Data Access Advisory Group (DAAG)

Minutes of meeting held 28 April 2015

Members: Alan Hassey, Eve Sariyiannidou, Dawn Foster, Sean Kirwan

In attendance: Frances Hancox, Alex Bell, Dickie Langley, Garry Coleman, Nicola Mallender-Ward, Jennifer Donald

Apologies: Patrick Coyle, John Craven

1	**Review of previous minutes and actions** The minutes of the 21 April 2015 meeting were reviewed and agreed as an accurate record. Action updates were provided (see table on page 5). A query was raised regarding a draft memorandum of understanding (MoU) and it was agreed that the Acting Chair would seek clarification regarding any HSCIC data disseminations that might not be considered by DAAG. **Action:** Acting Chair to seek clarification from Martin Severs regarding any HSCIC data disseminations that might not be considered by DAAG. Garry Coleman provided a brief update on appointments with the Information and Analytics directorate, and offered to provide an updated structure chart. The possibility of IAOs and case managers observing DAAG meetings was raised, and it was suggested that this could be arranged as part of a future training day. **Out of committee recommendations** The following application had previously been recommended for approval subject to caveats, and it had been confirmed out of committee that the caveats had now been fulfilled: • NIC-330126 Methods Insight Analytics
2 **2.1**	**Data applications** <u>University of Oxford – Missing data in PROMs (Presenter: Dickie Langley) NIC-332667-P2G0W</u> **Application:** This application was for pseudonymised, non-sensitive Hospital Episode Statistics (HES) data and sensitive Patient Reported Outcome Measures (PROMs) data focused on hip and knee operations, for a methodological study into missing data within PROMs. It was noted that this research was part of a DPhil project but that it had been funded by the Medical Research Council. **Discussion:** DAAG queried the data retention period, as a reference in the application summary to 'if Oxford wish to archive all electronic records of the data' appeared to be contradicted by a later statement that the University intended to retain all data for a minimum of three years. It was agreed that this would be clarified. DAAG noted that the application stated that ethics approval was not required for this research, and requested evidence of this. Queries were raised regarding the status of this research as part of a DPhil project, as it was not clear whether a student with access to the data would be subject to the same sanctions as a University employee would be in the event of a data confidentiality breach. It was agreed that the applicant would be asked to confirm what the consequences would be if data were misused.

	There was a discussion of how this application could potentially benefit health and social care. DAAG queried a statement in the application summary that the research aimed to create a better understanding of missing data in research, 'particularly randomised controlled trials', as it was not sufficiently clear how research into missing PROMs data focused on hip and knee replacements would impact directly on randomised controlled trials. Further information was requested regarding this, and regarding how the research was expected to impact on current practice **Outcome:** Unable to recommend for approval. Additional information was requested about the controls in place between the University and the student in question in the event of a confidentiality break. Clarification was requested of the explicit link between the data requested and the anticipated benefits, particularly for randomised controlled trials, and how this will impact on current practice in terms of clinical research and missing data. A clearer explanation was requested of the data retention period, and confirmation was requested that ethics approval was not required.
2.2	University of Sheffield - ScHARR (Presenter: Garry Coleman) NIC-311784-G0N4B **Application:** This was a new application for pseudonymised, non-sensitive HES data for the Yorkshire and Humber region only, in order to study groups of patients with long term conditions where unnecessary variation in hospital and A&E attendance could potentially be avoided. The outputs of this work would inform healthcare commissioners and policy makers, and aggregated outputs would be shared as part of evidence briefings for commissioners and NHS trusts in addition to publication in peer reviewed health journals. **Discussion:** A query was raised regarding a reference in the application papers to interviewing patient groups, and whether any data collected through these interviews would be linked to the data requested from the HSCIC. It was agreed that the application summary would be updated to clarify that the data provided will not be linked to any identifiable data from other sources. References in the application to a 'project' and 'study' were queried, and it was clarified that the study was part of a wider project of work but that the data requested could only be used for the purpose described in the application summary. The Acting Chair noted the excellence of this application summary, and commented that it might be used as an exemplar. **Outcome:** Recommendation to approve.
2.3	HSCIC Clinical Audit Support Unit (CASU) - Bowel Cancer Audit (Presenter: Dickie Langley) NIC-298631-R9Y3L **Application:** This application was to renew an existing data sharing agreement for data to flow to the HSCIC CASU and to the Royal College of Surgeons Clinical Effectiveness Unit (CEU), both of whom acted as data processors on behalf of the Health Quality Improvement Partnership (HQIP), the data controllers who commissioned the audit. Section 251 support was in place to cover the flows of HES data described, with Office for National Statistics (ONS) mortality data also supplied under section 42(4) of the Statistics and Registration Service Act 2007. The complexity of the data flows involved was acknowledged, and a data flow diagram was provided. It was noted that patient identifiers would be removed before data was shared with the Royal College of Surgeons CEU. **Discussion:** Some concerns were raised regarding the fair processing materials for this audit, as it was noted that there was an overlap between the materials used for this audit and those for the OG Cancer audit, which had been considered by DAAG on 21 April 2015 (NIC-303776-B2X1W). It was agreed that as DAAG had previously recommended that these materials should be updated, the applicant should be asked to provide an update on this. The Data Protection Act (DPA) registration wording for the Royal College of Surgeons was

