

**Database Monitoring sub-Group
Minutes of meeting held 7 May 2010**

Present

Members: Dr Patrick Coyle (Chair), Dr Ian Goodman, Ms Ros Levenson, Mr Terence Wiseman

In attendance: Ms Louise Dunn (IC, Leeds), Ms Claire Edgeworth (Approvals Officer), Ms Melanie Kingston (Deputy Approvals Manager), Mr Tom Latham (IC, Leeds) Ms Zoë Lawrence (NIGB Business Manager), Ms Diane Pryce (IC, Southport), Ms Clare Sanderson (IC, Leeds)

070510-01 Welcome and apologies for absence

1. Apologies were received from Mr Manny Devaux.

070510-02 Minutes of the previous meeting

2. The minutes of the previous meeting were approved.

070510-03 Matters Arising

3. No matters were raised.

070510-04 NIGB Office Report

4. Applications approved outside the meeting

MR1181 Phenotypic and genotypic characterisation of a COPD longitudinal cohort

4.1 This application was to flag the cohort's records and for current status to identify deaths. The study aimed to set up and maintain a cross-sectional registry of 1000 COPD patients with collection of mortality data obtained from the NHS Information Centre (IC), and a longitudinal cohort of 400 COPD patients. The study had two aims; one was to identify the role of genetic variation in responses to hypoxia and enable stratification of patients for treatment and selection for experimental medical studies; the other was to investigate infective exacerbation susceptibility in COPD. In particular to test the hypothesis that previously identified genetic polymorphisms that predict susceptibility to gram positive pneumonia predict the development and progression of COPD.

This was a fully consented study and was therefore approved by DMsG Chairman's action.

MR1189 Vertebral artery Ischaemia Stenting Trial (VIST)

4.2 This application was to flag the cohort's records and current status to receive death notifications and PCT information. This study was to compare the risks and benefits of vertebral angioplasty and stenting for symptomatic vertebral stenosis compared with best medical treatment. This was the feasibility phase in order to assess safety and recruitment feasibility, which if successful would run into a main trial.

This was a fully consented study and was therefore approved by DMsG Chairman's action.

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MR1201 Frequency for follow up for patients with intermediate grade colorectal adenomas

4.3 This application was to flag the cohort's records and current status for death notifications, cancer and exits from the NHS. The study aimed to determine the optimal surveillance intervals for people diagnosed with intermediate risk adenoma. The team would analyse patient-specific information on deaths and cancer diagnoses for people who underwent endoscopic colon examination in participating NHS trusts. This was in order to examine the effect of demographic and baseline adenoma characteristics as well as differing surveillance intervals on risk of colorectal cancer the applicant needed to identify everyone who was diagnosed with or died from colorectal cancer in the period since their first examination.

This work was covered by a previous section 251 application 1-05(e)/2006 and therefore the request was approved by the NIGB office.

070510-05 Hospital Episode Statistics (HES) Business

070510-5-a CMPO and Imperial College

5.1 This application was a request for an update to a previously approved extract to include data for the years 2008/2009 and provisional 2009/2010 data. The application requested Census Output Area, Consultant Code, Code of patient's registered or referring general practitioner and Person referring patient. The applicant planned to retain the data for three years to be used for longer term impacts of hospital mergers on outcomes and other long term projects. The information would be used for ongoing work on the impact of NHS reforms in the UK, analysis on the impact of competition on outcomes in the NHS and examination of the impact of mergers.

Members also noted that the application now included a request to analyse data at both the University of Bristol and Imperial College London.

Members approved the application subject to the condition that a separate System Level Security Policy (SLSP) was provided for Imperial College London.

Action: NIGB Office to inform applicant of outcome.

070510-5-b The King's Fund

5.2 This application from the King's Fund was a request for an update of a previously approved extract.

The data will be used for a number of studies researching health policy, specifically for the following projects: Upgrading the predictive risk algorithm on behalf of the Department of Health and the 10 NHS SHAs, Investigation of Referral Management Centres, Variations in cancer spending, Variations in provision and patterns of use of NHS services, Shifting care outside hospital, Inequalities in health, Analysis of end of life care

There were a number of queries with the application, in particular the level of identifiability. As there were a number of studies included in a single application, it was also not clear what information would be used for each study.

