Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 18 November 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member (Item 8 only)
Maria Clark	Lay Member (Item 8 only)
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Michael Ball	Data Access Request Service (DARS) (Items 3.2, 3.3, 8)
Laura Bellingham	Business and Operational Delivery (Item 8)
Catherine Day	Data Access Request Service (DARS) (Item 3.5)
Dr. Arjun Dhillon	Caldicott Guardian (Item 8)
Faris Dean	Data Access Request Service (DARS) (Items 3.4, 8)
Louise Dunn	Data Access Request Service (DARS) (Item 8)
Duncan Easton	Data Access Request Service (DARS) (Item 8)
Liz Gaffney	Head of Data Access, Data Access Request Service (DARS) (Item: 7.1)
Dan Goodwin	Data Access Request Service (DARS) (Item 8)
Jackie Gray	Executive Director, Privacy, Transparency and Ethics (Item 7.1)
Frances Hancox	Data Access Request Service (DARS) (Item 3.1)
Shaista Majid	Data Access Request Service (DARS) (Item 8)
Karen Myers	IGARD Secretariat
Dr. Jonathan Osborn	Deputy Caldicott Guardian (Item 8)

Tania Palmariellodiviney	Data Access Request Service (DARS) (Observer: items 1- 3.5, 8)
Kimberley Watson	Data Access Request Service (DARS) (Item 8)
Vicki Williams	IGARD Secretariat
Kevin Willis	Data Protection Officer (DPO), Privacy, Transparency & Ethics (Item 7.1)
Tom Wright	Data Services for Commissioners (Item 8)
ADDITIONAL WORKSHOP ATTENDEES (ITEM 8):	
Name:	**Area:**
Mark Bridges	DSCRO Central Midlands
John Coolican	DCSRO North West
Wendy Lee	DCSRO South Collaborative
Andy Norman	NHS North of England CSU

1	**Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising the Scientific Advisory Group for Emergencies (SAGE) on COVID-19. Maurice Smith noted a professional link with NHS Liverpool CCG, in his role as Liverpool CCG Caldicott Guardian (NIC NIC-422183-C3K9L and NIC-55752-D6X5Y); but noted no specific connections with the applications or staff involved and it was agreed that this was not a conflict of interest An NHS Digital colleague noted a professional role within NHS Herts Valleys CCG Reference Group NIC-55752-D6X5Y; it was agreed that the individual would not participate in the discussion about this application. **Review of previous minutes and actions:** The minutes of the 11th November 2021 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 A).
2	**Briefing Notes**
	There were no briefing papers submitted for review.
3	**Data Applications**

3.1	<u>St George's, University of London: MR1485 - Development of a linked, de-identified database resource for research into the health, mortality and educational outcomes of children with a congenital anomaly (Presenter: Frances Hancox) NIC-64474-V4B2D-v1.4</u> **Application:** This was a renewal and amendment application to **1)** remove the following Data Processors: University of Oxford, University of Leicester, University Hospitals Bristol and Weston NHS Foundation Trust, University Hospital Southampton NHS Foundation Trust and Newcastle University; and **2)** to add a new data backup location; **3)** to receive data for the remainder of the 2 cohorts. The purpose is for the 'British and Irish Network of Congenital Anomaly Researchers' (BINOCAR), which is a collaboration of congenital anomaly registries which had been involved in the surveillance of congenital anomalies from as early as 1985 until 2015. This Data Sharing Agreement (DSA) seeks to create a linked de-identified research database through a one-off linkage of previously collected case data from five regional registers in England to subsets of Hospital Episode Statistics (HES) and Civil Registrations (deaths). The historical BINOCAR data will also be independently linked to the National Pupil Database (NPD) under a separate DSA with the Department of Education (DfE), for a different study looking into educational outcomes associated with congenital anomalies, and will not involve the use of or linkage to NHS Digital data. However together these linked datasets will enable future, approved outcomes-research into the long-term survival, health and educational achievement of children with congenital anomalies to be conducted without the need or expense of re-linking the historical data. The study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital. NHS Digital advised IGARD that the Health Research Authority Confidentiality Advisory Group (HRA CAG) s251 support, was time limited; however, confirmed that the applicant was in the process of seeking a further extension to the s251 support. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 28th May 2020. IGARD noted the verbal update from NHS Digital in respect of the current s251 support being time limited, and that the applicant was in the process of seeking an extension from HRA CAG. IGARD asked that a copy of the written evidence was provided of the continuing HRA CAG support, and that once that continued support had been received, that a copy was uploaded to NHS Digital's Customer Relationship Management (CRM) system for future reference. IGARD noted that at the last IGARD BAU review on the 28th May 2020, IGARD had suggested that on renewal, the applicant should have clear evidence of the patient and public involvement and engagement (PPIE) that had taken place, including, but not limited to, lived experience. Noting that a satisfactory update had **not** been provided, and reiterating the importance of the ongoing PPIE, IGARD asked that the applicant provided a satisfactory indicative plan for the development and implementation of PPIE initiatives. In addition, and as part of their wider engagement with the PPIE group, IGARD suggested that the applicant consulted the PPIE group, in respect of the UK General Data Protection Regulation (UK GDPR) transparency about the nature of the research. IGARD also suggested that the applicant may wish to partner with the charity 'Antenatal Results and Choices' (ARC), who *"offers non-directive information and support to parents*

