# Independent Group Advising on the Release of Data (IGARD) Minutes of meeting held 29 August 2019

In attendance (IGARD Members): Sarah Baalham, Maria Clark, Nicola Fear, Kirsty Irvine (Chair), Geoffrey Schrecker.

In attendance (NHS Digital): Stuart Blake, Victoria Byrne-Watts, Garry Coleman (3), Dave Cronin, Louise Dunn (2.7), James Humphries-Hart, Vicki Williams.

**Not in attendance (IGARD Members):** Anomika Bedi, Priscilla McGuire, Eve Sariyiannidou, Maurice Smith.

#### 1 Declaration of interests:

There were no declarations of interest.

### Review of previous minutes and actions:

The minutes of the 15<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.

#### Out of committee recommendations:

An out of committee report was received (see Appendix B).

### 2 Data applications

# 2.1 NHS Wigan Borough CCG: risk stratification and commissioning (James Humphries-Hart) NIC-47221-T6B6Y

**Application:** This was a renewal application to receive pseudonymised data to provide intelligence to support the commissioning of health services and risk stratification which is a tool to identify and predict which patients are at high risk or are likely to be at high risk and prioritising the management of their care in order to prevent worse outcomes, and an amendment application to add the CCG as a data processor for risk stratification; add linking of primary care, social care and additional secondary care data; add Agilisys, NHS Midlands & Lancashire and NHS Oldham CCG as IT infrastructure providers and locations; and remove Advancing Quality Alliance (AQuA) & Salford Royal Academic Health Science Network (AHSN) and NHS Greater Manchester Shared Services (GMSS) processing activities from this application since they are covered under NIC-193456 and NIC-139091.

**Discussion:** IGARD noted that since a number of precedents were generally being used for CCG-related applications, it would be helpful to IGARD if a clear explanation be given in section 1 (Abstract) as to why in particular a CCG application was coming to IGARD for a full review and not via the precedent route.

**ACTION:** to provide a narrative in section 1 of CCG applications as to why a CCG application is coming to IGARD for review (such as multiple Data Processors, or linkage of data).

IGARD noted that this application had previously been reviewed as part of a group Sustainability and Transformation Partnership (STP) application on 15 March 2018 (GA02-NW-STP) but was not noted within the application and queried why the applicant required a duplication of data already received under another application / data sharing agreement (DSA). It was suggested that the application be revised throughout to remove reference to the data disseminated and processing already undertaken as part of this STP application to ensure that there was no duplication between this application and the earlier application. In addition, IGARD suggested that supporting document 1, the data flow diagram, be updated to remove reference to this duplicated data.

IGARD queried reference to the open pseudonymised tool and risk stratification tool referenced in section 5(b) (Processing Activities) and suggested the section be amended to clarity that the encryption key was kept separate to the pseudonymised data and could not be used for re-identification purposes.

As part of IGARD's oversight and assurance role, IGARD queried the amount of data held by CCGs in relation to the number of applications and data sharing agreements in place with NHS Digital, and queried for those CCGs with multiple storage and locations listed in section 1 if CCGs were storing a physical copy of the data at those locations, multiples of the same data, copies of particular datasets or parts of datasets. NHS Digital confirmed that the storage and locations listed for CCG's were usually part of the CCGs back up and storage of data.

**ACTION:** NHS Digital, separate to this application, to confirm that for CCG applications with multiple storage and locations listed within section 1, whether each storage or location listed in the application has a physical copy of data and how many multiple copies of the same data are held for CCG applications.

**Outcome:** recommendation to approve subject to the following condition:

 To revise the application throughout to remove reference to data disseminated and processing already undertaken as part of the applicant's STP application, previously presented to IGARD on 15 March 2018, to ensure that there is no duplication of data being disseminated between this application and the earlier application; and in addition to update the data flow diagram.

The following amendments were requested:

1. To amend section 5(b), processing activities, to clarify that the encryption key is kept separate from the pseudonymised data and cannot be used for re-identification.

It was agreed the condition would be approved OOC by the IGARD Chair.