discussed, and it was noted that the Royal College of Surgeons had made a request to the Information Commissioner's Office (ICO) for this wording to be amended.

Outcome: Recommendation to approve subject to the provision of evidence and an undertaking from the applicant that fair processing materials will be updated in line with examples of good practice.

2.4 UK Biobank (Presenter: Garry Coleman) NIC-300295-L8Y9K

Application: This application was presented to DAAG for advice only. In particular advice was requested on the consent model and materials used by UK Biobank, as it was noted that participant consent had been obtained some years previously and opinions regarding good practice for consent materials had progressed since then. Advice was also requested on the controls that should be in place for the onward sharing of data, given that UK Biobank would make the data provided by the HSCIC available to other researchers.

Discussion: DAAG discussed the importance of ensuring that appropriate controls were in place for the onward disclosure of data. It was suggested that these should be comparable to the controls that were in place for HSCIC data disclosures, and for example UK Biobank should maintain and publish a register of data disclosures as well as ensuring that any uses of data were compliant with the Care Act 2014. DAAG agreed that these controls should be comparable to those in place for other organisations that shared HSCIC data onwards for use by third parties, such as CPRD and Cegedim. Confirmation was requested of how UK Biobank handled patient objections or the withdrawal of participant consent, as well as how these were handled by third party organisations accessing data.

The consent materials were discussed and it was agreed that these would not be considered sufficient for any studies recruiting participants now, particularly as it was felt that the phrase 'access to health data' was not sufficiently clear. However it was acknowledged that recruitment had ended a number of years previously, and UK Biobank had consulted with appropriate bodies at the time when the consent materials were designed. DAAG agreed that the consent materials should be updated if any further participant recruitment was planned, but otherwise did not consider that this would be necessary. However, there were some concerns regarding the information made available to existing participants and DAAG emphasised the importance of ensuring that clearer information about how data was collected and used was made easily accessible to participants.

Outcome: DAAG's advice was that controls should be in place for the onward sharing of HSCIC supplied data that are comparable to those for other organisations such as CPRD and Cegedim. Clarification was requested of how the applicant addressed the requirements of the Care Act 2014, as well as how the applicant and its customers handled objections. DAAG advised that consent materials would only need to be updated if further recruitment was planned, but that clearer information should be made available to participants about how their data is collected and used.

2.5 Imperial College London - Dr Foster Unit (Presenter: Garry Coleman)

Application: This application, which had previously been considered by DAAG on 18 November 2014, was to renew the flow of sensitive and identifiable data HES data to the Dr Foster Unit at Imperial College London. A letter had been provided from the Health Research Authority Confidentiality Advisory Group (CAG) stating that section 251 support had been renewed subject to a number of caveats, but it was noted that not all these caveats had yet been completed.

It was explained that approval had previously been given for pseudonymised data to be shared onwards from the Dr Foster Unit to Dr Foster Intelligence, a commercial organisation. However as a result of the section 251 renewal a number of changes had been made to processes, including that the identifiable data received by Imperial College could now only be used to provide a re-identification service to acute NHS trusts if that trust was a customer of Dr Foster Intelligence.

