

Data Access Advisory Group (DAAG)

Minutes of meeting held 15 September 2015

Members: Eve Sariyannidou, James Wilson, Joanne Bailey, Dawn Foster

In attendance: Vicki Williams, Frances Hancox, Steve Hudson, Vijay Tailor, Jennifer Redman, Stuart Richardson, Sophie Fletcher, Dave Cronin, Gaynor Dalton, Dickie Langley

Apologies: Sean Kirwan, Alan Hassey, Patrick Coyle, John Craven

1	<p>Declaration of interests</p> <p>James Wilson declared a conflict of interest regarding the two University College London applications scheduled for discussion.</p> <p>Review of previous minutes and actions</p> <p>The minutes of the 8 September 2015 meeting were reviewed and agreed as an accurate record.</p> <p>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 met:</p> <ul style="list-style-type: none">• NIC-359692-Q4X1C Lightfoot Solutions UK Ltd
2 2.1	<p>Data applications</p> <p><u>Norwich Clinical Commissioning Group (CCG) (Presenter: Stuart Richardson) NIC-369503-Y7W1D</u></p> <p>Application: This was a new application for pseudonymised Secondary Uses Service (SUS) data. Data would be linked with local data flows from healthcare providers by the North of England Data Services for Commissioners Regional Office (DSCRO) then pseudonymised, and this pseudonymised data would flow through North East London Commissioning Support Unit (CSU) as data processor and then on to Norwich CCG. Data would be used to support the commissioning of health services. It was confirmed that both the CCG and the CSU held appropriate registrations under the Data Protection Act 1998 (DPA) and both had achieved satisfactory Information Governance (IG) Toolkit scores.</p> <p>DAAG were informed of an error in the application summary, and it was confirmed that the proposed agreement end date should be October 2016 rather than 2015.</p> <p>Discussion: The use of identifiable data was queried, and it was confirmed that there was a legal basis in place for the DSCRO to receive identifiable data from local providers but that this would be pseudonymised before data was shared with the CSU and CCG.</p> <p>DAAG noted the importance of ensuring that appropriate healthcare benefits would be achieved,</p>

and asked for any future renewal application to include information on how the data received had been used to achieve these benefits.

Outcome: Recommendation to approve. DAAG commented that the renewal application in one year's time would be expected to provide details of benefits that had been achieved.

2.2 University of Manchester - A case control study of sudden death in psychiatric inpatients and the relationship with psychotropic drugs (Presenter: Steve Hudson) NIC-365623-T3W4S

Application: This application was to renew and extend an existing agreement for the applicant to receive a bespoke extract of Hospital Episode Statistics (HES) data for patients with certain mental health diagnoses who had died while in hospital.

Discussion: DAAG noted that the HQIP funding letter that had been provided referred to the applicant developing a user involvement plan, while the section 251 letter from the Health Research Authority Confidentiality Advisory Group (HRA CAG) also referred to patient and service user engagement. DAAG asked if information about patient engagement could be provided in the fair processing section of the application summary.

The applicant's DPA registration was discussed, and DAAG asked if the additional detail provided in previous applications from this applicant could also be included. In addition to this, it was noted that a query had been raised with HRA CAG regarding whether all the fields requested were covered by the applicant's section 251 support. DAAG asked that for all instances when uncertainty had arisen regarding what was covered by a particular section 251 support, evidence of confirmation from HRA CAG should be provided in future.

It was felt that more detail should be provided regarding the expected benefits and any benefits already achieved with the data previously received. DAAG queried a reference in the application summary to relevant findings being used to inform NHS policy, and additional details were requested of how outputs would be disseminated to ensure an impact on NHS policy.

Outcome: Recommendation to approve subject to the following caveats:

- Details of the applicant's fair processing activities should be provided, as per the reference to a user involvement plan within the HQIP funding letter.
- The application summary should be updated to more clearly explain the expected benefits, as well as any benefits achieved with the data already received and how outputs will be disseminated to ensure an impact on health policy, as per the reference in the applicant's HQIP funding letter to developing a strategy for the dissemination of outputs.
- The application summary should also be updated to clarify the applicant's DPA registration wording.

