Ethics and Confidentiality Committee (ECC) Meeting – Wednesday 5 December 2012

Members:

Dr Mark Taylor (*Chairing*), Mrs Pauline Brown, Dr Tony Calland, Dr Robert Carr, Dr Patrick Coyle, Dr Tricia Cresswell, Dr Fiona Douglas, Dr Colin Harper, Mr Stephen Hinde, Professor Julia Hippisley-Cox, Ms Gillian Wells and Mr Terence Wiseman.

In attendance:

Ms Natasha Dunkley *(Approvals Manager),* Ms Claire Edgeworth *(Deputy Approvals Manager),* Mr David Evans *(Information Commissioner's Office),* Mr Martin Frowd *(NIGB Senior Business Support Officer).*

1. Welcome and apologies

Apologies were received from: Dr Andrew Harris, Ms Alison Emslie, Professor Jane Kaye and Mr Chris Wiltsher.

2. Declarations of Interest

Mr Stephen Hinde declared that his organisation, BUPA, had helped to establish Healthcode, the data processor for application 5b, but neither he nor BUPA had a direct interest in the application so it was agreed that there was no need for him to leave the room. Dr Robert Carr declared an interest in application 6a as the applicant was his wife, and agreed to leave the room for the duration of this item.

2a. Minutes of last meeting & matters arising

The minutes of the 19 September 2012 meeting were agreed as an accurate record. The minutes of the 20 September 2012 meeting were agreed as an accurate record subject to the clarification that the six ECC Members who had been identified to transfer to the Confidentiality Advisory Group would have the option to elect to remain on their current terms and conditions of service for a period of one year. It was also clarified that the meeting that took place was to develop existing Scottish arrangements.

Matters arising

Security assurance process

An update was provided on progress since the introduction of the IG toolkit submission as the mechanism by which security arrangements are assessed, and difficulties experienced by applicants were highlighted. It was noted that academic institutions had been finding the introduction particularly difficult and concerns had been raised about the Helpdesk's knowledge and response times to queries. The difficulties experienced by Wales were also highlighted. Members indicated that they did not want the process to frustrate the approval if it was conditional on the toolkit submission and agreed while that appropriate security assurance was essential, that it would need to be proportionate. Similar concerns had been received from the Data Access Advisory Group at the HSCIC and it was agreed that a meeting would need to take place with the DH IG delivery team to flag these concerns and seek to mitigate them as it was currently presenting as a reputational risk to the approval process.

NHS Constitution

It was confirmed that a formal NIGB response to the NHS Constitution would be circulated to members the following week

2b. NIGB Office Report [ECC 6-02 (b)/2012]

For information

Secretary of State (SofS) approval decisions

The Department of Health senior civil servant on behalf of the SofS agreed with the advice provided by the ECC in relation to the September 2012 meeting applications.

CQC patient survey security incidents

The CQC reported two incidences in relation to disclosures of patient information to the survey co-ordination centre, from an NHS Trust and survey contractor. In both instances sample files had been sent to the co-ordination centres which included identifiable information (this should be pseudonymised). Both the NHS trust and survey contractor were alerted to this immediately and action was taken to ensure that the data was destroyed. Both parties provided information to the CQC which outlined how they would ensure that these types of error would be prevented in future, including additional information governance training and steps to ensure that patient identifiable data would only be stored in separate software from any mail files. The CQC will undertake supplementary communication/briefing to trusts and contractors reminding them of the processes for transferring information and their obligation to remove identifiers.

Discussion with Information Services Division

Dr Mark Taylor and Ms Claire Edgeworth attended a teleconference with the Scottish Information Services Division to discuss the current ECC processes with a view to widening the remit of the National Privacy Advisory Committee for health in Scotland. Questions focused on the role of the Office and how the Committee reached a consensus.

Meeting with Public Health England (PHE)

A productive meeting took place on 31 October between Dr Mark Taylor, Dr Tricia Cresswell, Ms Natasha Dunkley, Dr Robert Kyffin (DH, Public Health Transition Team), Dr Julian Flowers (East of England PHO), Ms Deborah Terry (NIGB), Dr Radoslav Latinovic (NHS Sickle Cell and Thalassaemia Screening Programme), Dr Tariq Maliq (South West Cancer Registry), Dr Phil McCorry (NHS Cancer Screening Programme), Malcolm Roxburgh (National Treatment Agency) and Dr Jürgen Schmidt (PHE Transition Team). Attendees represented those organisational functions clearly intended to transfer to Public Health England. A number of functions transferring to PHE hold approvals, therefore the importance was emphasised of ensuring there is clarity on what purposes have legal support and ensuring activities remain within these frameworks. It was clear that there were a number of future proposed activities, but the importance of being clear on the legal support currently in place and the need to distinguish this from future anticipated uses was seen as a key internal management issue and challenge. The issue of providing a satisfactory IG Toolkit submission was raised, as technically any change of data controller must provide a satisfactory toolkit submission before approvals can 'transfer' over. It was agreed that the office would liaise accordingly with the IG Toolkit team to seek views on a proposed approach to managing this transitional aspect. The action arising from this point will be discussed at the December ECC meeting.

A key priority was the need to be clear on the legal basis for local authorities to process confidential patient information derived from the NHS, as currently there is legal uncertainty over this position, and there is a stated defined need for key public health staff to have access to this information. Key public health staff have already transferred to local authorities, however, the enhanced statutory responsibilities for local authorities do not come into effect until 01 April 2013. PHE confirmed that they were working closely with national and local partners to clarify the necessity of local authority public health requirements for record level and confidential information, and conversations were taking place with the

Information Centre and Commissioning Board to clarify how access to information could be defined and managed. It was acknowledged that this issue is causing difficulty for affected staff.

Transition communications

Dr Mark Taylor confirmed that he is a member of the Health Research Authority Project Board, in his capacity of establishing chair, established to lead the transition to the new advice function that will be coordiated by the Confidentiality Advisory Group. Ms Natasha Dunkley sits on the Project Team in order to support development of the operational arrangements and the Project Board. In September 2012 communications went out in a statement from the HRA that provided notification of the proposed changes. Following comment that this has caused some confusion over implications for existing applicants, the NIGB website has recently been amended to have a dedicated transition area (http://www.nigb.nhs.uk/s251/transition) that will reflect those communications issued by the HRA. At time of writing further communication is imminently expected that will confirm the name of the new advisory function; provide notification of the forthcoming advertisement dates, and two wider stakeholder events week commencing 14 January 2013. The office has also developed a set of brief FAQs following the initial announcement of the transfer of functions: these confirm the continuation of the legal framework, specify how the advice and approval functions interrelate, and confirm the position over access to confidential patient information post-April 2013.

Information Governance Toolkit consultation

Members had already received a link to the consultation document. The purpose of the review was to establish whether the Toolkit remains fit for purpose, systems costs and benefits, and to identify whether there are any alternatives to the Toolkit that could satisfy its current strategic objectives. The consultation was due to close on 11 January 2013. The Committee discussed and noted concerns from the academic community and from applicants in Wales regarding completion of the Toolkit, particularly where organisations were not otherwise required to complete the Toolkit unless making an application. Dialogue was ongoing with the Toolkit team in the Department of Health to facilitate smoother future processes, and the Health Research Authority would be involved in discussions once the appropriate resource had been recruited. Potential risks were highlighted as an organisation's overall Toolkit score might be beyond an individual applicant's power to influence. It was agreed that the NIGB's draft response to the Toolkit consultation would be circulated for Member input as the deadline fell before the next Committee meeting.

E-learning module development – NIHR CSP

A request for feedback on an e-learning module on Data Protection and Research was received from the National Institute for Health Research Clinical Research Network. The programme of training is aimed at staff who undertake governance reviews as part of the NIHR Coordinated System for gaining NHS Permissions (CSP). This includes a mixture of core CLRN staff as well as staff in the R&D offices at all NHS Trusts in England. The on-line training is part of a wider programme of work to encourage proportionate and pragmatic governance review. Comments have been provided via the Office and it is confirmed that the content of the module is generally good and captures the key legislative frameworks.

Human Fertilisation & Embryology Authority MoU

Members were reminded that a Memorandum of Understanding was in place with the HFEA under The Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 that state that where requested by the Authority, the NIGB may provide advice and assistance to the Authority in relation to the exercise by the Authority of its functions under these Regulations or such other matters as may arise in relation to the processing of information under these Regulations. This advice function is currently fulfilled by the ECC. However, with the abolition of the NIGB this requirement to provide advice is terminated. A brief meeting recently took place with the HFEA, NIGB Office and HRA in which the potential for continuing this MoU with the HRA was discussed. It was agreed that the current relationship for handling applications between the ECC and HFEA had been working well, and it would be in the HFEA's interests to continue this if feasible. The HFEA was seeking legal advice to determine

the feasibility of developing a MoU with the HRA in order to continue the streamlined handling of register applications.

Transfer of ECC Secretariat to Health Research Authority

The Committee received an update on ongoing work toward the transfer of three staff from NIGB to the HRA, to take place by 31 March 2013, and thanked the Office team for all their hard work during a challenging period.

Fast Track applications

ECC 6-02(FT1)/2012 Multisite pain and falls in older people

This application was considered via the fast track process under criteria 4; *time limited access to undertake record linkage/validation and to pseudonymise the data*. Members recommended support for this activity with conditions.

This research application from Keele University requested access to confidential patient information in order to carry out data linkages. All participants had previously completed questionnaires as part of a previous study called the NorStop study, and for some this included consent being provided for review of medical records. Confidential patient information would be provided to the University by GP practices and this data would be used to request HES and ONS data for all patients. Date of birth, postcode and NHS number would be required to carry out linkages; however analysis would be carried out using anonymised data only. Members considered this application to have clear public benefit, and noted that identifiable data would be used for a short period of time in order to carry out the linkage. It was agreed that seeking specific consent for this data linkage would not be feasible considering the large cohort involved and the retrospective nature of the study. In addition it was noted that many of the cohort had originally consented for the review of their medical records.

Members discussed those instances where patients had not provided consent for original medical record review; the applicant confirmed that this was the case for 4666 patients. Members noted the assertions that consent was time, place and situation specific and that it would therefore be difficult to assume that dissent for primary health care record review given 10 years ago would mean dissent to HES and ONS linkage today. Members discussed whether this assertion was correct; a view was raised that as this was an extension of the previous data collection the previous dissent could be considered to indicate dissent for data linkage for this activity. However, on balance, Members noted that only those who had completed the questionnaire would have their data used, that those who did not provide consent 10 years ago had not actively dissented and that the research team would only have time limited access to identifiable data. Members requested further confirmation that those who had actively dissented via their GPs would not be included in the data linkage. The applicant confirmed that this was the case. Members agreed that patient information should be displayed within GP practices.

