Ethics and Confidentiality Committee (ECC) Meeting – Wednesday 30 May 2012

Members:

Dr Andrew Harris (Chair), Mrs Pauline Brown, Dr Robert Carr, Dr Patrick Coyle, Dr Tricia Cresswell, Ms Alison Emslie (*items 1-3g and 4a onward*), Mr Stephen Hinde, Dr Mark Taylor, Ms Gillian Wells and Mr Chris Wiltsher.

In attendance:

Dr Alan Doyle *(NIGB Director)(item 4b),* Ms Natasha Dunkley *(Approvals Manager),* Mr Martin Frowd (*Senior Business Support Officer*), Mr Sean Kirwan (*Department of Health*) and Mr Richard Wild (*Information Governance Review Director)(item 4b).*

1. Welcome and apologies

Apologies were received from Dr Tony Calland, Dr Fiona Douglas, Dr Colin Harper, Professor Julia Hippisley-Cox and Mr Terence Wiseman.

2. Declarations of Interest

The following interests were declared:

i) Ms Alison Emslie declared an interest in item 3h as her employer was the data controller, and left the room during the discussion and final advice provided for this item.

ii) Dr Mark Taylor declared a potential perceived interest in items 3d and 3g as the applicants were employed by his employer, although he disavowed any involvement in the applications or direct relationship with the applicants. He remained in the room but did not contribute to the discussions.

2a. Minutes of last meeting & matters arising [ECC 2-03 (a)/2012]

The minutes from the meeting held on 28 March 2012 were approved as an accurate record.

Following on from consideration of the Cerner application [ECC 2-02 (a)/2012], members queried whether the policy intentions of the Department of Health in relation to the creation of honest brokers had been clarified. The Committee's current position was that it was desirable to ensure that large datasets were clearly and transparently managed with strong governance controls, and to avoid the proliferation of duplicated datasets held within and between organisations. The Committee typically encouraged the centralisation of large datasets that could be accessed by persons under controls and safeguards. For example, if the Committee was aware of a specific dataset that would meet researcher needs, the researcher would be directed to that rather than seeking to establish a duplicate. Members queried whether a policy decision had been reached on the subsequent establishment of further honest brokers as this would clarify whether the advice provided by the Committee would need to be modified or whether the current position was still sustainable. It was agreed that a letter would be sent to the Secretary of State's representative in order to seek clarification on the issue.

Action: Advice to be sought from the Department of Health on the policy steer for establishment of additional honest broker facilities. Dr Cresswell and Dr Taylor to review letter prior to sending.

2b. NIGB Office Report [ECC 2-03 (b)/2012]

For information

Secretary of State approval decisions

It was noted that the Secretary of State had agreed with the advice provided by the ECC at the March meeting applications.

IG Toolkit and System Level Security Policy (SLSP) submission

It had previously been reported that the Department of Health (DH) policy intention is for all bodies processing NHS data to provide assurance of their information management practices through an appropriate IG Toolkit submission. In relation to applications, the intent was to move from completion of a SLSP to providing the IG Toolkit submission, and this would be phased in between April and October 2012. Following discussion with the DH information governance team, they are currently undergoing organisational transition, therefore in the short-term the intention is to continue to accept SLSPs as evidence of sufficient assurance until the DH team have suitable arrangements in place to manage the change. Specific queries on IG Toolkit submission will continue to be directed to the DH specified lead.

ECC secretariat arrangements

It was noted that Mr Rick Borges has taken up a 12-month secondment opportunity within Ms Katie Davis' Private Office. Due to the need to maintain a business as usual service with reduced capacity, a number of changes have been placed on the NIGB website.

External meetings

1. The London School of Hygiene and Tropical Medicine, in conjunction with the National Cancer Research Institute, would be hosting a meeting of the National Cancer Research Network's Consumer Liaison Group on 31 May. The aim would be to present to a group of active volunteer cancer patients and carers. It would also cover background information on the role of the Group, issues around cancer survival, a discussion of inequalities within the UK and international comparisons of cancer survival. Dr Robert Carr would be attending this meeting.

2. Ms Claire Edgeworth recently delivered a training session at short notice to the Charing Cross REC on 08 May. This covered the role of the NIGB and ECC, particular considerations of the Committee and clarification on how the ECC and RECs work together.

3. A second workshop on data linkage using pseudonymisation, led by the University of Nottingham, would be taking place on 25th May. This would be a technical workshop involving a number of software developers, architects and database managers. The intention was for the scope to be distinct from, but complimentary to, the de-identification standard due to be reviewed by the Information Standards Board. Dr Patrick Coyle provided an update that that while technical in nature, the event was well attended and highlighted that primary care was still significantly more advanced in this area of work than secondary care but progress was being made.

4. The Health Research Authority will, following approval from DH, be launching its unified approval process at an e-submission launch event on 12 June. This was originally a commitment within the 'Plan for Growth' that indicated the HRA and MHRA would closely together on this aspect.

5. Following increasing requests to make audit data available, the Health and Social Care Information Centre is currently leading an activity to make clear to applicants the various approval routes required to access data, and arrangements for appropriate handling. In particular, it has been thought helpful to make explicit the statutory requirements around accessing data from ONS and the requirements of the Statistics and Registration Act 2007, which sets out the 'approved researcher' model. It is intended for this document to make clear those audits managed by the HSCIC and HQIP, what is covered within each and what falls outside of scope, to provide an overview of access, how amendments are managed and the services offered by the respective organisations.