2.2 NHS North and East London Commissioning Support Unit: HES data for all CSU's and NHS England (James Humphries-Hart) NIC-371243-H1P5T

**Application:** This was a renewal for pseudonymised Hospital Episodes Statistics (HES) Admitted Patient Care (APC), Outpatient (OP), Critical Care (CC), Accident & Emergency (A&E), Emergency Care Dataset (ECDS) and Diagnostic Imaging (DIDs) data and amendment application to include all Commissioning Support Unit (CSU) under one agreement; to add Microsoft Azure Cloud as a data processor, processing and storage location; and to add the Emergency Care dataset.

The CSU's use the data to support Clinical Commissioning Groups (CCGs), other commissioning bodies and local authorities to meet their statutory duties and to support health economy wide transformation projects by providing benchmarking and comparative information to their customers to support their needs.

**Discussion:** IGARD noted the application had been previously presented to IGARD on the 30<sup>th</sup> August 2018 and that NHS Digital had requested an audit be undertaken within 4 months but noted the key outcomes of the audit had not been included in section 1 (Abstract) and that these should be included, or an explanation as to why the audit had not taken place. However, NHS Digital confirmed, subsequent to the meeting ending, that an audit had not been undertaken and had provided written confirmation of this to IGARD out of committee. IGARD, on receipt of the written confirmation suggested that since the audit had not taken place that NHS Digital may wish to consider auditing this organisation in relation to this application / data sharing agreement (DSA).

It was noted that when previously seen an incorrect GDPR legal basis was noted in section 1 and suggested this was corrected to 9(2)(h).

IGARD queried reference to 'core customers' and 'customers' and who and what these were since the terminology was not clear. It was suggested that a definition of the term 'customer' and 'core customer' be provided in section 5 (Purpose, Methods, Outputs)

IGARD noted duplicate wording within the tables in section 3(a) (Data Access Already Given) and 3(b) (Additional Data Access Required) and suggested this be removed.

IGARD suggested that the application be updated throughout to pluralise or clearly state which CSU(s) were involved, where appropriate, and involved in which activity.

IGARD queried the sentence "...there is clearly a significant need for the NHS to manage the demand that flows into hospitals by ensuring that **only the most appropriate cases** are referred for face to face consultation..." within section 5(d) (yielded benefits) point 1, and suggested that the applicant may wish review the sentence to ensure it reflects what is intended.

Outcome: recommendation to approve.

The following amendments were requested:

- NHS Digital had requested an audit within 4 months of the applications previous
  presentation to IGARD on 30 August 2018 and IGARD requested NHS Digital provide
  a report of the outcomes of that audit including a copy of the audit summary which on
  receipt may indicate further queries, or if the audit had not been undertaken why not.
- 2. To correct section 1 (Abstract) to refer to Article 9(2)(h) GDPR
- 3. To provide within section 5 a definition of the term "customer" or "core customer" to clearly indicate who or what is a customer or core customer.
- 4. To amend the tables in section 3(a) and 3(b) to remove duplicate text.
- 5. To amend section 5 throughout to clearly state which CSU(s) is/are involved in which activity
- 6. To review the sentence in section 5(d) point 1 "...only in the most appropriate cases..." to ensure that it reflects what is intended.

#### 2.3 Dr Foster Limited: standard extract service feed (Stuart Blake) NIC-68697-R6F1T

**Application:** This was an amendment application to add pseudonymised Civil Registration (deaths) Data (CRD) and pseudonymised Hospital Episodes Statistics (HES) CRD bridge file which will be linked to already held HES data.

Dr Foster Limited require the pseudonymised HES datasets to help healthcare organisations achieve sustainable improvements in their performance, to gain insight and to inform decision making via three main strands: Dr Foster tools and services; bespoke analytics; and research for publication. The ability to link already held HES datasets with mortality data could provide valuable insights into how and why some patients with the same condition and at the same stage can have very different outcomes.

**Discussion:** IGARD noted that this application had been previously presented to IGARD on the 20<sup>th</sup> June 2019, alongside NIC-12828-M0K2D (Imperial College London Dr Foster Unit) but had been withdrawn by the presenter. At the meeting on 20 June, IGARD suggested that in future any linked applications should be provided to IGARD as supporting documents.

