Database Monitoring sub-Group
Minutes of meeting held 23rd February 2010

Present

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

In attendance: Ms Kathryn Anderson (IC, Southport), Ms Natasha Dunkley (Approvals Manager),), Ms Claire Edgeworth (Approvals Officer), Mr Paul Eveson (Department of Health), Ms Melanie Kingston (Deputy Approvals Manager), Ms Zoë Lawrence (NIGB Business Manager), Ms Susan Milner (IC, Leeds), Ms Diane Pryce (IC, Southport), Ms Kuldeep Sohal (IC, Leeds).

230210-01 Welcome and apologies for absence

Apologies were received from Mr Manny Devaux.

230210-02 Minutes of the previous meeting

Minutes of the previous meeting were approved subject to minor amendments.

230210-03 Matters Arising

230210-04 NIGB Office Report

Research Databases Working Group

At the NIGB Board meeting in October 2009, the ECC reported an increase in the number of applications it had received from clinicians and academic departments to establish research databases using identifiable patient information. In addition to this it reported an increase in the number of requests to local research committees to give 'secondary permission' to researchers to access data held in such databases. The ECC proposed that the NIGB should provide guidance on both the legal basis for research databases and on good practice governing 'secondary permissions' and access to data. To achieve this, the ECC suggested that the NIGB should establish a working group to assess the nature and scope of this problem and to make recommendations on practice. The Group were informed that the small working group had now been established and included membership from the NIGB, the ECC, and two external experts.

HES extensions / approvals since the last meeting

Doctor Foster Unit at Imperial

This application requested to receive A&E data from HES. This data was covered under Dr Foster's s251 approval.

Information Centre access to Mental Health Minimum Dataset

A temporary time extension was granted by Chair's action, which allowed a formal application to be submitted to the February DMsG meeting.

IC was granted approval by Chair's action to link the MHMDS with Lower Super Output geographic level data in order to release aggregated information to a customer.

MRIS extensions / approvals since the last meeting

MR1132 – OPERA. The minutes stated that this application was approved subject to clarification of consent issues. This was not concluded in writing. Application had been subsequently approved. Still awaiting completion of SLSP before final approval for release of data.

MR1164 – The Asymptomatic Carotid Surgery Trial (ACST-2) Application for current status and flagging for deaths, PCT and exits. Fully consented study therefore approved by NIGB Office.

MR1030 – Extension request to receive mortality information for those known to be dead. Fully consented study therefore approved by the NIGB Office.

MR1174 – Adjuvant Urokinase in the treatment of Malignant Pleural Effusion. Application for flagging for deaths. Fully consented study therefore approved by NIGB Office.

MR1176 – Defining the risk of kidney function decline and cardiovascular disease among patients with chronic kidney disease stage 3. Application for flagging for deaths and PCT. Fully consented study therefore approved by NIGB Office.

MR1178 - The Molecular Epidemiology of Lymphomas: The Epidemiology and Genetics Unit's Lymphoma Case-Control Study (ELCCS). Application for flagging for deaths with ICD10 codes. Consented study. Approved by NIGB Office.

MR1179 – INFANT study: A multicentre randomised controlled trial of an intelligent system to support decision making in the management of labour using the cardiotocogram. Fully consented study, application for flagging and current status for deaths of babies in England and Wales. Approved by NIGB Office.

MR1187 - Post-Authorization Safety Study (PASS) of GlaxoSmithKline Biologicals. Pandemic influenza Vaccine (GSK2340272A) in the United Kingdom. Fully consented study requesting current status for deaths. Approved by NIGB Office.

Demographic Batching Service /National Strategic Tracing Service queries.

SNAP trial. This application requested to use Demographic Batching Service to trace current addresses for patients lost to follow up. This was a fully consented trial. Whilst the consent did not directly refer to the DBS it did contain reference to there being long term follow up. The request was reviewed and approved by Chair's action.