2.3 Picker Institute Europe (Presenter: Gaynor Dalton) NIC-367152-K6Y1D

Application: This was a new application for identifiable and sensitive Personal Demographics Service (PDS) data for the purpose of list cleaning and mortality checking, for which section 251 support was in place. Picker Institute were acting as data processors on behalf of the University of Leeds, and list cleaning was required to enable the applicant to undertake a Patient Related Outcome Measures Survey (PROMS) survey of men diagnosed with prostate cancer while minimising the risk that the applicant might attempt to contact a deceased individual. DAAG were informed that while the study would include cancer patients in England, Wales, Scotland and Northern Ireland the current application only related to data for individuals in England and Wales.

Discussion: DAAG requested clarification of a reference in the application summary to 'commercial aspects'. It was clarified that the Picker Institute had been contracted by the University of Leeds to carry out this survey but that the purpose of the survey itself was not in any

way commercial.

The planned retention period for patient identifiers was queried, and it was confirmed that identifiers would be retained for three years while the fieldwork was underway to ensure that deceased individuals would not be included in the annual follow-up mailings. In addition a reference to the Demographics Batch Service (DBS) was queried; DAAG were informed that list cleaning would be carried out using PDS, and the reference to DBS would be removed from the application summary. An error in the proposed agreement end date was noted, as this should have stated 2016 rather than 2015.

The intended data flows were discussed, and it was confirmed that data would flow directly from the National Cancer Registry to the HSCIC rather than first flowing via the Picker Institute. A query was raised regarding whether list cleansing would take place only for the first survey mailing or for each annual survey; it was thought that this would be required for each annual survey, and DAAG suggested that this could have been described more clearly in the application summary. DAAG discussed the applicant's fair processing activities, and noted a reference to the initial invitation letter directing potential participants towards an information sheet on the study website. A query was raised regarding whether hard copies of this information would also be made available for any participants unable to access the internet.

Some concerns were raised regarding what legal basis was in place for the HSCIC to receive data and provide list cleaning, as it was noted that the section 251 letter from HRA CAG did not mention the HSCIC and a separate document provided stated that HRA CAG had asked who would carry out list cleaning activities for the applicant. It was agreed that this point would need to be clarified.

The opportunity for individuals to withdraw from the study was discussed, and it was noted that the study website stated that individuals had a six month window from when they were first contacted in which to withdraw, as removing data from the study after six months could pose difficulties. DAAG considered whether this time limit was reasonable, and although some uncertainties were expressed it was on balance felt to be appropriate. DAAG noted that the Research Ethics Committee (REC) approval letter referred to a number of different participant information sheets, and DAAG requested sight of these in order to determine what information would be given to participants about data sharing with other universities collaborating in the research team.

Outcome: Unable to recommend for approval.

- Clarification was required regarding the legal basis for the HSCIC to receive data and provide list cleaning.
- Copies of the patient information sheets were requested, to clarify what information was provided about sharing data with other organisations collaborating in the research team.
- The application summary should be updated to clarify data flows, to remove references to the Demographic Batch Service (DBS) and to correct the proposed agreement end date.

2.4 University College London - Whitehall II (Presenter: Dave Cronin) NIC-346693-F2X1G

Application: This application was to merge two existing data sharing agreements for HES data as well as PDS, Office for National Statistics (ONS) mortality data and cancer registration data, with the additional request to receive Mental Health and Learning Disabilities Data Set (MHLDDS) data. This data would be used as part of a long term public health study.

Discussion: DAAG noted that the application summary referred to the LIFEPAATH project receiving European Commission Horizon 2020 funding. It was acknowledged that the application summary stated that no raw data would be shared with other organisations; however, it was agreed that further information was required about the funding for this project in order to confirm this. The particular issues relating to projects funded by the European Commission Horizon 2020 were discussed, and it was noted that a paper on these projects had previously been drafted. It

was agreed a copy of this paper would be circulated. DAAG requested sight of additional information on this particular project, to help determine whether this would require data to be shared with research collaborators or require the commercial exploitation of outputs.

The legal basis for the dissemination of cancer registration data was queried, as two alternatives were referred to, and it was agreed that this would be clarified. In addition a query was raised regarding the fair processing activities undertaken by the applicant, and whether participants had been informed of the use of mortality data. DAAG requested clarification of data flows, and in particular what stages of the process would use identifiable data and at what stage data would be pseudonymised using a Study ID.

