

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

**Minutes of meeting held via videoconference 26 November 2020**

<b>IGARD MEMBERS IN ATTENDANCE:</b>	
<b>Name:</b>	<b>Position:</b>
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Kirsty Irvine (Chair)	IGARD Lay Chair
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
<b>IGARD MEMBERS NOT IN ATTENDANCE:</b>	
<b>Name:</b>	<b>Position:</b>
Prof. Nicola Fear	Specialist Academic Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
<b>NHS DIGITAL STAFF IN ATTENDANCE:</b>	
<b>Name:</b>	<b>Team:</b>
Vicky Byrne-Watts	Data Access Request Service (DARS)
Cher Cartwright	Data Access Request Service (DARS)
Duncan Easton	Data Access Request Service (DARS)
Joanne Geisler	Data Access Request Service (DARS)
Fran Hancox	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics and Deputy Caldicott Guardian (Observer: items 2.1 – 2.4)
Denise Pine	Data Access Request Service (DARS)
Chris Roebuck	Information, Analysis and Statistics (Observer: item 2.5)
Karen Myers	IGARD Secretariat
Vicki Williams	IGARD Secretariat
<b>GPES DATA FOR PANDEMIC PLANNING AND RESEARCH – PROFESSION ADVISORY GROUP (PAG) MEMBERS IN ATTENDANCE:</b>	
Amir Mehrkar	PAG (Observer: Items 2.5 – 5)

1	<p><b>Declaration of interests:</b></p> <p>Paul Affleck noted professional links to the Ministry of Defence Research Ethics Committee (MODREC) (NIC-148024-P8GSC Ministry of Defence) but no specific connection with the application or staff involved and it was agreed that there was no conflict of interest.</p> <p><b>Review of previous minutes and actions:</b></p> <p>The minutes of the 17<sup>th</sup> November 2020 and 19<sup>th</sup> November 2020 IGARD meetings 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 A).</p>
2	<p><b>Data Applications</b></p>
2.1	<p><u>Group Application<sup>1</sup>: Joint data sharing agreement between Leicester City CCG, West Leicestershire CCG, East Leicestershire &amp; Rutland CCG, Leicester City Council, Leicestershire County Council and Rutland County Council. (Presenter: Duncan Easton) NIC-398666-H2S4K</u></p> <p><b>Application:</b> This was a new application for pseudonymised Secondary Uses Service (SUS+), Local Provider Flows, Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registries Data (CRD), National Diabetes Audit (NDA), Patient Reported Outcome Measures (PROMs), e-Referral Service (eRS), Personal Demographics Service (PDS), and Summary Hospital-level Mortality Indicator (SHMI).</p> <p>The overall purpose of the application is to provide intelligence to support the commissioning of health services.</p> <p><b>Discussion:</b> IGARD noted that section 2(c) (Territory of Use) and section 4 (Privacy Notice) in the version of the application received for review had not been completed; and were advised by NHS Digital that this was a technical error. NHS Digital confirmed that the version of the application on NHS Digital's customer relationship management (CRM) system was correctly populated and contained the relevant information. IGARD noted and thanked NHS Digital for the update.</p> <p>IGARD noted that the CCGs and the Local Authorities listed within the application formed the Leicester, Leicestershire &amp; Rutland Sustainability and Transformation Partnership (STP), however discussed that, although the STP was a partnership, it was not a legal entity in its own right, and was therefore not responsible for the various activities outlined. IGARD asked</p>

---

<sup>1</sup> NHS Leicester City CCG, NHS West Leicestershire CCG, NHS East Leicestershire and Rutland CCG, Leicester City Council, Leicestershire County Council, Rutland County Council

<p>that section 1 (Abstract) and section 5(a) (Objective for Processing) were updated to clarify this.</p> <p>IGARD queried the volume of processing locations listed in section 2(a) (Processing Locations), in light of the partnership working arrangement outlined, and suggested that on renewal, extension or amendment, the applicant should give consideration if there was a need for all the processing sites, and if there were any opportunities for joint data processing and / or joint storage to reduce the need for multiple handling of data.</p> <p>IGARD also advised that, since this was a new application, that when this application comes up for renewal, extension or amendment, they would expect the yielded benefits to be clearly outlined in section 5(d) (Benefits) (iii) (Yielded Benefits), and to reflect the work that had been undertaken, and the benefits accrued since the application was last seen.</p> <p>IGARD queried the information within the last paragraph of section 5(b) (Processing Activities), in respect of re-identification, in the cases of the development of risk stratification or other similar primary use tools; and suggested that it was amended to confirm that any re-identification would only take place on a case-by-case basis, and in “<i>exceptional circumstances</i>”.</p> <p>IGARD noted the information outlined in section 5(a) in respect of the initiatives being implemented by the STP, in particular the statement that they were “<i>working to prevent or capture conditions early as they are cheaper to treat.</i>”; and asked that this was amended to a more sensitive or accurate term, for example, “<i>better to treat</i>”.</p> <p>IGARD noted the commissioning outputs listed in section 5(c) (Specific Outputs Expected), and queried the output “<i>Identifying gaps in care, missed diagnoses and triple fail events</i>”; and asked that the reference to “<i>triple fail events</i>” was removed as it was not relevant.</p> <p>In addition, IGARD also queried point 28 of the commissioning outputs listed in section 5(c), in particular the reference to patients dying, and asked this was amended and replaced with an assessment of the outcome.</p> <p>IGARD noted that the Leicester City Council's Data Security and Protection Toolkit (DSPT) for 2019/20 Standards had <b>not</b> been fully met and that a special condition had been inserted in section 6 (Special Conditions), however the special condition stated that they would “<i>...commit to complete the actions within the DSPT improvement plan</i>” and suggested this was updated with an indicative timeframe for completion.</p> <p>IGARD queried if NHS Digital were assured that the appropriate protections were in place for the NHS Digital data being disseminated, and asked that section 1 was updated with a statement from the Data Security and Protection Toolkit (DSPT) Team, confirming that they were content.</p> <p>IGARD noted and endorsed NHS Digital's review that Rutland County Council did <b>not</b> meet NHS Digital's Standard for privacy notices, and was not compliant with the General Data Protection Regulation (GDPR); and suggested that NHS Digital addressed this in line with internal procedures.</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To update section 1 and section 5(a) with clarity that the STP is in the form of a partnership and is not, as an entity, responsible for the various activities.</li> <li>2. To update the last paragraph in section 5(b), in respect of re-identification, to confirm that this would only take place in “<i>exceptional circumstances</i>”.</li> </ol>
---

