Data Access Advisory Group

Minutes of Meeting held 23rd August 2011

Members: Clare Sanderson, Sean Kirwin, Patrick Coyle

In attendance: Susan Milner, Tom Latham, Dawn Foster, Kathryn Anderson, Jackie Gallagher, Netta Hollings (items 230811-e and 230811-f only)

Apologies: Dr Mark Davies, Kuldeep Sohal, Diane Pryce

230811-a	**Welcome** Clare Sanderson chaired the meeting in the absence of Dr Mark Davies and welcomed everyone to the meeting.
230811-b	**Minutes of the Previous Meeting** The minutes of the previous meeting were ratified. A summary of actions from the July meeting are as follows: <u>MRIS - ECC Statement re MRIS death data, including case study (MR1222)</u> DP had provided an update for the previous meeting regarding the current situation with MRIS applications regarding death data following the ECC statement discussed at previous meeting. DP asked for the Group's agreement with the ECC statement that there is no requirement for Section 251 approval and that consent can be reasonably implied. ONS have implied that they are happy that audit/research applications which have used a third party require ECC Section 251 approval. However, where the local clinical care team have been involved in the patient's care then consent is implied. The group agreed that a patient record can be updated with secondary care information as part of the patients record but agreed this issue should be discussed further when DP could be present. The Group had previously requested that a letter be sent to ECC by DP. DP had confirmed that the letter had been sent and is awaiting ECC's response. <u>MR1250 – Survival of babies with trisomy 13 or trisomy 18 born in England and Wales since 2004 - BINOCAR</u> DP awaiting clarification from ECC regarding extension of Section 251 support. Group had also queried the different location shown on the current application in comparison to the Section 251 approval. Group requested application to be resubmitted once clarification is provided. <u>Application security assessments and IG Toolkit</u> CS had meeting with Phil Walker (DH) to discuss the implications of incorporating the proposed IG Toolkit assessment into the evidence to be used in the approval process. Whilst there is no objection to the concept, there will be an impact on the NHS IC as an organisation related to resource and monitoring of Toolkit assessments. PW is preparing a document for consideration. This will be passed to the Group for further discussion. It was also agreed that input from ECC would be required as they will also be using this method of assessment in Section 251 approvals. **Action: PW to provide document for further discussion**

	Requests for access to restricted data fields through HES Business Objects At the last meeting, the Group requested that a robust process be put in place for requests for access to HES sensitive and identifiable fields. The Group were advised that an application form has been prepared and will be circulated for comment. **Action: DAIS team to circulate draft application form W/C 12th Sept 2011.** 190411-c University Hospital Birmingham At the last meeting it was reported that the customer had been requested to submit a Protocol for approval by the NHS IC. This was to provide details around how access to consultant data would be managed and ensure that appropriate restrictions were in place where consultants had not consented to their data being shared outside the Trust. A document has been received but does not provide sufficient detail around access to the data. The DAIS team have therefore been asked to obtain clarification from the customer. **Action: DAIS team to contact applicant.** 190711-a - Dr Foster Intelligence Request for approval from DAAG to allow Dr Foster Unit at Imperial College (DFU) to provide Dr Foster Intelligence (DFI) with clear sensitive HES fields and diagnoses under DFU's section 251 approval. Currently only pseudonymised data is provided to DFI. The application was not approved and further information was requested. In addition the Group asked for a letter to be drafted to ECC for their comment. Outcome letter sent to applicant. Letter to ECC drafted and approved by MD and PC. In the meantime, however, it was brought to the notice of the NHS IC that the applicant was also discussing a Section 251 application with ECC. It was agreed that the ECC letter may therefore have been superseded and may need to be amended. **Action: DAIS team to update letter to ECC as appropriate. A teleconference is due to take place on 21st September or 27th October 2011 between the applicant, Clare Sanderson & Mark Davies to discuss further.** DAAG Website The URL for the new DAAG website had been circulated within the minutes of the previous meeting; however, some members had been unable to access the web page. SM advised that some minor amendments will be made to the website and the link will be sent to members of the group by email. **Action: DAIS team to re-circulate URL.**
230811-c	**Matters Arising** a) Overview of outstanding applications **HES Applications –** 190411-a - University of Kent Application for NHS number and DOB for a new theme in health care policy to give more control to patients about how they receive their care. Health professionals will identify individuals with long term health problems and will assess the cost-effectiveness of personal health budgets for different health conditions compared to conventional service delivery. The consent forms for the project were considered at the April meeting. DAAG informed the applicant that the consent statement used on the

patient information leaflet was not explicit enough and recommended that the consent statement on the leaflet was reworded in line with the DAAG approved consent wording.

