Minutes

NIGB

Ethics and Confidentiality Committee
Database Monitoring sub-Group

Database Monitoring sub-Group
Minutes of meeting held 20 July 2010

Present

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

In attendance: 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 Kuldeep Sohal (IC, Leeds)

200710-01 Welcome and apologies for absence

1. Apologies were received from Mr Manny Devaux.

200710-02 Minutes of the previous meeting

2. The minutes of the previous meeting were approved.

200710-03 Matters Arising

Medtronic – application for HES extract (230210-5-a)

This application from Medtronic Vascular had been considered at the February DMsG meeting. The request was for the purpose of using the data to analyse area of high patient risk, and to increase awareness in the senior population of abdominal aortic aneurysm (AAA). The application indicated that a regional map would be created to show uptake and diagnosis, which would subsequently be shared with the NHS in order to enable to identification of health inequalities in populations. Members had also noted that this data was to be used by a commercial organisation based in the United States.

The application was not approved at the meeting. Members were of the view that they had not been provided with sufficient justification to approve the use of these sensitive fields due to a lack of clarity as to how these fields would meet the stated aims of the activity.

The outcome letter stated ‘In noting the point made above that sensitive items in HES cannot be used for marketing purposes, should you wish to resubmit this application then it is recommended that you clearly articulate the precise purposes of the activity, and to fully justify the need for the sensitive data fields’

Members were informed that the applicant had informed the NHS Information Centre (NHS IC) that they no longer wished to pursue the request with NHS IC as a third party had satisfied their requirements.

The NHS IC had asked that the DMsG be informed of this and consider whether members wished to explore further the sources that the applicant referred to.

Members discussed that this was not within the remit of the Group and therefore agreed that it would not be appropriate to pursue the matter any further with the applicant.

200710-04 NIGB Office Report

Public Health Observatories (PHO's) and section 251 support

Following the application request for a full HES extract considered at the May DMsG meeting, the NIGB Office met with representatives from the PHO's to discuss the requirement for section 251 support.

The meeting was productive and the PHO's have agreed to submit an application for section 251 support for the September ECC meeting.

Applications closed since the last meeting

070510 –a CMPO and Imperial College.
Application approved subject to satisfactory security review, which had now been approved.

070510-g NE Public Health Observatory access to Mental Health Minimum Dataset**.**
Application approved subject to satisfactory security review, which had now been approved.

HES AOB 1 – Health Protection Agency.
Application for HES extract, the information was to be linked with tuberculosis cases reported to the national TB surveillance and used to answer a number of research questions. The request was for access to the following sensitive fields:

- Date of Birth - patient
- NHS Number
- Postcode of patient

This work fell under the scope of the HPA specific section 251 approval and was approved by Chair's action.

HES AOB 2 – UCL Whitehall II study
This application was for an update to a fully consented study and approved by Chair's action after the meeting.

Other applications fully approved

1170 - COIN - 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.
Application approved subject to satisfactory security review, this had now been approved.

1187 - Post-Authorization Safety Study (PASS) of GlaxoSmithKline Biologicals. Pandemic influenza Vaccine (GSK2340272A) in the United Kingdom.
This application had been approved subject to satisfactory security review, this had now been approved.

230210-h - Application for HES extract from the Queen Mary, University of London.
This application had been approved at February DMsG subject to clarification of queries and satisfactory security review. Responses to queries had been reviewed and approved by Chairman's action and SLSP now signed off, therefore now had full approval.

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Decisions taken outside the last meeting

Applications from the Health Protection Agency

1. Meningococcal disease

Application for HES extract to be used in a capture-recapture study aiming to evaluate the proportion of cases of confirmed meningococcal diseases that were not recognised by the enhanced meningococcal surveillance system in London.
This request was for access to the following sensitive HES fields:

- Date of Birth - patient
- Postcode of patient

2. Healthcare associated infections and antimicrobial resistance

This application for a HES extract was from the Healthcare Associated Infections and Antimicrobial Resistance Department. The data would be used for a range of national surveillance programmes collecting data on healthcare associated infections, antibiotic resistance, surgical site infections, non vaccine preventable invasive bacterial infections and invasive fungal infections.
HES data would be linked to the microbial information already contained within HPA datasets.
The request included the following sensitive data items:

- Date of birth
- NHS number
- Postcode of patient

Both applications were reviewed by the NIGB Office. The Office confirmed that they fell within the existing HPA specific section 251 regulations, and approved the applications.