ECC 6-02(FT2)/2012 The impact of a decision support tool for the early recognition and management of Acute Kidney Injury: implementation and an analysis of quality of care

This application was considered via the fast track process under criteria 3; *where applicants are accessing data on-site to extract anonymised or effectively pseudonymised data*. Members agreed that they could not recommend support at this time for access to inpatient data as consent for this aspect appeared to be feasible, however, Members agreed to recommend support where patients had died prior to consent being obtained and requested further information in relation to accessing data from emergency department records without consent.

This research application from Newcastle upon Tyne NHS Foundation Trust detailed a study to assess the impact of an electronic system, developed to alert the patient's doctor to the first signs of acute kidney injury. Data would be collected from a number of wards within the Freeman Hospital and risk factors in the emergency records of patients with AKI would also be examined. Access to confidential

information including name, hospital ID, date of birth and date of death would be used to link medical records within the Freeman Hospital. A dataset including date of death would be extracted for analysis purposes and retained at the Freeman Hospital. Members agreed that the benefits of the activity taking place were clear and were supportive of the activity as a whole. It was noted that there were three different aspects to the study and that support was requested for access to inpatient data for the quantitative aspect of the study and emergency department data for the risk analysis component without consent. Members focused discussion on the applicant assertions that seeking consent from inpatients via clinical care teams would be likely to have an effect on routine practice and therefore lead to bias in the results of the study. Members discussed that it appeared to be unlikely that clinical staff would not be aware of the study, given that they would be involved in identifying participants and would also partake in follow up interviews. Members therefore queried whether a consent based approach via the clinical care team could be pursued. In addition, Members noted that it was detailed that the consent process would take around 60 minutes. It was agreed that this seemed to be particularly long and Members requested further information regarding the process. Members noted that where patients had died from AKI or other causes, consent would not be feasible, and agreed to recommend support where a patient had died without having the opportunity to be asked for their consent. In relation to the risk analysis aspect, Members recognised that there would be difficulties in gaining consent in an emergency setting. Members queried whether the applicant had considered gaining consent at the point of discharge or transfer from the emergency departments and whether this approach would be feasible. Members advised that patient information should be displayed within relevant hospital wards.

ECC 6-02 (FT3)/2012 Stroke National Audit Programme (SSNAP)

This application was considered under fast track criteria 8; *Amendments to approved applications*. Members agreed that a recommendation of support could be made in order to allow the continued collection of the extended audit data and for historical SINAP data to be transferred to RCP, subject to conditions. This audit application from the Royal College of Physicians (RCP) detailed the Sentinel Stroke National Audit Programme (SSNAP). SSNAP would replace the Stroke Improvement National Audit Programme (SINAP) (ECC 5-04(g)/2010). SINAP data, including HES, MRIS and ambulance service data was currently collected by the Health and Social Care Information Centre. (HSCIC) The SSNAP application included two changes to the previous SINAP application: a change in data applicant from the HSCIC to RCP, and an extension of data collection to include data across the entire stroke pathway for 6 months post stroke. Confidential patient information including NHS number, name, date of birth, postcode and date of death were requested.

Members raised a number of queries in relation to the extent of identifiable data requested as a large amount of identifiable data was detailed and it was not clear who would have access to this and for what purposes. The applicant confirmed that audit data used for analysis at RCP would include date of death only and that other identifiable data items would not be available at this stage. The audit database would need to include all the specified data items in order to link accurately to MRIS data and because local care teams would use the system to provide care and treatment for the patient. The applicant specified that linkage with MRIS data would be undertaken automatically and would not require the RCP to access any identifiable data. Following this additional detail, the applicant was asked to update the application form to reflect that only local teams would have access to all identifiable data items and RCP would have access to date of death for analysis purposes. The applicant updated the application form to reflect this and confirmed that whilst it may be possible for the global administrator of the audit web tool to access patient identifiers, this access would be audited with penalties in place for malicious access. The application outlined a number of difficulties in relation to seeking consent, for example it was detailed that 30% of patients may die or be too severely unwell to provide consent. However, Members queried whether those that survived and would be subject to a follow up six months later could be approached for consent and what arrangements had been put in place for this. It was confirmed that it was intended that this would be a feature of the six month follow up and clinicians would be encouraged to provide the appropriate patient information and ask for consent at this stage. Members agreed that rather than being encouraged it should be made a requirement to ask patients for consent to continue processing there data at this stage. Members requested further confirmation regarding the consent process at six month follow up and provision and content of patient information leaflets.

ECC 6-02 (FT4)/2012 Lifelong health and wellbeing of the 'Scotland in Miniature' cohort

This application was considered under fast track criteria 4: *Time limited access to undertake record linkage/validation and to pseudonymise the data.* Members agreed that a recommendation of support could be made in order to allow identifiable study data to be sent to the HSCIC, linked to HES and MRIS data and provided to the applicant in an anonymised format. Members also agreed to recommend support for MRIS to carry out the mailing of invitations on the applicant's behalf and advised amending the NHS Central Register application (ECC 2-04 (c)/2010) for this specific activity. This recommendation was subject to conditions. This research application from the University of Edinburgh requested identifiable data (name, date of birth and NHS number) to be provided to the Scottish NHSCR who would then transfer data for those patients who have moved or been treated in England and Wales to MRIS. Linkage between HES, MRIS and study data would take place within the Health and Social Care Information Centre (HSCIC) who would access identifiable data on the applicant's behalf and link the data sets. A dataset including date of death only would be provided to applicants. MRIS would also carry out mailing of invitations to a follow up study for those surviving patients who were in England and Wales. Support was requested for a small minority of patients who had moved to England or Wales only. Members commented that this appeared to be a unique opportunity to follow up a cohort of participants recruited in 1947 aged 11. Members agreed that in these circumstances it would be disproportionately difficult to consent the historical cohort before sending their details to MRIS and commented that it would be likely that MRIS would be required to carry out tracing prior to consent being obtained in any case. Members agreed that it would be appropriate for MRIS to send out invitations to take part in further data linkages and follow up in this instance. Members were of the view that participants were likely to remember completing the first round of questionnaires and noted that demographic data only would be used to identify the cohort. Members noted the application stated that "the invitation letter would make it clear to all participants that if they feel they are unable to make the decision to take part in the study themselves, they should pass the invitation pack on to someone else who they trust to make that decision on their behalf." Members noted that the application had been reviewed by a REC in Scotland and sought assurance that this approach was compliant with the Mental Capacity Act in England and Wales. After correspondence with the National Research Ethics Service, it was confirmed that where research participants will be recruited within England, Wales and Scotland an application should be made to both a Scottish and an English or Welsh Research Ethics Committee.

ECC 6-02 (FT5)/2012 Infant deaths in the UK community following successful cardiac surgery building the evidence base for optimal surveillance

This application was considered under fast track criteria 4: *Time limited access to undertake record linkage/validation and to pseudonymise the data.* Members agreed to recommend support to the application. This research application from Great Ormond Street Hospital for Children NHS Trust detailed a study which aimed to find out more about which babies were most at risk of dying in the first year following heart surgery and would benefit from special home monitoring or support. Data from the Central Cardiac Audit Database (CCAD) would be linked to the Paediatric Intensive Care Audit Network (PICANET) to enable identification of babies readmitted to intensive care as an emergency after hospital discharge. The sample size was approximately 9,000 to 10,000 patients. Access to confidential patient information including NHS number was requested to allow the National Institute of Cardiovascular Outcomes Research (NICOR) to link CCAD and PICANET data and provide an anonymised dataset to researchers. Members noted that there would be very limited identifiable data items (NHS number only) disclosed for a short period of time in order to undertake linkages by NICOR. Cases of rare disease and ethnicity would be grouped to ensure that the inferential risk of identification from the linked dataset was low. Members agreed that the level of service user involvement that had been undertaken was good and that there was a significant public interest in the activity taking place.

ECC 6-02 (FT6)/2012 (i)Performance, regulation and competition in medical devices: a case-study on hip prostheses (CD) and (ii) Bayesian methods in the evaluation of medical devices: the case of total hip replacement prostheses (CI)

The application was considered under fast track criteria 4: *Time limited access to undertake record linkage/validation and to pseudonymise the data.* Members agreed that they were unable to recommend support to the application at this time due to the incomplete nature of the form. This research application

from the University of East Anglia detailed two projects. The first; Performance, regulation and competition in medical devices: a case-study on hip prostheses, aimed to investigate the determinants of the cost of Total Hip Replacement surgery and the affect of payment by results on the choice of prostheses, and in turn on the behaviour of the manufacturing industry. The second would implement recently developed Bayesian methods to investigate a number of methodological issues associated with the evaluation of medical devices. This would include: a) substantial equivalence between different hip prostheses and the effect of incremental device innovation; b) objective performance criterion set by National Institute for Health and Clinical Excellence in their guidance on selection of prostheses for primary total hip replacement (i.e. 10% revision rate in 10 years); c) learning curve effects and d) non randomisation. Access to confidential patient information including date or birth, patient's postcode and NHS number was requested to allow linkage to take place. It was noted that the datasets had been disclosed to the researcher and held since 2009 without consent or an application for support under the Regulations.

Members discussed that the application appeared to be missing some key information that would be required in order to make a recommendation. It was noted that sections o, p, q and y had not been completed and that other sections did not contain sufficient detail. For example, section m should include justification for each identifiable data item, section q should detail the justification for use of each identifiable data item in full and it should be confirmed whether confidentiality clauses exist within employment contract within section r. In addition, Members discussed that the number of patients whose data was included within the datasets was not clear and would need to be clarified and that the DPA responses in section r should be revised to reflect that even though anonymised data would be used for analysis, personal sensitive data was being retained by the applicant. Members agreed that further justification should be provided by the applicant in relation to why further linkage was required. It was noted that the application specified this was to ensure that no mistakes were made when the linkage was first carried out, however Members requested further details to ensure that the proposed activity was necessary in order to achieve the purposes. Members therefore queried whether there was any evidence or reasoning to suggest that the original data linkage would not have been accurate.

The applicant subsequently confirmed to the NIGB office that they would not seek to re-link the data but would instead carry out analysis on the already linked dataset and destroy all identifiable data.

