Data Access Advisory Group

Minutes of Meeting held 28th February 2012

Members: Clare Sanderson, Patrick Coyle, Sean Kirwan

In attendance: Dawn Foster, Tom Latham, Diane Pryce, Olivia Podesta-Atkin (Secretariat)

Apologies: Mark Davies, Susan Milner

280212-a	**Welcome** Clare Sanderson welcomed everyone to the meeting and chaired the meeting in the absence of Mark Davies.
280212-b	**Minutes of the Previous Meeting** An amendment was requested to the minutes of the previous meeting (item 310112-e), which was noted. Members were otherwise happy for the minutes of the previous meeting to be ratified. **Action:** Amended set of minutes for the January meeting to be sent out. Application security assessments and IG Toolkit Dawn Foster previously circulated a draft letter to Clare Sanderson and Mark Davies outlining the concerns of the members with regard to the move to using IGT scores rather than reviewing an SLSP. This letter is currently with Mark Davies to review. Agreed this action should remain open
280212-c	**Matters Arising** **a) Overview of outstanding applications** 310112-a- BUPA Health Dialog (BHD) Access was requested for the Admitted Patient Care (APC) Consultant code to be supplied in the HES monthly managed extract service data to enable internal BUPA Health Dialog (BHD) to analyse patterns of variation among consultants within a treatment specialty. This information will be shared with healthcare organisations at summary level. At the January meeting, concerns were raised by members around whether patient level data was being provided to the applicant, although the applicant confirmed in their original application that this would not be shared with requestors. It has now been confirmed by the HES team at the HSCIC that patient level data will be provided. Members also requested assurance that the data provided will only be used for the specific purpose set out in the application. The applicant has now responded to confirm this. In addition, the Data Re-use Agreement signed by the applicant will define the purpose for which they can use the data, and will also contain a number of standard Terms and Conditions which control the use and release of small numbers. The Group was happy to approve the application on that basis, provided that an individual of suitable seniority within BHD signs off the Data Re-use Agreement. This approval is also subject to satisfactory review of the applicant's SLSP. **Action:** Outcome letter to be sent out to applicant. **(b) Decisions Out of Committee** The Medical Trials Council, Clinical Trials Unit (N-ALIVE trial). The N-ALIVE trial compares the number of people in two different 'treatment' groups who have been admitted to Accident & Emergency for a non-fatal overdose in the 12 weeks after they were released

	from prison. The applicant will provide the Information Centre's Trusted Data Linkage Service with the identifiable data and receive details of the patient's arrival date and clinical diagnosis in return. They have participant consent to do this and the consent statement is in line with the DAAG-approved wording. Agreeing to this consent statement is marked as optional on the consent form, but the application was approved by the Chair on the basis that the HSCIC will only be able to provide linked HES data for those people who have opted into this statement. **(c) Other** DAAG Terms of Reference The DAAG Terms of Reference have been updated to include a reference to 'reserves' attending the DAAG meetings in a member's absence. It was also agreed that the ToR should identify when the Group are quorate. The Group agreed that we should include the opportunity for consent to go through the out of committee fast track process if necessary. Members also agreed that, once approved by DAAG, the completed Terms of Reference should be shared with NIGB. **Action:** Terms of Reference to be amended to incorporate above comments. Clare Sanderson to enquire with Ruth Miller regarding obtaining Executive approval of the Terms of Reference within the HSCIC.
280212-d	**HES Applications** No new HES applications were submitted to the meeting.
280212-e	**NHS Central Register – MRIS Applications** MR1258 – Early Rheumatoid Arthritis The primary aim for this study is to establish a database of long-term clinical data in order to monitor management and outcomes of patients with early Rheumatoid Arthritis (RA) in the United Kingdom. The Group discussed the content of the consent materials used at the start of recruitment in 2002. The initial documents do not contain information about the data provision and processing via the HSCIC (MRIS) or, as would have been the case at the start of recruitment, via the Office for National Statistics. The consent materials have since been amended to included specific mention of the data provision and processing via the HSCIC (MRIS) and will now be used until recruitment is complete. The application was approved subject to; • Contacting the members that have already been recruited to update them on the data processing and collection aspects of the study and to give the option for members to opt out. This is a standard request in cases where the consent obtained clearly covers involvement in the study but does not specifically cover the data linkage activities. • Satisfactory review of the system security documents. **Outcome:** Approved MR1274 – Wales Cancer Trials Unit, Cardiff University This clinical trial aims to see whether the addition of the drug zibotentan to FOLFIRI chemotherapy, a regimen widely used for patients with advanced CRC will make this drug regimen more effective at killing colorectal cancer cells such that disease progression is delayed.