230210-06 Hospital Episodes Statistics (HES) Applications

230210-05-a Medtronic Vascular, California

This application from Medtronic Vascular requested HES sensitive fields to enable marketing employees at Medtronic to understand diagnosis rates of aortic disease around the UK. The data would be used to analyse areas of high patient risk with the purpose of increasing

awareness in the senior population of abdominal aortic aneurysm and production of a map reflecting uptake and diagnosis within English regions which would then be shared with the NHS to enable identification of health inequalities in populations.

Members discussed this application at length and raised issues around its purpose and the requested sensitive data fields.

Members were unclear as to how the data fields requested would allow the stated purpose to be achieved. Members considered that if looking at population distributions in the UK, then non-sensitive geographical fields could be requested and might be more suitable in addressing the stated aims.

The discussion moved onto the reasons for requesting the sensitive data fields and it was agreed that it was not clear why consultant code and person referred were required; this led to further queries about the stated aims of the application. Members were of the view that these sensitive fields would allow potential identification of consultants and felt that the ability to make this inference from the data was not reflected in the purpose of the study. Members also sought clarification on how the study would achieve a patient benefit or whether it was to be used to market a service.

Members were of the view that as there would be potential for the requested information to be used to target individuals, that there was reasonable scope for the information to be used for a marketing purpose. This led to a consideration on the purposes to which HES could be used and it was agreed that HES should not be used for a marketing purpose.

As such, Members were of the view that they had not been provided with sufficient justification to approve the use of these sensitive fields due to the lack of clarity as to how these fields would meet the stated aims of the activity.

Action: NIGB Office to inform applicant of outcome.

230210-05-b University of Leeds, Paediatric Epidemiology Group

This application requested approval to receive a HES data extract from the North West Cancer Intelligence Service (NWCIS) in order to investigate the impact of cancer waiting times on individual health and long-term outcomes. The NWCIS already had approval to process linked HES data with national cancer registry data and it was noted that this request was for this linked data set. It was also noted that both in-patient and out-patient HES data would be used to examine health outcomes following the referral and diagnosis of cancer among Teenage and Young Adult Cancers.

Members agreed that the study and use of sensitive data fields was both proportionate and reasonable and agreed that the application provided justification of the data fields. It was noted that consultant code would not be pseudonymised as it was required for linkage purposes, and Members queried whether the applicant could pseudonymise the data themselves and asked whether this could be considered as an additional layer of security and that it would be a marker of best practice. Members agreed to provisionally approve the application, subject to the requests for clarification:

1. Members queried whether the intention was to publish by consultant code or GP?

2. Members considered that at some point it was expected the study would require mortality data from the Cancer Registry and therefore asked the applicant whether this had been considered?

Action: NIGB Office to inform applicant of outcome.

230210-05-c St George's University London

This application from the Outcomes Research Group aimed to use the data to audit death rates and HES data quality through examining the effect of data quality on conclusions regarding differences in death rates between trusts. This would be achieved through comparing HES data with the corresponding hospital case notes; looking at particular at number of cases and death rate, correspondence of secondary diagnosis and other HES fields.

This application from the Outcomes Research Group aimed to use the data to audit death rates and HES data quality through examining the effect of data quality on conclusions regarding differences in death rates between trusts. This would be achieved through comparing HES data with the corresponding hospital case notes; looking at particular at number of cases and death rate, correspondence of secondary diagnosis and other HES fields.

Members agreed that the principle of what would be investigated was worthwhile, and that it was important to check the accuracy of HES. However, the application raised a number of queries.

Members initially queried whether the activity was audit or research, the general principle being that local clinical audits should be carried out within the relevant Trust and this was usually carried out by staff employed at the Trust. Members noted from the application that the audit as described would be carried out by staff employed at an external academic institution and that there was the intention to publish the outcomes from this activity. As such, Members were of the view that this activity could be considered to be research and therefore a favourable opinion from a research ethics committee should be obtained.

