

Data Access Advisory Group (DAAG)

Minutes of meeting held 30 June 2015

Members: Alan Hassey (Acting Chair), Eve Sariyannidou, Joanne Bailey, John Craven, Patrick Coyle, Dawn Foster

In attendance: Frances Hancox, Victoria Williams, Diane Pryce, Dave Cronin, Steve Hudson, Dickie Langley, Gaynor Dalton, Garry Coleman

Apologies: Sean Kirwan

1	<p>Review of previous minutes and actions</p> <p>The minutes of the 16 June 2015 meeting were reviewed, and a minor correction was raised to the discussion of the University Hospitals Bristol NHS Foundation Trust application (NIC-319738-F3W3L). Subject to this amendment, the minutes were agreed as an accurate record.</p> <p>Action updates were provided (see table on page 9).</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-325964-L1W7R Imperial College London Healthcare NHS Trust
2	<p>Data applications</p>
2.1	<p><u>University of York - Department of Economics and Related Studies (Presenter: Dave Cronin)</u> <u>NIC-339273-J7S5V</u></p> <p>Application: This application was to enable the applicant to use the Hospital Episode Statistics (HES) and Office for National Statistics (ONS) mortality data that had previously been supplied under agreement NIC-324101-P4Y7Z (considered by DAAG on 27 May 2015) for an additional ninth project, in order to assess the impact of hospital admission survival rates on emergency re-admission rates. It was noted that Approved Researcher accreditation and Microdata Release Panel approval were in place for the use of ONS data.</p> <p>Discussion: DAAG noted that evidence of the relevant ONS approvals had not been provided in the application pack, and requested confirmation from the Data Access and Information Sharing (DAIS) team that these approvals were in place.</p> <p>The processing involved was queried, as it was not felt to be clear how the applicant would select a sample from the dataset. It was confirmed that the applicant would use the data that was already held by applying a query to that dataset, rather than receiving any additional data, and it was agreed that this dataset should be listed on the application form in the 'Data Already Held' section. DAAG suggested that a data flow diagram would have helped to clarify this point.</p> <p>DAAG queried the role of the funding organisation The Health Foundation, and whether this organisation would receive any specific outputs from the data. It was confirmed that an aggregated report would be shared with the Health Foundation in addition to findings being shared with the Department of Health. DAAG requested that in future the involvement of funding organisations should be described more clearly in applications.</p>

Outcome: Recommendation to approve subject to the application being updated to list the data already held by the applicant, and subject to confirmation from the DAIS team that the appropriate ONS approvals are in place.

2.2 University Hospitals Bristol NHS Foundation Trust - Benefit of CMR after PPCI pathway activation (Presenter: Dave Cronin) NIC-319738-F3W3L

Application: This application had previously been considered at the 10 March and 16 June 2015 DAAG meetings. DAAG had requested additional details of how fair processing information would be updated and made available to participants, as well as details of staff disciplinary arrangements between the Trust and the University of Bristol for those staff on honorary contracts. A response from the applicant had been provided for both these points.

Discussion: It was noted that a copy of the updated Staff Conduct Policy had been received but that this had not been available in time for the current DAAG meeting. This policy would be circulated to DAAG members out of committee for their input ahead of an updated application being brought to a future meeting. DAAG emphasised the need to ensure for all applications that individuals working under honorary contracts would be subject to appropriate disciplinary actions from their employing organisation should a confidentiality breach occur.

DAAG were informed that an email response had been received from the applicant regarding fair processing and the consent process, which had stated that the study website would be updated in July 2015 with information about the data requested from the HSCIC, what the data would be used for, and how participants could opt out. It was agreed that this would likely address the majority of DAAG's previously raised concerns, and DAAG requested sight of the email. References to the study newsletters were discussed, and DAAG suggested that the applicant should consider whether it would be practical to issue an updated newsletter to participants containing information about this data usage prior to receiving data from the HSCIC.

It was noted that the application pack did not include evidence of the relevant approvals for access to ONS data, and it was agreed that confirmation of this should be provided.

Outcome: Recommendation deferred. DAAG requested sight of the email response from the applicant regarding fair processing, confirmation that appropriate ONS approvals are in place, and sight of the relevant employment policies in order to confirm that a confidentiality breach while working under an honorary contract would be subject to appropriate disciplinary actions.