NHS Digital noted that when this application had been previously recommended for approval by IGARD on the 13<sup>th</sup> December 2018, it had incorrectly referenced Date of Death data, however NHS Digital confirmed that Date of Death had not flowed to Dr Foster Limited

under that agreement. IGARD suggested that an express statement be included in section 5 (Purpose, Methods, Outputs) that the Date of Death data would not flow directly to Dr Foster Limited and that any Date of Death Data that flowed to Dr Foster Limited via the Imperial College London Dr Foster Unit would be derived data or in aggregated form.

In addition, IGARD suggested that NHS Digital undertake an analysis and review of how the data under this application would be supplied to ensure that pseudonymised, aggregated or derived Date of Death data did not constitute an identifier, especially in light of the linkage to HES and other data sets referred to in the application, and therefore no patient information was owed a duty of confidence. IGARD noted that Imperial College London Dr Foster Unit under NIC-12828-M0K2D had s251 support for use of date of death data but that support did not reference Dr Foster Limited. IGARD further suggested that NHS Digital may wish to seek advice from the NHS Digital Office of the Data Protection Officer.

IGARD suggested that section 1 (Abstract) be updated to clearly reflect that the privacy notice did not meet NHS Digital's fair processing criteria.

IGARD noted the applicant had selected legitimate interests as a legal basis and suggested that the introduction to section 5(a) (Objective for Processing) be amended to clearly set out what the legitimate interests were and how they related to the legal basis for processing and related directly to the specific purpose outlined in this application.

IGARD noted reference to Dr Foster Intelligence in section 5(d) (Benefits) and it was suggested that section 5(a) be updated to include reference to Dr Foster Intelligence and where the other Dr Foster entities were listed, for transparency.

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

- To make an express statement in section 5 that the Date of Death data will not flow directly to Dr Foster Limited, the applicant, and that any Date of Death data that flows to Dr Foster Limited via the Imperial College London Dr Foster Unit will be in derived or aggregated form.
- To provide confirmation in writing that NHS Digital have undertaken an analysis and reviewed how the data will be supplied under this application and that such analysis considers that the pseudonymised, aggregated or derived Date of Death data does not constitute an identifier and is therefore not patient information owed a duty of confidence.

The following amendments were requested:

- 3. To update section 1 (Abstract) to clearly state where the Fair Processing Notice failed to meet NHS Digital's fair processing criteria.
- 4. To update the first paragraph in section 5(a) to provide a succinct summary of the legitimate interest relied on and how it directly relates to the specific purpose outlined in the application.
- 5. To update section 5(a) include reference to Dr Foster Intelligence where other Dr Foster entities are mentioned

It was agreed the conditions would be approved OOC by IGARD Members.

2.4 Competition and Markets Authority (CMA): national HES data for investigation of mergers (Stuart Blake) NIC-32833-M3M9V

The application was withdrawn by the customer.

The CMA had indicated that they were not intending to continue to hold data, and would be confirming data destruction. As a result the customer asked for the renewal application to be withdrawn.

# 2.5 University of Glasgow: the epidemiology of peripartum cardiomyopathy in the United Kingdom (Dave Cronin) NIC-262206-F1P5Z

**Application:** This was a new application for pseudonymised Civil Registration and Hospital Episodes Statistics (HES) data for a study aiming to collect data on Peripartum Cardiomyopathy (PPCM), which is a rare pregnancy-related type of heart failure and to describe the epidemiology of the condition in the UK. At present, there is no UK-based information to give to women with the condition or to guide decision-making with regards to their management and future pregnancy risk.