Fast Track applications

ECC 3-02(FT1)/2012 Surveys on patients using Radiotherapy and Imaging Departments in response to National Audit Office Report on Utilisation of Facilities

This application from the Department of Health detailed a survey of 14,680 patients attending radiotherapy and imaging appointments in 58 NHS trusts. The mailing of surveys would be carried out by NHS Quality Health. The survey aimed to investigate patient views as to whether they would use and benefit from longer opening hours within radiotherapy departments. Support was requested for NHS trusts to provide name and address to NHS Quality Health in order to disseminate surveys to patients. Date of birth was also required by Quality Health in order to carry out DBS mortality checks on behalf of trusts. Members noted this application followed a previously supported methodology and agreed that the proposed methodology, which did not request any clinical data, except that the patient had received the specified interventions, was reasonable and appropriate. Members advised that the minimum threshold of the Regulations appeared to have been met and recommended support to the Secretary of State.

ECC 3-02(FT2)/2012 British Cohort Study - Follow up

This application from the University of London requested support in order to allow tracing on the NHS Central Register for a cohort of men, who were recruited at birth, so that they could be contacted for a 42 year follow up. Current address was required in order to allow the men to be contacted for consent. Members noted that the individuals were already enrolled in the project and would be given future opportunities to withdraw. As the applicant was seeking only to update address details to enable them to follow up previous contact and no clinical data would be required Members agreed that it would be reasonable to advise support to the Secretary of State.

ECC 3-02(FT3)/2012 Healthy Living in ProtecT participants (HeLPP): use of data

This application from the University of Bristol, in partnership with Oxford and Cambridge universities, set out proposals to use a database containing patient identifiable information of 100,000 men who consented to be part of the ProtecT (Prostate testing for cancer and treatment) study for research. Patients originally provided consent to have their data used for prostate-related cancer research and for linkage with MRIS. The applicant would re-consent living individuals to use their information for non-prostate related research. However, the applicant specifically sought support for the use of deceased patient data for non-prostate related research. Members noted that third party researchers would be able to apply for anonymised extracts of data from the research database and a panel would review such applications. Members considered the description of 'anonymised extracts of data from the research database' and queried whether year of birth could be provided, rather than month and year, in order to reduce identifiability so that it was reasonably de-identified. If this was the case and as any data onwardly disclosed would not be identifiable, it was agreed that a recommendation of support would not be required to carry out this aspect of the activity.

An additional application to establish a research tissue bank *(Healthy Living in the ProtecT participants (HeLPP): use of samples)* was submitted with the application above. The same cohort of patients provided consent for their tissue samples to be used for prostate related research. For the use of deceased patient tissue the applicant intended to seek support under the Regulations. The applicant was informed that support under the Regulations could only apply to the data related to the tissue, not the actual tissue itself. It was confirmed that anonymised tissue would be provided to researchers, and they would have the option to link the research database with the research tissue bank, however they would link anonymised tissue with anonymised patient information using a unique study number. As this linkage was fully anonymised it was confirmed that this aspect did not require support under the Regulations 2002.

ECC 3-02(FT4)/2012 - Do interventions generate inequalities? An analysis of inequalities in the access to, uptake of and impact of Type 2 diabetes health interventions in South Tees

This application from Durham University (North East Public Health Observatory) for a PhD thesis set out a study to examine whether Type 2 diabetic patients in South Tees with different levels of deprivation experience unequal access, uptake and impact of health interventions. In particular, it aimed to identify whether particular health outcomes and interventions associated with type 2 diabetes had increased or decreased from 1999 to 2007 and whether these changes differed according to the deprivation level of the patients. The interventions and characteristics of general practices which varied according to deprivation level would be examined to establish if they caused or increased differences in health outcomes. A recommendation of support was sought for the South Tees Hospitals NHS Trust to provide NHS Numbers for patients who satisfied the inclusion criteria (approximately 11,000 patients) to the Health and Social Care Information Centre (HSCIC) without consent so pseudonymised HES data could be obtained by the applicant. The flow of identifiable data would be from the Trust to the IC only and the applicant would receive a pseudonymised dataset from the IC with unique study numbers for each patient. The applicant would also receive pseudonymised datasets from the Trust's Diabetes Register and Retinal Screening Programme. Following consideration of this application through the ECC fast track process ('Applications only requiring time-limited access to undertake record linkage and validation and then pseudonymising the data'), Members acknowledged that the applicant would not be able to seek consent as they would not be receiving identifiers. The information would be retrospective in nature and thus there would be limited practicable opportunity for consent to be obtained on a prospective basis. Members agreed that given the relatively low risks to patient privacy posed by the proposed research, the approach was appropriate and proportionate.

The Committee advised that the applicant should consider the practicability of informing the relevant population that the research would be ongoing, such as via notices included on websites and distributing patient information material, with some system in place whereby those accessing identifiable data for the researcher could manage patient opt-out where applicable. This would ensure that the applicant was operating in compliance with the Data Protection Act 1998 principles, particularly with the fair processing principle. As it was not clear whether patient dissent would be respected, Members advised the applicant to ensure that dissent would be respected before disclosure of identifiable information to the HSCIC.

