

Data Access Advisory Group (DAAG)

Minutes of meeting held 5 May 2015

Members: Alan Hassey, Eve Sariyannidou, Dawn Foster, Patrick Coyle, John Craven, Sean Kirwan

In attendance: Frances Hancox, Alex Bell, Victoria Williams, Dickie Langley, Garry Coleman, Susan Milner, Nicola Mallender-Ward, Jennifer Donald, Steve Hudson, Mark Taylor, Natasha Dunkley, David Evans, Jim Duffy, Joanne Bailey

Apologies: None

1	<p>Review of previous minutes and actions</p> <p>The Chair welcomed the attendees to the meeting, and there was a round of introductions. It was noted that Alex Bell would not attend DAAG meetings in future as she would be moving on to a new role, and DAAG formally thanked her for all the work she had done to support the group.</p> <p>The minutes of the 28 April 2015 meeting were reviewed and a correction was made to the discussion of the HSCIC Clinical Audit Support Unit (CASU) Bowel Cancer Audit application (NIC-298631-R9Y3L). Subject to this change, the minutes were agreed as an accurate record. Action updates were provided (see table on page 6).</p> <p>Out of committee recommendations</p> <p>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:</p> <ul style="list-style-type: none">• NIC-321421-Z4V4N - The Health Foundation
2 2.1	<p>Data applications</p> <p><u>HSCIC CASU – Chronic Obstructive Pulmonary Disease (COPD) audit (Presenter: Dickie Langley) NIC-310862-Q1W5Y</u></p> <p>Application: This application for Hospital Episode Statistics (HES) and Office for National Statistics (ONS) mortality data had previously been considered at the 17 March 2015 meeting, when DAAG had been unable to recommend approval particularly due to lack of clarity around the legal basis for the provision of ONS mortality data. A commissioning letter from NHS England had now been provided, and it had been confirmed that this provided a legal basis for the use of ONS data under section 42(4) of the Statistics and Registration Service Act 2007. A data flow diagram had been provided to clarify that identifiable data would flow into the HSCIC and be linked with other datasets, and then pseudonymised data would be shared with the Royal College of Physicians. DAAG were informed that the Data Protection Act (DPA) registration wording for the Royal College of Physicians had been updated since this application had last been considered.</p> <p>Discussion: DAAG were content that the queries previously raised regarding the legal basis for the use of ONS data had now been addressed. However, other concerns remained. In particular, DAAG had previously discussed the patient information leaflet for the audit and had noted that this did not refer to the role of the HSCIC. It was agreed that fair processing materials for the audit should clearly state where data would flow, including explaining the role of the HSCIC in processing data, and there were some concerns that based on the patient information leaflet members of the public could be led to assume that data would only be used within hospitals. The use of the term COPD was discussed, as there had previously been concerns that some members</p>

of the public might not understand this term, but on balance it was agreed that patients with a COPD diagnosis would be likely to be aware of the term.

Queries were raised regarding the flow of data to Wales and what the legal basis would be for sharing identifiable data with the NHS Wales Informatics Service (NWIS). DAAG were informed that this was currently under discussion, and that the current application excluded the flow of data to Wales, but DAAG noted that this was not stated in the application papers provided. Clarification was requested about precisely what data flows to and from Wales were planned.

Outcome: Unable to recommend for approval. Clarity was required around the intended data flows, particularly those involving Wales. Fair processing materials should be updated, including for patients whose data the HSCIC currently held, and the patient information leaflet should be updated for patients identified as part of the audit in future.

2.2 University College London – British Regional Heart Study (Presenter: Garry Coleman) NIC-311071-V4X1J

Application: This application for identifiable data requested an amendment to an existing data sharing agreement in order for the applicant to receive HES, Diagnostic Imaging Dataset (DIDs) and Mental Health Minimum Dataset (MHMDS) data for a specific cohort in addition to the ONS mortality and cancer registrations data already received. Identifiable data would be provided to the applicant, who would then remove the identifiers and provide the de-identified data on to researchers with a study identifier. DAAG were informed that the applicant required identifiable data to ensure that the linkage carried out by the HSCIC was accurate and aligned with the applicant's latest records. It was noted that recruitment for the study had ended in January 2015.