	<ol style="list-style-type: none"> <li>3. To amend the reference in section 5(a) to “<i>cheaper to treat</i>”, to a more sensitive or accurate term, for example, “<i>better to treat</i>”.</li> <li>4. To remove the reference in section 5(c) to “<i>triple fail events</i>”.</li> <li>5. To amend point 28 in section 5(c), to remove the reference to patients dying and replace with an assessment of the outcome.</li> <li>6. To update the ‘improvement plan’ special condition in section 6, to include a timeframe.</li> <li>7. To include in section 1 a statement from the NHS Digital DSPT team that they are assured that the appropriate protections are in place for NHS Digital data.</li> </ol> <p>The following advice was given:</p> <ol style="list-style-type: none"> <li>1. IGARD suggested that on renewal, the applicant should give consideration if there is a need for all the processing sites, and if there are any opportunities for joint data processing and / or joint storage to reduce the need for multiple handling of data.</li> <li>2. IGARD advised that when this application comes up for renewal, they would expect the yielded benefits to be clearly outlined, and to reflect the work that has been undertaken, and the benefits accrued since the application was last seen.</li> <li>3. IGARD noted that privacy notice for Rutland County Council was not GDPR compliant, and suggested that NHS Digital addressed this in line with internal procedures.</li> </ol>
2.2	<p><u>6 CCG Group Application<sup>2</sup>: DSfC - NHS Wakefield CCG-Consolidated-Amendment (Presenter: Duncan Easton) NIC-333880-G4H3T</u></p> <p><b>Application:</b> This was a renewal application for pseudonymised Secondary Uses Service (SUS+), Local Provider Flows, Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registries Data, National Diabetes Audit (NDA) and Patient Reported Outcome Measures (PROMs).</p> <p>It was also an amendment application to 1) add pseudonymised Personal Demographics Service (PDS), Summary Hospital-level Mortality Indicator (SHMI), and e-Referral Service (eRS) data sets for the purpose of commissioning; and 2) to add NHS Leeds CCG as a Data Controller.</p> <p>The overall purpose of the application is to provide intelligence to support the commissioning of health services.</p> <p>NHS Digital advised IGARD that supporting document 1, the data flow diagram, that had been provided to support IGARD’s review of the application, was incorrect and required a further update to include NHS Leeds CCG.</p> <p><b>Discussion:</b> IGARD noted and support the update from NHS Digital, in relation to the additional update to the data flow diagram.</p>

---

<sup>2</sup> NHS Bradford District and Craven CCG, NHS Calderdale CCG, NHS Greater Huddersfield CCG, NHS North Kirklees CCG, NHS Wakefield CCG, NHS Leeds CCG

	<p>IGARD noted the helpful summary at the end of section 5(a) (Objective for Processing) that outlined why the data was required, and asked that this was moved to sit at the beginning of this section, for ease of reference.</p> <p>IGARD queried point 14 of the commissioning outputs listed in section 5(c) (Specific Outcomes Expected), in particular the reference to patients dying, and asked this was amended and replaced with an assessment of the outcome.</p> <p>IGARD queried if NHS Digital were assured that the appropriate protections were in place for the NHS Digital data being disseminated, and asked that section 1 (Abstract) was updated with a statement from the Data Security and Protection Toolkit (DSPT) Team, confirming that they were content.</p> <p>IGARD noted and endorsed NHS Digital's review that NHS Calderdale CCG, NHS Greater Huddersfield CCG, NHS North Kirklees CCG, NHS Wakefield CCG, and NHS Leeds CCG did <b>not</b> meet NHS Digital's Standard for privacy notices; and were not compliant with the General Data Protection Regulation (GDPR); and suggested that NHS Digital addressed this in line with internal procedures.</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To move the final paragraph of section 5(a) to sit at the beginning of this section.</li> <li>2. To update point 14 in section 5(c), to remove the reference to patient's dying, and replace with an assessment of the outcome.</li> <li>3. To include in section 1 a statement from the NHS Digital DSPT team that they are assured that the appropriate protections are in place for NHS Digital data.</li> </ol> <p>The following advice was given:</p> <ol style="list-style-type: none"> <li>1. IGARD noted that privacy notices for a number of the CCG's were not GDPR compliant, and suggested that NHS Digital addressed this in line with internal procedures.</li> </ol>
2.3	<p><u>Swansea University: NIHR HS&amp;DR 18/03/02 STRETCHED (Snooks) (Presenter: Vicky Byrne-Watts) NIC-327960-M2P9M</u></p> <p><b>Application:</b> This was a new application for Civil Registration data and Hospital Episode Statistics (HES), for the purpose of the “<b>STR</b>ategies to manage <b>E</b>mergency ambulance <b>T</b>elephone <b>C</b>allers with sustained <b>H</b>igh needs – an <b>E</b>valuation using linked <b>D</b>ata” (STRETCHED) study, looking at the impact of multi-disciplinary case management approaches to handling frequent callers to the ambulance service. Frequent callers are defined as people who phone 999 more than 5 times in a month, or more than 12 times in three months. Frequent callers typically have complex medical needs, but often do not require immediate medical attention.</p> <p>The study will compare outcomes for frequent callers that do and do not receive case management according to a prespecified statistical analysis plan, to determine the safety and efficacy of this intervention. The aim is to understand the wider impact of the case management process, including whether any reduction in the number of 999 calls is a consequence of shifting demand elsewhere in the NHS.</p> <p><b>Discussion:</b> IGARD welcomed the application and noted the importance of the study, and the potential impact this could have on patient care and the Ambulance Service.</p>

IGARD also noted and commended NHS Digital on the effort that had gone into the application to date.