	before, during and after antenatal screening; when they are told their baby has an anomaly; when they are making difficult decisions about continuing with or ending a pregnancy, and when they are coping with complex and painful issues after making a decision, including bereavement". IGARD queried the statement in section 5(a) (Objective for Processing) *"Patient and public involvement concerning specific analyses on the linked databases from England has not occurred."*, and asked that this was reviewed and amended, noting that this could be incorrectly perceived as to not be of importance. IGARD reiterated the point made at the previous IGARD review, and when the conditions were reviewed out of committee (OOC), in respect of further clarification being provided in section 5 (Purpose / Methods / Outputs) of the application, as to what was meant by the statement that the research was *"to support the prevention of congenital anomalies"*. IGARD asked that further clarification was provided as to what this statement was referring to, for example, was this referring to pre-implantation genetic diagnosis, or termination of pregnancy, and were there other options enabling the prevention of babies being born with these congenital anomalies? Or was this referring to *"prevention of congenital anomalies"* by reducing the occurrence of certain congenital anomalies through adequate intake of folic acid, fortified foods, good antenatal care, smoking cessation, certain vaccinations, etc. IGARD strongly suggested that in either (or both) case(s) this wording ("*prevention"*) should be amended sensitively to avoid public misconception about the intention of the research, and to avoid causing offence. Consideration should be given to families who had given birth to babies with congenital abnormalities, and this was where a PPIE group or national charity such as ARC could offer support or suggestions. IGARD queried the statement in section 3(b) (Additional Data Access Requested) that *"GDPR does not apply to data solely relating to deceased individuals"*, however, noting that the status of those patients that are still alive would be revealed, asked that, this was updated to include a UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data; in accordance with the latest advice from the Privacy, Transparency and Ethics (PTE) Directorate. IGARD noted the references in section 5 to *"substantive employees"* accessing the data, however asked that for clarity, this was updated to confirm substantive employees would only have access to the data, for the purposes set out in this DSA. IGARD noted the out-of-date information in section 5, that referred to there being more than one Data Processor; and asked that section 5 was updated throughout, to ensure that it reflected the amendment, in respect of there being a sole Data Processor, including, but not limited to, removing the reference to *"access to the data"* and the *"University of Newcastle"*. IGARD noted a number of acronyms and technical terms in section 5, and asked that this public facing section, that forms NHS Digital's data uses register, was amended throughout, to ensure acronyms be defined upon first use, if the meaning is not self-evident, for example *"PIAG/NIGB/CAG"*. IGARD queried the statements in section 5(b) (Processing Activities) that referred to the linked data being *"sense checked"*, and asked that further information was provided, for example, noting who would be completing the sense check, as this was not clear. IGARD also noted that section 1 stated that a review by IGARD was not required in response to the question *"review requested by IGARD"* the answer given was *"no"*; and suggested that

	NHS Digital may wish to review their internal processes and IT systems, for example, to ensure this doesn't incorrectly default to state *"no"* and to update to say *"yes"*. **Outcome:** recommendation to approve subject to the following conditions: 1. In respect of the HRA CAG support: a) To provide written evidence of the continuing HRA CAG support. b) To upload the written evidence of this to NHS Digital's CRM system. 2. In respect of the PPIE advice point previously made on the 28th May 2020: to provide a satisfactory indicative plan for the development and implementation of PPIE initiatives. The following amendments were requested: 1. To review and amend the statement in section 5(a) that there was no current PPIE. 2. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this accords with the latest advice from PTE. 3. To update the statements in section 5 that only *"substantive employees"* will have access to the data, to confirm that this will only be for the purposes set out in this DSA. 4. As section 5 forms NHS Digital's data uses register, to amend section 5 to ensure that all acronyms upon first use be defined and further explained if the meaning is not self-evident, or example *"PIAG/NIGB/CAG"*. 5. To amend section 5 throughout to ensure that it reflects the amendment in respect of there being a sole Data Processor, including (but not limited to) removing the reference to *"access to the data"*, *"University of Newcastle"*. 6. To provide information in section 5(b) on the reference to the linked data being *"sense checked"*, for example, noting who will be completing the sense check. 7. To amend section 5(d) (iii) to provide a brief explanation as to why there are no yielded benefits to date. 8. To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will…*" or *"it can"*. The following advice was given: 1. IGARD reiterated the point made at the previous IGARD review (and when the conditions were reviewed OOC), in respect of further clarification being provided in section 5 of the application, as to what was meant by the statement that the research is *"to support the prevention of congenital anomalies"*. IGARD asked that further clarification was provided as to what this statement was referring to, for example, was this referring to pre-implantation genetic diagnosis, or termination of pregnancy, and were there other options enabling the prevention of babies being born with these congenital anomalies? Or is this referring to *"prevention of congenital anomalies"* by reducing the occurrence of certain congenital anomalies through adequate intake of folic acid, fortified foods, good antenatal care, smoking cessation, certain vaccinations, etc. IGARD strongly suggested that in either (or both) case(s) this wording ("*prevention"*) should be amended sensitively to avoid public misconception about the intention of the research, and to avoid causing offence. Consideration should be given to families who had given birth to babies with congenital abnormalities, and this is where a PPIE group or national charity such as ARC could offer support or suggestions. 2. IGARD noted that section 1 stated that a review by IGARD was not required; and again requested that NHS Digital review their internal processes and IT systems to ensure this doesn't incorrectly default to state *"no"*.