Members were also unclear on the number of institutions that would be involved and requested further clarity on the number of Trusts that would be involved in the activity. Members also felt that they were not entirely clear on the disease being studied and requested clarification on whether only abdominal aortic aneurysm (AAA) would be investigated or whether the scope would be wider. In particular, Members agreed that a large number of data fields had been requested and were not persuaded that sufficient justification had been provided to justify these fields. Members queried why mental health data would be required, along with other fields such as marital status and psychiatric fields, and agreed that further information would be required before a decision could be taken on whether the use of this data was justified in the context of the application.

Members also requested clarification on who would be accessing the records, and requested confirmation as to whether these people would be members of the clinical teams responsible for the care and treatment of the cohort in question. If they were not part of the clinical team then any access to patient identifiable data without consent would be a breach of confidentiality and Members highlighted that an application for support under section 251 would need to be made to the Ethics and Confidentiality Committee.

Action: NIGB office to inform applicant of outcome.

230210-05-d Care Quality Commission

This application requested extracts on a bi-monthly basis until the end of the financial year to continue on from the DMsG approval provided in September 2009. It was noted that a new submission would be made in the future to cover the data for 2010-2011. Members noted that this bi-monthly extract service was not currently available via the NHS Information Centre (NHS IC) and that the CQC were discussing options directly with the NHS IC.

Members were also asked to consider the position on linking HES data between in-patient, outpatient and A & E datasets, and the use of linking HES and Mental Health Minimum Dataset (MHMDS) as a tool for analysing the wider care pathway and indicator of adverse events.

Members noted that the Care Quality Commission had statutory powers to obtain the requested data, and appreciated the application coming to DMsG as a mark of good practice, and expressed the view that it would be helpful if this approach could continue. Members agreed that the use of requested fields was legitimate and essential to achieve the functions of the CQC, and agreed this was an appropriate use of the sensitive data fields. As such, the request was approved by the Group.

Members considered the position on linking HES data with other datasets and noted that using HES ID to link activity information might provide a misleading picture of a care pathway as this would include more than one episode of care. Members suggested that it might be better to use a pathway identifier.

In terms of linking HES with the MHMDS, Members noted that the dataset would be pseudonymised before it went to HES and therefore queried whether it would actually be feasible to link the dataset to HES. It was agreed that the NHS IC would take up this issue and that the applicant should discuss the practicability of this aspect directly with the NHS IC.

Action: NIGB Office to inform applicant of outcome.

230210-05-e Co-operation and competitions panel, Department of Health

This application from the Cooperation and Competitions Panel set out a number of purposes for requesting the HES dataset. Members understood that the applicants would be looking at how far patients travel for healthcare purposes; factors that cause variations in this aspect, and the impact on quality of care.

Members queried how the stated aim of the application would improve understanding of quality of care, and they were not immediately clear in how looking at distances from patient to GP practice would further this aim. Members also requested further clarification on why data was required back to 2003-04. Members also requested clarification on why different data fields had been requested between A & E and outpatients and felt that this area would need to be clarified. It was noted that the NHS IC had worked with the applicant on completing the form and therefore the NHS IC agreed that they would check with the applicant and clarify the precise fields that they required. Finally, Members also agreed that they could see no justification for Local Patient ID as they were of the view that the activity could be carried out with the HES ID.

Upon balance, as the Group were supportive in principle of the application, they agreed to provide provisional approval to the study, subject to the following areas for clarification being satisfactorily resolved, and acceptance of the conditions of approval.

Request for clarification

1. Clarification how the stated aim of the study would lead to improved patient care.

2. Clarification over the reason for seeking data going back to 2003-04.

Action: NIGB Office to inform applicant of outcome.

230210-05-f Cancer Epidemiology Unit, University of Oxford

This application from the University of Oxford for the Million Women Study is an on-going prospective study that looks at relationships between lifestyle, reproductive factors and illness outcomes including cardiovascular disease and joint replacements.

Members noted that this was an extension of a previously approved study that was approved in November 2006 where the retention period had been stated to be for a period of 3 years. This specific request was to extend the data set to include HES.

