

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 12th December 2019

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

In attendance (NHS Digital): Stuart Blake, Dave Cronin, James Humphries-Hart, Karen Myers, Kimberley Watson, Vicki Williams.

Not in attendance (IGARD Members): Anomika Bedi, Sarah Baalham, Maurice Smith.

Observers: David Morris.

1	<p>Declaration of interests:</p> <p>Nicola Fear noted a professional link with the team at King's College London (NIC-320217-X9P0W) and the University of Bristol (NIC-319171-G7H8K). These applications were returning as part of the oversight process and it was agreed that Nicola would remain in the meeting for the discussion of the review process for these applications.</p> <p>Geoffrey Schrecker noted a professional link with Group application for 7 CCG's (NIC-129507-J0H0D) but noted no specific connection with the application or staff involved and it was agreed that this was not a conflict of interest.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 5th December 2019 IGARD meeting were reviewed and, subject to a number of minor amendments, were agreed as an accurate record the meeting.</p> <p>Out of committee recommendations:</p> <p>An out of committee report was received (see Appendix B).</p>
2	Data applications
2.1	<p><u>Swansea University: GPs-in-EDs (Phase 2) NIHR HS&DR 15/145/04 (Presenter: Dave Cronin) NIC-267223-D4Q3F</u></p> <p>Application: This was a new application for pseudonymised Hospital Episodes Statistics (HES) data for a study with the purpose of determining the clinical and cost effectiveness of General Practitioners working within Emergency Departments (GPs-in-Eds) models and to understand the ways in which service design and setting (context) generate variations in outcomes. The study is intended to evaluate the ability of different GPs-in-EDs models to achieve the key outcomes described in an effective practice framework (addressing greatest health needs first; only doing what is needed; reducing inappropriate variation) and the resources needed to deliver these outcomes.</p> <p>Discussion: IGARD noted the type of data requested for this study and queried if this would be sufficient in meeting the stated outputs outlined within the application, in particular, would it be able to accurately capture all of the GP models that were being studied, for example primary care services co-located within Emergency Departments versus a primary care service embedded within an Emergency Department; and how patients that were admitted under each model would be recorded in the data sets requested. IGARD therefore requested that a satisfactory explanation was provided in section 5 (Purpose / Methods / Outputs) confirming that the data requested under this application was sufficiently detailed and robust and would be able to achieve the outputs stated.</p> <p>IGARD queried the conflicting information within supporting document 1.0, the study protocol that stated ethics approval was required and section 7 (Approval Considerations) of the application</p>

