

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

### Minutes of meeting held 11 April 2019

**Members:** Nicola Fear (Acting Chair), Priscilla McGuire, Eve Sariyannidou (Acting Chair – Item 2.3), Geoffrey Schrecker, Maurice Smith.

**In attendance:** Stuart Blake, Garry Coleman (item 2.5), Netta Hollings, Kimberley Watson, Vicki Williams.

**Apologies:** Sarah Baalham, Joanne Bailey, Anomika Bedi, Maria Clark, Kirsty Irvine.

1	<p><b>Declaration of interests:</b></p> <p>Nicola Fear noted a professional link with Kings College London [NIC-156409-F4P2D] and would not be part of the discussion. It was agreed Nicola would not remain in the meeting for the discussion of that application</p> <p>Maurice Smith noted a professional link with NHS Liverpool Clinical Commissioning Group (CCG) [NIC-287049-F7M1P] and would not be part of the discussion. It was agreed that Maurice would not remain in the meeting for the discussion of that application.</p> <p>Priscilla McGuire noted a professional link with NHS Greater Huddersfield CCG, NHS Sheffield CCG, NHS Barnsley CCG, NHS Rotherham CCG, NHS Doncaster CCG and NHS Derbyshire CCG and would not be part of the discussion. It was agreed that Priscilla would not remain in the meeting for the discussion of that applications.</p> <p><b>Review of previous minutes and actions:</b></p> <p>The minutes of the 4<sup>th</sup> April 2019 IGARD meeting were reviewed were agreed as an accurate record the meeting.</p> <p><b>Out of committee recommendations:</b></p> <p>An out of committee report was received (see Appendix B).</p>
2	<b>Data applications</b>
2.1	<p><u>Emergency Care Data Set (ECDS) Briefing Paper (Presenter: Netta Hollings)</u></p> <p>The briefing paper was to inform IGARD that the Emergency Care Data Set (ECDS) was now available through the Data Access Request Service (DARS).</p> <p>The Emergency Care Dataset will replace the existing Accident &amp; Emergency (A&amp;E) Commissioning Data Set (made available as HES (Hospital Episode Statistics) A&amp;E) dataset, building on this by capturing a much greater level of clinical detail in relation to emergency care provided by the NHS.</p> <p>IGARD welcomed the briefing note and that a previous briefing note had been presented to IGARD on 14<sup>th</sup> September 2017 detailing commissioning and inclusion of secondary use service (SUS). IGARD noted that since the data being obtained via ECDS was more useful from a clinical perspective, that further background be included within section 1.</p> <p>IGARD noted that the dataset contained pseudonymised data however there was a permission to get identifiable, and since it was personal data that the legal basis under General Data Protection Regulation (GDPR) for processing the data should be included within the briefing note. IGARD also suggested that section 7 referencing the Information Commissioner's Office (ICO) code of practice on anonymisation be removed, since the whole policy was currently being revised in the context of the GDPR.</p>

	<p>IGARD noted that since this new dataset would be made available to researchers through the DARS service and suggested that 'research community' be included within section 4.</p> <p>It was noted that ethnicity was not included within the 'ECDS record information' and suggested that section 2 be updated to outline all data included in the ECDS record.</p> <p>IGARD queried the types of sub-groups flagged, and suggested that NHS Digital may wish to seek further guidance from the ECDS technical coding group in order to flag other sub groups of interest such as veterans and those with learning difficulties.</p> <p><b>Outcome:</b> IGARD welcomed the briefing note and made the following comments:</p> <ol style="list-style-type: none"> <li>1. To include the legal basis under GDPR for the processing of data</li> <li>2. To include within section 1 further background that the data being obtained via ECDS is more useful from a clinical perspective</li> <li>3. To include within section 2, further information about the data included within the 'ECDS record'</li> <li>4. To include within section 4 reference to the 'research community'.</li> <li>5. To remove section 7, covering the ICO code of practice on anonymisation, since it is currently being revised in the context of the GDPR.</li> <li>6. IGARD suggested that NHS Digital may wish to seek further guidance from the ECDS technical coding group in order to flag other sub groups of interest, including those with learning disabilities, veterans.</li> </ol> <p><b>ACTION:</b> IGARD asked that the briefing note be updated and be re-presented to IGARD either via OOC or under AOB so that a final version could be kept on file.</p>
2.2	<p><u>Competition and Markets Authority (CMA): National HES Data for Investigation of mergers (Presenter: Stuart Blake) NIC-32833-M3M9V</u></p> <p><b>Application:</b> This was a renewal (for the latest available data) and extension (to continue to hold and process previously held data from 2014/15 onwards) for pseudonymised Hospital Episode Statistics (HES) Admitted Patient Care (APC) data, HES Accident &amp; Emergency (A&amp;E) and HES Outpatient data.</p> <p>Where there is a planned merger of Trusts, the CMA has a remit to investigate and determine whether that merger would have an adverse impact on patients by reducing choice / competition. In order to analyse the potential impact, the CMA require access to HES data to look at which treatments / services are provided, over what geographical area.</p> <p><b>Discussion:</b> IGARD queried the request for national data and how it met the necessity test and noting the confidentiality of any planned mergers, asked that NHS Digital provide written assurance of the number of ongoing and planned mergers over the next twelve months including assurance of the geographical spread to support the request for national data.</p> <p>IGARD asked how many mergers had taken place in 2018 and NHS Digital confirmed that according to the CMA website two mergers had been undertaken in Manchester and Birmingham. It was suggested that this clarification be included in section 5(d) (Yielded Benefits).</p> <p>IGARD noted that they had been unable to view the applicant's fair processing notice via the link provided within section 4 (Privacy Notice) and suggested the link be tested to ensure it worked across a variety of internet browsers.</p> <p><b>Outcome:</b> recommendation to approve subject to the following condition:</p>

