Meeting held on Monday 28th March

Present

Members: Professor Sir Denis Pereira Gray (Deputy Chair), Mrs Pauline Brown, Dr Tony Calland, Professor Michael Catchpole, Dr Patrick Coyle, Dr Fiona Douglas, Ms Stephanie Ellis (to item 3c), Mr Michael Hake, Dr Colin Harper, Professor Julia Hippisley-Cox, Professor Jane Kaye, Ms Sue Parroy, Dr Mark Taylor, Mr Terence Wiseman.

In attendance: Dr Alan Doyle *(NIGB Director),* Ms Natasha Dunkley *(Approvals Manager),* Ms Claire Edgeworth *(Approvals Officer),* Ms Melanie Kingston *(Deputy Approvals Manager)*, Mr Sean Kirwan (Department of Health)

1. Welcome and apologies

Apologies were received from Dr Andrew Harris (Chair) and Dr Tricia Cresswell. Professor Sir Denis Pereira Gray chaired the meeting in the Chair's absence.

Dr Abigail Knight from NHS Tower Hamlets and Ms Briony Elliott from Experian attended to provide further information for item 3A.

Members were informed that Professor Carol Dezateux had handed in her resignation as an ECC member with immediate effect due to recent work commitments. The Chair expressed his thanks to the valuable contribution she had made as a member. As Professor Dezateux was an NIGB member, all NIGB members would be approached to apply to replace Professor Dezateux as an ECC member.

Declarations of Interest

Dr Michael Catchpole declared a professional interest in item 4A and Professor Julia Hippisley-Cox was the applicant for item 4E.

2. Minutes of last meeting [ECC 1-02/2011] and matters arising

The minutes from the meetings held on 2nd and 3rd of February were approved.

ECC Chair's Report [ECC 3-02(a)/2011]

The minutes for the NIGB meeting held on the 24th February would be available on the NIGB website following the Board meeting on the 12th May.

Healthcare Quality Improvement Partnership (HQIP) Lecture

The Chair and Deputy Chair had recently attended a HQIP sponsored event to present a lecture about the legal basis for consent and the background and role of the ECC.

NIGB Office Report [ECC3-02(b)/2011]

Update on the interaction between the Health Service (Control of Patient Information) Regulations 2002 and the NHS Trusts and Primary Care Trusts (Sexually Transmitted Diseases) Directions 2000 ("Sexual Health Directions") [ECC 8-03(a)/2010]

Members were provided with an update on the progress of this item considered in the December 2010 meeting. Legal advice had been sought from Department of Health lawyers and a dialogue established which was ongoing, with the Chair of the ECC having direct contact with lawyers to discuss the issue. The Deputy Chair noted that it was important that written legal advice was provided as the issue involved highly sensitive data, and it would be important to have a clear position that could be relied upon for future decisions. The Deputy Chair therefore requested a written statement in layperson's terms on how the Directions apply and its interaction with the Regulations.

Members considered that clarity was required on the status of current approvals under section 251 which included sexual health data and that this could not be gained until legal advice was given. It was noted that clarification was required about how the Sexual Health Directions interacted with section 251.

Action: Chair to provide summary of DH legal advice and its effect on ECC applications.

Fast Track applications

ECC 3-02(FT1)/2011 Endstage Renal Disease in Early Infancy

This application from the Belfast Health and Social Care Trust detailed a study which, using the BPSU methodology, aimed to identify all infants with End stage renal disease (ESRD) within the UK and Ireland. The study aimed to identify the prevalence of the condition, examine the treatment received and what medical complications arose. The information would be gathered with an aim to help inform decisions and management of the disease and provide information for the planning of hospital and outpatient services in neonatology and nephrology in the UK & Ireland.

Members agreed to give provisional approval contingent on satisfactory clarification of the points below and subject to the specific and standard conditions of approval:

Request for clarification:

1. Clarification how long identifiable data items kept for analysis would be retained.

2. Members requested further justification on the retention of postcode data.

3. Confirmation whether the study had received Research Ethics Committee approval.

Conditions of Approval

1. That each clinician who notifies a child should make readily available to patients the BPSU patient information leaflet for this study. This should include informing parents of data subjects opportunistically that data collection is taking place and respecting any dissent from future data usage in line with the principles in the Data Protection Act.

2. Any section 251 approval could only apply to data collected in England and Wales.

Satisfactory clarification had subsequently been provided by the applicant.

ECC 3-02(FT5)/2011 The AHEAD study: Managing anticoagulated patients who suffer head injury

This application aimed to identify the incidence of clinically significant brain injury in patients taking anticoagulating drugs as defined by death or neurosurgery resulting from the initial injury and determine best management options for these patients. This required section 251 support in order for research nurses to access patient information within accident and emergency sites without consent in order to extract anonymised information and write to patients to consent to take part in the study.

Approval was given subject to the following condition:

1. Provision of a REC favourable opinion letter.

ECC 3-02(FT6)/2011 Evaluating the use of the Neonatal Illness Prognosis Indicator

This application from Glan Clwyd Hospital aimed to evaluate the use of the Neonatal Illness Prognosis Indicator (NIPI) as a scoring system within the neonatal unit at the hospital. The application required section 251 to allow a medical student to access medical records of very low birth weight neonates to collate data on gestation and life threatening malformation and create an NIPI score for each individual.

Members concluded the application would not require section 251 support as access by a medical student for the stated purposes would not constitute a breach of the patient's confidentiality.

Members made the following fair processing recommendation in relation to this study and other similar work that may be undertaken:

1. If not already displayed, posters should be put up within the neonatal unit to notify patients that medical students are involved in audit work. If any objection is made to the use of data for this purpose then that dissent should be respected.

