

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 30 May 2019

In attendance (IGARD Members): Sarah Baalham, Nicola Fear (Acting Chair), Priscilla McGuire, Geoffrey Schrecker.

In attendance (NHS Digital): Louise Dunn, Rachel Farrand, Karen Myers.

Not in attendance (IGARD Members): Anomika Bedi, Maria Clark, Kirsty Irvine (Chair), Eve Sariyannidou, Maurice Smith.

1	<p>Declaration of interests:</p> <p>Priscilla McGuire noted a professional link with NHS Derby and Derbyshire CCG (NIC-281073-Y5G3F), 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 23rd 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>Kingston University London: Use and impact of the pre-hospital 12-lead electrocardiogram in the primary PCI era. Mixed method study (PHECG-2) (Presenter: Louise Dunn) NIC-216853-V1V1H</u></p> <p>Application: This was a new application for pseudonymised Civil Registrations (mortality) data to link to the Myocardial Ischaemia National Audit Project (MINAP) dataset (collected as part of National Clinical Audit of Acute Coronary Syndromes). The purpose of the study is to look at the long-term patient outcome data, in this case mortality / survival at 30 days and one year after admission and will be linked to patients with acute coronary syndrome. The study will also explore reasons for variations in practice and highlight opportunities to improve care and outcomes.</p> <p>NHS Digital advised that section 3(c) (Patient Objections) incorrectly noted that patient objections were not being applied and that this this would need amending to correctly state that patient objections were being applied.</p> <p>Discussion: IGARD noted and supported the amendment outlined by NHS Digital in relation to section 3(c) being updated to reflect that patient objections were being applied.</p> <p>IGARD noted that the dates for the data being provided were inconsistent in supporting document 1, the Health Research Authority Confidentiality Advisory Group (HRA CAG) Integrated Research Application System form which noted 2010-2016; and the application which noted 2010-2017; and asked that these were reviewed and updated as necessary to ensure consistency.</p> <p>IGARD noted that section 5(a) (Objective for Processing) should be updated to include clearer examples for processing and how the applicant has been using the data. IGARD also suggested that the applicant provide further details of pathways for disseminating the outputs of the study to patients and the public including specific examples of public / patient engagement.</p> <p>Outcome Summary: recommendation to approve</p>

	<p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 3(c) to correctly state that patient objections are being applied. 2. To ensure that the dates for the data being provided are consistent throughout the application and supporting documents. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested on renewal that further details of pathways of dissemination of the outputs be provided including examples of public / patient engagement.
2.2	<p><u>University of East Anglia: Falls in Care Homes (FinCH) study: Data Access Request (Presenter: Rachel Farrand) NIC-195235-Q0B5T</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) data for a trial monitoring the number of hospital admissions, Accident and Emergency visits, outpatient visits and ambulance call outs for participants recruited; which will enable the research team to estimate the secondary care costs over the trial period for all participants in the study. This will enable a more accurate estimate of the cost effectiveness of the falls prevention intervention compared to usual care and will in turn help inform the evidence base used to decide which fall prevention interventions should be funded in the care home setting.</p> <p>The application was been previously considered on the 9th May 2019 when IGARD had deferred pending: to clarify within section 5 how the researchers have considered the legal power of the consultees to sign the personal consultee consent forms, since in the absence of an explanation, the legal power for the consultee to sign the forms has not been established; to confirm the nature of the 'sites' referred to in the study since the REC approval provided refers only to approval for 'NHS sites'; to clarify in section 5(a) and 5(d) what the reference to "2.5 falls per year" relates to (fall per person, per care home or other); to confirm if the funding conditions as outlined in supporting document 9 have been completed; and to clarify that the funding as described in the application is ongoing; since REC approved version 1 of the protocol, to provide clarification on what changes have been made in version 6 of the protocol provided for review and if the REC approval is applicable to this current version of the protocol; to clarify in section 5 that the study covers England and Wales; to amend the legal basis table in section 3(b) to capture the appropriate legal basis for dissemination of pseudonymised data.</p> <p>Discussion: IGARD noted that the application had been updated to reflect most of the comments previously made.</p> <p>IGARD queried conflicting information provided in supporting document 1 and supporting document 10, the NHS Health Research Authority Research Ethics Committee letters dated March and April 2016 and asked that evidence was provided confirming that approvals were in place for non-NHS care homes.</p> <p>IGARD noted that supporting document 2, The University of Nottingham Care Home Agreement provided a further explanation of the justification for consent being provided by the consultees; and asked that section 5(a) (Objective for Processing) was updated to reflect this information.</p> <p>Outcome Summary: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 1. To provide evidence confirming that the approvals are in place for non-NHS care homes. <p>The following amendment was requested:</p>

