

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 19 November 2020

IGARD MEMBERS IN ATTENDANCE:	
Name:	Position:
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Prof. Nicola Fear	Specialist Academic Member
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	Position:
Kirsty Irvine (Chair)	IGARD Lay Chair
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	Team:
Vicky Byrne-Watts	Data Access Request Service (DARS)
Garry Coleman	Data Access Request Service (DARS) (Observer: Item 2.1)
Dave Cronin	Data Access Request Service (DARS)
Duncan Easton	Data Access Request Service (DARS) (Observer: Items 2.2 – 2.3)
Dan Goodwin	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics and Deputy Caldicott Guardian (Observer: items 2.1 – 2.4)
Karen Myers	IGARD Secretariat
Vicki Williams	IGARD Secretariat

1	<p>Declaration of interests:</p> <p>Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19.</p> <p>Nicola Fear noted a professional link to Kings College London [NIC-365602-V5H3Z] but noted no specific connection with the application or staff involved. It was agreed this did not preclude</p>
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	<p>Nicola from taking part in the discussions about this application, however agreed that she would not participate in making a recommendation about the application.</p> <p>Review of previous minutes and actions:</p> <p>The outcomes of the 12th November 2020 IGARD meeting were reviewed and were agreed as an accurate record of that aspect of the meeting.</p> <p>The minutes of the 12th November 2020 IGARD meeting were reviewed out of committee by IGARD following conclusion of the meeting, and subject to a number of minor changes were agreed as an accurate record of the meetings.</p> <p>Out of committee recommendations:</p> <p>An out of committee report was received (see Appendix A).</p>
2	Data Applications
2.1	<p><u>King's College London: A population-based retrospective cohort study into the factors associated with Emergency Department attendance by people with dementia in the last year of life. (Presenter: Vicky Byrne-Watts) NIC-365602-V5H3Z</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) and Civil Registrations data for the purpose of a study aiming to identify the factors associated with Emergency Department (ED) attendance by people with dementia in the last year of life. The objectives of the study are, 1) To examine the frequency of ED attendance and re-attendance by people with dementia in the last year of life; 2) To ascertain the reasons for ED attendance among people with dementia in the last year of life; 3) To identify the predictors of ED attendance by people with dementia in the last year of life.</p> <p>The study aims to improve the care and management of patients, it is important to understand the factors associated with ED attendance at the end of life. It is proposed that by analysing the frequency of, reasons for, and factors associated with ED attendance at the end of life, high-risk patients can be profiled, and modifiable risk factors identified to direct future targeted policy and service interventions. It is also aiming to generate further research avenues into the effectiveness of these interventions and to address any gaps identified in the evidence base as a result of the findings of this study.</p> <p>Discussion: IGARD noted within section 3(c) the data was not considered confidential under the Health and Social Care Act 2012 and was therefore not owed a duty of confidence; and queried if this was correct for the 'date of death' requested, in light of the other data sets that had been requested in section 3 (Datasets Held / Requested). IGARD asked that a rationale was provided for this, and in line with NHS Digital policy. In addition, if this was correct, IGARD asked that section 1 (Abstract) was updated with a statement, asserting that, in light of an assessment of the facts, the 'date of death' data was not owed a duty of confidence.</p> <p>IGARD noted that in respect of data minimisation, S-flags (sensitive status) had been applied to the data requested, and asked that a rationale was provided as to why, noting that the data was pseudonymous, and the subjects had died. If the S-flags were deemed unnecessary, they should be removed.</p> <p>IGARD queried if the project had been reviewed by King's College London Ethics Committee, and were advised by NHS Digital that as the data was pseudonymous, the Ethics Committee had confirmed that they did not need to review. IGARD noted the update from NHS Digital and confirmed that on that basis, they were content.</p>