ECC 6-02(FT7)/2012 Development of a National Joint Registry DNA Biobank: A Proof of Concept Study

This application was considered outside the Committee meeting under fast track criteria 1: *Applications to identify a cohort of patients and subsequently to seek their consent.* Members advised that in this instance support would not be necessary as consent appeared to be satisfactory. This research application from the University of Sheffield detailed a request to allow the National Joint Registry (NJR) to write to patients on behalf of a researcher in order to invite them to take part in a DNA Biobank. It was confirmed that Northgate (who process the NJR database on behalf of the data controllers HQIP) would write to patients. Members considered whether the consent provided by patients in order for Northgate to process their data as part of the NJR dataset would be sufficient to cover this request. Members noted that patients would have an expectation of being contacted from the patient information provided and also that they were informed that their data may be used for research purposes. As there was no further disclosure in this instance Members agreed that the consent appeared to be sufficient to allow Northgate, with HQIP's agreement, to write to NJR patients in order to invite them to take part in the DNA Biobank. It was noted that no data would be disclosed to the University of Sheffield without prior consent. Members advised that only those patients who had provided consent should be approached and those who had been entered onto the NJR without consent but with support under the Regulations should not be written to. Members advised that if this kind of research request was likely to be frequent in future the NJR consent form should be amended to make this explicit to patients.

ECC 6-02 (FT8)/2012 IBIS-II PREVENTION Trial
ECC 6-02 (FT9)/2012 IBIS-II DCIS Trial

These research applications from Queen Mary University of London were considered under fast track criteria 7 '*validity of consent'.* The applications set out details of blinded randomised placebo controlled trials with the primary endpoint being the development of histologically confirmed breast cancer, both invasive and non-invasive (i.e. including new or recurrent DCIS). These would be separately categorised as local recurrence (all ipsilateral disease), distant recurrence or new contralateral tumour. Breast cancer mortality would also be analysed. Support was sought under these Regulations to confirm the validity of the consent, and if not considered sufficient, to provide support for flagging and to receive details of cause of death and relevant HES data on trial participants from the Health and Social Care Information Centre. This would involve linking name, NHS number, date of birth and postcode, collected with consent from trial participants, to obtain this information. Data would be returned in a pseudonymised format using a unique trial participant number. These applications were reviewed together due to their similarities and that the information provided to participants was identical for each. It was noted that the protocol stated that participants would be followed up for cancer incidence and cause of death using national tracking systems, however, there was a question as to whether this was sufficiently explicit. It was agreed that these were important trials with an ongoing public interest in the outcomes, and that in order to obtain full benefit from the trial data it would be important to receive these outcomes. It was also noted that these applications followed on from the IBIS-I trial that had been approved. While noting that funding and cost issues were not considered to be an appropriate justification for legal support under these Regulations, access to the requested data was considered to be in the spirit of the original consent, the numbers involved meant that it would not be feasible to seek to explicitly re-consent the trial participants, and therefore a recommendation of support was advised to provide a secure legal basis for the requested activity.

ECC 6-02 (FT10)/2012 East Midland Patient Experience Service (EMPES) - Mental Health

This application was considered under fast track criteria 1: *Applications to identify a cohort of patients and subsequently to seek their consent.* Members agreed to recommend support for this application. This service evaluation application from a number of NHS Trusts (Lincolnshire Partnership, Leicestershire Partnership, Derbyshire Mental Health, Northamptonshire Partnership, and Milton Keynes Community Health Services Trust) detailed a survey methodology which aimed to assess the differences in scores between teams within Trusts. The application followed the same methodology, guidance and survey paperwork as the existing CQC Mental Health Community Survey (ECC 8-05(a)/2011), however a larger sample would be required (up to 30,000) to allow comparisons to be made within Trusts between different care teams. Support under the Regulations was requested to allow identifiable data including name, full postal address, gender, year of birth, ethnicity, date of last contact, Care Programme Approach (CPA) status and GP code to be sent to Quality Health in order to send questionnaires and allow subsequent analysis. It was noted that this application followed the exact same methodology as the CQC Community Mental Health Survey which had previously been approved. As the methodology had been assessed in detail and the Committee had agreed that prior consent would not be feasible in this instance, Members agreed that support could be recommended for this application.

ECC 6-02 (FT11)/2012 Complete Kawasaki Disease National Survey

The application was considered under fast track criteria 5: *Applicants utilising the British Paediatric Surveillance Unit (BPSU) methodology.* Members agreed to recommend support to the application, subject to conditions. This research application from University Hospitals Bristol NHS Foundation Trust detailed a surveillance study using the BPSU methodology which would collect information in relation to the epidemiology, clinical outcomes and current clinical management of Kawasaki disease in patients under 16 within the UK and Ireland. Access to confidential patient information including date of birth, hospital number, NHS number, partial postcode (first four digits) and date of death was requested to allow duplications to be removed. Month/ year of birth and death only would be used for analysis purposes. Members agreed that this was an important study into a rare condition (estimated to be around 300 cases in the study period) looking at incidence and clinical features, therefore the BPSU methodology was appropriate in this instance. Members were pleased to note that the minimum

identifiable data items necessary were requested and that these would be separated from clinical data as soon as possible. Members noted that a patient information leaflet had not been included within the application and requested that a copy of this be provided, along with confirmation that this is given to clinicians in order to ensure that they meet the fair processing requirements within the Data Protection Act 1998 (DPA).

Members considered there to be an inaccuracy within the application form which appeared in sections b and k. Where the application stated "*We are conducting the research as a prospective study of routinely collected, anonymised data and ask the Committee to waive the requirement for informed consent..",* Members highlighted that identifiable data would be accessed as part of the study and therefore the statement was not accurate. In addition, Members noted that, in response to the question around compliance with the first principle of the DPA, it was detailed that sensitive personal data would not be used. It was reiterated that as identifiable data was collected which included information pertaining to an individual's physical health; this would be classed as sensitive personal data under the DPA and should be managed appropriately.

ECC 6-02(FT12)/2012 Surveillance of Acute Pancreatitis in children aged 14 years in UK and Ireland

This application was considered via the proportionate review process under criteria 5; *Applicants utilising the British Paediatric Surveillance Unit (BPSU) methodology.* Members agreed to recommend support to the application, subject to clarification and conditions. This research application from the University Hospitals Bristol NHS Foundation Trust detailed a BPSU surveillance study of children with Acute Pancreatitis over 13 months in England. The project aimed to establish the incidence of AP; examine associated agents in the UK, including the potential influence of obesity and viral disease; examine current investigation and management strategies and medium term morbidity; and examine standard and child-specific severity scoring systems. Data would be collected from consultant paediatricians using the BPSU methodology. Follow up data would be requested after one year and HES data would be used in order to obtain information on any missed cases. Confidential patient information was requested in order to allow de-duplication to take place. Access was requested to data including NHS number, date of birth and date of death. Age in months and date of death would be used for analysis purposes. Members agreed that this study would be of significant public benefit, noting that the serious condition was rare and that little was known about its clinical course and epidemiology. It was noted that there would be an estimated 120 cases within the UK over the study period and that complete ascertainment was therefore important. It was noted that minimal identifiers would be required to allow duplication and analysis. Members were pleased to note that clinical information would be separated from identifiable demographic data as soon as possible. Members sought confirmation that de-identified data only would be retained for 20 years. Members were pleased to note that a patient information leaflet had been developed. However it was advised that the applicant should ensure that this was available to clinicians to distribute to patients in order to meet their fair processing responsibilities under the Data Protection Act 1998.

ECC 6-02(FT13)/2012 NHS Litigation Authority Learning Lessons from Claims

This application was considered under fast track criteria 3: *where applicants are accessing data on-site to extract anonymised or effectively pseudonymised data.* Members agreed to recommend support for this activity, subject to conditions. This service evaluation application from NHS Litigation Authority (NHSLA) detailed a review of the NHSLA claims database by NHSLA staff and sub-contractors in order to analyse factors which gave rise to negligence claims against the NHS. The overall aim of this activity would be to improve patient care and reduce the extent and cost of litigation. Support under the Regulations was requested in order to provide a legitimate basis for risk management team staff and relevant sub-contractors to access the NHSLA claims database on a retrospective basis prior to January 2013. From January 2013 a letter would be sent to claimant solicitors to inform them of the use of their client's data and opportunities to dissent would be provided. The data on this database was compiled from different sources for cases handled by the NHS Litigation Authority. It was noted that the application detailed carrying out risk assessment activities which were part of the NHSLA's statutory objectives and would be used to improve patient care. In addition, Members noted that no identifiable

data would be extracted from the database and that data would be accessed on NHSLA premises only. Members were pleased to note that a letter would be provided on a prospective basis to the claimant's solicitor to allow opt out. Members considered whether the information included within the database could be classed as patient information under the Regulations as it was noted that much of this information would have been generated as part of the litigation process. It was noted that the NHS Act 2006 stated that patient information could be defined as *"information (however recorded) which relates to the physical or mental health or condition of an individual, to the diagnosis of their condition or to their care or treatments"* and also to information *"which is to any extent derived, directly or indirectly, from such information".* Members agreed that in this instance the information contained within the NHSLA claims database could be included within this definition.

ECC 6-02 (FT14)/2012 Chemotherapy Patient Experience Survey of NHS patients treated as patients in NHS Trust Outpatient/Day Case Departments following up on the National Cancer Patient Experience Surveys 2010 and 2012

This application was considered via the proportionate review process under criteria 1: *Applications to identify a cohort of patients and subsequently to seek their consent.* Members recommended support for this activity. This application from the Department of Health and Quality Health detailed a Chemotherapy patient experience survey. The survey would take place over 50 NHS trusts and include around 15,000 patients treated in the summer of 2012. Confidential patient information requested included name and address in order for Quality Health to write to patients with a questionnaire. It was detailed that no clinical data would be disclosed prior to consent and that Quality Health would only be aware that the patient had attended a chemotherapy appointment. Date of birth would be disclosed in order to allow DBS checks for mortality to be made prior to sending questionnaires. Members discussed that the survey followed the same methodology which had been used in previous approved applications where consent had been deemed as unfeasible. It was also noted that security measures within Quality Health would remain identical to those applications. It was noted that fair processing information would be provided at trust level and patients would be provided with the opportunity to opt out.

ECC 6-02(FT15)/2012 The lifetime risk of cancer in renal transplant recipients

This application was considered under proportionate review criteria 4: *Time limited access to undertake record linkage/validation and to pseudonymise the data.* Members agreed to recommend support for this activity, subject to clarification and conditions. This research application from Leeds Teaching Hospitals NHS Trust detailed accessing cancer registry data relating to all patients who had had a renal transplant within the Renal Unit of St James University Hospital (approx 3500 patients). Data including NHS number, date of birth and address would be sent to the cancer registries who would then identify which patients had developed cancer following their transplant. It was anticipated that linkage would take approximately 3 weeks and following this no identifiable data would be retained within the dataset (dates would be reduced to intervals and postcode converted to deprivation score). Members agreed that the application aims would be of public benefit and commented that the research was well designed.