	3. IGARD suggested that the PPIE group be consulted in in respect of the UK GDPR transparency about the nature of the research. 4. IGARD suggested that the applicant may wish to partner with ARC. 5. IGARD advised that they would wish to review this application when it comes up for renewal, to review the PPIE activities undertaken. It was agreed the conditions would be approved out of committee (OOC) by IGARD members.
3.2	NHS Bedfordshire, Luton and Milton Keynes CCG: DSfC NHS Bedfordshire, Luton and Milton Keynes CCG - IV, RS and COMM (ICS Sub-License) (Presenter: Michael Ball) NIC-422183-C3K9L-v3.2 **Application:** This was an amendment application to add sub-licensing to the Data Sharing Agreement (DSA), for the purpose of sharing data with the legal entities that make-up the Integrated Care Systems (ICSs) for the Data Controller's area. The overall purpose for this application is for: Invoice Validation (IV) which is part of a process by which providers of care or services are paid for the work they do; Risk Stratification (RS) which is a tool for identifying and predicting which patients are at high risk or likely to be at high risk and prioritising the management of their care; and to provide intelligence to support the commissioning of health services. The study is relying on s251 of the NHS Act 2006, for the flow of (the confidential) data out of NHS Digital. **Discussion:** NHS Digital noted that the application had not previously been presented at an IGARD business as usual (BAU) or at the Data Access Advisory Group (DAAG) meeting's (IGARD's predecessor). IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD advised NHS Digital, that they had undertaken a high level review of the sub-license supporting document provided only, and confirmed that it appeared to be fit for purpose; however advised that they had worked on the assumption that NHS Digital had undertaken a thorough review, in line with NHS Digital DARS Standard for Sub-licencing and Onward Sharing of Data. IGARD noted that there was a risk to NHS Digital in respect of Risk Stratification, in that the application of the National Data Opt-out (NDO) and Type 1 objections may affect direct care for individuals who have either of these in place, despite being told that their direct care would not be affected by them. In addition, IGARD advised that they would raise this issue directly with Health Research Authority Confidentiality Advisory Group (HRA CAG). IGARD queried the information provided in section 5(b) (Processing Activities) that outlined the activities to be undertaken by Liaison Financial Services Ltd and the CSU as joint Data Processors; and noting that both had the same activities listed, asked that clarification was provided why the same activities were being undertaken by both Liaison Financial Services Ltd **and** the CSU, in line with NHS Digital DARS Standard for Data Processors; or, if there was a delineation of work, that further detail was provided; and that any suggestion of duplication of processing was removed. Further, any yielded benefits of Invoice Validation should be reported. IGARD noted the statement in supporting document 2, the Terms of Reference, that in respect of the membership, there would be a *"Member representing public view (when required)…"*;

	and asked that this was removed, and instead give a public representative(s) a position on the oversight group forming part of the permanent membership. IGARD noted the large number of storage and processing locations in section 2 (Locations), and noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital worked with the applicant to review and consider if the locations could be consolidated. IGARD noted the statement in section 5(b) to *"a different organisation name but has now merged into this CCG"*, and asked that for future reference, section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) was updated with information on the historical information in respect of the applicant's name change. IGARD queried the statement in section 5(c) (Specific Outputs Expected) that CCGs would be able to *"Reduce hospital readmissions and targeting clinical interventions to high risk patients"*; and asked that this was updated to make it clear that that the commissioners themselves would **not** be reducing hospital readmissions, noting that this was a provider function. IGARD noted the statement in section 5(c) *"GP Practices will be able to view the risk scores for individual patients with the ability to display the underlying SUS+ data for the individual patients…"*; and asked that the reference to *"individual patients"*, was updated to refer to *"cohorts of patients"*. IGARD noted that there were ongoing discussions with NHS Digital, in respect of the yielded benefits for CCGs, and that those discussions may impact on the yielded benefits section of the application moving forward; however asked that further details were provided in section 5(d) (Benefits) (iii) (Yielded Benefits) of a small representative sample of yielded benefits accrued to date and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD suggested that NHS Digital may wish to consider auditing this organisation in relation to this application / Data Sharing Agreement (DSA), due to the novel sub-licensing arrangements. **Outcome:** recommendation to approve The following amendments were requested: 1. To remove the reference within the ToR to the members representing the public view being involved *"when required"* and instead give a public representative(s) a position on the oversight group forming part of the permanent membership. 2. IGARD noted the large number of storage and processing locations, and, noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital worked with the applicant to review and consider if the locations could be consolidated. 3. To update section 1 and section 5 to include the historical information in respect of the applicant's name change. 4. To update section 5(c) to make clear that the commissioners themselves will **not** be reducing hospital readmissions (since this is a provider function). 5. To amend the reference in section 5(c) from *"individual patients"* to *"cohorts of patients"*. 6. To provide clarification in section 5(b) why Liaison Financial Services Ltd **and** the CSU, who are both listed as joint Data Processors, are doing the same activities (or if there is a delineation of work to provide further detail), to remove any suggestion of duplication of processing.

