Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 15 June 2017

Members: Sarah Baalham, Joanne Bailey, Anomika Bedi, Chris Carrigan, Nicola Fear, Debby Lennard Eve Sariyiannidou, James Wilson

In attendance: Arjun Dhillon, Jen Donald, Frances Hancox, Vicky May (observer), Stuart Richardson, Andrea Shires (observer), Kimberley Watson, Vicki Williams

Apologies: Jon Fistein, Kirsty Irvine

1 Declaration of interests

No relevant interests were declared.

Review of previous minutes and actions

The minutes of the 8 June 2017 IGARD meeting were reviewed and agreed as an accurate record of the meeting.

Action updates were provided (see Appendix A).

Out of committee recommendations

An out of committee report was received (see Appendix B).

2 Data applications

2.1 <u>University Hospital Southampton NHS Foundation Trust - To investigate the association</u>
<u>between HsTrop and acute presentation with tachyarrhythmias (Presenter: Jen Donald) NIC-52397-Z8D8N</u>

Application: This new application requested Personal Demographics Service (PDS) 'removal type' data and its associated date for a cohort of approximately 800 patients, only where the reason for removal was recorded as death. This would be used for initial work to determine mortality rates for the cohort, with the potential next step then being a randomised clinical trial.

Discussion: There was a discussion of the type of PDS data requested, and how this was different from other types of data such as ONS mortality data or carrying out list cleaning for a cohort via the MIDAS system. It was acknowledged that the PDS 'removal type' date would not necessarily be an individual's precise date of death. IGARD queried how useful this information would be for the cohort in the absence of any information about the cause of death, and it was noted that the applicant might in future wish to apply for additional data to undertake further analysis. IGARD noted that the application referred to using the data from this application to draw 'strong conclusions' and suggested this wording should be amended to acknowledge that while this might enable the applicant to draw initial conclusion, additional data might later be required to strengthen the conclusions.

There was a brief discussion about type two objections, as it was noted that objections would be applied to this dissemination. IGARD noted the potential difficulties that could arise for researchers due to patient objections. There was a suggestion that the applicant might wish to further consider how outputs could be disseminated to patient groups, although it was acknowledged that it might not be appropriate to disseminate the initial findings more widely at this stage. It was suggested that section 5C of the application should be updated to reflect

plans to publish a patient newspaper. It was noted that section 5A contained an incomplete sentence referring to survival rates being 'different to patients' and IGARD asked for this sentence to be completed.

IGARD discussed the applicant's legal basis under section 251 support, which described the use of HES data as well as mortality data. It was confirmed that HES data was not requested as part of this application, as following discussions with NHS Digital the applicant had confirmed that this was not currently required. IGARD noted that the section 251 support did not explicitly refer to PDS data, but that linkage to mortality data was described and it was considered that providing this type of PDS data rather than full ONS date of death was an appropriate data minimisation effort.

IGARD also discussed the applicant's website and noted that this seemed out of date as it referred to the use of ONS mortality data, rather than PDS data, and did not clearly describe the role of NHS Digital. It was confirmed that NHS Digital would work with the applicant to ensure their website accurately reflected the proposed data processing.

There was a discussion about the indicative data retention period, which was listed as 15 years. IGARD queried whether it would be necessary to retain the PDS data separately for that length of time, or if only the linked data would be retained and the stand-alone PDS data would be destroyed as soon as linkage had taken place and been verified. IGARD requested further information about the standard approach taken by NHS Digital to applicants retaining the unlinked data following linkage in this type of situation.

Outcome: Recommendation to approve.

Section 5A of the application should be amended to more clearly reflect that while this data will help draw initial conclusions, further data may be required in future to draw strong conclusions; and to complete a sentence about outcomes being 'different to patients'. Section 5C should be amended to include information about the publication of a newsletter for patients.

Action: NHS Digital to provide information about the standard approach to data destruction where an applicant has been provided with data for linkage, and whether the original data should be retained as well as the linked data.

