Ethics and Confidentiality Committee (ECC) Meeting – Wednesday 28 March 2012

Members:

Dr Andrew Harris (Chair), Dr Mark Taylor, Dr Tony Calland, Dr Tricia Cresswell, Ms Alison Emslie, Mr Stephen Hinde (*items 1 and 2c-7)*, Professor Julia Hippisley-Cox, Dr Jane Kaye, Ms Gillian Wells, Mr Chris Wiltsher and Mr Terence Wiseman.

In attendance:

Mr Rick Borges (*Deputy Operations Manager*), Dr Alan Doyle *(NIGB Director),* Ms Natasha Dunkley *(Approvals Manager),* Ms Claire Edgeworth *(Deputy Approvals Manager),* Mr Cole Erdmann (*Program Manager, Cerner Ltd*, *item 2a*), Ms Helen Forbes (*Clinical Information Manager*, item 2b), Mr Martin Frowd (*Senior Business Support Officer*), Mr Mathew Fry (*Operations Manager*, *items 4c-5*), Mr David Knight (*Department of Health*) and Professor Matthew Swindells (*Senior Vice President and Managing Director, Cerner Ltd*, *item 2a*).

1. Welcome and apologies

Apologies were received from Mrs Pauline Brown, Dr Robert Carr, Dr Fiona Douglas and Mr Colin Harper.

The Chair advised Members that Professor Michael Catchpole had resigned from the Committee in order to take up a seat on the Information Governance Review being chaired by Fiona Caldicott, NIGB Chair, due to a conflict of interest. Following discussion with the Department of Health sponsor, it had been agreed to co-opt Dr Patrick Coyle, who had recently retired from the Committee, back as a Member. The Chair regretted that Members had not had an opportunity to bid farewell to Professor Catchpole, due to timing.

It was noted that the order of the meeting had changed from the usual format due to the presence of external attendees and to ensure that sufficient time was allocated to application review.

Declarations of Interest

The following interests were declared:

a) Mr Stephen Hinde declared an interest in item 2a on the grounds that Cerner were a competitor of BUPA's American subsidiary, and left the room for the duration of the discussion of this item.

b) Mr Terence Wiseman declared that he had recently accepted hospitality from the Royal College of Paediatrics and Child Health, the applicant for item 3c, and remained present but did not take part in discussion of this item.

2. New applications

2a. ECC 2-02(a)/2012 Cerner Health Facts

This was an application for the establishment of an 'honest broker' service from Cerner Ltd. Support was requested to enable participating Trusts to submit all electronic health records consisting of patient identifiable and clinical data to Cerner, who would then process the information to render it unidentifiable. This de-identified dataset would be made available to support retrospective observational research and other research activities. A recommendation of support was requested as the activity would involve the transfer of confidential patient information without patient consent, in advance of patients being informed of this specific data processing activity.

Professor Matthew Swindells and Mr Cole Erdmann attended to provide contextual background and to respond to arising queries. The current role of Cerner was discussed; how they currently work with Trusts and the legal basis for this; the extent of patient involvement with the current application, the developing new role of the Health and Social Care Information Centre, the extent of data items requested and arrangements for the provision of fair processing materials.

Members noted that Cerner currently work with a number of trusts to deliver a service so as to support direct care provision. The scope of this application meant that identifiable and clinical data would be used to support retrospective observational research and other similar activities. As these are classed as secondary uses of data (as the intention would be to use the data for a purpose different to that from which it was originally collected), a legal gateway was sought so as to provide statutory protection to those submitting data to Cerner so these data controllers would not breach the common law duty of confidentiality. It was noted that while interest in this potential service had been expressed by specific Trusts, these would not be definitively confirmed until all relevant approvals had been obtained.

It was indicated that the Committee advises the Secretary of State for Health on whether thresholds have been achieved within the framework of the Health Service (Control of Patient Information) Regulations 2002 (the 'Regulations'). In particular, the discussion highlighted the question whether the scope of the application was too broad to legitimately fit within the framework of these Regulations.

The application sought approval for an honest broker service to receive identifiable data so as to enable the appropriate de-identification of information and to supply datasets to third parties. It was noted that protocolised research studies were not available to which the service could potentially deliver against, and that the potential uses the service could offer and deliver were broadly phrased, and that they had not been confirmed. The Committee had previously provided a recommendation of support to the Research Capability Programme (RCP, [ECC 7-04 (a)/2010]) in its testing of its capabilities to deliver an honest broker service, however the Cerner application was distinguished from that activity as the RCP had sought approval in relation to specific protocolised research studies. This had enabled a review of specific purposes, proportionality of access to identifiable data items and public interest considerations.

In discussing this application, members raised the following key points which guided their review and advice. Ultimately, it was concluded that the current lack of specificity of the proposed outputs and research activities to which information would be supplied meant that the Committee was unable to carry out a typical review of the extent of public interest, feasibility of consent, practicable alternatives and proportionality of the proposed disclosure to Cerner.

1. Purpose

The application cited activities that the service could deliver against, but these were not confirmed and were generic in nature. Terminology varied throughout the application therefore members noted they would need to see consistency in terms of describing the scope. Some purposes appeared aspirational so members agreed they would need to see clearer boundaries on what the service could and could not deliver against, along with clear criteria governing this aspect. Without this level of granularity, the Committee were unable to review whether the proposed breach of confidentiality would be commensurate with the overarching purpose and aims of the activity.

2. Proportionality

Members were clear that in order to advise whether the proposed breach of confidentiality would represent a proportionate interference with patient privacy would require the purposes to be closely defined. As the activity involved uploading Trust-wide entire patient health records to Cerner, the extensive nature of the data transfer would require detailed scrutiny to advise on this proportionality aspect. Noting the large volume of data transfer, members queried whether the system was sophisticated enough to extract specific data items necessary to deliver against a particular research activity, rather than all patient records. The system would also need to exclude particularly sensitive clinical items related to sexual and mental health. The attendees indicated that the data controllers

submitting the data would take the decision as to whether they would share the entire patient health record, or provide a subset; however, members agreed some further exploration of this aspect would be helpful.

3. Public interest

Members discussed the general public interest in this activity taking place and concluded that further information would be required to evidence this specific aspect. In particular, the Committee had previously indicated at the December meeting that meaningful patient involvement would be essential to aid consideration of the public interest. It was noted the intention was to contact INVOLVE, and the Committee therefore requested that the resubmission should provide details of patient views on the proposed breach of confidentiality as this would aid significantly in any further Committee consideration.

4. Practicability

Members noted that the data specification document appeared to reflect clinical data items generated within the United States, and was not specific to clinical records generated within the UK. Members highlighted that not all records are held electronically, therefore some of the items could not be transferred to Cerner. Members therefore requested clarification on the specific data items that could realistically be obtained from current hospital systems, and indicated that the data specification document should be revised to reflect current UK systems. Members also queried whether it would be feasible to pseudonymise at data source and discussed potential options for this aspect.

5. Fair processing

Members considered it highly important that if Cerner were to resubmit any application, that there must be clear evidence on how compliance with the fair processing aspect of the Data Protection Act 1998 would be achieved. It was noted that such issues would need to be handled at a local level, however, the Committee were clear that Cerner must ensure they are legitimately receiving data, and therefore had a role to play in ensuring this was carried out. Members also advised that fair processing information about the transfer of information to Cerner should be disseminated to the relevant local patient population in advance of such transfer, and evidence of this should be included in the resubmission, in order to comply with the provisions of the Data Protection Act 1998.

