Database Monitoring sub-Group
Minutes of meeting held 17th June 2009

170609 – 01 Present

Members: Dr Patrick Coyle (Chair), Mr Manny Devaux, Ms Ros Levenson, Mr Terence Wiseman

In attendance: Ms Natasha Dunkley (ECC Approvals Manager), Ms Claire Edgeworth (NIGB Business Support Officer), Mr Paul Eveson (Department of Health), Ms Louise Dunn (IC, Leeds), Ms Melanie Kingston (ECC Approvals Officer), Ms Zoë Lawrence (NIGB Business Manager), Ms Susan Milner (IC, Leeds), Ms Diane Pryce (IC, Southport)

170609 - 02 Welcome and apologies for absence

The Chair welcomed Paul Eveson from the Department of Health and Claire Edgeworth to the meeting. Paul had principally been invited in regard to the small numbers item and was welcome to attend the whole meeting and future meetings. Claire had been newly appointed to the NIGB office and would be taking the minutes. Apologies were received from Dr Ian Goodman.

170609 – 03 Matters arising

The minutes of the last meeting were approved subject to minor amendments.

170609 – 04 NIGB Office Report

Administration of HES and MRIS applications following the ECC administration review

It was agreed that the NIGB office would write the formal response outcome letters for HES applications within ten working days of meeting.

The Information Centre

NIGB office and several ECC Members have had a series of meetings with the NHS Information Centre (IC) to discuss Section 251 specific support for current activities.

Establishment of research databases and disease registers

The ECC reported an increased number of applications from researchers wishing to establish databases with no clear specification of how the information will be used. The ECC did not support the establishment of databases without clear research questions and consent and had noticed an increased number of “advisory committees” being established to govern these databases. These databases raised a number of concerns about the duplication of activity, the legal basis for the work of these committees and the recruitment of members for these.

ECC applications

13 new Section 251 applications were considered by the ECC at their meeting on 21 May 2009. The next ECC meeting will take place on 20 July 2009.

170609 – 05 NHS Strategic Tracing Service update report

The NSTS Security Manager provided an update for the group about the closure of the NSTS. Members were content with the process currently being undertaken by the NSTS.

170609 – 06 Hospital Episode Statistics (HES) Business

HES small numbers disclosure

The Group were asked to consider the HES small numbers policy that applied to those organisations given access to HES data by the NHS IC. As the policy did not prevent the disclosure of small numbers to external organisations, but only restricted how they could use the data, small numbers which could be potentially identifiable could be released. Since the DMsG could only consider sensitive data items, potentially identifiable information would have to apply for Section 251 support and be considered by the ECC.

It was considered whether it would be practical for all recipients of these data extracts to gain Section 251 support. It was noted that the NHS IC received a large number of requests for extracts of this nature and that it was not possible to determine if small numbers would be obtained until the extract had been run. If the extract had been run and the researcher told that they would need to apply for section 251 support they may not want to proceed, which may result in resources being used unnecessarily.

The Group concluded that the ECC would need to discuss this issue at their next meeting..

Action: NHS IC to prepare a paper for the ECC meeting on 20 July setting out existing practices and business implications of any change.

Applications

170609-6-a Audit Commission – online access to consultant code

This application from the Audit Commission was to extend their current online HES access to include actual consultant codes for a project that they were undertaking. It was noted that currently they were only in receipt of pseudonymised consultant codes.

The Group raised concerns over the justification given for allowing access to actual consultant codes. It was likely that it was required for validation purposes; however Members agreed that the applicant had not been explicit enough in their explanation as to why this data was needed and how long this data would be held.

It was accepted that to some extent the information being requested was already in the public domain because the role of the consultant was public information. The Group also acknowledged that consultants would have been informed by the Department of Health (DH) that identifiable data may be used for these types of purposes. However Members felt that, in line with fair processing in the Data Protection Act 1998, consultants should be informed that their data is being used for this study by the Audit Commission.

The risk of duplication of a similar database held by another organisation was a further issue considered by the Group.

The Group requested clarification on certain issues before this application could be approved:

- Justification from the applicant regarding why the actual consultant code was required and why the pseudonymised code would not be sufficient.

- Clarification that only data of the 50 -100 Trusts mentioned in the application would be accessed or whether data would be accessed from all Trusts in the country.
- Members queried if it would be practicable to write to the Trusts involved and ask them to communicate to consultants that this information was being used in this way. This would ensure the Data Protection Act requirements were fulfilled.