Members agreed there was not enough information provided to make a decision. The application was referred pending clarification.

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Application referred, NIGB office to follow up the queries DMSG raised.

070510-5-c University of York

5.3 This application from the University of York was a request for an update for the years 2008/2009 for a previously approved data extract. This included the sensitive data item – Consultant code.

The data would be used for a research project looking at variations in hospital consultant activity rates. Patient episodes data would be aggregated by consultant code and linked with other information about the consultant.

It was also noted that clarification had been sought following an application in November 2008 from the same applicant regarding the level of linkage to country of origin and ethnic group of the consultant. Members were satisfied with the responses to their queries and subsequently approved the initial application in February 2008.

Action: NIGB Office to inform applicant of outcome.

070510-5-d Clatterbridge

5.4 This application was for an update for years 2008-2009 to a previously approved extract. The data would be used to conduct data analysis on the provision of cancer services including provision of aggregate data without identifiers to the service regarding number of episodes, bed days, procedures for cancer and cardiac service, prediction of patient flows and volumes for reconfigured services using geographical information systems. The sensitive data items requested were; Date of Birth, NHS number, Postcode of patient, Census Output Area 2001, Ordinance Survey Grid Reference, Consultant Code and Code of Patient's registered or referring general medical practitioner.

It was noted that Clatterbridge have a number of Section 251 approvals in order to receive patient identifiable data. Members were of the view that the activity for the extract was covered by the following applications: 1-05(d)/2006, 4-09(g)/2003 and 3-09(h)/2003.

This application was approved.

Action: NIGB Office to inform applicant of outcome.

070510-5-E Care Quality Commission (CQC)

5.5 This application was a request for an update of a previously approved application. The extract would be used to provide patients and users of service with clear assessment of the safety, quality, efficiency and effectiveness of the services they receive, and provide patients, the public and health and social care professionals with sound and fair information about health and social care, both at a national and local level. The CQC had their own statutory powers; under section 64 of the Health and Social Care Act 2008, to receive the data and the proposed use of the data would assist the CQC in performing their statutory function.

Members were content to allow the release of the requested data.

Action: NIGB Office to inform applicant of outcome.

070510-5-f Centre for Suicide

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5.6 This application was a request for an update of a previously approved application to include the years 2008-09. The sensitive data items requested included: Date of Birth, Local Patient Identifier, NHS Number, Consultant Code, and Code of patient's registered or referring general medical practitioner.

Members confirmed that the use of data was covered by the National Confidential Inquiries section 251 approval, PIAG 4-08(d)/2003 and this application was approved.

Action: NIGB Office to inform applicant of outcome.

070510-5-g Public Health Observatories Mental Health Minimum Dataset Extract request

5.7 This request was for access to the 2008-09 MHMDS and for annual extracts going forward as new data became available. The data would be used to support the activities of PHOs within their regions, in work including regular briefings on healthcare data, balanced scorecard digests of topics of agreed interest and responsive analyses for individual PCTs and Trusts.

Members noted that the request stated that the applicant intended to retain the data indefinitely. According to the Data Protection Act principles, data should not be retained for longer than necessary, and as such, a general principle of DMsG was that it did not give approval for longer than a three year period. This was to ensure that the justification for holding the data remained valid.

Members approved this application with the condition that the applicant was to submit a request for a time extension if they wished to retain this data for longer than three years.

Action: NIGB Office to inform applicant of outcome.

070510-5-h Public Health Observatories national HES extract

5.8 Members noted that this extract requested patient identifiable data and therefore concluded that the DMsG did not have the remit to approve such a request. Members advised that an application should be made to the ECC.

Action: NIGB Office to inform applicant of outcome.