This application was previously considered on the 8<sup>th</sup> August 2019 when IGARD had deferred making a recommendation pending: To clearly describe in section 5(a) that this application relates to a fellowship that will lead to a PhD for the applicant from the University of Glasgow; and provide confirmation that all other individuals named within the application act in the role of supervisor; To clarify how research will be carried out on child mortality and morbidity (as referenced in the application / protocol) since the datasets requested only contain the mothers' data; To update section 5(a) to clarify if the study is looking at all women or women within specific ethnic groups; To update section 6 to include a special condition to explicitly state that the British Heart Foundation will have no access to the data under this application, with the exception of aggregated reports; To provide further information and justification for the amount of data being collected in particular: in the case of the cohort with PPCM, confirmation as to whether the data is being requested for a follow-up period of 10 years as stated in the protocol, or 29 years, or until the end of life; and to provide an clear justification as to why this volume of data is required; confirmation as to when follow-up data will be collected from, for example first symptom or diagnosis etc; confirmation that data is requested only for women who have been pregnant with a recorded event of heart failure (HF) and cardiomyopathy (CM); and whether there is the intention to follow up these individuals and for what period; clarification as to how the volume of data requested for the cohort, data to be requested for a control group, as well as any end-of-life follow up, are considered appropriate and necessary processing for the relatively short span of a fellowship project which will lead to a PhD; Provide clarification as to whether the applicant has NOT considered seeking the consent of women who have experienced PPCM given the rarity of this condition; and in light of the significant lengthy period for which the data is requested, the applicant to clarify if and how it has considered any additional permissions and approvals that may be required especially in the case of end-of-life follow-up.

**Discussion:** IGARD noted that the application had been updated to reflect most of the comments previously made. IGARD, in particular, noted that a focus group had taken place with 6 women with PPCM in Scotland and acknowledged the feedback and support received by the applicant from this focus group.

IGARD noted that the application had been updated to provide greater clarity regarding data controllership and the roles of the organisations, however suggested that the sentence in section 5(a) (Objective for Processing) "...the Chief Investigator and Study Statistician..." be updated to remove the word "and" and replace with "/" since they were one and the same person. It was also suggested that for clarity, the sentence in section 5(d) (Benefits) "...only the Data Controller's Research Fellow..." be updated to include the words "(PHD Student)" after "fellow" since only they would have access to the data.

IGARD noted that researching the infant / child mortality and maternal outcomes still remained an aim for the applicant which could only be determined following analysis of the data received, however suggested that the sentence in section 5(b) (Processing Activities) "...routinely collected hospitalisation data (HES) will be used and linked with death records..." be updated to include "...to carry out analysis" after the word "records", to be clearer this was the overall aim.

IGARD noted the applicant had provided justification for the amount of data being collected however it was still not clear why the applicant needed patient data for an obstetric episode 5 years after a cardiac episode, along with 5 years before a cardiac episode, and why for instance the applicant had not requested patient data for an obstetric episode of 1 year after a cardiac episode and suggested that section 5 (Purpose, Methods, Outputs) include justification for this data.

**Outcome:** recommendation to approve subject to the following condition:

1. To clarify, in section 5, why the applicant needs patient data with an obstetric episode 5 years after a cardiac episode and why an obstetric episode during a period of, for instance, 1 year after a cardiac episode would not suffice.

The following amendments were requested

- 1. To amend the sentence in section 5(a) "...The Chief Investigator and Study Statistician..." be removing the word "and" and replacing with "/" since they are one and the same person.
- 2. To amend the sentence in section 5(b) "...Only the Data Controller's Research fellow..." to include the words "(PhD Student)"
- 3. To amend the sentence in section 5(b) "...routinely collected HES data will be used..." to insert the following words "to carry out an analysis..."

It was agreed the condition would be approved OOC by IGARD Members.

## 2.6 University Hospitals Bristol NHS Foundation Trust: evaluation of centralisation in head and neck cancer (Dave Cronin) NIC-147901-2XMLG

**Application:** This is an application to amend, extend and renew identifiable Medical Research Information Service (MRIS) cohort event notification report, MRIS cause of death report, MRIS flagging current status report and MRIS members and postings report.

The study recruited 5,511 people diagnosed with head and neck cancer, with recruitment ending in 2014, in order to evaluate the care these patients were receiving and assess whether practice within these cost-intensive services is both clinically effective and cost effective in order to ensure that patients are receiving the best quality care and that NHS resources are being used efficiently.

