Data Access Advisory Group (DAAG)

Minutes of meeting held 10 February 2015

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

In attendance: Alex Bell, Frances Hancox, David Evans, Nicola Mallender-Ward, Garry Coleman, Dickie Langley, Stuart Richardson, Paula Moss

Apologies: Sean Kirwan

1	**Review of previous minutes and actions** The minutes of the 3 February 2015 meeting were reviewed and agreed as an accurate record. Action updates were provided (see table on page 6). **Out of committee recommendations** No recommendations had been made out of committee. The Group had drafted feedback out of committee on a draft consent leaflet created by the Nuffield Trust, following the application considered at the 27 January 2015 meeting (Nuffield Trust, NIC-283419-T9H7X). It was agreed that the amended application form would be shared with the applicant as an example of the areas that DAAG would wish to see improved in future consent forms. The Acting Chair thanked the members for the advice they had provided between meetings. The Group discussed the suggestion that advice on consent materials could be published on the HSCIC website, so that this would be available to anyone considering applying for data. It was agreed that this would be discussed in more detail at a future DAAG training session.
2 **2.1**	**Data applications** <u>National Institute of Economic and Social Research (NIESR) (Presenter: Garry Coleman) NIC-289602-C2N5W</u> **Application summary:** This application was for pseudonymised, non-sensitive Hospital Episode Statistics (HES) data. The Group were informed that this application was for a work package as part of a wider project that had been funded by the European Commission. This wider project involved partner organisations in different countries and it was noted that data would be shared with organisations in Hungary and Germany, but it was emphasised that only aggregated analysis would be shared rather than the record level data provided by the HSCIC. The applicant had stated that the data received would not be used for any commercial purpose. The application form specified that data would be used to investigate the impact of intangible investments on the provision of health services, with the intended benefit being to provide insight into variation in performance across NHS acute trusts and inform healthcare policy. **Discussion:** The Group discussed the statement that the data received would not be used for any commercial purpose, and suggested that it would have been helpful to have sight of the exploitation plan for how other elements of the wider project would be commercialised. It was suggested that this should also be requested for any future applications that were part of

	European Commission funded projects. There was a query regarding whether the data received for this particular work package would be used to support other work packages within the project, and in particular what data might be shared with partner organisations in other countries. It was confirmed that the applicant had stated that the only data shared outside of their organisation would be aggregated data with small number suppression applied to ensure that it was fully anonymised. There were concerns that the application form did not clearly explain how data would be used and did not specify precisely what 'intangibles' the applicant intended to study. A reference to austerity was queried, as it was not explained how this applied to the work described. In addition there were concerns that the benefits described within the application form were not sufficiently specific and it was not clearly explained why HES data was required to realise these benefits. Overall, the Group felt that the application form did not provide a clear justification for how this use of data would be compliant with the Care Act 2014 requirement for the HSCIC to share data only for the purpose of healthcare or the promotion of health. It was agreed that the application should be asked to provide a clearer explanation of what hypothesis their work intended to address. **Outcome:** Unable to recommend for approval. Further information requested regarding what 'intangibles' in particular will be studied and what hypothesis the applicant is seeking to address. Justification required for how this use of data is compliant with the relevant provisions of the Care Act 2014. The Group discussed the possibility of inviting the applicant to meet with a small number of DAAG members to discuss this application in more detail prior to resubmitting it to a future DAAG meeting. It was agreed that the applicant would need to provide a written response to the Group's recommendation prior to this meeting.
2.2	<u>University College London – Children Born After ART (Presenter: Jen Donald) NIC-180665-GJMW5</u> **Application summary:** This application was to receive pseudonymised HES data as well as mortality data from the Office for National Statistics (ONS). The applicant had obtained section 251 approval and had Approved Researcher status to receive ONS data. The data would be used to study health outcomes in children born after assisted reproductive technology (ART) in comparison to siblings born spontaneously as well as the general population. It was noted that the data flow involved was relatively complex. Details of mothers who had undergone ART would be supplied to ONS, and ONS would identify all children who had been born to those mothers and return that data to the HSCIC; the HSCIC would then use data from the Human Fertilisation and Embryology Authority (HFEA) to identify which of these children had been born following ART and which had not. That data would then be supplied back to ONS and matched to a control cohort, and the HSCIC would link all three cohorts to HES data. Following this, the applicant would receive pseudonymised data including current status, mortality data and HES data. The application referred to identifiable ONS data being supplied to the HFEA via the HSCIC due to their legal mandate to hold these data items. However it was noted that the legal gateway for this flow of data had been queried, and a response had not yet been received from the Health Research Authority Confidentiality Advisory Group (HRA CAG). **Discussion:** The Group discussed the proposed data flow, and acknowledged that while this was complex it appeared to be the best way to minimise the use of identifiable data. The potential importance of this work was noted, and the need to obtain data for the control cohorts was recognised.