	<p>which stated that ethics approval was not required; and asked that this was addressed and clarification was provided as to whether ethics approval was required or not.</p> <p>IGARD noted the useful information within the study protocol that outlined the efforts that had been set out to engage with the patients and public, and asked that this was replicated within the application; and that reference was made to any lay representation that had been or that may be established.</p> <p>Outcome Summary: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 1. To provide a satisfactory explanation in section 5 confirming that the data requested under this application is sufficiently detailed and robust and will be able to produce the stated outputs; in particular will be able to accurately capture all of the GP models that are being studied (e.g. co-located versus embedded) and how (for example) patients admitted under each model will be recorded in the data sets requested. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To address the conflicting information in the protocol and the application with regard to ethics approval and to clarify whether ethics approval is or is not required. 2. To replicate information from the Protocol into the application that outlines the efforts set out to engage with the patient and public, and to make reference to any lay representation that has been or may be established. <p>It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members (including a medical specialist member).</p>
2.2	<p><u>NHS England: NHS England - DSfC - NCDR amendment 2019 (Presenter: James Humphries-Hart) NIC-139035-X4B7K</u></p> <p>Application: This was an renewal application to NHS England's National Commissioning Data Repository agreement to include Clinical Registry data; and a renewal application for pseudonymised Children and Young People's Health Services (CYPHS), Secondary Use Service (SUS) for Commissioners, Local Provider Flows, Community Services Data Set (CSDS), Mental Health Learning Disability Data Set (MHLDDS), Diagnostic Imaging Data Set (DIDs), Improving Access to Psychological Therapies (IAPT), Mental Health Minimum Data Set (MHMDS), Maternity Services Data Set (MSDS), Civil Registration, Mental Health Services Data Set (MHSDS), National Cancer Waiting Times (CWT), National Diabetes Audit (NDA), Community Services Data Set (CSDS), Assuring Transformation (AT), Patient Reported Outcome Measures (PROMs).</p> <p>NHS England requires access to data collected within Clinical Registries, Databases and Audits. Part of NHS England's responsibility is to oversee the budget, planning, delivery and day-to-day operation of the commissioning side of the NHS in England as set out in the Health and Social Care Act 2012.</p> <p>The application had previously been presented to IGARD on the 17th October 2019 and IGARD had recommended for approval for a period of 2 months, in conjunction with the revision of the Clinical Registries Briefing Paper.</p> <p>Discussion: IGARD discussed the revised Clinical Registries Briefing Paper that had been presented to IGARD on the 5th December 2019 and asked if there was an update on the specific point raised during this discussion where IGARD has requested that NHS Digital's Office of the Data Protection Officer (DPO) provide a detailed response as to why the parties referenced were considered Data Controller(s) and Data Processor(s) for each of the clinical registries outlined in the application. NHS Digital advised that they were currently liaising with the DPO and a response would be provided in due course. IGARD noted the update from NHS Digital and</p>

	<p>advised that depending on the outcome of this response, it could potentially raise substantive issues within the application and this was a temporary solution and they may comment further once all the facts were established and recorded in the briefing paper and appendices.</p> <p>IGARD queried the proposed outputs that were outlined in section 5 (Purpose / Methods / Outputs) and asked that the applicant ensure these were both realistic and achievable with the data requested.</p> <p>IGARD noted the references throughout the application to “<i>aggregated data</i>” and asked that in light of the new clinical registries data that had been added to the Data Sharing Agreement (DSA), that all references clearly specified whether or not this included small numbers suppressed.</p> <p>IGARD also suggested that following the inclusion of the new clinical registry datasets, a more detailed description was included in section 5 outlining how the change control processes would be undertaken.</p> <p>Outcome Summary: The application was recommended for approval for a period of 2 months by which time IGARD would expect a detailed response from NHS Digital's DPO clarifying the Data Controllershship issues and the data controller and data processor analysis for each of the clinical registries outlined in the application (the specifics of this previously-raised request are set out in the Clinical Registries Briefing paper discussion on 5 December 2019), and should be presented again to IGARD on or before the 13th February 2020.</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To ensure that in section 5 that all proposed outputs outlined are realistic and achievable. 2. To ensure that, in light of the new clinical registries added, that all references to “aggregated data” specifies whether or not this includes small numbers suppressed. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested that a more detailed description be included in section 5 outlining how the change control processes will be undertaken following the inclusion of new clinical registry datasets.
2.3	<p><u>Group Application 3 CCG's¹: DSfC - NHS Surrey Heartlands - Comm (Presenter: James Humphries-Hart) NIC-162677-S1D8W</u></p> <p>Application: This was an amendment group application for 3 CCG's to receive 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) and Patient Reported Outcome Measures (PROMs).</p> <p>The amendments are to 1) add Optum Health Solutions UK Limited as an additional Data Processor, 2) to include novel linkage between GP data and data released by NHS Digital, 3) to add Microsoft Azure as Cloud Storage for North East London Commissioning Support Unit.</p> <p>The purpose of the application is to provide intelligence to support the commissioning of health services.</p>

¹ NIC-162677-S1D8W NHS Guildford and Waverley CCG, NHS Surrey Downs CCG and NHS North West Surrey CCG