Members noted limited patient involvement in this activity and advised the applicant to engage with patients where possible. The Committee considered the processing of data of 16-17 year old patients. Members enquired whether type 2 diabetes was a rare condition in this age group. Members agreed that if it was not a rare condition and the incidence was large enough to prevent the identification of patients there would be no particular sensitivities; and clarification on this point was requested. In line with the considerations above, the Committee agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending provisional support to the Secretary of State for Health, subject to ensuring compliance with the

Data Protection Act 1998, the observation of recorded patient dissent and clarification as to whether there was a small numbers issue with the 16-17 year old cohort.

ECC 3-02(FT5)/2012 A prospective randomised, multicentre trial to assess the impact of laboratory based rapid diagnosis on outcome in patients with Blood Stream Infections - RAPIDO

This application from North Bristol NHS Trust set out a proposal for a five-centre randomised controlled trial designed to assess the impact of new laboratory technology that provided rapid laboratory diagnosis on death rates in patients with Blood Stream Infections (BSI). Patients with symptoms of BSI would have their blood tested as part of their routine care and would be divided into two groups: one which would be subject to current diagnostic approach (current technology blood test) and another subject to the current diagnostic approach plus the new rapid diagnostic technology. When the patient was considered to be in reasonable physical and mental state to consent the ward nurse would approach them and ask whether they were content to be approached by a member of the microbiology clinical team to carry out the test. The microbiology team would explain the study and obtain consent from living patients to access their medical records, extract name, NHS Number, date of birth and hospital ID number, and link their data with HES and laboratory data. Patients who were discharged from hospital would receive a letter from the clinical care team seeking consent on behalf of the researcher. A recommendation of support for classes one, four, five and six was requested in order to access deceased patient identifiable information without consent. The applicant intended to access medical records of patients who died as a consequence of BSI in order to extract name, NHS number, date of birth and hospital ID number, and carry out linkages. The aim would be to recruit 5,000 patients and it was estimated that approximately 1,000 would be deceased.

Following consideration of this application through the ECC fast track process (applications for access to deceased patients data), Members acknowledged the strong public interest in this activity. Members noted that the question of accelerated laboratory diagnosis of infection was topical and the study design raised an interesting question regarding the effect of excluding part of a study population as a consequence of lack of consent, itself a consequence of death before consent could be obtained. Members noted that a comparison of microbiological and clinical data from those who die and those who survive must be pivotal to understanding the benefit of quicker identification of causative organism provided by the newer technology being investigated. The Committee noted that the inclusion of data from patients who die was of central importance, as these individuals might provide the most informative data for the study outcome. It was agreed that access to records was essential to address the aims of the study. Members agreed that seeking retrospective assent from relatives or personal representatives would be inappropriate and distressing in this specific case.

Members considered the issue of living patients who did not consent to participate in the trial and the applicant's proposal to retain the randomisation number (unique study number), gender, age (not date of birth) and laboratory number for these patients. Members felt that laboratory number could potentially identify patients and therefore should not be retained for living patients who did not consent. Members agreed that laboratory number could be collected for deceased patients under this support. The Committee commended the patient and public involvement carried out for this study, particularly the applicant's initiative to amend the design of the study following patient suggestions. In line with the considerations above, the Committee agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised the Secretary of State for Health to approve this application, subject to the condition that reasonable steps should be taken to inform relatives of deceased patients about this study and make provisions for them to opt out on behalf of their deceased relatives if they so wished.

ECC 3-02(FT6)/2012 Surgically ligated patent ductus arteriosus in premature babies

This application from Nottingham University Hospitals NHS Trust set out a study which aimed to find out the number of premature babies in the UK referred for a patent ductus arteriosus surgical ligation, their age when they had surgery and their health status before and after operation. The researcher would use the British Paediatric Surveillance Unit (BPSU) methodology to collect patient identifiable data without consent. BPSU orange cards would be sent to every paediatrician in the UK and returned to BPSU. Paediatricians who selected 'surgically ligated PDA in premature babies' would receive a questionnaire from the applicant requesting patient's NHS Number, date of birth, sex, ethnicity, date and cause of death (if applicable), hospital number, hospital where baby received care and other clinical data. Patient identifiable data would be stored separately from clinical data and a unique number assigned to each patient. The information would then be analysed by the researcher and the findings published in anonymised format. The cohort size was 250 patients.

Members agreed that the issue was an important one and the results would have a direct impact on advice given to parents in relation to the risks and benefits of early litigation in premature babies. It was noted that seeking consent would be particularly difficult as babies would have already been referred to cardiothoracic units when the BPSU surveillance card was received by the paediatrician. Members were pleased to note that identifiable data items would be separated from the clinical information as soon as possible. Members noted that the public information leaflet provided did not include any information regarding how a patient could opt out of the use of their data and advised that any support provided under the Regulations could not be used to override dissent. Members requested that patient information leaflets were updated to inform patients how they could dissent from the use of their data and that local clinicians were informed that any dissent should be respected. The Committee agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending provisional support to the Secretary of State subject to amending the public information leaflets to include details on how to dissent.