	<p>IGARD queried statements made within section 5(d) (Benefits), for example “<i>we will</i>”, and “<i>This study will affect every person dying with dementia...</i>”, and asked that this was reviewed to amend any hyperbolic statements.</p> <p>IGARD suggested that the statement in section 5(a) (Objective for Processing) “<i>...there are no moral or ethical issues...</i>” was removed since it was not necessary to include in the application.</p> <p>Outcome: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 1. In respect of the date of death (noting NHS Digital policy): <ol style="list-style-type: none"> a) To provide a rationale as to why the date of death is considered not to be owed a duty of confidence given the other data sets involved and the context within which this data sits. b) To provide a statement in section 1 asserting that, in light of an assessment of the facts, the data is not owed a duty of confidence. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. In respect of data minimisation: <ol style="list-style-type: none"> a) To provide a rationale as to why the S-flags have being applied since the data is pseudonymous and the subjects have died; b) If S-flags are deemed unnecessary, to remove. 2. To remove from section 5(a) reference to “<i>there are no moral or ethical issues</i>”. 3. To review any hyperbolic statements made in section 5(d), for example “<i>we will...</i>”. <p>It was agreed the condition would be approved out of committee (OOC) by IGARD members</p>
2.2	<p><u>Group Application¹: DSfC - NHS Devon CCG, NHS Kernow CCG & Cornwall Council - Commissioning (Presenter: Dan Goodwin) NIC-348357-W0P1W</u></p> <p>Application: This was an amendment application to 1) add Cornwall Council as a Data Controller, 2) to update NHS South Central and West Commissioning Support Unit (CSU) processing and storage locations, 3) to add Microsoft Limited as they provide cloud services to the CSU, 4) to add ANS Group Limited as a Data Processor, 5) to add e-referral (ERS), Personal Demographic Services (PDS) and summary hospital-level mortality indicator (SHMI) data.</p> <p>The overall purpose of the application is to provide intelligence to support the commissioning of health services.</p> <p>Discussion: IGARD noted the statement in section 5(b) (Processing Activities) that “<i>Patient level data will not be shared outside of the data controllers / processors unless it is for the purpose of Direct Care...</i>”, and asked that section 5(a) (Objective for Processing) was updated to correct the contradictory information in section 5(a) that stated the data would not be linked.</p> <p>IGARD also asked that section 5(a) was updated to ensure that it clearly stated that individuals could only be linked on a case by case basis, in exceptional circumstances, and for the specific purpose of direct care. In addition, that a specific example or examples were provided of when data may be linked in exceptional circumstances and for the specific purpose of direct care.</p>

• ¹ NHS Devon CCG, NHS Kernow CCG, Cornwall Council

IGARD noted that both NHS Devon CCG and NHS Kernow CCG would be working collaboratively with Cornwall Council, and queried if the council would have access to data regarding patients in Devon. If this was the case, IGARD asked that if there were no immediate plans to form an Integrated Care System (ICS), that a justification was provided within section 5 (Purpose / Methods / Outputs) as to why the Council required access to the Devon data. However, IGARD asked that section 5 was updated with clarification of any future plans to become an ICS that would justify the need for the Council to access the Devon data, if access was still required.

IGARD thanked NHS Digital for providing supporting document 1, the data flow diagram, however noted that information was missing, specifically the flow of data to Cornwall Council, as outlined within the application. IGARD asked that the diagram was updated to include this. In addition, IGARD also asked that a copy of the process data flow diagram for the purpose of direct care was provided, and that both diagrams were uploaded to NHS Digital's customer relationships management (CRM) system for future reference.

IGARD queried why the CCGs were flowing the data to the Local Authorities, rather than the Data Services for Commissioners Regional Office (DSCRO) flowing the data, and asked that confirmation of this was provided in section 5(b).

IGARD queried the hyperbolic statements made within section 5, for example *"To allow the requirements, set out by NHS England..."* and instead suggested that this was updated to state *"To meet the challenge set by NHS England of achieving the goals of better health outcomes and reducing health inequalities through effective population management, data needs to be shared between the CCGs and Local Authority to allow detailed insights that could facilitate change"*. IGARD also noted the reference to *"value as redesign principle"*, when outlining what the pseudonymised data was required for, and also asked that this was amended, or removed if not deemed necessary.

IGARD noted and endorsed NHS Digital's review that Cornwall Council did **not** meet NHS Digital's Standard for privacy notices.

Outcome: recommendation to approve subject to the following conditions:

1. In respect of direct care:
 - a) To update the contradictory information within section 5(a);
 - b) To update section 5(a) to ensure that it clearly states that individuals can only be linked, on a case by case basis, in exceptional circumstances and for the specific purpose of direct care;
 - c) To provide a specific example or examples of when data may be linked in exceptional circumstances and for the specific purpose of direct care.
2. In respect of Cornwall Council:
 - a) To provide a justification within section 5 as to why the Council require access to the Devon data (if there are no immediate plans to form an ICS); or
 - b) To clarify in section 5 of any future plans to become an ICS, to justify the need for Devon data by the Council.