	DAAG were asked to consider the use of a sublicense for pseudonymised data to flow from Imperial College to Dr Foster Intelligence. It was noted that this application did not yet have a NIC reference number. **Discussion:** DAAG noted that the section 251 letter from CAG stated that it should be read in conjunction with two additional letters, which had not been provided. Copies of these two letters were requested. In addition, a query was raised regarding whether the sensitive fields requested by the applicant were covered by the section 251 support as this was not specified in the letter. References to Dr Foster Limited and Dr Foster Intelligence were queried. It was confirmed that these two names referred to the same organisation, and the application would be updated to clarify this. It was agreed that the application would also be updated to include a commitment that data would not be shared outside the European Economic Area. A query was raised regarding the DPA registration wording for Dr Foster Intelligence, as it was not thought that this covered the work described. In addition DAAG queried the amount of data requested, and requested a clearer justification for this. It was noted that DAAG had previously raised some concerns regarding the fair processing notice for this use of data, and that an updated link had now been provided for the amended fair processing notice. Confirmation was requested of whether the previous version had been removed from the applicant's website. **Outcome:** Unable to recommend for approval. DAAG requested sight of the two additional letters from HRA CAG and confirmation of whether the sensitive fields requested are included in the section 251 support. The applicant's DPA wording did not appear to cover the work described. A clearer justification was requested for the amount of data requested. The application would be updated to include a commitment that data will not be shared outside the European Economic Area, to clarify references to Dr Foster Limited and Dr Foster Intelligence, and to clarify whether the fair processing materials linked to are in addition to or a replacement of the fair processing statement previously linked to.
3	**Any other business** There was a further discussion regarding the University of Dundee – SCOT Trial application (NIC-323893-J8B4H) that had been considered at the 21 April 2015 meeting. DAAG reiterated their advice that the consent materials did not appear to provide a legal basis to release the HES data requested. It was agreed that Jennifer Donald and the Head of IG would discuss the history of the application in more detail.

Summary of Open Actions

Date raised	Action	Owner	Updates	Status
24/02/15	DAIS team to discuss the approach to local patient identifiers (LOPATID) with HRA CAG.	DAIS team	03/03/15: Discussions were taking place with HRA CAG, and the response would be fed back to a future DAAG meeting. 10/03/15: An initial response had been received and this would be shared with DAAG members for information. 17/03/15: Ongoing. 25/03/15: Ongoing. 31/03/15: Ongoing. 07/04/15: Ongoing. 13/04/15: Ongoing. 21/04/15: Discussions were underway between HRA CAG and David Evans. 28/04/15: Ongoing.	Open
24/02/15	DAIS team to raise with HRA CAG the possibility of stage 1 accredited safe havens receiving both data that is identifiable by NHS number and data that is identifiable by postcode.	Diane Pryce	03/03/15: Discussions were taking place with HRA CAG, and the response would be fed back to a future DAAG meeting. 10/03/15: An initial response had been received and this would be shared with DAAG members for information. A further query had been raised and discussions were ongoing. 17/03/15: Ongoing. 25/03/15: Ongoing. 31/03/15: Ongoing. 07/04/15: Ongoing. 13/04/15: Ongoing. 21/04/15: Ongoing. 28/04/15: Ongoing.	Open
25/03/15	Dawn Foster and Eve Sariyiannidou to update the recommended consent wording following discussions at 25 March training	Dawn Foster	31/03/15: Ongoing. 07/04/15: Ongoing. 13/04/15: Email discussion was underway regarding the draft wording. It	Open

	day.		was suggested that it would not be possible to specify one recommended phrase that could be used for all studies, but that advice could be given on the type of wording that would best fit a range of different scenarios. It was also suggested that the guidance on consent should be dated and version controlled, to ensure that if advice changed in future then it would be possible to determine whether applicants had followed the appropriate advice at the time when they had sought consent. 21/04/15: It was agreed that rather than providing a specific paragraph of recommended consent wording, the existing consent guidance should be updated to include a breakdown of what consent wording should cover. 28/04/15: Ongoing.	
25/03/15	DAAG dashboard to be updated to include recommendation themes, the number of times applications are considered by DAAG and a breakdown of recommendations by applicant type (academic, NHS trust, commissioning organisation, commercial organisation).	Alex Bell	31/03/15: Ongoing. 07/04/15: Ongoing. 13/04/15: It was agreed that an updated dashboard would be provided for the next training session, and DAAG asked for a copy to be circulated prior to the meeting. 21/04/15: Ongoing. 28/04/15: The applications tracker had been updated to include additional fields, and the updated dashboard would be provided in advance of the 5 May meeting.	Closed
13/04/15	Garry to raise with the DARS team that DAAG have requested sight of the draft MOU between the HSCIC and Public Health England.	Garry Coleman	21/04/15: Ongoing. 28/04/15: Sight of the draft MOU had been requested, and a copy would be provided following other internal review.	Closed
13/04/15	Garry Coleman and Dawn Foster to discuss the process for applications requesting access to ONS data.	Dawn Foster	21/04/15: Ongoing. 28/04/15: This had been discussed and resolved.	Closed
21/04/15	DAAG Secretariat to confirm June date for DAAG training day.	DAAG Secretariat	28/04/15: The date was confirmed as 2 June 2015.	Closed
28/04/15	Acting Chair to seek clarification from Martin Severs about HSCIC data disseminations that might not be considered by DAAG.	Acting Chair		