2.3 Imperial College London – Department of Surgery and Cancer (Presenter: Dave Cronin) NIC-315716-L0F4M

Application: This application was for the applicant to receive a pseudonymised, non-sensitive HES dataset that would then be used for six separate projects within the Department of Surgery and Cancer. The application summary specified what data would be used for which project, and what the processing, outputs and expected benefits of each project would be.

Discussion: DAAG acknowledged that including multiple projects in one application followed the process that had been agreed for other applications, but some concerns were expressed regarding the difficulty of reviewing six new projects in a single application.

In general DAAG expressed support for the projects outlined but it was felt that the third project, a patient experience study, did not provide sufficient information about how data would be used and how this would provide benefit to the health and social care system. In addition it was agreed that further details should be provided of the dissemination plans for all the projects described, to determine whether outputs would be appropriately disseminated to ensure impact within health and social care.

The planned data retention period was queried, and it was confirmed that the data required for each project would be destroyed as each project came to an end rather than retaining the entire dataset until the final project had ended. It was agreed that the application form would be amended to clarify this point. A reference to one project's funding ending 'one year from June 2014' was queried and it was agreed that this would also be clarified.

It was noted that the Memorandum of Understanding (MoU) that had been supplied was dated March 2012, while the application summary referred to a version dated 2013, and DAAG requested sight of the updated MoU. A reference to raw data being held subject to ethical approval was queried, and it was agreed that this reference would be removed from the application summary.

The disciplinary code that would apply to any PhD students accessing data without proper authorisation was queried. It was agreed that particular issues relating to students and to honorary contracts should be picked up during the development of the next updated version of the HSCIC Data Sharing Framework Contract.

Outcome: Recommendation to approve all but project 3, subject to the provision of further details of dissemination plans for the remaining five projects. DAAG did not feel that they were in a position to recommend approval for project 3 due to concerns around the outputs and how benefits to health and social care would be achieved. The application form would be updated to clarify the data retention period, and the current version of the MoU would be provided.

Action: DAIS team to inform the development of the next version of the HSCIC Data Sharing Framework Contract to ensure that it will cover the appropriate arrangements for students and those working under honorary contracts.

2.4

University of Leicester - NHS Abdominal Aortic Aneurysm Screening Programme (NAAASP)
(Presenter: Dickie Langley) NIC-362262-N8L8R

Application: This application had previously been considered by DAAG, most recently on 19 May 2015 when DAAG had been unable to recommend approval and on 27 May 2015, when an update had been provided and DAAG had suggested that the applicant should determine what steps could feasibly be taken to inform individuals and to give them the opportunity to opt out. A response from the applicant had now been provided, along with additional details of how data would be pseudonymised prior to linkage to ensure that identifiable data would not need to be shared. It was noted that the application had now been updated to include a request for HES-ONS mortality data.

Discussion: DAAG noted the importance of this screening programme and reiterated their support for the work described. However, there remained some concerns.

DAAG discussed the applicant's response, which stated that the screening programme intended to continue containing verbal rather than written consent from patients. It was felt that while verbal consent would be considered appropriate for the screening itself, the consent for this procedure appeared to be conflated with the consent for participants' data to be used and linked in the way described in the application. The reference to standard wording used by screening staff when obtaining verbal consent was queried, as DAAG had not yet been provided a copy of this standard wording. It was agreed that the updated screening invitation letter wording ought to more clearly separate consent for the screening procedure from consent for data to be used. DAAG recognised the efforts that the applicant had made to progress this issue and it was suggested that the DAIS team should offer to support the applicant in amending their consent wording.

It was noted that the applicant's support under section 251 of the NHS Act 2006 was shortly due for annual review, and this therefore would need to be raised with the DAIS team. In addition,

evidence was requested that the appropriate approvals to access ONS data were in place.

There was a discussion of the proposed data flow, and some DAAG members felt that the data flow diagram provided was unhelpful as the data was referred to as either 'pseudonymised' or 'anonymised' in a way that did not seem consistent with the rest of the application. The need for consistent terminology was emphasised. It was explained that pseudonymised data would be sent to the HSCIC, and that this would then be linked to HES and ONS data before sending pseudonymised data onwards to the applicant, but DAAG noted that due to the proposed linkage the data could potentially be considered identifiable within the HSCIC.