ECC 3-02(FT7)/2012 Study of avoidable variations in weekday hospital mortality

The application from Western Sussex Hospitals NHS Trust detailed a case control study investigating the variations in hospital mortality rates. It would compare weekday and weekend admissions and attempt to identify opportunities for improvement in hospital outcomes. The study included patients admitted to two hospital sites, Worthing Hospital and St Richard's Hospital. Confidential patient information was requested in relation to 120 patients who had died in hospital on a weekend and 120 patients who had died in hospital on a weekday. Support was requested to allow the public health practitioners, on honorary contracts with the trust, to access pseudonymised patient data in order to extract a dataset which included date of death, gender and ethnicity. Members discussed the alternatives available to the applicant and noted that consent could not be sought for this retrospective data collection, which sought to access data relating to deceased patients only. In addition, it was agreed that the data extraction tool was complex and required a level of judgement, which meant that it would be difficult to train clinical staff to carry out the extraction in a way that would provide reproducible results. Members were pleased to note that reasonable efforts would be made to ensure that patient confidentiality was respected following the extraction of information for analysis and agreed that the exclusion criteria were appropriate. Members noted that children would be excluded from analysis and advised that this should include those patients up to the age of 18. Members agreed that the minimum threshold of the regulations appeared to have been met and agreed to advise support to the Secretary of State.

ECC 3-02(FT8)/2012 Hypertension & CKD in Kent Studies (HyCKS)

This application from East Kent Hospitals University NHS Foundation Trust (EKHUFT) detailed two studies. Support was sought for the second study as the first detailed a methodology where

anonymised data was automatically extracted. The second study required NHS number to be used to allow linkage between data held on the System for Early Identification of Kidney (SEIK) disease database and data from EKHUFT PAS, EKHUFT Pathology and Ambulance Service databases. NHS number would be removed once the datasets were linked and the resulting dataset would then be anonymised. Members were supportive of this application and agreed that the specified activity was in the public interest. They were pleased to note that the only identifiable data item used for linkage was NHS number, which would be deleted once linkages were completed. As the disclosure was minimal and the public interest high, Members agreed to recommend support to the Secretary of State.

Amendments

PIAG 4-08 (c)/2003 - Maternal, Newborn and Infant Clinical Outcome Review Programme (MNI-CORP) (Previously CMACE) Application to examine and analyse existing legacy and interim data collection.

This amendment indicated that the National Perinatal Epidemiology Unit (NPEU) had been contracted by the data controller, the Healthcare Quality Improvement Partnership (HQIP) to undertake examination and analysis to assess the validity and completeness of MNI-CORP data previously collected by CMACE, and the interim data collected since the end of the CMACE contract that ended on 31 March 2011. This exercise would be conducted over a six month period. The purpose of this exercise would be to reach a view as to whether the data would be sufficiently robust to carry out further audit work, as the data had previously been unprocessed and unreported. It was considered that this exercise would be essential in ensuring the data was sufficiently robust in order for further analyses to be carried out, and therefore it was advised that support should be provided for this six-month period.

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

This amendment set out the issue that notification of deaths from suicide or open verdicts were currently obtained from ONS on a quarterly basis. Apparently there was an administrative delay in receiving data from ONS, leading to delays in following up potential cases with Trusts. The amendment specified that there would be no changes to any data items currently collected and approved within the Inquiry. However, it set out a change of data source: Medical or Clinical Directors would be asked to notify the Inquiry directly if there was a relevant inpatient death. This would facilitate the obtaining of data on inpatient death in 2011 so as to report more current numbers and trends related to deaths in psychiatric inpatient facilities in the 2012 annual report. This process would operate in parallel to obtaining data from ONS. The advice from the Chair was that such a disclosure would be a discretionary one by the appropriate Director. Ideally, such a Director should also be the appropriate Caldicott Guardian within each Trust. As there was no change to the requested data items, only the source, and as this would be a discretionary disclosure by the relevant Trust, the Chair advised that the current recommendation of support could be extended to cover this aspect if such a Director wished to rely upon this legal protection, but in effect this amendment did not constitute a significant change from the details already approved. It was also noted that the relevant REC had confirmed their acceptance of this change.

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

This amendment confirmed that the Manchester Self-Harm (MaSH) project collected psychosocial and demographic details of individuals presenting to three Greater Manchester Emergency Departments following self-harm. The Medical Research Information Service (MRIS) traces these individuals and provides monthly mortality updates (MRIS ref: MR1135), allowing the Project to carry out research on causes of mortality and, in particular, suicide following self-harm. The current support under the Regulations allowed the project to receive monthly mortality updates from MRIS on the cohort of patients first presenting with self-harm between 2000 and 2009. This amendment specifically requested an extension to the MRIS mortality updates to cover the cohort of patients first presenting with self-harm in 2010, and followed on from a detailed review of an amendment presented in February 2011. As this represented an update to the existing support, it was agreed that a recommendation of support would be

provided to the Secretary of State, on the condition that further funding, once confirmed, would be provided so that the application could be updated with a definitive timescale for continuation of the study.

PIAG 1-05(c)/2007 Linkage of National Cancer Registry data to national Hospital Episode Statistics (HES) data

The Cancer Survival Group holds a 5-year programme grant funded by Cancer Research UK. This is a programme of applied public health research which aims to produce a comprehensive range of information on patterns of cancer survival, their impact on the population and provide insight into the extent and the causes of inequalities in the outcome of cancer treatment. It also aims to evaluate the population impact of strategies designed to improve survival or to reduce inequalities in outcome. In 2007 PIAG advised approval for linkage of individual tumour records from the National Cancer Registry at ONS with individual HES records for all patients in England from 1989 up to the most recent year of diagnosis available, 2005 at the time. The applicant had since submitted a series of amendments to cover patients 0-14 years old from 1971 -1988, receive data from the National Cancer Intelligence Network (National Cancer Data Repository), include patients diagnosed up until 2010 and to receive data from the Bowel Cancer Audit, Lung Cancer Audit, Head and Neck Cancer Audit managed by the IC's Clinical Audit Support Unit. The applicant submitted two further amendment requests.

