Database Monitoring sub-Group
Minutes of meeting held 2nd September 2009

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), 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)

020909-01 Welcome and apologies for absence

Apologies were received from Mr Manny Devaux.

020909-02 Minutes of the previous meeting

The minutes of the last meeting were approved.

020909-03 Matters Arising

1) MR1153 - Pallister Killian Study

Members were given an update on a study that had gained DMsG approval for the NHS Information Centre (IC) to gain consent from a cohort on their behalf. They had subsequently found that they had gained a better than expected response through accessing potential participants via a voluntary organisation and no longer required NHS IC assistance to gain consent. Members agreed that since the participants were volunteering and approaching the researcher themselves this was an acceptable. It was noted that the consent form and patient information had already been approved. The Group were pleased to note that the study had obtained good support.

Action: NIGB Office to write formal response

2) UCL UKCTOCS IC update

This study had been reviewed at previous DMsG meetings but the consent form had not been available which meant that it could not be approved. Members were informed that the consent form was now available and requested for it to be circulated so that a decision could be made outside the meeting.

Action: NIGB Office to circulate consent form

020909-04 NIGB Office Report

Actions closed since the last meeting

Members were given an update of actions closed since the last meeting.

- University of Liverpool – AOB extension request for mortality data 07/08. Approved 23.6.09 by Chairman's action.
- Doctor Foster Intelligence (DFI) & Centre for Market & Public Organisations (CMPO) update and ECC small numbers discussion. Members were informed that both applications were now approved.
- The Patient Outcomes in Surgery (POiS) audit. This request from the Department of Health (DH) was declined at the last DMsG. Members were informed that the applicant was not happy with the outcome and requested DMsG review its decision. The applicant also asked advice on whether an application to ECC would be appropriate.

Following discussion with DMsG and ECC chairs, it was agreed that Section 251 support would not be appropriate and suggested the DH seek advice from the Information Commissioner's Office, as the query was regarding a change in data controller, and therefore was a data protection issue.

Demographics Batch Service (DBS)

Members were informed that a request was received from Connecting for Health (CFH) that DMsG implemented an application process for access to DBS data similar to that for NSTS. Following discussions with colleagues at CFH it was likely that the majority of applications will require Section 251 support and therefore will be considered by ECC.

For information:

Care Record Guarantee

An update was provided to the Committee on the review of the NHS Care Record Guarantee. The NIGB Terms of Reference state that the NHS Care Record Guarantee (CRG) for England must be reviewed annually. The review included input from the NHS, patients, the public and NHS Connecting for Health. The number of changes requested were very small and did not affect the overall intention of the Guarantee or any of its 12 commitments. The changes made reflected:

- The closure of the Patient Information Advisory Group (PIAG) and the transfer of its functions to the NIGB as part of the Health and Social Care Act 2008.
- Requests for additional clarity from the NHS. These areas for clarification included the following:
    - That the CRG applied to both paper and electronic patient records.
    - That both technology and business processes could be used to comply with the 12 commitments.
    - That the CRG applied to all staff who access patient records, not just to healthcare professionals.
    - That sample audits were appropriate when seeking to identify inappropriate access to records.

Members were informed that the NIGB Office had recently written to the Secretary of State and relevant ministers to inform them of the NIGB's intention to re-issue the CRG on this basis.

Disputes Resolution Document – Issued for public consultation

On 05 June 2009 the NIGB Office issued for public consultation a report of the Working Group on Disputes Resolution entitled *Guidance on the amendment of medical and social care*

records following a request from a person receiving care. The closing date for responses was 04 September and the final version would be made available on the NIGB website. Current plans were that the final version of the guidance would be launched at the NIGB public meeting in November.

Informing the public of their NHS number

PIAG had previously considered an application for support under Section 251 for NHS Direct to establish a new system to support FluLine. The system intended to facilitate large numbers of people obtaining treatment for influenza in the event of a pandemic being sufficiently serious as to warrant deployment. The purpose of the application was to allow 'live' data (real data) to be used for the final stages of testing after thorough testing with synthetic data. This was to ensure that the system could cope with large volumes of data.