Amendments and extensions

ECC 6-02 (FT2)/2010 - Confidential Inquiry into premature deaths with people with learning disabilities - extension of geographical area

This application sought an extension to cover those geographical areas outside the current areas (Bristol, Bath and North East Somerset, South Gloucestershire, North Somerset, and Gloucestershire) where services have had contact with the person in the year before their death, and where the provision of information from those services was essential to the Confidential Inquiry. There would be no change to the purpose, process, data flows or change to data items.

ECC 4-15(c)/2009 Routine Assessment of symptoms and functioning in Cancer patients: Pilot study to compare routine assessment versus standard care in managing social difficulties in routine oncology practice

This application was for an extension of a previous approval which had outlined a programme of studies. The Pilot study to compare routine assessment versus standard care in managing social difficulties in routine oncology practice protocol detailed a randomised pilot study design to compare implementation of the Social Difficulties Inventory (SDI-21) by trained nurses against standard care.

It was noted that this extension had been detailed within the original application but that the protocol had not yet been finalised and therefore this particular study could not be approved at that time. The methodology for using patient identifiable data in order to obtain consent was identical to the previous application.

Members commented on the clear and helpful information presented within the comparison document submitted. They approved this application as an extension to the programme of studies by the same group of researchers.

Update on British Association of Urological Surgeons (BAUS) audit PIAG 2-07(g)/2004

The applicant informed the NIGB Office that their new data collection system would allow only clinical care teams at a local level to view patient identifiable data.

A document was provided that confirmed that access to patient identifiable data would be restricted to those who had provided care and treatment for patients at the local level. Local users would only be able to access data on patients for whom they had been responsible. At a national level the system would not make available identifiable data and would allow the data to be used in an anonymised format for audit purposes, but the encryption would be such that it would allow for the identification of duplicate data.

The document was forwarded to the ECC security advisers who confirmed that the security arrangements were satisfactory and that the system provided adequate assurance that identifiable data would only be available at a local level.

Therefore as no identifiable information would leave the local clinical care teams this application no longer required section 251 approval.

Update on previous applications

Transfer of cardiac audits to the National Institute for Clinical Outcomes Research (NICOR) at University College London. ECC 1-06 (d)/2011

This application involved a change to the data processor (from the NHS Information Centre to NICOR) and was therefore being processed outside the formal Committee meeting schedule as there was no change to data items or purposes. The security arrangements had been confirmed as satisfactory and relevant governance documents provided. Members were informed that the application had now received support under section 251, subject to a number of conditions which included exclusion of research activities without a separate application, commitment to encouragement of dissemination of patient information leaflets, engagement with patient groups, and a review of retention of identifiable information

Research Capability Programme Honest Broker Research Support Services ECC 7-04 (a)/2010

Subsequent to recommending provisional support under section 251, a number of requests for clarification had arisen from the NHS Information Centre over the scope of approval. Subsequently, a teleconference took place to establish the boundaries of the approval. A final recommendation of support had been provided. It was noted that a number of amendments had been made to cover extension of cohort period and the addition of non-identifiable data items.

Change of data processor for the national confidentiality enquiries and mortality audits

An update had previously been provided in the February NIGB Office report. Members were informed that the activity was progressing with no unexpected aspects arising, and was pending the outcome of satisfactory security review. The National Patient Safety Agency (NPSA) had confirmed that if the new data processor was unable to 'take over' approval by 21st March, suitable postal redirection mechanisms would be put into place and redirected to the NPSA offices as they remained data controllers for the activity.

Update on NCASP application

Previously, it had been agreed that the National Clinical Audit Support Programme application would be separated into individual audits, and would be submitted to the Committee on an individual basis. Members were asked to note for information the timetable for submissions to the Committee that had been provided by the applicant.

3. Resubmissions

3A Tower Hamlets Bespoke Population Segmentation [ECC 7-04(g)/2010]

This resubmitted application from Tower Hamlets PCT and Experian Ltd had originally been considered at the Committee meeting in September 2010 and set out the purpose of utilising patient level data to create a bespoke population segmentation. The segmentation was to be commissioned by NHS Tower Hamlets, and created by Experian Ltd. The segmentation would form the standardised framework of an integrated commissioning strategy, which addressed health inequalities. Section 251 was sought to provide a legitimate basis to allow an Experian employee to access medical records to allow a number of linkages to Experian data to be made.

Dr Abigail Knight from Tower Hamlets PCT and Ms Briony Elliott from Experian Ltd attended the meeting to provide responses to members' queries about their resubmitted application.

During the discussion, Members were informed that advertisements would be displayed in local newspapers in order to inform members of the public whose data would be involved and allow the opportunity to opt out if they wished.

The attendees provided further information about linkage processes and reassured the Committee that identifiers would be used when matching the data only, following this the identifiers would be removed and the actual segmentation would be created using only anonymised data. It was noted that Experian, although anonymising NHS data at the source, would retain the key to decoding the data and that whilst it was not intended that the key would be used, it would be possible. Personal identifiers, rather than household level identifiers, were required for matching given the nature of housing within Tower Hamlets.

Members raised concerns that the data requested was of an extremely sensitive nature and were informed that a large amount of data had been requested as when building segmentation models it could not be determined what data items in particular would be useful.

Members queried whether there had been previous work or peer reviewed articles which could be used as evidence to reflect that the proposed outcome would have a benefit to the management of NHS services and therefore a public interest. The applicant confirmed that they were not aware of any precedents or articles which could be used to evidence this.

The Committee welcomed the opportunity to discuss the activity with the applicant and noted the applicants request for further advice in order to improve the processes. The Committee discussed this application at length and considered what advice could be provided to the applicant to help in the preparation of a resubmission.

1. Legal basis for holding data

The Committee queried the legal basis for receiving detailed data from local government. Some members of the Committee with substantial experience of local government understood that even within local government there were restrictions on data transmission, for example information about people both on benefits and social work records. The Committee therefore requested clarification over the legal basis for Tower Hamlets NHS Trust holding this information before any resubmission was made.