The applicant requested an extension to collect three additional data items from HES for all cancers: GP practice code, patient registered or referring general medical practitioner code and consultant code. Support was already in place to process NHS Number, date of birth, postcode, sex, date of diagnosis and date of death of patients. The extension stated that the characteristics of the General Practitioner and the GP Practice might influence the diagnosis and treatment pathway, and ultimately the cancer outcome (survival). The qualifications, specialty and experience of the consultant (all information publicly available) might influence the tumour staging and treatment options and then the cancer survival. It was confirmed that publication would not identify any particular practice, GP or consultant.

The applicant requested to add individual level data on radiotherapy from the NHS National Radiotherapy Dataset (RTDS) to the National Cancer Registry data linked to HES. The RTDS covers the whole of England since 2009 and includes for each patient: date(s) of radiotherapy delivery, prescribed doses and fractions, delivered doses and fractions. In addition to these items, the applicant would receive NHS Number, postcode, date of birth and sex from RTDS to carry out linkage with the records held by the Registry. This was justified against the aims of measuring and assessing access to and delivery of radiotherapy in the UK, identifying the disparities in radiotherapy between regions and between deprivation groups using individual data for all cancer patients, including those who were not referred to radiotherapy.

The reviewers noted that the applicant was not seeking additional identifiers but "sensitive" items as defined within HES, particularly codes that identified GPs and consultants. The Committee highlighted that in considering these sensitive items it was important to be aware of why they might be considered sensitive i.e. possession of these sensitive items might make identification of the patient more likely. The GPs and consultants had no general right to confidentiality in respect of their public role although it was not considered appropriate or in the public interest generally to name them. However, for the purposes of audit (and this could be considered partly audit) and service assessment Members agreed that it was appropriate to use their codes. In this case, as the applicant already had support to process patient identifiers, the use of these codes for doctors would not render patients any more identifiable. Therefore, given the clinical importance of this activity and the reduced impact on patient identifiability, the reviewers were supportive. It was advised that, in future, the applicant should consider the use of de-identified data taking into account technological developments, or move towards a consent approach. Members suggested that new technologies would reduce the need to process patient identifiable information without consent or at least reduce

the number of identifiers needed to carry out this activity. In line with the considerations above, the Committee agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support for these two amendment requests to the Secretary of State, subject to provision of favourable opinions from the relevant RECs for the amendments as necessary.

ECC 2-02 (a)/2011 – UK Lung Cancer Screening Trial

This application from the University of Liverpool had previously set out the purpose of piloting a randomised cancer screening trial. This aimed to provide an evidence base for the possible introduction of population screening for high risk patients with lung cancer. A recommendation of support was sought to permit access to patient identifiable data from PCTs so as to ascertain eligibility and to facilitate the sending of invitations by RADAR to the eligible population. In particular, access to NHS Number, name, GP registration, date of birth, gender, address and postcode had been requested and approved. Approval had previously been provided for a pilot phase to contact 82,000 (50-75 years old) patients by sending them a questionnaire which they could complete and send back to the trial.

This specific amendment sought to access an additional 160,000 patients in order to ascertain eligibility and facilitate sending of invitations to participate in the trial. This would take place in six PCTs. According to the applicant, the methodology, design and identifiers collected for the trial were exactly the same as stated in the original application. When the original application was submitted the applicant predicted that approaching 82,000 patients would provide the trial with 29% of patients meeting 5% Liverpool Lung Project (LLP) risk score (patients with high risk of lung cancer), a total of 4,000 individuals. However, only 11% of patients who completed the questionnaire met the risk score criteria reducing the prediction to 1,386 – 1,604 individuals. This was the reason why the applicant sought to approach an additional 160,000 patients so that they could potentially reach their target of 4,000 patients. This request was considered by the Chair and it was agreed that the minimum criteria under the Regulations appeared to have been met, and therefore the Secretary of State was advised that the application should be approved.

PIAG 1-07(c)/2004 UK Renal Registry

The UK Renal Registry (UKRR), part of the Renal Association, has been established to report on Established Renal Failure service provision, management and outcomes in the UK. The UKRR collects data on all patients with Established Renal Failure (ERF) in the UK. This information is subsequently analysed and published in a publically accessible annual report and plays an important role in improving the care and outcomes for patients with advanced kidney disease. Data is sent quarterly by renal units to the Registry using a secure electronic method. The UKRR currently has an established link with NHS Blood and Transplant to allow information regarding renal transplantation to be shared between the two organisations. In 2004 the Patient Information Advisory Group had provided support for the UKRR to receive and process patient identifiable information, i.e. name, address, postcode, date of birth and ethnicity, without consent.

UKRR submitted an amendment request to pilot linkage of UKRR dataset with MRIS to collect cause of death and cancer registration data (i.e. date of diagnosis and primary cancer diagnosis (ICD)). NHS Number would be disclosed from UKRR to MRIS for linkage. Currently the UKRR collects cause of death information electronically from the Renal IT system of an individual's recorded renal centre. The data recorded is physician reported, and therefore may differ from the cause of death recorded on the death certificate. Data completeness was indicated to be poor at around 50%; this in part reflected patients dying at a location other than their renal centre. Accurate and complete mortality data would strengthen UKRR analyses and allow more valid conclusions to be made. This request was considered by the Chair and the ongoing work to ensure that the NHS Number was available in legacy datasets was welcomed, along with plans to reduce the number of

identifiers used by the UKRR, for example, name. The Chair agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending provisional approval to the Secretary of State for this amendment subject to amendment of patient information materials to include disclosure of NHS Number to the Health and Social Care Information Centre (IC) and receipt of mortality and cancer registration data from the IC.