	<p>1. To provide written confirmation from NHS Digital outlining the number of ongoing and planned mergers over the next twelve months including assurance of the geographical spread to support the request for national data.</p> <p>The following advice was given</p> <p>1. IGARD suggested that the fair processing links within section 4 were tested to ensure they worked across a variety of internet browsers</p> <p>It was agreed the condition be approved OOC by IGARD Members</p>
2.3	<p><u>King's College Hospital (KCL): Practice-level PCMD (Presenter: Stuart Blake) NIC-156409-F4P2D</u></p> <p><b>Application:</b> 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>This application had been previously considered for advice on the 17<sup>th</sup> January 2019, when IGARD had provided advice both in-meeting and outside the meeting.</p> <p><b>Discussion:</b> IGARD noted their thanks for the work undertaken by NHS Digital and the applicant since it was previously considered for advice. IGARD welcomed the application and noted the sensitive issues it raised and the steps taken by the applicant to consider those sensitivities.</p> <p>IGARD noted that reference to 'small numbers suppressed' had been removed from the application since it was previously reviewed, however noted an incorrect statement within the abstract "IGARD recommended that this application... without need to suppress small numbers" should be removed, since it was factually incorrect.</p> <p>NHS Digital noted that the previous application considered for advice had contained only two age groups: under 75 and over 75, however since that time the applicant had revised age groups to four age ranges: 0-18, 19-64, 65-74 and 75 and over for the breakdown of total number of deaths per year of patients per practice.</p> <p>IGARD queried the inclusion of study 2 and study 3 within the application and suggested that they be removed from the application, leaving just study 1 for consideration and that study 1 was part of a wider set of studies.</p> <p>IGARD noted that supporting document 1, funding letter, referenced only study 2 requiring NHS Research Ethics Committee (REC) approval, and asked that written confirmation be provided from the National Institute for Health Research (NIHR ) that no ethics approval was required for study 1 and since the application had been updated to remove small number suppression.</p> <p>IGARD queried the sentence in section 5(a) (Objective for Processing) "there are no moral or ethical issues raised by the proposed dissemination..." and suggested that the applicant clearly address the ethical and moral issues relating to the type of and nature of data requested under this application, since any outputs may cause anxiety to the public or draw out any areas of high mortality for further investigation. Since it was not clear what the outputs will actually be or whether GP practices would be identified within published outputs, IGARD asked for further clarification within section 5 (Purpose, Methods, Outputs).</p>