It was noted that while the Health and Social Care Information Centre would have an honest broker function via the new Bill, it was seen as a NHS body. For a commercial entity to carry out such an activity would be likely to be publicly sensitive, and therefore the importance of effective patient consultation would be required in order to develop credibility with the public because of a possible negative perception of such bodies. As a point of principle, the Committee agreed that any similar activities must ensure there has been an effective consultation with patients and evidence of such consultation presented. Members noted that the issue of commercial bodies becoming honest brokers would be a policy issue that would lie more appropriately with the Department of Health.

In line with the comments above, the Committee agreed that the application as currently phrased extended beyond the remit of the Regulations, and therefore the Committee could not advise support to the Secretary of State. The Committee also sought advice from Department of Health officials outside of the meeting on the issue of honest brokers, and it was confirmed that the current framing of the Regulations was not suitable for a robust consideration to take place for this type of broad activity. The chair also indicated that the policy around establishment of potential future honest broker services fell outside the remit of the Committee, and it would be for the Department of Health to take the policy lead on this aspect.

Notwithstanding the issues above, the Committee viewed the application positively and confirmed they would welcome an appropriately framed application within the current framework if the applicant wished to pursue this option. In line with this, the Committee offered the following advice.

It was noted that the intention was to carry out a pilot phase of this activity, in order to test consent, technical arrangements to deliver and information provision. The Committee advised that in order to clearly fit within the Regulations, the application should be significantly refined to reflect this pilot nature; this could be achieved through identifying defined specific research projects against which Health Facts intended to deliver, identifiable data items required for each protocol, and the specific Trusts that would be involved. As numbers involved were likely to be smaller, the Committee advised that the application should be explicit on how consent would be tested. Members also advised that certain aspects of the application fell outside the remit of the Regulations; and in particular, members emphasised that the service should be one that the public are aware of and have confidence in. Members highlighted that the service should be independent with no conflicts of interest, clear accountability and reporting. Members also discussed the possibility of Cerner having more of a data processor role, separating out the more commercial aspects, and running the service with a strong lead from academic clinicians as this could improve public confidence.

Further discussions indicated that the Health and Social Care Information Centre (HSCIC) would receive a statutory role as an honest broker from April 2013. The data requested by Cerner was identified not to be collected by the HSCIC, and it was noted that Cerner had been in discussion with the HSCIC regarding their application. Members suggested exploring the viability of working in partnership with the HSCIC as there could be potential to develop a national system within the current regulatory framework where Cerner Health Facts could be appropriately embedded.

The Committee concluded that it was supportive of the principles of this activity, and that it would welcome a refined application to enable the Committee to provide a recommendation to the Secretary of State under the Regulations.

2b. ECC 2-02(b)/2012 NATCANSAT NWSHA Data Warehouse

This application from the Clatterbridge Cancer Centre NHS Foundation Trust detailed an extension to an existing application (PIAG 1-05(d)/2006 Analysis of attendances at hospital, GP surgeries and emergency ambulance journeys in the NWSHA). Cancer registry data was requested for the purposes of evaluating an advertising campaign within the NWSHA, "*Don't be a Cancer Chancer*". In addition it was proposed that confidential patient information would be used to create a pseudonymised data warehouse in order to provide data for analysis for future projects. In order to ensure that the database could be added to where necessary it was proposed that NHS number, date of birth and postcode would be retained separately with a pseudonymous link to clinical data. This application had originally been processed as an amendment, however, it was subsequently referred to the meeting as it was noted that due to the scope it was essentially a new application.

Members welcomed the opportunity to discuss the application with Helen Forbes, Clinical Information Manager within the National Cancer Services Analysis Team (NATCANSAT). Initial discussion focused on the request for cancer registration data. Members agreed that access to confidential patient information should be limited to as few organisations as possible. In line with this they highlighted an email that had been received from Chris Carrigan, Head of Coordinating Team at the National Cancer Intelligence Network, which detailed that the linkage activity could potentially be carried out with the North West Cancer Registry by the end of 2012 due to a number of changes in the way that cancer registries collected data. The applicant explained that publication delays in the current systems used by the cancer registries meant that cancer registration data was only available up to the end of 2009 through the North West Cancer Registry. In addition the cancer registries currently did not collect GP data and therefore could not provide all data that was required for this project. Members noted the assertion that currently the cancer registries could not provide the linkages required for the "*Don't be a Cancer Chancer*" and as there was no practicable alternative, agreed that the minimum threshold of the Regulations had been met for this aspect of the application. It was noted that alternatives to NATCANSAT undertaking linkages might be available in future due to the development of the ENCORE system within the cancer registries. It was also noted that GP data might be available through the Health and Social Care Information Centre in the future. Members therefore reiterated that when it became

feasible for the cancer registries to undertake the linkages on the applicant's behalf, this should be utilised as soon as possible.

The proposal to create a pseudonymised data warehouse was discussed. Members agreed that they considered the activities outlined within the application were of clear public benefit. However, Members requested further information in relation to the scope of what was included within the data warehouse and how the data was collected. In particular, clarity was requested over the inclusion of GP data.

Members raised additional concerns that fair processing information was currently not provided within GP practices and provisions to allow patients to opt out of the use of their data for these purposes did not seem to be established. Members requested that the applicant make efforts to ensure that patient information leaflets were disseminated where possible. It was noted that this would be possible within participating GP surgeries. Further details of how the applicant would comply with the first principle of the Data Protection Act 1998 should be forwarded to the Committee. It was confirmed that data relating to patients with particular symptom codes were extracted from a specific group of GP surgeries. This was done automatically via the EMIS systems with the GP practices' consent, linked using NHS number only and no free text information was extracted. Members requested further information detailing how patients could register dissent and confirmation that this would be respected, in order to comply with the sixth principle of the DPA which requires data to be processed in line with the rights of the data subject.

The level of identifiable data requested and retained was discussed. Members were pleased to note that linkages took place using NHS number alone. In particular, Members discussed whether data items such as postcode and date of birth could be removed once appropriate derivations had been made and how often the requirement to retain data items was reviewed. It was confirmed that NHS number alone was adequate for linkage purposes as the work that was undertaken using the data meant that the rare outlier would not adversely affect analysis of the data. The applicant confirmed that data was currently retained in the warehouse until it was no longer of use. In relation to the retention of potentially identifiable data within the warehouse, it was noted that some projects required grid references and Members raised concerns that these referred to a small area and could be used as a potential identifier. Members agreed that further information should be provided in relation to those studies which required grid reference to be retained.

Members raised queries regarding the pseudonymisation techniques used, particularly whether the applicant had explored pseudonymising data at source, and queried the governance arrangements for the identifiable data. It was confirmed that currently NATCANSAT retained identifiable data in a separate archived linkage table which was not accessed unless updates to the data warehouse were required. Members highlighted that requesting a third party hold the linkage table would provide an additional level of security. However the applicant raised concerns that updates were run regularly and that it would add delays and complexities to request that the linkage table was held by another organisation.