	Fair processing was queried, and it was explained that fertility clinics had been engaged in a campaign to inform patients of how their data would be used as well as how they could opt out. Information about the study was also available on the University College London website. It was agreed that the reference to providing identifiable ONS data to the HFEA should be removed until the legal gateway could be confirmed. There was a discussion about the intended outputs, which included the intention to publish results in a medical journal, and whether the data shared would include small numbers; in particular there were concerns about the perceived sensitivity of the data due to the potential media interest in the topic, and whether this could make it more likely that the data could be vulnerable to attempts to re-identify individuals. It was agreed that the application form should be updated to clarify that the data outputs would only include aggregated data with small numbers supressed. **Outcome:** Recommendation to approve subject to removal of the reference to supplying identifiable ONS data for children born after ART to the HFEA via the HSCIC. Also subject to updating the application form to clarify that the outputs shared will only contain aggregated data with small numbers supressed, and to this being reflected in the data sharing agreement.
2.3	<u>Barts Health NHS Trust (Presenter: Jen Donald) NIC-313531-L7P4C</u> **Application summary:** This application was to amend an existing data sharing agreement so that the applicant could receive HES outpatient and ONS mortality data in addition to the bespoke extracts of HES data already received. This data would be used to consolidate and update the United Kingdom Immune Thrombocytopenia (UK ITP) Registry held by the applicant. Data was requested for two cohorts of individuals with ITP – those who had consented to be included in the Registry and those who had a diagnosis of ITP but had not given consent to be included in the Registry. Identifiable data would be provided for those who had consented, but only pseudonymised data would be provided for those who had not given their consent. It was noted that the applicant had been granted Approved Researcher status to receive the ONS data requested. It was clarified that the consent forms originally used by this study had not included linkage to other datasets, and section 251 approval had therefore been required to cover individuals who had provided consent using the original form. A new consent form was now in use which included this data linkage. **Discussion:** The Group expressed their support for the study. However some concerns were raised regarding a reference in the patient information document to individuals potentially having to pay their own legal costs in the event that they were harmed, as it was felt that this could be unnecessarily alarming for participants. In addition there was a query regarding whether participants were informed of how to withdraw their consent and what would happen to the samples provided if they did so, and it was confirmed that this information was provided in the patient information document. A query was raised regarding whether any identifiable data would be shared for the patients who had not provided consent, and how these individuals would be found. It was explained that individuals who had not given their consent to participate would be detected within the HES dataset based on their diagnosis, and no identifiable data would be shared about these individuals. A further query was raised about a reference to the applicant sharing data with GlaxoSmithKline, and it was clarified that this would only be data already held by the registry and would not include any of the data provided by the HSCIC. Participants had given their consent to this use of data.

	It was noted that the application form listed the applicant as an academic organisation rather than an NHS trust, and it was agreed that this would be corrected. It was also noted that the application form did not specify the data controller, and this would also be corrected. **Outcome:** Recommendation to approve
2.4	<u>University of Leeds - Yorkshire Specialist Register of Cancer in Children and Young People (Presenter: Dickie Langley) NIC-316673-T0G2R</u> **Application summary:** The applicant had requested identifiable, sensitive HES and Mental Health and Learning Disabilities Dataset (MHLDDS) data for patients aged under 30 within the former Yorkshire and Humber Strategic Health Authority region who had been diagnosed with cancer. This data would be used to support the applicant's epidemiology and health services research programme, evaluating pathways and time to diagnosis for children and young adults. **Discussion:** There were significant concerns regarding the patient information document that had been provided; it was noted that the HRA CAG approval letter stated that this document would need to be updated to include details of how patients could opt out, but those details were not included in the document provided. There were also concerns that the document did not make it sufficiently clear to patients how their data would be used. The statement that the applicant wished to hold data indefinitely was queried. It was noted that although this might be their aspiration dependent on the renewal of relevant approvals, the data sharing agreement between the HSCIC and the applicant would have an end date in February 2016 with the applicant being required to either apply for renewal or delete the data following that date. There were some concerns regarding whether the intention to hold data indefinitely could be considered compatible with the Data Protection Act 1998. A query was raised regarding whether the data requested was for the whole of England or for the local population only; it was confirmed that only data from the Yorkshire and Humber area was requested. In addition there was a query regarding why identifiable data was required rather than pseudonymised data, and how long the applicant would need to retain identifiers for. The Group queried the legal basis for this request; it was noted that while cancer registries as a whole had moved to become part of Public Health England the applicant was based at the University of Leeds and therefore it was not thought that the same regulations were now applicable. It was also noted that the approval letter from HRA CAG did not refer to either mental health data or the specific sensitive data items that had been requested, so it was not clear whether these were included in the approval. The Group also noted that if any researchers wished to use the data provided to the applicant to carry out other research in future, or if the data were to be disclosed onwards, a separate approval from HRA CAG was likely to be required. **Outcome:** Unable to recommend for approval. Patient information leaflet to be amended to include details of how data will be used as well as how individuals can opt out of being included in the register. Clarification requested about any onward disclosure of data. Applicant requested to provide justification for why identifiable data is required rather than pseudonymised data and why identifiers must be retained for the length of time requested. Clarification also requested regarding the legal basis for this disclosure and whether the section 251 approval covers the mental health data and sensitive data items requested.

