

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 13 June 2019

In attendance (IGARD Members): Kirsty Irvine (Chair), Priscilla McGuire, Eve Sariyiannidou, Geoffrey Schrecker, Maurice Smith.

In attendance (NHS Digital): Stuart Blake, Louise Dunn, Rachel Farrand, Karen Myers, Vicki Williams.

Not in attendance (IGARD Members): Sarah Baalham, Anomika Bedi, Maria Clark, Nicola Fear.

1	<p>Declaration of interests:</p> <p>Eve Sariyiannidou noted professional links to HQIP [NIC-170564-P9F0D London School of Hygiene and Tropical Medicine] but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 30th May 2019 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of 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>King's College Hospital (KCL): Practice-level PCMD (Presenter: Stuart Blake) NIC-156409-F4P2D</u></p> <p>Application: This was a new application for a tabulation of Primary Care Mortality Data (PCMD) without small numbers suppressed, for a research study aiming to investigate the relationship between general practice (GP) funding, staffing and healthcare outcomes. The six primary healthcare outcomes include primary care mortality, secondary care utilisation, patient safety, patient experience, clinical achievements / quality and outcomes framework and health reported quality of life.</p> <p>The application was been previously considered on the 11th April 2019 when IGARD had deferred pending: to remove study 2 and 3 from this application; to provide written confirmation from NHIR that no ethics approval is required for study 1, despite the removal of small number suppression; section 5(a) to be written in language suitable for a lay reader and to clearly address the moral and ethical issues relating to type of and nature of data requested under study 1; to remove the sentence from the abstract that "IGARD recommended that this application... without need to suppress small numbers" since it was factually incorrect; to clarify the planned routes to dissemination to the public and what is meant by the 'groups' noted within section 5 of the application; to clarify what the outputs of study 1 will actually be and whether GP practices will be identified within the published outputs.</p> <p>Discussion: IGARD noted that the application had been updated to reflect all of the comments previously made.</p> <p>IGARD queried the reference to General Practices 'learning and improving' from the research outlined in the application; and asked that this was updated to ensure that the focus of the outputs outlined was on the Commissioners, CCGs and NHS England and not specifically on</p>

	<p>the General Practice, since General Practices do not dictate their funding as this is based on a national formula set by NHS England.</p> <p>IGARD noted in section 5(c) (Specific Outputs Expected) that seven key audiences would be targeted for dissemination of the research, which included General Practices; and asked that explicit details were provided on which General Practices would be in receipt of the information, for example to those practices for whom the research was particularly relevant and to include further detail of how the dissemination would take place.</p> <p>IGARD queried the sentence in section 5(d) (Benefits) “<i>Measurable patient outcomes are expected by September 2020.</i>” and asked that this was removed since mortality as a patient outcome is not an outcome that can be changed by this research in the short term.</p> <p>Outcome Summary: recommendation to approve subject to the following conditions:</p> <ol style="list-style-type: none"> 1. To update the application throughout to remove reference to General Practices learning and improving from this research and ensure the focus of the output is on Commissioners, CCGs and NHS England. 2. To update the reference in section 5(c) to disseminating to General Practices and provide explicit detail on which General Practices will be in receipt of the information (for example to those practices for whom the research is particularly relevant) and how the dissemination will take place. <p>The following amendment was requested:</p> <ol style="list-style-type: none"> 1. To update section 5(d) (ii) to remove the sentence “<i>Measurable patient outcomes are expected by September 2020.</i>” <p>It was agreed the conditions be approved Out of Committee (OOC) by IGARD Members.</p>
2.2	<p><u>University College London: MR1362: Extension of NIC-349413-F1J1N - Next Steps Cohort Study (Presenter: Stuart Blake) NIC-15226-X7Z9R</u></p> <p>Application: This was an amendment and renewal application for identifiable Medical Research Information Service (MRIS) data for an established longitudinal study which has followed the lives of 15,620 people born in 1989/90, since year 9 of secondary school. Information was collected from cohort members on many aspects of their lives such as education, employment, health and well-being, relationships and family life, housing and finances, social participation and attitudes. Data collection focused on young people’s transitions into further/higher education and the labour market or to other outcomes, such as parenthood.</p> <p>NHS Digital noted that the applicant’s Data Sharing Agreement (DSA) had expired.</p> <p>Discussion: IGARD welcomed the application and noted the importance of the longitudinal study.</p> <p>IGARD noted that two legal basis were listed within section 1 (Abstract) and queried what the correct legal basis was under General Data Protection Regulation (GDPR) and asked that the application was updated to reflect the correctly justified legal basis.</p> <p>IGARD noted that the s251 support was for ‘date of death’ and queried the ‘cause of death’ data field that was being requested and asked if s251 supported this; and that the relevant evidence was provided. IGARD also asked that if s251 support did support ‘cause of death’ that the application was amended throughout, justifying how this field would be used and for what purpose.</p> <p>IGARD queried the discrepancies in the cohort figures provided in the application and supporting document 10, the NHS Health Research Authority Annual Progress Report to the Main Research Ethics Committee; and asked that a further explanation was provided; along with a clear and</p>