	<p>NHS Digital advised IGARD that the reference in section 5(a) (Objective for Processing) to “NHS East Surrey CCG” would need removing as it was not relevant to this application.</p> <p>Discussion: IGARD noted and supported the amendment highlighted by NHS Digital in respect of the amendment to section 5(a) to remove the reference to “NHS East Surrey CCG”.</p> <p>IGARD advised NHS Digital that at the meeting on the 14th November 2019, there was a discussion on NHS Digital’s Cloud Standard that was still in draft form and was currently with NHS Digital for review. It was noted that section 1 (Abstract) would need amending to use the full wording from the NHS Digital security adviser regarding Cloud Storage, which had been agreed as a temporary measure whilst the Cloud Standard was finalised. IGARD had agreed that they would continue to review Cloud-related applications (with the temporary NHS Digital security adviser assurance in the application abstracts) until the 1st March 2020, by which time IGARD would anticipate that the Cloud Standard would be finalised.</p> <p>Outcome Summary: recommendation to approve</p> <p>The following amendments was requested:</p> <ol style="list-style-type: none"> 1. To amend section 1 to revise NHS Digital’s Security Advisor’s advice on Cloud storage and to use the full agreed wording.
2.4	<p><u>Group Application 7 CCG’s²: DSfC - NEL Joint DC CCG App (Presenter: James Humphries-Hart) NIC-129507-J0H0D</u></p> <p>Application: This was a renewal and amendment group application for 7 CCG’s to receive 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) (Births and Deaths), National Diabetes Audit (NDA) and Patient Reported Outcome Measures (PROMs).</p> <p>The amendments were to 1) include Queen Mary University of London as a Data Processor for 3 of the CCG’s listed (NHS Newham CCG, NHS City and Hackney CCG and NHS Tower Hamlets CCG), and 2) To include new processing and storage locations for 3 of the CCG’s (NHS Barking and Dagenham CCG, NHS Havering CCG and NHS Redbridge CCG).</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 28th November 2019 when IGARD had deferred pending: to provide a clear narrative in section 1 and section 5(a) on the role of the STP, how the STP informs the named CCG’s commissioning and how it differs from the commissioning role carried out by the CCGs; if the commissioning is directed by the STP, to address the data controllership issues that arise as the STP comprises parties beyond the CCGs named in the application; in reference to the national HES data requested: to provide a clear justification for requesting the national HES data, specifically in relation to the named CCG’s core commissioning function. If the justification relates to wider STP initiatives, to address the associated data controllership issues raised by the involvement of the STP; to confirm why other national resources available to the CCG’s (for example CWT data from NHS England) are not satisfactory to establish national</p>

² NIC-129507-J0H0D NHS Waltham Forest CCG, NHS City and Hackney CCG, NHS Redbridge CCG, NHS Newham CCG, NHS Barking and Dagenham CCG, NHS Havering CCG, NHS Tower Hamlets CCG

