

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 13 April 2017

Members: Anomika Bedi, Nicola Fear, Jon Fistein, Eve Sariyiannidou (item 2.2 onwards), James Wilson

In attendance: Diane Clark, Garry Coleman, Gaynor Dalton, Frances Hancox, Louise Hill, Terry Hill, Joanne Treddenick, Kimberley Watson, Vicki Williams

Apologies: Sarah Baalham, Joanne Bailey, Chris Carrigan, Kirsty Irvine, Debby Lennard

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| 1 | <p>It was agreed that in the absence of the IGARD Chair, Jon Fistein would act as chair for this meeting.</p> <p>Declaration of interests</p> <p>Jon Fistein declared a potential interest in the group application from University of Leeds (NIC-11809-H1Y3W; NIC-155843-0MQMK) due to his employment by that organisation. Nicola Fear also declared a potential interest in that group application due to previous professional relationships with the applicants.</p> <p>In addition Jon Fistein declared a potential interest in the Genomics England application NIC-12784-R8W7V, and noted that he had previously worked with IMS Health Ltd but had no current connection with the organisation. James Wilson declared a professional relationship with the chair of the Ethics Advisory Group for Genomics England and noted some involvement with the organisation via the National Data Guardian's panel.</p> <p>In addition James Wilson noted that the National Amyloidosis Centre, which was involved in the application from IMS Health Ltd (NIC-60624-B1R2Q), was hosted by his employing organisation University College London.</p> <p>Review of previous minutes and actions</p> <p>The minutes of the 6 April 2017 IGARD meeting were reviewed and agreed as an accurate record of the meeting.</p> <p>Action updates were provided (see Appendix A).</p> <p>Out of committee recommendations</p> <p>An out of committee report was received (see Appendix B).</p> |
| 2 2.1 | <p>Data applications</p> <p><u>Group of two applications¹ University of Leeds - Yorkshire Specialist Register of Cancer in Children and Young People (Presenter: Gaynor Dalton)</u></p> <p>Application: This was a group of two connected applications requesting Hospital Episode Statistics (HES) and mental health data for two cohorts: identifiable HES and mental health data for a specific cancer cohort (with section 251 support as legal basis), and pseudonymised HES data for a comparison cohort filtered to a specific geographic area. IGARD were informed</p> |

¹ NIC-11809-H1Y3W; NIC-155843-0MQMK

that although NHS Digital would not disseminate any identifiable fields, the data for the first cohort was considered identifiable as the applicant would be able to re-identify the cohort on receipt. It was noted that the study funding had recently been extended.

Discussion: A query was raised about the planned data retention period, as this was described inconsistently at different points within the application. It was suggested that this had been due to uncertainty as to whether funding would be extended, and it was agreed the wording should be updated to clarify this. A further query was raised about a reference in the application to identifying 'those individuals who are at greatest risk of hospitalization'; it was suggested this wording should be amended to be clear that this referred to identifying risk factors rather than identifying specific individuals. A statement about substantive employees and third party access to data was queried and IGARD asked for this wording to also be clarified.

IGARD queried the legal basis for data dissemination under the Health and Social Care Act 2012. It was explained that NHS Digital's IG staff undertook work in the previous year to explain which sections and sub-sections of the Act might provide a legal basis for various types of data disseminations, and it was agreed this would be shared with IGARD members for information.

There was a brief discussion about processing locations and it was confirmed that the Data Sharing Agreement would require the University of Leeds to only process data at the stated locations. There was a further discussion about the control cohort, and it was agreed the application wording should be updated to be clear whether this would exclude the individuals in the cancer registry cohort or whether there would be the potential for overlap between the two cohorts.

Outcome: Recommendation to approve

The applications should be amended to remove a reference to only retaining data until December 2017, to clarify a reference to identifying patients at higher risk of hospitalisation, to confirm whether the pseudonymised dataset excludes the cancer registry cohort, and to clarify the statement about only substantive employees having access to data and not sharing with third parties.

Action: IGARD Secretariat to provide IGARD with a copy of the IG ISA work on legal basis for dissemination under the Health and Social Care Act 2012.