IGARD noted that section 2(c) (Territory of Use) and section 4, in the version of the application received for review, had not been completed; and were advised by NHS Digital, that this was a technical error. IGARD noted and thanked NHS Digital for the update, and asked that they ensure section 2(c) was updated to reflect that the territory of use was England / Wales.

IGARD also noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices; asked that section 4 was updated with the agreed privacy notice standard wording.

IGARD noted a number of references throughout section 5 (Purpose / Methods / Outputs) to "*presumed consent*", for example, "*Ethical considerations include the use of presumed consent to follow-up patients*", and queried what this meant, in light of the s251 support. IGARD asked that section 5 was updated to remove all references to "*presumed consent*", and to replace with a clear explanation of how the cohort members were selected and identified. In addition, IGARD also asked that the legal basis for flowing and processing the cohort's health information, for example by referencing the s251 support, was included in section 5.

In addition, IGARD also queried the statement in section 5 "*...as STRETCHED is a retrospective observational study, it cannot adversely affect patient care...*", and asked that this was removed as it was not necessary.

IGARD queried whether the Data Security and Protection Toolkit (DSPT), as referenced within the supporting documents provided, should also be referenced alongside the ISO27001 assurance. IGARD commended the applicant for having both in place.

IGARD queried the cohort number stated within the data minimisation column in section 3(b) (Additional Data Access Requested) since the figure also appeared to include Welsh cohort participants, and asked that this was amended to ensure it only reflected the three English cohorts, and did not include any Welsh data.

IGARD suggested that section 5(a) (Objective for Processing) be updated to ensure that where appropriate, the term "*gender*" was replaced with the term "*sex*" to reflect the available field in the data set requested.

IGARD noted a number of references in section 5 to "*aggregated data*", and asked that these were updated to include the qualifying statement "*with small numbers suppressed*".

IGARD noted the statement within paragraph 3 of section 5(b) (Processing Activities) "*Equivalent data for the Welsh Ambulance Service will instead be uploaded to the NHS Wales Informatics Service...*", and asked that the reference to "*instead*" was removed, as this was not necessary to include.

IGARD queried the benefits outlined in section 5(d) (Benefits), and noted that some of the information provided were outputs, and asked that section 5(d) was updated to remove any outputs and edit to only leave examples that reflect the benefits to the Health and Social Care System.

IGARD note the benefits outlined in section 5(d), however asked that these were updated, to ensure they were set out in the appropriate qualified language, for example, it is "*hoped*".

IGARD noted the information within the protocol, in relation to the patient and public involvement (PPI), for example, "*We will seek to widen PPI links during the study to better*

reflect the diverse patient population”, and strongly suggested that the applicant endeavoured to widen their PPI to ensure that the input reflects the composition of the cohort.

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

1. In respect of the references to “*presumed consent*”, to update section 5 throughout:
  - a) To remove all references to “*presumed consent*”.
  - b) To replace with a clear explanation of how the cohort members are selected and identified.
  - c) To also include the legal basis for following and processing the cohort’s health information (for example by reference to the s251 support).

The following amendments were requested:

1. To confirm with the NHS Digital Security Adviser whether the DSPT (referred to in supporting document) should also be referenced alongside the ISO assurance.
2. To amend the data minimisation column in section 3(b), to ensure this **only** reflects the three English cohorts.
3. To update section 5(a) to remove the statement “*cannot adversely affect patient care*”, as this is not necessary.
4. To ensure that, where appropriate, the term “*gender*” is replaced with the term “*sex*” to reflect the available field in the data set requested.
5. To update section 5 to ensure the references to “*aggregated data*” also include the qualifying statement “*with small numbers suppressed*”.
6. To update paragraph 3 in section 5(b) to remove the reference to “*instead*”.
7. To remove any specific outputs from section 5(d) and move to section 5(c).
8. To update the benefits in section 5(d), to ensure they are set out in appropriate qualified language, for example “*hope*”.
9. To ensure section 2(c) reflects that the territory of use is England Wales.
10. To update section 4 with the agreed privacy notice standard wording.

The following advice was given:

1. IGARD strongly suggested that, in light of the undertaking made in the protocol, that the applicant endeavours to widen their PPI to ensure that the input reflects the composition of the cohort.

It was agreed the condition would be approved out of committee (OOC) by IGARD members.

**2.4** University of Cambridge: Optimising Management of Patients with Heart Failure with Preserved Ejection Fraction in Primary Care (OPTIMISE HFpEF) (Presenter: Fran Hancox) NIC-182098-Y4H0W

**Application:** This was a new application for Emergency Care Data Set (ECDS), Civil Registration data and Hospital Episode Statistics (HES), for the purpose of the ‘Optimising Management for Patients with Heart Failure with Preserved Ejection Fraction (HFpEF) in Primary Care’ project.