In response to the outcome letter, Michael Haslam (lead contact from DH for the evaluation of the personal health budgets pilot programme) discussed by telephone the issue of the patient consent form with CS and Dr Mark Davies. It was agreed that, by ticking the relevant box on the consent form, the patient is agreeing to sharing information held on HES and, although it would be best practice to explain what the data sharing means on the patient information sheet, this is not sufficient reason for DAAG to withhold approval.

At the April meeting, the Group asked for clarification that the applicant understood and had fully complied with section 32 of the Mental Capacity Act 2005. The applicant has now confirmed that they have approached the Department of Health's Legal Services for clarification, and that NRES and R&D offices have reviewed the evaluation process and provided approval to include Mental Capacity.

The applicant was also asked to confirm that it would be a member of a potential participant's local care team who would initially approach those taking part in the study. The applicant has confirmed that this will be the case.

In response to the Group's query regarding the lack of filters requested on the application, The applicant has now clarified that they only wish to receive data relating to their own cohort.

In view of the above responses, the Group agreed that the application could now be approved.

It was noted by the Group that the applicant had approached other bodies for guidance before submitting their application to DAAG. Members emphasized the importance of applicants engaging with DAAG as early as possible, and suggested that ways to ensure this could be investigated.

ACTION: DAIS team to inform applicant of decision.

<u>170511-a - University of Cardiff</u>

Application for sensitive HES data to support the Building Blocks study. The applicant wishes to link HES data to a cohort of teenage mothers, and obtain highly sensitive information on deaths and abortions in order to verify information provided by study participants.

The application was originally considered at the May 2011 DAAG meeting. At that time, DAAG noted that supporting documentation referred to contact between the applicant and 'Abortion statistics', and asked for clarification as to who the applicant had been discussing this issue with and confirmation of the outcome of these discussions. The applicant has now confirmed that they have consulted the Abortion Statistics Manager at the Department of Health about this issue, and intend to submit a request to the CMO who will ensure that the data is for 'bona fide scientific research' purposes. DAAG members confirmed that CMO approval is outside of the Group's remit.

The Group also felt that the consent statement used in the consent form and participant information leaflet was not explicit enough, given that some of the data sought is particularly sensitive in an identifiable form, as no specific mention is made of national databases, HES, or NHS IC datasets. It was therefore recommended that the consent statement should be reworded in line with the DAAG approved wording and explicit consent regained from all the participants in the study. The Group also asked the applicant to consider the implications of regaining consent from the cohort and provide feedback on this.

The applicant has now responded to confirm that, in their opinion, regaining consent from the cohort would be extremely difficult. This is because they are largely drawn from a vulnerable and mobile population, and the applicant confirmed that recruiting the cohort in the first place was a difficult task.

Members were generally in agreement with this, although they also recognized that the applicant's consent is not entirely appropriate. However, the existing consent does mention the data which the applicant wishes to obtain (although not the source) and in light of this, and the likely difficulties mentioned above with regaining consent, the Group was content to approve the application.

ACTION: DAIS team to inform applicant of decision.

	(b) Decisions Out of Committee - HES applications, August 2011 OC/HES/012 - North Bristol NHS Trust This request is for an update of data years for a HES Extract which was originally approved by the DAAG Chair outside of the formal meeting structure. The applicant has already received approval from DAAG to receive 2009-10 data (and holds Section 251 approval to receive identifiable data items) and now wishes to receive 2010-11 data as well. The data is required for the National Vascular Database (NVD) which is a free online web based tool available to all vascular clinicians. The sensitive data requested (as well as the identifiable fields approved by ECC) are to help validate data submitted to the NVD. **Application approved by Chair.**
230811-d	**NHS Central Register – MRIS Applications** MR1229 - The University of Manchester: BILAG Biologics Prospective Cohort: The Use of Novel Biological Therapies in the Treatment of Systemic Lupus Erythematosus (SLE): DP had advised that changes had been made to the parent consent. Application had been submitted to ethics committee and changes will be put in place. The Group agreed that the consent was now appropriate and approved the application, subject to a satisfactory review of the System Level Security Policy. **Action: DP to provide outcome to applicant and submit SLSP for approval when received.** MR1251 - UCL Institute of Child Health - Safety and appropriateness of growth hormone treatments in Europe (SAGHE) The Group requested clarification about whether the person contacting the patient was appropriate. If this would be a member of the care team then this would be acceptable, however, if contact was to be made by the researcher, then Section 251 support would be required. The Group advised that this application could be approved out of committee, subject to clarification regarding consent. **Action: DP to provide clarification regarding consent.** MR1252 – ICNARC, Tavistock Square, London DP had submitted this application for Chair's action; however this was brought to the Group for consideration in his absence. The Group agreed that the consent was acceptable and mentioned that this was a good application. The application was not clear however regarding who would make contact with patients without capacity. The Group requested clarification on whether the person providing advice was appropriate. There was also no mention of power of attorney in place. The Group gave conditional approval subject to appropriate representation for patients without capacity. **Action: DP to provide clarification regarding consent for patients without capacity.** MR787 – Childhood Cancer Survivors Study **For notification to the committee only. No approval required. Noted by the Group.**