2.2 Nuffield Trust - The care of frail older people, and the role of the Comprehensive Geriatric Assessment (Presenter: Jen Donald) NIC-383324-D6B8T

Application: This was a renewal and amendment application for the continued receipt of HES data, as well as ONS mortality data including cause and date of death. It was noted that the applicant held ONS data under a previous, separate agreement (NIC-316705-C9F9J) and that this amendment would enable them to link the ONS and HES data for this purpose. IGARD were informed that DAAG had previously recommended to approve the dissemination of HES data for this purpose on 22 December 2015, but that data had not yet been supplied to the applicant as not all the data supplied to NHS Digital had NHS numbers available for linkage.

An error was noted in the listed data minimisation for ONS data, and it was agreed this would be corrected to state that data would be minimised to the cohort. It was noted the applicant had been asked to update their DPA registration wording to include processing data about patients.

Discussion: A query was raised about the section 251 supporting documents provided, as one letter appeared to be dated January 2016 but to have been written later. It was confirmed that this was an error on the letter and that it had in fact been sent in January 2017, following the most recent review by HRA CAG. IGARD were informed that a corrected letter should have been included with the supporting documents, but this had been omitted due to an administrative error. IGARD requested sight of the corrected letter and any other supporting

documents that had been inadvertently left out of the application pack. In addition IGARD suggested section 7 of the application should be updated to reflect the additional supporting documents.

Fair processing was discussed. IGARD noted that while Nuffield Trust had committed to update their notices in line with NHS Digital guidance, the collaborating universities involved in this application would also need to update their published fair processing information in the same way. It was agreed that a special condition should be included in the application for the collaborating organisations to use the Nuffield Trust's updated fair processing information once available.

IGARD queried what progress had been made towards the application's intended outcomes since the previous application, but it was confirmed that data had not yet been disseminated to the applicant. A reference to PROMs data was queried and it was confirmed that no PROMs data was requested as part of the current application. In addition IGARD queried the social care data referred to in the applicant's section 251 support; it was confirmed that social care data could not be shared under this application, and that if the applicant required this data from NHS Digital in future it would need to be subject to a further updated application.

There was a brief discussion about the standard ONS Terms and Conditions under which data could be used, and there was a suggestion that it might be helpful to publish these so that the information in applications could then refer to the published Terms and Conditions.

IGARD queried the amount of identifiers that would be provided to NHS Digital to enable linkage. It was explained that this was required as not all the data provided would contain an NHS number, in which case the other identifiers such as date of birth would be required to ensure an accurate match. IGARD asked for the application to be amended to explain this more clearly.

Outcome: Recommendation to approve, subject to a condition:

 Providing a copy of the updated section 251 letter with a corrected date, and updating section 7 of the application to reflect this.

A special condition should be added for the collaborating universities to use the updated fair processing information from the Nuffield Trust. Section 5 should be amended to include an explanation of why this number of patient identifiers will be provided to NHS Digital for the purpose of matching.

The description of data minimisation for ONS data will be corrected to confirm this is limited to the cohort.

IGARD advised that the applicant should update their DPA registration wording to reflect the use of data about patients or health service users.

It was agreed that the above condition would be reviewed out of committee by the IGARD Chair.

2.3 Harvey Walsh (Presenter: Kimberley Watson) NIC-05934-M7V9K

This applicant was withdrawn by the presenter prior to the meeting.

2.4 Imperial College London - Improving the value of surgical care by evaluating low value services and exploring mechanisms for effective and selective disinvestment (Presenter: Kimberley Watson) NIC-72318-M4W8J

Application: This was a new application requesting pseudonymised HES data for use in a PhD study. IGARD were informed that the application had been submitted by the Big Data and Analytical Unit within Imperial College London, as this Unit supported PhD students requesting health data. An error on the application was noted as the proposed agreement end date was

listed as May 2017, when this should be May 2018.