Members noted that the application would utilise data from the past 40 years and recognised that patients may be difficult to trace and/or may be deceased. It would therefore be difficult to obtain consent from the cohort. Members were pleased to note that fair processing information would be displayed within the hospital which would allow the patients the opportunity to be informed of the study and opt out. It was noted that clinical information would be separated from demographic data for the purposes of analysis and that a unique study identifier would be allocated to allow the applicant to link back to original records if further validation was required. Members sought confirmation that this unique identifier would be destroyed once analysis was complete. Members discussed the statement that consent was not thought to be required within section 5.2 of the protocol and agreed that this was not the view of the ECC and asserted that where feasible consent should be obtained to disclose confidential patient information. However, in circumstances where consent is not practicable and the disclosure is in the public interest, support to disclose without consent under the Regulations can be provided. It was noted that no patient involvement had taken place and Members advised that the applicant consider ways to engage with patients in relation to research activities undertaken by the trust. For example, trust members could be informed of research studies at routine meetings.

ECC 6-02 (FT16)/2012 CQC 2013 Maternity Survey

The application was considered under fast track criteria 1: *Applications to identify a cohort of patients and subsequently to seek their consent.* Members recommended support to the application, subject to conditions. This application from the Care Quality Commission (CQC) was for a recommendation of support for the transfer of patient identifiable data from acute trusts to an approved survey contractor (Over 250 patients would be identified from each trust who had had a live birth prior to the 28 February 2013), for the purpose of mailing out questionnaires for the 2013 maternity survey. The application indicated that the list of survey contractors was yet to be confirmed but the vast majority trusts involved would probably opt to use either: Picker Institute Europe, Quality Health or Patient Perspective. Picker

Institute Europe would act as the survey coordination centre for the survey. Two files would be created, a mailing file and sampling file. These would both be sent to the approved survey contractor, and the sampling file would be sent to the coordination centre for further analysis purposes and to identify women who had received antenatal and postnatal care from the trust. The mailing file would include; full name, address and postcode. The sampling file would include; mother's year of birth, ethnicity, date of delivery, place of delivery, GP practice code, sector level postcode and trust held provider information. It was noted that this application followed the same methodology as previously approved CQC survey applications. As the methodology had been assessed in detail and the Committee had agreed that prior consent would not be feasible in this instance Members recommended that support be provided to allow trust data to be submitted to approved contractors and to the patient coordination centre.

Members discussed that the age range for the maternity survey included 16 and 17 year olds. Concerns were raised that the risk of distress to mothers was higher in those who were under 18. Members therefore considered that a higher justification would be necessary to balance the risks of the disclosure of data for these patients. It was agreed that a recommendation of support could not be provided for access to data regarding 16 and 17 year olds, for the purpose of disseminating a patient survey relating to maternity episodes.

Establishment of the TPP ResearchOne Database (unreferenced)

This research database application from TPP set out the establishment of a pseudonymised research database. Advice was sought from the Committee on whether this application required a recommendation of support. Due to various potential conflicts of interests (Dr Mark Taylor, Professor Julia Hippisley-Cox) that were identified through review of the application, this was reviewed and considered by Dr Patrick Coyle and Dr Chris Wiltsher. Following an initial review of this application, it appeared to Members that this activity could proceed on the basis of utilising pseudonymised data, and therefore advice was provided with a view to ensuring that confidential patient information would not be processed by the applicant. This was also in line with the expressed wishes of the applicant. A number of clarifications had been requested to confirm whether identifiers would be processed at any point. The following was confirmed:

1. Data transfer from SystmOne to ResearchOne was stated to be an automated process with no manual intervention
2. The link database and ResearchOne databases would be held in separate data centres, and both would only be accessible to the technical team.
3. Postcode would be automatically converted to sector level via an automated process.
4. Dates of birth and death are similarly reduced to year and month automatically.
5. Free or narrative text would not be included within the data extraction. The letter indicated that there might be possibility of controlled text fields, however, Members were clear that this should not be identifiable to the patient, or anyone associated with the patient.
6. De-identified sexual and mental health data items would be included; terminations data would not be extracted.
7. Marital status psychiatric, NJR data and flags showing military affiliations would be excluded.
8. Read code diagnoses showing under 5 would be suppressed / not transferred.
9. System rebuilds would automatically remove those who had recently dissented from inclusion
10. There was a stated intention to increase lay involvement.
11. Linkages to HES would be undertaken using pseudonymisation software so that there would be no disclosure to or from HES of identifiers

Following recent communication of this database in E-Health Insider, it was noted that the article incorrectly reported that the database had received approval from the NIGB. As there would be no transfer of identifiable information to the database or applicant, it was confirmed that approval would not be required for the activity to proceed.

Amendments

PIAG 4-08(b)/2003 National Confidential Enquiry into Patient Outcome and Death (NCEPOD)

NCEPOD has support in order to carry out a number of studies with the aim to review clinical practice and identify potentially remediable factors in the practice of anaesthesia, surgery and other invasive medical procedures including primary care. This amendment request detailed using confidential patient information relating to 19000 cases from the previously approved study of peri-operative care in order to carry out further analysis in partnership with academic departments (Barts and the London NHS Trust and University College London Hospital). Identifiable data would be used to request and link study data to HES data fields, including ICU admissions, date of admission and NHS number. This linkage would take place within NCEPOD and no identifiable data would be disclosed to external researchers. Once HES data was linked with study data the data set would be anonymised and aggregated. It was anticipated that this would take no longer than 6 months. Members agreed that this could be considered as an amendment to the original application. It was noted that the further analysis purposes were encompassed within the original purpose of the confidential enquiry and that identifiable data would be purely for the purposes of linkage. Once linkage had been undertaken anonymised data only would be used for analysis purposes.

ECC 7-05(g)/2011The Trauma and Audit Research Network (TARN)

This application from the University of Manchester set out details of an activity which would allow PCTs to link SUS activity data to TARN data. TARN data provides an assessment of injury severity of patient injuries, seniority of clinicians treating the patient, time to transfer for non-emergency referrals for specialist care and presence of a prescription for rehabilitation. It was noted that the collection of confidential patient information for these purposes was included within a separate application, PIAG 3-04(e)/2006. The datasets would be linked at PCT level in order to support the implementation of the Best Practice tariff for trusts receiving major trauma and continue monitoring standard of care across the country. A recommendation for classes 4, 5 and 6 support was requested to provide a legitimate basis for TARN to access confidential patient information for the purposes of providing PCTs with a method to link TARN data to SUS activity data. Access to NHS number and date of birth by TARN was requested to facilitate linkage at PCT level. This amendment request detailed accessing HES data from the Health and Social Care Information Centre for all patients who met the TARN inclusion criteria. HES data would include NHS number, ICD10 code and NHS trust. This would allow TARN to feed back NHS numbers to trust and PCTs for patients who had not been included in the trusts submission who would then identify patients who should form part of the TARN audit. This amendment was forwarded to Members for their consideration. Members noted that TARN already had approval to obtain NHS number for patients and agreed that it was important to improve the quality of data received from trusts. Members therefore agreed to recommend support for this additional data flow.

ECC 5-02(FT6)/2012 Rate of thromboembolic disease and other complications in total ankle replacement surgery

This research application from the Royal National Orthopaedics Hospital detailed the linkage of National Joint Registry (NJR) and Hospital Episode Statistics (HES) data in order to provide better understanding of the thromboembolic disease risk associated with ankle replacement surgery. Access to confidential patient information including date of birth, hospital/NHS number, postcode and gender was requested in order to link the two datasets. Following confirmation of final approval for this application, an amendment was submitted which detailed that the Health and Social Care Information Centre (HSCIC) were able to carry out the linkage on the applicants behalf and provide a de-identified dataset for the purposes of analysis. The linkage would be managed within the Trusted Data Linkage Service environment in the HSCIC and negate the requirement for the applicant to have access to identifiable data. The amendment was processed via Chair's action. It was noted that this method would involve less disclosure than providing the HES and NJR dataset to the applicant in order for them to carry out the linkage themselves. The Chair recommended providing support for the amended data flow.

PIAG 2-05 (j)/2006 National Joint Registry – additional audit request

This amendment request from the Healthcare Quality Improvement Partnership (HQIP) set out the issue that the MHRA had published two device alerts relating to all metal on metal hip (MoM) replacements, but had since raised concerns with the DePuy Pinnacle acetabular cup when used with a MoM bearing. The MHRA had asked the Department of Health and the NJR for support in undertaking an audit with the twelve largest users of the pinnacle cup. It was noted that the audit would go back to 2003, and that it had been identified that procedure details had not been previously submitted to the NJR for almost 20% of all sales by DePuy to these Trusts. This figure did not include revision procedures and it was indicated that some of the revisions procedures had also not been submitted. It was considered essential that in order to undertake the required analyses by the MHRA that the all missing primary and revision procedures be submitted to the NJR retrospectively. It was agreed that completion of this audit was in the public interest and it would be important to obtain details of the missing procedures in order for the audit to be effectively carried out. It was also noted that there would be likely to be similar audits in future and it was agreed that the original application form would be revised to incorporate such activity in future. It was highlighted that one of the standard conditions of approval is that support under the Regulations could not override a pre-recorded expression of dissent. In such instances, the applicant was advised to discuss any such issues with those locally submitting data to reach a satisfactory conclusion. In line with the comments above, a recommendation of support was provided to this amendment request. The SofS agreed with this recommendation.

PIAG 03 (a)/2001 – confirmation of activity within cancer registries specific support

This query was made under Regulation 2 of Statutory Instrument 1438, and related to seeking an enhancement to the HES dataset currently available to the cancer registries. It has been previously raised in late 2011 but halted as confirmation to queries had been pending from the applicant. The Health and Social Care Information Centre (HSCIC) supplies the English cancer registries with periodic patient identifiable extracts of all admitted-care HES episodes for all patients with a recorded diagnosis of cancer in admitted care HES. These extracts are received under the English cancer registries section 251 specific support, (PIAG 03-(a)/2001) and are managed on behalf of the English cancer registries by Thames Cancer Registry. The registries requested receipt of admitted care, outpatient and A&E HES episodes relating to all cancer registrations in the National Cancer Data Repository (NCDR), in addition to admitted care HES episodes for patients with a recorded diagnosis of cancer in admitted care HES. The reasons for this requirement were to fill in missing admitted care HES data in the NCDR and to enable enhanced analyses of the cancer patients in the NCDR using linked outpatient and A&E HES episodes. The query stated that not all cancer registrations (approx 25%) in the NCDR link at person level to episodes in the admitted care 'cancer HES' extracts, and vice versa. These missing HES data prevent the full value of the NCDR from being realised. A proportion of the admitted care HES episodes provided through this application would therefore relate to HES patients who did not have a cancer diagnosis recorded in admitted care HES. However, all cancer registrations in the NCDR have definitely been diagnosed with cancer to the best of the English cancer registries' knowledge, using multiple data sources to confirm diagnoses. Following subsequent helpful clarifications, it was confirmed that the transfer of patient identifiers to the Health and Social Care Information Centre for the stated purposes was covered by the scope of the existing legal support provided to the Registries.