	7. Noting the ongoing discussions on this topic, to provide further details in section 5(d)(iii) of a small representative sample of yielded benefits accrued to date and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. The following advice was given: 1. IGARD suggested that NHS Digital may wish to consider auditing this organisation in relation to this application / DSA, due to the novel sub-licensing arrangements. **Significant Risk Area:** 1. There is a risk to NHS Digital in respect of Risk Stratification, that the current flows of data, mean that the NDO or Type 1 Opt-out, may affect direct care for individuals who have these opt-outs in place, despite their being told that their direct care would not be affected.
3.3	NHS Herts Valleys CCG: DSfC - NHS Herts Valleys CCG - IV & Comm (ICS Sub-License) (Presenter: Michael Ball) NIC-55752-D6X5Y-v10.2 **Application:** This was a renewal to permit the holding and processing of 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 Registration Data (Births), Civil Registration Data (Deaths), National Diabetes Audit (NDA), Patient Reported Outcome Measures (PROMs), e-Referral Service (eRS), Personal Demographics Service (PDS), Summary Hospital-level Mortality Indicator (SHMI), Medicines Dispensed in Primary Care (NHSBSA Data) and Adult Social Care Data. It was also an amendment to **1)** Incorporate the entire ICS footprint (NHS Herts Valleys CCG, NHS East and North Hertfordshire CCG and West Essex CCG)"; and **2)** to add sub-licensing to the Data Sharing Agreement (DSA), for the purpose of sharing data with the legal entities that make-up the Integrated Care Systems (ICSs) for the Data Controller's area. The overall purpose for this application is for: Invoice Validation (IV) which is part of a process by which providers of care or services are paid for the work they do; and to provide intelligence to support the commissioning of health services. The study is relying on s251 of the NHS Act 2006, for the flow of (the confidential) data out of NHS Digital. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (DAAG) (IGARD's predecessor) on the 6th December 2016; and the IGARD business as usual (BAU) meetings on the 19th December 2019 and the 15th July 2021. IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD advised NHS Digital, that they had undertaken a high level review of the sub-license supporting document provided only, and confirmed that it appeared to be fit for purpose; however advised that they had worked on the assumption that NHS Digital had undertaken a thorough review, in line with NHS Digital DARS Standard for Sub-licencing and Onward Sharing of Data.

	IGARD also asked that section 5 (Purpose / Methods / Outputs) was updated, with an explanation of how the CCG sub-licence model would in effect help data minimisation, and ensure that only data relevant for processing flows to the relevant partners. IGARD noted that section 5(a) (Objective for Processing) only referred to Invoice Validation as the purpose of processing, and that this was also covered under s251; however noted that it was silent on the Risk Stratification purpose that would be taking place with the pseudonymised data; and asked that for transparency, section 5(a) was updated to clarify that this application does relate to Risk Stratification. In addition, IGARD commended the applicant for the use of pseudonymised data for Risk Stratification, and that this was an exemplar to other applicants. IGARD queried the information provided in section 5(b) (Processing Activities) that outlined the activities to be undertaken by Liaison Financial Services Ltd and the CSU as joint Data Processors; and noting that both had the same activities listed, asked that clarification was provided why the same activities were being undertaken by both Liaison Financial Services Ltd **and** the CSU, in line with NHS Digital DARS Standard for Data Processors; or, if there was a delineation of work, that further detail was provided; and that any suggestion of duplication of processing was removed. IGARD noted the statement in supporting document 4, the Terms of Reference, that in respect of the membership, there was not a member listed that was representing the public view; and asked that this was amended, and give a public representative(s) a position on the oversight group forming part of the permanent membership. IGARD noted the large number of storage and processing locations in section 2 (Locations), and noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital worked with the applicant to review and consider if the locations could be consolidated IGARD queried the statement in section 5(c) (Specific Outputs Expected) that CCGs would be able to *"Reduce hospital readmissions and targeting clinical interventions to high risk patients"*; however asked that this was updated to make it clear that that the commissioners themselves would **not** be reducing hospital readmissions, noting that this was a provider function. IGARD noted the statement in section 5(c) *"GP Practices will be able to view the risk scores for individual patients with the ability to display the underlying SUS+ data for the individual patients…"*; and asked that the reference to *"individual patients"*, was updated to refer to *"cohorts of patients"*. IGARD noted that there were ongoing discussions with NHS Digital, in respect of the yielded benefits for CCGs, and that those discussions may impact on the yielded benefits section of the application moving forward; however asked that section 5(d) (Benefits) (iii) (Yielded Benefits) was reviewed, and any text that was not relevant was removed, in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD also noted the reference in section 5(d) (iii) to a yielded benefit being a reduction in hospital A&E attendances; and asked that further information was provided, including, but not limited to, additional information in quantifiable terms, for example by percentage(s), and any links to publicly available reports or summaries, in line with NHS Digital DARS Standard for Expected Measurable Benefits. In addition, IGARD asked that a further explanation was added to section 5(d) (iii), as to how this ground-breaking work has been shared with other CCGs: or, that an update was provided, as to how this work will be shared with other CCGs.