The following amendments were requested:

1. In respect of the hyperbolic statements made in section 5:
 - a) To amend the wording in section 5(a) *"To allow the requirements, set out by NHS England..."*, and to instead reference *"To meet the challenge set by NHS England of achieving the goals..."*.
 - b) To amend the statement relating to *"value as redesign principle"*.

	<p>2. In respect of the data flow diagrams:</p> <ol style="list-style-type: none"> To update the data flow diagram to include the flow of data to Cornwall Council; To provide a copy of the process data flow diagram for the purpose of direct care. To ensure that the two data flow diagrams are uploaded to NHS Digital's CRM system. <p>3. To provide confirmation in 5(b) as to why the CCGs are flowing the data to the Local Authorities, rather than the DSCRO.</p> <p>It was agreed the conditions would be approved out of committee (OOC) by IGARD members</p>
2.3	<p><u>Group Application²: DSfC - Joint Controller Agreement: NHS Birmingham and Solihull CCG, Birmingham City Council, Solihull Metropolitan Borough Council - Comm (Presenter: Duncan Easton) NIC-360432-Z1Q8K</u></p> <p>Application: 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) and e-Referral Service (eRS).</p> <p>The purpose of the application is to provide intelligence to support the commissioning of health services.</p> <p>The application was been previously considered on the 1st October 2020 when IGARD had deferred pending: In respect of the legal basis: a) To provide a copy of NHS Digital's IG advice which confirms the appropriate legal basis for dissemination of the data; b) To ensure that the IG advice is uploaded to NHS Digital's CRM system; c) To update the legal basis table in section 3 accordingly. In relation to patient stratification: a) To update section 5(b) to clarify if the application allows the identification of individuals <i>or</i> cohorts of patients with common identifying features; b) If the application does allow the identification of individuals, to explain the mechanism for the re-identification and the legal gateway for doing so; c) If no individuals are re-identified, to update section 5 (including section 5(d) where this is specifically referenced) to make this explicitly clear. In respect of the Local Authority: a) To update section 5(a) to provide clarification of the role of the Local Authority; b) If this application permits re-identification of individuals, to clarify that the Local Authority will not be involved in this activity nor have access to this data. To provide a brief statement in section 1 that the NHS Digital Security Advisor is satisfied with the data risk model ranking for the cloud storage (as outlined in the supporting documents). To address the mismatch between the 11 storage locations in section 2(b) and the reference in section 5 to one platform. To insert a special condition in section 6 that within 1 month of signing the DSA the applicant will have published a GDPR compliant privacy notice. To update section 5(b) be clear what datasets are being linked, and if this includes other datasets already held or external datasets. To amend section 5(a) to remove the paragraph on data minimisation, and if there is any relevant information not</p>

² NHS Birmingham and Solihull CCG, Birmingham City Council, Solihull Metropolitan Borough Council

included elsewhere, to add this to the data minimisation paragraph in section 5(b). In respect of section 5(d): a) To clarify what benefits will flow from the collaborative working of the larger group of Data Controllers; b) To amend the outputs to reflect that the parties involved are commissioning only and to ensure that the stated aims are appropriate given the role and nature of the data controllers. The following advice was given: IGARD suggested that, upon renewal or amendment, the applicants took the opportunity to restate the outputs by aligning the activity/output to the applicants' statutory requirements, rights and obligations.

NHS Digital advised IGARD, that the minutes from the previous IGARD review on the 1st October 2020, had not been included within section 1 of the application, and that the application would be updated as per usual process to include.

Discussion: IGARD noted and supported the update outlined by NHS Digital in updating section 1 (Abstract), to include the minutes from the previous IGARD review.

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

IGARD discussed deferral point 1, *"To provide a copy of NHS Digital's IG advice which confirms the appropriate legal basis for dissemination of the data."*, and noted that confirmation had not yet been received confirming contentment with the proposed legal basis. IGARD therefore reiterated their comment that written confirmation was provided that NHS Digital's Privacy, Transparency and Ethics (PTE) Directorate (formerly Information Governance Directorate) was content with the proposed legal basis; and that this was uploaded to NHS Digital's customer relationships management (CRM) system for audit purposes and future reference.