Discussion: IGARD questioned the amount of data requested, as the application did not appear to justify the wide range of data requested on all procedures given that the described PhD study seemed to focus on certain specific interventions. Concerns were raised that the application did not clearly explain the link between the described PhD study and any wider project or projects that would make use of this data, and the specific purposes involved. A reference to producing a White Paper was queried as it was unclear how this would form part of the PhD study described or whether this would be part of a wider project making use of the data. In addition IGARD considered it to be unclear what individuals would have access to data in addition to the specific PhD student referred to, given that the application described data processing by 'Imperial College London researchers'.

IGARD also requested clarification of the data years requested, as section five described this as data from 2006 onwards whereas section three included 2005-06 data. Confirmation was requested of whether the 2005 data would be included.

A query was raised about the involvement of Global Health Innovation and the potential for outputs to be shared worldwide; however it was felt that this would be appropriate provided that all outputs would only contain aggregated data with small numbers appropriately suppressed. IGARD noted the use of technical and academic language in section five of the application and advised that applicants should keep in mind the need for this section to be comprehensible to a lay audience when published as part of the data release register. It was noted that the language used in the study protocol was simpler and easier to follow for a lay audience, and IGARD noted that NHS Digital had advised the Unit submitting the application to mirror that type of language within the application but it was not clear how well this advice had been followed. IGARD suggested that the Unit should work closely with NHS Digital in submitting any future applications.

Outcome: Not recommended for approval.

- Clarification was needed of the specific purposes for which data would be used, and in
 what way the purposes of the proposed project or projects are wider than the limited
 range of procedures in section 5, as well as clarifying the role of this project in the
 production of a White Paper.
- It was considered that the amount of data requested was not justified by the stated purposes.
- Confirmation was requested of what members of staff would have access to the data in addition to the PhD student referred to.

The data years requested should be clarified to be clear whether this only includes data from 2006 onwards, or also 2005-06 data as per section 5.

IGARD emphasised the importance of describing the use of data clearly for a lay audience within section 5.

It was noted that the proposed agreement end date would be corrected to 31 May 2018. IGARD advised that the Unit submitting this application should work closely with NHS Digital in the construction of any future applications

2.5 <u>Imperial College London - An evaluation of the relationship between surgical performance metrics with clinical patient outcomes (Presenter: Kimberley Watson) NIC-80304-H6P6R</u>

Application: This was a new application requesting pseudonymised HES data linked to GMC consultant codes for use in a PhD study, with the application itself submitted on behalf of the PhD student by the Big Data and Analytical Unit. IGARD were informed that the surgeons included in the cohort had consented to their involvement and the use of their GMC code, but that pseudonymised data would be disseminated from NHS Digital using the Health and Social Care Act 2012 as the legal basis.

Discussion: The potential benefits of this work were acknowledged but a number of queried were raised about the application. IGARD queried who would have access to the data in addition to the individual PhD student, given that the application referred to the 'research team' and 'researchers' processing data. In addition IGARD noted that the study protocol version reviewed by Research Ethics Committee (REC) only referred to using data about 20 surgeons, and it was unclear whether updated REC approval had been sought for the increased cohort size of 400 surgeons. It was also unclear where these surgeons would be geographically based, and how outputs would be presented in a way that would prevent individual surgeons from being reidentified. In general it was agreed that the purpose of the study and its scope should be described more clearly within the application along with how data would be used in a way that would result in the anticipated outputs and benefits.

It was noted that the territory of use was currently listed as EEA but without an explanation of why this should be the case; IGARD asked for this to be amended to restrict the territory of use to England and Wales. In addition it was agreed that the application should be amended to include that the applicant must not attempt to reidentify the data.

There was a discussion of the consultant consent forms and IGARD requested clarification of whether all surgeons had consented using the updated materials, or whether some had consented using the old materials only as the older materials were felt to be inadequate. IGARD agreed that for any ongoing recruitment, the consent materials should be updated to avoid using confusing terminology such as 'de-anonymised' and to instead describe data as pseudonymised within the information sheet in the same way that the data was described in the actual consent form.

Outcome: Not recommended for approval.