If the Chair was satisfied by the response to the above requests for clarification this application could be approved outside of meetings by way of Chair's action.

Action: NIGB Office to notify applicant of Group decision.

170609-6-b Audit Commission – online access to legal information

This application from the Audit Commission requested access to 07/08 information on patient's legal status who were admitted under the Mental Health Act. An application had previously been approved by the Group for this data for 06/07.

The Group were not satisfied that sufficient justification had been provided by the applicant for the purpose of access to the data. Members requested further information and if satisfied the Chair could approve by way of Chair's action.

Action: NIGB Office to notify applicant of Group decision

170609-6-c King's Fund addition of researcher

Notification of an additional researcher requiring access to HES data was received from the King's Fund.

The Group noted and approved this information.

Action: NIGB Office to write to the Kings Fund to confirm approval of additional researcher.

170609-6-d English Registries annual review

The English Cancer Registries submitted a HES system annual review.

The Group felt that because the review outlined security procedures it should be assessed by the Security Advisor and if satisfied it would be approved by way of Chair's action.

It was questioned whether an annual review submitted to the Group would be necessary in future. Advice was to be sought from the Security Advisor to advise on the frequency of reviews.

Action: NIGB Office to seek further advice from ECC Security Advisor.

170609-6-e UCL – resubmitted application

This application from University College London was originally submitted to the June 2008 meeting, where concerns were raised with regard to consent. The additional information requested regarding consent was submitted in July 2008. The application was subsequently held up in the organisational changes with the NIGB.

The Group were unable to consider this application as the consent forms to be considered had not been provided.

Since the application had existed for a while it was considered important that it should be dealt with as soon as possible to negate further delay. The Group therefore decided that the information sheet should be examined by the Chair and, if satisfied, the Chair would approve.

Action: NHS IC to forward consent forms for consideration by Chair.

170609-6-f Oxford University

This application from Oxford University requested HES data to validate HES diagnostic coding with acute vascular events identified by other methods in patients recruited to the Oxford Vascular study.

The information sheet had not been attached and so the Committee could not consider it at the meeting. Concerns were raised over the extraction method to be used by the applicant. It was not explicit in the application that the extract from HES would be run so as to filter only those NHS numbers who have provided consent for the study. It was noted that this procedure was stated within the application but NHS Number was not selected from the filter list.

The Group were satisfied with the consent form given to participants.

This application was approved subject to clarification that the applicant intended to provide the NHS numbers of those patients who had consented to the NHS IC for them to run the extract for the consented cohort.

Action: NIGB Office to notify applicant of Group decision.

170609-6-g UCL – Whitehall II

The University College London Whitehall II cohort study submitted this application for extension of their existing DMsG approval in order to gain approval for access to Admitted Patient data between 1989 – 2003/04 and Out Patient data between 2003/04 – 2007/08. The study aimed to explore the relationship between socio-economic status and cardiovascular disease by examining the inter-relationships between biological, psychosocial and behavioural factors.

It was noted that the applicant also required data for 2006/07.

This application was approved by Members.

Action: NIGB Office to notify applicant of Group decision.

170609-6-h Update on HES applications 2009

An update on HES applications was provided to the Members from the NHS IC. Members noted that some of the open applications had been around for a significant length of time and it was felt that some clarification was needed regarding how long it was reasonable to keep them “open”. The Group also commented that some of the oldest applications would need resubmitted documents, such as security policy, when they were reconsidered. Members thought that it may be advisable for the applicant’s letter from the NIGB Office to contain date for response.

Action: Response letters to HES applicants to contain deadlines for responses.

HES Any Other Business

University of Liverpool

The University of Liverpool submitted an application requesting linked mortality data. An application had previously been approved in November 2008 and had mentioned that mortality data maybe required in the future, the approval given had stipulated that the applicant must submit justification for access to mortality data if needed.

Members had not had an opportunity to examine the letter submitted and it was agreed that the application could be submitted to the Chair and if satisfactory could be approved of by way of Chair's action.

Action: NHS IC to forward submitted application for consideration by Chair.

170609 – 07 NHS Central Register, MRIS Applications

Members were informed that MRIS applications requiring Section 251 support would now be submitted to the ECC. The applications considered at the meeting did not require S251 support.

Applications

MR1155 Which oxygen saturation level should we use for very premature infants? A randomised controlled trial (BOOST-II UK)

This application aimed to investigate whether varying the concentration of inspired oxygen so as to target a low versus high functional arterial oxygen saturation, from the day of birth until the baby is breathing air, would affect a number of health related factors in their lives. The application required the flagging and current status of 100 patients to provide fact and cause of death, exits, re-entries and Health Authority notifications.

