Data Access Advisory Group (DAAG)

Minutes of meeting held 8 September 2015

Members: Alan Hassey (Acting Chair), Patrick Coyle, Eve Sariyiannidou, John Craven, James Wilson, Joanne Bailey (items 1 to 2 only)

In attendance: Frances Hancox, Diane Pryce, Garry Coleman, Jennifer Donald, Dickie Langley, Dave Cronin, Gaynor Dalton, Steve Hudson, Vicki Hartley

Apologies: Sean Kirwan, Dawn Foster

1	**Declaration of interests** The Acting Chair declared a potential conflict of interest for application 3.3 (University of Nottingham, NIC-376367-M5V9H) due to previous membership of a QResearch advisory group and it was agreed that he would not contribute to the discussion of this application. In addition, Patrick Coyle declared a potential conflict of interest for the same application due to a working relationship with the applicant on HRA CAG, but it was agreed that this conflict was not significant enough to prevent him participating in the discussion. **Review of previous minutes and actions** The minutes of the 1 September 2015 meeting were reviewed and agreed as an accurate record. Action updates were provided (see table on page 6). **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 met: • NIC-302792-X4T6B University of Warwick • NIC-358253-S5N7T NHS England • NIC-324116-W0K9R Swansea University • NIC-350318-T4Z0H Herts Valley CCG (Stage One Accredited Safe Haven) • NIC-330562-P8S0R University of Nottingham In addition, the Acting Chair had been notified out of committee of a technical change to an application (Royal College of Physicians, NIC-312474-H5Q0T) such that the fields listed as being provided were amended to agree with the detail within the purpose section. The nature of the dataset was unchanged.
2	**Discussion of MRIS suspended studies** DAAG discussed a number of examples of long term Medical Research Information Service (MRIS) studies that were currently suspended.
3	**Data applications**

3.1 University of Oxford - The Arthroplasty Candidacy Help Engine (ACHE) Tool (Presenter: Dave Cronin) NIC-359084-W8G8T

Application: This application for pseudonymised Hospital Episode Statistics (HES) and Patient Reported Outcome Measures (PROMs) data had previously been considered at the 18 August 2015 DAAG meeting, when DAAG had deferred making a recommendation as further information was required. The application summary had now been significantly updated, and DAAG were also informed that a previous application from the University of Oxford Health Economics Research Centre (NIC-275706-T4D6W) that had included the use of a small amount of data for the ACHE tool had now been amended to remove that purpose.

Discussion: A query was raised regarding why the two different departments had been listed as data processors but not as data controllers, and it was confirmed that the University of Oxford as the relevant legal entity would act as data controller. DAAG asked whether data entered into the ACHE tool by GPs to determine candidacy for joint replacement surgery would be shared with the University of Oxford, but it was confirmed that this data would remain confidential and would not be shared. The applicant's registration under the Data Protection Act 1998 (DPA) was queried, as the application summary stated that this would shortly expire, and it was confirmed that this registration had been renewed.

The planned data retention period was discussed, as the stated reason for this period appeared to contradict the date listed. DAAG were informed that the proposed retention period should end in December 2020 and that the application summary would be updated to reflect this.

It was noted that the applicant had not yet sought approval from a Research Ethics Committee, which applicants would normally be expected to complete before applications were considered by DAAG. In addition the applicant's methodology had changed since the study protocol was drafted, but the protocol had not yet been updated. DAAG noted that the application summary would need to reflect the final study protocol.

DAAG discussed the fact that the previous application (NIC-275706-T4D6W) had been amended to remove the use of data for the ACHE tool, and some concerns were raised that this therefore reduced the potential healthcare benefits that could be realised by that application alone. It was suggested that that application should include a statement that outputs and benefits would be linked to the use of data in this current application, and it was agreed that the updated application would be reviewed out of committee.

Outcome: Unable to recommend for approval.

- The applicant needs to provide evidence of a favourable ethics review.
- The application summary must reflect the final study protocol.

3.2 University of Nottingham - Helicobacter Eradication Aspirin Trial (Presenter: Dave Cronin) NIC-340577-H8T7N

Application: This was a new application for bespoke linkage of a cohort of approximately 40,000 trial participants to HES data, using participant consent as the legal basis. Copies of the updated participant information sheet were provided, along with a draft follow-up letter that the applicant intended to send out to participants.