PIAG had agreed to support the application but felt that as whole population data was required it should be approved by the Secretary of State directly.

Following this, PIAG's advice was sought on a related activity; a pilot run in the North East to inform people of their NHS number, which would be required to be able to obtain flu treatments via FluLine. This pilot made no direct mention of FluLine. Advice was sought in relation to the use of an independent sector provider to undertake research on public awareness and understanding both before and after the letters were sent out. They also provided a call centre to take calls from the public notifying the NHS of errors or changes that were needed. This was agreed as acceptable as it was for NHS administrative purposes, being undertaken under a data processing agreement and did not involve the disclosure of any clinical information. It was also felt to be an acceptable approach as it was a pilot and limited to one area. Consideration had been given as to whether it was feasible to undertake the mailing in-house but given the timescales involved this was not felt to be practicable.

020909-05 DMsG Interim Terms of Reference (TOR)

The NIGB Office provided an update on the development of the DMsG's TOR. These were being developed in order to provide a definitive description of what the Group does and what the operating arrangements for it were. Members were invited to comment on the interim terms of reference. The ToR were intended to be interim until it was clear how the DMsG would relate to the General Practice Extract Service Independent Advisory Board.

Members commented that the membership information in the operating arrangements should be clearer, the Group expertise should be explicitly stated and a discussion should be held about the size of the DMsG. The number of Members needed to deliver the ToR needed to be explained in more depth, for example including what expertise should be present and how many lay members etc.

The Group were informed that once the TOR's were established then Members would be able to give a preference on the length of term..

Action: Comments from DMsG members to be reflected in the draft, and for draft TOR to be agreed by the ECC at its meeting on 21 September.

020909-06 Hospital Episode Statistics (HES) Business

HES Sensitive Items

Members were informed that the HES sensitive items would be discussed by the ECC. The NHS IC advised that they had drafted the letter that would be sent out to mental health groups in order to gain their advice and feedback on what items should be considered sensitive in the mental health field. The draft letter was to be sent to the NIGB Office and the NHS IC agreed to feedback the responses at the next DMsG meeting.

Action: NHS IC to forward letter to NIGB Office
Action: NHS IC to feedback responses at next DMsG meeting

Applications

020909-6-a Care Quality Commission – Access to HES for the support of functions

The Care Quality Commission (CQC) requested access to HES data in order to perform a variety of its functions. The CQC had permission to access patient identifiable data under section 64 of the Health and Social Care Act 2008 for use in its activities.

Members noted that as the CQC already had statutory powers to allow access to this information it was not within the Groups remit to either approve or reject this application. However Members did feel that it was good practice for applications of this type to continue coming to the DMsG for review.

Members were supportive of the release of data for the purposes described in the application. As the CQC had already confirmed that the internal arrangements regarding data transfer and storage remain the same as previously agreed for the Healthcare Commission the Group did not feel that a further security review was necessary.

Action: NIGB Office to notify applicant of Group decision.

The Group noted that under section 80 of the Health and Social Care Act the CQC were required to prepare and publish a code in respect of the practice it proposed to follow in relation to confidential personal information. The Act stated that the NIGB should be consulted before this is published.

Action: NIGB Business Manager to ascertain what progress was being made concerning consultation on the Code of Practice.

020909-6-b English Cancer Registries- update of extract data years

The English Cancer Registries required an update to the current HES extract held. The extract was needed to cover data in the years 2008/09 and 2009/10. The dataset was required to enable production of version 3 of the all-England linkage between the HES dataset and to support the UK Flexible Sigmoidoscopy Screening Trial.