ECC 6-02 (FT4) 2011 Investigating the burden of gender identity disorder (GID) in children and adolescents: a surveillance study of incidence, clinical presentation, comorbidities and natural history.

This application from University College London, approved in November 2011, had detailed a study following the BPSU methodology. The study aimed to collect information about the prevalence and features of childhood/adolescent gender identity disorder (GID) and measure how the condition progressed over time. Support had been provided to provide a legitimate basis to process patient identifiable data in order to ensure the de-duplication of data, match follow-up data and describe the population presenting with GID. This amendment was considered by the office as it related to a time extension, rather than a change to purposes or data items. It was noted that the 13 month surveillance period was due to complete by the end of November 2012, and the request was to extend this

surveillance period for a further six months. A notice of substantial amendment had been submitted to Bloomsbury Research Ethics Committee for a favourable opinion. The request confirmed that there had been 271 notifications to date which was considered to be an excellent response; however, the request stated that the extension would allow an increase in the accuracy of the incidence estimate. Rationale for the extension included the small number of validated cases due to a large number of exclusions, which included prevalent cases, over 16's and notifications of children with disorders of sexual differentiation rather than GID, which suggested over-reporting rather than under-reporting; duplication of reporting, where the child had been reported to both the BPSU and CAPSS, and where the child had been reported by both a local and specialist child psychiatrist; the potential for an increased sample size to improve the accuracy of associations and conclusions drawn from the study; and the potential for an extended timescale to ensure ascertainment of all cases in the North East of England, which had to date reported fewer cases than other regions and where targeted follow-up communications were ongoing. It was agreed that a strong case had been made to justify the increased time for surveillance and there was a continued public interest in seeking to increase the number of valid cases and accuracy of incidence estimates. As this would not involve any changes to the approved arrangements, it was agreed to provide a recommendation of support to the Secretary of State for Health that this extension be approved.

HQIP / HSCIC audits – change of purpose

A request was received that sought clarification on what steps would need to be taken in relation to national clinical audits processed by the Health and Social Care Information Centre to enable anonymised audit data to be used for research purposes. This amendment request was only in relation to those national audits where the data controller was the Healthcare Quality Improvement Partnership and the data processor was the HSCIC. Following Committee review of the HQIP/NICOR application and discussion with the ECC Deputy Chair, it was agreed to be supportive of this issue, particularly as this was in line with the future strategic position of the HSCIC and the governance controls had been reviewed within previous applications and were known to be robust. However, this was with the caveat that once this amendment had been concluded, where a national audit that was currently processed by the HSCIC was due to transfer over to another data processor, the data controller must ensure that there are equivalent governance controls to those currently in place by the HSCIC, particularly over the governance arrangements of ensuring appropriate anonymisation prior to onward disclosure for research purposes. It had been advised that these governance arrangements must be confirmed via the NIGB Office before any new data processor discloses anonymised data. Taking into account the caveat above, it was agreed that the handling of this amendment could take place at the office level and could be managed through confirmation of the relevant audits. In particular, patient information leaflets applicable to the relevant audits must be updated and published to cover this additional purpose of processing. This should be confirmed prior to any amendment coming into effect and was fundamental to any such amendment being approved in order to ensure compliance with the fair processing principle of the Data Protection Act 1998. Further conditions to this amendment were that the data disclosed by the HSCIC for research purposes must be in an anonymised format; the research purposes should be in line with the overall purposes of the application, and emphasis was placed on the need to continually improve processes and refine granularity so as to ensure proper respect for any expressed dissent.

RCPCH National Epilepsy12 national audit

The Office had previously engaged with this group, who had sought advice at an early stage in development of the audit in 2010. A request had been received from the Royal College of Paediatric and Child Health (RCPCH) in terms of a second stage of the audit, and sought confirmation as to whether approval would be advised. The letter confirmed that the data collected for service descriptors and clinical performance indicators would remain the same as those previously discussed in July 2010, and the encryption and pseudonymisation methodologies had not changed and the audit team would not be in receipt of any identifiable confidential patient information. It was noted that NHS Number and date of birth, which are considered to be identifiable, would be submitted, however, NHS Number would be encrypted when uploaded and date of birth would be converted to age upon submission. The letter also confirmed that patient user experience data will be collected via return of patient questionnaires provided at epilepsy clinics; patient information leaflets and posters would be used to provide suitable fair

processing information about the audit and use of data, with patient opportunity to register dissent to the processing provided within this information. Based upon the information provided, it was advised that approval would not be required.

Health and Social Care Information Centre annual reviews update

Following the September meeting where Ms Claire Sanderson presented to the Committee (item 3a), it had been noted that a number of annual reviews were due for submission shortly before 01 April 2013. Once the HSCIC's statutory powers come into effect on 01 April, many of these would no longer require support under the Regulations. It was confirmed that HES, the Central Register and Diagnostic Imaging Dataset were extended until 01 April 2013. However, the Integrated Access to Psychological Therapies (ECC 7-04 (f)/2010) had a specific condition of support attached to it that requested feedback at time of annual review on the transfer of pseudonymised data to commissioners on a trial basis for commissioning purposes. As the annual review for this application was not due until March 2013, feedback had been requested on this aspect as it would provide an important evidence base for similar issues. This application had therefore not been included in this extension pending receipt of feedback or provision of an update on feasibility.

Update on previous applications

ECC 5-05 (c)/2012 Enhancing the multi-agency management of individuals with EMHN

This application was considered at the September ECC meeting where Members agreed that they were supportive of the application but requested clarification as to why trust employees with legitimate access to the RiO system could not be identified and asked to pseudonymise the data on the applicant's behalf. The applicant provided further information in relation to this aspect. This included a letter from the Medical Director within Cornwall Partnership NHS Foundation Trust which detailed that the trust did not have the resource capacity to support the pseudonymisation and extraction of details relating to the 100 patient sample, which was estimated would take up to 5 hours per patient, and that the level of technical expertise required was substantial and required a trained researcher. This information was forwarded to Members who originally reviewed the application and it was agreed that in this instance it would not be practicable for trust employees to pseudonymise data on the applicant's behalf. Members therefore recommended support to this application.

ECC 5-05 (e)/2012 National Drug Treatment Monitoring System (NDTMS)

This application was provisionally approved at the September 2013 meeting. As part of the conditions of approval the applicant was asked to contact the Information Commissioner's Office to ensure that the requirements of the Data Protection Act were met in relation to informing patients that were no longer in NHS treatment about the data collection. The applicant reported that they had contacted the ICO and were advised to ensure that the public facing web presence of the NTA and Public Health England (once set up) should make clear that this change was occurring, and to ensure that record retention policies were reviewed and that there was an operational justification for retaining identifiable data. The ICO also advised that it would not be necessary to re-consent the entire cohort who were still in treatment. This response was forwarded to Members who originally reviewed the application. It was also clarified that final approval would not be provided until PHE was established.

ECC 5-05 (m)/2012 Hypoxic-ischaemic encephalopathy (HIE) definition validation study

This application was provisionally approved at the September 2012 meeting subject to clarification of the justified need for collection and retention of each specified identifiable data item. The applicant submitted further information in relation to this request and this was forwarded to Members who originally reviewed the application. Members agreed that the response was satisfactory and requested that postcode should be deleted as soon as possible once deprivation score had been derived. This would be a condition of the approval.

ECC 2-02(d)/2012 Resurrection of the Database of the Oxford Survey of Childhood Cancers (OSCC) as a Research Resource and its use to investigate Xray exposure

This application was considered at the March 2012 ECC meeting where clarification was requested on how access to the database would be managed and why the future management of the database could not be under the auspices of the cancer registries' specific support. Subsequent clarification was received from the applicant which detailed the following:

- Access to the database would be provided to *bona fide* researcher workers whose proposal would be subject to NIGB approval where appropriate and ethical approval. Any disclosure would be managed in line with the Childhood Cancer Research Group policies and procedures. Only the created anonymised digital database would be made available.
- It was considered that the terms of the cancer registry specific support would not adequately cover the accommodation of survey data, specifically with regard to matched control children; therefore a separate application for class support was submitted.
- The microfilm copies of the data would be kept until it was certain that the data had been safely electronically stored. The cost of the process would be tested in a pilot phase; if this proved too expensive parts of the records would be transferred to a digital format or additional funding would be requested. Progress towards anonymising the data would be reported on in the annual review.

Responses were sent to Members who queried how it would be ensured that the honorary research fellow would owe an equivalent duty of confidentiality to that of a health professional. The applicant confirmed that disciplinary procedures would be in place for breaches of confidentiality and where necessary prosecution would be pursued. Members agreed to recommend support to the application, subject to any further access to identifiable data being notified to the NIGB office so it could be determined whether a further application should be made and there being a signed confidentiality agreement in place which included disciplinary measures and referral to the GMC if appropriate.

ECC 5-05 (a)/2012 Clinical Practice Research Datalink service

This application was reviewed in September 2012 and deferred while the stated points and clarifications were resolved. It had been advised that a resubmission should be provided, and an offer of a meeting between the applicant and ECC representatives was extended, to be taken up at the appropriate time. A verbal update confirmed that the applicant would not be seeking to submit a revised application to the December 2012 meeting, and they had been working with colleagues and seeking advice from the Information Commissioner's Office. It was proposed that at the relevant time the revised model could be discussed outside the formal meeting schedule with potentially Chair's action being taken in terms of a recommendation; however, as the precise nature of revisions is currently unknown it is not clear whether this approach would be appropriate. At time of writing, no further meeting has taken place with the applicant.