ECC 5-07(b)/2009 Prescription Event Monitoring

This application had previously received support to carry out a surveillance monitoring system to detect, assess, prevent and manage the risks of adverse effects of recently marketed medicines. The Drug Safety Research Unit conducts pharmacoepidemiological studies using the technique of prescription event monitoring. The amendment detailed a request to carry out linkage with MRIS data in order to receive mortality data. DSRU would provide first name, surname, sex, year of birth, address including post code and date of death to MRIS (NHS IC) to receive back date of death (confirmation), cause of death and the underlying cause of death. The Chair noted that this would not increase the identifiability of the DSRU dataset and therefore advised this amendment request should be approved.

PIAG 1-05(d)/2008 European Prospective Investigation in Cancer (EPIC-Oxford)

This application from the University of Oxford for the EPIC study detailed the primary aim of examining the associations of nutritional factors with common diseases. The study involved 65,000 men and women who had provided consent to participate in the study. The purpose of the application was to enable the applicant to increase the scientific value of EPIC-Oxford by obtaining information from the HES database for disease outcomes rather than cancer, such as cardiovascular diseases and musculoskeletal disorders. Support under the Regulations had been obtained to allow linkage with HES in 2008 to collect name, address, date of birth, NHS number, details on diet, lifestyle and health, information on hospital admissions and procedures performed. The amendment request sought to extend support in order to allow the linkage of PEDW data without consent**.** This amendment request was considered by the Chair who noted that the original application included linkage to HES data and therefore this was essentially a geographical amendment to include PEDW data for patients within Wales. The Chair therefore advised the Secretary of State that the geographical amendment should be approved.

ECC 1-06(c)/2009 Clinical Audit Support Unit (CASU) – formerly National Clinical Audit Support Programme (NCASP) – National Paediatric Diabetes Audit

This request from the Health and Social Care Information Centre (HSCIC) detailed a time extension to the above approval for the National Paediatric Diabetes Audit. This was to allow transitional arrangements to be put into place for the transfer of data to the Royal College of Paediatric and Child Health (RCPCH) once approval was in place. It was anticipated that this time extension would be required until the end of June 2012. It was noted that the application for the National Paediatric Diabetes Audit from RCPCH had been submitted to the March 2012 ECC meeting and had been provisionally approved pending a security review. It was therefore considered appropriate that the HSCIC continued to hold the data until the necessary approvals were in place for the RCPCH to take responsibility for the data. This request was considered by the NIGB Office.

Update on previous applications

ECC 1-05(b)/2012 – ALSPAC Study Young Adults: Enrolment and Consent for Record Linkage

This application was considered at the February ECC meeting where the Committee had sought confirmation how additional data sets including benefit, employment, education and criminal data

would be linked to health data. It was confirmed that linkages of would take place through a data safe haven. Arrangements to link with Department of Work and Pensions data and Her Majesty's Revenue and Customs data were still to be finalised. However it was confirmed that in all circumstances linkages would be undertaken with the data controllers permission using a third party linkage service and linked using ALSPAC ID. The Committee had also asked for clarification on how individuals would be able to dissent from further inclusion in the ALSPAC cohort now and in the future and how they would be informed of this right on an ongoing basis. It was confirmed that each newsletter sent to ALSPAC participants would include details of how individuals could contact ALSPAC to opt out if they wanted to. The responses were forwarded to the original reviewers of the application and the Chair who confirmed that support would now be recommended to the Secretary of State, subject to the conditions specified at the February 2012 meeting of the Committee.

ECC 1-05(a)/2012 End of Life Care Repository

The application was considered at the February meeting where Members had requested clarification, prior to advising support, regarding the feasibility of the Health and Social Care Information Centre (HSCIC) carrying out provision of data and pseudonymisation of NHS number on behalf of the applicant. Provision of data was to be for all patients recorded on the ONS PCMD (within the specified time frame) linked to the ONS Communal Establishment data and ONS LSOA data. For those patients admitted to hospital prior to their death, provision of HES data linked to the ONS PCMD was requested. The pseudonymised NHS number within the dataset was required to use a method that, if required in future, could be repeated to allow future linkage to other data. The HSCIC were able to replace full postcode with LSOA, 4 digit postcode and establishment code of residence which is an appropriate replacement for full postcode for the purposes of analysis. These are not classed as sensitive fields by the IC. NHS number would be replaced with an encrypted NHS number key by the IC who would retain the ability to unlock this key to allow future linkage of data within the End of Life Care repository as per the details within the NIGB application. Patient General Practitioner would be replaced with GP Practice Code. It was confirmed that the HSCIC did not have access to the ONS PCMD and those ONS death registrations which the HSCIC did hold could not be released due to current contractual arrangements. Further discussions would take place with ONS and the outcome would be reported to the ECC in due course. Members agreed to recommend partial approval.