2.5	Group application: North West CCGs[1] (Presenter: Stuart Richardson) **Application summary:** This was a class application from a group of 7 CGGs in the North West of England. The applicants requested SUS data that would be identifiable at the level of NHS number ('weakly pseudonymised') under the section 251 approval granted by HRA CAG for Stage 1 Accredited Safe Havens, in order to support local commissioning purposes. The applicants had previously received this data under the same section 251 approval, and an extension was now requested until the end of the section 251 approval. It was noted that all applicants had achieved a satisfactory IG Toolkit score, but that 3 applicants had not yet signed the data sharing framework contract and no data would be shared until that had been completed. **Discussion:** The Group noted that the application forms provided referred to pseudonymised data, but that the data provided would in fact be identifiable at the level of NHS number (weakly pseudonymised). It was agreed that the application form would be updated to clarify this point. A number of minor points were raised that would need to be corrected on the application forms. These included the need to list the data controller on each form, an error where the wrong CCG area had been referred to on one form, the need to list the section 251 approval review date and a typographical error. It was also agreed that where the applicants' objectives for processing data, the word 'including' would be removed to emphasise that the data provided could only be used for the objectives listed. In addition, it was noted that the DPA registration wording for South Manchester CCG did not appear to cover the work described although the wording used for the other CCGs did; it was agreed that this would be queried. **Outcome:** Recommendation to approve The Group requested that for future class applications, the individual organisations involved should be clearly listed on the meeting agenda and the differences between each organisation's application form should be clarified as part of the application papers.
3	**Any other business** No other business was raised.

[1] Bolton CCG NIC-309348-K2N3B, Central Manchester NIC-309341-S7G3P, Eastern Cheshire CCG NIC-309329-M8K2B, North Manchester CCG NIC-309306-B2W5C, Salford CCG NIC-308855-C3K4T, South Manchester CCG NIC-308819-F9Y0M, Wirral CCG NIC-257111-H2K3W

Summary of Open Actions

Date raised	Action	Owner	Updates	Status
13/01/15	Garry Coleman to provide DAAG with a briefing paper on HDIS.	Garry Coleman	20/01/15: It was agreed that a briefing paper would be circulated, but it was noted that no further HDIS applications would be brought to DAAG at this stage while internal discussions were ongoing. 27/01/15: Ongoing. 03/02/15: A briefing paper had been drafted and would be shared by email following clarification regarding HDIS extracts. 10/02/15: Clarification had not yet been received.	Open
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.	Alex Bell	27/01/15: This discussion had been scheduled, and details would be fed back to DAAG. 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. 10/02/15: Discussions had taken place about making changes to how information would be added to application forms.	Open
03/02/15	David Evans to raise the importance of fair processing in ongoing audits with HQIP.	David Evans	10/02/15: Ongoing.	Open
03/02/15	Karen Myers to provide David Evans with a copy of the outcome letter for this application (University College London, NIC-291217-K6M8H) once sent.	Karen Myers	10/02/15: Ongoing.	Open
03/02/15	Alan Hassey to draft a response to the Nuffield Trust regarding their application (NIC-283419-T9H7X).	Alan Hassey	10/02/15: This action had been completed and was closed.	Closed