	<p>1. To update section 5(a) with a further explanation of the justification for consent being provided by the consultees.</p> <p>It was agreed the condition be approved OOC by the IGARD Chair.</p>
2.3	<p><u>NHS Derby and Derbyshire CCG: DSfC - NHS Derby and Derbyshire CCG, Comm. IV and RS (Presenter: Louise Dunn) NIC-281073-Y5G3F</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), Diagnostic Imaging Data Set (DIDS), Community Services Data Set (CSDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registries Data – Births and Deaths (CRD), National Diabetes Audit (NDA), Patient Reported Outcome Measures (PROMs). NHS Derby and Derbyshire Clinical Commissioning Group (CCG) is a new organisation that has merged four other CCGs. The data required is for Risk Stratification (RS) which is a tool for identifying and predicting which patients are at high risk or likely to be at high risk and prioritising the management of their care; Invoice Validation (IV) which is part of a process by which providers of care or services are paid for the work they do; and to provide intelligence to support the commissioning of health services.</p> <p>NHS Digital advised that this application had come to IGARD for a recommendation due to NHS Derby and Derbyshire CCG being a new organisation and advised that all four of the CCGs that have been merged have held data previously.</p> <p>Discussion: IGARD noted and supported the explanation provided by NHS Digital outlining why this application had come to IGARD for a recommendation and asked that for clarity section 1 (Abstract) was updated to reflect this.</p> <p>IGARD queried if the data originally held by the four (merged) CCG's had been destroyed and asked that for transparency confirmation was provided in section 1 and section 5(a) (Objective for Processing).</p> <p>Outcome Summary: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 1 clarifying why this application has come to IGARD for a recommendation. 2. To provide confirmation in section 1 and section 5(a) that the data originally held by the four (merged) CCG's has been destroyed.
2.4	<p><u>NHS Bedfordshire CCG: DSfC - NHS Bedfordshire CCG - RS (Presenter: Louise Dunn) NIC-294268-B3Q6J</u></p> <p>Application: This was a new application for identifiable Secondary Uses Service (SUS+) data for Risk Stratification (RS) which is a tool for identifying and predicting which patients are at high risk or likely to be at high risk and prioritising the management of their care.</p> <p>NHS Digital advised that this application had come to IGARD for a recommendation due to the applicant not currently have an active Data Sharing Agreement (DSA) for Risk Stratification and that this was a new agreement with a new purpose.</p> <p>Discussion: IGARD noted and supported the explanation provided by NHS Digital outlining why this application had come to IGARD for a recommendation and asked that for clarity section 1 (Abstract) was updated to reflect this. IGARD queried if there was a change to the</p>

	<p>Data Processor and asked that if so, that for clarity section 5 (Purpose / Methods / Outputs) was updated to state this.</p> <p>IGARD noted that the bullet point in section 5(b) (Processing Activities) under the heading 'For the purpose of Risk Stratification' was incomplete and asked that this was updated.</p> <p>Outcome Summary: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 1 clarifying why this application has come to IGARD for a recommendation; and if this is due to a change in the Data Processor that section 5 should be updated to state this. 2. To complete the bullet point in section 5(b) under the risk stratification purpose.
3	<p>AOB:</p> <p>There was no further business raised, 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:</p> <ul style="list-style-type: none"> • Processes

Independent Group Advising on Releases of Data (IGARD): Out of committee report 24/05/19

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)
N/A						

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

- None