The Members noted that Mr Terence Wiseman declared a potential conflict of interests in the study as he had been a member or the Research Ethics Committee that had approved this study. Members felt that it was acceptable for him to continue to consider this application.

The Group agreed that this was a worthwhile study. It was noted that as the applicant had no NHS sponsorship they would need to comply with the Office of National Statistics (ONS) checks in order to satisfy requirements to be an approved researcher. The checks would apply to each individual researcher.

It was noticed that the information would have to be stored for a significant length of time and would be of a large quantity. However it was felt that this was justified as it was crucial to this study.

Members were satisfied that consent was adequately in place for the study and approved the application.

Action: NIGB Office to notify applicant of Group decision.

MR1163 Standardisation of Breast Radiotherapy (START) Trials A and B. A randomised comparison of fractionation regimens after local excision or mastectomy in women with early stage breast cancer

This application aimed to maintain the integrity of the START trials. Patients initially recruited into the START trials between January 1999 and December 2002 had become difficult to trace, in order to ensure that trial data remained accurate the applicant requested the flagging of all patients on the study for deaths, cancers, PCT and exits.

Members recognised the importance of the study. Concern was raised as consent was not in place for all the information requested. Members discussed that consent could perhaps be implied for this information due to the nature of the study, however this was not certain. It was also noted that the data requested on death could be potentially identifiable, although this data was already in the public domain.

As consent was not in place for all information requested it was concluded that this application may need to be considered by the ECC and that the Chair of the ECC should be consulted.

Action: NIGB Office to notify applicant of Group decision.

MR1166 Evaluation of Mammographic Surveillance Services In Women Under 50 with A Family History of Breast Cancer

This application was for a study that aimed to estimate the benefit of annually mammographic surveillance in terms of reducing late stage breast cancer and mortality from the disease in women aged 40-49 with a significant family history in breast cancer. Flagging and tracing for deaths and cancer, including ICD coding was requested in order to validate the predicted mortality results.

The Members were satisfied that consent was in place for the information and that the information leaflet provided adequate detail. The application was approved.

Action: NIGB Office to notify applicant of Group decision.

170609 – 08 POiS Audit

The Patient Outcomes in Surgery (POiS) Audit submitted a paper for approval to the Group regarding changes to the previously proposed methodology. The Audit invited patients to complete a pre-operative Patient Reported Outcomes Measures (PROMs) questionnaire immediately before surgery and then complete another three to six months post surgery. A key aspect of the study was the linkage of the PROMs data with HES and National Joint Registry. Consent was originally in place and the Royal College of Surgeons were to carry out the linkage of this data, however due to policy reasons it was proposed that the POiS data would now be shared with the National PROMs programme and that in turn the linkage would be undertaken by the NHS IC.

The paper concerned the changes and the effect that they may have on the consent arrangements that were in place. The paper proposed that there were three separate groups that could be identified. Those who had completed both sets of questionnaires, those who had completed pre-surgery questionnaires and those who were yet to be recruited into the study. It was proposed that the later two groups would receive an explanation about the changes and be given a chance to opt out. However it was anticipated that those who had completed both questionnaires would not be contacted. The DMsG were asked to consider whether they endorsed this solution.

The Group recognised that consent was in place but not for the amended methodology that the applicant planned. Extensive discussion was had about whether the patient had actually already consented to PROMs carrying out the analysis of data. It was noted that PROMs was

a programme run by the DH and that consent had already been given for information to be used in “other NHS databases”. It was discussed whether the patient would regard the PROMs database as an NHS database, and it was agreed that the majority of patients would assume that it was.

The questionnaire contained information that the data collected would not be disclosed from POiS or the Royal College of Surgeons unless the participants were informed and it was of public interest.

It was felt that this was an important study and it was in the public interest for it to be continued. Members concluded that reasonable attempts should be made to contact and inform patients about changes and to give them the option to withdraw.

Action NIGB Office to notify applicant of Group decision.

170609 - 09 Any Other Business

The NIGB Business Manager confirmed that discussions were taking place with the NIGB Chair to determine the best path of action to take regarding access to the DBS.

Attention was drawn to the emerging trend of PCT’s charging researchers for access to medical information.

070609 – 10 Dates and venue of next meeting at New Kings Beam House

- Wednesday 2nd September 09 – room 11.1.6
- Wednesday 4th November 09 – room 5.2.1