- Confirmation was requested of what members of staff would have access to the data in addition to the PhD student referred to.
- Confirmation was requested of whether all surgeons consented using the updated consent materials, and the materials should be updated for ongoing recruitment to correct the description of 'anonymised' data in line with how this is described in the consent form.
- Confirming was also requested whether updated REC approval is in place to cover the expanded cohort from 20 surgeons to 400 surgeons.
- A clearer explanation was required of the scope of this project, the purpose of the work and how data will be processed in a way that will lead to the expected benefits, with clarification of how outputs will be presented in a way that will prevent identifying individual surgeons.

Section 5 should be amended to include that the applicant must not attempt to re-identify data, and the territory of use should be corrected to England/Wales.

IGARD advised that the Unit submitting this application should work closely with NHS Digital in the construction of any future applications

2.6 Group of 4 CCGs¹ (Presenter: Stuart Richardson)

Application: This application requested a new flow of pseudonymised mental health (MHMDS, MHLDDS, MHSDS), Improving Access to Psychological Therapies (IAPT) and Children and Young People's Health (CYPHS) data. IGARD were informed that a previous agreement was in place for the CCGs to receive this data via a CSU, but due to local contractual arrangements it was not possible for that data flow to continue at this point in time. South Kent Coast CCG would therefore act as a data processor on behalf of all four CCGs, with each CCG only receiving the relevant data for their own CCG population. It was confirmed that the CCGs would need to serve a data destruction notice on the CSU that currently held

¹ NIC-72957-B6S3P NHS South Kent Coast CCG; NIC-72971-J6V4C NHS Ashford CCG; NIC-72982-T7F3W NHS Thanet CCG; NIC-72994-C1X0P NHS Canterbury & Coastal CCG

this data, to ensure duplicate data would not be held.

Discussion: IGARD noted that the application referred to the CCGs' statutory responsibilities, and asked for the template wording to be amended to specify what statute this relates to in terms of the data requested within this application. It was suggested that a reference to data access being limited to 'substantive employees' should be amended to be clear this included employees of the data processor as well as the data controllers. In addition IGARD noted a reference to each CCG only receiving its own data; it was suggested that this wording should be clarified to allow for the CCG that would act as a data processor on behalf of all four CCGs. IGARD were informed that this wording appeared slightly differently in the application version held by the presenter, and some concerns were raised about the importance of version control and ensuring that the version reviewed by IGARD would be the version reflected in any data sharing agreement.

A query was raised about the contractual arrangements for this type of group application, and it was confirmed that the application would result in a separate Data Sharing Agreement for each of the four CCGs.

IGARD queried the data sharing framework contract extension letter provided for Thanet CCG, as this referred to the CCG IG Toolkit score being found satisfactory but the application indicated that version 14 had not yet been reviewed. It was agreed the application would be updated to indicate that the CCG's version 14 IG Toolkit score had now been reviewed as satisfactory.

Some concerns were raised about the privacy notices as it was felt that some used outdated or inappropriate terms such as 'weakly pseudonymised' and others did not explain that data would be received from NHS Digital. It was suggested that the team should work with NHS Digital IG staff to check these particular privacy notices as part of the ongoing learning and training process, and IGARD requested sight of the outcome of that check for information. It was acknowledged that for these particular CCGs, the privacy notice review had taken place prior to the relevant IG privacy notice training.

Outcome: Recommendation to approve.

A reference to the CCGs having a statutory responsibility to process this data should be amended to specify which statute this relates to with specific reference to the data requested within this application. A statement that each CCG will only have access to records of its own CCG should be amended to "The CCG will only have access to records of its own CCG. The Data processor will have access to the records of the CCGs for which it is carrying out data processing." A reference to limiting access to substantive employees should be amended to be clear this refers to substantive employees of the data controllers as well as data processor. The IG Toolkit version 14 score for Thanet CCG should be updated in the application to reflect that this has now been reviewed as satisfactory.

A special condition should be added that the CCGs must serve a data destruction notice on the CSU for this data.