Members noted that the purposes of the original application had been extended considerably and queried how this would be controlled in future. The applicant explained that there would be rigid controls in place to determine what would be included within the data warehouse. Any significant changes, for example to add identifiable data, would be subject to an application to the Committee. Access to anonymised data would be restricted to NHS organisations only and any requests from outside the NHS would be referred to the Committee in the first instance. The applicant agreed that guidelines should be established to ensure that data collection did not extend outside the purposes specified within the application. Patient involvement was discussed and Members suggested that the applicant could further improve patient engagement by contacting HealthWatch England, which would be launched in October 2012, and also by joining local patient meetings to discuss issues of confidentiality in relation to the proposed data warehouse. The applicant explained that they had experienced difficulties engaging patients in relation to issues of patient confidentiality and the data warehouse and committed to exploring these suggestions.

Members sought confirmation of the hosting arrangements of NATCANSAT within Clatterbridge Centre for Oncology NHS Trust and queried what arrangements would be in place to host NATCANSAT once the changes in the Health and Social Care Bill came into effect in 2013. It was confirmed that NATCANSAT was hosted by the Trust and therefore they would be accountable for the uses of the data. The applicant recognised that suitable arrangements would need to be in place to ensure the continued hosting of both the national and local datasets that were collected by NATCANSAT.
Members raised concerns over the proposed data warehouse and agreed that the processes outlined seemed person specific. Members advised that suitable processes to monitor disclosures and inclusions into the data warehouse should be established as soon as possible. This would ensure that the process was consistent in the event of staffing changes.

It was noted that NATCANSAT collected data on behalf of cancer registries and also for specific projects on behalf of the North West SHA. Members advised that the respective datasets should be kept separately and governance arrangements should be implemented to ensure this. Members advised that retention periods for data should be specific depending on the datasets to which they related to and the purposes for which they were collected, and requested details of how data retention periods would be reviewed. Members requested that the details of these aspects, along with plans for GP data should be provided to the Committee.
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Members requested that the applicant explore the possibility of organisations providing data with NHS numbers which were pseudonymised using an algorithm that could be repeated by other organisations when further linkages were required. This would negate the requirement for the applicant to access NHS number in the clear. In addition Members recommended that the linkage table was kept by a trusted third party when not required and that appropriate controls were in place to ensure that access to this was restricted.

Members agreed to recommend to the Secretary of State that support continue to be provided for the applicant to access cancer registration data specifically in relation to the specified "*Don't be a Cancer Chancer*" project. Members agreed that they were supportive of the pseudonymised data warehouse in principle and requested clarification on areas indicated above. The Committee agreed that once clarification on all these points was received, they would be in a position to advise the Secretary of State that support be provided for the pseudonymised data warehouse.

2c. ECC 2-02(c)/2012 Development of models to predict survival in intestinal failure

This application from Addenbrooke's Hospital sought approval to study patients with chronic intestinal failure in order to create a scoring system with the aim of predicting the survival chance and quality of life for each patient group. The application detailed that there were two parts to the study. The first would involve the collection of information from existing databases and case notes and the second involved questionnaire dissemination. It was noted that questionnaires would be disseminated via care teams and therefore support would not be required for this aspect of the study. Support was requested to allow access to confidential patient information held on hospital databases (St Marks, Manchester, Glasgow, Cardiff, Southampton, Nottingham, Newcastle and Oxford) for those patients who were deceased in order to extract a dataset, including date of birth and date of death, for analysis. Following correspondence with the NIGB Office it had been confirmed that consent would be obtained for extracting information from hospital databases for living patients via the local care teams at each hospital. Members were pleased to note that the applicant had confirmed that consent would be taken from patients who were alive. However Members noted that this was not reflected within the application form itself, and therefore asked that the applicant provide further confirmation that consent would be sought from the living for the collection of data from existing databases. Members were concerned that the consent form did not fully inform participants what data would be accessed and collected about them, how long it would be stored for and who it would be shared with. Members recommended that the consent form be revised to fully reflect the extent of the risk to an individual's privacy. Members noted that references were made to the application being a feasibility study which would inform a larger study.

Members requested further information regarding the relationship between the two and whether the data collected for this study would be used as part of a larger study.

Members noted that references were made to collaborating with a number of centres in the United States and queried whether any identifiable data would be shared with these centres. If this was the case Members advised that the information leaflet should be updated to accurately reflect the data sharing. Members sought clarification regarding who would carry out the extraction of data. Members noted that the application specified that information relating to the patient's diagnosis and other factors the researchers felt might be of significance in answering the study question would be collected. Members requested that further information be provided regarding what specific types of information was to be collected and stored from the patient record. Members raised concerns that there appeared to have been no patient involvement in the development of the study and asked whether the applicant had considered approaching an appropriate patient group to test the acceptability of the use of data without consent. Members agreed that any recommendation of support would be subject to user involvement.

Members agreed that the minimum threshold of the Regulations had been met for access to deceased patients' data only and therefore agreed to advise the Secretary of State that support be provided, on the basis that consent would be obtained via care teams for all patients who were alive, prior to the collection of any data. Members added that their advice would be conditional upon clarifying whether the application and related data formed part of a larger feasibility study; whether any identifiable information would be shared with international collaborators, and further information relating to the extent of patient information to be collected from the patient records. Members also recommended that the patient information leaflet and consent form be revised to reflect these clarifications and to make explicit the detail of the activity.

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

This research application from the University of Oxford detailed the transfer of the Oxford Survey of Childhood Cancers database, which commenced in 1953, from the University of Birmingham to the Childhood Cancer Research Group (CCRG) at the University of Oxford. The application detailed that the data was currently held in an identifiable format and it was proposed that this would be transferred to an anonymised digital format to be utilised in further research. Microfiche records would continue to be held in an identifiable format whilst the possibility of systematically removing identifiers was explored. A recommendation of support was requested to provide a legitimate basis for the University of Oxford to access and continue processing data held on the OSCC for research purposes.

Members agreed that the data contained within the database was important and that there was a clear public interest in ensuring it was maintained and used appropriately. Members noted that when the information was collected it was likely that some form of consent would have been provided from data subjects. However, due to the historic nature of the database this was unlikely to have been to modern standards. It was recognised that providing fair processing information at this stage would be difficult due to the historic nature of the cohort. In line with this Members agreed that support could be recommended to allow the personal data to be transferred into an anonymised digital format to ensure the dataset was preserved for future use. Members queried what arrangements would be made to anonymise the manual data. It was noted that there was a cost element involved and that the applicant proposed to anonymise the manual data once the possibility of systematically removing names had been investigated. Members requested further information in relation to the proposals to anonymise the manual records in future.

Members discussed the future arrangements for storage and access to the database and requested further information in relation to the controls in place to allow appropriate access and use of the database. In addition Members noted that the cancer registries had been given specific support to undertake activities such as this and highlighted the response from the cancer registries in reply to the NIGB Office queries regarding the management of the database. It was noted that the database would be linked to the National Registry of Childhood Tumours (NRCT) and held at the Childhood Cancer

Research Group. Members therefore requested clarification as to why the database, once created, could not be managed under the auspices of the cancer registries' specific support. Members agreed to recommend to the Secretary of State that he grant support to allow the University of Oxford to access and anonymise the data, subject to clarification on how access to the database would be managed and why the database could not be managed under the cancer registries' specific support.