2.2

University of York - Evaluating the cost-effectiveness of the Best Practice Tariff for hip fracture (Presenter: Kimberley Watson) NIC-50329-G1L1P

Application: This was a new application requesting HES IDs only in a bridging file, to enable pseudonymised HES data already held to be linked with national hip fracture audit data provided by the Royal College of Physicians (RCP). IGARD were informed that section 251 support was in place for the RCP to share this data with the University of York, and that the HRA CAG register had been updated to reflect extension. The data would be used to assess the cost-effectiveness of the hip fracture best practice tariff, with regular reports to be provided to NHS England.

Discussion: An IGARD member had raised a number of questions about this application prior to the meeting; it was noted that one question had already been addressed as an action had been raised to share information about the legal basis to disseminate data under the Health and Social Care Act 2012 section 261(1). A copy of the data sharing request form was also now available as requested, and this clearly confirmed that the University of York would link audit data with HES. A further question had been raised about the data controller and processor roles; it was explained that for the purpose of this application the University of York would act as data controller and processor, but that HQIP would be data controllers for the

audit data that the RCP (acting as their data processor) would provide to the University of York. It was noted that the work was funded by NHS England, but that they had not been considered a data controller for this or other similar applications.

There was a lack of clarity within the application around the different data flows involved in this application and the legal basis or bases for each flow, as well as which organisations were involved at what point in the data flow. IGARD suggested that the use of a data flow diagram, which clearly stated the legal basis for each flow, would help to clarify this. In addition it was considered unclear which of the various supporting documents provided related to the legal basis for which data flows, particularly as these referred to a number of different data flows and data linkages that were not part of the current application, as well as the involvement of other organisations such as the Royal College of Surgeons.

A query was raised about the requirement for the RCP to delete identifier 1 following linkage and it was agreed the application should be amended to confirm that NHS Digital would seek confirmation from HQIP of this. In addition IGARD suggested it would have been helpful to have more information about the planned outputs.

The patient information wording was briefly discussed. IGARD suggested that it would likely be more practical for patients to contact the national audit team rather than contacting their local hospital, and suggested that the national contact details could be made more prominent.

Outcome: Recommendation deferred, pending:

- Updating the application to more clearly state which data flows relate to this specific application, what organisations are involved in this application, the legal basis for each data flow and what documents relate to the different legal bases. It was suggested that a data flow diagram might help to clarify the flows involved.

The application should be amended to include that NHS Digital will seek confirmation from HQIP that RCP will destroy identifier 1 once audit data has flowed to the University of York.

2.3

The Health Foundation - Assessment of health inequality (Presenter: Kimberley Watson) NIC-90019-Q8P9K

Application: This was a new application for pseudonymised HES data across a number of years to build an evidence base around health inequalities relating to the current period of austerity. IGARD were informed that since submission the applicant's IG Toolkit version 14 score had been reviewed as satisfactory and the application would be updated to reflect this.

Discussion: IGARD noted the potential public interest in this work and expressed their support. The proposed data minimisation was discussed and it was acknowledged that although a large number of data years were requested, the number of fields had been limited and a clear justification had been provided for the amount of data necessary.

There was a brief discussion about the organisation's privacy notice and while it was noted that only pseudonymised data would be shared, the applicant might wish to consider more clearly describing their use of data on their website.

IGARD noted that the application used the terms 'researchers' and 'analysts' to describe the individuals accessing data, but only included assurances about the employment arrangements for researchers. It was agreed the application wording should be amended to be clear that only substantive employees would have access to data, whether researchers or analysts.

Outcome: Recommendation to approve

The application should be amended to be clear that all researchers and analysts with access to data are substantive employees. It was noted the application would be updated to reflect the applicant's reviewed version 14 IG Toolkit score.

2.4**The Health Foundation - The impact of introducing Any Qualified Providers on hospital performance in England (Presenter: Kimberley Watson) NIC-90070-F3K4Z**

Application: This new application requested pseudonymised HES data to study the impact of Any Qualified Provider, with the intention to report to organisations such as NHS England, the Department of Health and NHS Improvement.