IGARD noted the update in respect of deferral point 7, *"To update section 5(b) (Processing Activities) to be clear what datasets are being linked, and if this includes other datasets already held or external datasets."*, and reiterated their comment that the reference to *"both data sets"* in section 5(b) was updated to correctly reference *"multiple data sets"*, and that this was reflected throughout the application.

IGARD noted that deferral point 9, in respect of updating and clarifying the outputs and benefits had been partially addressed, however asked that benefits outlined within section 5(c) (Specific Outputs Expected) were moved to correctly sit within section 5(d) (Benefits); and that the benefits included were real examples of actual benefits to patients, and not simply outputs.

IGARD noted that supporting document 3, the 'Generic Re-identification Business Process: Process step diagram', referred to *"Type 2 Objections"*, and asked that if available, an updated document was provided, that clarified the current approach, in respect of the National Data Opt-out (NDO). In addition, that section 5 (Purpose / Methods / Outputs) was also updated to clearly explain the approach of the NDO.

IGARD noted the statement in section 5(b) that *"Patient level data will not be shared outside of the data controllers / processors unless it is for the purpose of Direct Care..."*, and asked that section 5(a) (Objective for Processing) was updated to correct the contradictory information in section 5(a) that stated the data would not be linked.

IGARD also asked that section 5(a) was updated to ensure that it clearly stated that individuals could only be linked, on a case by case basis, in exceptional circumstances and for the specific purpose of direct care. In addition, that a specific example or examples were provided, of when data may be linked in exceptional circumstances and for the specific purpose of direct care.

IGARD queried the hyperbolic statements made within section 5(d), for example *“Providing greater understanding of the underlying courses and look to commission improved supportive networks...”*, and *“Insight to understand the numerous factors that play a role in the outcome for both datasets...”*; and asked that these were reviewed.

Outcome: recommendation to approve subject to the following conditions:

1. In respect of deferral point 1:
 - a) To provide written confirmation that NHS Digital’s PTE Directorate is content with the proposed legal basis;
 - b) To ensure that the written confirmation from PTE is uploaded to NHS Digital’s CRM system.
2. In respect of the NDO:
 - a) To update section 5 to clearly explain the approach of the NDO;
 - b) To provide an updated supporting document 3 (if available) to clarify the current approach in respect of the NDO.
3. In respect of direct care:
 - a) To update the contradictory information within section 5(a);
 - b) To update section 5(a) to ensure that it clearly states that individuals can only be linked, on a case by case basis, in exceptional circumstances and for the specific purpose of direct care;
 - c) To provide a specific example or examples of when data may be linked in exceptional circumstances and for the specific purpose of direct care.

The following amendments were requested:

1. In respect of deferral point 9: To remove any benefits from section 5(c) and move to section 5(d) ensuring that the benefits included are real examples of actual benefits to patients and not simply outputs.
2. In respect to deferral point 7, To amend the wording from ‘both data sets’ in section 5(b) to ‘multiple data sets’ (remainder of application) and ensure consistency throughout.
3. To review any hyperbolic statements made in section 5(d), for example *“...providing greater understanding...”* and *“...insight factors...”*.
4. To update section 1 to include the minutes from the previous IGARD review.

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

2.4

University of York: Economic Analyses of Health and Social Care -Evaluation of differences in the performance of health care providers in terms of the amount and cost of provision and in patient outcomes including mortality and self-reported morbidity; (Presenter: Dave Cronin) NIC-84254-J2G1Q

Application: This was a renewal application for pseudonymised Hospital Episode Statistics (HES), Civil Registrations, Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS) and Mental Health Services Data Set (MHSDS); and an amendment to 1) add a new project under ‘Project 4’ ; 2) to supply ECDS data as a direct replacement for the HES A&E data supplied under previous iterations of this DSA; 3) to change the frequency of data dissemination from annually to monthly; 4) to update the funding information under 'Project 2'.

The data is required for a number of projects which all involve economic analyses of health and social care, the aim being to study the way in which services are provided and the outcomes of those services in order to improve health and healthcare services in the NHS.