Outcome: Recommendation deferred, pending clarification of the following points:

- Detail of the EU funded project, with confirmation that record level data will not be shared with any third parties or internationally.
- Clarification of the legal basis for dissemination of cancer registration data.
- Further information regarding fair processing activities, and whether participants are informed via newsletters of the use of mortality data.
- The application summary should be updated to clarify the flow of identifiable data and at what point data will be pseudonymised.

Action: Eve Sariyannidou to circulate paper on EU funded projects.

2.5 University College London - PREVAIL Trial (Presenter: Dickie Langley) NIC-378109-D3D5X

Application: This application was presented to DAAG for advice on draft consent materials only. The applicant intended to apply for data to support the study into preventing infection using antimicrobial impregnated long lines (PREVAIL), and had requested feedback on whether the draft consent materials would provide an appropriate legal basis for the receipt and linkage of HES and ONS mortality data.

Discussion: DAAG noted that no information had been provided about the intended data processing, and it was therefore not possible to advise fully on consent. However, a number of specific points were raised as advice for the applicant.

The legal basis to share patient identifiers outside the study team was queried, as the parent information sheet stated that 'only people working on the study or working to ensure the study is run correctly will have access to the data'. In addition it was not felt to be made sufficiently clear at what point hospital data would be requested, as the information sheet could be interpreted to mean that this data would only be requested at school age. On the draft consent form, a reference to accessing hospital records 'including pregnancy' was queried as it was considered unclear whether this also referred to the mother's health records.

DAAG did not feel that the consent materials provided an adequate legal basis for the receipt of ONS mortality data, as these only referred to collecting neonatal data, NHS hospital data and education records and did not specifically refer to collecting mortality data. It was also felt that data linkage was not currently covered by the consent materials, as again this was not specifically referred to in the patient information sheet and the consent form only referred to linking data at school age. There was a suggestion that a reference to collecting 'NHS records' at school age could be considered to include PDS mortality data, but that this would not cover the use of PDS mortality data at younger ages.

Given the nature of the study, DAAG acknowledged the likelihood that parents would be under an emotional strain while reading the consent materials. DAAG therefore noted the need to balance providing enough information for informed consent, with not making the consent materials overly long and not using language that would be likely to cause further distress. DAAG also noted the

	<p>efforts that the applicant had been made to make the consent materials readable and easy for parents to understand.</p> <p>Outcome: DAAG gave advice on the consent materials provided, but noted that they could not provide more detailed advice as no information was provided about the intended data processing. In particular the following points were emphasised:</p> <ul style="list-style-type: none"> • The legal basis to share data outside the research team was unclear, given the statement that data will only be accessed by 'people working on the study or working to ensure the study is run correctly'. • Linkage to other data was not mentioned, except for at school age. • The consent materials did not appear to cover the use of ONS mortality data. <p>This advice was given without prejudice to the consideration of future applications</p>
3	<p>Any other business</p> <p>No other business was raised.</p>

Summary of Open Actions

Date raised	Action	Owner	Updates	Status
04/08/15	DAAG Secretariat to send DAAG members a copy of the HSCIC Board minutes that covered the discussion of changes to HSCIC Executive Director team and Caldicott Guardian arrangements.	DAAG Secretariat	13/08/15: The relevant Board minutes had not yet been published. 18/08/15: The next meeting of the Board is on the 23 September after which the draft minutes will be agreed. DAAG secretariat to circulate following publication 25/08/15: Ongoing – DAAG secretariat to circulate following ratification at the 23 September 2015 Board meeting. 01/09/15: Ongoing, pending publication.	Open
13/08/15	Stuart Richardson to ensure that the privacy notice for Castle Point and Rochford CCG is appropriately updated.	Stuart Richardson	18/08/15: Stuart Richardson to continue to work with applicants and feedback update at future DAAG. 25/8/15: Stuart Richardson to update members on the 8 September with regard to fair processing notices in general and progress to date – Secretariat to add to agenda as discussion item 01/09/15: An update would be provided at the 8 September meeting. 15/09/15: It was confirmed that Stuart Richardson would provide an update at the 22 September meeting.	Open
15/09/15	Eve Sariyiannidou to circulate paper on EU funded projects.	Eve Sariyiannidou		Open