Discussion: IGARD noted their general support for the proposed work. There was a discussion of the planned outputs and how these would be disseminated to help produce benefits; it was noted that the dissemination described focused on health economists, and IGARD suggested the application wording should be updated to be clearer that outputs would also be shared with patient advocate groups. IGARD queried whether the proposed work was in the spirit of the requirements of the Care Act 2014; on balance it was considered to be appropriate, but further information was requested about the expected healthcare benefits.

Outcome: Recommendation to approve

The application should be amended to state that outputs of this work will be shared with patient advocate groups and to more clearly state the expected benefit to the NHS. It was noted the application would be updated to reflect the applicant's reviewed version 14 IG Toolkit score.

2.5**Group application for 3 CCGs² (Presenter: Garry Coleman) GA04-AMD-SL**

Application: This application requested the use of Secondary Uses Service (SUS) data identifiable at the level of NHS number for the purpose of risk stratification; it was noted an application from these CCGs had previously been considered at the 20 December 2016 DAAG meeting, but that in that application the use of data for risk stratification had been removed due to concerns around the proposed arrangements. It was confirmed that the applicant now proposed to use a more standard risk stratification model. The application also requested the continued use of pseudonymised SUS data, local provider flows, mental health (MHMDS, MHLDDS, MHSDS), Maternity Services Dataset (MSDS), Improving Access to Psychological Therapies (IAPT), Children and Young People's Health Dataset (CYPHs), and Diagnostic Imaging Dataset (DIDs) data for commissioning purposes as well as using SUS data identifiable at the level of NHS number for invoice validation.

IGARD were informed that although the table of data requested appeared to indicate an overlap with the data already held by the applicant, NHS Digital would not be re-supplying data already held. In addition an error was noted in the wording around access to risk stratification data and IGARD were informed this would be amended to be clear the CCG and data processors would only process data related to that particular CCG, and that access would be limited to staff with authorised user accounts.

Discussion: There was a discussion of how the risk stratification data processing had changed since this was previously removed from the application. IGARD were informed that there would no longer be any use of NHAIS or the Patient Master Index for the purpose of risk stratification.

IGARD queried the description of small number suppression and whether NHS Digital were content with the approach taken for datasets that did not use the HES Analysis Guide. It was agreed the application should also include the description of small number suppression in section five, rather than just in the unpublished summary section.

² NIC-88542-J1S6S NHS Dartford, Gravesham and Swanley CCG; NIC-88562-G4W4K NHS Medway CCG; NIC-88564-W3R5K NHS Swale CCG

A reference to a supporting document was queried as this had not been provided with the application. IGARD were informed that this text was a quote from a previous version of the application, and that the supporting document was not considered relevant to the current application.

It was noted that the application summary described the request as an amendment only, whereas a renewal was also requested. IGARD asked for the processing activities section to be updated to be clear that the restrictions around only substantive employees accessing data would apply to all data flows, not just the SUS or mental health flows. In addition IGARD asked for the application to reflect the standard special condition wording regarding the review of version 14 IG Toolkit scores.

The data flow diagram was discussed and IGARD suggested it would be helpful if these diagrams indicated which data flow related to what section of the application, although it was acknowledged there were some restrictions around ensuring that section five of the application would be sufficiently clear in isolation.

Outcome: Recommendation to approve.

The application should be amended to confirm that NHS Digital is content with the approach taken to small number suppression, to include the explanation of small number suppression in section five, to include a requirement to limit data access to substantive employees for all data flows, and to be clear that the request is for both an amendment and a renewal. The application should include the standard special condition wording regarding version 14 IG Toolkit submission.

IGARD advised that a special condition should be included within the DSA to state that: "As a result of your application IGARD would like to draw your attention to the importance of the accessibility and clarity of your Privacy Notice. In the interests of transparency, you are advised to regularly review your notice against the ICO's Privacy Notices Code of Practice to ensure it reflects best practice. You will be expected to demonstrate progress against this recommendation in any audit undertaken and for any renewal or new application for data."

It was agreed that NHS Digital should consider how data flow diagrams are presented for this type of application in future and clarify which arrows relate to which data flows within the application.