2e. ECC 2-02(e)/2012 The Loss of Consciousness Key (LOCK) scale version

This application from the Royal Free Hospital NHS Trust detailed a study which aimed to develop a scale (LOCK) which would improve the diagnosis of episodes of transient loss of consciousness. The LOCK scale would be applied retrospectively to the medical records of 100 patients referred to the neurology department of the Royal Free Hospital and prospectively to 100 patients presenting at the emergency department. The validity of the scale would be evaluated after 12 months, which would require access to records held either by the Royal Free Hospital or by GP practices. Support was requested for a research nurse to apply the LOCK scale to records held at the Royal Free Hospital Emergency Department and to access GP record data to confirm diagnosis after 12 months.

The Committee can only recommend support where there is no practicable alternative to accessing confidential patient information without consent. With this in mind Members discussed the assertions that consent could not be obtained for the access to medical records. Whilst Members appreciated that gaining consent at the time of admission to the emergency department would not be feasible they noted the relatively small numbers involved and queried whether the applicant had explored the feasibility of obtaining consent when the patient was discharged. Members noted the assertion that writing to patients would potentially invade their privacy and that any information regarding the study could potentially cause uncertainty where patients were still undergoing treatment for LOCK. Members were of the view that a carefully worded letter could potentially allay these concerns and allow consent to be obtained to follow up patients with their GPs at 12 months and carry out prospective case note reviews. In addition Members queried whether consent could be obtained via GPs. The Committee recognised that these options would require access to a certain amount of demographic patient information in order to gain consent and agreed that support could be recommended to allow access to patient contact or GP details if this methodology were to be adopted. Members noted that the DPA registration number detailed within the application was not showing on the public register and requested a valid registration number for the organisation. As consent appeared to be practicable Members requested that the applicant explore the alternatives detailed above. Members agreed to advise the Secretary of State that support be provided for access to demographic details in order to write to patients to seek consent and for those patients who were deceased. If consent proved not to be feasible then Members advised that evidence of this should be submitted to the Committee.

2f. ECC 2-02 (f)/2012 Application withdrawn

The Committee noted that this application had been withdrawn by the applicant after the agenda had been finalised, on the assertion they intended to modify the approach so only de-identified data would be accessed.

2g. ECC 2-02(g)/2012 Metal on metal joint replacement and malignancy

This application from Kings College London detailed a study to compare National Joint Registry (NJR) and National Cancer Registry data in order to investigate whether the risk of developing malignant disease could be affected by the implantation of a hip or knee joint replacement prosthesis whether made of metal, ceramic or plastic. Support was requested in order to allow access to patient identifiable data including name, sex, date of birth, date of death and NHS number to link NJR and Cancer Registry data. Data linkages would be carried out within the Thames Cancer Registry.

Members agreed that the activity was topical and important and that there was a clear public interest in the linkage taking place. Members raised concerns around the consent form used by the National Joint

Registry and noted that this included a commitment to patients that their data would not be used by a third party in an identifiable format. In line with this Members noted that the extent of patient identifiable data requested would result in a patient being fully identifiable, particularly as name was detailed. Members agreed that the amount of identifiable data items requested appeared to be excessive for the linkage activity. Members noted that linkages should be carried out using NHS number only in the first instance. This would allow the suitability of this data item alone to be assessed, prior to access to direct identifiers such as name. Members queried whether the applicant had explored the practicability of pseudonymising the NHS number within both datasets using the same technique prior to disclosure, allowing data to be linked without disclosing a potential identifier. In addition Members noted that if linkage could be undertaken using NHS number only, then month and year of birth, rather than full date of birth, should be used to calculate age.

Members queried whether there would be a control arm to the study and how data on these patients would be obtained. It was noted that the study had been considered by the patient liaison group of the British Orthopaedic Association. In line with this Members requested further details of what feedback had been received in relation to the activity. Members agreed to recommend to the Secretary of State that he grant support for this application, subject to confirmation of the feasibility of pseudonymisation of NHS numbers in both datasets using a common method; clarification of whether the study would include a control arm and if so how data for the control arm patients would be obtained; confirmation of feedback received, if any, from the British Orthopaedic Association.

3. For consideration items

3a. NHS Information Centre – National Cancer Audit applications

ECC 1-03(c)/2012 National Head and Neck Cancer Audit
ECC 1-03(d)/2012 National Bowel Cancer Audit
ECC 1-03(e)/2012 National Lung Cancer Audit

Dr Mark Taylor assumed the Chair for this item as discussion followed on from the February 2012 meeting where he had chaired in the absence of Dr Andrew Harris.

These three applications from the NHS Information Centre had previously been considered at the February 2012 meeting where the Committee had advised supporting the collection of NHS Number, date of birth, date of death and postcode. All three had been approved in principle, however, clarification had been sought on the use of name as a required data item. Discussions therefore focused on whether an adequate justification had been provided for collection of name within the audits.

The applicant confirmed that the Lung and Bowel cancer audits did not require name as an identifier. The Head and Neck audit collected patient name in order to aid local users in Trusts to identify patients, but it was confirmed that name would not be extracted, seen or processed by the Information Centre. Based upon this clarification, it was confirmed that name was not required for the audit, and was not disclosed or used, other than by local care teams. It was therefore agreed that as support would not be required for local teams to access their own patients' names, name should not be included within the application. Members agreed to recommend to the Secretary of State that he continue to support these applications, with name excluded from the data collection. This advice was subject to the condition that there would be a further review at the Committee's September 2012 meeting. The Committee considered that the Information Centre had a key role to play in encouraging the appropriate dissemination of patient leaflets at a local level, therefore this further review would focus on evidence of the level of dissemination of patient information leaflets at a local level and consideration of alternative methods of informing patients; details regarding how dissent would be managed for all national audit applications; and confirmation of the amount of valid NHS numbers submitted at a local level.

3b. University College London – National cardiac clinical audits separate application details

Update on conditions of support for ECC 1-06(d)/2011 – Application for transfer of responsibility for national cardiac audits to the National Institute for Cardiovascular Outcomes Research (NICOR) at University College London

Dr Andrew Harris resumed as Chair.

An update from the University College London was provided in response to a condition of approval made in September 2011. For those audits where NHS number ascertainment was nearly complete, the expectation was to move towards the pseudonymisation of data. The overall activity was to be completed by 30 April 2012, including the purposes of each audit, required identifiers, linkages involved in each and an assessment of each item to identify where identifiability could be reduced and at what point. Additionally, at the September 2011 meeting, the Committee had requested further investigation into the proposed alternative that NHS number be validated automatically at a local level when the submission to the NICOR was made, using the Personal Demographics Service, in order to negate the need for patient name; significant movement towards the reduction of collection of identifiable data items by NICOR, particularly patient name and postcode; and information about the percentage of inaccurate NHS numbers following linkage with the NHS central register. At the September 2011 meeting Members had proposed a view that if NHS number could be validated automatically at the local level, then NHS number ascertainment would be greatly improved, and had requested further justification that 100% NHS number ascertainment was required if local validation proved to be unfeasible, noting that nearly 100% of cases did have NHS number submitted.

