

Data Access Advisory Group (DAAG)

Minutes of meeting held 21 April 2015

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

In attendance: Frances Hancox, Susan Milner, Dickie Langley, Peter Hall, Jenny Westaway, Jonathan Hope, Jennifer Donald, Stephen Cowley

Apologies: Patrick Coyle, John Craven

1	<p>Review of previous minutes and actions</p> <p>The minutes of the 14 April 2015 meeting were reviewed and agreed as an accurate record, subject to correcting the meeting date. Action updates were provided (see table on page 5).</p> <p>Out of committee recommendations</p> <p>The following applications had previously been recommended for approval subject to caveats, and it had been confirmed out of committee that the caveats had now been fulfilled:</p> <ul style="list-style-type: none">• University of Cambridge NIC-330892-Q5J3T• Competition and Markets Authority NIC-330916-S9Q1W
2 2.1	<p>Data applications</p> <p><u>HSCIC Clinical Audit Support Unit (CASU) OG Cancer Audit (Presenter: Dickie Langley) NIC-303776-B2X1W</u></p> <p>Application summary: This was an application for the HSCIC Clinical Audit Support Unit (CASU) to process identifiable, sensitive linked Hospital Episode Statistics (HES) and Office for National Statistics (ONS) mortality data on behalf of the Health Quality Improvement Partnership (HQIP), who would act as data controller. The data provided to CASU would be linked with data from other sources such as Patient Episode Data for Wales and then pseudonymised and disseminated to the Royal College of Surgeons for linkage to audit data they already held using the Audit Tumour ID. It was confirmed that support was in place for this under section 251 of the NHS Act 2006, and a letter had been provided from the Health Research Authority Confidentiality Advisory Group (HRA CAG) confirming support. The annual renewal process for this support was underway.</p> <p>Discussion: Due to the complexity of the data flows involved in this application, there was a suggestion that a data flow diagram would help to provide a clearer explanation. It was agreed that a data flow diagram would be appended to the application summary, and would also be included with the data sharing agreement. DAAG queried where the data linkage referred to in the application would take place, and it was confirmed that data would be linked within the HSCIC before it was provided to the Royal College of Surgeons.</p> <p>A query was raised regarding whether the questions previously raised regarding this application had been answered. It was noted that HQIP had not yet signed a data sharing framework contract with the HSCIC, and therefore no data would be provided until that was in place. The legal basis for the receipt of ONS data had been resolved, as a commissioning letter from NHS England had been provided and it had been confirmed that this fulfilled the requirements for data to be provided under section 42(4) of the Statistics and Registration Service Act 2007. It was note that HQIP had not completed the Information Governance (IG) Toolkit, but as that organisation would not handle</p>

any data IG Toolkit scores had instead been provided for the HSCIC and the Royal College of Surgeons. In addition, the Data Protection Act (DPA) registration wording for the Royal College of Surgeons did not currently appear to cover the work described, and confirmation had been requested that this would be updated.

DAAG discussed the fair processing materials for this application. While it was generally felt that the applicant had made efforts to inform the general public of this use of data, there were concerns that some of the information given did not appear sufficient. In particular it was felt that some of the question headings referred to in the application summary, such as 'Who provides what data and in what form' were not clearly answered. It was agreed that the patient materials should answer this question more clearly, and specify what information would be shared and linked, and whether this would be identifiable or not.

Outcome: Recommendation to approve subject to confirmation of an appropriate updated DPA registration for the Royal College of Surgeons, and subject to fair processing materials being improved in line with DAAG's comments. Data flow diagram to be appended to the application summary and to the data sharing agreement.

2.2 The Health Foundation (Presenter: Dickie Langley) NIC-321421-Z4V4N

Application summary: This application from an independent charity requested pseudonymised, non-sensitive HES data to support four specific projects around healthcare funding pressures, hospital phenotyping, readmission penalisation and factors associated with A&E performance.

Discussion: DAAG noted the potential importance of this work, and the likely interest in the outputs. However further information was requested regarding how outputs would be disseminated and how benefits to health and social care would be realised, and in particular it was suggested that it would be helpful if specific examples could be provided of how data had been used to achieve benefits in the past.

The need to ensure proportionality was discussed, and it was agreed that while on balance the amount of data requested seemed to be proportionate to the purposes for which the data would be used it would have been helpful if a clearer justification had been provided for the amount of data requested. Given the amount of data requested, it was agreed that the applicant should be asked to confirm that they would not seek to combine this with any other datasets that could increase the risk of individuals being re-identified.