Action: Data Services for Commissioners to work with NHS Digital IG staff to check the privacy notices for these 4 CCGs (South Kent Coast CCG; Ashford CCG; Thanet CCG; Canterbury & Coastal CCG) as part of the ongoing training, and provide a copy of the outcome of this check to IGARD for information.

3 Any other business

There was a brief discussion about the suggestion for an IGARD communications plan.

There was also a discussion about the number of members attending each IGARD meeting, and the need to maintain an appropriate balance.

Appendix A: Summary of Open Actions

Date raised	Action	Owner	Updates	Status
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	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. 20/12/16: It was anticipated an update would be available in mid-January. 10/01/17: Ongoing. It was agreed that this action would be taken forward by Alan Hassey rather than Peter Short. 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. 31/01/17: Ongoing. It was agreed the IGARD Chair would request an update on progress of this action. 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. 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. 11/05/17: This action was not discussed due to time restrictions. 18/05/17: IGARD received a verbal update on work underway to develop 'dummy data' for the purpose of developing tools and algorithms. 15/06/17: It was agreed the IGARD Chair would contact Garry Coleman about this action and ask whether an update could be provided in the near future, or if not then agree to close the action	Open

			and to raise the topic again at a later date.	
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. 27/04/17: Gaynor offered to provide a marked up application to demonstrate the types of comments raised at Pre-IGARD, but IGARD felt that this could be potentially prejudicial to the consideration of that application. 04/05/17: Ongoing. This had been discussed as part of the morning educational session. 18/05/17: IGARD received a verbal update about the increased involvement of the IG Advisor in Pre-IGARD and about the role of Operational IG staff within DARS. There was a suggestion that the Deputy Caldicott Guardian could also attend Pre-IGARD. IGARD advised that it would still be helpful to have sight of a checklist to confirm what items should be checked prior to an application reaching an IGARD meeting. 01/06/17: IGARD were given a brief update about the work underway, including involving the IG Advisor more actively in the Pre-IGARD process and it was hoped the Deputy Caldicott Guardian could also attend Pre-IGARD. 15/06/17: IGARD noted the steps that had been taken with Pre-IGARD, such as the increased involvement of the IG Advisor, and there had been a discussion of a possible checklist at the June education session and it was acknowledged that some points such as due diligence would be picked up elsewhere in the application process rather than specifically at Pre-IGARD. It was agreed a further education session should be scheduled to discuss the application process before IGARD, and the action was closed.	Closed
23/03/17	To provide a response to previously raised IGARD	IGARD	06/04/17: An update had been provided and the action remained	Open

	queries about indemnity.	Secretariat	open. 13/04/17: This was ongoing within NHS Digital. 01/06/17: The Caldicott Guardian had request a meeting with the IGARD Chair and others to discuss this. 08/06/17: A call had been scheduled to discuss this. 15/06/17: Ongoing pending the scheduled call.	
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.	IGARD Chair	06/04/17: This had been raised but a response had not yet been received. 18/05/17: IGARD noted a verbal update provided about upcoming changes to the IG Toolkit and how this would be reviewed. It was agreed further clarity was still required about how this issue would be handled with existing applications until the IG Toolkit changes came into effect. 15/06/17: IGARD noted the upcoming changes to the IG Toolkit and requested a future education session item to discuss this in more detail. It was agreed the action should be closed for the time being.	Closed
20/04/17	IGARD Chair to contact key stakeholder organisations regarding the benefits of uses of data to feed into the IGARD annual report.	IGARD Chair	15/06/17: Ongoing.	Open
27/04/17	IGARD Chair to contact the NHS Digital Caldicott Guardian regarding GPs' data controller responsibilities for fair processing around risk stratification.	IGARD Chair	18/05/17: Ongoing. It was agreed this would be discussed with the Deputy Caldicott Guardian. 15/06/17: Ongoing.	Open
04/05/17	Robyn Wilson and Joanne Treddenick to agree updated wording for the PCMD application template on type two objections, ensuring that this is consistent with published NHS Digital information about exceptions to type two objections.	Robyn Wilson	11/05/17: The IG Advisor gave a verbal update with confirmation that in October 2016 NHS Digital had confirmed a decision that type two objections would not be considered to apply to this flow of data due to the specific legal gateways around ONS data sharing. Further work was planned to agree the specific application wording to describe this. 18/05/17: IGARD were informed by the Secretariat that Robyn and Joanne had agreed new draft wording, and that this would be circulated to IGARD for discussion out of committee. 25/05/17: The new draft wording had been circulated out of	Open