The Committee also queried the assumption in the application that GPs were able to transmit personally identifiable information including sensitive clinical details about people to a third party without the patient's knowledge or consent. The common law duty of confidentiality was a right which patients had and the Committee understood that doctors could not override it.

The Committee considered the consent form given to GPs and doubts were expressed as to whether it constituted informed consent for the clinician, for example a prominent heading included "clinical audit". It was not clear whether the GPs would fully understand the whole proposal and who does what, therefore further clarification was sought over this aspect.

2. Proportionality

The Committee advised that one of the legal frameworks governing the work of ECC was the Human Rights Act 1998, and in particular Article 8 and the right to privacy. Members considered whether the scope of the proposal and the extent of the disclosure of sensitive data were proportionate to the public interest that the activity would bring. Queries were raised about the need for the whole population approach as planned or whether a sample could serve the main purpose. The Committee was not convinced that the model would provide a high enough public benefit in order to justify the breach of confidentiality. Members agreed that this was difficult to assess as there were no publications in scientific literature which proved the benefits detailed within the application.

3. Consulting and involving patients

Members noted that the size and scale of the application, the number of people involved, and agreed that the sensitivity of some of the data made the consultation of patients highly desirable. It was discussed that the NHS had a long history of public consultation when significant changes were being proposed to arrangements, and members advised that similar consultations should take place when proposals such as the activity detailed were taking place.

Only through informing people could factual or non factual perceptions of participants and non-factual fears be discussed. Members advised that public perceptions were also important in maintaining public trust and as such public consultations would provide multiple opportunities to set

out the advantages and gains for the NHS from the activity. The Committee were pleased to read that plans had already been developed to inform and consult the population.

The Committee noted that details of the consultation activity that had been undertaken would help strengthen any future application.

4. Experian's role

The Committee reviewed the contractual documentation and specific queries were raised about how subject access requests would be handled by Experian. The Committee heard that Experian had very strict rules on re-identification and that this process required sign off by a Director at Experian. The Committee considered the possibilities for de-identification after the initial processes of anonymisation had been completed. Clarification was requested setting out who could authorise de-identification, who would do it, where and on what grounds.

5. Research framework

Several members of the Committee wondered if the application might be strengthened by using a research framework, since it was noted that the proposal was in effect an important research question. The application would then benefit from the rigour associated with research and the advice of a Research Ethics Committee.

6. Re-submission

The Committee advised that any re-submission should include a clear statement of the expected benefits, as well as details of any other development which gave grounds for the activity. The Committee recognised that any re-submission could not include scientific articles in the peer reviewed literature since these had not appeared yet. However, members thought it would be helpful to include as much background material regarding similar projects as possible.

Action: NIGB Office to notify applicant of Committee decision.

3B. National Community Child Health Dataset for Wales [PIAG 1-07(b)/2004]

This application had been considered by the Committee at its meeting on the 1 December 2010 where the following issues had been identified as requiring further review:

1. Suitable exit strategy from section 251 support
2. Reduction of postcode and date of birth
3. Management of inferential risk
4. Opt-out provisions and compliance with the DPA
5. Patient and user involvement.

Members were provided with a report submitted by the applicant in response to the Committee's comments.

The Committee agreed that this was an important activity which was required in order to fulfil an important function. It was agreed that the applicant had provided a satisfactory response to previous concerns regarding the management of inferential risk when publishing information as the policy provided was compliant with ONS guidance on statistical disclosure.

The Committee noted that it had no power to alter the requirements of the Data Protection Act 1998 and sought to ensure that these requirements were met. Within the application, the Committee had difficulties in establishing that these conditions were met, for example it was not clear that people know that their personal information was being held of how it was being used.

In reviewing an appropriate exit strategy, the Committee had previously agreed that pseudonymisation was the most appropriate exit strategy. However, it appeared that this had been understood to mean that consent should not be sought, and the Committee requested an update on attempts to seek consent where feasible, or for further information to be provided about the importance of 100% ascertainment. It appeared to the Committee that issues around opt-out and consent had been misunderstood, and therefore the response did not fully address the requirement. In addition, the leaflet provided did not provide a mechanism for opt-out and this caused some concern.

Members were disappointed to find limited evidence of suitable patient involvement and it appeared that there had been limited progression on this aspect, and that future plans were unclear, despite a significant time period since the requirement was outlined.

Questions also arose around continued retention of postcode and date of birth once derivations had taken place, as it appeared that these would not be deleted but transferred to a different server. Members queried why a reduction in identifiability (e.g. reducing date of birth to month and year) could not take place once derivations had been carried out. Members felt that if the retention of these identifiers was needed then further information justifying this would need to be provided.

Members discussed that currently legislation allowed the Committee to make recommendations for the common law duty of confidentiality to be lifted, in the public interest, in England and Wales. However, it was noted that the new Health Bill progressing though the UK Parliament, if enacted, would be likely to separate England and Wales as far as the governance of information was concerned. This situation would make it important that the work detailed within the application should be on a secure legal basis as soon as possible. The Committee advised that the applicant open discussions with the new Welsh Assembly Government about the operation of the common law duty of confidentiality in Wales, once the ECC, or its successor body, would no longer able to provide support for applications involving Welsh data.

As a whole, the Committee were unable to identify evidence of compliance with all principles of the Data Protection Act 1998 and therefore were unable to recommend support to the information provided.

The Committee agreed to offer a meeting with its representatives to the applicants.

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Action: NIGB Office to inform applicant of Committee decision.

Ms Stephanie Ellis provided apologies and left the Committee meeting

3C Secondary Uses Service (SUS) Annual Review follow up [PIAG 2-05(b)/2007]

The committee were informed that following previous discussion with the Chair and deputy Chair, consideration of this item would be postponed to the following day when the Chair would be present.