Outcome: Recommendation to approve subject to the applicant providing further information about dissemination and how data has been used in the past, and subject to confirmation that given the size of the dataset requested, the applicant will not combine it with any other data that could increase the risk of individuals being re-identified.

2.4 University of Leeds - Yorkshire Specialist Register of Cancer in Children and Young People (Presenter: Dickie Langley) NIC-316673-T0G2R

Application summary: This application had previously been considered by DAAG on 10 February 2015, when they had been unable to recommend approval, and an updated application was now provided for advice only. Additional wording had been provided that would be added to the applicant's fair processing materials depending on the feedback from DAAG.

Discussion: DAAG had previously queried why the applicant required identifiable data rather than pseudonymised data to carry out work, and an explanation for this had been provided. However clarification had also been requested regarding the geographic area for which data was requested, the legal basis for the data currently held by the applicant, and whether the section 251 support covered all the data requested and these points had not been addressed in the updated

application summary provided.

A reference to onward disclosure was queried, and it was suggested that the updated application should clarify that data was requested for this particular purpose only. It was also suggested that the updated application should include an explanation of how regional registries could inform policy on a national level, with consideration to the requirements of the Care Act 2014. There was a query regarding The Candlelighters Trust, which was referred to as a funding organisation, and clarification was requested of whether this organisation would have access to any of the data provided.

There was some uncertainty regarding the patient information leaflets provided and whether these were the most up to date versions, as it was noted that HRA CAG had asked for changes to be made as part of the section 251 review process. In addition it was not felt to be clear which leaflet would be provided to what group of participants. There also remained some concerns regarding the wording of the leaflets, as in particular it was felt that a reference to a law regarding cancer registration could be misleading for participants, and the importance of clearly informing participants that participation was not obligatory was emphasised.

In addition to these points, it was noted that a version 12 IG Toolkit score had not been provided and the applicant's DPA registration wording did not appear to cover the work described.

Outcome: DAAG provided advice on the points that would need to be addressed in a future application, and suggested that the application summary be updated to address the points raised by DAAG previously. There remained concerns around the patient information and fair processing materials, with a particular query about whether the most up to date materials had been provided and which version leaflet would be shared with what group of patients, and it was suggested that the updated draft materials should be provided to DAAG. The DAIS team would be asked to confirm whether all the data requested was appropriately covered by the section 251 support. Clarification was requested about the current legal basis for the applicant to hold data previously received. Clarification was also requested of what geographical area data is requested for, and of the role of the Candlelighters Trust as a funding organisation and whether they would be given access to any data. The applicant's version 12 IG Toolkit score was requested, as well as updated DPA registration wording as this was currently not appropriate.

2.3 British Society of Gastroenterology - IBD Registry (Presenter: Stephen Cowley) NIC-332294-X9L6Y

Application summary: This application was for advice only. It was intended that an application would in future be brought to DAAG for pseudonymised, non-sensitive Inflammatory Bowel Disease (IBD) Registry data linked to HES data. It was noted that the British Society of Gastroenterology had not yet completed the IG Toolkit, although this was underway, and they would therefore not handle any individual level data until this had been completed.

Discussion: Queries were raised regarding some of the language used in the application summary, the legal basis referred to in the data flow diagram, and which organisation would act as data controller and processor.

There was some uncertainty regarding what advice was sought from DAAG, as well as what documents in particular DAAG were being asked to review. The application was therefore withdrawn. DAAG emphasised the importance of ensuring that when an application was submitted for advice it was made clear what particular aspects of the application DAAG were required to advise on.

Outcome: Application withdrawn, as it was unclear what advice was sought from DAAG.