	<p>benchmarks; to confirm if it is possible to identify local health and care priorities and request national data just to benchmark those priorities? Refer to Data Minimisation Standard; to be clear on the circumstances of how the proposed national HES data requested supports the CCG's core commissioning function; to provide further clarity on the "collaborative working" outlined in section 5(a) and explicitly detail which actors are undertaking the work described; to include a clear statement in the application clarifying that there are no other active DSA's for commissioning for the CCG's listed.</p> <p>Discussion: IGARD noted that the application had been updated to reflect all of the comments previously made.</p> <p>IGARD noted the reference to Sustainability and Transformation Partnerships (STPs) within the updated application in section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) and asked that it was made clear that the application did not relate to any STP activities.</p> <p>Outcome Summary: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To ensure that it is clear throughout section 1 and section 5 that the application does not relate to any STP activities.
2.5	<p><u>Queen Mary University of London: MR774 - The Evaluation of Breast Screening (Presenter: Stuart Blake) NIC-147747-KRTQ8</u></p> <p>Application: This was a renewal application for identifiable Medical Research Information Service (MRIS) data for the purpose of evaluating the breast cancer screening programme in terms of the reduction in breast cancer mortality associated with individual participation in the NHS Breast Screening Programme; the corresponding reduction in breast cancer mortality associated with individual participation in the NHS Breast Screening Programme; and the risk of overdiagnosis associated with participation in the programme.</p> <p>The application was been previously considered on the 14th March 2019 when IGARD had deferred pending: to provide evidence of the scope of the original s251 support which provides the legal basis and the data covered, any special considerations, parameters of support and to provide evidence that the support is continuing; throughout section 5 to consider the use of the term 'overdiagnosis' and to consider using a different phrase or to remove; to clarify the legal status of the Policy Research Unit (PRU) and to clarify that it is a legal entity of the Queen Mary University of London; to remove reference to "not-yet-invited women" in section 5(c).</p> <p>Discussion: IGARD noted that the application had been updated to reflect all of the comments previously made.</p> <p>IGARD queried if the data that flowed to the Queen Mary University of London contained patient names and were advised by NHS Digital that patient names would only be provided for deceased patients. IGARD asked that it was expressly stated in section 5 (Purpose / Methods / Outputs) that patient names would not be used for data linkage or for any other processing activities.</p> <p>IGARD noted the references in section 5(b) (Processing Activities) to "<i>details of de-reg and re-reg within the NHS (source PDS)</i>" fields and asked that an explanation was provided to clearly outline what each of these fields contained.</p> <p>IGARD noted that within section 5(a) (Objective for Processing) there were two descriptions of the cohort and suggested that this was amended to reflect the simple cohort description that was outlined in supporting document 12, the NHS Health Research Authority Confidentiality Advisory Group (HRA CAG) letter dated the 8th November 2019.</p>

	<p>IGARD suggested that the statement in section 5 that stated “...<i>there are no moral or ethical issues...</i>” was removed since it was not necessary to include in the application.</p> <p>IGARD noted the reference in section 5(a) to the Information Commissioner’s Office (ICO) Code of Practice and asked that this was removed or amended in line with a form of wording agreed with NHS Digital Information Governance (IG).</p> <p>IGARD queried the conflicting information in section 1 (Abstract) and section 4 (Privacy Notice) in relation to the applicant’s Fair Processing Notice and whether it did / did not meet the NHS Digital criteria set; and asked that these were aligned to reflect the correct information.</p> <p>Outcome Summary: recommendation to approve subject to the following conditions:</p> <ol style="list-style-type: none"> 1. To expressly state in section 5 that patient names will not be used for linkage or any other processing activities. 2. To provide an explanation of what the “de-reg and re-reg” data fields contain. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To amend the two descriptions to the cohort in section 5(a) to reflect the simple cohort description outlined in the most recent HRA CAG letter. 2. To remove from section 5(a) reference to ‘<i>there are no moral or ethical issues</i>’. 3. To remove reference to the ICO Code of Practice and/or amend in line with a form of wording agreed with NHS Digital IG. 4. To ensure the references to the Fair Processing Notice are aligned within section 1 and NHS Digital’s assessment in section 4 (i.e. it does / does not meet the criteria set) <p>It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members</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. The review process for the following applications was examined:</p> <ul style="list-style-type: none"> • NIC 68740 X7R2N Barts Health NHS Trust • NIC 161422 Q0K1M Royal Liverpool University Hospital • NIC 319171 G7H8K University of Bristol • NIC 320217 X9P0W King’s College London <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 which would be published separately to the minutes of the meetings, for transparency of process, on a quarterly basis.</p>
4	<p><u>AOB:</u></p>
4.1	<p><u>CPRD</u></p> <p>Following a request from IGARD, NHS Digital attended the meeting to discuss a recent news article in relation to the Clinical Practice Research Datalink (CPRD).</p>
4.2	<p><u>NIC-148369-8PPWK - University of Oxford – briefing papers and updated application</u></p> <p>NHS Digital submitted the briefing paper to IGARD in relation to the above application which was previously reviewed on the 2nd May 2019. The condition was reviewed by IGARD out of committee however noting that NHS Digital’s Caldicott Guardian had reviewed the application</p>

prior to it being submitted for review, IGARD opted to seek further advice from the Caldicott Guardian on how the applicant had proposed to satisfy the condition.