Discussion: DAAG expressed their support for the aims of this work, but it was noted that only the consent forms had been provided and not any additional consent materials such as patient information leaflets. Copies of these consent materials were requested.

DAAG noted that the consent form provided referred to the General Register Office but not to ONS, and to the NHS Information Centre rather than the HSCIC. It was suggested that if the form were updated for use again in future then this would need to be corrected.

There was some confusion regarding the different legal bases referred to in the application summary, and what elements of the work were covered by consent versus what was covered by section 251 support. It was clarified that section 251 support had been sought for the individuals who had originally agreed to participate in the study but with whom the applicant had lost touch, so that they could be contacted and asked to re-consent. It was noted that the section 251 letter from the Health Research Authority Confidentiality Advisory Group (HRA CAG) had asked the applicant to consider how the fair processing requirements of the Data Protection Act 1998 could be demonstrated at the next annual review, and DAAG requested evidence of how the applicant had made progress against this.

Outcome: Unable to recommend for approval. DAAG requested sight of consent materials and would like the applicant to provide evidence that fair processing materials demonstrate progress against the points previously set out in the section 251 approval letter from HRA CAG.

2.3 NA Wilson Associates (Presenter: Garry Coleman) NIC-313490-W2X2D

Application: This was an application to amend an existing data sharing agreement for the applicant to receive additional pseudonymised HES data, in order to support NHS organisations during financial turn-around. The applicant had previously received pseudonymised HES data for this purpose, and DAAG were informed that some of the older data previously provided had been deleted and a data destruction certificate provided. It was noted that national data was requested

in order to support work with organisations across the country, and to inform benchmarking.

Discussion: The request for national data was discussed, and DAAG queried whether it would be possible for the applicant to instead request geographic data for the specific trusts that they worked with. However it was explained that the applicant worked with various NHS organisations across the country for a limited period of time, in order to support financial turn-around, and it would not be practical to submit a new application for data for each organisation within these time constraints. It was also noted that national data was required in order to inform national benchmarking of the NHS organisations.

DAAG were informed that the applicant had made a request to the Information Commissioner's Office for their DPA registration wording to be updated. A reference to data linkage was queried, and it was clarified that this referred to how the HES data would be processed and no other datasets would be linked to. It was noted that the application summary stated that the applicant 'can supply many examples' of financial savings that had previously resulted from this work, and DAAG asked for these additional examples to be added to the application summary.

DAAG noted that the application stated that the applicant would not allow access to the Financial Benchmarking System to any organisations that wished to use the data for commercial purposes, and queried how this would be ensured. It was suggested that the sublicenses for organisations to use this data should include a statement preventing the use of data for commercial purposes.

It was noted that the applicant had provided a System Level Security Policy, which had been reviewed by the relevant HSCIC team, but that the applicant had not completed the Information Governance (IG) Toolkit. DAAG emphasised the importance of applicants completing the IG Toolkit where possible, and noted that the applicant would need to move to completing the IG Toolkit by 2016 in order to renew their data sharing framework contract.

Outcome: Recommendation to approve.

It was agreed that the application summary would be updated in line with the comments raised by DAAG, in particular providing additional details of expected benefits and ensuring that a statement preventing the use of data for commercial purposes would be included in sublicenses. DAAG noted that the applicant should have moved to completing the IG Toolkit by 2016.

2.4 NHS England – CCG Allocations (Presenter: Garry Coleman)

Application: This application was for NHS England staff to access a dataset of linked, pseudonymised Secondary Uses Service (SUS) and Personal Demographics Service (PDS) data within the HSCIC Secure Data Facility. The output of this work would be an aggregated dataset used to update the allocation formula for clinical commission groups (CCG) funding. No record level data would leave the HSCIC.