070510-06 NHS Central Register

MR1184 Screening for diabetes and intermediate hyperglycaemia in primary care (NewHype)

6.1 This application requested the flagging of the cohort's records and current status for death notifications, cancers, exits and re-entries of a cohort of 650 patients. The aims of the study included indentifying the true prevalence of type 2 diabetes in those aged over 60 years in a GP practice with a low prevalence of know diabetes, identifying the proportion of those with unknown diabetes that would have been identified using established diabetes risk scores and studying the implications for total mortality and morbidity of different levels of hyperglycaemia in people aged over 60 years.

Members noted that this was a consented study and that recruitment to the study had begun and was ongoing. Members reviewed the consent forms and information that had been provided to study participants. Members were satisfied that the information provided adequately described the process of obtaining and linking mortality and cancer information. They noted that the information did not specifically mention the NHS Information Centre or the

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Central Register however Members agreed that on balance the information provided was acceptable and approved this application.

Action: NIGB Office to inform applicant of outcome.

MR1193 Investigation of the effect of Interleukin 1-receptor antagonist (IL-1ra) on markers of inflammation in non-ST evaluation acute coronary syndromes (The MRC-ILA-Heart Study)

6.2 Members considered this application for flagging cohort's records and current status for death notifications, PCTs and exits from the NHS. The application outlined a study to assess whether treatment of non ST elevation myocardial infarction acute coronary syndrome with IL-1ra alters the inflammatory processes involved with the condition.

Members noted that the study was fully consented and that the recruitment was completed in 2007. Members reviewed the consent forms and information provided to study participants. Members felt that whilst they would have been acceptable at the time of recruitment, the reference to linkage with the ONS was now out of date and that it should in fact make reference to the Information Centre. Members noted that whilst this was a minor point it was a requirement of the Data Protection Act to inform people about the full uses of their information and as such concluded that it was important that participants of the study were made aware of any changes to the way their data was processed.

This application was approved and Members suggested that the applicant write to living participants to provide an update in the uses of their information.

Action: NIGB Office to inform applicant of outcome.

MR1196 The CHiP Study

6.3 This application was for flagging of the cohort's records and current status for death notifications, PCT and exits from the NHS. The study aimed to determine whether a policy of strictly controlling blood glucose using insulin in children admitted to paediatric intensive care reduced mortality, morbidity and/or the use of healthcare resources.

Members noted that this study was consented and that recruitment to the study had begun but was not yet complete. Members reviewed the consent forms and information provided to study participants. Members noted that this information did not adequately mention the involvement of the NHS Information Centre. In addition, the materials stated that all study information would remain confidential, which prevented the disclosure of participant information to the Information Centre. Member reiterated that it was a requirement of the Data Protection Act that people were aware of the use of their data and therefore it was important that participants were provided with accurate information.

Members concluded that this application could be approved for those who had already been recruited into the study, but suggested that the applicant write to people to inform them of the changes to the use of their data. Members did not approve the application for the potential cohort who had not yet been recruited, and requested that the consent form and information leaflet be amended to fully explain the flow of information from the study to the NHS IC.

Action: NIGB Office to inform applicant of outcome.

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070510-07 Future of the DMsG

Clare Sanderson, Director of Information Governance at the NHS IC, attended the meeting to discuss with Members the migration of the role of the DMsG to the NHS IC. Members were informed that the group would be a sub-committee of the Information Advisory Group, whose Chair would be appointed via the Appointments Commission. Members were asked for any advice they may be able to give in relation to the approval process and an induction process for new members.

Members advised that future members of the group should be appropriately remunerated for their time and this included not only attendance at meetings but preparation time. They advised that a thorough induction should be established which would include advice about when an application should be made to the ECC. It was indicated that a manual available online for easy reference would also be beneficial.

Questions relating to the role of the group were raised by Members and they were informed that the group would be advisory to the NHS IC and whilst it would be likely that the decisions would be followed the NHS IC were the data controllers for the information and had the ultimate decision over the release of data. The Group advised that it could be established as a "Committee of record" in order to allow transparency over decision making.

Members were informed that if they wished they would be welcome to continue their role on the IAG once the migration had taken place. It was planned that this would take place by September 2010.

070510-08 Any Other Business

No further business was discussed.

070510-09 Dates of next meetings

- Tuesday 20th July 2010
- Tuesday 14th September 2010