coherent narrative which was consistent with the cohort numbers throughout the application. IGARD also asked for further clarification of who was in the cohort; whose data was being tracked and obtained by this agreement and that the data for those who have withdrawn from the study / cohort was not being accessed via this agreement.

IGARD recognised the work that the applicant had undertaken to update their fair processing notice however it was noted the applicant should provide a fair processing notice that is compliant with the notice requirements under the GDPR and suggested that they work with NHS Digital to amend their current privacy notice including specifically state that identifiers are sent to NHS Digital for the purpose of tracking and to clarify that tracking is through NHS Digital.

IGARD noted that the applicant's fair processing notice did not meet NHS Digital's fair processing criteria for privacy notices and suggested that section 4 (Privacy Notice) be updated to clearly state that the application privacy notice 'does not' meet the criteria.

IGARD noted that section 5(b) (Processing Activities) referred to "subcontractors" and asked that this was updated to correctly reference "Copyprint UK Limited" as the subcontractor.

IGARD queried what data the UK Data Service would obtain under this agreement and asked that further clarification was provided with an explanation of the data flows and in what format.

IGARD queried the societal impact of the study and asked that section 5(c) (Specific Outputs Expected) and section 5(d) (Benefits) was updated clearly outlining the impact

IGARD noted that there was a named Member of Parliament referred to in section 5(d) and asked that this was removed, since it was not relevant.

IGARD noted the reference in the application to 'anonymised' data and asked that this was amended to correctly reference 'pseudonymised' data.

Outcome Summary: Recommendation to defer, pending:

1. To update the application to ensure one legal basis is put forward and justified under GDPR.
2. In respect of the s251 support which appears to be for 'date of death', to provide relevant evidence that 'cause of death' is a supported field.
3. In respect of the cohort, to clarify:
 - a. who is in the cohort;
 - b. whose data is being tracked and obtained by this agreement; and
 - c. that the data for those who have withdrawn from the study / cohort are not being accessed via this agreement.
4. To provide an explanation of any discrepancies between the description of the cohort in SD10 and the application and provide a clear and coherent narrative which is consistent to the cohort numbers throughout the application.
5. To amend the fair processing notice to ensure it is GDPR compliant including (but not limited to) to specifically state that identifiers are sent to NHS Digital for the purpose of tracking and to clarify that tracking is through NHS Digital.
6. To update section 4 to clearly state the applicant's fair processing notice 'does not' meet the NHS Digital's fair processing criteria for privacy notices.
7. To update section 5(b) to amend the "subcontractor" reference to "Copyprint UK Limited".
8. To provide clarification and an explanation of what data the UK Data Service will obtain under this application and in what format.
9. To updated section 5c and 5d to clearly outline the societal impact.
10. To update section 5(d) to remove reference to the named MP.