	IGARD suggested that NHS Digital may wish to consider auditing this organisation in relation to this application / Data Sharing Agreement (DSA), due to the novel sub-licensing arrangements. **Outcome:** recommendation to approve The following amendments were requested: 1. To amend the ToR to ensure there is a public representative on the oversight group forming part of the permanent membership. 2. IGARD noted the large number of storage and processing locations, and, noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital worked with the applicant to review and consider if the locations could be consolidated. 3. To update section 5(c) to make clear that the commissioners themselves will **not** be reducing hospital readmissions (since this is a provider function). 4. To amend the reference in section 5(c) from *"individual patients"* to *"cohorts of patients"*. 5. To provide clarification in section 5(b) why Liaison Financial Services Ltd **and** the CSU, who are both listed as joint Data Processors, are doing the same activities (or if there is a delineation of work to provide further detail), to remove any suggestion of duplication of processing. 6. To update section 5(a) to clarify that this application does relate to Risk Stratification (with pseudonymised data). 7. In respect of the benefits and in line with NHS Digital DARS Standard for Expected Measurable Benefits (noting the ongoing discussions on this topic): a) To remove the text from section 5(d) (iii) that is no longer relevant. In respect of the reduction in hospital A&E attendances: b) To update section 5(d) (iii) to include additional information in quantifiable terms. c) To update section 5(d) (iii) with any links to publicly available reports or summaries. d) To provide an explanation in section 5(d) (iii) as to how they have shared this ground-breaking work with other CCGs: or, e) To provide an update in section 5(d) (iii) as to how this work will be shared with other CCGs. 8. To update section 5 with an explanation of how the CCG sub-licence model will, in effect, help data minimisation and ensures that only data relevant for processing, flows to the relevant partners. The following advice was given: 1. IGARD suggested that NHS Digital may wish to consider auditing this organisation in relation to this application / Data Sharing Agreement, due to the novel sub-licensing arrangements.
3.4	Barts Health NHS Trust: Epidemiology of traumatic brain injury in England (Presenter: Faris Dean) NIC-465144-J4C3T-v0.6 **Application:** This was a new application for pseudonymised Bridge file: Hospital Episode Statistics (HES) to Diagnostic Imaging Dataset (DIDs), Civil Registration (Deaths), Emergency Care Data Set (ECDS), HES Civil Registration (Deaths) bridge and HES Admitted Patient Care (APC). The purpose is to determine at a population level, the incidence of head injury (the event of a person receiving a blow to the head), traumatic brain injury (a dysfunction in the normal

working of the brain due to a head injury), intracranial hemorrhage, neurosurgical intervention, and death within 28 days of injury.

Traumatic brain injuries can result in significant morbidity and mortality, therefore the research aims to be the first national study of head and brain injury epidemiology.

The data subjects are all patients that attended an Emergency Department in England in 2019, with a head injury, based on the set criteria.

Discussion: IGARD welcomed the application and noted the importance of the research.

IGARD queried the conflicting information in section 7 (Ethics Approval) of the application, that stated *"Ethics approval is not required because the request does not include the flow of confidential data"*; and supporting document 1.0, the protocol, that referred to ethics approval being sought. IGARD asked that confirmation was provided in section 1 (Abstract) that the Health Research Authority Research Ethics Committee (HRA REC) support was **not** required. In addition, IGARD asked that confirmation was provided in section 1 that appropriate University procedures had been followed, with regards to any requirement to seek University Ethics support.

IGARD also suggested that given the national importance of the research, and the quantum of data requested, that the applicant may wish to pro-actively seek University Ethics support.

IGARD noted that all the datasets requested had been minimised to focus specifically on head injuries obtained, however the ECDS dataset did not appear to have been minimised and that all national data was required for the timescale outlined. Noting that it was unclear within the application as to why this volume of national data was flowing, IGARD asked that written confirmation was provided in section 1 and section 5 (Purpose / Methods / Outputs), as to what steps have been taken to ensure that the ECDS dataset had been appropriately minimised; in line with NHS Digital's DARS standard for data minimisation.

IGARD noted a number of organisations referred to at the end of section 5(a) (Objective for Processing), and that other than Barts Health NHS Trust, none of the organisations listed would have access to the data. IGARD noted that just because a specific party does not have access to the data, that is not determinative of data controllership; and asked that confirmation was provided in section 5(a), that none of the organisations listed were considered joint Data Controllers; in line with NHS Digital's DARS Standard for Data Controllers.

In addition, IGARD asked that for future reference, section 1 was updated with clarity as to the work undertaken to determine that none of the organisations listed were considered joint Data Controllers.

IGARD noted the reference to PPIE in section 5 of the application, however suggested that the applicant may wish to consider involving the relevant charities and public groups as early as possible, and not just at the end of the study; in line with HRA guidance on Public Involvement.

IGARD queried the statement in section 5(a) (Objective for Processing) *"The existing data are therefore both out of date and incomplete and are of no use to health care planners."*, and asked that the reference to *"no use"* was updated to being of *"limited utility"* or similar.

IGARD noted the inclusion of a number of technical phrases and words within section 5(a), such as *"prevalent pool effect"* and suggested that this was updated to be written in a language suitable for a lay reader and technical terms used only where necessary, or further explained upon first use.

IGARD noted that some of the information in section 5 was not clear and suggested that it was updated to ensure that it was written in a language suitable for a lay reader including reference

	to '*burden of care*' and that further sensitive consideration was given to the patient audience and how this type of language could be perceived. IGARD noted the references in section 5 to *"patients that…"*, and asked that these were updated to *"patients who…"*. IGARD suggested that section 5(d) (Benefits) be updated to remove reference to *"it can…"*, and instead use a form of words such as "*it is hoped*…" **Outcome:** recommendation to approve subject to the following conditions: 1. In light of the volume of national data flowing, to provide written confirmation in section 1 and section 5 as to what steps have been taken to ensure that the ECDS dataset has been appropriately minimised; in line with NHS Digital's DARS standard for data minimisation. 2. In respect of the REC: a) To provide confirmation in section 1 that HRA REC support is not required; **and**, b) To provide confirmation in section 1 that appropriate University procedures have been followed, with regards to any requirement to seek University Ethics support. The following amendments were requested: 1. In respect of the organisations listed at the end of section 5(a): a) To provide confirmation in section 5(a) that none of the organisations listed are considered joint Data Controllers. b) To provide clarity in section 1 as to the work undertaken to determine that none of the organisations listed are considered joint Data Controllers. 2. To amend the reference in section 5(a) from the data being of *"no use"*, to being of *"limited utility"* or similar. 3. To update section 5(a) to ensure technical terms are explained in a manner suitable for a lay audience, for example *"prevalent pool effect"*. 4. To update section 5 to ensure it is written in language suitable for a lay reader and that sensitive consideration is given to the patient audience (for example when referring to patients being a *"burden")*. 5. To amend the references in section 5 from *"patients that…"* to *"patients who…"*. 6. To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than *"it can"*. The following advice was given: 1. IGARD noted the reference to PPIE in the application, however suggested that the applicant may wish to consider involving the relevant charities and public groups as early as possible, and not just at the end of the study; in line with HRA guidance on Public Involvement. 2. IGARD noted that just because a specific party does not have access to the data, that is not determinative of data controllership. 3. IGARD suggested that given the national importance of the research and the quantum of data requested, that the applicant may wish to pro-actively seek University Ethics support. It was agreed the conditions would be approved out of committee (OOC) by IGARD members.
3.5	University of Oxford: The impact of the COVID-19 pandemic on the management and outcome of cardiovascular diseases and cancer (Presenter: Catherine Day) NIC-448634-S2Z8L-v0.5