Nuffield re-use of data request

Request to use data already held (up to years 2008-09, inpatient and outpatient HES extract) for the following new studies:
1) Analysis of admission rates COPD : a time series analysis.
2) Whole system demonstrator project
3) Patient Flows
4) Evaluation of service innovation and impact on the use of secondary care
5) Development of indicators for effective commissioning
6) End of life care

The extract did not contain any identifiable data, this was reviewed and approved by Chair's action.

SCOOP study

This was an application for an update of a previously approved extract.

The information would be used as part of the SCOOP trial, a large scale, randomised controlled trial of the effectiveness and cost effectiveness of screening for prevention of fracture in older women. All participants had consented to take part in the study. The request included NHS number and date of birth.

This application was reviewed by the NIGB Office and approved.

200710-05 Hospital Episode Statistics (HES) Business

200710-5-a Dr Foster Intelligence

This request from Dr Foster Intelligence detailed an update to the previously approved application for an extract of the Mental Health Minimum Data Set (MHMDS). The data would be used for solely for the purposes of processing the data through the Mental Health Activity Tracker (MHAT), a tool designed for NHS organisations that provide or commission mental health services to enable them to analyse information about inpatient and community activity, to plan and monitor service improvements and to drive more effective allocation and commissioning of resources.

This extended scope request included:

- To allow the Dr Foster Unit at Imperial College, London access to the data, in order to produce risk models and indicators
- To make the MHAT Available to wider audience including: Strategic Health Authorities, Care Quality Commission, NHS Information Centre, private mental health service providers
- To analyse the data received down to team, ward and consultant level
- To allow the Dr Foster Analytics department to use the data for bespoke analytical work to support MH providers and commissioners including those who did not presently have the MHAT Tool
- To provide analysis and / or supplement the MHMDS data with other datasets including demographic and other population type data sources and publicly available datasets such as those available from data.gov

Members discussed that the application detailed a wider range of activities than the existing one and also that the data would be analysed to lower levels, such as ward, and distributed further. Members also noted that the applicant stated that they wished to “supplement the MHMDS data with other data sets including demographic and population type data sources.” Members requested that clarification be provided in relation to the additional data sets, what additional information would be linked and what the process for this would include.

Members discussed that there may be small numbers involved in the extract but were satisfied with the safeguards that the HES protocol included which all recipients of data had to sign up to.

Members noted that the information would be shared with the Dr Foster Unit at Imperial College and wished to reiterate that DFI did not have approval to process identifiable data. However the committee was pleased to note the controls in place, and the continued efforts to meet this condition.

Members approved this application subject to the clarification requested over additional linkages and confirmation of satisfactory security arrangements.

Action: NIGB Office to inform applicant of outcome.

200710-6 NHS Central Register, MRIS Applications

MR1148 Markers of risk and myocardial injury in patients undergoing coronary angioplasty The OPERA study

This application for the British Heart Foundation Heart Research Centre was for flagging and current status of 1000 patients' records in order to receive fact and cause of death notifications as part of a study into markers of risk for patients undergoing coronary angioplasty.

The aim of the study was to discover:

1) Does the very small amount of damage that can occur to the heart muscle during angioplasty have any long term implications for the health of the patient?
2) Can we predict which patients are more at risk of developing damage to the heart muscle during angioplasty?

The primary outcome measures for the study are major cardio vascular events (Death, Myocardial injury hospitalisation and repeat coronary angioplasty) and therefore the long term mortality data was required for this purpose.

Members noted a slight inconsistency between the HES application and the consent materials provided to participants. The application stated that the data would be retained for at least 10 years, yet the consent form and information leaflets which the participants received stated that the blood sample taken would be retained for 10 years only.

Members agreed that in line with the consent form, data should only be retained for a maximum of 10 years and it would be necessary to re-consent participants if the applicant wished to retain data for longer than this agreed period.

This application was approved subject to the data being retained for a maximum of 10 years, if the data was to be retained further then consent should be obtained for this.

Action: NIGB Office to inform applicant of Committee decision.