Members noted that this was a consented study and agreed that their specific issue of focus was whether the original consent could be considered sufficient to include the use of HES in the study. Members noted that there was no explicit mention of HES in the original consent, and debated whether this would be necessary to render the original consent as being sufficiently informed so as to constitute valid consent for this extended activity. Members noted that most national databases comprised information that had been derived from medical records, and therefore were of the view that consent could be implied to cover HES data in this instance as the cohort had previously consented to researcher access to medical records. Members agreed that if recruitment had closed that there was sufficient justification to imply consent, however, if recruitment was ongoing, then any new cohort members should be informed that there would be access to their information held in national databases.

This application was approved subject to confirmation of satisfactory security arrangements.

Action: NIGB Office to inform applicant of outcome.

230210-05-g The UK Renal Registry

This was a consented study to investigate specific rare diseases of the kidney through establishment of a registry populated with clinical information in order to provide a resource for other clinicians and to use as an anonymised data source for research activities.

Members noted that the applicants had established a National Registry of Rare Kidney Diseases (RaDaR) on a consented basis. Whilst generally supportive of the purposes of the application, Members did raise some queries as set out below.

Members discussed the original consent form and patient information leaflets and raised some concerns around this as they felt an aspect required further explanation. The issue arose in relation to ‘freezing’ a record should a patient reach the age of 18 and they had not consented or actively withdrawn. Members felt that this term had not been explained in terms suitable to patients as the term did not make explicit what this would mean in governance terms in relation to previously collected data. Members therefore requested further clarification on this aspect.
Members also discussed the approach that when patients withdrew from the Registry their data would be removed and they would lose access to their own data and disease specific information. In particular, Members noted that when consenting to the study that the patient agreed to receive information from RaDaR and the disease specific research group from time to time. Members were of the view that removing access to disease specific information was a relatively punitive measure and felt that any withdrawal should not be of any detriment to the patient. As such, Members asked that the applicant consider this view and respond to this concern.

Based upon a balance of the above considerations, the application was provisionally approved subject to satisfactory responses provided to the request for clarification.

Request for clarification

1.. Members requested clarification on what was involved in ‘freezing’ the record, for example, would the record still be readily accessible? The applicant was asked to confirm what was meant by this term and its implications.

2. The applicant was asked to consider and respond to the issue of allowing patients, if they withdrew, to still maintain access to disease specific information, outline any difficulties with this approach and whether they would consider this to be feasible.

Action: NIGB Office to inform applicant of outcome.

230210-05-h Queen Mary, University of London

This was an application to ascertain the association between treatment for cervical disease resulting in colposcopy treatment, and the potential risk of preterm delivery from the colposcopy treatment.

Approval was sought from the Database Monitoring sub-Group by the Wolfson Institute to receive anonymised sensitive data for analysis purposes. The anonymised data would be obtained from NHS employees carrying out linkage of data regarding women attending colposcopy clinics between 1995 and 2005 with data from Hospital Episode Statistics (HES).

Members commented that this was a worthwhile and useful study, but considered that there were a number of areas that required clarification prior to a final decision being made.

The Group agreed that it would not be practicable to obtain consent with regard to identifying the cohort of 40,000 women treated for cervical disease. However, Members considered that it would be practicable to obtain consent from the nested case-control sample of 1,700 women (which included 850 colposcopy treatment cases and 850 controls) and therefore requested clarification from the applicant as to why consent for this part of the cohort had not been pursued.

Members noted that the study would use data from clinical records and link them to Hospital Episode Statistics. However, Members were not clear from the application as to the exact nature of the information that would be passed on to the applicants by the NHS employees. Members therefore requested further clarification as to whether any identifiers would be contained within the information that would be passed from the NHS employees to the applicant.

Members noted that NHS employees would be accessing patient identifiable information of a cohort which included women who had been treated over ten years ago. Concern was expressed that access to the identifiable information may not be solely by members of the direct clinical care team involved in the treatment of the individual cohort. The Group therefore requested clarification that those involved in accessing the data from the cohort had been involved in the care and treatment of the cohort.