Discussion: It was noted that at the time the application was written it had been intended that data would be accessed through the HSCIC Secure Data Facility, but that as discussions were ongoing it might be that an alternative method was used to provide access to the data. DAAG requested confirmation that whatever method was used to provide access, no record level data would leave the HSCIC and access would be restricted to specific named users only.

DAAG queried whether all the named users who would access data would be NHS England employees, or whether any contractors would also potentially be given access, and it was agreed that this would be clarified. DAAG also requested confirmation that any individuals who would access data had completed the appropriate IG training.

Outcome: Recommendation to approve subject to confirmation that no record level data will leave the HSCIC, and that only named users will have access to data. Also subject to confirmation that

the named users are NHS England employees and have completed the appropriate IG training.

2.5 Imperial College London (Presenter: Dickie Langley) NIC-334380-R0J8H

Application: This application was for pseudonymised, non-sensitive HES data and had previously been considered by DAAG on 10 March 2015 (NIC-315184-V9T1R). DAAG had requested additional information regarding funding organisations as well as clarification of a reference to linking data. Additional information had been provided about funding, and it had been clarified that no additional record level data would be linked to.

Discussion: It was agreed that the queries regarding funding and data linkage had been addressed, but DAAG had also requested a clearer justification for why this amount of data had been required and there were concerns that this had not been provided. There was a suggestion that the applicant should provide evidence of the benefits that had previously been achieved by using the substantial amount of data that had already been provided.

A query was raised regarding a statement in the application summary that in some cases data would be aggregated to site level, and in some cases data would be aggregated by Trust level. It was confirmed that the approach to small number suppression set out in the HSCIC HES Analysis Guide would be adhered to.

Outcome: Unable to recommend for approval. There remained concerns regarding the lack of a clear justification for the amount data requested, in line with concerns raised when the application was previously considered, and DAAG requested clearer evidence of benefits that had been achieved from the considerable amount of data already received.

2.6 Salford Royal NHS Foundation Trust – Advancing Quality Alliance (AQuA) (Presenter: Dickie Langley) NIC-330478

Application: This application had previously been considered on 29 January 2015 (NIC-292305-D5Z1B), when DAAG had been unable to recommend approval. Clarification had been requested regarding the status of AQuA, and it had now been confirmed that AQuA was part of Salford Royal NHS Foundation Trust and was not a separate legal entity. The applicant had confirmed that ONS data was not used for any commercial purposes, and had also provided a justification for the volume of data requested. Additional information had also been provided regarding the customers and expected benefits for this use of data. DAAG were informed that work was underway within the HSCIC to confirm the legal basis for the use of ONS data under section 42(4) of the Statistics and Registration Service Act 2007.

Discussion: DAAG discussed the additional information that had been provided regarding customers and benefits, and overall agreed that the majority of their queries had been addressed. However, DAAG had previously queried whether the ONS mortality data requested included date of death or only fact of death, as this could affect the likelihood of data being re-identified, but this had not been clarified in the application summary. It was noted that there were outstanding queries regarding the legal basis for the use of ONS data, and clarification was requested regarding the legal base for the data already held by the applicant. DAAG agreed that it would be appropriate for the applicant to continue to hold ONS data while clarification was sought regarding legal basis, but that an updated application including this clarification should be submitted within two weeks.

The amount of data requested was discussed, and DAAG considered whether it should be considered proportionate to use national data for this type of work. It was suggested that this was a wider issue pertaining to a number of applications that also requested national data.

A query was raised regarding whether any of the individuals with access to the data provided were employed by other organisations, but it was confirmed that all individuals with access to the data

would be employees of Salford Royal NHS Foundation Trust.

DAAG noted the confusion that had been caused by references to AQuA as the applicant for this data and suggested that it would be helpful if the application papers could more clearly state that Salford Royal NHS Foundation Trust was the relevant legal entity for this application.