Discussion: The updated participant information sheet was discussed, and it was acknowledged that a number of improvements had been made to this. However DAAG noted that recruitment to the trial was still underway, and that they would therefore expect the consent form to be updated in line with current advice. In particular it was noted that the consent form provided did not mention the HSCIC and did not clearly describe the use of identifiable data and what identifiers would be shared.

The role of the data processors was queried, and DAAG asked for the data flow diagram to be updated to clarify this. In addition, DAAG queried a reference in the application summary to including patient initials in anonymised data and asked for this point to be clarified.

Outcome: Unable to recommend for approval.

- The patient information leaflet and consent form need to be updated in line with current guidance, particularly given that recruitment is ongoing.
- Clarification is required of references to patient initials being included in anonymised data.
- The data flow diagram should be updated to reflect the form of data, data controller and organisation involved at each step of the process.

3.3 University of Nottingham - QResearch Data Linkage Project (Presenter: Dave Cronin) NIC-376367-M5V9H

The Acting Chair reiterated that he would not participate in the discussion of this agenda item due to a potential conflict of interest.

Application: This application for pseudonymised HES data had previously been discussed at the 18 August 2015 meeting, when DAAG had been unable to recommend approval. Clarification had now been provided that QResearch was a collaboration between EMIS and the University of Nottingham, not a separate legal entity, and the application summary had been amended to clarify that the University of Nottingham would act as data controller and that only University of Nottingham staff would have access to the data provided. The possibility of using sub-licenses had been discussed within the HSCIC, and it had been determined that this would not be required as outputs made available to researchers would not include record level data.

Discussion: The involvement of EMIS was discussed, as it was felt that this was still not clearly explained in the application summary provided. DAAG were informed that EMIS provided the general practice data used in QResearch, but that EMIS staff would not have access to the HES data provided to the University of Nottingham. DAAG suggested that the applicant should consider providing a clearer explanation of the relationship between the University, EMIS and QResearch on the QResearch website.

DAAG discussed the applicant's use of pseudonymised data, and the statement that data would not become identifiable when linked to other data. It was noted that the former National Information Governance Board had reviewed the applicant's methodology in 2011 and had concluded that data would not carry a significant risk of reidentification.

The need to ensure healthcare benefits was discussed, and DAAG noted that a large number of published journal articles using QResearch were cited. It was felt that it would be helpful if more information on how QResearch benefits patients and the public could be made available, potentially as part of the patient information material available on the applicant's website.

Outcome: Recommendation to approve.

- DAAG commented that additional information regarding benefits for patients and the public would be helpful.
- The applicant should also consider clarifying the relationships between EMIS, the University of Nottingham and QResearch. This could be done through the applicant's fair processing notice.

3.4 University of Leicester – NAAASP (Presenter: Dickie Langley) NIC-370641-K0J0T

Application: This application for HES and linked Office for National Statistics (ONS) mortality data had previously been discussed by DAAG a number of times, most recently at the 30 June 2015