NHS Digital advised IGARD that it had been mutually agreed with the applicant, that further work was required on this application, prior to any renewal, and in line with NHS Digital's DARS Standards, for example, providing a clearer outline as to how the data was being used and a clearer purpose.

Discussion: IGARD noted and supported the update outlined by NHS Digital, in respect of the application being updated prior to any renewal, and in line with NHS Digital DARS Standards.

IGARD noted that the General Data Protection Regulation (GDPR) Article 6 legal basis stated in section 5 (Purpose / Methods / Outputs), differed, from what was stated in section 3 (Datasets Held / Requested), and asked that the two were aligned, and section 5 was updated with the correct legal basis.

IGARD noted that section 4 (Privacy Notice) stated that the published privacy notice did meet the criteria set, however noted that there were a number of issues that needed addressing within the privacy notice, which included, but were not limited to; ensuring that there were no misleading statements within the privacy notice; ensuring that it was clear that National Data Opt-out's would **not** be applied as the data was pseudonymised; and that the reference to contacting NHS Digital in respect of opt-outs was revised. In addition, IGARD asked that NHS Digital provided written confirmation that the published privacy notice had been reviewed as outlined and that a copy be uploaded to NHS Digital's Customer Relationship Management (CRM) system for future reference.

IGARD noted that section 5(a) (Objective for Processing) provided minimal details on the work programme and specific projects, and asked that for the purpose of transparency, that this was updated with further information. In addition, the applicant should also provide further information on their website, for the wider public.

IGARD noted the good work undertaken by the research team and the patient and public involvement (PPI) panel, and asked that section 5(a) was updated with further examples of the good work.

IGARD queried the references in section 5(a) to consultant codes, and asked whether information was published at identifiable consultant level, as this was not clear. In addition, and noting the potential sensitivities around this, and in line with advice on similar applications, IGARD suggested that the applicant may wish to consider involving external bodies, such as the British Medical Association (BMA) and the Royal Colleges.

IGARD noted that a number of web links were provided in section 5(c) (Specific Outputs Expected), however advised that not all the links were working correctly; and asked that the applicant updated section 5(c) with the updated links.

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.

Outcome: recommendation to approve subject to the following conditions:

1. NHS Digital to provide written confirmation that the applicant has reviewed the published Privacy Notice including (but not limited to):
 - a) Ensuring there are no misleading statements;
 - b) Ensuring that it is clear that data opt outs will not apply as the data is pseudonymised data;
 - c) To remove reference to contacting NHS Digital.
2. To clarify in section 5 the correct Article 6 legal basis.

	<p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To confirm within section 5(a) whether information is published at identifiable consultant level. 2. To ensure that all web links within section 5(c) are working correctly. 3. In respect of transparency: <ol style="list-style-type: none"> a) To update section 5(a) to provide further details on the work programme and each project. b) To provide further details of the projects on the applicant's website. 4. To update section 5(a) with further examples of the good work undertaken by the research team and the PPI Panel. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested that the applicant may wish to consider involving external bodies, such as the BMA and the Royal Colleges. 2. IGARD support NHS Digital and the applicant reviewing the current application prior to any renewal, and in line with NHS Digital DARS Standards. 3. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. 4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. <p>It was agreed the conditions would be approved out of committee (OOC) by IGARD members</p>
2.5	<p><u>Office for National Statistics (ONS): Use of PDS data to support the linkage of data required to inform statistical analysis of factors associated with the COVID-19 pandemic, by providing NHS number where the quality or completeness of personal identifiers are otherwise insufficient. (Presenter: Dave Cronin) NIC-413717-C8Y6K</u></p> <p>Application: This was a new application to request permission to access identifiable Personal Demographics Service (PDS) data under a separate ONS Data Sharing Agreement (NIC-20951-D2K6S).</p> <p>The purpose is to reuse the PDS data, to facilitate linkage between other datasets for the purpose of COVID-19 related work. The proposed methodology is that datasets without complete sets of patient identifying details (for example missing NHS Numbers) would be matched against the PDS data to obtain complete and latest identifying details before being linked with another dataset.</p> <p>Since the start of the COVID-19 pandemic, ONS has been frequently requested to provide urgent statistical support to contribute to the wider understanding of the virus, helping to inform a range of policy decisions taken by central government, health services and others.</p> <p>NHS Digital advised IGARD, that due to the urgency of the data requested, a partially complete application had been submitted, and that although this was not in line with usual process, NHS Digital were keen to support the applicant in progressing the application.</p> <p>NHS Digital provided a verbal update of further substantial amendments that had been made to the application, following submission of the application to IGARD for review, the updates included, further information on the proposed legal basis, how the data would be used, proposed linkage and benefits.</p> <p>Discussion: IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed.</p>