The applicant has requested the MRIS current status service for cause of death information. The request relates only to those members who have given explicit consent for follow up through MRIS, it will not involve the full cohort. The consent materials to be used adequately inform participants of the data processing via the HSCIC.

Outcome: Approved

MR1276 – Jenny Castle enq: A pilot study of twins

There is a significant body of evidence demonstrating the effects of prenatal (i.e. during pregnancy) environment on both physical and psychological development in the offspring. To date, little research has explored the extent to which these associations are mediated via purely environmental, purely genetic or combined environmental and genetic pathways. Identifying prenatal environments that act as independent risks for later health outcomes has profound implications for aetiological research and early intervention. The applicant proposes to use the wealth of prenatal data collected on all twins (approximately 600 twin pairs) scanned at St Thomas' hospital from 2005-2010 to examine the association between prenatal risk factors and child outcome at ages 2- 5.

The applicant requires MRIS to find out whether the children of the mothers they aim to contact are still alive. This is extremely important to establish in advance of making contact with those families as it would be extremely distressing to contact a woman asking research information about her deceased child as if it were alive.

The Group noted that the applicant intends to contact the parents three times, then follow up with a phone call in order to gain consent, but the Group advised that repeated follow ups would not be considered to be best practise. These should be raised with the applicant but not conditional on approval.

Outcome: Approved.

MR1265 – National Vascular Database (NVD) & NHS Abdominal Aortic Aneurysm Screening Programme (NAAASP)

Regarding the issue of the proposal of a verbal consent model.

The Group commented that this would create a precedent; a verbal consent model has not been approved previously and was of the opinion that a verbal consent model could not be approved at this time. The general consensus was that written consent should be possible.

Outcome: The Group requested that when obtaining consent prospectively the consent form should include the recommended wording in relation to accessing HES and MRIS data:

'I understand that information held and managed by The Health and Social Care Information Centre and other central UK NHS bodies may be used in order to help contact me or provide information about my health status.'

MR1273 – Functional, cognitive & emotional outcomes after Transient Ischemic Attack (TIA)

The neurological symptoms associated with Transient Ischemic Attack (TIA) should persist for no longer than 24 hours. However little is known about the long term impact of TIA on patient reported outcomes such as mood, quality of life and return to usual activities/social life. The aim of this study is to investigate whether or not patients have depressed mood, and/or residual functional or cognitive problems that adversely influence their day to day living, after being diagnosed with TIA. The study will also examine the costs associated with TIA, including personal economic losses e.g. time off work due to illness, and health and social care service provision.

The study requires MRIS data for 'List Cleaning', which can be used to determine which members are living (or not) and update their records before making contact.

Outcome: Approved

280212-f	**Any other business:** Glossary of terms for MHMDS applications At the December meeting, Jo Simpson from the MHMDS team was asked to provide a glossary of terms for the MHMDS data items to assist the Group in considering such applications. Jo Simpson produced a glossary of terms for sensitive data items for the Group to review. Any comments should go Tom Latham directly or should be raised at the next meeting in March. Future Forum - Consent As discussed at the November meeting, Dame Fiona Caldicott has been asked to carry out a review of consent and it was suggested that DAAG put together some points to submit to the Future Forum. Clare Sanderson confirmed that no further details were available at present, but that this item should continue to be held as an open action as the initial stages of this work will take some time. Nomination from ECC for member to participate in DAAG The Ethics and Confidentiality Committee has not identified a suitable representative at this time. DAAG may need to contact NIGB in order to obtain a representative, and in order to establish whether they think that an ECC member should participate in DAAG meetings. **Action**: Clare Sanderson to discuss this with Alan Doyle.
	Date of next meeting: 27th March 2012, 2-3pm