MR1192 A randomised controlled trial of iodine supplementation in preterm infants (I2S2)

Member considered this application from the University of Oxford for flagging for deaths, PCT and list cleaning of 1700 individuals' records. The information would be used for a study in order to investigate whether iodide supplementation of extreme preterm infants changes neuro-developmental outcome at 2 years corrected age.

In addition, mortality information was requested in order to prevent contacting parents of babies who had died, and PCT information was required in order to trace and follow up participants after 2 and 5 years.

In discussing this application, Members focused upon the participant information materials and consent form in detail. It was noted that whilst the information leaflet did contain the recommended wording for follow up through the Central Register, the consent forms did not make any mention of this. Members were especially concerned over this aspect as long term follow up was considered to be of significant importance and therefore this should be included in the consent forms so that the participant is fully aware as to the uses of their data. Members felt that it was important for consent forms to reflect the required uses of data as this was often the document retained on record, and often patient information leaflets can undergo a number of changes.

Additionally, Members also noted that the applicant wished to hold the study data indefinitely. A general principle of the Group was that in order for the consent to be considered valid, the information provided should be specific enough so that the participant was clear as to the proposed processing of data. Members agreed that the participants should be informed about the details of the processing of their personal data and how long it would be retained for. It was also noted that the applicant had stated that the intended follow up period was at 2 and 5 years, members agreed that this should be included within the information leaflet and that if identifiable data was to be retained for longer than this period then consent should be sought.

Members were mindful that changes to the patient information materials would necessitate further engagement with the research ethics committee in order to identify whether a substantial amendment would be required. However, the Group agreed that these issues were sufficiently important to warrant this.

Additionally, should longer term follow up take place (for example 12 yrs plus) members felt that the applicant should give consideration to the children gaining competency and being able give their own consent to be part of the study.

Members also noted that the patient information leaflet made reference to the website for further information, members felts that all information should be available on the patient information leaflet and that participants should not be expected to have access to the internet access.

This application was approved subject to the following conditions:

1. That the consent form was amended to contain the recommended wording to allow for long term follow up through the Central Register.

2. That the information leaflet was amended to include a specific data retention period for the study data.

3. Satisfactory review of the security arrangements.

Action: NIGB Office to inform applicants of committee decision.

MR1205 Observational study of treatment outcome in early diffused cutaneous systemic sclerosis (SSc) in Europe. European Scleroderma Observational Study (ESOS)

Members considered this application for a study to examine the effectiveness of different immunosuppressive drugs currently favoured by clinicians treating early diffuse systemic sclerosis (SSc).

The information requested was current status for deaths, direct cause of death ICD and complication or disease leading to death ICD. This was required in order to provide information about the efficiency of treatments and their ability to prevent organ damage.

Members noted that this was a fully consented study and the consent materials contained the recommended wording to allow for this activity.

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

Action: NIGB Office to inform applicant of committee decision.

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MR1202 BALTI-2: Beta Agonist Lung injury Trial 2

This application from the University of Warwick was to receive fact and date of death for study participants in the BALTI-2 trial. This was a randomised controlled trial to test if intravenous infusion of salbutamol could be used as a treatment for Acute Respiratory Distress Syndrome (ARDS) which improved patient survival.

The information was required in order to 1) prevent sending follow-up questionnaires to participants who had died and 2) determine accurate mortality in the 12 months after randomisation.

It was noted that all participants had consented to take part in the study and that recruitment had closed.

Members reviewed the consent form and information leaflet provided to participants and noted that the consent materials made no mention of receiving follow up data from the Central Register. The committee however agreed that on balance, the consent materials provided did explain that medical records would be reviewed in order to check the outcome of the treatment. Members took into account that the cohort was fully recruited, and that the applicant was only requesting minimal mortality information and agreed to approve the application on this occasion.

Members advised that any future studies should use the approved wording that was available on the NHS IC website.

This application was approved subject to satisfactory security arrangements.

Action: NIGB Office to inform applicant of committee decision.

Update of outstanding MRIS applications

Diane Pryce provided an update on all outstanding MRIS applications which had not yet received full approval.

200710-07 Any Other Business

No further business was discussed.

200710-08 Dates of next meetings

- Tuesday 14th September 2010