Members noted that clinical staff would identify the cohort by using NHS number and date of birth information and then pass on pseudonymised data using a study ID (instead of the NHS number and date of birth) to the chief investigator who would then select a subsample of cases and controls from the wider cohort. The study IDs selected by the Chief Investigator would then be sent back to the NHS study sites. The NHS employees would then link back the study IDs using NHS number and date of birth identifiers in order to retrieve the full treatment details which would in turn be linked with HES data, anonymised and then sent back to the Chief Investigator. Therefore the Chief Investigator would anonymously receive a sample cohort fitting the criteria of the study. However, it was advised that as this study involved a cohort going back over ten years that reliance on the NHS number to perform linkage might not be possible as it was not in use prior to 2002. Members therefore suggested that further identifiers would be required for linkage purposes and requested information as to what further identifiers would be required in addition to the NHS number.

The Group requested clarification on the following:

1. The reasons for why consent could not be obtained from the case-control sample of 1,700 women

2. Whether information passed onto the applicant by the NHS employees contained any identifiers.

3. Whether all the NHS employees accessing patient identifiable data were part of the direct clinical care team involved in the treatment of the cohort.

4. What further identifiers would be required for linkage purposes in addition to the NHS number

5. Whether data could be linked using the PDS instead of HES data.

Once these responses had been received, they would be considered by the DMsG Chair.

Action: NIGB Office to inform applicant of outcome.

230210-05-i Request from NHS IC to receive MHMDS Data

This was a request from the NHS Information Centre (NHS IC) to receive the MHMDS quarterly and on an annual basis for a further 3 years. After this point, a further application would be made to the DMsG. The purposes behind the use of the data was to supply customers with MHMDS data and to publish official statistics about uses of the Mental Health Act in order to support the NHS in planning, commissioning and monitoring the delivery of services.

Members noted that the required data was record level and pseudonymised, and did not include any patient identifiers. In clarifying the scope of the request, Members noted that in addition the data set items listed on pages 133-177 that the applicant was seeking to receive an additional derivation from the patients postcode; lower super output area, and that the NHS IC did not receive full postcode.

As the NHS IC would be in receipt of pseudonymised data, the Group agreed that it would be reasonable to approve the use of the sensitive data items, and as such, approved the application.

Action: NIGB Office to notify applicant of outcome.

230210-06 NHS Central Register, MRIS applications

MR1168 IMPROVE aneurysm trial

This was an application for flagging of deaths so as to compare the mortality from ruptured abdominal aortic aneurysm (AAA) in patients treated by an endovascular first strategy versus the conventional treatment of immediate open repair. This trial would recruit a total of 600 patients over a 27-month period.

Members agreed that this was a worthwhile study; that its outcomes could help to reduce mortality, and thus it served a wide public interest.

Members highlighted that they wished to commend the applicant on their service user involvement and felt that it had been particularly meaningful in the context of this study. Members were also pleased to note that following a previous request that the information provided to patients had been amended to include the NHS Central Register and the NHS Information Centre.

Members noted that there would be difficulties in obtaining consent in emergency situations where a patient has presented with a ruptured abdominal aortic aneurysm, and emphasised that the applicant would need to fully take into account the requirements of the Mental Capacity Act when carrying out research on this sub-cohort.

In taking into account the public interest of the activity, Members agreed that it would be reasonable to provide support to this application.

Whilst not a condition of approval, Members strongly suggested that the use of the word 'stent' in the patient leaflets was likely to be an unknown term to the cohort. Members noted that other clinical terms had been clarified within the information provided to patients, but felt that consideration should be given to further explaining this term in order to ensure that the consent obtained would be specific and fully informed so as to be considered valid.

Action: NIGB office to inform applicant of outcome.

MR1180 Parkinson's Disease

This application set out the purpose of investigating whether patients with Early Onset Parkinson's Disease (EOPD) have particular genetic and environmental factors which lead to early onset disease. This would be achieved through establishing, amongst other areas, the prevalence of EOPD in a community based representative study in Cardiff and comparing outcomes against a control group. This application specifically requested flagging of deaths, cancer, PCT and exits so as to calculate mortality and cancer incidence in the prevalent Parkinson's disease case and control population. This would comprise initial vital status and cancer registration notification and then quarterly mortality cancer updates.