Following advice from the Caldicott Guardian, NHS Digital proposed a number of actions, which included: 1) extending the previous Data Sharing Agreement (DSA) permitting the applicant to retain but not otherwise process the data provided under previous iterations of the DSA; 2) The DSA to permit the applicant to share identifying details with NHS Digital for the purpose of List cleaning; and 3) to include a number of special conditions.

IGARD noted the information provided in the briefing paper and acknowledged their contentment with most of the NHS Digital proposals / actions including removing the condition previously set by IGARD, for those consented with supporting document 3.1 onwards (v2 of the consent form post November 2006).

Outcome Summary: recommendation to approve for those consented with supporting document 3.1 onwards (v2 of the consent form post November 2006)

The following amendments were requested:

1. To amend the Data sharing Agreement (DSA) to permit the applicant to retain but not otherwise process the data provided under previous iterations of the DSA.
2. To amend the DSA to permit the applicant to share identifying details with NHS Digital for the purpose of List Cleaning.
3. To insert special conditions into section 6 for the applicant to:
 - i. To send the PIS to study participants only once NHS Digital has confirmed the Notification meets the specified requirements;
 - ii. To produce and supply a Patient Information Sheet (PIS) that meets specific requirements, to be sent to directly to or otherwise directly provided to all contactable study participants;
 - iii. To use the List Cleaning service within a defined time period;
 - iv. To EITHER apply for support under section 251 of the NHS Act 2006 to continue processing confidential data of participants who are deceased, uncontactable or deemed to lack sufficient mental capacity to comprehend the Patient Information Sheet OR to destroy or pseudonymise the data of those participants before the end of the DSA.

The following advice was given:

1. IGARD suggested that the applicant's Fair Processing Notice required some additional work and offered a number of comments, including (but not limited to):
 - i. To remove the General Data Protection Regulation (GDPR) heading and the paragraph that sits under this relating to "Data Controllorship";
 - ii. To amend the 3rd paragraph to reflect the processing activities (similar to the information provided in section 5(a) of the application);
 - iii. To be more explicit on data controllership and who has access to the data;
 - iv. To provide further information on who has supervisory authority;
 - v. To clarify that further information about the rights of participants in relation to personal data can be obtained directly from the Information Commissioner's Office (ICO) and not via the Study Team.

<p>4.3</p>	<p>IGARD offered additional out of committee support with this and asked that the minutes from the previous meeting held on the 2nd May included a footnote to reference the 12th December minutes to ensure a clear transparent audit trail.</p> <p>Outcome Summary: Unable to recommend for approval for any patients that consented on supporting document 3.0 (v1 of the consent form pre-December 2006) and were not subsequently re-consented on any of the later materials. IGARD recommend that the applicant hold but not otherwise process data.</p> <ol style="list-style-type: none"> 1. The nature of the of the materials would not be compatible, even with the additional transparency measures; and IGARD suggested that alternatives be sought and s251 support be considered. <p>There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.</p>
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Independent Group Advising on Releases of Data (IGARD): Out of committee report 06/12/19

These applications were previously recommended for approval with conditions by IGARD, and since the previous Out of Committee Report the conditions have been agreed as met out of committee.

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
None						

In addition, a number of applications were processed by NHS Digital following the Precedents approval route without direct IGARD review. IGARD carries out oversight of such approvals and further details of this process can be found in the quarterly Oversight and Assurance Report.