2.6

Leicestershire County Council (Presenter: Garry Coleman) NIC-93640-K3Z1Y

Application: This application for pseudonymised SUS data, for public health and commissioning purposes, had previously been considered at the 30 March 2017 IGARD meeting when IGARD had recommended approval for a limited time period, with the expectation that an updated application would be submitted shortly to address a number of concerns raised. This updated application now attempted to reflect the changes discussed, including clarifying a number of specific points raised about the description of commissioning purposes. The application also now included Arden and GEM CSU as a data processor and it was explained this organisation would provide a tool through which the Council could access data.

Discussion: IGARD queried the application wording in relation to the Licensing Act and suggested this should be updated in line with the previously agreed wording.

In addition IGARD queried the controls in place to restrict linkage to other datasets. It was agreed the application wording should be amended to specifically state that the SUS data would not be linked to local provider data, and the commitment not to link to other record level datasets should be included in section five of the application to ensure it would be reflected in the Data Sharing Agreement.

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| <p>2.7</p> | <p>Outcome: Recommendation to approve The wording regarding the Licensing Act should be amended as previously raised. The application should also be amended to explicitly state that there will be no linkage to local provider data, and to include the commitment to not link to other record level data in section five.</p> <p><u>Poole Hospital Foundation Trust - National Audit on Route of Hysterectomy (Presenter: Gaynor Dalton) NIC-82980-V6D4Q</u></p> <p>Application: This application requested pseudonymised HES data for patients who had undergone a hysterectomy operation within a certain time period, in order to analyse the route of hysterectomy and map geographic variation. A number of data years were requested to help consider changes over time and whether this was likely to be as a result of training offered.</p> <p>It was noted that this work had been commissioned by the British Society for Gynaecological Endoscopy (BSGE), with that organisation acting as the data controller, but that all processing would take place at Poole Hospital Foundation Trust. Both organisations had submitted a version 14 IG Toolkit score that had not yet been reviewed, and it was confirmed the application contained the standard special condition around version 14 review.</p> <p>Discussion: IGARD noted that the application listed a DPA registration expiry date for BSGE that had already passed.</p> <p>A number of queries were raised about the intended goal of this work, as it was unclear from the application whether the applicant wished to test a specific hypothesis about which hysterectomy route provided the most benefit for patients. In addition IGARD felt that more information about the planned outputs and how these would be disseminated in order to achieved benefits would have been helpful, such as a clearer description of how this might lead to changes in NICE guidelines. IGARD queried what other actions would be taken to help provide healthcare benefits, such as whether the outcome of the audit might lead to developing a training initiative.</p> <p>Outcome: Recommendation to approve The application should be amended to more clearly state the intended purpose of this application and its expected benefits, such as whether this would lead to planning a training initiative. It was noted the DPA registration for the BSGE appeared to have expired and would need to be renewed in order for data to be disseminated.</p> <p>2.9</p> <p><u>IMS Health Ltd - Using Patient Data in Amyloidosis to Understand Complex Diagnosis Pathways and Treatment Patterns (Presenter: Gaynor Dalton) NIC-60624-B1R2Q</u></p> <p>Application: This application had previously been considered at the 10 January 2017 DAAG meeting, when DAAG had been unable to recommend approval. The application requested pseudonymised HES data for a specific cohort, with identifiers being provided to NHS Digital under section 251 support to allow linkage for the study cohort, and it was noted that the work was funded by GlaxoSmithKline. A copy of the updated collaboration agreement between the organisations was provided and the application had been updated to address the points previously raised by DAAG, including confirmation that the section 251 support requirements for patient notification had been met.</p> <p>Discussion: IGARD discussed the various points that had previously been raised by DAAG</p> |
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| 2.8 | <p>and whether these had adequately been addressed. It was noted that the updated collaboration agreement further clarified the role of GlaxoSmithKline and included them as a party to the agreement, but it was agreed the application wording should be updated to state that this organisation would not have the ability to suppress the dissemination of outputs. The assurances given to make the predictive algorithm open access were noted and IGARD requested further information about how this would be made open access.</p> <p>The update regarding fair processing was noted and IGARD suggested additional improvements; specifically to more clearly state how the data would be de-identified, explaining which organisation or organisations were referred to as 'we', amending a statement that the risk of re-identification would be extremely low, clarifying references to a company outside the NHS to specify the involvement of commercial organisations, and there was a suggestion that information could potentially be made available through the National Amyloidosis Centre website. IGARD noted the information provided about the collaboration agreement between IMS Health Ltd and Royal Free London NHS Foundation Trust, and asked for the application to be amended so that references to a re-use agreement instead referred to this document.</p> <p>It was agreed that the other points raised by DAAG seemed to have been appropriately answered.</p> <p>IGARD noted that the application incorrectly referred to IMS Health Ltd as sole data controller, while elsewhere referring to Royal Free London NHS Foundation Trust as joint data controller, and it was agreed this would be corrected. In addition a reference to IMS Health Ltd as a data processor was queried, and IGARD asked for this wording to be clarified.</p> <p>The role of University College London was queried, as it was noted that the protocol referred to the involvement of an individual employed by that organisation. IGARD requested confirmation that either this individual would not have access to data (other than aggregated data with small numbers appropriately suppressed), or that if the individual did access data then that this was under appropriate contractual arrangements with Royal Free London NHS Foundation Trust.</p> <p>Outcome: Recommendation to approve, subject to the following condition:</p> <ul style="list-style-type: none"> Confirmation that an individual employed by University College London does not have access to record level data, or if the individual does have access then confirmation that this is under appropriate contractual arrangements with Royal Free. <p>The application wording should be amended to be clear that no organisation on the clinical interpretation group will have the ability to suppress the dissemination of findings or outputs from this work, to clarify in section five how the algorithm will be made available with open access, to refer to a collaboration agreement rather than a reuse agreement, to consistently describe IMS and Royal Free as joint data controllers and to clarify a statement about IMS as a data processor.</p> <p>IGARD advised IMS to update their fair processing material in line with the comments raised during the discussion and suggested that they should consider making this information available on the NAC website.</p> <p>It was agreed these conditions would be reviewed out of committee by IGARD.</p> <p><u>IMS Health Ltd - Pulmonary Arterial Hypertension (PAH) population epidemiological analysis platform formation (Presenter: Gaynor Dalton) NIC-58999-K6P8B</u></p> <p>Application: This application requested linkage of patient data held by Sheffield Teaching Hospitals NHS Foundation Trust to HES data, in order to support research into pulmonary arterial hypertension funded by GlaxoSmithKline. IMS Health Technology Services Ltd would also act as a joint data controller and processor along with IMS Health Ltd and Sheffield</p> |
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Teaching Hospitals NHS FT.