The proposed timescales for the fair processing materials to be updated were discussed, and DAAG agreed that the applicant should be asked to provide the specific updated text and commit to a date when this would be published.

Outcome: Unable to recommend for approval. Consent materials should be updated, with support from the DAIS team. The applicant should undertake to update fair processing information and provide evidence of the specific text that will be published and the planned publication date. The data flow diagram should be updated to use terminology consistent with the rest of the application, section 251 renewal details should be confirmed and the application pack needs to include evidence of ONS approvals.

2.6 Health and Safety Laboratory - Pesticide Users' Health Study (Presenter: Steve Hudson) NIC-351522-Y6W3L

Application: This application was to amend an existing agreement relating to patient tracking for identifiable ONS mortality, ONS cancer and Personal Demographic Service (PDS) data, in addition to a one-off extract of linked HES data. DAAG were informed that section 251 support was in place, with Approved Researcher accreditation and Microdata Release Panel approval for the use of ONS data. The data would be used to analyse hospital admissions, cancer incidence and mortality within the Pesticide Users' Health Study cohort. It was noted that the applicant's Data Protection Act 1998 (DPA) registration wording had recently been amended to include the use of data for research purposes.

Discussion: DAAG queried a reference in the application summary to an amendment to the applicant's section 251 support, as it was not thought to be clear from the letter provided if this covered the use of HES Admitted Patient Care data. Clarification from the application case manager was requested.

The applicant's fair processing information was discussed, and it was agreed that the information available to participants should be updated to more clearly describe the data processing and to state how participants could opt out. DAAG noted that the applicant's 251 support included three specific conditions, one of which had related to fair processing information.

Clarification was requested regarding how the applicant would make use of identifiable, pseudonymised or anonymised data as this was not felt to be clearly explained in the application summary.

Outcome: Recommendation to approve subject to clarification of how the applicant will make use of identifiable, pseudonymised or anonymised data. Also subject to evidence of how fair processing information will be updated to include details of what data will be used and how participants can opt out, which should be published within a reasonable timeframe, in line with the specific conditions of support referred to in the Health Research Authority Confidentiality Advisory Group (HRA CAG) support letter.

2.7**University College London – British Regional Heart Study (Presenter: Steve Hudson) NIC-350862-Q5V8G**

Application: This application, which had previously been considered by DAAG on 5 May 2015, 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. DAAG had requested sight of consent materials as well as evidence that fair processing materials had been updated; the original consent materials had now been provided, and it was noted that recruitment had ceased so it would not be appropriate to update the consent materials at this stage.

Discussion: DAAG discussed the applicant's fair processing information, and there were some concerns regarding the response provided and how participants would be informed of how they could opt out. Further information was requested about how the applicant would meet the fair processing requirements of the DPA, and in particular DAAG suggested that the applicant should consider the Information Commissioner's Office (ICO) Privacy Notices Code of Practice. The importance of taking a layered approach to informing participants was also noted, for example by combining website updates with information provided in newsletters.

DAAG noted the large amount of identifiable data requested, and queried what progress had been made against the suggestion made by HRA CAG that the possibility of using pseudonymised data instead should be explored with the HSCIC.

Outcome: Unable to recommend for approval. DAAG requested an update on the applicant's progress against the comments made by HRA CAG during the annual review process that the use of pseudonymised data should be discussed with the HSCIC. The applicant also needed to demonstrate that they meet the fair processing requirements linked to the first principle of the Data Protection Act 1998, and DAAG strongly advised that the applicant should take into account the ICO Privacy Notices Code of Practice and consider a layer approach, including website and newsletter updates, to informing participants of how their data is being used and the opportunity to opt out.

2.8**Local Authorities – Public Health (Presenter: Steve Hudson)**

Application: This template application was presented for advice. DAAG's comments were sought on whether the application for a pseudonymised, non-sensitive HES data extract would provide sufficient information to serve as a framework for future applications from the public health directorates within Local Authorities. It was stated that receiving HES data would support the effective discharge of the Local Authorities' statutory duty and wider responsibilities to improve and protect the health and wellbeing of their local populations.