	<p>It was also noted that section 5 contained a lot of technical information and suggested that it be written in a language suitable for a lay reader, since this section would be published on the NHS Digital release register.</p> <p><b>Outcome:</b> Recommendation deferred, pending:</p> <ol style="list-style-type: none"> <li>1. To remove study 2 and 3 from this application.</li> <li>2. To provide written confirmation from NHIR that no ethics approval is required for study 1, despite the removal of small number suppression.</li> <li>3. 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.</li> <li>4. To remove the sentence from the abstract that “IGARD recommended that this application... without need to suppress small numbers” since it was factually incorrect.</li> <li>5. To clarify the planned routes to dissemination to the public and what is meant by the ‘groups’ noted within section 5 of the application.</li> <li>6. To clarify what the outputs of study 1 will actually be and whether GP practices will be identified within the published outputs.</li> </ol>
2.4	<p><u>Northgate Public Services (UK) Limited: Neurological National Audit Programme (NNAP) (Presenter: Kimberley Watson)NIC-233512-B7C4W</u></p> <p><b>Application:</b> This was a new application for Hospital Episode Statistics (HES) Civil Registration (Deaths) Bridge data, HES Admitted Patient Care (APC) data and Civil Registration (Deaths) secondary care cut data to facilitate the Neurological National Audit Programme (NNAP).</p> <p>NNAP was established by the Society of British Neurological Surgeons (SBNS) in 2013 as part of a major quality improvement initiative which aims to support neurological units in the UK to improve patient care, outcomes, safety and experiences by providing high quality, robust audit data this is analysed and presented in consistency and clinically relevant way.</p> <p><b>Discussion:</b> IGARD had raised a number of issues of clarification prior to the meeting and received an adequate response from NHS Digital.</p> <p>NHS Digital noted that the Healthcare Quality Improvement Partnership (HQIP) had not commissioned the audit nor were they Data Controllers of this audit programme and were providing the funding. IGARD suggested that this be included in the abstract for future reference.</p> <p>IGARD queried the role of the Leeds Teaching Hospital NHS Foundation Trust (FT) and noting that its inclusion was to satisfy the medical oversight element of GDPR Article 9(2)(j) suggested that section 5 be updated to confirm the role of the hospital, that it was not involved in the project nor had access to the data.</p> <p>IGARD queried the Local Patient Identifier (LOPATID) field requested, since it would usually be classed as an identifiable field and the NHS Digital had determined that the field could be released as a non-identifiable field, however since this was an issue of confidentiality, IGARD asked for written confirmation from Health Research Authority Confidential Advisory Group (HRA CAG) that s.251 support was not required for the dissemination of LOPATID.</p> <p>IGARD queried the appropriateness of whether the applicant had given sufficient information for the legal basis under General Data Protection Regulation (GDPR) and whether it was appropriate for the type of organisation. IGARD asked that the appropriate legal basis for the Data Controller to process the requested data be provided.</p>

	<p>IGARD suggested that section 5 (Purpose, Methods, Outputs) and section 1 (Abstract) be updated to be clear that the data requested under this application was to enable the consultants to validate the outcome data relating to the procedures they had performed.</p> <p>IGARD noted that determining the scale and scope of the adverse effect from lessening competition on patients and commissioners, and that ensuring that only mergers that were on balance beneficial to patients was not explicit, and suggested additional information be included that patients would be better informed on the NHS Choices website about the procedures undertaken by their consultant.</p> <p><b>Outcome:</b> recommendation to approve subject to the following conditions</p> <ol style="list-style-type: none"> <li>1. To provide written confirmation from HRA CAG that s251 support is not required for the dissemination of LOPATID.</li> <li>2. To provide the appropriate legal basis under GDPR for the Data Controller (The Society for British Neurological Surgeons) to process the requested data.</li> </ol> <p>The following amendments were requested.</p> <ol style="list-style-type: none"> <li>1. Confirmation of the role of HQIP</li> <li>2. To amend the abstract and section 5 to make it clear that the data requested is to enable consultants to validate the outcome data relating to the procedures they performed.</li> <li>3. To update section 5(d) that patients will be better informed on NHS Choices website about procedures undertaken by their consultant.</li> <li>4. Confirmation within section 5 of the role of Leeds Teaching Hospital NHS Foundation Trust outlined in the application, and that it is not involved in the project or has access to data.</li> </ol> <p>It was agreed the conditions be approved OOC by IGARD Members</p>
2.5	<p><u>195 CCG's Class Action (Presenter: Kimberley Watson) NIC-287049-F7M1P</u></p> <p><b>Application:</b> This was a class action amendment application for 195 CCG's to receive National Diabetes Audit (NDA) data, Hospital Episode Statistics (HES) data and Patient Reported Outcome Measures (PROMs) data.</p> <p>The NDA core audit collects information about general diabetes care and measures the effectiveness of diabetes healthcare against National Institute of Clinical Excellence (NICE) Clinical Guidelines and NICE Quality Standards in England and Wales. The HES data will allow for complex and detailed modelling and benchmarking of activities essential to successful commissioning of services and contract monitoring, including analysing relationships and influences between Accident &amp; Emergency (A&amp;E), Inpatient and outpatient care. The PROMs allows CCG's to understand the difference that healthcare interventions that they commission make to people's quality of life.</p> <p><b>Discussion:</b> NHS Digital noted that the national HES data had been removed from the application since submitting to IGARD for review. IGARD noted the withdrawal of HES data from the application and asked that the application be updated throughout to remove reference.</p> <p>IGARD noted the discussion and outcomes for this application be read alongside the item under Any Other Business (AOB): 'National Diabetes Audit Briefing Note'.</p> <p>IGARD queried the legal basis for the collection of the PROMs data under the Duty of Confidentiality and asked that this be clarified.</p>