	<p>11. To amend the application to remove the references to “anonymised” data and replace with “pseudonymised” data.</p> <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD noted that the applicant’s Data Sharing Agreement with NHS Digital had expired / was due to expire, and in light of this it was suggested that NHS Digital might wish to consider a short term extension to permit the applicant to hold but not in any other way process the data while work was undertaken to address the queries raised by IGARD.
2.3	<p><u>Imperial College London: MR1201 - Frequency of follow-up for patients with low-, intermediate and high-risk colorectal adenomas (Presenter: Louise Dunn) NIC-147827-NC2TC</u></p> <p>Application: This was a renewal and amendment to add Public Health England as a Data Processor application; requesting identifiable Medical Research Information Service (MRIS) data for a study investigating the most suitable frequency of follow-up for patients with intermediate-risk adenomas detected during colonoscopy. The work on the primary outcome reporting has completed and the study is now working on the secondary outcome papers which they hope to publish in 2018/19.</p> <p>Discussion: IGARD noted information provided in supporting document 16.1, the protocol clearly outlined that the University of Oxford was a joint Data Controller and asked that the application was updated to reflect this.</p> <p>IGARD queried the reference within the application to the subset of the cohort of 30,000 and how this had been formed and asked that section 1 (Abstract) and section 3(b) (Additional Data Access Requested) were updated with clarification of how the subset was formed.</p> <p>IGARD queried if s251 support and (NHS Health Research Authority) Research Ethics Committee (REC) approval extends to the “all adenomas” project, not just “intermediate adenomas” and suggested that NHS Digital should satisfy itself of this point.</p> <p>Outcome Summary: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 1. To add the University of Oxford as a joint Data Controller. <p>The following amendments was requested:</p> <ol style="list-style-type: none"> 1. To update the abstract and section 3(b) to provide clarification of how the subset of 30,000 has been formed. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested that NHS Digital should satisfy itself that both s251 support and REC approval extends to the “all adenomas” project (not just “intermediate adenomas”). <p>It was agreed the condition be approved Out of Committee (OOC) by the IGARD Chair.</p>
2.4	<p><u>University of Hull: Examining the characteristics and predictors of alcohol withdrawal readmissions and emergency department attendances (Presenters: Louise Dunn) NIC-226185-B6C2J</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) data for a study aiming to examine routine hospital data to look at characteristics and predictors of alcohol withdrawal in relation to admissions and Accident and Emergency attendances in England. Patients experiencing wholly attributable alcohol diagnosis often present with acute clinical presentations related to alcohol use or secondary clinical conditions. With over 1 million alcohol-related hospital admissions the burden and unmet</p>

	<p>needs of excessive alcohol consumption and related conditions remain a priority under the NHS 10-year plan and for Public Health England.</p> <p>The application was been previously considered on the 16th May 2019 when IGARD had deferred pending: to provide a copy of the protocol; to provide written evidence of the funding outlined in the application; to update section 1 to further expand on the public task section under GDPR; to amend section 1 review of the privacy notice checklist to correctly state which criteria were not met; to explain where the “previous data” came from and what has happened to this data; to update section 3(b) to include a narrative to support the percentage of HES fields requested (example: selected by age / condition); to update section 5 to provide a further explanation of the involvement of other parties outlined now, and in the future, and to provide further detail on the PhD project, if is this is part of a wider project and how it is linked to the earlier research undertaken at Kings College London; to update section 3 text to remove reference to ‘common law’.</p> <p>NHS Digital advised that the applicant did not currently have a protocol document available for IGARD to review.</p> <p>Discussion: IGARD noted that the application had been updated to reflect most of the comments previously made.</p> <p>IGARD welcomed the application and supported the initiative of the study, however IGARD noted that that the relevant supporting documents, essential to IGARD’s review were not available. IGARD asked that a copy of the protocol was provided or further information which clearly defined the scope of the project in sufficient detail to allow an assessment of, inter alia, data controllership, data minimisation efforts and the necessity of the data for the specific research project.</p> <p>IGARD queried the involvement of other parties, specifically who would be involved in the ‘small team of researchers’ and who are the ‘collaborators’ with whom the data will be shared. As the topic of the completed PhD appears to be very similar to the topic of the proposed project under this application, IGARD asked for further detail as to how the latter project is distinguishable from the PhD.</p> <p>IGARD offered their support to NHS Digital.</p> <p>Outcome Summary: Unable to recommend for approval as the relevant supporting documents, essential to IGARD’s review, were not available.</p> <ol style="list-style-type: none"> 1. To provide a copy of the protocol or further information which clearly defines the scope of the project in sufficient detail to allow an assessment of, inter alia, data controllership, data minimisation efforts and the necessity of the data for the specific research project. 2. To provide a further explanation specifically who would be involved in the ‘small team of researchers’ and who are the ‘collaborators’ with whom the data will be shared. 3. To provide further detail as to how the proposed project under this application is distinguishable from the earlier PhD project.
2.5	<p><u>The Health Foundation: Monitoring the quality of healthcare in England (Presenter: Louise Dunn) NIC-276970-B8Y4H</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistic (HES) and Civil Registrations data for an in-house programme of analyses to be completed over the course of the next five years. The aim being to produce new insights into quality of patient care; investigate how the quality of care can be improved; and understand the demand for health care in the UK using linked HES data and innovative analytical methods. The overall purpose and benefit of this work is to inform the NHS and policy makers about changes in the</p>