Discussion: IGARD queried the role of GlaxoSmithKline in this application and it was noted a collaboration agreement was in place, similar to the one discussed under the previous IMS Health application (NIC-60624-B1R2Q). A reference in this agreement to IMS World Publications Ltd was queried, as this entity did not seem to be otherwise referred to, and it was agreed the role of this organisation should be clarified. A reference to the University of Sheffield was also queried and it was suggested the application should clarify that this organisation would only receive aggregated outputs with small numbers suppressed. IGARD requested confirmation within the application that the GlaxoSmithKline clinical experts referred to would not have any access to record level data or small numbers during the regular sessions described. In addition it was suggested the application should state that the clinical interpretation group would not have the ability to suppress the findings or the dissemination of outputs. Given the use of a collaboration agreement IGARD noted that if any changes were made to this agreement that would impact the use of data received via this application, then an updated application ought to be submitted; it was agreed this would be reflected in a special condition.

The use of a controlled environment to access data was noted and IGARD asked that when a renewal application was submitted, this should include more information about the purposes for which data had been accessed through this environment.

IGARD discussed the development of a predictive algorithm and queried whether this would be made available with open access, or if this did not turn out to be feasible then whether IMS Health Ltd would publish information about their methodology so that some healthcare benefits might still be achieved. A reference to an overview document about the algorithm was noted and IGARD requested sight of this for information.