The aim of the project, is to explore the views of people with HFpEF and the multiple stakeholders involved in HFpEF care; phenotype a UK cohort; and undertake consensus methods to develop an optimised programme that would provide guidance to clinicians in diagnosing and managing HFpEF.

HFpEF is less well understood than Heart Failure with Reduced Ejection Fraction (HFrEF) and is associated with greater diagnostic difficulty and management uncertainty. Half of all HF cases may be attributable to HFpEF, and prevalence is rising at a rate of 1% annually.

Although mortality for all-cause HF in the UK has modestly improved, no treatment has yet been shown to improve mortality and morbidity in HFpEF.

NHS Digital advised IGARD that any references within the application to cohort “*postcodes*” being sent to NHS Digital, was incorrect and would be removed from the application.

NHS Digital also advised that following submission of the application to IGARD for review, the Research Ethics Committee (REC) letter of support for the study had been received.

**Discussion:** IGARD noted the update from NHS Digital, in respect of the incorrect references to cohort “*postcodes*” being sent to NHS Digital, and supported the update to the application to remove these.

IGARD also noted that NHS Digital had received the REC letter of support and asked that this was uploaded to NHS Digital’s customer relationships management (CRM) system for future reference.

IGARD noted that the patient information sheet provided was version 4, and the consent form was version 3, and queried if **all** the relevant versions of the consent form and patient information sheet had been reviewed and asked that confirmation was provided; and that if there were other versions of the consent materials, asked that NHS Digital confirm that they had assessed them as compatible with the use of the data.

In addition, IGARD discussed the consent materials and agreed that they were broadly consistent with the proposed processing outlined, however advised that there could be some additional transparency in respect of the types of data sets flowing, particularly cause of death and date of death. IGARD suggested that the applicant communicated directly with the cohort, by way of a newsletter, since they appeared to be in regular contact, that clearly described the processing set out in the application and the datasets being sought, and that included a sensitive reference to the nature of the Civil Registration data.

IGARD noted in section 1(b) (Data Controller(s)) that the University of Cambridge was the sole Data Controller, however queried the roles of the University of Oxford and the Cambridge University NHS Foundation Trust in light of the information outlined within the supporting documents and that two co-investigators were based out with the University of Oxford. IGARD asked that written confirmation was provided, in alignment with the General Data Protection Regulation (GDPR) and NHS Digital’s DARS Standard on Data Controllers, why they were not considered joint Data Controllers. If the University of Oxford and / or the Cambridge University NHS Foundation Trust were considered joint Data Controllers, IGARD asked that the application was updated throughout to reflect this statement of fact.

IGARD noted that the reference to the legal basis for the dissemination of the Civil Registration data had not been included in section 3(b) (Additional Data Access Requested), and asked that this was updated accordingly.

IGARD noted the references in section 5(b) (Processing Activities) to the Secure Data Hosting Service (SDHS), and asked that this was updated to also include an explanation of what data was being held and how it was separated from other data held.

IGARD also queried the statement “*SDHS network and access is provided by a secure Virtual Desktop*”, and asked that this was amended to remove reference to a named product as it was not necessary.

IGARD queried the statement in section 5(c) (Specific Outputs Expected) “*GPs have low awareness and knowledge about HFpEF...*”, and asked that, as this was not necessarily correct, this statement was removed.



IGARD noted a number of references in section 5(d) to “cost”, for example “*Hospitalisation is the major cost associated with care of patients with heart failure...*”, and asked that this was amended to make it clear that this was referring to “*financial cost*”.

IGARD noted and applauded the involvement of Pumping Marvellous, and the patient group referenced within the application, in the later stages of disseminating results; however, IGARD suggested that the applicant may wish to involve them earlier to support the ongoing study.

IGARD noted that the territory of use in section 2(c) (Territory of Use) had not been completed, and asked that this was updated to correctly state that the territory of use was England and Wales.

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

1. In respect of the data controllership:
  - a) To provide a written explanation (in terms of the GDPR and NHS Digital’s DARS Standard on Data Controllers) why the University of Oxford and the Cambridge University NHS Foundation Trust were **not** considered joint Data Controllers, in light of the information provided in the supporting documents.
  - b) If the University of Oxford and/or the Cambridge University NHS Foundation Trust are considered joint Data Controllers, to update the application throughout to reflect this.
2. In respect of REC approval:
  - a) To provide confirmation that **all** the versions of the consent materials have been approved by REC.
  - b) To provide confirmation that there are no other versions of the consent materials available, that have not been provided to NHS Digital.
  - c) If there are other versions of the consent materials, to confirm that NHS Digital have assessed them as compatible with the use of the data.
  - d) To upload a copy of the ethics approval to NHS Digital’s CRM system.

The following amendments were requested:

1. To update section 3(b) to reference the legal basis for disseminating the Civil Registration data.
2. To update section 5(b), to ensure the references to SDHS include an explanation of what data is being held and how it is separated.
3. To update section 5(b) to remove reference to the specific virtual desktop network.
4. To update section 5(c) to remove reference to GPs having “*low awareness*” about HFpEF.
5. To amend section 5(d) to make clear that reference to “*cost*” is a “*financial cost*”.
6. To ensure section 2(c) reflects that the territory of use is England and Wales.

The following advice was given:

1. IGARD suggested that the applicant communicate directly with the cohort, by way of a newsletter, that clearly describes the processing set out in the application and the datasets being sought (including a sensitive reference to the nature of the Civil Registration data).
2. IGARD applauded the involvement of Pumping Marvellous, and the patient group, in the later stages of disseminating results, however suggested that the applicant may wish to involve them earlier to support the ongoing study.

It was agreed the conditions would be approved out of committee (OOC) by IGARD members.