			committee and members were reminded to provide any comments by email if they wished to do so. 08/06/17: There had been a further discussion of the wording by email. 15/06/17: IGARD had received an updated email response to the queries raised. IGARD were asked to provide any comments on this by the following week's meeting.	
18/05/17	Garry Coleman to provide information about different arrangements for data storage and backup locations, for consideration of whether the organisations involved would be considered to be processing data.	Garry Coleman	15/06/17: IGARD had been advised by email that a paper about this would be submitted to an upcoming IGARD meeting.	Open
25/05/17	Dave Cronin to provide information to IGARD regarding the NHS Digital policy on how different types of data sharing agreement breaches are classified and handled.	Dave Cronin	08/06/17: This had been provided by email. It was agreed IGARD members would share any questions or comments by the following meeting. 15/06/17: The information was noted and the action was closed.	Closed
25/05/17	IGARD Chair to contact Garry Coleman regarding the special condition wording around version 14 IG Toolkit review, and the associated risk of requiring applicants to report back to NHS Digital.	Garry Coleman	01/06/17: The IGARD Chair had contacted Garry Coleman but had not yet had a response due to annual leave. 08/06/17: It was agreed that the action owner would be changed to Garry Coleman, pending a response. 15/06/17: IGARD agreed to close this action.	Closed
01/06/17	IGARD Chair to contact the Director of Data Dissemination regarding the out of committee sign- off for Monitor NIC-15814-C6W9R.	IGARD Chair	08/06/17: The IGARD Chair had sent an email regarding this and it would be discussed further in person. 15/06/17: This discussion had now taken place. IGARD acknowledged the need to be clear in outcome wording, particular with regards to references to the application abstract as this would not form part of the data sharing agreement. IGARD emphasised the need for transparency and for the Director to inform the IGARD Chair of the reason for any out of committee sign-off outside the usual agreed processes, and for this to be reflected in the out of committee report included in the published IGARD minutes.	Closed
01/06/17	IGARD Chair to feedback to NHS Digital about the need to ensure applications coming to IGARD include the appropriate, up to date documentation	IGARD Chair	15/06/17: This had been raised within NHS Digital and the action was closed.	Closed

	such as the most recent commissioning letter.			
01/06/17	IGARD Chair to contact the Wellcome Trust about their work around 'Understanding Patient Data' communications and how this could influence NHS Digital's applications.	IGARD Chair	15/06/17: The IGARD Chair had contacted Nicola Perrin about this work and it was hoped she could attend an upcoming IGARD meeting to discuss this.	Closed
01/06/17	Garry Coleman to provide information about the process for applicants moving from the use of identifiable to pseudonymised data and what standard steps are taken when they opt to retain identifiable data as well as receiving new pseudonymised data.	Garry Coleman	15/06/17: Ongoing.	Open
15/06/17	NHS Digital to provide information about the standard approach to data destruction where an applicant has been provided with data for linkage, and whether the original data should be retained as well as the linked data.	Jen Donald		Open
15/06/17	Data Services for Commissioners to work with NHS Digital IG staff to check the privacy notices for these 4 CCGs (South Kent Coast CCG; Ashford CCG; Thanet CCG; Canterbury & Coastal CCG) as part of the ongoing training, and provide a copy of the outcome of this check to IGARD for information.	Stuart Richardson		Open

Appendix B: Out of committee report (as of 09/06/17)

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

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

 NIC 63345 London School of Hygiene & Tropical Medicine (Considered at 1st June 2017 IGARD meeting)