**Discussion:** NHS Digital noted that this was a long running study that had been previously recommended for approval by IGARD's predecessor: the Data Access and Advisory Group (DAAG) in June 2011. NHS Digital noted there had been a Data Sharing Agreement (DSA) between NHS Digital's predecessor the Information Centre and the School of Oral and Dental Sciences, Bristol Dental School within the University of Bristol (UoB). However, following review of the DSA and confirmation that the University Hospitals Bristol NHS Foundation Trust (UHB) was the Data Controller not the UoB as specified in the original agreement, NHS Digital agreed that the agreement with UoB was invalid, however IGARD stated that they did not agree with NHS Digital's assessment that the agreement was invalid since not receiving data did not, prima facie, invalidate an agreement. It was suggested that reference to the NHS Digital analysis be removed from section 1 (Abstract). NHS Digital noted that they had

informed the applicant that since this was an important long running study that they were permitted to store but not otherwise process the data and IGARD endorsed this approach.

IGARD also endorsed NHS Digital's request for an audit of the organisation in relation to this application / DSA.

IGARD noted that supporting document 7, NHS Digital's consent review, was an exemplar analysis document which gave a comprehensive review of the analysis undertaken by NHS Digital and suggested that NHS Digital may wish to consider using it as a template for others to use.

IGARD suggested that section 5(a) (Objective for Processing) be reviewed to reduce the duplicated wording with regard to onward sharing and suggested that a summary of the restrictions of sharing aggregated data also be replicated in section 6 (Special Conditions).

IGARD noted reference to "...substantive employees of University Hospitals Bristol and the University of Bristol..." and suggested the sentence in section 5(b) be amended to remove the word "and" and replace with "or" to be clear that they are employees of one organisation or the other.

IGARD noted NHS Digital's suggested amendment to section 5(d) (Benefits) to remove reference to "...154 peer reviewed papers..." and replacing with "15", however suggested that the Yielded Benefits section should be expanded further to include, but not limited to, the outcomes of those 15 published peer review papers.

Outcome: recommendation to approve

The following amendments were requested:

- 1. To remove reference to the analysis and validity of the agreement held by University of Bristol in the abstract.
- 2. To update section 5(a) to reduce the duplication of wording with regard to onward data sharing and aggregated data.
- 3. To replicate as a special condition in Section 6, a summary of the restrictions of sharing aggregated data.
- 4. To amend the sentences in section 5(b) "...who are substantive employees of University Hospitals Bristol and the University of Bristol..." to remove "and" and replace with "or"
- 5. To expand the yielded benefits outlined in section 5(d) to reflect, but not limited to, the outcomes of the published peer review papers.

The following advice was given:

- 1. IGARD noted and endorsed NHS Digital's request for an audit on the organisation in relation to this application / data sharing agreement
- 2.7 NHS Bristol, North Somerset and South Gloucestershire CCG: making CCG operational planning more robust by using a large activity sample size to derive data (Victoria Byrne-Watts) NIC-238370-G8Z6V

**Application:** This is a new application for pseudonymised Hospital Episodes Statistics (HES) Admitted Patient Care (APC), HES Outpatient (OP) and HES Accident & Emergency (A&E) for the purpose of analysing pseudonymised non-sensitive patient level data to derive empirical probability distributions for the processes of interest and from these fit theoretical distributions which can be used in simulation modelling and statistical analysis of existing and proposed patient pathways.

**Discussion:** IGARD welcomed this innovative modelling application.

IGARD queried why the applicant had requested national HES data and it was explained that getting either a random sample or local geographical area may raise gaps in the analysis work being undertaken. IGARD encouraged this innovative approach, however suggested that section 5(c) (Specific Outputs Expected) should be significantly redrafted to reflect that national data was being received and that the applicant should consider, but not limited to, questions such as whether the models would be made available to other CCG's and whether they would be charging for any outputs or sharing of the models. In addition, section 5(d) (Benefits) should also be updated to reflect that national data was being received and to clearly outline the benefits that would impact nationally by receiving national HES data. IGARD asked that NHS Digital provide them with a review of progress made and the benefits achieved by the applicant 6 months from the receipt of the data under this application.