	<p>IGARD had not had sight of the Health Research Authority Confidential Advisory Group (HRA CAG) s.251 support letter and suggested that clarification be included within section 5(b) (Processing Activities) that processing under this application excluded any data of patients registered in Wales or resident in Wales.</p> <p>IGARD suggested that NHS Digital update their fair processing notice to ensure it is compliant with General Data Protection Regulation (GDPR) including (but not limited to) being accessible to the public..</p> <p>IGARD suggested that NHS Digital amend the abstract to clearly state that for the purposes of the presentation to IGARD and administrative ease the 195 CCG's had been grouped together, however the application as <b>not</b> a multi-purpose application with joint Data Controllers but instead an application of individual CCG's with individual NIC numbers, Data Sharing Framework Contracts (DSFCs) and Data Sharing Agreement (DSAs) with no linkage of data, the CCG's being the sole Data Controllers.</p> <p><b>Outcome:</b> IGARD made a positive statement and were supportive of the application but unable to make a formal recommendation as there was not a quorum of members present. The following comments were made:</p> <ol style="list-style-type: none"> <li>1. To clarify in Section 5b that processing under this application excludes any data of patients registered or resident in Wales.</li> <li>1. To clarify the legal basis for the collection of PROMs data</li> <li>2. To remove reference to the national HES data from the application, since it was no longer required as part of this application.</li> </ol> <p>The following advice was given</p> <ol style="list-style-type: none"> <li>1. IGARD suggested that NHS Digital update their fair processing notice, including (but not limited to) ensuring it is accessible to the public and compliant with GDPR</li> </ol> <p>It was agreed that the conditions be approved OOC by the IGARD Chair.</p>
<p><b>3</b></p> <p><b>3.1</b></p>	<p><b>AOB</b></p> <p><b>National Diabetes Audit (NDA) Briefing Note</b></p> <p>IGARD noted that a briefing note had been previously provided to IGARD on the 4<sup>th</sup> October and subsequent comments received from NHS Digital on the 31<sup>st</sup> October, noting that issues previously made had been mostly addressed.</p> <p>It was noted that the NDA programme was the first HQIP-managed audit programme to be conducted under Direction and as part of their statutory functions NHS Digital had been directed by NHS England under Direction, therefore both were considered Data Controllers. It was suggested that it be explicit that Healthcare Quality Improvement Partnership (HQIP) was not considered a Data Controller. IGARD noted that the Direction set aside the Duty of Confidentiality and that this be clear within the briefing note. IGARD also suggested that 'next steps' be clearly articulated within this briefing note and any future briefing note on new datasets to IGARD.</p> <p>NHS Digital noted that they had reviewed the s251 support, however IGARD queried the conditions of support that were part of Health Research Authority Confidential Advisory Group (HRA CAG) s251 letter of support and that a copy be provided with the briefing note.</p> <p>IGARD confirmed that section on Information Commissioner's Office (ICO) code of practice code on anonymisation was no longer relevant because the policy was currently being revised in the context of the General Data Protection Regulation (GDPR) and that this section be removed from this briefing note and any subsequent NHS Digital briefing notes to IGARD.</p>

IGARD suggested that since NHS Digital would make available record level data to researchers, a further briefing note should be brought to IGARD when researchers make applications for this type of data.

1. To provide a copy of the s.251 support letter.
2. To explicitly state within the briefing note that NHS England and NHS Digital are the Data Controllers for this data and as part of their statutory functions, NHS Digital have been directed by NHS England under Direction.
3. To explicitly state that HQIP are not a Data Controller since the clinical audit is contracted under Direction.
4. To remove reference to the ICO code of practice on anonymisation since the whole policy is under review in the context of the GDPR.
5. To be clear that the Direction sets aside the Duty of Confidentiality.

**ACTION:** IGARD asked that the updated briefing note, and any supporting documents, be re-submitted to IGARD for inclusion under AOB at a future IGARD meeting, so that a final version could be kept on file.

**ACTION:** IGARD suggested that since NHS Digital would make available record level data to researchers, a briefing note should be brought to IGARD before researchers make applications for this type of data.

### Independent Group Advising on Releases of Data (IGARD): Out of committee report 05/04/19

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-15411-C9Z9L	The Health Foundation	21/03/2019	1. To insert an explanatory paragraph in section 5(a) outlining the nature of the 'international study' as referenced within the abstract and to confirm that no sharing of data will take place other than that outlined in this application; and to further explain how this study fits into the wider international study.	OOC by IGARD Chair	OOC by IGARD Chair	N/A
NIC-113025-X7Z3L	CPRD	14/03/2019	1. To articulate the legal basis for the flow of confidential information from HFEA to NHS Digital for the cohort of participants consented on the materials pre-2009.	OOC by IGARD Members	OOC by quorum of IGARD Members	N/A
NIC-167794-K1P8H	Newcastle University	28/02/2019	1. To clarify within section 5(a) that the GP Practice codes are part of the specification and provide justification of why they are included, including the consideration of the measures taken to determine that the GP Practice codes are in fact necessary; and a description of any data minimisation efforts undertaken.	OOC by IGARD Members	OOC by quorum of IGARD Members	N/A

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

- None