Members noted that the applicant had also requested information on deaths from the Office of National Statistics (ONS) but not cause of death. Members also noted that the mortality data on its own would be covered under the Cancer Registries existing section 251 support. Therefore, the Group were content to approve the application subject to the clarification that the applicant did not want to receive cause of death for this update.

The Group agreed that as this data would be requested regularly, and the Cancer Registries had section 251 support, the NHS IC could release the data without consulting DMsG as long as no additional identifiers were requested.

Action: **NIGB Office to notify applicant of Group decision**

020909-6-c London School of Economics

The London School of Economics required access to sensitive HES data to carry out a project until 2010/11 studying the demand for healthcare services, in particular the effect of expanded patient choice on the choice of hospital and the competition between hospitals. The data required included Census Output Area from 1989-2008.

Members discussed whether the sensitive data requested was in any way identifiable. It was agreed that the chance of identification would be remote and that the data was not particularly sensitive.

The application was approved.

Action: **NIGB Office to notify applicant of Group decision.**

020909-6-d HES Extract Request from Master's Student

This request for sensitive HES data came from a student who required the data in order to complete a research project as part of a Masters in Public Health degree. The Group was informed that the applicant had withdrawn her request for sensitive data since the application was made but that still required date of death from ONS.

Members discussed whether there was still any data requested that could be classed as sensitive, they concluded that there wasn't but were concerned about the security arrangements of this application. There was some uncertainty about where the information would be kept and who would be responsible for it. It was agreed that even if the information was to be kept independently by the student, the student's educational institution should still take responsibility.

The Group also discussed the research methodology and the proposed outcomes of the study. There were some concerns raised over whether there were legitimate reasons stated within the application for disclosing the data and whether the data requested would give the answers required. Members concluded that although the methodology was doubted it was not within the Group's remit to advise on research methodology. However the Group could comment on the appropriate use of information and whether sensitive data was necessary and therefore requested that their concerns were fed back to the applicant.

Members decided that it would be necessary for the IC to have an informal discussion with the applicant regarding the Group's concerns before proceeding.

Action: **NHS IC to discuss Group's concerns with applicant**

HES AOB

Whipps Cross Hospital

The Group was informed that a HES extract had been requested by a member of the clinical care team at Whipps Cross Hospital who wanted to pilot research on patients. HES data had been requested even though the applicant already had access to the data. There was some concern as the applicant was unsure whether they required Research Ethics Committee (REC) approval.

The Group advised that although the applicant was a member of the clinical care team they would still need to apply to the REC for approval and that they should contact their local ethics committee.

Action: NIGB Office to advise applicant

020909 – 07 NHS Central Register, MRIS Applications

Applications

MR1156 European Male Ageing Study

This study required access to the Central Register in order to flag 800 patients in England and Wales to provide fact and cause of death, cancer and exit notification. The study aimed to identify and quantify any disparities in the prevalence, incidence, nature and severity of symptoms and disabilities of ageing in the general male population in the European Union.

The study protocol required participants to identify two friends for the purpose of ensuring contact with cohort was maintained. The Group discussed whether this was suitable or whether PCT data would provide them with the same output negating the need for contact details to be shared. Concerns were raised over this method but the Group agreed that as the cohort had provided details of the contacts it was not within the Group's remit to comment.

The Group questioned the REC approval date as it appeared to be quite old.

This application was considered to be properly consented and was approved by Members.

Action: NHS IC to check REC approval date
Action: NIGB Office to notify applicant of Group decision

MR1162 British Breast Cancer Study

London School of Hygiene and Tropical Medicine required the flagging of deaths, cancer, PCT and exits for a study aiming to identify low penetrance breast cancer susceptibility alleles.

Members noted that recruitment for the trial would often include the cohort approaching their relatives; the Group discussed that this may result in people feeling pressured to take part. However, the Group agreed that this was outwith their remit.

Although the recruitment process was unusual it was decided that it was fully consented and the Group approved the application.

Action: NIGB Office to notify applicant of Group decision.