3D Palliative Care in Children and Teenagers with Cancer (deceased persons) [ECC 5-06(FT1)/2009]

This item was postponed until the 29th March meeting as it was noted that Dr Tricia Cresswell had previously advised the applicant in relation to the original application, and was a reviewer to this submitted documentation.

4. New applications for section 251 support

4A. Public Health Wales – application for activities to come under specific support [ECC 3-04(a)/2011]

Dr Michael Catchpole declared a professional interest in this item as some of the data collections flowed into the Health Protection Agency, left the room and did not take part in any of the discussion or decision.

This application from Public Health Wales provided a number of applications with differing purposes around public health surveillance:

1. Surveillance of surgical site infections in Wales
2. Detection, investigation and control of communicable disease outbreaks & incidents
3. Laboratory-based surveillance of healthcare associated infections in Wales
4. Detection, investigation and control of environmental health protection incidents
5. Surveillance of device-related infections in critical care units in Wales
6. Infections disease registers for public health surveillance policy development and audit (plus table of identifiers required for each register)
7. Pseudonymised data for HIV positives
8. Pseudonymised data for HIV/AIDS (SOPHID)
9. Evaluation of the sexual health in Wales surveillance scheme (SWS) for timely person and residence based sexually transmitted infection (STI) surveillance in Wales
10. Surveillance of surgical instruments and devices in Wales
11. Enhanced Tuberculosis Surveillance in Wales

The Committee welcomed the work that had taken place and could appreciate the complexity of the differing applications. Members noted that there were a number of issues that were common to most if not all applications and therefore sought to summarise these as it was agreed that the Committee could not recommend support under section 251 without further information and clarification.

Based upon the details within the application, it appeared that some activities could take place under Public Health Wales' own statutory powers, and would therefore not require support under section 251. Clarification was requested over what activities would require section 251 support and which had their own existing statutory basis. In particular, further clarity on the specific communicable diseases being investigated were requested to identify which activities could be carried out under public health regulations in relation to notifiable diseases.

Members noted that one of the applications referred to the fact that they did not have direct access to patients as a reason not to gain consent; the Committee were of the view that patients could be consented via the clinical care teams. However the Committee were mindful that large numbers may be involved in data collection and this might make consent difficult, however there was not sufficient information included within the application for a judgement to be made. Another application claimed that 100% ascertainment was required and members agreed that the reasons for this needed to be clearer in order for members to make a decision.

Members reiterated that they did not consider the lack of NHS number to be a legitimate reason for collecting identifiable data as attempts should be made to encourage the use of NHS number where ever possible in line with Department of Health policy.

It was noted that the purposes and data collections seemed vague and wide ranging. Further aspects were highlighted including the need for clarification over data flows, data sources,

specification of linkages and retention of information to achieve the purposes. Members also noted the absence of patient information leaflets within the application and agreed that they would like to see these.

Due to the number of areas highlighted for clarification members could not recommend section 251 support, however they advised that a resubmission would be welcomed. It was agreed that a meeting should be offered between the applicant and the NIGB Office in order to aid any resubmission.

Additionally, members discussed that legislation currently allowed the Committee to make recommendations for the common law duty of confidentiality to be lifted, in the public interest, in England and Wales. However, it was noted that the new Health Bill progressing though the UK Parliament, if enacted, would be likely to separate England and Wales as far as the governance of information was concerned. This situation would make it important that the work detailed within the application should be on a secure legal basis as soon as possible. The Committee advised that the applicant open discussions with the new Welsh Assembly Government about the operation of the common law duty of confidentiality in Wales, once the ECC, or its successor body, would no longer able to provide support for applications from Wales.

Action: NIGB Office to inform applicant of Committee decision.

4B. Community Datasets – extension to SUS [ECC 3-02(b)/2011]

This application was an extension to the Secondary Uses Service (SUS) and it was agreed that it would be appropriate to postpone this until 29th March when item 3C, SUS annual review, would be considered.

4C. National Dementia and Antipsychotic Prescribing Audit [ECC 3-04(c)/2011]

This application from the NHS Information Centre set out the purpose of a one-year audit on prescribing of antipsychotic medication for people with dementia. This was designed to assess whether prescribing of antipsychotics and alternative pharmaceutical interventions for people with dementia were changing with time. It would also evaluate how emerging clinical practice affected outcomes for these patients.

Section 251 support was requested in order to permit the transfer of data on patients registered with a GP practice who had been prescribed antipsychotic medication. The data would be extracted from general practice systems in England and linked to additional data sources following validation. NHS Number would be validated against the Demographics Batch Service (DBS) and then linked to Hospital Episode Statistics data and mortality data from NHS Central Register to enhance data completeness and give a wider view of prescribing and outcomes in dementia.

Members noted that this involved sensitive information, however, the public interest was considered to be extremely high due to the stated large numbers of inappropriate prescribing. The Committee also agreed that due to the large numbers (approximately 240,000) that consent would not be feasible. In particular, it was noted that there appeared to be a good and appropriate level of patient and user involvement via the Alzheimer's Society and Alzheimer's Research Trust, and this was to be commended. Members also agreed that the patient information leaflet was clear and provided a right of opt-out.

However it was noted that that responses to the Office queries prior to the meeting had not been received and these were considered fundamental in ascertaining the status of the activities within the application. In line with this, the Committee did not consider this to be a complete application

as much of the detail appeared to be proposed, rather than definitive, and therefore the robustness of the details were questioned.

As the Committee considered there to be a high public interest and wished to facilitate this activity, members agreed to provide a recommendation of provisional support under section 251 to the application. This support would be subject to appropriate responses to Office queries by the applicant, subsequent integration into the main application and clarification over all details where it was unclear whether the aspect was confirmed or a potential development.