IGARD queried the description of how honorary contracts might be used and suggested that this wording should be clarified. It was explained that only the substantive employees of the IMS Health Group would be able to access data via the use of honorary contracts, rather than honorary contracts being used for any other third party organisation. A reference to employees of 'IMS Health' was also queried as it was unclear which legal entity this was intended to refer to.

The amount of data for the control cohort was queried, as it was unclear whether national data was required or whether this cohort would be for the Sheffield area only. In addition the data years requested were queried and it was clarified that data from 2000-01 onwards was requested for HES APC data only, not for all datasets. IGARD requested a clearer justification for why this number of data years would be required.

The patient information materials were briefly discussed and IGARD suggested that it was potentially misleading to refer to 'anonymous patient data' when identifiable data would be processed under section 251 support. However it was noted that the description of how data would be de-identified seemed clear. IGARD also suggested that the applicant should consider updating the patient information to specify which commercial organisations were involved in processing data.

IGARD noted a number of references within the application to 'the applicant' carrying out certain activities, and suggested that given the different parties involved this should be amended to clearly state the relevant organisation name.

Outcome: Recommendation to approve, subject to the following conditions:

- Clarifying a reference to regular sessions with GlaxoSmithKline clinical experts to be explicit that these staff would not have any access to record level data.
- Clarification of whether the comparison cohort requires national data or data for individuals in Sheffield only, with clarification of why this number of data years are

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| <p>2.10</p> | <p>required.</p> <ul style="list-style-type: none"> Confirmation that the predictive algorithm will be made available with open access, or that if unable to do so then appropriate information about their methodology will be made available. <p>The application should be amended to clarify the involvement of IMS World Publications Ltd, to clarify a reference to honorary contracts to use clearer wording, and a statement that only substantive employees access data should be corrected to include the potential use of honorary contracts within the IMS Group. The application should also be amended to clarify that references to data from 2000-1 are for HES APC data only.</p> <p>The application wording should be amended to be clear that no organisation on the clinical interpretation group will have the ability to suppress the dissemination of findings or outputs from this work. A reference to 'the applicant' developing a dataset should be amended to name the organisation. A reference to IMS Health should be amended to be clear which organisation is referred to, and a clearer statement should be added that GlaxoSmithKline or University of Sheffield staff will not have access to record level data.</p> <p>A special condition should be added that if the collaboration agreement is to be amended in a way that will affect the use of this data, an updated application should be submitted to IGARD. A further special condition should be added that when a renewal application is next submitted, IMS should provide a summary of the purposes for which data has been accessed within the controlled environment.</p> <p>IGARD advised that the patient information poster should be updated to remove the reference to 'anonymous' data, and to specify which commercial organisations are involved.</p> <p>IGARD requested sight of a document referred to in the application about an overview of the predictive algorithm.</p> <p>It was agreed these conditions would be reviewed out of committee by IGARD.</p> <p><u>Genomics England (Presenter: Gaynor Dalton) NIC-12784-R8W7V</u></p> <p>Application: This application was to renew and amend the applicant's current data sharing agreement, which covered the use of identifiable HES data, with the amendment requested being to include Patient Reported Outcome Measures (PROMs), Office for National Statistics (ONS) mortality data, DIDs and mental health data. It was noted that while patient consent was considered to provide a legal basis for most of these datasets, concerns had previously been raised about whether the consent materials covered the use of mortality data and an alternative legal basis was now in place for the use of this data under Section 42(4) of the Statistics and Registration Service Act 2007. Updated consent materials had been provided as supporting documents.</p> <p>Discussion: IGARD noted the potential benefits from the 100,000 Genomes project and noted the letter of support submitted by the Participant Panel.</p> <p>IGARD acknowledged the previous discussions held by DAAG around the consent materials, noting in particular that the previous concerns raised had primarily related to whether consent could provide a sufficient legal basis for the proposed use of mortality data. IGARD queried whether Section 42(4) was intended to provide a legal basis for the previously recruited cohort only, or for all future participants as well; IGARD were informed that this would be the legal basis for all participants and it was agreed the application would need to be updated to more clearly state this, to be clear that the new consent materials were not intended to provide a legal basis for mortality data.</p> <p>A reference to involvement by NHS Digital's IG ISA team was queried and it was agreed the application should be updated to indicate that this team had reviewed the updated consent materials and were content. IGARD suggested that Genomics England might in future wish to consider reviewing the terminology used in patient materials in line with the patient task force work led by the Wellcome Trust in this area, and it was suggested terms such as 'your data'</p> |
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| | <p>could be misleading when referring to de-identified data.</p> <p>The involvement of Skyscape Cloud Services / UKCloud was noted and it was confirmed this organisation had appropriate security assurances in place. IGARD asked for the application to be amended to refer to the organisation consistently or to be clear that references to Skyscape referred to the legal entity UKCloud.</p> <p>IGARD noted that Queen Mary University of London was listed as a processing and storage location. It was explained that Genomics England were based at that location, but that the organisation Queen Mary University of London would not itself have access to the data.</p> <p>It was noted that the data flow diagram provided with the application was particularly unclear and IGARD requested sight of a clearer diagram. The use of PROMs data was noted and IGARD suggested NHS Digital should ensure the applicant was aware of the particular restrictions around the use of this dataset, as this could have implications for any onward sharing or future use of the data.</p> <p>There was a brief discussion about the proposed updated website text and IGARD suggested this should be circulated out of committee for further advice.</p> <p>Outcome: Recommendation to approve, subject to the following condition:</p> <ul style="list-style-type: none"> • Providing confirmation that this use of ONS mortality data is covered under section 42(4) of SRSA 2007 for both the previously recruited cohort and any future participants, and updating the application to state this. <p>The application should be amended to include a statement that NHS Digital's IG ISA staff have reviewed the consent materials and are content with the updates made. References to Skyscape should be amended to be clear that this refers to the legal entity UKCloud Ltd. The application should also be amended to clarify that although Genomics England are based at Queen Mary University of London, this does not mean that Queen Mary University of London have any involvement in data processing. A clearer data flow diagram should be provided.</p> <p>IGARD suggested that NHS Digital should ensure Genomics England is aware of the restrictions preventing the use of PROMs data for commercial purposes. It was also suggested the applicant should consider reviewing their patient materials against the Wellcome Trust's patient data task force work around using consistent vocabulary (particular around data types or the identifiability of data). It was agreed the proposed updated text for the Genomics England website would be circulated out of committee for further advice.</p> <p>It was agreed these conditions would be reviewed out of committee by IGARD.</p> |
| 3 | <p>Any other business</p> <p>No other business was raised.</p> |

