Controllers under this application.</p> <p><b>Outcome Summary:</b> recommendation to approve subject to the following condition</p>

	<p>1. The NHS Digital IG Advisor to review the applicant's assessment of joint Data Controllership and provide clarification to IGARD why the other members of the Cancer Alliance are not also considered joint Data Controllers</p> <p>The following amendments were requested:</p> <p>1. To update the application throughout to pluralise the terminology used to clearly reference the two organisations and joint Data Controllership.</p> <p>It was agreed the condition would be approved OOC by the IGARD Chair</p>
3	<p><u>Data Release Register (Presenter: Dr Tom Foley)</u></p> <p>NHS Digital's vision is to improve health and care through information and technology, with many organisations contributing to the value chain of national health data. NHS Digital produce almost 300 open data statistical publications per year, downloaded over 350,000 times.</p> <p>Dr Foley attended to discuss the impacts created by data released through the Data Access Request Service (DARS) and how NHS Digital could support change throughout the health and social care system by enabling the system to learn from even patient who is treated. The work could standardise how NHS Digital may wish to record impacts in the future, with changes in impacts over time monitored to possibly show the individual patients the impacts generated by data sets they have contributed to.</p> <p>IGARD welcomed the discussion and suggested a small number of clarifications to the paper including IGARD's role as an independent oversight, reference to 'all new applications reviewed by IGARD' to be amended to align with the current published Terms of Reference and that future DARS Standards be updated to include key referenced words to enable an update to this report in the future.</p>
4	<p><b>AOB:</b></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>

### Independent Group Advising on Releases of Data (IGARD): Out of committee report 26/07/19

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-147827-NC2TC	Imperial College London	13/06/2019	1. To add the University of Oxford as a joint Data Controller.	OOO by IGARD Chair	OOO by IGARD Chair and Specialist IGARD Member	N/A
NIC-228637-P6N0L	Imperial College London	18/07/2019	1 To provide a clear justification why small numbers suppression is not appropriate. 2. Provide a clear narrative in section 5(a) to distinguishing between the qualitative and quantitative parts of the study and why Imperial College London are the sole Data Controller.	OOO by quorum of IGARD members	OOO by quorum of IGARD members	N/A
NIC-47225-D8S4S	NHS Warrington CCG	28/03/2019	1. To insert appropriate security assurance wording relating to the use of cloud storage and to give due consideration of anything additional needed given that identifying data that is being stored.	OOO by quorum of IGARD members	OOO by quorum of IGARD members	N/A
NIC-16016-Y9H1D	Wilmington Healthcare	23/05/19	1. In order to meet the necessity test, the applicant should: a) Provide further details of the data minimisations efforts undertaken and update the application to provide further	IGARD Members	Quorum of IGARD Members	IGARD noted the effort undertaken to address the issues raised and the applicant's overall response to the conditions, in particular that they have taken on board and

			<p>detail supporting the proposition that the quantum of data requested is proportionate.</p> <p>b) To provide an indicative work plan for the projects to be undertaken for the next 12 months.</p> <p>c) To clarify how the HES fields and years requested will map to the indicative work plan for the next 12 months.</p> <p>2. In order to establish that the proposal is primarily for the benefit of health and social care, to provide details of the Life Sciences Company / pharmaceutical companies and, in particular, how that work will ultimately flow through to the NHS and how this will benefit the NHS.</p> <p>3. In respect of the governance arrangements:</p> <p>a) To include at least one permanent lay member as part of the decision-making body (such condition to be satisfied within three months of the signing of the agreement – see amendment one below),</p> <p>b) To continue, in addition, to utilise the mechanism in place to include additional lay members to work on specialist projects of particular interest to them,</p> <p>1. To update section 5 with additional details about the advisory board and the lay membership.</p>			made actual changes to address the issue of governance including lay membership
--	--	--	---	--	--	---

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



- None