Members noted that it appeared that the report provided no further detail regarding the alternative proposed by the Committee that NHS number could be validated at a local level when submitted to NICOR. Members noted that the applicant asserted they were exploring the feasibility of the Medical Research Information Service (MRIS) collecting demographic data in order to provide valid NHS numbers to NICOR. It was detailed that this would allow NICOR to reduce the amount of identifiable data items collected for the purposes of NHS number validation. As it appeared that this solution negated the requirement for patient name, Members agreed that it was important for this solution to be pursued as soon as possible and requested further clarification regarding the timescales involved. The Committee also requested confirmation of the data flows utilised within the proposed solution and how this would lead to the overall reduction of identifiable information being collected. The Committee was mindful that these additional data flows would require an additional security review and requested that an amended system level security policy be provided. The Committee noted and recognised that further consideration might be required in relation to the retention of patient postcode, given the current uncertainties about healthcare geographies in England. Members queried whether the first four digits of the postcode would be sufficient for these purposes.

The report stated that NHS number ascertainment for most audits was above 97% and Members noted the assertion that complete ascertainment was required to in order to avoid bias. Members queried whether complete ascertainment would make a significant difference to the analyses that were being carried out, given that 97% ascertainment of NHS number was in place. Members requested that a routine analysis be carried out on those 97% of patients for whom NHS number was submitted, in order to determine the extent of the differences in the results and provide evidence of the requirement for full ascertainment. This request was communicated to the applicant prior to the March meeting and the applicant confirmed that discussions with the Healthcare Quality Improvement Partnership (HQIP), the commissioners for the audits, would take place to determine whether this would be feasible in terms of costs involved. Members requested that evidence of the requirement for 100% ascertainment of NHS number should be submitted as part of the next review. The applicant confirmed that they were currently exploring the costs for obtaining information relating to the accuracy of NHS numbers currently held by NICOR. It was confirmed that from 1st April 2012 NICOR would submit NHS numbers along with demographic details so that the accuracy of existing NHS numbers could be ascertained. Members queried what effect this would have on the requirement to retain identifiable data within the existing data set.

Members noted the applicant's assertion that patient name would continue to be required for the cardiac rhythm management audit to allow accurate identification of a deceased patient with an implantable device in order to ensure the health and safety of other individuals, such as mortuary operators, who might be at risk from the device. Members agreed that it was clearly important to be able to identify these patients; however this was considered to be for the purposes of health and safety, not audit, and it was discussed that at the very least fair processing information could be provided to patients to ensure that they were aware the data collection took place. Therefore, whilst name would be essential to manage health and safety issues, this aspect was clearly not an audit issue and therefore this specific data item was excluded from the current recommendation of support. It was noted that the next annual review would not be due until April 2013 and due to the abolition of the NIGB, the Committee would no longer exist in its current form at that time. Members therefore requested that the next report be provided for the first meeting in 2013.

Members agreed to advise the Secretary of State that he continue to provide approval. This would be subject to the original conditions of support and the following additional conditions: confirmation of data flows involved in the proposed MRIS solution and further information regarding how this would lead to an overall reduction in identifiable data being collected; full details of timescales involved in pursuing the proposed MRIS solution; an amended system level security policy including changes to data flows; analysis of the 97% of patients for whom NHS numbers were submitted in order to determine the extent of the differences in the results and provide evidence of the requirement for 100% ascertainment; and confirmation that the use of name within the cardiac rhythm management audit would be for health and safety purposes only and name would not be used or retained for audit purposes. Members requested that these conditions be met by 12 May 2012.

3c. Royal College of Paediatrics and Child Health – National Paediatric Diabetes Audit

This application was submitted by the Royal College of Paediatrics (data processors) on behalf of the Healthcare Quality Improvement Partnership (HQIP), who would act as data controllers, and detailed the transfer of data controller responsibilities from the Health and Social Care Information Centre (HSCIC) to HQIP. It was confirmed that the purposes of the application remained the same. Confidential patient information was requested to track patients throughout care pathways and to remove duplicate entries. Identifiable information was also requested to link with national datasets, HES and child mortality data. NHS number, date of birth, postcode and date of death were required. Postcode would be deleted once deprivation score had been calculated. The HSCIC had been asked to provide separate applications for all audits under the original overarching approval which were to include details of the reduction in identifiable data items. As this audit was included within the original overarching approval the application was submitted to the Committee for review.

Members discussed the application in the context of previous conditions given to the HSCIC application, in particular the requirement to reduce the collection of identifiable data items and detail an exit strategy from support under the regulations. The Committee agreed that the identifiable data items were fully justified and were pleased to note that once postcode had been converted to lower super output area it would be deleted. Members welcomed the intention to move towards a consent model in the future as an exit strategy from reliance on support under the Regulations, and noted the aim to reach a level of consent for 75% of patients by 2014. As a whole, Members agreed that the application was well written and sufficiently detailed, and congratulated the applicant on this.

Members agreed that the minimum threshold of the regulations appeared to have been met and agreed to recommend to the Secretary of State that he continue to approve this application, subject to confirmation that the application purposes did not include research at this time and receipt of a letter of support from HQIP as the data controller to the Office.

4a. Minutes of last meeting [ECC 2-04(a)/2012] and matters arising

The minutes from the meeting held on 1 February 2012 were approved as an accurate record.
There were no matters arising.

4b. NIGB Office Report [ECC 2-04(b)/2012]

Fast Track applications

ECC 2-02 (FT1)/2012 Community Stroke Reviews V.1

This application from the University of Southampton set out a study for a master's degree in leadership and health and social care management. It was a retrospective exploratory comparative study which would measure the efficacy of stroke reviews using the Community Strokes Review tool in two groups of patients: those who had a six week review only compared to those who had a six week and six month review. Stroke clinicians in four different sites would be approached by the researcher. The stroke clinician would provide patient identifiable information of stroke patients (80 in total) who had a review between January and February 2011. Clinicians would populate a spreadsheet with patients' NHS number, date of birth, post code, sex, GP, date of hospital discharge, date of reviews, Barthel score and co-morbidities to be sent directly to the NHS Information Centre Trusted Data Linkage Service (TDLS) for linkage. A recommendation for classes two, four, five and six support was requested so stroke clinicians could disclose patient identifiable information to the NHS IC TDLS for linkage with HES and MRIS (ONS) and the NHS IC could provide a pseudonymised data set to the researcher containing date of death, cause of death, partial postcode, month/year of birth, sex, ethnicity GP, date of hospital discharge, date of reviews, Barthel score and co-morbidities amongst other clinical data.

Following consideration of this application through the fast track process (category five - *Applications only requiring time-limited access to undertake record linkage and validation and then pseudonymising the data*) the Committee agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised the Secretary of State for Health that support be provided, subject to confirmation that the applicant would take reasonable steps to comply with the fair processing principle of the Data Protection Act 1998 by informing patients about this study and giving them the opportunity to opt-out; confirmation that the applicant would request stroke clinicians to observe and respect patient dissent before disclosing information to the NHs IC, and confirmation that the applicant would receive age only instead of month and year of birth from the NHS IC.