IGARD noted the update from NHS Digital outlining why the partially application had been submitted for review; and advised that, in principle, they were supportive of the application, noting the value and importance of the work outlined, and with supporting NHS Digital in progressing this, with the information that had been made available to date.

IGARD also noted and thanked NHS Digital for provided a verbal update of further substantial amendments that had been made to the application, following submission of the application to IGARD for review. In addition, although NHS Digital had provided a verbal update of the amendments made, as section 5(b) (Processing Activities), section 5(c) (Specific Outputs Expected) and section 5(d) (Benefits) were empty of narrative, in the version of the application that IGARD had received for review, that the application would need updating, to include, but not limited to, the verbal update provided.

IGARD had a lengthy discussion in respect of the proposal that ONS was exercising its legal power to request the data under the Statistics and Registration Service Act (SRSA) 2007, and whether use of this legislation was appropriate. NHS Digital advised IGARD that NHS Digital's Privacy, Transparency and Ethics (PTE) Directorate (formerly Information Governance Directorate), had been involved with the discussions around the legal basis, and noting the urgency of the work outlined, had supported the use of SRSA, and had provided two potential options if this legislation was deemed appropriate.

IGARD discussed various other legal basis options, including consent, noting that participants had provided consent. IGARD therefore asked that consideration should be given as to whether consent rather than SRSA was the most appropriate way of addressing the common law duty of confidentiality, and that if consent was not appropriate, that further consideration should be given to relying on the Health Service Control of Patient Information (COPI) Regulations 2002 (COPI).

IGARD noted that section 3(b) (Additional Data Access Requested) cited a different General Data Protection Regulation (GDPR) Article 9 legal basis, to the one cited in section 5(a) (Objective for Processing), and were advised by NHS Digital that section 5(a) was correct. IGARD noted the confirmation from NHS Digital and asked that section 3(b) was updated with the correct legal basis.

IGARD noted that section 1(b) (Data Controller(s)) and section 1(b) (Data Processor(s)) stated that ONS were the sole Data Controller and Data Processor for the work outlined, however the patient information sheet stated that the University of Oxford were joint Data Controllers. NHS Digital advised IGARD that University of Oxford were joint Data Controllers for the Coronavirus Infection Survey (CIS), and ONS were permitted to use the PDS data to support linkage between the CIS dataset. IGARD noted the update from NHS Digital and asked that the application was updated throughout to reflect the correct data controllership arrangements.

IGARD noted that section 7 (Approval Considerations) stated that ethics approval was not required, however asked that this was updated to provide details of the ethics approval that was already in place for the CIS.

IGARD suggested that the statement in section 5(a) that stated "*...there are no moral or ethical issues...*" was removed since it was not necessary to include in the application.

IGARD queried the list of PDS variables that would be used to assist in COVID linkage work, outlined in section 5(a), in particularly the "*business effective from date*" and the "*address business effective from date*"; and suggested that these were removed as they were not relevant.