London North West University Healthcare NHS Trust: Colonoscopic Surveillance for Familial Risk of Colorectal Cancer (Presenter: Denise Pine) NIC-148406-2YXPR

**Application:** This was an extension application for identifiable Medical Research Information Service (MRIS) data; and an amendment to 1) to add King's College London (KCL) as a Data Processor, 2) to remove Queen Mary University of London (QMUL) as a Data Processor; 3) to reflect the storage and processing locations used by KCL; 4) to add new expected outputs; 5) to add the yielded benefits.

The purpose is for a long-running surveillance programme, with the aim of seeing if surveillance is successful in preventing cases of colorectal and other cancers. It also allows an assessment of whether there are other causes of death that occur more frequently than expected in the cohort. In addition to service evaluation, associated research is being undertaken with the following aims: 1) to ensure best practice in offering appropriate surveillance to individuals at increased risk of colorectal cancer due to a strong family history of colorectal cancer; 2) to quantify the risk of colorectal cancer associated with different family histories and individual characteristics including molecular genetic testing of patients' tumours and germline DNA; 3) To understand the natural history of colorectal neoplasia and effectiveness of colonoscopy in different groups.

**Discussion:** IGARD noted that there were a number of points outlined in section 1 (Abstract) of the application, in relation to previously raised and / or ongoing points; which were discussed, and the following advice was provided.

IGARD noted that the application was granted s251 support for non-research purposes, and that supporting document 2.3, the Health Research Authority Confidentiality Advisory Group (HRA CAG) letter of support dated the 8<sup>th</sup> September 2017, stated that the applicant would "*undertake public and patient engagement work and report back at annual review*". The applicant had submitted a signed and dated version of the annual review report to HRA CAG in 2020 (precise date unknown), however NHS Digital had not received a copy prior to the submission of the application for IGARD's review. IGARD agreed with NHS Digital's assessment with regard to s251 support, and asked that a signed and dated version of their annual review report was provided to NHS Digital.

IGARD noted that s251 support only permitted access to data of the historical cohort, with the intention to seek prospective consent from participants going forward, and that NHS Digital had not received any further update on the steps being taken to seek consent from participants and had not received copies of any consent materials for that purpose. NHS Digital advised that if any of the data subjects in the current cohort had given consent, consent would be the legal basis for accessing their data, in respect of the common law duty of confidentiality, and not section 251 support; or if they had been invited to give consent but declined, they would be removed from the cohort. IGARD agreed with NHS Digital's assessment with regard to informed consent. Noting the HRA CAG position, the applicant should provide an update and copies of any documentation.

IGARD noted the appropriate and up to date Research Ethics Committee (REC) support was in place, however, suggested that NHS Digital clarified the "*serious breach*" of the protocol referred to in the February 2020 annual progress report to the main REC.

IGARD noted that the applicant had notified NHS Digital that all data stored at Queen Mary University of London (QMUL) had been destroyed, and supported NHS Digital's request for a completed certificate of destruction.

	<p>IGARD noted the list of publications in section 5(c) (Specific Outputs Expected), and agreed with NHS Digital's assessment that they should be edited to provide a lay friendly explanation of the outputs produced.</p> <p>IGARD repeated a query raised at a previous review, whether the data was being used for direct clinical care, and asked that confirmation was provided; in light of IGARD's observation that the National Data Opt-out should <b>not</b> be applied to any data flow that was being used for the purpose of direct care.</p> <p>IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent.</p> <p>IGARD confirmed that they would be supportive of an extension to the Data Sharing Agreement (DSA) for an additional 6 months, to allow the applicant to address the outstanding points raised. IGARD advised that, in light of the time that had elapsed since the points were initially raised, they would expect to see significant progress to have been made during this time.</p> <p><b>Outcome:</b> recommendation to approve for 6 months only</p> <p>The following advice was given:</p> <ol style="list-style-type: none"> <li>1. IGARD agreed with NHS Digital's assessment with regard to s251 support, and that a signed and dated version of their annual review report is provided to NHS Digital.</li> <li>2. IGARD agreed with NHS Digital's assessment with regard to informed consent (and noting there was an assertion to CAG that the evaluation would transition to this model), and that the applicant, provide an update, and copies of any documentation.</li> <li>3. IGARD noted appropriate and up to date REC support was in place, but suggested that NHS Digital clarify the "<i>serious breach</i>" of the protocol referred to in the February 2020 annual progress report to the main REC.</li> <li>4. IGARD agreed with NHS Digital's assessment with regard to destruction of data, and that a completed certification of destruction was provided to NHS Digital.</li> <li>5. IGARD agreed with NHS Digital's assessment with regard to section 5(c), outputs expected, that they should be edited to provide a lay friendly explanation of the outputs produced.</li> <li>6. IGARD repeated a previous query raised when the application was last reviewed at IGARD; if there was an element of the data being used for direct care then the National Data Opt-Out does not apply to direct care.</li> <li>7. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment.</li> <li>8. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent.</li> </ol>
3	<p><u>Mental Health of Children and Young People (MHCYP) – COVID-19 Data and Analyses</u> (Presenters: Cher Cartwright and Joanne Geisler)</p> <p>The presentation was to inform IGARD about the Mental Health of Children and Young People (MHCYP) is a national survey providing data on the prevalence of mental disorders in children and young people (aged 2-19 years old) living in England.</p> <p>There have been three surveys commissioned so far. The latest, in 2017, was conducted for NHS Digital by a consortium consisting of the National Centre for Social Research (NatCen), the Office for National Statistics (ONS) and YouthinMind.</p>