3. New applications

3a. SAFER2 – support and assessment for fall emergency referrals [3-03(a)/2012]

This application from the University of Swansea followed on from a pre-existing randomised clinical trial. This trial set out to assess the costs and safety benefits of introducing protocols for emergency ambulance paramedics to assess and refer older people who had fallen to appropriate community based care, and to compare the outcomes, processes and costs of care between intervention and control groups. This application had previously been considered by the Committee in 2009, and following advice, the approach to consent had been amended so that it was sought by ambulance staff and a further application at that time was no longer necessary as there would be no breach of confidentiality. This particular application sought support to enable the ambulance services at two sites to provide patient identifiers and a unique study identifier to the Trusted Data Linkage Service (TDLS) at the Health and Social Care Information Centre. The TDLS would link routine HES and ONS data with clinical data, anonymise it and return it to the Secure Anonymised Information Linkage service based at the University of Swansea. Name, full postal address, date of birth and gender would be required for linkage purposes. Members noted that the rationale for this request was to provide statistically significant outcomes in order to complete this randomised controlled clinical trial. Following a recruitment phase over a twelve-month period and from the 4,000 participants invited, only 23% had provided consent to follow-up. It was noted that participants had been provided with two opportunities to provide consent, and also had the opportunity to opt out of identifiable follow-up. The rationale for the application was that the current consented population did not provide a large enough sample to statistically validate the outcomes and

was likely to be biased in favour of younger, healthier patients, so outcomes could not be extrapolated to the wider population. Support was therefore requested to allow follow-up for those who had not responded to the requests for consent and those who had not provided consent.

Members were sympathetic to the situation, noted that all reasonable attempts had been made to obtain consent, and appreciated the difficulties involved within this specific patient group. It was also agreed that without producing statistically significant outcomes, essentially the trial would be unable to deliver an outcome, and it was agreed that it would not be in the public interest for this to occur. However, one of the standard conditions of support advised by the Committee is that support under the Regulations cannot be used to override pre-existing dissent. In line with this, Members concluded that for those who had already been contacted and had explicitly refused consent, that support could not be advised as it would in effect be countermanding their expressed wish not to be included in identifiable follow-up. While the application requested follow-up in a de-identified format, Members were of the view that to recommend support for this aspect would be going against the spirit of the expressed dissent. Where participants had not been able to be contacted, or had not responded, Members were of the view that they had expressed neither consent nor dissent. It was for this group that the Committee advised they would be sympathetic to recommending support due to the public interest in obtaining a statistically significant outcome from the trial.

While the Committee were provisionally supportive in relation to this latter group, before providing their final recommendation to the Secretary of State, they requested clarification in relation to the tranche of patients who had not been contacted or had been contacted but had not responded. Clarity was sought on the methodology used for defining and recording dissent; confirmation of the specific number of patients, or proportion of the study group, that had not explicitly dissented; and whether the application related to the retrospective cohort of 4,000 alone or whether there was a prospective element. Finally, the Committee reiterated that approval under the Regulations applies only to patients treated in England and Wales.

3b. Extraction, linkage and anonymisation of Islington GP data to hospital admissions data [3-03 (b)/2012]

This application from Islington Primary Care Trust (PCT) set out details of the creation of an anonymised dataset linking Islington GP data, hospital admissions and demographics to enable population level analyses. Outputs from the analyses would be used to inform commissioning and strategic decision-making by Health and Wellbeing Partners in Islington. The application requested access to full postcode from GP data to enable linkage to lower super output areas for deprivation analysis. NHS Number was also requested to enable linkages between GP records and hospital admission records. The data would be anonymised once linkages had taken place.

Members agreed consent would not be practicable due to the large numbers involved of approximately 218,000, and that the overarching purpose of the application was a medical one as defined within the Regulations. They considered there to be a wide variety of purposes within the application and they were not clear whether they all supported secondary uses. In particular, Members noted the use of prescribing and mental health data. Members queried whether this aspect was being carried out in compliance with NICE guidelines and therefore could be considered more of a local audit. Due to the questions raised, Members suggested exploring the purposes further and identifying whether they could be discharged through other means rather than relying upon this support. While broadly supportive of this activity, comments were raised in terms of the changing landscape for PCTs and it was noted that there was a lack of clarity on what would be the statutory successor organisation to the PCT. Members were therefore clear that they could only recommend support for the PCT as the appropriate custodian of the data, and that the support would last only until 31 March 2013.

In reviewing the dataset, whilst the application stated that an anonymised dataset would be used once linkages had taken place, Members highlighted that the richness of data items could lead to potential re-identification through 'jigsaw identification'. This was of primary concern to Members and they advised that the final dataset should be handled as if it were identifiable. It was considered that diligently following guidance from the Health and Social Care Information Centre, such as small number

suppression and disclosing age in bandings, should mitigate against this risk. Clarification was requested on the specific safeguards the applicant would put into place to manage this potential risk of re-identification, particularly with regard to sensitive data and/or children. Clarification was also sought on arrangements for ownership of the database and related activities following the abolition of PCTs after 31 March 2013; fair processing information provided to patients by GPs; and a time frame for the rollout of EMIS Web, which would enable the use of fully anonymised data in future. In conclusion, the Committee advised they were broadly supportive of this activity, and subject to satisfactory responses to the requests for clarification, agreed to recommend provisional support to the Secretary of State.