	<p>Outcome: IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed.</p> <ol style="list-style-type: none"> 1. Consideration should be given as to whether consent rather than SRSA is the legal basis and if consent is not appropriate, to consider relying on COPI. 2. To update the application, to reflect the correct data controllership. 3. To update section 5(b), 5(c) and 5(d) in the application as they are empty of narrative. 4. To update section 3(b) to reference the correct legal basis. 5. To remove from section 5(a) reference to ‘<i>there are no moral or ethical issues</i>’. 6. To update section 5(a) to remove the wording “<i>business effective from date</i>” and ‘<i>address business effective from date</i>’. 7. To update section 7 to include details of ethics approval for the CIS.
2.6	<p><u>Office for National Statistics (ONS): Investigating COVID-19 - request for acquisition of GDPPR & ECDS data (Presenter: Dave Cronin) NIC-400304-S1P1B</u></p> <p>Application: This was an amendment application to reuse GPES Data for Pandemic Planning and Research (GDPPR), Hospital Episode Statistics (HES) and Emergency Care Data Set (ECDS) received for an exercise, to quality assure the QCOVID algorithm which is used to identify the risk of hospital admission and mortality from coronavirus 19 in adults.</p> <p>ONS wants to urgently quality assure a QCOVID algorithm developed by Oxford University to identify clinical vulnerability to COVID-19. This algorithm will be used operationally by Public Health England as a replacement for the previously used shielding list. The purpose is to determine the population-level relative risk of hospitalisation or death that COVID-19 presents to different people. This is being achieved by linking information on outcomes with information on characteristics and underlying health conditions.</p> <p>Discussion: IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 8th September and 15th September 2020.</p> <p>IGARD also noted that this application had also been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 9th September 2020, and that notes from this meeting had been attached to the IGARD minutes from the 17th September 2020; and the 18th November 2020 (see Appendix B).</p> <p>IGARD supported and endorsed most of the comments made by PAG, however, noted that PAG supported the ONS view that ethical approval was not required. IGARD advised NHS Digital, that it was their view, that ethical approval should be sought, and asked that either, written evidence was provided that a positive ethics opinion had been sought; or, that written confirmation was provided that the Data Ethics Advisory Committee was satisfied that an updated opinion was not required. A copy of the relevant evidence should also be uploaded to NHS Digital’s customer relationships management (CRM) system for future reference.</p> <p>IGARD also noted PAG’s comments that “...ONS had the appropriate experience to validate the algorithm...”, and the reference within section 5(a) to the “...independent team of experts, providing the highest level of assurance regarding the performance of the algorithm in line with TRIPOD guidance...”; and asked that section 5 was updated to confirm the make-up of the group responsible for validating the algorithms given that this was potentially a clinical tool and not simply a statistical tool.</p> <p>IGARD queried the reference to the “TRIPOD” guidance, and noting that there was no additional information on this, asked that section 5 was updated with a brief explanation.</p>

IGARD noted the information within section 5(a) that stated one of the three high-level cluster code groups not required for analysis was the 'vaccinations and immunisation' codes cluster; however later in section 5(a), it stated that the GPPR data used in the work outlined, would include 'vaccinations and immunisation' codes cluster. IGARD asked that section 5(a) was reviewed and that any contradictory text was updated as appropriate.

IGARD noted the statement in section 5(c), in relation to the outputs of the exercise, being "...to validate the QCOVID algorithm will be a concordance statistic (c-statistic)...", with "the outcome determining whether the model will be used (or continue to be used) based on a threshold"; and asked that section 5 was updated to clarify if there was a pre-determined c-statistic, which meets the threshold. In addition, to clarify who makes the decision on approving use of QCOVID based on the output of the c statistic, if the algorithm was successfully validated.

IGARD queried if there was a commercial element to the work, for example if QCOVID was used for purposes other than academic, and asked that if there was any commercial element, that section 5(a) and section 5(e) were updated to reflect this for transparency.

IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices.

IGARD noted that the results of the exercise would be shared with the Scientific Advisory Group for Emergencies (SAGE), Public Health England (PHE) and the University of Oxford, and suggested that in addition, the application should also consider including the British Medical Association (BMA) and the Royal Colleges.

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 in section 5(d).

Outcome: recommendation to approve subject to the following condition:

1. In respect of the ethical approval, to either:
 - a) Provide written evidence that a positive Ethics opinion has been sought; or;
 - b) Provide written confirmation that the Data Ethics Advisory Committee is satisfied that an updated opinion is not required;
 - 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.