IGARD noted reference to "events / shocks" in relation to how these would be mitigated in any given local system but suggested that since the examples given seemed to relate to "events" that section 1 (Abstract) and section 5(a) (Objective for Processing) be updated to provide examples of "shocks".

IGARD suggested that the last three paragraphs of section 5(a) starting "Outputs from this project..." should be deleted since they were not relevant to the objective for processing. In addition, IGARD suggested that a brief introduction be included at the start of section 5(a) including examples of the types of activities the applicant would be looking at, as outlined in section 1 and written in a language suitable for a lay audience

IGARD suggested that the sentences "This work will not be directly contributing to a PhD study..." in section 5(d) and "...no moral or ethical issues..." in section 5(a) be removed since they were not relevant to this application.

**ACTION**: IGARD Secretariat, separate to this application, to email NHS Digital to remind them that statements in the Standards such as 'moral or ethical issues' or 'PhD Study' may not be relevant to an application and therefore not required to be inserted into section 5 and that by not including them, does not mean the application does not meet the standard.

As part of IGARD's oversight and assurance role, IGARD queried the amount of data held by CCGs in relation to the number of applications and data sharing agreements in place with NHS Digital, and queried for those CCGs with multiple storage and locations listed in section 1 if CCGs were storing a physical copy of the data at those locations, multiples of the same data, copies of particular datasets or parts of datasets. NHS Digital confirmed that the storage and locations listed for CCG's were usually part of the CCGs back up and storage of data.

**ACTION:** NHS Digital, separate to this application, to confirm that for CCG applications with multiple storage and locations listed within section 1, whether each storage or location listed in the application has a physical copy of data and how many multiple copies of the same data are held for CCG applications.

**Outcome:** recommendation to approve subject to the following the conditions for one year:

- To significantly redraft section 5(c) to reflect that national data is being received and to consider questions, but not limited to, how the models would be made available to other CCG's and whether the applicant will be charging for any outputs or sharing the models.
- 2. To reflect within section 5(d) that national data is being received and to clearly outline the benefits that will have an impact nationally.

The following amendments were requested

	<ol> <li>To amend section 5(a) to include a brief lay introduction including brief examples of types of activities the applicant would be looking at.</li> </ol>						
	4. To delete the last three paragraphs in section 5(a).						
	<ol><li>To amend section 1 and section 5(a) to provide examples of "shocks", since the examples given appear to relate to "events".</li></ol>						
	6. To remove from section 5(d) reference to a "PhD study' since it is not relevant to this application.						
	The following advice was given						
	<ol><li>IGARD advised that they would wish to review this application again when it comes up for renewal.</li></ol>						
	<b>ACTION:</b> NHS Digital to provide to IGARD a review of the progress made and benefits achieved by the applicant 6 months from receipt of data.						
3	Associate Director, Data Access (Garry Coleman)						
	The Associate Director, Data Access, attended IGARD to update members on a number of key NHS Digital process items including the clinical trials service, recruitment and retention, and standards and precedents.						
	IGARD thanked the Associate Director for attending.						
4	AOB:						
	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.						

### Independent Group Advising on Releases of Data (IGARD): Out of committee report 23/08/19

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-258780- S9H7G	University of Cambridge	18/07/2019	<ol> <li>To provide a clear justification why small numbers suppression is not appropriate.</li> <li>To provide further clarification why the University of Edinburgh and the Royal Brompton Hospital are not considered Data Controllers given they are involved in the study design, outputs, described in the protocol and part of the study team.</li> </ol>	IGARD Members	Quorum of IGARD members (15/08/19)	N/A
NIC-368233- L2N0W	McKinsey & Co Inc UK	04/07/2019	<ol> <li>The applicant should work with NHS         Digital on a fair processing notice that         is GDPR compliant, particularly         addressing the points previously raised         by IGARD.</li> </ol>	IGARD Chair	IGARD Chair (20/08/2019)	N/A

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

• None