This application was recommended for provisional support under section 251, subject to satisfactory responses to the requests for clarification as specified above.

Action: NIGB Office to notify applicant of Committee decision.

4D. National Cancer Patients' Experience Survey [ECC 3-04(d)/2011]

This application from the Department of Health set out the purpose of a national survey of cancer patients in order to obtain feedback and inform commissioning, and would provide the NHS Commissioning Board with an overview of cancer patient experience. Support under section 251 was requested to provide a legitimate basis for the transfer of patient data from NHS Acute Trusts to Quality Health, and for Quality Health to liaise with Trusts so that patient questionnaires would be sent to patients under Trust-headed paper.

The Committee agreed that patient experience surveys were an important part of measuring the quality of healthcare provision, and therefore there was a public interest in the activity taking place.

In understanding the importance of this work, members were mindful that the whole purpose of the activity was to value patients and to take account of their views and feelings. However, the Committee agreed that there appeared to be a contradiction in policy to seek to use a legal power to process patient's personal data without their knowledge and that this would disempower patients.

The Committee considered whether consent would be feasible for this study. Members agreed that they did not consider some of the specific reasons given within the application as evidence that consent would not be feasible. For example the application suggested that consent could not be obtained until the patients had seen the survey, however, the Committee agreed that consent could be taken to use patient data to send the survey, without the patients having to see the survey itself.

The Committee noted that as a result of previous work by the applicants a large numbers of patients had indicated they were happy to participate. The Committee was not clear whether some of these participants could be approached on the basis of the previous consent taken. The Committee were mindful that as cancer was a serious condition people with it would usually have a large number of consultations with specialists and their general practitioners. Therefore the Committee advised that further work should be undertaken to explore how far it would be possible for consent to be given or an opt out mechanism to be provided for the patient experience survey at one of the many consultations in the typical patient's journey. The Committee noted that patients should know and understand how their data was being used, and the indicated that they would expect this work to be undertaken in future so as to reduce the need for reliance upon section 251 support, and move towards a consent-based approach.

Members reviewed the practicability of consent being obtained in advance of the disclosure to Quality Health and agreed that, in this specific situation, the large numbers, scale and cost would render this unfeasible. Members sought clarification on how checks would be undertaken to ensure that the questionnaire was not sent to the deceased.

The Committee agreed to provide provisional section 251 support to the application following satisfactory response to the request for clarification.

Action: NIGB Office to notify applicant of Committee decision.

4E. Q-Research Data Linkage [ECC 3-04(e)/2011]

Professor Julia Hippisley-Cox declared an interest in this item as she was the applicant, she left the room and did not take part in any of the discussion.

This application from the University of Nottingham set out details of a database which consisted of pseudonymised electronic health records from primary care patients registered with approximately 600 general practices throughout the UK. The original database was established in 2002 and was used for medical research into the causes of disease, history, treatment and outcomes. Section 251 support was requested in order to provide a legitimate basis for the extension of the database to include secondary care data, via linkages with HES, cancer registry, death and Myocardial Infarction National Audit Project (MINAP) data to permit further research activities and the development of clinical risk predictors. In particular, access was required to NHS Number, GP Registration, date of birth and postcode in order to carry out the linkages.

Members considered this to be a clearly constructed application with a high public interest and a number of appropriate governance protections in place, which included opt out provisions, de-identification of data and appropriate confidentiality agreements. It was noted that the data was required to provide a clearer picture of patient care pathways. However, the Committee noted that in light of the large amount of records involved within the database and its considerable importance, strong representation from patients/lay persons would be important and should be strengthened.

Further assurance was requested over clarification of safeguards to ensure that researchers would not re-use the data for purposes other than those stated. Members also noted that section 251 approval could only be applied to data generated in England and Wales as the application stated that data from Scotland and Northern Ireland would also be included.

The Committee agreed to provisionally recommend section 251 approval to this study subject to a satisfactory response to the request for clarification above, and the following conditions of approval.

1. An increase in lay/patient representation in activities, which should be reported in the next annual review

2. This recommendation of support would apply to patient identifiable information generated within England and Wales. Data generated in Scotland and Northern Ireland fell outside the scope of the decision.

Action: NIGB Office to notify applicant of Committee decision.

4F. SLAM IG Clinical Dataset Linking Service [ECC 3-04(f)/2011]

This application from the South London & Maudsley NHS Foundation Trust set out the purpose of investigating associations between specific mental disorders in secondary mental health care (schizophrenia, schizoaffective disorder, bipolar disorder and dementia) and physical illness. This proposed to create a new linked dataset containing health records for patients with these disorders

from the SLAM BRC Case Register Interactive Search (CRIS) and general hospital records from the Hospital Episode Statistics (HES) database.

Section 251 was required to provide a legitimate basis for the processing of patient identifiable information, to effectively test the 'honest broker' capability and permit the linkage and subsequent anonymisation of the datasets. Access to name, date of birth, sex, address, postcode and NHS Number would be required for this purpose.

Members agreed that the value of the research question to be tested was significant, and therefore there would be a public interest in this activity taking place. It was also agreed that the large numbers involved (up to 20,000) would render consent impracticable. As a whole, the Committee were broadly satisfied with the application, and considered the use of identifiers to be proportionate to carrying out the activity.

However, the Committee were of the view that the user involvement appeared to be relatively generic and recommended that a representative of the relevant patient population should be included. Members also noted that this appeared to be a short-term project with time restrictions, and therefore queried whether there would be sufficient time and whether it would be adequately resourced.

Members noted that the file would be sent to the NHS Information Centre (NHS IC) and the NHS IC would send back a record of all hospital episodes. Members queried whether it would include details of patients who were seen outside the Borough, or whether the applicant would effectively receive more information than they needed for the activity; members therefore requested further clarity on this aspect.