ECC 4-03 (e)/2012 Patient Outcomes Registry

This application was provisionally approved at the July 2012 meeting, pending confirmation as to whether the data controller for this would be HQIP or NICOR and confirmation of a favourable REC opinion for this research database. Despite requests for progress, there has still been no confirmation as to the appropriate data controller and no receipt of a REC opinion, therefore this application remains provisional, with the consequence that anonymised data cannot yet be used for research purposes for these audits. The Registry also intended to include the TAVI audit: however, as it had been confirmed that HQIP were not the data controllers and as accountability would need to be established an application was advised that would follow the content of the similar approved audits. At time of writing and despite requests for progress, no further update has been received.

3. For consideration

3a. ECC 2-06(a)/2009 Small Area Health Statistics Unit amendment

The original application from Imperial College London requested support to process a number of datasets; ONS data relating to births and stillbirths, cancer, mortality, NCAR and HES data. This was for the purposes of advice provision, development of methodology to interpret health outcomes for small areas and to act as a centre of expertise. The data was to be held for a period from 5 years up until April 2014.

This request from the Small Area Health Statistics Unit (SAHSU) at Imperial College detailed three following amendments to the original application: to hold NHS number and address level data for all SAHSU datasets where these were available; a proposed review process to allow additional linkage to be reviewed in a timely and proportionate manner; and three new data linkage projects. Members agreed that the public interest in the work SAHSU carried out was particularly high and were mindful of this when discussing the requested amendments. Members were informed that a meeting had taken place with a sub-group of Members and the applicant prior to the Committee meeting and a number of recommendations (detailed in a letter dated 12 October 2012) were made following this. It was noted that address level data was requested to accurately calculate exposure levels and to allow data checking and cleaning to take place whilst maintaining acceptable timescales for individual linkage requests. Members agreed with the sub-group recommendation that support should be provided for this aspect of the amendment.

It was noted that detailed geographical analysis would need to take place as part of SAHSU's work. It was proposed that individual linkage projects be considered as amendments to the overarching application. Each individual project would submit details of purpose for linkage; linkage identifiers required; number of records being linked with justification; technical linkage methodology; process of anonymisation after linkage; and disclosive risk. The overarching application would include details of the data linkage process, identifiers and datasets held by SAHSU and governance arrangements. Members agreed with the sub-group recommendation that future linkages should be considered via the proportionate review process as amendments to the original application.

Three linkage projects were submitted to the meeting in addition to the above amendment requests. The first was a study of traffic pollution and health in London, which detailed a one-off linkage of ONS births and HES data with the primary aim of describing and understanding the patterns of exposure of the population in London to traffic pollution and relationships to health outcomes. The second was a study of acute coronary syndrome admission rate and outcome in Indian Asians, detailing linkage between HES and ONS mortality records (1998 – 2008) in order to identify patients who die subsequent to an admission for acute coronary syndrome, requiring month and year of birth and death for research purposes. The third study, on incinerators, detailed linkage of ONS-HES live and still births to gestational age, ethnicity and birth weight from HES. Month and year of birth would be required for research purposes. Members agreed that these were all important studies and noted that the use of identifiers would be restricted to the database team for linkage purposes, except where specified above. Researchers would be provided with pseudonymised NHS number and postcode in each of the outlined projects. Members agreed to recommend support for the linkage projects. It was noted that amendments to the overarching REC approval would need to be submitted for each additional linkage project. Members discussed that the forms used to submit the amendments were very clear and thanked the applicant for submitting all requested information. Members agreed that refining the application form could be an iterative process and invited the applicant to make any further suggestions on improvements if necessary.

4. Resubmissions

Members were advised that the resubmitted application had been withdrawn by the applicant prior to the meeting.

5. New Applications

5a. Use of patient identifiers from the MHMDS to facilitate linkage to HES in order to test the provision of a regular routine linked data extract containing anonymised record level mental health and HES data [ECC 6-05(a)/2012]

This application from the Health and Social care Information Centre detailed linking Hospital Episode Statistics (HES) data and Mental Health Minimum Dataset (MHMDS) data. This was in order to help understand any data quality issues with patient identifiers within the datasets which might affect the rate of successful linkage, establish the feasibility of the proposed linkage and ensure acceptable linkage rates were achievable prior to the proposed trusted data linkage service go live in April 2013.

Members agreed that they were supportive of the overall aims of the activity. It was noted that the application was to allow the HSCIC to pilot the linkage with a view to providing this service to researchers following 1 April 2013 under the HSCIC's statutory powers. Members queried whether the applicant had considered whether the extent of identifiable data items requested were the minimum necessary. Members discussed that postcode could be particularly identifiable in certain contexts and requested that the applicant provide further justification for the use of this data item. Members commented that a report detailing results of the linkage pilot would be useful and, in particular, information relating to the completeness of NHS number within the HES dataset, the number of records that were able to be linked using NHS number alone and how linkage was improved by the addition of other data items. Members requested that the HSCIC share this information with the Committee. It was also suggested that this information would be of use to others carrying out data linkage activities.

Members agreed that the minimum requirements of the Regulations appeared to have been met and agreed to provide a recommendation of approval for this activity, subject to clarification as to whether the applicant had considered whether linkage could take place without the use of full postcode and, if it could not, could provide further justification for the use of this data item.

5b. HES linkage to Private HES [ECC 6-05 (b)/2012]

This service evaluation application from the Private Healthcare Information Network (PHIN) detailed a pilot exercise which aimed to evaluate the linkage of HES data with a dataset which included details of care within private hospitals (PHES, currently processed by Healthcode). The activity aimed to significantly improve the measurement and understanding of core clinical indicators for patients receiving private treatment, to support proper regulation of the private healthcare industry and provide a more informed patient choice. Support was requested to allow the Health and Social Care Information Centre (HSCIC) to obtain identifiable patient information from Healthcode (date of birth, name, postcode and NHS number), identify HES data in relation to patients and provide this data in pseudonymised format (including date of death) for linkage by Northgate Information Services (NIS).

Members were supportive of the aims of this activity and agreed that it was important to establish an accurate reflection of private healthcare provider outcomes. It was noted that whilst the primary aims of the application were not to improve NHS care the public benefit in monitoring private healthcare was clear. Members noted that the application sought to provide a legal basis for disclosure of private healthcare data to the HSCIC. Members were unsure whether the definition of patient information within the Regulations was broad enough to cover private patient information as well as NHS patient information. Members were informed that legal advice had been sought from Department of Health lawyers in relation to this point, as it would set a precedent in terms of applications under the Regulations. At the time of the meeting this advice had not been provided. Members agreed that they could provide an indication of the discussion to the applicant, however a final recommendation would have to be deferred until it was clarified whether the initial flow of data from private healthcare providers could fall within the remit of the Regulations.

Members noted that dates of treatment would not be provided to the HSCIC to allow them to disclose only 30 day outcomes. This would allow only the minimal amount of data required for each patient to be disclosed. Members queried what period of HES data would be disclosed and whether the applicant had considered providing dates of treatment to the HSCIC. Members noted that the data would be linked

pseudonymously by Northgate Information Solutions; however Members were unclear of future uses and disclosure of the created dataset. Members queried whether data would be analysed by NIS only, whether the specified activity was in order to test the linkage concept only and when data would be fully anonymised. In addition, Members advised that the combination of data items meant that the data would be identifiable in certain contexts, for example if disclosed back to service providers. Members requested further information regarding how onward disclosure and analysis would be managed and how it would be ensured that the dataset was anonymous in different contexts. Members agreed that it appeared that consent would be feasible in future. Members noted the applicant's assertions regarding the comparison to the HES consent model, and were mindful that in most situation patients would actively opt in to receiving private care and therefore there were opportunities for consent.

Members discussed whether the application met the transparency requirements of the first principle of the Data Protection Act 1998. It was noted that no patient information or other activities to raise patient awareness had been specified within the application. Members advised that as a minimum, information should be provided on healthcare provider websites in relation to the uses of personal data. In line with this, Members also advised that where dissent was expressed as a result of a patient's awareness of the proposed activity, this should be respected. Members raised concerns that no patient involvement had been specified and advised that this consultation with patients should take place if the activity was to be repeated following the pilot. This would give patients an opportunity to comment on the uses of their data and also raise awareness of the processing.

Members indicated that they were supportive of the application in principle but were unable to provide a final outcome until legal advice had been received. In order to inform the final recommendation, Members requested clarification on the period for which HES data would be disclosed and whether the applicant had considered providing dates of treatment to ensure that only the minimum amount of identifiable data necessary would be disclosed; further information regarding the proposed uses of the linked dataset and which organisations this would be disclosed to; further information regarding how onward disclosure and analysis would be managed and how it would be ensured that the dataset was anonymous in different contexts; and what reasonable efforts would be made to inform data subjects of the purposes of data processing.

5c. Department for Work and Pensions – National Treatment Agency Data Transfer [ECC 6-05 (c)/2012]

This application detailed the linkage of Department of Work and Pensions (DWP), HM Revenue and Customs (HMRC) and National Treatment Agency (NTA) data. This linkage would enable analysis of the effect that drug use has on employment, understanding of the role that employment plays in the recovery journey and would help build a cost benefit case for further investment in employment support for this group. Access to confidential patient information was requested to allow National Drug Treatment Monitoring System (NDTMS) data to be transferred to DWP with an identifiable unique reference attached (ORCID) which would allow the data to be linked to specified HMRC and DWP data in relation to employment, tax credits and benefit claims. As the ORCID is a reference number assigned by the DWP, it would be possible for re-identification to occur using other datasets held by DWP.

Members noted that in order for an application to receive support under the Regulations it is necessary to demonstrate that the processing has a medical purpose. Members discussed the purposes of this application in detail and concerns were raised that the medical purpose was not sufficiently defined. It was noted that the application aimed to assess whether employment was a key factor in the recovery journey. However, views were raised that it was clear that employment would be a relevant factor and Members requested further details regarding what additional medical benefit this linkage would bring. Members agreed that they would consider the purposes of the linkage to be socioeconomic, with the intention to influence DWP policy, rather than clearly falling within the definition of medical purpose. Members advised that as a clear health benefit, which would support public interest considerations, could not be identified, they would be unable to recommend support under the Regulations. Members were also particularly mindful of the fair processing requirements of the first principle of the Data Protection Act. It was noted that consent forms would not be updated to include details of this additional data linkage prospectively, due to concerns that patients would not consent to their data being included

within the NDTMS if the NTA could not commit to sharing only anonymised data with other government departments. However, Members were mindful that the fair processing requirement of the DPA directs that all processing of personal data should be as transparent as practicable and there was a clear opportunity to inform patients in this instance. Members noted the examples quoted that people objected to having their data stored on the NDTMS in the past when these commitments were not made. However, it was agreed that as support could not be provided where the requirements of the DPA were not met, patient information would need to be updated in the future in order to ensure DPA compliance and fair processing.