Appendix A: Summary of Open Actions

| Date raised | Action | Owner | Updates | Status |
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| 15/11/16 | To update DAAG on the feasibility of providing random samples of data to applicants, and to ask the Production Team to provide DAAG with further information about the options for data minimisation | Garry Coleman | <p>06/12/16: This action was ongoing and it was anticipated an update would be available in mid-January. There had also been a discussion during the training session about data minimisation, with a suggestion for Peter Short to contact the Production Team for further information, and it was agreed that would be incorporated into this action.</p> <p>20/12/16: It was anticipated an update would be available in mid-January.</p> <p>10/01/17: Ongoing. It was agreed that this action would be taken forward by Alan Hassey rather than Peter Short.</p> <p>17/01/17: A number of internal discussions had taken place and it was anticipated an update would be brought to DAAG within the next few weeks.</p> <p>31/01/17: Ongoing. It was agreed the IGARD Chair would request an update on progress of this action.</p> <p>09/03/17: Ongoing. A number of internal discussions continued to take place and it was agreed the action would be taken forward by Garry Colman.</p> <p>23/03/17: Ongoing. There was a suggestion it might be helpful to discuss the type of sampling used by the Department for Work and Pensions.</p> <p>13/04/17: Ongoing.</p> | Open |
| 06/12/16 | To query the privacy notice review process within NHS Digital. | Chris Carrigan | <p>13/12/16: This had been discussed with the Caldicott Guardian but further clarification was needed.</p> <p>20/12/16: This action was ongoing in light of developments in other areas, including the drafting of minimum criteria. It was agreed that the action would be taken forward by Dawn Foster and Noela Almeida.</p> | Closed |