Members agreed to provide provisional section 251 support to the application subject to satisfactory resolution of the clarifications requested around receipt of information and improved patient involvement.

Action: NIGB Office to inform applicant of Committee decision.

4H. Mechanism of Child Health Injury [ECC 3-04(h)/2011]

This application from Cardiff University set out the purpose of investigating children less than 3 years of age who had been diagnosed with head injury in order to measure the nature and occurrence of circumstances prior to injury. An additional purpose was to develop a computational model of an infant head and neck which could then predict the pattern of injury that would be sustained following a known trauma.

It was noted that an anonymised version of the head injury assessment form used by the emergency department would be used, however section 251 support was requested to enable legitimate access to full patient notes in order to obtain information if it was missing from the assessment form.

The Committee agreed that this was an important study and a well presented application. Members noted that the applicant responses to the consent questions were brief and requested more information on this aspect. The committee discussed that there was a possibility that seeking consent might introduce bias into the study, however further justification about how this could affect results would be required from the applicant.

The Committee noted that the Chief Investigator for the study was not a clinician or a health professional. The Committee queried whether the duty of confidentiality owed by the Chief Investigator could be regarded as the same as that of medical staff, or if their employment contract

required an equivalent duty of confidentiality. The Committee understood that the study was to be supervised by a doctor with such a duty but requested further clarification on this aspect.

The Committee noted that the applicant might come across some injuries that, from a clinical perspective, be suspected as non accidental. The Committee queried whether the applicant would owe a duty to the child to inform the relevant parties and therefore requested information on what processes would be put in place to deal with this situation and what appropriate action should be taken by the applicant.

The Committee agreed to provide provisional approval under section 251, subject to the following requests for clarification.

Request for clarification

1. Clarification over the duty of confidentiality owed by the Chief Invesitigator in relation to the study data.

2. Further information to be provided regarding why consent could not be obtained.

3. Confirmation over protocol to deal with situations where non accidental injury was confirmed.

Action: NIGB Office to inform applicant of Committee decision.

4l. Cancer survival in five continents: a worldwide population based study (CONCORD2) [ECC 3-04(i)/2011]

This application from the London School of Hygiene and Tropical Medicine set out details of the UK arm of a global surveillance of cancer survival systematic comparison of international differences and trends in cancer survival.

Members noted that this methodology was closely based upon a previous application 'International Cancer Benchmarking Project' which had previously been reviewed and approved by the Committee.

Members reviewed the patient involvement that had been undertaken and noted that a number of steering committees had been listed, however, they could not find evidence of patient involvement. Involving patients in the activity was considered important as a counter-balance to the provision of a recommendation of support to access patient identifiable data without consent. In particular, the Committee noted the high public interest in the activity and excellent reputation of the applicant, and considered that as a mark of best practice appropriate patient involvement should be included.

Members noted that opt out provisions for the study relied on people opting out of the cancer registry collection and felt that this could be strengthened as the study was additional to the purposes of the cancer registry. In line with this the Committee were also mindful that the fair processing requirement of the DPA could be readdressed to further inform patients about the uses of their data in relation to this study.

As a whole, the Committee were broadly satisfied with the details of the application. Additionally, members reviewed the statement made by the applicant about cancer registries not providing an annual review under section 251, and wanted to correct this assertion as cancer registries did receive review.

Members agreed to recommend approval under section 251 support for this study.

Action: NIGB Office to inform applicant of Committee decision.

4J. Safety and Appropriateness of Growth Hormone treatments in Europe (SAGHE) [ECC 3-04(j)/2011]

This application from University College London set out the purpose to investigate the long term efficacy on quality of life for those young adults who received Recombinant Growth Hormone treatment. This application detailed a cohort cross sectional study to investigate the efficacy, psychosocial outcomes, long term mortality and long term cancer incidence in individuals treated with growth hormone in childhood. Section 251 support was requested to enable legitimate access linkage between clinical databases and registers in order to identify suitable participants. Consent would be sought from all participants; however section 251 was also requested so that information about deceased and non-responders could be retained. It was noted that any patient who dissented would have their request respected, and their records would not be used for this study.

Members agreed that this was an important study, and were supportive of the purpose subject to receiving clarification on some points raised at the meeting. Members highlighted that the level of patient involvement which had been undertaken was suitable.

Members noted that this study covered Europe, however it was not clear from the information provided if this involved disclosure of identifiable UK data to other study sites in Europe.

A query was raised around one aspect of the application which mentioned pituitary derived hormones, and members requested clarity over whether this was an error in the form or if the study would additionally be looking at pituitary derived hormones.

It was noted that this application included research sites across England, Wales, Scotland and Northern Ireland and members reiterated that any approval given by the ECC would only relate to data regarding patients treated in England and Wales.

The Committee agreed to recommend provisional support under section 251 to this study; this was provisional upon receiving satisfactory responses to the requests for clarification.

1. The applicant was requested to confirm if this study would be limited to recombinant growth hormone, or if it was also intended to study pituitary derived hormones.

2. Clarification if there would be any linkage of study data outside of the UK.

Action: NIGB Office to inform applicant of Committee decision.

4K. UK surveillance of primary congenital hypothyroidism in children [ECC 3-04(k)/2011]

This application from University College London set out the purpose to determine the incidence in the UK of confirmed diagnoses of primary Congenital Hypothyroidism (CHT) in children up to and including age 5 years, and to report the distribution by age, sex and ethnic group. It was noted that this application followed a very similar methodology to the British Paediatric Surveillance Unit (BPSU) ‘orange card’ reporting method. However, the application would retain identifiable data for the purpose of long term monitoring of outcomes via Hospital Episodes Statistics (HES) and the Office for National Statistics (ONS). Section 251 support was requested to enable legitimate access to NHS number, hospital ID number, date of birth, date of death, postcode and sex.