	<p>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.</p> <p>It was agreed the condition would be approved out of committee (OOC) by IGARD members</p> <p>Subsequent to the meeting: A further discussion was held with NHS Digital in respect of the condition for this application, please refer to the IGARD meeting minutes from the 26th November 2020 for further information.</p>
3	<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"> • NIC-74625-S1Q8X Cardiff University • NIC-60624-B1R1Q IQVIA Ltd • NIC-147885-0TV66 University of Oxford • NIC-203509-L9P1P Guy's & St Thomas' NHS Foundation Trust <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 oversight and assurance review, not just those that were approved via NHS Digital's precedent route.</p>
4 4.1	<p><u>AOB:</u></p> <p><u>Associate Director, Data Access</u></p> <p>The Associate Director, Data Access attended (part of) the meeting as part of his regular catch-up with IGARD.</p> <p>There was no further business raised, the Alternate Deputy IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.</p>

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 13/11/20

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-174209-R8G8N	King's College London	08/10/2020	<ol style="list-style-type: none"> In respect of the data controllership: <ol style="list-style-type: none"> To provide a written explanation why Heartfelt Technologies are not considered joint Data Controllers. If Heartfelt Technologies is considered a joint Data Controller, to update the application throughout to reflect this. To provide a written explanation as to why Legitimate Interests is considered the appropriate legal bases for KCL to undertake the research. 	IGARD members	Quorum of IGARD members	<p><i>"On the facts available to IGARD there is still a significant risk that a regulator assessing the arrangements may find that Heartfelt Technologies is acting as data controller*. Accordingly, there is, inter alia, a risk that NHS Digital is not contracting with all the relevant parties.</i></p> <p><i>"It is IGARD's understanding that every other DSA with KCL is under public task legal basis; it should be expressly noted why this DSA is under legitimate interests (for example, because of the commercial exploitation angle of the research)."</i></p>
NIC-332338-X1N2G	University of Leeds	08/10/2020	<ol style="list-style-type: none"> In respect of the consent materials: <ol style="list-style-type: none"> To confirm if any cohort members were consented with an earlier version of the consent materials. 	IGARD members	Quorum of IGARD members	<p><i>"IGARD have confirmed that the conditions have been MET if the presenter can confirm that no other consent forms were used (ie other</i></p>

			b) If so, to confirm that the proposed processing is compatible with the earlier consent materials. c) To provide copies of the earlier consent materials if available. d) To upload a copy of the earlier consent materials to NHS Digital's CRM system.			<i>than v1.1, 1.3 or 1.4, as provided) relating to either EMMACE 3 or EMMACE 4 or both."</i>
NIC-195377-M9L8Z	The Nuffield Trust For Research And Policy Studies In Health Services	29/10/2020	1. In respect of the prison postcode: a) To clarify in section 5 that the prison postcode will 'usually' include only the prison population and not those working in the prison or residential properties in close proximity. b) To clarify what checks are made to validate the use of prison postcodes and include an explanation in section 5 of the measures undertaken.	IGARD members	Quorum of IGARD members	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 and Cloud storage):

- None

Optum Health Solutions UK Limited Class Actions:

- NIC-186888-X2K6T NHS Buckinghamshire CCG
- NIC-362254-Q6S4W NHS South East London CCG

Appendix B

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 18th November 2020

Application & application version: DARS-NIC-400304-S1P1B version 1.2 Organisation name: Office for National Statistics (ONS) Profession Advisory Group Agenda item: 2
<p>PAG noted the additional purpose that related to QCOVID.</p> <p>PAG considered the relevance of the datasets for the additional purpose outlined, and that there was no date cap in place for relevant events. It was noted that there may be issues around the data quality of the data, and it was queried as to the means by which ONS could feed back to improve the quality - this could be achieved through the national Service Desk, but it was understood that the analysis would mainly be at group rather than individual level.</p> <p>PAG noted the statement around ethics, and that ONS did not feel that ethical consideration by its panel needed to be considered which PAG accepted. However, PAG would expect that the commissioner of the work would have had sufficient assurance that ONS had the appropriate experience to validate the algorithm noting the difference between such work and official statistics. The professions would appreciate transparency from ONS about their track record in validating algorithms that are used by care professionals in the service.</p> <p>PAG would expect that if the QCOVID algorithm is validated it would also meet the necessary requirements set by the MHRA for medical devices as well as clinical safety case requirements.</p>

Attendees	Role	Organisation
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Peter Short	Deputy Chair	NHS Digital
Garry Coleman	Associate Director of Data Access	NHS Digital
Mark Coley	Deputy IT Policy Lead	BMA
Amir Mehrkar	GP, Clinical Researcher	RCGP
Julian Costello	GP	RCGP
Pam Soorma	Secretariat	NHS Digital