	<p>characteristics and health needs of patients, factors that drive health care utilisation and health outcomes, and variation in health need, and quality of care.</p> <p>Discussion: IGARD noted that legitimate interest was being relied on and asked that section 1 (Abstract), section 5(a) (Objective for Processing) and section 5(d) (Benefits) were amended to clearly set out what the legitimate interests relied on were; and also how they related to the processing. IGARD also asked that the first paragraph in section 5(a) was updated to include further detailed information on the legitimate interest relied upon.</p> <p>IGARD queried the information provided in section 5(d) on the benefits and asked that this was updated to link each case project to the specific legitimate interest pursued, for example NHS Digital Standard 5b (Processing Activities), paragraph 8(i) which states <i>“Where data was processed as a “legitimate interest “ (Article 6(1)(f)), it should be clear how the legitimate interest is fulfilled through the benefits.”</i></p> <p>IGARD queried how the data requested had been minimised and asked for a further explanation of this, including linking each dataset to each project as outlined in section 5 (Purpose / Methods / Outputs), for example as outlined in NHS Digital Standard 3 (Data Minimisation).</p> <p>IGARD noted that section 5(b) (Processing Activities) referred to the ICO Code of Practice and asked that this was removed, as it was not relevant.</p> <p>IGARD noted that the information provided in section 7 (Ethics Approval) was incomplete and asked that this was updated to correctly reflect that ethics approval was not required.</p> <p>IGARD queried the conflicting information provided in section 1 (Abstract) and section 3(b) (Additional Data Access Requested) in relation to the number of data years requested and asked that section 1 was updated to reflect the correct information.</p> <p>IGARD queried the statement in section 1 (Abstract) that <i>“...that they would reasonably expect the processing and it would not cause unjustified harm.”</i> and asked that this was removed.</p> <p>Outcome Summary: Recommendation to defer, pending:</p> <ol style="list-style-type: none"> 1. To amend section 1, section 5(a) and section 5(d) to clearly set out what the legitimate interests relied on are and how they relate to the processing; and to update the first paragraph in section 5(a) to provide further detailed information on the legitimate interest. 2. To update section 5(d) to link each case project to the specific legitimate interest pursued (see for example NHS Digital Standard 5b with regard to how legitimate interest should be documented). 3. To provide an explanation of how the data has been minimised and link each dataset to each project outlined in section 5; (see for example NHS Digital Standard 3 with regard to how data minimisation should be documented). 4. To amend section 5(b) to remove reference to the ICO Code of Practice. 5. To update section 7 to correctly reflect that ethics approval is not required. 6. To update section 1 to ensure the number of data years reflects the correct information in section 3(b). 7. To update section 1 to remove the statement <i>“...that they would reasonably expect the processing and it would not cause unjustified harm.”</i>
2.6	<p><u>London School of Hygiene and Tropical Medicine: Long-term follow-up and further analyses of the National Chronic Kidney Disease Audit (Presenter: Rachel Farrand) NIC-170564-P9F0D</u></p>

Application: This was a new application for pseudonymised Hospital Episode Statistic (HES) and Civil Registrations data to establish a research database to address a number of research questions such as; What are the long-term outcomes of patients at risk of and with CKD and which aspects of primary care management influences outcomes; How and where are patients with CKD managed; What is the burden of progressive kidney disease and what are its consequences; To which extent does acute kidney injury contribute to progressive kidney disease and incidence of acute and chronic dialysis; What are the disability adjusted life years, years of life lost, healthy life expectancy and cost associated with CKD, AKI and progressive renal disease; and data validation to enable analyses of single existing datasets (e.g. primary care, or HES data) so that these do not require future linkages.

NHS Digital noted the efforts undertaken by the applicant with regard to the dissemination of outputs to different audiences.

Discussion: IGARD noted the data flows information provided in supporting document 9, the protocol and supporting document 5, (NHS Health Research Authority) Research Ethics Committee approval and asked that section 5 (Purpose / Methods / Outputs) (in particular section 5(b) (Processing Activities)) was updated to provide a clear explanation of each stage of the data flows.

IGARD queried if s251 support covered the flows of data into NHS Digital from either residents in Wales or people registered with a General Practice in Wales and were advised by NHS Digital that the date of death for this cohort would flow into NHS Digital for processing; and s251 support was not required for this flow.