Members were supportive of this application and agreed that there was a public interest in the activity taking place. However members discussed that it was unclear how long identifiable data would be retained for and its future uses and agreed that this should be further clarified by the applicant.

In addition to this, members discussed that consideration should be given to children attaining competency if the data would be retained past the age of 16. The Committee agreed that they would expect that consent be sought from patients directly if they passed the age of 16 and were still being followed up for the purposes of the trial.

The Committee agreed to recommend provisional approval under section 251, subject to the following requests for clarification.

1. Confirmation over how long data would be retained for the purposes of follow up.

2. Clarification over action to be taken when the children became competent to make the decision to consent for themselves.

Action: NIGB Office to notify applicant of Committee decision.

4L. Vascular Resection during Pancreatectomy [ECC 3-04(l)/2011]

This application from the Royal Free Hampstead NHS Trust detailed a study which would compare the survival difference between pancreatico-duodectomy with vascular resection (PDVR), a standard pancreatico-duodectomy (PD) and surgical bypass (SB) in patients with pancreatic cancer.

It was noted the Thames Valley Cancer Registry would provide the basic study population which would be sent to local investigators at each Trust. Each local investigator would then be responsible for collecting patient data relevant to each Trust. Once complete, the local investigator would then forward the dataset (with reduced identifiers) to the chief investigator. Section 251 support was requested to enable legitimate access to NHS number, date of birth, date of death, district level postcode, and details of the Trust where the patient was treated.

Members were supportive of the study and noted that there was a significant public interest in this research taking place.

Concerns were raised over the responses regarding compliance with the Data Protection Act principles. In particular members noted that further information was required in relation to fair processing information that would be provided to patients, and mechanisms in place to allow opt out. When providing section 251 support, the Committee needed to assure itself that the application has demonstrated compliance with the Data Protection Act. Given that a large number of the cohort would be deceased members agreed that in this instance the details within the application were sufficient.

Members also noted that any consent bias from those who were alive would affect the results of the study as it was particularly important to collect data on those who had survived. It was also noted that reduced identifiers for these patients would be retained.

Members agreed that they could recommend section 251 support for this study and approved with the following condition of approval.

Condition of approval

1. This recommendation of support would apply to patient identifiable information generated within England and Wales. Data generated in Scotland and Northern Ireland fell outside the scope of this decision.

Action: NIGB Office to notify applicant of Committee decision.

4M. Colorectal cancer in the UK liver transplant population [ECC 3-04(m)/2011]

This application from the Royal Free Hampstead NHS Trust set out the details of a retrospective review with a number of purposes. These were to identify if there was an increased risk of colorectal cancer in the liver transplant patient population, whether cancer survival outcomes in liver transplant patients with or without ulcerative colitis were comparable to the general population, and to determine if the timing of colectomy in patients with ulcerative colitis contributed to recurrent primary sclerosing cholangitis and liver allograft failure. Section 251 support was requested to enable legitimate access to NHS number, date of birth, date of death, district level postcode and patient initials.

Members agreed that this was an important study and that the outcomes would help inform care of patients undergoing liver transplants and their follow up. Members agreed that consent would be difficult as any bias from survivors would mean that the results of the study would be affected.

It was noted that the responses to the Data Protection Act could be improved upon and members asked that this was highlighted in the response to the applicant. Members also agreed that user involvement could be strengthened within the application.

Members concluded that due to the importance of the study and the difficulties in obtaining consent they could recommend support under section 251, this would be subject to the following condition of approval.

Condition of approval

1. This recommendation of support would apply to patient identifiable information generated within England and Wales. Data generated in Scotland and Northern Ireland fell outside the scope of this decision.

Action: NIGB Office to notify applicant of Committee decision.

4N. NHS Abdominal Aortic Aneurysm Screening Programme (NAAASP) – deceased persons [ECC 3-04(n)/2011]

This application from Gloucestershire Hospitals NHS Trust set out a request to collect, store and process information about men who had died prior to consent being sought.

It was noted that a national screening programme for abdominal aortic aneurysm (AAA) had been established in 2009 and funded by the Department of Health. This was used to identify men aged 65 with an Abdominal Aortic Aneurysm (AAA) so that they may be offered surveillance or treatment to prevent AAA rupture. This was linked with the National Vascular Database to enable end to end monitoring of men with or without AAA. Consent would be sought from all men who were screened as part of the screening programme, and from those who had undergone elective surgery. Section 251 support was requested to enable legitimate access to NHS number, name, date of birth and address for men who are admitted as an emergency and who do not survive.

Members reviewed the consent form used in the screening programme and noted that in the form it was stated that '*Your personal information will only be used by the NHS AAA screening programme. It will not be passed on to third parties other than healthcare professionals directly involved in screening or any subsequent investigations or treatment…..*' Members advised that by stating that patient information would be kept confidentially within the screening programme, the applicant maybe preventing the possibility of any future additional linkages which would require the disclosure of patient information that might assist longer term follow up.

Additionally, it was noted that Dr Foster Ltd would be the technology provider for the database. It was not clear within the application what level of access to the identifiable information this would entail, or if Dr Foster would be permitted to use the data for any of their own analyses. Members therefore requested additional information regarding this point.

The Committee agreed to recommend provisional approval under section 251, subject to receiving a satisfactory response to the following request for clarification.

Request for clarification

1. Clarification to be provided to the NIGB Office regarding the involvement of the technology provider Dr Foster Ltd and whether they would be able to access this data for the purposes of their own analysis.

Action: NIGB Office to notify applicant of Committee decision.