Discussion: The security arrangements for these public health teams were queried, and it was confirmed that all would be expected to have completed the Information Governance (IG) Toolkit. The specific IG Toolkit scores for each organisation would be provided with the relevant applications.

DAAG noted the importance of ensuring that each applicant specified what data they would require, rather than risking that some applicants might apply for the whole dataset under a blanket purpose statement while only intending to make use of some of the data provided. The possibility of auditing Local Authority public health teams in future was raised.

Concerns were raised regarding some references in the application to Local Authorities making use of data; DAAG emphasised that HES data would only be provided to the public health teams for specific health-related purposes, and that data could not be shared within the Local Authorities

to be used for other purposes. It was agreed that this would need to be clearly stated in future applications.

Outcome: Advice was given on the content of future applications, which would need to clearly specify the purposes for which data will be used and include appropriate DPA registration wording. Applications should clearly state that data can only be used by Public Health Departments within Local Authorities, and not shared more widely within the Local Authority.

2.5

IMS Health Technology Services (Presenter: Steve Hudson) NIC-324360-T8R3T

Application: This application was to renew an existing agreement for the applicant to receive pseudonymised, non-sensitive HES data. It was noted that the previous agreement had been with Ardentia Ltd; this organisation had subsequently become part of the IMS Health group of companies and was now known as IMS Health Technology Services. The data would be used to support a number of 'offerings' to clients including pharmaceutical companies and NHS provider organisations.

Discussion: It was noted that Sunguard AS had been listed as a storage address but not as a data processor, and DAAG requested that this organisation should also be listed as a data processor. In addition DAAG noted that IMS Health should be listed as a data processor in addition to IMS Health Technology Services. It was noted that although these two organisations were described as separate legal entities, IG Toolkit and DPA registration details had only been provided for IMS Health Technology Services. Overall it was felt that the relationship between IMS Health and IMS Health Technology Services was not clearly explained, and in particular references to analysts working across projects for both companies were queried as it was not clear what access controls or disciplinary arrangements would be in place for these staff working across companies.

DAAG queried the statement that the planned data retention period was 'ongoing' but that data would only be retained while a contract was in place. It was confirmed that this was intended to convey that the applicant would be obliged to destroy the data if their Data Sharing Framework Contract with the HSCIC was in place, and it was suggested that this should be worded more clearly in the application summary.

It was noted that IMS Health Technology Services was part of the international IMS Health group of companies, but DAAG were informed that the data shared would not be used outside England.

DAAG expressed significant concerns regarding the commercial purposes described, and whether this could be considered to be compatible with the requirements placed on the HSCIC by the Care Act 2014. The description of the applicant's customer base as being split '6:3' between the pharmaceutical industry and NHS provider organisations was queried, and the description of the applicant's 'current and potential customer base' without specifying the current customers was felt to be unhelpful. Whilst it was noted that the Information Asset Owner had asked for the potential customer base to be included, DAAG requested specific details of how many NHS organisations were currently customers for the tools described. Further details were also requested of what controls were in place for the applicant's customers and their use of data.

It was noted that the applicant was currently in receipt of data, and given the concerns around the compatibility with the Care Act 2014 DAAG recommended that this data flow should be halted, but agreed that any data currently held could continue to be retained. It was agreed that this would be raised with the HSCIC SIRO and Caldicott Guardian.

Outcome: Unable to recommend for approval. DAAG raised concerns about how this application could be compatible with the requirements of the Care Act 2014, particularly in terms of demonstrating how this was not for solely commercial purposes. DAAG also listed a number of detailed concerns that should be raised with the applicant, which included needing details of

specific health organisations that are currently clients of the applicant and further clarity on the relationship between IMS Health and IMS Health Technology Services as well as clarity on the controls in place for clients to access data.

Action: DAAG Secretariat to notify HSCIC SIRO and Caldicott Guardian of DAAG's recommendation regarding this application.

2.9 University College London - Metal-on-metal hip prostheses (Presenter: Dickie Langley) NIC-344986-Y3R8M

Application: This application was presented to DAAG for advice only. The background of the application was described, as it was noted that the application had been inadvertently delayed within the HSCIC for some time. The role of the National Joint Registry (NJR) in tracking patients with certain types of prostheses in order to monitor outcomes and improve patient safety was also described, and DAAG noted the importance of this work.