	Application: This was a new application for pseudonymised Oxford Bespoke Secondary Uses Service (SUS) Commissioning Data Set (CDS); accessed within NHS Digital's Trusted Research Environment (TRE). The request is to refresh analyses published in May 2020, which were instigated at the start of the COVID-19 pandemic when it became evident that intelligence was needed on how the NHS could manage both COVID-19 and other health conditions. The results of the work have been, and will continue to be, fed back to the Chief Medical Officer for England and other senior NHS leaders. The work was a collaboration between NHS Digital, the University of Oxford and other leading scientists specialising in cardiovascular disease and epidemiology The work undertaken to date has revealed a substantial detrimental impact on those with both acute coronary syndromes (ACS) and cancer; and there is a strong public interest to ensure these analyses are continually updated as new data become available to ensure there is evidence available to continuously inform the maintenance and recovery of NHS services. **Discussion:** IGARD noted the bespoke dataset that was flowing under this Data Sharing Agreement (DSA), and queried what datasets made up the data flow and if this bespoke dataset could be requested by other researchers, noting that this was not outlined anywhere within the application. IGARD asked that for clarity and transparency, section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) was updated with a clear description of the datasets that make up the bespoke data flow. IGARD noted that it was not clear in the public facing section 5(a) (Objective for Processing), exactly what the purpose of processing was with the bespoke data set; and asked that section 5(a) was updated with a succinct explanation of the purpose of processing, including, but not limited to, what areas the research was looking at, for example, was it all cardiovascular events and all cancers or subsets of each since the narrative appeared to change throughout section 5; and in line with NHS Digital DARS Standard for Objective for Processing. IGARD also queried the inconsistent references within section 5(a) to the various projects, and asked that this was reviewed and updated and / or aligned as appropriate, to reflect the purpose for processing, for example, was the research looking at all cancers, or just colorectal cancer. IGARD noted that Civil Registration (death) data was referred to in section 5, and highlighted that where this data specific data was flowing, that NHS Digital would review on a case-by-case basis, to determine if there was an increased risk of identification. IGARD agreed, that in this particular case, there was less risk due to NHS Digital undertaking the linkage. IGARD asked that section 1 was updated confirming that the flow of date of death data, was in line with NHS Digital's policy assessment and would not increase the likelihood of re-identification of data subjects. IGARD queried the reference in section 5(a) to a partnership between NHS Digital and the University of Oxford, however noted that this was not reflected anywhere else in the application. NHS Digital advised that when the application was initially submitted, the application reflected a joint working arrangement between the University of Oxford and NHS Digital, however this was no longer correct, and the application would need updating. IGARD noted the verbal update from NHS Digital, and asked that section 1 and section 5(a) were updated, with confirmation that NHS Digital was no longer a joint Data Controller. IGARD noted the journals referenced within section 5(a) but that there was not always reference to using NHS Digital data, and suggested that the applicant ensure NHS Digital

	were consistently credited as the source of the data, in order to improve public awareness about the use of their health data. IGARD noted the first paragraph within the yielded benefits in section 5(d) (iii) (Yielded Benefits), however noted that this was more of a benefit than a yielded benefit; and asked in line with NHS Digital DARS Standard for Expected Measurable Benefits, the paragraph was moved to correctly to sit in section 5(d) (i) (Expected Measurable Benefits). IGARD noted the second paragraph of the yielded benefits which stated *"…the initial results from this project were disseminated rapidly to the Chief Medical Officer of England and other senior leaders within the NHS. They were so striking they led to a change in messaging from Government to make sure the public were aware that if they experienced concerning symptoms then they must contact their GP or the NHS to receive the care they needed…"*; and asked that this was updated further, to make a specific reference to, or link to the specific nationwide public health campaigns and, if possible, the impact of these, in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD noted that some of the information in section 5 was unclear and suggested that it was updated to ensure that it was written in a language suitable for a lay reader and that further consideration was given to the public audience, for example when referring to *"data wranglers".* IGARD noted a number of acronyms in section 5 and asked that this public facing section, that forms NHS Digital's data uses register, be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader, for example *"CDS".* IGARD suggested that section 5(d) (Benefits) be updated to remove reference to "*it will*…", and instead use a form of words such as "*it is hoped*…" IGARD queried the reference to the bespoke dataset being *"aggregated"*, in section 1 and asked that this was removed as it was incorrect. **Outcome:** recommendation to approve subject to the following conditions: 1. To provide a succinct explanation in section 5(a) of the purpose of processing, including (but not limited to) what areas the research is looking at (e.g. is it all cardiovascular events and all cancers or subsets of each). 2. To update section 1 and section 5 with a clear description of the datasets that make up the bespoke data flow. The following amendments were requested: 1. To review the inconsistent references to the various projects in Section 5(a) (e.g. all cancers or just colorectal), and update / align as appropriate, to reflect the purpose for processing. 2. To update section 1 confirming that the flow of date of death data, is in line with NHS Digital's policy assessment and will not increase the likelihood of re-identification of data subjects. 3. To update section 1 and section 5(a) with confirmation that NHS Digital is no longer a joint Data Controller. 4. In respect of the benefits and in line with NHS Digital DARS Standard for Expected Measurable Benefits:

	a) To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will…*". b) To move the first paragraph in section 5(d) (iii) to 5(d) (i). c) To update the (current) second paragraph in section 5(d) (iii) to refer to or link to the specific nationwide public health campaigns and, if possible, the impact of these. 5. To update section 5 to ensure it is written in language suitable for a lay reader and that consideration is given to the public audience, for example when referring to *"data wranglers".* 6. As section 5 forms NHS Digital's data uses register, to amend section 5 to ensure that all acronyms upon first use are defined and further explained if the meaning is not self-evident, for example *"CDS"*. 7. To amend section 1 to remove reference to *"aggregated"* data. The following advice was given: 1. IGARD suggested that the applicant ensured NHS Digital were consistently credited as the source of the data, in order to improve public awareness about the use of their health data.
4	Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent Applications that have been progressed via NHS Digital's Precedent route, including the SIRO Precedent, and NHS Digital have notified IGARD in writing (via the Secretariat). *No items discussed.*
5	Oversight & Assurance 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. Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any Data Access Request Service (DARS) applications as part of their oversight and assurance role. IGARD noted that they had requested, an IG COVID-19 release register suite of documents on a particular data release for review by IGARD as part of their oversight and assurance, and as agreed in June 2020 with the Executive Director Privacy, Transparency and Ethics (PTE) when it had been agreed that IGARD review an agreed number per month, by way of a review of all documentation revised by PTE, and as part of continuous improvement and quality. IGARD Members noted that they had not yet been updated on the issues raised at the 27th May 2021 IGARD business as usual (BAU) meeting with regard to previous comments made on the IG COVID-19 release registers. IGARD Members noted that the last IG COVID-19 release register that they had reviewed and provided comments on was July 2021.

6	COVID-19 update To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. IGARD noted that due to conflicting priorities for IGARD members and the IGARD Secretariat, the COVID-19 response meeting on Tuesday, 16th November 2021 was cancelled.
7 **7.1**	AOB: ICO Consultation - Anonymisation, pseudonymisation and privacy enhancing technologies guidance Noting that the above consultation was due to close on the 28th November 2021, IGARD shared their initial collective feedback with senior NHS Digital colleagues. The IGARD Chair thanked NHS Digital colleagues for attending the meeting, and it was agreed that a further discussion would take place at the IGARD business as usual meeting on the 25th November 2021. 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.
8	Workshop: IGARD / DSCRO's / Business Leads / IAO for Commissioning / DARS Following conclusion of the IGARD business as usual (BAU) section of the meeting, IGARD held a workshop with colleagues (as outlined on page 1 / 2), primarily to discuss the issues around using data for direct care, with a secondary discussion in respect of documenting yielded benefits. The meeting was chaired by the IGARD Chair, and the following high-level observations and comments were agreed: **Data for direct care** • It was agreed that "*direct care*" should be called that in applications for transparency for the public, and so applications from CCGs should be for "*commissioning / risk stratification / invoice validation / direct care*", noting that section 5 of all applications submitted through the DARS process formed the NHS Digital data uses register. • IGARD noted that there were broadly two silos: where a patient in need of care may be spotted by the CCG as part of routine work and it would be remiss of the CCG not to alert the provider; and where programmes of work, designed in collaboration with, and driven by, clinicians, picked up a patient or cohort of patients that needed to be re-identified. • IGARD noted that, although the GP provider does have access to the same data, it was agreed by those present that the DARS application needed to be explicitly clear that the data requested was giving a different, more accessible view, and that it was more likely to be utilised by the GP to re-identifying the patient for a clinical need.

- It was agreed by those present, that the application through DARS should also take the opportunity to clearly explain the safeguards and mechanisms in place that sit over the re-identification for direct care, such as the various NHS Digital policy documents which have been created and are in use, and to clearly describe them.
- All agreed that using data for direct care which had had the NDO applied was problematic (because patients are told that an NDO only stops confidential patient information being used for research and planning). However, if such a dataset was being used in this way then it should be transparent to the public. In addition, it was agreed that the applications through DARS should clearly articulate whether the NDO has been applied to the data being used, or not.
- IGARD noted that NHS X held the NDO policy, and that NHS Digital may wish to take the opportunity to speak to NHS X and HRA CAG with regard to the application of NDOs to data which is being used for direct care.
- NHS Digital's Caldicott Guardian noted no specific reference in SUS Directions for direct care, but it may be performed under a permissive route (Spine services (no 2) 2014 Direction - NHS Digital and Informatics systems for the collection or analysis of information Directions 2016 - NHS Digital).
- Going forward, all agreed that the system agreed would need to work for everyone, and especially noting the current and future landscape. IGARD were supportive of ensuring a robust system approach.
- All agreed that the current templated applications through DARS required an urgent uplift to include the direct care element, and that the team should work with the DSCROs to ensure the wording within the templated applications was fit for purpose, before providing a copy of the updated template application at a future IGARD BAU meeting.