230811-e	**Mental Health Minimum Data Set (MHMDS) Applications** 230811-a - University of Cambridge This is the first application to DAAG for an extract of sensitive MHMDS data. The request is for MHMDS data for a Department of Health-funded project comparing the demographics and treatment in hospital of those who are detained under the Mental Health Act and as well as those deprived of liberty under Deprivation of Liberty Safeguards (DoLS) with those informally held. The applicant requires more detailed information than that which is routinely released, in particular the sensitive fields "MHD Legal Status Restrictiveness" and "MHD Days Liable for Detention". "MHD Legal Status Restrictiveness" is required to allow the applicant to select the appropriate comparator groups, while "MHD Days Liable for Detention" will be used to calculate the total time spent in hospital for individuals from these groups. The results of the analysis will be anonymised (the data provided is anonymised patient level data) and will be incorporated into a report for the Department of Health. The data itself will not otherwise be distributed outside of the research group. Although the applicant has expressed an interest in receiving the two sensitive fields mentioned above only, the Group were advised that it is not possible for the MHMDS team at the NHS IC to provide selected sensitive data items from the dataset and the supplied MHMDS extract would therefore include additional sensitive data items that the customer had not specifically requested. Netta Hollings from the Mental Health team at the NHS IC reported that the combination of data which the applicant would receive will never become identifiable unless very small numbers are involved, or if the applicant already holds information about patients (the University of Cambridge do not). Providing additional sensitive data items would not make the data any more identifiable, and would provide a fuller picture by providing more information about the same data – all the sensitive items relate to use of the Mental Health Act and are inter-linked. In addition, there are technical and resource constraints to providing only selected sensitive data items; the MHMDS team are unable to verify the usefulness of every individual data item and therefore provide all of them as part of a sensitive extract. DAAG members felt that this was a worthwhile piece of research, and were content for the applicant to receive an extract containing all sensitive MHMDS fields in the context of the information provided by Netta. In addition, the Group were assured that appropriate terms and conditions would be set out in the Data Re-Use Agreement to control the use of the data and suppression of small numbers. The Group therefore approved the application subject to the submission and approval of a System Level Security Policy (SLSP). **ACTION: DAIS team to provide outcome to applicant and submit SLSP for approval when received.**
230811-f	**Any other business:** Proposed linkage of MHMDS with Primary Care Mortality Database (PCMD) Netta Hollings reported to the Group on a proposal to link MHMDS data with the Primary Care Mortality Database. This would populate the outcome indicator tool providing data on the mortality of patients with serious mental health problems. Both databases are populated by the Exeter system (CfH) and it was therefore proposed that both databases could be linked at Exeter. Brief discussion followed however it was agreed that further detail was required on how the databases could be linked and any potential approval issues relating to possible linkage by NHS number. **Action: Further details to be provided regarding PCMD, data controller for PCMD and whether Section 251 required. SM to have initial discussion with Susan Mayne at the NHS IC around data controllership for PCMD and any requirement for Section 251 support.**

	East Midlands Health Observatory – request for SUS/HES data DF reported on a request for national consultant data for the Right Care Project. The original request was for SUS data, however due to difficulties in providing national SUS data it was proposed to supply an extract of HES data. The Group were advised that the applicant required Consultant Code which from SUS is non-sensitive but from HES is deemed a sensitive field. The Group queried why National Consultant data was required. The Group advised that they were unable to approve the request and the applicant to be advised that pseudonymised Consultant data should be sufficient. **Action: DF to advise HES team at NHS IC of Group's decision** Out of committee application (Ref: OC/HES/013) - Care Quality Commission The application was to receive A&E data through the HES monthly managed service. The Care Quality Commission (CQC) already receives Inpatient and Outpatient data through this service. This would normally have been dealt with out of committee, as CQC have statutory regulations in place to receive the data, but as the Chair is currently on leave, the Group were asked for their view. The Group welcomed the continued diligence of CQC to approach the Group for their approval and were content to approve the application. **Action: DAIS team to complete and sign off Data Re-Use Agreement** Meeting dates for 2012 The Group were advised that they will be contacted shortly to ascertain suitable dates for meetings of DAAG next year. PC advised that his tenure with the ECC would shortly be coming to an end and wondered whether the Group would wish him to continue as a member of DAAG or whether a replacement from ECC would be required. CS advised that it may be necessary to consult ECC for advice on whether they expected a member of ECC to join the Group. CS continued that it had been extremely helpful to have Patrick's knowledge and insight into applications in the Group and hoped it could be possible for him to continue.
	Date of next meeting: 20 September 2011