The applicant had requested the creation of four datasets: NJR data linked with Clinical Practice Research Datalink data (CPRD), NJR linked with National Heart Failure Audit data, NJR linked with HES and NJR linked with ONS. It was noted that the HSCIC were not the data controller for the first two datasets and would act as data processor in those instances. Queries had been raised regarding the legal basis for linking these four datasets, as it was noted that the applicant's current section 251 support only covered the individuals within the cohort who had a consent status of 'not recorded' and it was unclear whether there was an appropriate legal basis under the existing participant consent. DAAG were informed that recruitment to the cohort had ended, and that re-contacting over 50,000 cohort members to seek updated consent was not considered appropriate or feasible.

Discussion: DAAG considered the consent materials provided, and while a number of positive points were noted there were some concerns. In particular DAAG noted that although the consent materials referred to data being used for medical research, the statement on the consent form that 'The majority of our research uses only anonymised information that means it is impossible to identify individuals' could be interpreted by participants as meaning their identifiable data would not be shared at all. It was also noted that the consent form stated that if researchers wished to access further information, NJR would seek participants' approval prior to disclosing contact details.

A query was raised about how patient care would be affected by the data requested, and it was explained that evidence on the potential harm that could be caused by these prostheses would help to inform evidence-based clinical decisions about the risk of replacing hip replacements versus the potential cardiac risks of the existing replacements.

DAAG noted that the applicant referred to this work as a patient safety study, and queried a reference within the application to an Australian study that could indicate increased rates of heart failures. Further evidence was requested to confirm that this was considered a patient safety issue in order for DAAG to make a risk based assessment of whether the application should proceed on the basis of public interest, as it was noted that the NJR consent form stated that personal data would be shared 'where there is a clear overriding public interest in disclosure'.

It was suggested that if the applicant were unable to provide this additional evidence then they could consider applying for section 251 support, and it was agreed that the Acting DAAG Chair would support this application going through the HRA CAG proportionate review process.

Outcome: DAAG advised that as the application indicated that this is a patient safety matter, DAAG would require additional evidence to support this claim in order to make a risk based assessment to determine whether they could recommend to approve this application on the basis of public interest. Alternatively the applicant could consider applying to HRA CAG for section 251,

	potentially via the proportionate review process which the Acting DAAG Chair would be happy to support.
3	<p>Any other business</p> <p>DAAG members requested that no Outlook .MSG files should be included with meeting papers, and that where required email text should be copied into Word documents instead. The need to avoid embedding files within Word documents was noted.</p> <p>It was noted that an update about ONS would be provided at the training session the following week.</p>

Summary of Open Actions

Date raised	Action	Owner	Updates	Status
24/02/15	Dawn Foster 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> <p>21/04/15: Ongoing.</p> <p>28/04/15: Ongoing.</p> <p>05/05/15: It was agreed that Dawn Foster would raise this separately with CAG.</p> <p>12/05/15: Clarification had been requested from NHS England regarding a particular request for both identifiers.</p> <p>19/05/15: Ongoing.</p> <p>27/05/15: Ongoing.</p> <p>02/06/15: Ongoing.</p> <p>09/06/15: Ongoing.</p> <p>30/06/15: No response had yet been received from NHS England, and a further reminder would be sent.</p>	Open
16/06/15	Garry Coleman to speak to Chris Roebuck regarding Public Health England's approach to fair processing.	Garry Coleman	30/06/15: No update available.	Open
16/06/15	DAAG Secretariat to include HSCIC Data	DAAG	30/06/15: This action had been completed and was closed.	Closed

	Disseminations Approvals Policy and ongoing work with HRA CAG as topics for a future DAAG training session.	Secretariat		
30/06/15	DAIS team to inform the development of the next version of the HSCIC Data Sharing Framework Contract to ensure that it will cover the appropriate arrangements for students and those working under honorary contracts.	Diane Pryce		Open
30/06/15	DAAG Secretariat to notify HSCIC SIRO and Caldicott Guardian of DAAG's recommendation regarding this application (IMS Health Technology Services, NIC-324360-T8R3T).	DAAG Secretariat		Open