The applicant made reference to advice from the Information Commissioner's Office (ICO) in relation to informing patients retrospectively that the NTA would become part of Public Health England (PHE) in future and therefore NDTMS would be processed by civil servants and a government department. (This change had received provisional approval under the Regulations, ECC 5-05(e)/2012) It was suggested that this advice would also apply in the current situation. However, Members highlighted that although the NTA would become part of government in future, there would be no changes to the specified purposes of processing. In the current application, the purposes of the data processing would differ from that outlined in the patient information sheet and therefore Members were of the view that more significant efforts to inform patients should be carried out. Members discussed that as sensitive personal data was to be processed the first principle of the DPA required not only a schedule 2 condition to be met but also a schedule 3 condition. Members queried which schedule 3 condition would apply in this instance, taking into consideration comments above in relation to the medical purposes of processing. Mr David Evans advised that the applicant carry out a privacy impact assessment and consult with the ICO in relation to meeting the requirements of the DPA. Members noted the example highlighted within the query responses that where data had been shared with criminal justice agencies there had been a reduction in the number of individuals seeking treatment. Members raised concerns that sharing identifiable data with other government departments would result in some patients losing trust in NHS services and that this would appear to contravene public interest as people would not seek treatment or allow their data to be submitted for the primary purposes of the NDTMS.

Members discussed whether it would be possible to link datasets without requiring identifiable data to be disclosed. In particular it was suggested that the ORCID could be added to each dataset and an algorithm could be applied to the ORCID which would allow this to be pseudonymised in a replicable way for each. This could then be linked by a third party. This would mean that no identifiable data would need to be disclosed from any party. If an algorithm could be applied which was irreversible, linkage could be undertaken by one of the existing data controllers as it would then not be possible to re-identify the ORCID. Members highlighted that if either of these alternatives were utilised controls would need to be in place to ensure that the dataset could not be re-identified using any datasets already in the data controller's possession. Members noted the key outcomes stated within the application and queried whether these were research questions, in which case any application for support would also require an opinion from a Research Ethics Committee. The applicant was therefore advised to consult with National Research Ethics Service if a resubmission was made to determine whether an application should be made to a REC. Members agreed that they could not recommend support at this time and the applicant was advised to carry out a privacy impact assessment and consultation with the ICO to ensure DPA compliance, explore practicable alternatives as set out above, and provide adequate justification for the claim that the processing would fulfil a 'medical purpose' before resubmitting the application.

5d. Vascular Governance North West Database [ECC 6-05 (d)/2012]

This application from University of South Manchester NHS Foundation Trust (UHSM) detailed linking HES and mortality data to the existing Vascular Governance North West (VGNW) database. The data collected would include information regarding patients undergoing carotid endarterectomy or abdominal aortic aneurysm repair in the North West of the UK. The database would be anonymised and disclosed for research purposes. Data would be collected from hospital records, HES and DBS at a trust level. Access to name, NHS number, hospital ID, date of birth and postcode would be required in order to carry out DBS mortality checks within the trust and link to HES readmission data.

Members agreed that the database aims were important and were broadly supportive of the application. Members noted that the legal entity responsible for storage of the data, the University Hospital of South Manchester NHS Foundation Trust, and the name of the applicant, who came from the University of Manchester, were contradictory and requested clarifications regarding who the applying organisation was and who would have access to the data. Members noted that the data had been collected since 2000 and approximately 11,000 patients were included. It was noted that retrospective consent for additional data linkages would be particularly difficult to obtain as many were likely to have died. Members noted that the applicant was working towards formalising the existing dataset and preserving it for research use, which they were supportive of.

However, Members discussed that the legal basis for the disclosure of data to VGNW, prior to consent being obtained from 2010, was not clear and requested further clarification. Members noted that consent would be obtained verbally on a prospective basis. Members advised that in order to ensure the consent was adequate to allow linkage to HES data; the applicant should consult the Health and Social Care Information Centre (HSCIC). Members recognised that it would not be practicable to take consent prior to a procedure, but advised that this should take place as soon as possible following the procedure and there should be a method in place in order to record that consent had been obtained by a health professional. For those patients who died or lacked capacity following the procedure, Members agreed that support could be recommended to allow their data to be included on the VGNW. Members considered the extent of identifiable data requested and queried how it would be ensured that the minimum amount of identifiable information required would be retained for each patient, including whether it would be possible to destroy identifiable data once it was confirmed that a patient had died. Members noted that data would be made available for research purposes and requested further information regarding the controls in place to ensure that disclosed data would be fully anonymised and used for specified purposes.

Members agreed that the minimum requirements of the Regulations appeared to have been met and agreed to provide a recommendation of support for this activity to collect data from HES regarding hospital readmissions and DBS in relation to the retrospective cohort and to collect data from hospital records, HES and DBS in relation to those who die or lack capacity to consent prospectively. This recommendation was subject to clarification of the identity of the data controller and any parties with access to the data for the purpose of maintaining the dataset; further information in relation to the legal basis for the retrospective data collection; and confirmation of which data items would be made available for research purposes and the disclosure protocols in place.

5e. Case-control evaluation of NHS Breast Screening Programme [ECC 6-05 (e)/2012

This research application from Queen Mary University of London (QMUL) detailed a case control study to evaluate the impact of the National Breast Screening Programme. The study would incorporate four case control comparisons: breast cancer deaths with living controls to assess impact on mortality; all breast cancer cases with disease-free controls to assess the effect on breast cancer incidence; late stage breast cancer cases with controls to assess the effect on incidence of late stage disease; and breast cancer deaths with surviving breast cancer cases to assess the interplay of early detection, tumour attributes and treatment on mortality from breast cancer. Support was requested to allow disclosure of MRIS and cancer registry data to Connecting for Health. Connecting for Health would then link MRIS, cancer registry and NHAIS screening data and identify controls. A linked dataset including NHS number, date of birth and date of death would be transferred to QMUL for analysis purposes.

Members agreed that this was an important subject and that the results of the study would be of particular public benefit. Members noted that whilst consent from such a large retrospective cohort would not be feasible, efforts should be made to inform patients of the purposes of processing. It was recognised that it would be difficult to reach all patients, however at the very minimum the study should be detailed on relevant websites with details of how to opt out. Members advised that carrying out further patient involvement, such as arranging focus groups, would also help to inform the patient population and recommended exploring this option if ongoing evaluations were planned. If patients contacted the University to record dissent as a result of this, it was advised that this should be respected and the patient's data should be removed from the study. Members noted that the protocol specified that

a general population cohort would be required for control group f and requested confirmation of the source of this information. Members agreed that the minimum requirements of the Regulations appeared to have been met and agreed to provide a recommendation of approval for this activity, subject to clarification of the information that would be used to identify control group f and confirmation that patient dissent would be respected.

5f. Confidential Enquiry into Major Burns in Children [ECC 6-05 (f)/2012]

This research application from the University of Leicester detailed an enquiry to determine the national incidence of severe burns in children aged between 0 and 16 years. Patients who were admitted to hospital with burns covering 40% of body surface area or who died following burns injury would be included. The process would be used to describe and compare aspects of care provided and identify avoidable factors/lessons by multidisciplinary panel review of individual cases. Support was requested to allow access to data including name, date of birth and postcode to allow researchers to identify eligible patients and ensure all relevant records were included within the review. Medical notes would be anonymised prior to submission to the research team.

Members agreed that the application detailed an important study which would have significant benefits to patients. Members discussed that there was an extremely low incidence of cases and for this reason it might appear that consent would be feasible. Members noted the assertion that consent could not be obtained as informing parents might cause concern that a sub-standard level of care had been received. Members highlighted that they did not agree with this particular assertion. However, it was agreed that because numbers were so low it was particularly important to ensure that all cases were included within the study and for this reason Members agreed that asking for individual consent would not be practicable. As consent was not considered to be feasible, Members discussed whether there were opportunities to inform the cohort that data collection was taking place and allow patients (or their guardians) to dissent. Observations were made that there might be, in some circumstances, particular individuals who would wish to request that a patient's details were not shared due to the circumstances which had resulted in the child being admitted to hospital, such as non-accidental injury. For this reason it was agreed that, whilst reasonable efforts should be made to inform individuals of the uses of their data, including displaying posters and publishing information on relevant websites), individuals would need to establish a substantial damage or distress argument if they wished to request that their child's data was not included in the study. This was in line with the requirements of the Data Protection Act 1998.

The REC favourable opinion letter was reviewed by Members. This stated that the REC had asked who would be looking at identifiable data and that the applicant had confirmed that only those working in the units who routinely had access would be looking at identifiable data. Members noted that the Office had requested further clarification in relation to this point as it appeared to contradict the application that had been submitted to the ECC. It was confirmed that this statement was incorrect and identifiers would be required to ensure that all case notes had been collected. Members advised that the applicant should contact the REC to ensure that the opinion was still valid given this change. Members agreed that the minimum requirements of the Regulations appeared to have been met and agreed to recommend approval for this activity.

5g. Development and validation of prognostic models for IVF treatment [ECC 6-05 (g)/2012]

It has been agreed that the HFEA would delegate the handling and assessment of all relevant applications to access their research register under the Human Fertilisation and Embryology (HFE) Act 1990 to the NIGB Ethics and Confidentiality Committee (ECC) until March 31st 2013. Under this delegated authority, the ECC would consider and recommend to the HFEA whether to grant or refuse permission to use identifiable register information (or to impose conditions upon its use). As data controller of the Register, the HFEA would take a final decision on access to the register based upon this recommendation, and then if disclosure was permitted would work with the applicant to enable use of the appropriate dataset. In terms of disclosure of patient information not contained in the HFEA register, for example the linking of register data to other data sources in England and Wales (and Scotland and

Northern Ireland until March 31st 2013) the ECC would provide a recommendation to the Secretary of State for Health on whether those aspects should be approved.

This application from the University of Aberdeen detailed a study which aimed to develop a clinical prediction model that could estimate the probability of pregnancy and delivery in a woman with different causes of infertility commencing IVF treatments. The model would be created using the HFEA dataset and attempt to determine how many cycles of treatment would be optimal for a woman given her age, duration of sub fertility and other clinical characteristics. The application detailed accessing HFEA data for women who had had IVF treatment between 1992 and 2011. HFEA staff would identify multiple IVF cycles before disclosure to the applicant. The intent would be to extract a dataset including baby date of birth from the Register and there was no stated intention to link to any further data sources. Baby date of birth would be kept for a minimal amount of time whilst time intervals were calculated; following this the data item would be destroyed.