ECC 2-02 (FT2)/2012 CRF Logical Extraction of Adverse Reactions and Events

This application from the University of Newcastle set out proposals for a research study for a master's degree in clinical research. The applicant's aim was to investigate whether or not the current processes for the extraction of data from medical notes for entry onto trial-specific case report forms was an accurate process when reviewed against the medical notes. A clinical trial team leader who had consent from trial participants to access their identifiable information at Sir Bobby Robson Cancer Trials Research Centre would identify 150 patients who participated in trials and went through cycle two of chemotherapy having four specific chemotherapy side effects (diarrhoea, nausea, vomiting and fatigue) recorded in their clinical trial notes. The clinical trial team leader would then provide a list to the applicant with patients' name, surname, date of birth, hospital ID, study ID, date of second cycle of chemotherapy and four grades of side effects. Subsequently the applicant would retrieve patients' medical records to compare grades recorded by the trial team against those recorded by doctors and nurses. A recommendation for classes four, five and six support was requested to provide a legitimate basis for the researcher to receive the specified identifiers and access patients' records for comparison.
Following consideration of this application through the fast track process (category five - *Applications only requiring time-limited access to undertake record linkage and validation and then pseudonymising the data*) the Committee had advised in January 2012 that this activity did not require support under the Regulations 2002 based on the information provided by the applicant. However, further information from the applicant had since been received by the NIGB Office which led to Members agreeing that support under the Regulations 2002 should be provided to this activity in order to ensure that the appropriate legal basis was in place for the processing of patient identifiable information by the researcher. The Committee agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised the Secretary of State for Health that support be provided.

ECC 2-05(FT4)/2012 Evaluation for users of Maternity Services in Greater Manchester

This application from NHS North of England and NHS Quality Health detailed a survey of 3400 users of maternity and neonatal services across the Greater Manchester area with an aim to determine the impact on user experience of the Making it Better reconfiguration. The survey was a repeat of the Care Quality Commission survey undertaken in 2007 and 2010 and comparisons of results would be made to assess user experience. This application was considered via the fast track process under criterion 9; *applications to identify a cohort of patients in order to seek their consent where the inclusion criteria only includes administrative/ demographic data & excluding both small & very large numbers.* Class 2 and 6 support was requested to allow Quality Health access to name and address of patients who attended nine maternity units in Greater Manchester, between October 2011 and September 2012, in order to write to them to complete a patient experience survey. Members noted the issues asserted by the applicant regarding the feasibility of care teams within maternity units distributing questionnaires. Members queried whether it would be possible for health visitors to carry out the distribution of questionnaires. The applicant advised that this suggestion would not be possible as health visitors only visited a small minority of mothers and babies within Greater Manchester. The applicant also asserted the validity of concerns regarding the risk of the health visitor influencing the patient as a reason to reject distribution of questionnaires by the care team. Members agreed that it would not be feasible to seek consent prior to the distribution of questionnaires and therefore agreed to advise the Secretary of State that support be provided to allow demographic information to be disclosed from NHS trusts to Quality Health for the purposes specified within the application.

ECC 2-02 (FT5)/2012 Screening for diabetes and intermediate hyperglycaemia in primary care

This application from Newcastle University set out a study carried out in 2009 where 1375 patients aged 60 years and older registered with a GP practice in Newcastle were invited to have a screening for raised blood glucose. 584 patients provided consent to participate in the study. The first phase of this study had subsequently been published in a medical journal. The applicant now sought to link the dataset collected for the study with HES data, specifically data on diagnosis of diabetes and cardiovascular disease. The NHS Information Centre Information Governance team did not consider the consent to cover linkage with HES data adequate and advised the applicant to either seek renewed consent from patients or to submit an application for support under the Regulations. This application was considered through the fast track process (category five - *Applications only requiring time-limited access to undertake record linkage and validation and then pseudonymising the data*). The Committee reviewed the study consent form and the patient information material submitted by the applicant with the application. Members agreed that the consent provided by patients to participate in the study in 2009 would cover this linkage of the dataset with HES and therefore advised the Secretary of State for Health that this application did not require support under the Health Service (Control of Patient Information) Regulations 2002.

ECC 2-02 (FT6)/2012 Analysing steroids by LCMSMS and establishing reference ranges

This application from Southampton University set out a research study which aimed to determine what the normal range for each hormone (testosterone, androstenedione, DHEAS, 17hydroxyprogesterone, cortisol and corticosterone) was for each sex at different ages which would allow easy differentiation of patients with abnormal levels of these hormones and patients with normal levels. A recommendation for classes four and six support was requested so that a researcher could have access to patient medical records in order to link pathology and neonatal data. It was confirmed that the applicant had access to pathology data as part of his role in the care and treatment of patients, but support for access to the additional data from neonatal records was requested. This application was considered through the fast track process (category four – *Applications where applicants are only accessing data on site to extract an anonymised/ effectively pseudonymised dataset*). Members discussed whether there was a practicable alternative to the use of patient identifiable data without consent and expressed concerns related to the fact that the cohort of patients was relatively small and therefore seeking consent could

potentially be feasible. Members advised that consent should be the primary option for studies of this nature and therefore applicants should consider and exhaust any alternative which involved seeking consent.

After detailed consideration of the reasons stated in the application on why consent was not practical and possible, Members agreed that in this specific case the applicant should attempt to seek consent from parents of patients in relation to samples collected retrospectively or, alternatively, amend the methodology to carry out the study prospectively with a consent based approach. Members highlighted that the explanation in the application and the additional information provided in the query sheet suggested that a prospective method based on consent was possible and noted that this alternative had already been considered by the applicant. In particular, Members noted that the application form stated that the study would be carried out on a prospective basis. The Committee agreed that the minimum criteria under the Regulations appeared not to have been met as an alternative to the breach in patient confidentiality had been identified. Members therefore advised the Secretary of State for Health that support should not be provided as a practicable alternative seemed to be available to the applicant which did not require support under the Health Service (Control of Patient Information) Regulations 2002. Members advised that this alternative should be explored in full.

ECC 2-02(FT7)/2012 CQC 2012 A&E patient survey

This application from the Care Quality Commission detailed a survey of patients, aged 16 or over, who had visited an accident and emergency department between January and March 2012. Support was requested for trusts to submit a mailing and a sample file to an approved contractor to carry out mailing of surveys on the trusts behalf. Members considered the application via the fast track procedure as it was noted that the application followed the same methodology as previous CQC surveys which had been considered and recommended for support by the Committee. A request for class 5 and 6 support was made to allow named contractors to access name and address in order to write to patients. In addition a sample file including PCT code, date and time of attendance, NHS site code, ethnicity, gender, year of birth and GP code was requested. Members agreed that the outcome of the survey would be beneficial in terms of improving patient care. Members noted that the application was very similar to the previously approved methodology for the CQC inpatient and mental health survey (ECC 8-05(a)/2011 2012 Community Mental Health Survey and ECC 8-02 (FT1)/ 2011 2011 Acute inpatient survey). It was noted that no clinical information would be transferred and that 16-18 year olds would be included within the survey. Members agreed that this differed from the Mental Health Survey, where Members had requested that this age group was excluded, as this age group would present to A&E and be treated as adults. Members agreed that it was appropriate that the exclusions at trust level included those patients seeking contraception or with adverse pregnancy outcome, deceased patients and those who were current inpatients. The Committee agreed to advise the Secretary of State that support be provided, subject to confirmation that a guidance document would be provided to trusts in relation to meeting fair processing requirements for this survey.