	<p>The MHCYP 2017 survey will be introduced to NHS Digital's Data Access Request Service (DARS) once the <b>Mental Health Surveys Direction</b> is signed off by Department of Health and Social Care and NHS Digital. Draft Direction documentation has been submitted to IGARD for information.</p> <p>In 2020, DHSC commissioned NHS Digital to carry out a follow up study of the MHCYP 2017 cohort. The survey was designed to look at changes in mental health disorders over time and also to capture information that was relevant to understanding the impact of the COVID-19 pandemic on children and young people's mental health.</p> <p>IGARD were supportive of this important work and made the following comments on the briefing note:</p> <ol style="list-style-type: none"> <li>1. IGARD advised NHS Digital that they would welcome a further discussion at future IGARD – NHS Digital COVID-19 Response meeting and prior to any application being submitted to a business as usual meeting on a Thursday.</li> <li>2. IGARD suggested that NHS Digital may wish to give further consideration as to how the age ranges were split, for example, 11-15 year olds (currently 11-16), and 16-19 year olds (currently 17-19); and that further information could be sought from NHS Digital's Caldicott Guardian.</li> <li>3. Noting that the use of the Health Service Control of Patient Information (COPI) Regulations 2002, is due to expire in March 2021, further consideration should be given to those applicants receiving the data, and how the data will be used in a meaningful way within such a short timeframe.</li> <li>4. IGARD advised that sight of the consent materials alongside the presentation, would have been beneficial.</li> <li>5. IGARD suggested that further consideration should be given, to how potential applicants are made aware that the data is available.</li> <li>6. IGARD suggested that when the first of type application is submitted to IGARD, further information as to why the application submitted is going first, should also be provided.</li> <li>7. To ensure that positive language is used when referencing the data, for example, replacing the term "<i>disorders</i>" with "<i>health conditions</i>".</li> </ol> <p><b>Outcome:</b> IGARD welcomed the briefing / presentation and looked forward to receiving a first of type application.</p>
4	<p><u>Returning Applications</u></p> <p>IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital.</p> <ul style="list-style-type: none"> <li>• NIC-381632-M4D9L University of Oxford</li> <li>• NIC-315716-L0F4M Imperial College London</li> <li>• NIC-220105-B3Z3S University of Liverpool</li> <li>• NIC-148024-P8GSC Ministry of Defence</li> </ul> <p>IGARD welcomed the four applications as part of their oversight and assurance role and noted a number of comments to NHS Digital and suggested that further information and comments be provided in an IGARD Oversight and Assurance Report.</p> <p>Moving forward, IGARD agreed that COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 applications may also be included as part of the</p>

	oversight and assurance review, not just those that were approved via NHS Digital's precedent route.
5	<p><u>COVID-19 update</u></p> <p>To support NHS Digital's response to COVID-19, from Tuesday 21<sup>st</sup> 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.</p> <p>The ratified action notes from Tuesday 24<sup>th</sup> November 2020 can be found attached to these minutes as Appendix C.</p>
6	<p><u>AOB:</u></p>
6.1	<p><u>Direction for Mental Health Surveys</u></p> <p>NHS Digital are currently working on securing the Direction for Mental Health Surveys. The Direction has been drafted and shared with the Department of Health and Social Care (DHSC); and is due to be presented to NHS Digital's Executive Management Team (EMT). The draft Direction was shared with IGARD for information.</p> <p>IGARD thanked NHS Digital with providing a copy of the draft Direction, and provided the following comments, in line with the earlier discussion on the Mental Health of Children and Young People (MHCYP) – COVID-19 Data and Analyses.</p> <ol style="list-style-type: none"> <li>1. IGARD advised NHS Digital that they would welcome a further discussion at future IGARD – NHS Digital COVID-19 Response meeting.</li> <li>2. IGARD would welcome receiving a copy of the consent materials for the 2020 wave 1 cohort.</li> <li>3. IGARD suggested that NHS Digital may wish to give further consideration as to how the age ranges were split, for example, 11-15 year olds (currently 11-16), and 16-19 year olds (currently 17-19); and that further information could be sought from NHS Digital's Caldicott Guardian.</li> <li>4. Noting the reference to the "<i>Information Commissioner's Office (ICO) Anonymisation Code of Practice</i>" within the documents provided, IGARD suggested that it was made clear, that this was not being relied upon, and that it was being used as a proxy, to further pseudonymise data in lieu of any other guidance from the ICO.</li> </ol>
6.2	<p><u>NIC-400304-S1P1B - Office for National Statistics (ONS)</u></p> <p>This application was discussed at the IGARD meeting on the 19<sup>th</sup> November 2020, and was recommended for approval with the following condition (and amendments):</p> <p><b>Outcome:</b> recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> <li>1. In respect of the ethical approval, to either: <ol style="list-style-type: none"> <li>a) Provide written evidence that a positive Ethics opinion has been sought; or;</li> <li>b) Provide written confirmation that the Data Ethics Advisory Committee is satisfied that an updated opinion is not required;</li> </ol> </li> </ol>

- c) To upload a copy of the ethics approval; or a suitable response from Ethics confirming that updated ethics approval is not required, to NHS Digital's CRM system.

The following amendments were requested:

1. To update section 5 to confirm the make-up of the group responsible for validating the algorithms given that this is potentially a clinical tool and not simply a statistical tool.
2. To update section 5 with regard to cluster codes and update relevant contradictory text.
3. To provide a brief explanation in section 5 with regard to "Tripod".
4. To clarify in section 5:
  - a) If there is a pre-determined c statistic, which meet the threshold;
  - b) To clarify who makes the decision on approving use of QCOVID based on the output of the c statistic, if the algorithm is successfully validated.
5. To clarify if there is a commercial element to the application, and if so, to update section 5(a) and section 5(e).

The following advice was given:

1. IGARD suggested that in addition to sending the results to SAGE, they also include the BMA and Royal Colleges.
2. IGARD advised that when this application comes up for renewal, they would expect the benefits accrued since the application was last seen to be clearly outlined.