4O. NHS Abdominal Aortic Aneurysm Screening Programme (NAAASP) – rollout [ECC 3-04(o)/2011]

This application from Gloucestershire Hospitals NHS Trust requested section 251 to allow NAAASP to receive the whole of England cohort (men in their 65th year registered with a GP) prior to the full rollout of the screening programme in 2013. Once included in the screening programme, consent would be obtained and section 251 would no longer be necessary. Section 251 support was requested to enable legitimate access to NHS number, name, date of birth, date of death, address and postcode and registered GP Practice.

The application detailed that information would be required prior to full rollout in order to obtain accurate numbers to inform the full roll out, which would help prevent GP practices being missed from programme areas if a new practice was opened and also allow more timely notification of deaths which would prevent invites being sent to men who were deceased.

Members noted that the application stated that only demographic data which was available within the public domain would be used. Members discussed that whilst it was true that registration data such as date of birth and date of death was in the public domain, NHS number and GP registration details are considered confidential patient information. Members reiterated that it was this breach of confidence which would require section 251 support.

Given the benefits that the activity would bring and the limited demographic data that was requested members agreed to recommend approval for section 251 for this application.

Action: NIGB Office to notify applicant of Committee decision.

4P. FIT for Followup Study [ECC 3-04(p)/2011]

This application from Imperial College London detailed a study to investigate the sensitivity of a 3 yearly programme of immunochemical testing for hidden blood in the stool, to indicate the presence of large polyps in the bowel.

Section 251 support was requested to enable legitimate access to name, NHS number, date of birth, date of death, postcode and identification number for the person in the bowel screening programme. This information would be used to invite potential participants to take part in this study. The invitation process would be managed by the South of England bowel cancer screening hub.

Members were supportive of the purpose of the application and acknowledged the high public interest surrounding the study.

The only aspect of the study requiring section 251 support was the disclosure of suitable participant information to the South of England hub for the purpose of sending out invitations. Members were unsure why the South of England hub was required to act as the central coordinator for the invitations. Members questioned whether any consideration had been given to asking each hub to manage the process for patients in their area, as this would then not require section 251 support.

Members were unable to provide section 251 until a satisfactory response had been provided to the following request for clarification:

Request for clarification

1. Further justification why the South of England hub must act as a central coordinator for the study and why it would not be feasible for each hub to manage the invitation process for patients in their own area should be provided to the NIGB Office.

If sufficient justification could be provided detailing why the suggested approach would not be feasible then members agreed that this could be approved outside of a Committee meeting.

Action: NIGB Office to notify applicant of Committee decision.

4Q. CALMS2 Study [ECC 3-04(q)/2011]

This application from Oxford Radcliffe Hospitals Trust set out the purpose of a study to evaluate whether continuous monitoring of vital signs with computer modelled alerting to detect patient deteriorations reduced patients' stay in hospital.

It was noted this was the second stage to a previously approved study (ECC 6-05(i)/2010 – A randomised stepped wedge trial comparing the effects of an integrated 'track and trigger' system and a paper-based 'track and trigger' system)

Section 251 support was requested to enable legitimate access to name, hospital number and postcode for the purposes of identifying suitable participants. Consent would then be sought from all patients who took part in the trial.

Members noted that this was a variation on a previously approved application and agreed that the purpose was in the public interest. It was agreed that there would be difficulty in obtaining consent due to the fact that the opportunity would arise at the time that the patient would be receiving distressing news.

Members recommended this application for support under section 251.

Action: NIGB Office to notify applicant of Committee decision.

4R. National Diabetes Audit (audits) [ECC 3-04(r)/2011]

This application from the NHS Information Centre set out the purpose of a three-year audit on all patients diagnosed with diabetes. Section 251 support was sought in order to provide a legitimate basis for access to NHS Number, postcode, date of birth, GP practice code and date of death for linkage purposes. For analysis purposes, postcode, date of birth and date of death were required.

In reviewing this application, members considered the patient leaflet content to be good, and were broadly satisfied with the use of identifiers. It was noted that the system would reject data submission without valid NHS number which the Committee found encouraging.

The Committee was conscious that diabetes was a particularly important disease affecting millions of people in the UK and that a national audit would be especially relevant. It was understood that the modern care of people with diabetes involved encouraging them to take personal responsibility for the care of their condition, including the results of investigations.

Therefore the Committee was of the view that it would be a contradiction in policy for people with diabetes to have their medical records accessed by people they would not know, without their knowledge, or consent. Members agreed that it would be particularly desirable that people with diabetes should be fully informed and given a reasonable option not just to participate in the national audit but to take a close interest in the results.

An additional consideration for the Committee was the pattern of care for diabetes. As it was, a chronic disease lasting for years, people with diabetes would see their general practitioners usually at least twice a year and many would receive additional hospital care. There were therefore a large number of opportunities to obtain consent from patients.

Members noted the involvement of Diabetes UK and agreed that given its distinguished standing and reputation it would seem logical for it to develop pilot arrangements in suitable GP practices and hospital diabetic clinics to explore the best ways of obtaining and recording consent. The Committee were also aware from previous applications that diabetes was a condition for which a Read code to allow dissent from secondary uses already existed.

The Committee considered that the nature of diabetes meant that in this context it could act as a model condition for national audits for chronic diseases. The Committee agreed that the NHS Information Centre, working with Diabetes UK, should give early consideration to tackling the issue of informed consent and pilot ways of achieving this. In line with this, the Committee sought further information on the feasibility of seeking to integrate a consent-based approach.

Members were concerned that the application did not identify a clear exit strategy from the use of patient identifiable data and that this could be achieved by using a consent based approach or exploring pseudonymisation.

Members recommended approval under section 251 for the study subject to the following clarification requests.

Request for clarification

1. Provision of details of a suitable exit strategy, with timescales, to the NIGB Office.

2. Emphasis on engagement with consent, in conjunction with Diabetes UK, to be reported against in six months time and in the annual review.

Action: NIGB Office to notify applicant of Committee decision.