In considering this study, the Group agreed that the purposes of the study would serve a wider public interest and that its outcomes would be of value. Members also noted that recruitment had been completed and debated whether it would be reasonable to go back and seek consent from the cohort to inform them about the activity. Members were mindful that although the recruitment had been completed the cohort should be made aware about the use of their data. As such, they agreed that it would be reasonable to write to the cohort and inform them of this activity.

Members also debated the reasons for the requested information and requested that the applicant provide more information on why cancer information was required as it was not considered that this had been fully justified.

Members raised a final concern about the long retention period of 25 years and queried the justification for this. It was not clear as to why this time period was necessary and they requested further clarification upon this aspect. Related to this, Members also queried whether any of the data items could be reduced in terms of their identifiability at set points.

Upon balance, Members agreed to provisionally approve this study; subject to a satisfactory response being provided to the requests for clarification.

Request for clarification

1. Members could not identify sufficient detail to justify a retention period of 25 years and requested that this justification be provided. The applicant was also asked to consider reducing the identifiability of data items at set points or to specify reasons why this would not be feasible.

2. Confirmation from the applicant that it would be feasible to write to the cohort to inform them about this proposed activity. Any issues over this approach should also be highlighted.

3. Further justification from the applicant for requesting cancer incidence

Once responses to queries had been received the Group agreed that the Chair could make a decision whether to give final approval.

Action: NIGB Office to inform applicant of outcome.

MR1182 Genetic Longitudinal study of Ageing

This application set out a longitudinal study of ageing from King's College London in order to assess the extent to which age-related deterioration was correlated between different organ systems, and to assess whether variations of deterioration was due to genetic and environmental factors . The application had been presented to the DMsG as the applicant proposed to follow up previously consented study subjects; from which data had been collected from the previous 10 years. In particular, flagging and current status for deaths and cancer was requested.

Members noted that the cohort consisted of 8,000 people and that a view was required from the Group as the original information provided to the cohort did not make clear that the NHS IC would be involved in the process and that cancer and mortality were to be linked. Members noted that consent for this activity had not been sought from the cohort as at the time consent was obtained, it was not known that this activity would take place. Members were also mindful that when providing the original consent, the twins consented to providing information about any cancers they have had, informing the researchers about the deaths of the siblings and consent to contact the GP where necessary.

Members remained firmly of the view that the cohort should be informed as to the use of their data, and queried whether any of the cohort were still involved in the study. If so, then they should be informed of this data linkage activity. Members were mindful that the size of the cohort was relatively large and therefore reasonable steps should be taken to inform the cohort of this data linkage.

Conditions of approval

1. That those still involved in the study to be informed of this data linkage activity

2. That any new participants should be provided with clear information on how their data would be used and linked

Action: NIGB Office to inform applicant of outcome.

MR1185 Does the presence of thrombophilia increase the risk of developing idiopathic pulmonary fibrosis?

This was a case control study from the University of Nottingham where participants had been invited by local respiratory consultants at each hospital who would send out letters of invitation directly to eligible participants; who could then respond directly to the researcher. The aim of the study was to investigate the aetiology and pathogenesis of the condition and the impact of the presence of a thrombophilia upon the condition.

This application requested approval to receive flagging for death, cancer, PCT and exits from the NHS in order to determine mean length of survival and the number of patients that develop lung cancer.

Members assessed version 2 of the consent forms and noted that the applicant had amended these to reflect the role of the NHS Information Centre and use of the Central Register to follow up health status. As such, the Group considered that the consent forms were sufficiently specific to cover this activity and approved this application.

Action: NIGB Office to inform applicant of outcome.

230210-07 Any Other Business

No further business was discussed.

230210-08 Dates of next meetings

- Friday 7th May 2010
- Tuesday 20th July 2010
- Tuesday 14th September 2010
- Tuesday 23 November 2010