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| | | | <p>10/01/17: Ongoing, pending updated criteria.</p> <p>17/01/17: DAAG were given a brief verbal update on the work taking place.</p> <p>24/01/17: Work was ongoing following receipt of the final DAAG comments on the minimum review criteria.</p> <p>31/01/17: A meeting was scheduled to discuss this later in the week.</p> <p>09/02/17: Ongoing. It was agreed this action would be taken forward by the IGARD Chair.</p> <p>16/02/17: It was noted that a meeting with the NHS Digital Caldicott Guardian was scheduled to discuss this.</p> <p>02/03/17: This had been discussed at the educational session and it was agreed the IGARD Chair would contact the Caldicott Guardian following that discussion.</p> <p>16/03/17: IGARD's comments had been shared with the Caldicott Guardian, particularly regarding an unclear table, and the IGARD Chair had requested sight of the updated paper.</p> <p>23/03/17: Ongoing, pending sight of the updated paper.</p> <p>06/04/17: An updated paper had been agreed within NHS Digital and was now circulated to IGARD members. It was agreed IGARD members would review the updated paper and share any comments at the following week's meeting so that the action could be closed.</p> <p>13/04/17: It was confirmed the updated paper had been circulated and the action was closed.</p> | |
| 10/01/17 | To speak to NHS Digital colleagues regarding security assurance for HQIP. | Garry Coleman | <p>24/01/17: This had been raised with NHS Digital.</p> <p>31/01/17: This had been raised with HQIP and it was thought that work was underway to provide assurances.</p> <p>16/02/17: Ongoing. It was suggested that Jon Fistein could support this work.</p> <p>02/03/17: It was agreed the action should be taken forward by Garry Coleman.</p> <p>09/03/17: Security assurance discussions with HQIP and NHS</p> | Open |

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| | | | Digital had taken place and it was hoped to be resolved by the end of the month. 16/03/17: NHS Digital had received a System Level Security Policy (SLSP) from HQIP and this was currently under review. 13/04/17: Ongoing. | |
| 17/01/17 | To provide an update on the security assurances that NHS Digital would seek for applicants using contractors. | Garry Coleman | 24/01/17: It was anticipated this update would be provided to a meeting within the next few weeks. 09/03/17: Ongoing. It was agreed that the IGARD chair would contact Garry Coleman. 16/03/17: An update had been provided by email; it was agreed this would be circulated to confirm whether this had addressed IGARD's query. 23/03/17: It was confirmed one query had been addressed by email; confirmation was requested if any queries remained outstanding. 13/04/17: Ongoing. | Open |
| 23/03/17 | To provide additional information about the application checks made by the Pre-IGARD process before applications are submitted to an IGARD meeting. | Gaynor Dalton | 06/04/17: Ongoing. It was anticipated a response would be provided at the following IGARD meeting. 13/04/17: A verbal update was given on the Pre-IGARD process and it was agreed that it would be helpful on both sides to develop a Pre-IGARD checklist to define what checks would be carried out as standard for each application before reaching IGARD. | Open |
| 23/03/17 | To provide a response to previously raised IGARD queries about indemnity. | IGARD Secretariat | 06/04/17: An update had been provided and the action remained open. 13/04/17: This was ongoing within NHS Digital. | Open |
| 30/03/17 | To contact the NHS Digital Caldicott Guardian regarding how NHS Digital handles applications from organisations whose IG Toolkit has been reviewed as satisfactory with an improvement plan. | Chris Carrigan | 06/04/17: This had been raised but a response had not yet been received. 13/04/17: Ongoing. | Open |
| 13/04/17 | IGARD Secretariat to provide IGARD with a copy of the IG ISA work on legal basis for dissemination under the Health and Social Care Act 2012. | IGARD Secretariat | | Open |

Appendix B: Out of committee report (as of 07/04/17)

These applications were previously recommended for approval with conditions by DAAG or IGARD, and the conditions have subsequently been agreed as met out of committee.

The following application caveats have been signed off by the IGARD Chair:

- NIC-83772 Calderdale CCG (Vanguard) (considered at 09/03/17 IGARD meeting)