Outcome: Recommendation to approve the request for pseudonymised HES data only, but unable to recommend approval for the additional ONS data requested. Any ONS data provided by the HSCIC currently held by Salford Royal NHS FT could continue to be held, pending clarification of the legal basis for this and a revised application back to DAAG within two weeks.

3 Any other business

University of Dundee – SCOT Trial (Presenter: Jennifer Donald) NIC-323893-J8B4H

Application summary: This application had been considered by DAAG at the 21 April 2015 meeting, and discussed again under Any Other Business at the 28 April 2015 meeting. DAAG's advice had been that the consent material provided did not seem to provide a legal basis to release the data requested. Clarification had been requested about the history of this application, as it had previously been considered by DAAG in November 2012 and recommended for approval out of committee in early 2013, and additional information about this had now been provided.

Discussion: DAAG considered the history of this application and it was explained that while concerns regarding the applicant's consent materials had been raised by DAAG at the 22 November 2012 meeting, the Group had been informed by email in January 2013 that recruitment for the study was about to end. No changes had been made to the consent materials and the application had subsequently been approved out of committee.

DAAG noted that the understanding of consent had progressed in recent years, and as when this application was considered at the 21 and 28 April 2015 meetings their advice was that the consent materials alone did not appear to provide an appropriate legal basis to release the data requested.

The applicant's time restrictions due to the impending database lock data was acknowledged and DAAG advised that the applicant should commence fair processing activities to inform participants of the described use of data. This should include writing to participants, notifying general practices where participants were registered, and updating the information that was available about the study online. DAAG agreed that while it would not be practical for these activities to be completed prior to the database lock date, the applicant should ensure that activities were underway by that date. It was felt that in combination with the previously obtained participant consent, this could provide the required basis for HES data to be shared in addition to PDS and ONS data. However if the applicant was unable to undertake these fair processing activities, it was suggested that they should approach HRA CAG in order to apply for section 251 support.

Outcome: Recommendation to approve for a period of three months subject to an undertaking from the applicant that fair processing work will commence before the database lock date, including writing to participants, writing to general practices and updating the information available online. If this is not practicable, DAAG's advice is that the applicant should approach HRA CAG to apply for section 251 support.

DAAG were informed of a correction that had been made to the 13 April 2015 minutes, and these updated minutes were now available on the HSCIC website.

DAAG members were invited to review the materials provided for advice on the DAAG webpages.

Action: DAAG members to review the materials provided for advice on the DAAG webpages.

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	<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> <p>31/03/15: Ongoing.</p> <p>07/04/15: Ongoing.</p> <p>13/04/15: Ongoing.</p> <p>21/04/15: Discussions were underway between CAG and David Evans.</p> <p>28/04/15: Ongoing.</p> <p>05/05/15: Advice had been sought from CAG on the approach they took to handling applications which include access to the field LOPATID as DAAG members had questioned how identifiable this data field was. DAAG were informed that CAG assess each application on a case by case basis taking into account the other data items already held, the data items being requested, and the purpose the data is to be used for as this can impact whether this field should be classed as identifiable or not.</p>	Closed
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.	Dawn Foster	<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. A further query had been raised and discussions were ongoing.</p> <p>17/03/15: Ongoing.</p> <p>25/03/15: Ongoing.</p> <p>31/03/15: Ongoing.</p> <p>07/04/15: Ongoing.</p> <p>13/04/15: Ongoing.</p>	Open

			21/04/15: Ongoing. 28/04/15: Ongoing. 05/05/15: It was agreed that Dawn Foster would raise this separately with CAG.	
25/03/15	Dawn Foster and Eve Sariyiannidou 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. 28/04/15: Ongoing. 05/05/15: The example wording had been updated, and it was agreed that this would be used to update the advice on consent published on the DAAG webpages.	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	05/05/15: This had been raised, and the action was closed.	Closed
05/05/15	DAAG members to review the materials provided for advice on the DAAG webpages.	Acting Chair		Open