Members considered this to be a straightforward application and that thorough justification had been provided for access to the specified data. It was also recognised that consent would not generally be feasible and that the applicant would respect dissent recorded post September 2009. Members noted that the applicant had specified plans to liaise with a patient advisory group through Infertility UK and requested that the results of this were reported to the NIGB office. The Committee provided a recommendation in relation to accessing the research register; as there would be no other disclosures the application would not require a recommendation of support under the Health Service (Control of Patient Information) Regulations 2002.

The Committee agreed to advise the HFEA that permission to access the research register for the stated medical purposes should be granted for those patients whose details were collected prior to 30 September 2009, noting that the Committee could not advise on any data subjects whose details had been included on the Register after this date as the assumption was that these would have provided consent for their details to be included within the Register and the ensuing research requests. Members also emphasised that any dissent recorded post-30 September 2009 should be respected and access not granted for the purposes of this application, and requested that the results of liaison with a patient advisory group through Infertility UK should be reported to the NIGB office. The Committee's recommendation was subject to the restrictions on disclosure as set out in Regulation 3 and 4 of the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010. It was noted that as the applicant was not seeking to link research register data to any other data sources, for the purposes of this recommendation there had not been a review of the security aspects.

5h. Can improved oral hygiene improve pulmonary health in children with Cystic Fibrosis? [ECC 6-05 (h)/2012]

This research application from the University of Southampton detailed an observational pilot study which aimed to detect whether there was a difference in 10 year outcomes in pulmonary health between patients with good oral hygiene versus those with poor oral hygiene. The project would include all subjects enrolled in a previous study which was undertaken in 2001. Medical records would be accessed at the Royal Brompton Hospital under the supervision of Professor Andrew Bush, who was a member of the original care team for patients in 2001. Support was requested to allow a student to carry out a review of patient records (approximately 181 patients) at the Royal Brompton Hospital. Members agreed that they were supportive of the overall aims of the study.

Members noted that consent had previously been obtained for a similar study in 2001; however there were no records of what level of access to confidential patient information had been included and for what purposes. Members concluded that they would have to disregard the previous consent as it was unclear whether this would have included researcher access for the current purposes. With this in mind, Members discussed whether it would be feasible to obtain consent from some of the cohort, in particular those who were still in treatment, via the local clinical care team. Members agreed that support should be provided for those patients who were dead or lost to follow up, but that those who were still being treated at the Royal Brompton Hospital should be asked for their consent. Consent should be taken by the local clinical care team prior to disclosure of information to a researcher. It was noted that the study

had not yet obtained a favourable REC opinion as further information had been requested in relation to the consent provided for the original study. In addition, it was noted that the REC outcome letter suggested that consent would need to be sought in order to allow a student to access medical records. Members reiterated that in their considerations they had disregarded the previous study and agreed that consent should be obtained for those still in treatment. However, the Committee clarified that for those who had died or no longer in treatment, support under the Regulations could provide a legal basis to access medical records without patient consent. Members agreed that the minimum requirements of the Regulations appeared to have been met for part of the activity and agreed to provide a recommendation of approval for access to data in relation to those patients who had died or were no longer in treatment at the Royal Brompton Hospital. This was subject to confirmation that the applicant would extract and retain only month and year of birth and age at death for analysis purposes, and confirmation of support from the Caldicott Guardian at the Royal Brompton Hospital for access to patient records for the specified purposes. The recommendation excluded patients still in treatment at the Royal Brompton Hospital on the basis that consent should be obtained from these patients via the clinical care team prior to the disclosure of data to a researcher.

6. Any other business

6a. Amendment for ECC 4-03(c)/2012 - Child Health Reviews-UK – notification process for living patients

This child health component of the Confidential Enquiries work programme application (previously managed by CMACE) was originally reviewed in July 2012 and approved. It set out the aim to improve service provision and quality of clinical care through learning from adverse outcomes. This was achieved through case note review of mortality and morbidity in children and young people (ages 1-18) with epilepsy who received intensive or high dependency care following a prolonged seizure, or who had died of any cause throughout the care pathway. Support had been provided to enable the accurate identification of eligible cases, avoid duplicate reporting and to enable the collection of clinical information and case note assessments. It involved some changes to the typical Confidential Enquiry methodology however the high public interest and strength of the protocol had persuaded the Committee that the changes were justifiable. This amendment was originally reviewed outside the formal Committee meeting schedule; however, one of the aspects (amendment 2) constituted a significant deviation from the Confidential Enquiries methodology and as such, required subsequent consideration by the full Committee. In reviewing the detail of the amendment and subsequent clarifications, Members approached the amendment in two parts.

The Committee were informed that HQIP had requested that the RCPCH broaden the notification methodology to include groups such as nurses and Child Death Overview Panel (CDOP) managers, in order to try and increase the likelihood of RCPCH hearing of a case. The rationale for the amendment as stated was that the second group would not have the required knowledge to fill out the clinical questionnaire and so the main focus of the process would be to ask them to forward a link to the relevant paediatrician as a means of 'triangulation'; the intent was to avoid asking secondary notifiers to send links to the primary notifiers to prevent the paediatricians being overloaded with email links and disengaging with the primary notification process; there would be a need to monitor take-up of this process through matching responses to notifications obtained from primary notifiers, through collecting date of incident (admission/death depending on the case), location (first part of postcode), age of child and gender of child. This would enable the RCPCH to keep track of the cases which they did not believe had been notified by paediatricians, as RCPCH might be able to follow them up via a nurse/CDOP manager (secondary notifier). In terms of the line of secondary notification by specialist epilepsy nurses/CDOP managers, Members agreed that as this related to children who were deceased there were no substantive issues over this aspect as it was in line with the Confidential Enquiries purpose, and it was agreed that it was reasonable to try to increase ascertainment as the issue was an important one. The data items were also considered to be suitable. It was concluded that the Committee would recommend support to the Secretary of State for Health for this amendment. Members however queried who would explicitly be covered within this secondary notification process, for example, whether these would be an identified group of specialist nurses. The Committee required clarification on the group for which they would be recommending support to disclose what the Committee effectively considered to be

identifiable data. The response to this clarification request was that the main aim of this secondary notification process is to provide a less formal mechanism by which people can notify RCPCH of a case, aiming to open up notifications as widely as possible through improving effectiveness of the process by following up any notifications not reported by a paediatrician, raising awareness amongst CDOP managers and epilepsy specialist nurses. The applicant indicated that to broaden the notification the plan is to make information available on the website, enabling anyone to notify RCPCH of a case, provided they were able to contact the paediatrician overseeing the case. It was expected that there might be notifications from third sector organisations. The intent was to collect a minimal dataset to enable correlation with a secondary notification where it did not match any paediatrician-notified cases. RCPCH indicated that in these situations they would make attempts to ask the notifier to contact the paediatrician overseeing the case

Members agreed that while the dataset was a minimal one to enable appropriate follow-up, it was considered that month of incident (admission), location (district), age of child in years and gender were identifiers when linked to the rare event of admission to critical care. They also noted that the proposed notification process in relation to the living was a significant deviation from the typical Confidential Enquiries methodology. Members had sought clarification on who would be able to provide notifications for this secondary process, and the response indicated that it could potentially be any person. This broad and unspecified nature was considered to pose a number of challenges for the applicant in seeking a recommendation of support under the Health Service (Control of Patient Information) Regulations 2002. Members were clear that they can currently only advise on NHS-generated patient information. In opening up the secondary notification process to technically anyone, there was a significant possibility that the notifier source could be non-NHS and therefore the subsequent processing of this initial information by RCPCH (through following the approved methodology) would fall outside the scope of the existing approval; therefore requiring another legal basis to be found to legitimately process this data from these data sources. Members also highlighted that, as the amendment relates to living persons, the weighting of considerations of the common law duty of confidentiality differ from those relating to deceased patients.

It was highlighted that due care should be taken to ensure appropriate fair processing information would be provided along with compliance with the first principle of the Data Protection Act 1998. Members commented that as the nature of the person was unknown, it was unclear how the RCPCH could be assured that they were legitimately receiving information where, for example, the actual patient was unaware that the notifier had provided information on them via this web notification process. This would mean that without suitable steps being taken there would be a strong risk that the activity, regardless of whether support under the Regulations was in place or not, would not be compliant with the provisions of the Data Protection Act 1998. Members queried the rationale behind this change, and while appreciating the aim was to broaden notifications, queried what evidence was in place to support this requested change. Members sought clarification and evidence on why the current system in place was not achieving the desired levels of ascertainment, why this was a significant issue, how this data gap had arisen and whether this was the only method to close this gap. Members concluded that while they would be open to receiving more detailed evidence on the rationale behind the change for the amendment, strong views were expressed that the unrestrained nature of the notification process would pose challenges for legitimately being able to bring this subsequent processing of this information under any potential approval as specified above. Based upon these comments, Members agreed that they would be unable to provide a recommendation of support to the Secretary of State for Health at this time in relation to living patients, although they agreed that they would reconsider this advice in light of any submitted evidence in line with the points above.

6b. ECC 6-02(FT16)/2012 Care Quality Commission 2013 Maternity Survey – access to data relating to patients under the age of 18

This application from the Care Quality Commission (CQC) had initially been considered under the proportionate review methodology (*see page 10*) and support had been recommended with respect to patients aged 18 and over, but not for patients aged 16-17 due to concerns that this patient group would be more vulnerable than others. The CQC had appealed against this exclusion, particularly as this age group was seen as hard to reach, and so the application was considered by the full Committee.

Members felt that the proposed questionnaire might be inappropriately long and complex, particularly for what was likely to be a target group with below average literacy, and suggested literacy issues might be a factor in this group historically being difficult to reach. It was noted that a REC opinion was awaited, and suggested that potential distress to the target group as a result of the questionnaire would not be in the public interest. Members agreed the application showed good Data Protection Act compliance. A sub group of Members comprising Dr Tony Calland, Dr Robert Carr, Mr Colin Harper and Professor Julia Hippisley-Cox was delegated to hold a discussion with the CQC to explore alternative options.

6c. ECC Deputy Chair

Following an internal call for nominations and support for nominees, the Committee unanimously ratified Tricia Cresswell's appointment as Deputy Chair.

6d. Chairing arrangements for proportionate review applications

The Committee agreed that, in order to alleviate the workload of the Chair and Deputy Chair up to 31 March 2013 due to the forthcoming transition to the HRA, Dr Patrick Coyle would act as Chair for consideration of proportionate review applications during this period.

Meeting ended.