Amendments

PIAG 4-08(d)/2003 National Confidential Inquiry into Suicide and Homicide (NCISH)

The NCISH was established in 1996 to collect clinical data on people who died by suicide or committed homicide who were in contact with the mental health services (within 12 months) so that policies and practices could be developed to reduce the risk of suicide and homicide by people under mental health care. The clinical data is collected in a questionnaire completed by the consultant psychiatrist responsible for the patient's care and sent to the NCISH. Further information is also collected from psychiatric reports prepared for homicide trials. Since 2001, psychiatrist reports have no longer been mandatory for homicide trials and annually the number of reports prepared has been diminishing. This has an impact on the Inquiry's ability to monitor and report on the prevalence of mental illness as a factor in general population homicides, and specifically on the changing number and trends in homicide committed by people with serious mental illness – particularly schizophrenia. In light of this, the NCISH requested an amendment to its current support to collect data from an additional source, the SystmOne

Prison Health Database, to pilot the acquisition of psychiatric history and mental health data from this database on all individuals remanded on charge of homicide in selected prisons in London and North West England for six months.

This request was considered by the Chair. The Chair noted that no additional information other than that already processed under the NCISH's current support would be collected from the additional source, SystmOne Prison Health Database. SystmOne staff would complete a pro forma with the data requested by the NCISH and therefore NCISH would not have access to SystmOne prison health database. The Chair agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised the Secretary of State for Health that support be provided, subject to provision by the applicant of feedback on the outcomes of this pilot once complete.

PIAG 2-07(c)/2004 Manchester Self Harm Project MaSH

In 2005 PIAG provided a favourable recommendation of support for Manchester University, Manchester Self-Harm Project (MSHP), to collect patient identifiable information of patients attending A&E Departments at three different Trusts following self harm. Identifiers collected were name, address, date of birth, postcode, NHS number and hospital number. In 2009 the MSHP submitted an application to the Database Monitoring Sub Group and an amendment to the Committee to link patient information collected from 2000 to 2007 to MRIS data and receive date of death, cause of death (ICD10 code), place of death, registration district, occupation and address. This request was approved.

Following the amendment in 2009 the applicant requested to link the MSHP dataset collected from 2008 to 2009 with MRIS data to receive the same data items previously specified in the 2009 amendment. No additional data items would be collected. The receipt of mortality data from MRIS for the 2008/2009 cohort would allow the MSHP to identify any recent trends in self-harm and suicide behaviour and to continue monitoring trends over time. This request was considered by the Chair of the Committee. The Chair noted that no additional information other than that already processed under the MSHP's current support would be collected and the same data items received from MRIS for 2000-2007 cohort, previously approved, would be received for the 2008-2009 cohort. The Chair agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised the Secretary of State for Health that support be provided.

PIAG 3-07(h)/2002 National Cancer Research Institute (NCRI) Randomized Controlled Trial into annual mammographic screening

This application was for a NCRI randomised controlled trial of the effect of breast cancer mortality on annual mammographic screening of women starting at age 40, and for cancer registration details, pathology reports and slides to be obtained to provide timely information and review of pathology and for breast screening data to be collected. Support under the Regulations had been provided in 2002 for data to be linked to allow the records of patients included in cohort studies to be flagged so that upon death, researchers would be notified and receive information about the cause of death. The applicant submitted a request to amend the sponsor organisation (data controller) which is now Queen Mary University of London and not the Institute of Cancer Research. A revised System Level Security Policy and supporting policies were submitted to the NIGB Office and reviewed by the Department of Health Security Review team. Confirmation of satisfactory security arrangements was received and the application approved.

Update on previous applications

ECC 8-05(k)/2011 Improving the responses of health services to domestic violence part 2: pilot interventions

This application from the University of Bristol detailed two work streams of a larger research project which aimed to improve the quality of health care for victims and perpetrators of domestic violence. The work streams would be used to pilot an educational intervention, with the aim to improve enquiry about

domestic violence, documentation and referral to specialist community agencies, with health professionals in general practice and sexual health clinics. Following consideration of the application at the December 2011 meeting the Committee advised that there appeared to be alternatives to the use of patient identifiable data without consent. In particular the Committee were of the view that it would be possible to obtain resource from the GP practices to carry out the extraction of anonymised data on the applicant's behalf. The Secretary of State for Health, having considered the advice from the Committee, determined not to approve the application and requested that the alternatives to the use of confidential patient information without consent be explored further.

Following this outcome the applicant requested further information in relation to the practicable alternatives recommended by the Committee. It was agreed that a telephone conference should take place between Members of the Committee who had reviewed the application, the NIGB Office and the applicant, in order to explore the alternatives in further detail and allow opportunity for any potential difficulties to be raised by the applicant. The teleconference took place on 21 December and was attended by Dr Mark Taylor (Committee member and Chair when application was considered), Professor Sir Denis Pereira Gray (Committee Deputy Chair), Professor Julia Hippisley-Cox (Committee member), Professor Gene Feder (Chief Investigator, PROVIDE study) and Sue Jones (Research Associate, PROVIDE study). Members queried whether the applicant had explored the option of funding the GP practice to carry out the data extraction on their behalf. Members' attention was drawn to the flow diagram included within the application which reflected that a number of judgements were involved in the data extraction and the applicant explained that if any more than one person were involved this could potentially introduce variation into the data and mean the data were not robust.

Members queried whether the applicant had considered a method whereby the researcher would sit by a member of GP practice staff and could be provided with details of what was recorded, without actually being exposed to the record themselves. Members advised that this process was referred to as the "sitting in" method. In addition Members queried whether the GP practice could print the patient record and completely redact any identifiable data recorded within it. The applicant expressed some concern that the redaction method might prove difficult due to the length of some records and the level of third party data contained within a patient record, but recognised that the "sitting in" method might prove feasible and provide a way forward. Professor Hippisley-Cox advised that she had completed studies using a mixture of these methods and agreed to circulate published articles in relation to these. The applicant agreed that a mixture of both the "sitting in" and redaction method might prove feasible and agreed to trial these methods, recognising that an amendment to the current Research Ethics Committee approval would be required. Members advised that if the above methods proved not to be feasible a resubmission should be made detailing the evidence collected from testing these methods.

ECC 8-05(d)/2011 Do specialist cancer services for teenagers and young adults (TYA) add value?

This application from University College London detailed a cohort study to determine whether specialist Teenage and Young Adult (TYA) specialist care affected outcomes. All patients aged 13-24 diagnosed with cancer in England would be invited to participate. A recommendation for class 2, 3 and 6 support was requested to allow National Cancer Research Network (NCRN) nurses to access data from the North West Cancer Intelligence Service (NWCIS) in order to identify patients and request their consent for entry into the study. At the December 2011 meeting, the Committee requested clarification from the applicant as to whether consultants could be identified to NCRN in order for them to contact care teams to ask them if they could approach patients for consent to speak to a research nurse. The applicant asserted that relying on clinicians to recruit patients would be unlikely to capture the whole cohort, which was key to the study design. In addition it was noted that consultant codes would not be included within the primary dataset at the time of recruitment into the study. Members noted the difficulties in identifying clinicians, rather than patients, and asking them to approach patients for consent. In particular Members noted the evidence included within the application that suggested recruitment into non-clinical trials was particularly low where clinicians approached individuals for consent. In addition the research aimed to compare differences in specialist and non-specialist treatment centres and therefore an approach which would ensure limited bias would be preferable. Members therefore agreed to advise the Secretary of State that the application should be supported.