Yielded Benefits

- IGARD noted that comments made on the yielded benefits section of the DARS application were in line with the NHS Digital DARS Standard for Expected Measurable Benefits, with a future eye on the National Data Guardian (NDG) guidance on public benefit assessments which NHS Digital must have regard to, including all other organisations such as NHS England and CCGs (ICSs from 1st April 2022). IGARD noted that everyone will need to have due regard to demonstrating the specific benefits flowing to the public from the use of health data and in order to fulfil their obligations, and IGARD noted that CCGs (soon to be ICSs) may wish to explore the use of documents already in the public domain (such as their statutory annual reports): Putting Good into Practice – a public dialogue on making public benefit assessments when using health and care data. IGARD noted there was a limit in terms of what could be resolved before the NDG guidance was published and that further discussions may be needed.
- IGARD noted that it would seem reasonable to update yielded benefits annually in line with their statutory published annual reports. IGARD were **not** looking at CCGs to update their yielded benefits section for every amendment application, and suggested that DARS may wish to clarify this point in their published DARS Standards.
- IGARD also suggested that CCGs (soon to be ICSs) may wish to also consider, alongside providing a link and narrative in yielded benefits around their annual report, 2 or 3 local 'flavour' yielded benefits that link back to their purpose statement, and draw

	out key areas of improvement or success that the CCG has had over the preceding year. IGARD felt that this would be a great opportunity for the CCG to promote the work they are doing in their community for the citizens that reside there. **Multiple processor and storage locations** • The DSCROs outlined to IGARD why the applications via DARS had so many multiple processor and storage locations, and that this was because of the time taken to re-submit an application every time a small amendment was required through the DARS process. • IGARD noted that NHS Digital's DARS had in place a number of precedents, including "*simple amendment*" to pick up this type of event, but had presumed for CCGs and such like that a "*fast track*" approach was taken for these type of applications, and for those organisations that supported the NHS service. IGARD suggested that NHS Digital may wish to consider a fast-track approach for certain types of applications so that they were not going through the full end to end CRM process for the simple inclusion of a new data processor or storage location, for example, since it appeared via the verbal update from DSCROs on behalf of the CCGs, to be a particularly onerous and overly bureaucratic process. **Next steps** – all agreed that the workshop had been a great opportunity to learn more about issues and discuss solutions, and that they should meet in the New Year to discuss the published NDG guidance on public benefit assessments, the changing landscape as CCGs moved to be ICB / ICSs, etc. The IGARD Chair thanked members and colleagues for their time, and noted that although everyone was coming to the workshop from a different background, it was important to remember that IGARD are an **advisory** group to NHS Digital's board, not decision making, and their specific remit is outlined in their published Terms of Reference.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 12/11/21

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-331142-P5K6M-v0.10	University of Bristol	19/08/2021	1. In respect of the legal basis: a) To provide a copy of the written analyses from NHS Digital's PTE supporting the use of COPI, instead of The Children's Act 2004, as the legal gateway for all aspects of the processing (including, for example, the aim of improving services to bereaved families where covid-19 is not necessarily the cause of death). b) to upload a copy of the written analysis from PTE to NHS Digital's CRM system c) To update section 1 with a narrative why The Children Act 2004 is no longer deemed a suitable legal basis for the flow of data, noting that The Children Act has previously been used to flow HES and MSDS from NHS Digital and is currently referenced as the legal gateway for the flow of HES data in the supporting documents.	IGARD members	Quorum of IGARD members	**Condition 1(a)** An analysis had been provided. However in the interests of transparency, IGARD would request that the full emails are uploaded to NHS Digitals CRM to ensure that the excerpts represent the full written analysis. **Condition 1(c)** Although narrative is provided as to why The Children's Act 2004 is no longer deemed a suitable legal basis, it was noted that supporting documents included references to data linkage of the MSDS utilising the Statutory Authority of the Children Act 2004 to cover the transfer of data throughout the process. These appear to be proposed data flows rather than already agreed. IGARD suggest that this condition

						would be met if an explicit statement was made in section 1 that no other flows of data occur to the NCMD from NHS Digital under any other agreement.
NIC-408951-K3C1Y-v0.12	PrescQIPP CIC	28/102/2021	1. In respect of the legal basis: a. If the applicant is relying on Article 9(2)(g) (substantial public interest) then sections 1 and 5 should be updated to clearly describe how the scheduled conditions are met under DPA 2018, and b. To provide a full justification for use of Article 9(2)(g) legal basis in line with the ICO's "what are reasons of substantial public interest" and the high bar set, or c. To amend the Article 9 legal basis to ensure an appropriate legal gateway for the dissemination of data by NHS Digital. 2. With regards the Article 9 legal basis, provide confirmation of how the provision of a dashboard provides a benefit to **all**, in relation to the safety and effectiveness of medicines, and not just those who subscribe to the organisation's medicines optimisation service.	IGARD members	Quorum of IGARD members	IGARD noted that following the OOC response from NHS Digital, conditions 1(a), 1(b) and 2, were no longer applicable.

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 Oversight and Assurance Report.

In addition, a number of applications were approved under class action addition of:

Liaison Financial Service and Cloud storage:

- None

Optum Health Solutions UK Limited Class Actions:

- None

Graphnet Class Actions:

- None