2.5	<p>University of Dundee – SCOT Trial (Presenter: Jennifer Donald) NIC-323893-J8B4H</p> <p>Application: This application was brought to DAAG for advice only, due to concerns that had been raised by the IAO about the adequacy of the consent materials supplied as part of this application. A data sharing agreement was currently in place for the applicant to receive Personal Demographics Service (PDS) data and ONS mortality data for a consented cohort as part of a trial comparing anti-inflammatory painkillers. This application was to amend that agreement so that the applicant could also receive HES data for the cohort.</p> <p>It was explained that the trial database would be locked in June, and the applicant was therefore under a significant time restraint as no additional data could be added to the database after that date. The applicant had raised concerns about the impact on the trial and therefore the potential negative impact on drug safety if the requested data could not be provided prior to the database lock date. DAAG was therefore asked to review the consent materials provided to see if they might be adequate , and on what practical steps might be taken given the impending research deadline.</p> <p>Discussion: It was noted that DAAG had previously considered an application from this applicant at the 22 November 2012 meeting (application reference MR1305), when it had been recommended that the applicant should amend their consent materials. The application had subsequently been approved on 29 January 2013. However, it was not clear from the papers provided whether any changes to consent materials had been made as a result of DAAG’s previous recommendation.</p> <p>DAAG members raised concerns regarding the consent materials provided, particularly as these included Scotland-specific references that would not be applicable to English participants. It was felt that these consent materials would not provide a current legal basis to provide HES data to the applicant.</p> <p>On that basis, DAAG requested that the DAIS team should review the history of this application, including what approvals had previously been given and whether the applicant had addressed the concerns regarding the consent materials that had been raised in November 2012.</p> <p>Outcome: DAAG’s view was that the consent material provided did not seem to provide a legal basis to release the data requested. The DAIS team were asked to review the history of this application and report back to the Head of IG.</p>
3	<p>Any other business</p> <p>There was a query about future DAAG training dates, and it was agreed that the DAAG Secretariat would confirm a June date.</p> <p>Action: DAAG Secretariat to confirm June date for DAAG training day.</p>

Summary of Open Actions

Date raised	Action	Owner	Updates	Status
20/01/15	Alex Bell to discuss the application form template with DARS team and consider adding a section asking applicants to demonstrate how their intended use of data and dissemination of results would be compliant with the Care Act 2014.	Garry Coleman	<p>27/01/15: This discussion had been scheduled, and details would be fed back to DAAG.</p> <p>03/02/15: It was agreed that this should be discussed with Garry Coleman in the context of the papers on data sharing drafted following the recent DAAG training day.</p> <p>10/02/15: Discussions had taken place about making changes to how information would be added to application forms.</p> <p>17/02/15: Ongoing.</p> <p>24/02/15: Ongoing.</p> <p>03/03/15: Ongoing.</p> <p>10/03/15: Ongoing.</p> <p>17/03/15: An update was requested on when the next planned update of the application form was scheduled to take place.</p> <p>25/03/15: Ongoing.</p> <p>31/03/15: Ongoing.</p> <p>07/04/15: Ongoing.</p> <p>13/04/15: DAAG requested an update on when the application form was next scheduled to be updated, and Garry Coleman agreed to seek clarification on this point.</p> <p>21/04/15: The application form would be updated through the new process, and an update on this would be provided for the June training session.</p>	Closed
24/02/15	DAIS team to discuss the approach to local patient identifiers (LOPATID) with HRA CAG.	David Evans	<p>03/03/15: Discussions were taking place with HRA CAG, and the response would be fed back to a future DAAG meeting.</p> <p>10/03/15: An initial response had been received and this would be shared with DAAG members for information.</p> <p>17/03/15: Ongoing.</p> <p>25/03/15: Ongoing.</p>	Open

			31/03/15: Ongoing. 07/04/15: Ongoing. 13/04/15: Ongoing. 21/04/15: Discussions were underway between HRA CAG and David Evans.	
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.	Open
25/03/15	Dawn Foster and Eve Sariyannidou to update the recommended consent wording following discussions at 25 March training day.	Dawn Foster	31/03/15: Ongoing. 07/04/15: Ongoing. 13/04/15: Email discussion was underway regarding the draft wording. It 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.	Open
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	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	Open

	applicant type (academic, NHS trust, commissioning organisation, commercial organisation).		prior to the meeting. 21/04/15: Ongoing.	
07/04/15	DAAG members to provide feedback on National OG Cancer Audit application (NIC-303776) by email.	Acting DAAG Chair	13/04/15: DAAG members were reminded to provide feedback on this application, although it was noted that one set of comments had been emailed directly to the application presenter. 21/04/15: Comments had been provided and an updated application had been submitted.	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.	Open
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.	Open
13/04/15	DAAG Secretariat to notify DARS team that all applications should now include version 12 IG Toolkit scores rather than version 11.	DAAG Secretariat	21/04/15: The DARS team had been notified.	Closed
13/04/15	Acting DAAG Chair to write to HSCIC SIRO regarding SIGGAR/SOCCER studies at Imperial College London.	Acting DAAG Chair	21/04/15: This action had been completed.	Closed
27/04/15	DAAG Secretariat to confirm June date for DAAG training day.	DAAG Secretariat		