ECC 1-05 (f)/2012 The CAPE Study: Community Care Pathways at the end of life

This application from the Institute of Public Health, University of Cambridge set out a study to access patient identifiable information from GP and Community Nurse records of 400 recently deceased patients in order to summarise the care the patient received in the last year of life. Twenty GP practices would be recruited over two years, the first ten within Cambridgeshire PCT. The remaining practices would be recruited more widely across the East of England. The patient clinical information would be summarised and inform discussions with health professionals, social care professionals, carers, next of kin and potentially care home managers (if the patient lived at a care home before death) involved in the care of the patient in their final year. At the February 2012 meeting, the Committee had requested clarification from the applicant regarding safeguards to be put in place to ensure that researchers interviewing third parties about a patients care would not disclose any confidential patient information included within medical notes, and whether medical notes dating back to six months prior to a patient's death and any information on chronic diagnoses prior to this would be sufficient for the purposes of the study. The applicant confirmed that interviews with professionals and family members would be carried out by a researcher who had not had prior access to medical records of patients, and clarified that current End of Life Care policy encouraged early recognition of patients that were potentially approaching end of life and that twelve months prior to death was therefore the time over which good clinical practice was focused. The Committee agreed to recommend to the Secretary of State that he grant support for this application.

Clinical audit support unit (previously NCASP) ECC 1-06 (c)/2009

As part of the conditions of approval for this application the Health and Social Care Information Centre (HSCIC) were asked to provide separate applications for each audit under the NCASP approval. The HSCIC had already provided applications for the National Diabetes, Bowel Cancer, Lung Cancer and Head and Neck Cancer audits. The National Audit of Cardiac Rehabilitation was the final audit application that was due to be submitted to the March 2012 meeting as part of the response to the conditions of approval. The HSCIC had requested that this be submitted to the May 2012 meeting as issues had been identified which required clarification prior to an update being provided to the Committee. An interim update had been provided which reported that analysts at the University of York were currently receiving audit data including postcode and date of birth. The HSCIC had confirmed that immediate steps would be taken to ensure that this information was pseudonymised. In addition it was reported that in some cases local clinical teams were using the national audit collection platform for local purposes and the HSCIC were currently working with them to establish alternative arrangements. Confirmation of the steps taken would be provided in the updated application.

National Research Ethics Service training event

Mark Taylor, ECC Deputy Chair, and the NIGB Office attended a training event on 29 February 2012 organised by NRES; *Personal data in research: a workshop for Research Ethics Committee Members.* Dr Taylor and Natasha Dunkley, NIGB Approvals Manager, provided a presentation detailing the role of the ECC in the use of personal data in research and covered issues such as consent for processing and determining the identifiability of datasets. Other presenters included representatives from the National Institute for Health Research (NIHR), the Medical Research Council Regulatory Governance and Advice Centre and the University of Nottingham to discuss the governance of the QResearch database.

4c. ECC Chair's Report

The Chair had attended the February 2012 NIGB Board meeting and reported back to the Committee that this meeting had included discussions with the Health Research Authority (HRA), Public Health England transition team (PHE) and the National Commissioning Board (NCB) over the future location of the advice currently carried out by the Committee. The Chair emphasised the importance of preserving independence, and the perception of independence, within the advice and approval functions in order to preserve public trust in the process, and suggested that on this basis the NCB might not be an appropriate home for the functions, due to potential conflict of interest with its proposed powers to

mandate release of patient information from NHS data controllers. The Chair was concerned that insufficient consideration was being given to conflict of interest in information governance in future arrangements, and suggested that the Committee could propose alternative options, such as provision of advice to the data controller responsible for disclosing patient information rather than to the applicant seeking it.

Members suggested managing perceived and actual conflicts of interest was key. Members highlighted the risk of significant incidents during the transition period and potential inconsistencies in future decisions if the functions were split among multiple organisations, and noted the difficulties sometimes inherent in clearly defining an application type with consequent risks that applications might be directed along the wrong pathway to approval. The Chair noted that discussions with the HRA, PHE and NCB were ongoing and also included the NIGB's Department of Health Sponsor. Members suggested that there might be a role for HealthWatch England with respect to the advice and support functions. The Office advised that the HRA had indicated a desire for the advice function and support function to remain integrated, but noted that currently applications to use a legal power to process patient information without consent constituted under 3% of total research applications nationally and suggested that as a consequence, the Committee's functions might not be perceived as a priority for the HRA.

Dr Doyle advised the Committee that Kathy Mason, Director of Policy, Planning and Information Governance in the Department of Health Informatics Directorate, had been appointed the new Sponsor for NIGB following the sad death of Steve Collins. NIGB Office representatives had attended Steve's funeral and Dr Doyle paid respect to Steve's wealth of experience and significant contribution. A new Director was still to be appointed for the Information Governance Review and was likely to be sourced from the Department of Health but outside the Informatics Directorate. Dr Doyle updated the Committee on the Department of Health's own structural reforms. The IG review was discussed and Members were invited to feed into the Review on an individual basis in addition to a coordinated response from the Committee and NIGB. The Chair emphasised the importance of separating engagement with the Review regarding the specific future of the Committee's functions and engagement with the Review regarding general information governance processes, systems and structures.

Dr Doyle advised the Committee that NIGB were planning a workshop in conjunction with Dr Jane Kaye, to take place in Oxford, probably in November 2012.

5. ECC Business Improvement Project update

Mr Mathew Fry provided an update to the Business Improvement Project and thanked Dr Mark Taylor and Dr Tricia Cresswell for their key input as champions of the Project. The NIGB office and Dr Mark Taylor jointly gave a presentation on the outputs of the Business Improvement Project, which arose from the July 2011 Strategy Day. The remit of the Project was to more clearly articulate the advice offered by the Committee and streamline processes to improve future applications, and to ensure a robust system was handed over to the successor organisation(s). The work of the Project was taken forward through an array of Task and Finish groups involving Members and the Office and outputs included a criteria-driven pre-screening tool and a revised criteria-driven proportionate review (formerly known as fast track) process to better define which applications required submission to the full Committee and which could be taken outside of the Committee meeting. The intention was to publish the criteria-based tools on the NIGB website to inform applicants at the pre-application stage. The Project would be presented to the NIGB Board in April 2012 for endorsement and a final report would be published in May 2012. The Office hoped that the Project would have a beneficial impact on the transition period and processes, particularly given the current level of fragmentation and lack of clarity between the different potential successor organisations.

The Chair commended the Office for the considerable achievement of the finished Project, highlighting issues around the IRAS form that had been highlighted through the outputs, and emphasised the need to showcase the Project to maximise its benefits, including mitigation of risks and duplication and

maximisation of cost efficiency during the transition period. Further work on pseudonymisation was ongoing with Dr Mark Taylor, Professor Julia Hippisley-Cox and Dr Jane Kaye.

6. Any other business

Dr Mark Taylor announced that he had received a fellowship from the British Academy commencing from September 2012

7. Upcoming meeting dates

30 and 31 May 2012.