Following the IGARD meeting, the condition was reviewed out of committee (OOC) by members, however, the requisite three positive responses were not received, and the condition was therefore deemed not to have been met.

IGARD held a further discussion about the OOC, and the IGARD Chair advised that she was prepared to take Chair's action, and set aside that condition, replacing with the following: *"Suitable confirmation that updated ethics approval is not required"*, and confirmed that she was content that the amended condition had been met.

In addition, the IGARD Chair advised, notwithstanding the above confirmation, as and when future data sets or purposes were added to this project, IGARD would expect contact to be made with the Data Ethics Advisory Committee directly, and for them to expressly confirm that they did not consider there was a need to refresh or review their opinion; or to review and issue a refreshed opinion.

The IGARD Secretariat, as per agreed process, formally notified NHS Digital of this decision in writing following this meeting.

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.

## Appendix A

### Independent Group Advising on Releases of Data (IGARD): Out of committee report 20/1120

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)
None						

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, Cloud storage, Optum as a Data Processor):

- None

## Appendix B

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

#### Action Notes from the IGARD – NHS Digital COVID-19 Response Meeting

held via videoconference, Tuesday, 24<sup>th</sup> November 2020

**In attendance (IGARD Members):** Paul Affleck (Specialist Ethics Member / Acting Chair)

Prof Nicola Fear (Specialist Academic Member)

Dr Imran Khan (Specialist GP Member)

**In attendance (NHS Digital):** Cath Day (DARS)

Louise Dunn (DARS)

Liz Gaffney (DARS)

Karen Myers (IGARD Secretariat)

Vicki Williams (IGARD Secretariat)

2	<p><b>Welcome</b></p> <p>The Acting IGARD Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (BAU) meetings. IGARD members present would only be making comments and observations on any items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual Data Access Request Service (DARS) process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting would be received at the next Thursday meeting of IGARD and published as part of those minutes as an appendix.</p> <p><b>Declaration of interests:</b></p> <p>Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19.</p>
2.1	<p><u>NIC-381078-Y9C5K - Health Data Research UK</u></p> <p><b>Background:</b> This was an update to previous presentations of an application at the COVID-19 response meetings on the 26 May, 2 June, 9 June, 16 June and 23 June 2020, and suite of documentation at the BAU Thursday meetings on the 25 June, 23 July and 15 October 2020.</p> <p>The amendments to the application were to add future datasets from the National Institute for Cardiovascular Outcome Research (NICOR): the Intensive Care National Audit and Research Centre (ICNARC); the Trans-catheter Aortic Valve Implantation (TAVI) registry; the Stroke Sentinel National Audit Programme (SSNAP), and the National Vascular Registry (NVR). Also, to add Electronic Prescribing and Medicines Administration (EPMA) data and to remove the special condition relating to Privacy Notices.</p> <p>The following observations were made on the basis of the updated application only.</p> <p><b>IGARD Observations:</b></p>



	<p>IGARD noted the update from NHS Digital that the application and relevant supporting documents in relation to this amendment would be presented to a future business as usual (BAU) meeting, and welcomed that approach.</p> <p>IGARD noted the update from NHS Digital with regard to the number of joint Data Controllers and the fact that the applicant was to publish a joint Data Sharing Agreement (DSA) on their website. IGARD members reiterated their previous comments made at both the COVID-19 response meeting and BAU meetings with regard to addressing Article 26 of the General Data Protection Regulation (GDPR), which is to ensure a factual analysis of responsibilities had been undertaken and that their respective responsibilities are transparently available to the data subjects (using the NHS Digital DARS Standard for Data Controllers and Data Processors) and the rights of subjects in respect of that analysis. IGARD members suggested that the applicant provide more detailed information on their website and that a copy of the relevant joint DSA be provided as supporting documentation at a future IGARD BAU meeting.</p> <p>IGARD members also suggested that consideration be given to data minimisation, noting NHS Digital's DARS Standard for Data Minimisation, in respect of providing future rationale and justification for the new datasets to be included in the amendment application, such as, for example, what were the indirect effects of COVID-19 on strokes, effects on any procedures etc.</p> <p>IGARD members noted that section 3 (datasets held / requested) didn't provide detail on the previous datasets disseminated and asked that this section be updated to reflect the plethora of data already held.</p> <p>IGARD members noted that when the application had been previously considered at their BAU meeting on the 15<sup>th</sup> October, they had been advised by NHS Digital that the first CVD-COVID-UK Oversight Committee meeting would take place on the 30<sup>th</sup> October 2020 and NHS Digital representation would form part of the committee, and it was expected that the first report would be produced following this. IGARD members noted that they would expect to see a copy of the minutes, or other documentation, as supporting documentation when the application was presented to a future IGARD BAU meeting.</p> <p>IGARD members noted that NHS Digital had removed the special condition from section 6 (Special Conditions) that "<i>A GDPR compliant privacy notice will be published by each data controller within 2 months of signing the DSA...</i>" noting that the policy with NHS digital had recently changed and only from November 2020, IGARD members noted that for those Data Controllers who were party to the agreement prior to the policy change, the special condition would still apply and that appropriate steps should be taken to ensure compliance. IGARD members noted that if the current Data Controllers have met the special condition it would seem reasonable to remove it.</p> <p>Significant risk areas to address (before presentation at an IGARD BAU meeting):</p> <ul style="list-style-type: none"> <li>• Data minimisation</li> <li>• Justification of new datasets</li> <li>• Transparency regarding joint data controllership</li> </ul>
2.2	<p><u>NIC-331142-P5K6M University of Bristol: National Child Mortality Database (NCMD)</u></p>

**Background:** This was an update to previous early discussion of an application at the COVID-19 response meeting on the 7<sup>th</sup> July 2020.