MR1164 Asymptomatic Carotid Surgery trial

This application required current status data and flagging for deaths, PCT and exits in order to carry out the Asymptomatic Carotid Surgery trial comparing carotid endarterectomy (CEA) and carotid artery stenting (CAS) incorporated into the routine healthcare of participating centres. The data obtained via MRIS would be used to ascertain the long-term safety of CEA and CAS.

Extensive discussion was had over the wording used in the patient information leaflets. Concerns were raised that the wording should be clearer. Particularly when detailing how long

the patient would be contacted for, which the Group felt should be stated in maximum time limits rather than minimum. Members recognised that this may mean returning to the REC but felt that it was more important to be clear. Members also agreed that the confidentiality policy in the detailed patient information sheet should be included within the simpler leaflet.

The Group approved the application and advised that the information leaflet should be made clearer in future and that the confidentiality policy should be moved onto the first, simpler leaflet the patient would receive.

Action: NIGB Office to notify applicant of Group decision.

MR1170 COIN

This application was for the COIN study; a three-arm randomised controlled trial comparing either continuous chemotherapy plus cetuximab or intermittent chemotherapy with standard continuous palliative combination chemotherapy with oxaliplatin and a fluoropyrimidine in first line treatment of metastatic colorectal cancer. The application requested flagging of deaths.

Members were concerned that the consent form created some confusion over the role of the NHS Strategic Tracing Service (NSTS). Discussion was had about the use of generic terms in patient information. Members felt that generic terms should not be used just because the consenting cohort might be unaware of the nature of the databases that information was to be obtained from.

The Group were informed that recruitment had already been completed and therefore the issue was whether they had been consented using the correct information and whether it was valid. A view was raised that it may be disproportionate to expect the researcher to reconsent the cohort in the circumstances.

Due to the uncertainty over the validity of consent Members requested that the application be assessed by the ECC Chair to determine whether it would be necessary to obtain section 251.

Action: NIGB Office to consult ECC Chair about application

MR1172 CE-MARC – Clinical Evaluation of Magnetic Resonance imaging in Coronary heart disease

This application required flagging for death notification with the primary intention being the assessment of the diagnostic accuracy of Cardiac Magnetic Resonance (CMR) in detecting coronary heart diseases (CHD) compared to the current “gold standard” X-ray angiography.

The Members were content that consent was in place for this study and granted approval.

Action: NIGB Office to notify applicant of Group decision.

020909-09 Any Other Business

MR1166 - Evaluation of Mammographic Surveillance Services in Women under 50 with a family history of breast cancer

The NHS IC provided an update on a study (MR1166) that was granted approval in the June DMsG meeting. This study had subsequently been to the GRO Scotland who felt that the study had not gained consent to obtain cancer data.

Members agreed that they would not reconsider this decision as their original reasoning still stood. DMsG had previously stated that due to the nature of the study it would have been clear to participants that cancer data would be requested.

ONS Approved Researcher Update

The Group was informed that if consent had been obtained for data then a researcher applying for ONS data would not have to obtain an approved researcher status.

Validity of Consent

Members were asked to consider what route should be taken if a study changed either its data requirements or purpose long after it had begun. Members felt that the decision made in these cases should be based upon the time scales involved and the degree of change. If a short time had passed, e.g. two or three years, then the cohort should be informed and asked to reconsent. However if there was a longer time lag then Members felt it was reasonable for Section 251 to be considered. It was agreed that it would be a proportionality judgement and that the decision should be taken by the ECC. It was noted that in order to gain REC approval researchers may be required to reconsent.

It was concluded that the issue should be discussed at the next ECC meeting.

Action: To raise validity of consent issue at ECC meeting on 21 Sept.

020909 – 10 Dates and venue of next meeting at New Kings Beam House

- Wednesday 4th November 09 – room 5.2.1
- Tuesday 23rd February 2010 – venue tbc
- Wednesday 5th May 2010 – venue tbc