	meeting. Concerns had been raised regarding the applicant's consent materials, and updates to the initial invitation to screening letter as well as an FAQ document had now been drafted. Confirmation had also been provided that the applicant's section 251 support had been renewed, and evidence of ONS approval was provided. **Discussion:** The need to ensure that there was appropriate evidence of participant consent was discussed, as it was noted that the study currently relied on verbal consent obtained at the point of screening. DAAG emphasised the importance of clearly separating participant consent to undergo screening from consent for participants' data to be used for this purpose, and it was agreed that the applicant should update their materials to make this separation clear within a reasonable time period. DAAG discussed the updated FAQ document provided, and there remained some concerns that this had not sufficiently separated participants' consent for the screening procedure from consent for their data to be used for the evaluation of the screening programme. In particular, there were concerns about the implication that if an individual did not consent for their personal data to be used for research purposes then 'the programme will not be able to monitor your AAA or refer you to a vascular surgeon if this becomes necessary.' However, it was felt that the updated section 'What does the programme do with personal information?' clearly explained how data would be used and would help enable participants to give informed consent. DAAG discussed the amount of time that would be required by the applicant to update the information made available to participants. It was agreed that the applicant should ensure materials were updated within six months. **Outcome:** Recommendation to approve for a period of six months. • Within that six month period, the applicant's information materials should be updated to more clearly distinguish between consent for screening and consent for data to be used for the purpose of audit.
3.5	<u>NIC-359603 Care Quality Commission (CQC) (Presenter: Gaynor Dalton)</u> **Application:** This application was to extend and renew an existing data sharing agreement for the applicant to receive identifiable and sensitive HES data, HES-ONS linked mortality data, and Mental Health and Learning Disabilities Data Set (MHLDDS) data. It was noted that when the previous application for this data was recommended for approval in December 2014, DAAG had asked for any future applications to include a clear justification for why identifiable data was required. Confirmation had been provided by the applicant that identifiable data was still required, and that this was consistent with the published CQC code of practice on confidential personal information. **Discussion:** DAAG noted that the application summary indicated pseudonymised data had been requested in addition to identifiable data; it was confirmed that this was an error and the application summary would be amended to indicate that only identifiable data was requested. The amount of data requested was noted, and it was acknowledged that the need for this amount of data could be justified under the CQC's statutory powers. The legal basis for receipt of ONS mortality data was queried, and it was confirmed that this was covered by Section 42(4) of the Statistics and Registration Service Act (2007) as amended by section 287 of the Health and Social Care Act (2012). A query was raised regarding the request for 'all available fields' and what identifiers this would include, as it was noted that the applicant's published privacy notice stated that the data received from the HSCIC did not include names and addresses. It was confirmed that the HES data provided would include full postcodes, but would not contain other address details or names. DAAG noted the importance of ensuring that fair processing notices accurately reflect any use of identifiable data.

	The possibility of the applicant moving to use pseudonymised data in future was raised, and DAAG suggested that the HSCIC should consider working with CQC to explore whether the data quality of pseudonymised data could be improved to minimise the need to use identifiable data. **Outcome:** Recommendation to approve. • DAAG strongly recommended that the applicant's fair processing notice should be aligned with the data they hold and accurately reflect any use of identifiable data. • DAAG suggested that the HSCIC explore with CQC the possibility of improving the data quality of deidentified data, to minimise the need to use identifiable data.
3.6	<u>Civil Eyes Research Ltd (Presenter: Gaynor Dalton) NIC-377358</u> **Application:** This application was to extend and renew an agreement for the receipt of pseudonymised, non-sensitive HES data. DAAG had previously discussed an application at the 25 August 2015 meeting (NIC-369539-S1P8K), when they had recommended to approve the extension of the agreement for a three month period but had been unable to recommend approval of the requested renewal. DAAG had requested clarification around University involvement as well as clarification of how much data was required and the intended purpose and use of that data, and further information on these points had now been provided in response to DAAG's recommendation. It was confirmed that the applicant did not work with any third party organisations other than Keele University to deliver services to clients. The number of hospital trusts participating in the different workshops and networks was noted, and additional information on outputs and benefits was provided. **Discussion:** DAAG agreed that the applicant had now addressed the points previously raised. However, it was agreed that when the next annual renewal application was made the applicant would need to provide evidence of clear benefits to healthcare outcomes. Some concerns were expressed regarding the volume of data requested for the whole country, given that a relatively small number of NHS organisations would be benchmarked against this data. DAAG noted that this point had been raised when discussing some previous benchmarking applications from other applicants, and suggested that the HSCIC should review whether data sampling could instead be used to enable applicants to carry out benchmarking activities with a smaller amount of data. **Outcome:** Recommendation to approve. • DAAG noted ongoing concerns regarding the volume of data provided in order to benchmark a relatively small number of organisations, and suggested that the HSCIC should review the possibility of providing subsets or samples of data for these purposes. • The applicant would be expected to provide evidence of clear benefits to healthcare outcomes when making a renewal application in one year's time.
4	**Any other business** The Acting Chair provided some initial feedback from the IGARD consultation analysis. The availability of DAAG members for the 15 September meeting was noted, and it was proposed that Eve Sariyiannidou would chair that meeting in the absence of the Acting Chair.

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.		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.	Open