This was a draft application for the National Child Mortality Database (NCMD) request for mortality data, following a request from NHS England and NHS Improvement (NHSE&I) for the NCMD Programme to set up a child monitoring system to provide real time surveillance on child mortality in England, in order to inform NHSE&I and the Department of Health & Social Care (DHSC). NCMD holds data on all children in England who were liveborn and died before their 18<sup>th</sup> birthday. This is a statutory process and provision is made within the Children Act 2004 for the collection and processing of this data without consent and the legal basis for the NCMD to receive, hold and analyse the data collected is rooted in the statutory authority set out in the Children Act 2004.

The University of Bristol have been commissioned by NHS England via Healthcare Quality Improvement Partnership (HQIP) to undertake a real time survey of COVID-19 related mortality data.

The system is to help reduce the uncertainties around child deaths related to COVID-19 (both direct and indirect) which in turn will help to inform agency decision making to limit the direct and indirect impacts of the epidemic.

The NCMD currently provide daily and weekly mortality figures and weekly trend reports to NHSE and Chief Medical Officer (CMO) team, in order to produce briefing reports for the Scientific Advisory Group for Emergencies (SAGE) as and when required. NCMD have been requested to compare and validate their data with the Office for National Statistics (ONS) record to improve understanding of whether the real time surveillance system captures all child deaths in the country.

The following observations were made on the basis of the draft application only.

**IGARD observations:**

IGARD members noted that this was a valuable and fascinating piece of work and were supportive of the application, noting that a very early draft of documentation had been seen at the 7<sup>th</sup> July COVID-19 response meeting.

IGARD members queried why NHS England were not considered a joint Data Controller for this application and that the applicant should consider the facts of the parties' involvements and as laid out in NHS Digital's DARS Standard for Data Controllers / Data Processors. In addition, and noting that the University of Bristol was listed in the application as a Data Processor and was also the applicant, consideration should be given, as borne out of the facts presented, whether the University should also be considered a joint Data Controller. Furthermore, consideration should be given to any software provider as to whether they would be considered a Data Processor, as set out in the DARS Standard for Data Processors.

When previously presented at the COVID-19 response meeting, and given the limited information available at that time, IGARD members had suggested that the applicant may wish to rely on provision under the Children Act 2004 as a legal basis, rather than emergency National Health Service (Control of Patient Information Regulations) 2002 (COPI) powers, which will fall away at some point in the future, but suggested that NHS Digital's Privacy, Transparency and Ethics (PET) Directorate (formally Information Governance Directorate) would need to be content with the proposed legal basis of Section 16M-N of the Children Act

	<p>2004, and that written confirmation be provided as a future supporting document and uploaded to NHS Digital's customer relationship management (CRM) system.</p> <p>IGARD members were unclear if identifiers were to be sent to NHS Digital for them to do the linkage before providing the relevant data back, and that further clarification be sought and included in section 5(b) (Processing Activities). It also wasn't clear within the application what NHS Digital data was being linked to, and that further information should be provided, noting the reference in section 5(b) to data linkage with the national neonatal intensive care dataset (a clinical system called BadgerNet). In addition, further clarity should be sought as to whether the data requested would be to ascertain cases, to validate their own data, or a mixture of both.</p> <p>Noting the applicant was to provide real time analysis to SAGE and the CMO, NHS Digital confirmed that the applicant would be receiving monthly drops of data, and so IGARD suggested that the terminology be updated to reflect that they would be receiving regular data drops.</p> <p>IGARD members noted the data flow diagrams on the applicant's website and suggested that these be updated to include reference to NHS Digital data and that a copy be provided as a future supporting document.</p> <p>Noting the sensitivities of a child death, IGARD members commented that there was little patient and public involvement (PPI) noted within section 5 of the application and suggested that further information be included, for transparency and in line with the applicant's website.</p> <p>IGARD members noted that this was a draft application and would expect when presented formally at an IGARD business as usual (BAU) meeting that the relevant public facing sections would be further populated including, but not limited to, section 5(d) (Benefits).</p> <p>Significant risk area to address (before presentation at an IGARD BAU meeting):</p> <ul style="list-style-type: none"> <li>• Data Controllorship / Data Processorship</li> <li>• Legal Basis</li> </ul>
2.3	<p><u>IQVIA NIC-409290-L1F3L: Permission to Contact</u></p> <p><b>Background:</b> Documentation had been presented at the COVID-19 response meetings on the 1<sup>st</sup> September, 8<sup>th</sup> September, 3<sup>rd</sup> November and 10<sup>th</sup> November, and business as usual (BAU) meeting on the 22<sup>nd</sup> October 2020.</p> <p>This was a new application to utilise the COVID-19 Permission to Contact (CV19 PtC) dataset for the purpose of recruiting participants in the PROVENT vaccine trial.</p> <p>IGARD members had agreed at their meeting on the 10<sup>th</sup> November to review any further documentation out of committee (OOC).</p> <p><b>Out of Committee Review:</b></p> <p>The IGARD Chair and IGARD Deputy Chair received a copy of the Health Research Authority (HRA) and Health and Care Research Wales (HCRW) approval letter dated 18 November 2020 and the Health Research Authority (HRA) London – Fulham Research Ethics Committee (REC) letter dated 18 November 2020 for review out of committee.</p> <p>The IGARD Chair and IGARD Deputy Chair noted that the REC favourable approval was in place for England and Wales.</p>

	IGARD members noted the subtle differences between England and Wales re respect of non-NHS sites.
<b>3</b>	<u>AOB</u> There was no further business raised, the Acting IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.