IGARD queried if the only identifiers flowing into NHS Digital were from the University College London and asked that this was explicitly stated in the application for clarity. IGARD also queried if s251 support extended to NHS Digital processing data and asked that NHS Digital satisfy itself of this point.

IGARD queried information provided in section 5(a) (Objective for Processing) on the short and long-term outcomes and asked that this was updated to clearly distinguish between the two types of outcomes.

IGARD noted the issues provided in the original audit report and asked that section 5(d) (Benefits) was updated to clarify how the research would address these issues.

IGARD also asked that each specific benefit in section 5(d) was broken down to link to the aims that were outlined in section 5(a).

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

1. To clearly explain each of the data flows within section 5 (and in particular section 5(b)) of the application to reflect the data flows set out in SD9 and SD5.
2. To explicitly state that the only identifiers flowing into NHS Digital are from UCL.

The following amendments were requested:

1. NHS Digital to satisfy itself that s251 support extends to NHS Digital processing data.
2. To update section 5(a) to clearly distinguish the short and long-term outcomes.
3. To clarify in section 5(d) how this research will address the issues raised in the original audit report.
4. To update section 5(d) to break down each specific benefit to link to the aims outlined in section 5(a).

It was agreed the conditions be approved Out of Committee (OOC) by IGARD Members.

2.7	<p><u>Mental Health of Children and Young People – Briefing Paper and Precedent (Presenter: Alison Neave)</u></p> <p>The briefing paper was to inform IGARD of the 2017 Mental Health of Children and Young People (MHCYP) data set, that is due to be made available through the Data Access Request Service (DARS).</p> <p>The MHCYP survey provides data on the prevalence of mental disorders in children and young people (aged 2-19 years old) living in England. The latest, 2017 survey is the third in the series and was conducted for NHS Digital by a consortium consisting of the NatCen Social Research (NatCen), Office for National Statistics (ONS) and YouthinMind.</p> <p>Data from the earlier surveys was made available to external customers via the UK Data Service (UKDS). The 2017 survey will be a new asset and new to the DARS processes. This will allow a greater scrutiny over the process of dissemination of the health and social care data.</p> <p>IGARD welcomed the briefing paper but were unable to make a recommendation on the draft precedent since they were not in receipt of all the evidence required, however agreed to provide an overview of the key issues outside of the meeting in order to support NHS Digital.</p>
3	<p>Digital Ethics and the GDPR</p> <p>There was a discussion, presented by IGARD, with regard to digital ethics and the General Data Protection Regulations (GDPR).</p> <p>The discussion touched on socio-cultural shifts, new technology trends and challenges; the interface between GDPR compliance and digital ethics; the European Data Protection Supervisor (EDPS) initiative on digital ethics; the new data protection 'eco-system' where the law and ethics coexist; and ethics guidelines for trustworthy artificial intelligence (AI). IGARD suggested that NHS Digital may wish to include the ethics guidance as part of their drafting of a standard for 'artificial intelligence'</p>
<p>4</p> <p>4.1</p> <p>4.2</p>	<p>AOB:</p> <p>IGARD Deputy Chair and Alternate Deputy Chair</p> <p>It was discussed and agreed by IGARD members that Geoff Schrecker would be the IGARD Deputy Chair and Maria Clark would be the Alternate Deputy Chair (when Geoff was not available) from 13th June and for one year, as per agreed procedures.</p> <p>The IGARD Acting Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.</p> <p>As part of their oversight role, IGARD discussed the following matters with NHS Digital:</p> <ul style="list-style-type: none"> • Data Controllershship and its application, which may support NHS Digital with its discussions with customers • DARS Dashboard

Independent Group Advising on Releases of Data (IGARD): Out of committee report 07/06/19

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

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-195235-Q0B5T	University of East Anglia	30/05/2019	1. To provide evidence confirming that the approvals are in place for non-NHS care homes.	OOO by IGARD Chair	OOO by IGARD Chair	
NIC-143888-H0W2N	University of Leicester	23/05/2019	1. To amend section 5(b) to note the relevant NIC numbers and previous agreements that this application covers and refer to any other relevant data sharing agreements relating to the data used under this agreement so that the fuller picture of the initial audit and additional research with audit data is clearly articulated.	OOO by quorum of IGARD members	OOO by quorum of IGARD members	

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

- None