3c. Biobank collection [3-03(c)/2012]

This application from the Christie NHS Foundation Trust detailed the establishment of a research tissue bank for patients with all types of cancer, under the title of the Manchester Cancer Research Centre Biobank. Support was requested to cover access to local hospital records and cancer registry data for those patients whose tissue samples were stored within the Biobank pre-2006; provide a legitimate basis for Biobank staff to access local patient lists to identify which patients to approach for consent prospectively; and cover handling of samples collected post-2006 to the present. Where data was required for a specific project then the Biobank team would contact the local care team to undertake the consent process. It was understood that there was a need to access identifiable data to link to clinical records so as to create follow-up data for this subgroup (pre-2006), and that this would require access to local hospital and cancer registry databases. Currently samples were held in a link anonymised format and as the Biobank staff did not have access to identifiable information, these staff would need to request the linked demographic data from hospitals to allow further records to be accessed. Biobank staff would carry out data extraction at local sites, and requests for follow-up data on individual samples would be on a project specific basis. Anonymised data would be released to the collaborators (age, gender, ethnicity and clinical information).

Members noted that access to tissue was governed by the Human Tissue Act and therefore outside the remit of the Committee's consideration. However, access to the relevant data would require a legitimate basis. It was agreed that this aspect would constitute a valuable resource, that tissue is of limited value without accompanying data, and it was likely that this could include large numbers, deceased patients or patients who would be hard to track. It was agreed that there was likely to be no other reasonably practicable method to carry out this specific aspect, therefore Members agreed to recommend support to this aspect for access to data for the pre-2006 cohort.

The prospective aspect for patients treated post-2006 sought approval for Biobank staff to request information about patients around their potential diagnosis and when they would next present to hospital in order to identify whether they would be suitable to be included within the Biobank, before approaching them for consent. Members noted the view that researchers would need to consent the potential participant as only certain patients would be eligible and this would be dependent upon the projects received by the Biobank. Currently, care teams sought consent but the application stated that this was not a successful approach and there was currently a low level of obtained consent. Members considered the stated arguments for consent to be carried out by the Biobank staff not to be sufficiently persuasive. However, after detailed review and finely balanced arguments over the potential utility of the Biobank resource and public interest considerations, it was proposed that the medical usefulness of the Biobank was such that it warranted an approach by the researcher in the first instance. This was with the caveat that there should be strict controls in place for the Biobank staff, including operating under NHS contracts and governance arrangements. Members also took into account that the Biobank staff would have limited access to identifiable data before seeking to obtain consent. It was noted that this advice deviated from the Committee's usual principle, and that it could not be considered to set a precedent for other applications. Members also advised that a pilot study should be carried out in relation to this cohort where those having a biopsy should be provided with information stating that it would be used for research within the Biobank, and this would represent an effective exit strategy from the operation of this support, although Members indicated that ethical issues around coercion should be considered within this pilot.

Noting that the consent process for samples collected post-2006 would be managed by the local care team, Members were unclear whether a recommendation of support would be required for this aspect as it was unclear where the breach of confidentiality would occur. It was noted that no research projects had as yet been defined and that researchers would not receive identifiable data for their research projects. Members therefore agreed to defer their advice on this aspect until further clarification had been obtained. Members strongly advised that there should be greater public/lay involvement on the future use of the Biobank as it was relatively limited at present, although the patient leaflet was seen to be very good.

Members suggested that prospectively, the applicant might wish to obtain death data from the Medical Research Information Service (MRIS). It was suggested that if wished, the applicant should engage with the Health and Social Care Information Centre to identify suitable wording for inclusion within the consent form on a prospective basis, and that the NIGB Office could provide the relevant contacts. Members noted that onward disclosure to researchers would be in a de-identified format, but advised that there should be strict governance controls around this, such as ensuring researchers sign up to an agreement preventing re-identification. It was highlighted that the Health and Social Care Information Centre employed a HES protocol that could usefully be adapted to manage such risks. Members also emphasised that any disclosure of data overseas should be in a de-identified format and should be carried out in line with the Data Protection Act 1998.

In conclusion, Members agreed to recommend provisional support to the first two aspects of the application, subject to clarification on the methodology and consent process for the control aspect and on disclosure issues and potential need for support relating to the third arm of the study. Following this clarification, support would be conditional on a renewed favourable opinion from a research ethics committee, as the previous one had been obtained in 2007 for a five year period, and on commitment to carrying out a pilot study within the next twelve months for the prospective arm where consent was obtained at the point of biopsy, or alternatively where referrals were received for clinical staff looking after the patient, for an appropriate consent process to be built in.

3d. Pre-hospital Outcomes for Evidence Based Evaluation (PhOEBE) [3-03(d)/2012]

This application from the University of Sheffield set out a study to develop new methods of measuring the impact of ambulance service care. In particular, it aimed to measure how well ambulance services perform and the quality of care provided; develop a set of outcome measures to be used by ambulance staff to measure quality; and investigate whether a risk-adjustment model could be used to measure the effectiveness and quality of pre-hospital care. Support was specifically requested to enable the transfer of patient identifiable data from East Midlands and Yorkshire Ambulance Services to the Health and Social Care Information Centre. Ambulance dispatch data would be linked with HES, HES A & E and ONS data by the Trusted Data Linkage Service, and anonymised data would be provided to the applicant. NHS number, date of birth, sex and postcode would be supplied to the TDLS. Name and postcode would be required to enable the Health and Social Care Information Centre to trace NHS Numbers where these were not present. Members noted that GP registration was requested to enable linkage to primary care data (this aspect is highlighted later). The applicant would receive date of death, district level postcode, gender, ethnicity and age for analysis purposes.

The Committee agreed that consent was not feasible due to potentially large numbers and that seeking retrospective consent would be difficult. They also agreed that the methods employed were robust, the risks to confidentiality small and the outcomes likely to be in the public interest as it was important to understand and audit the work of the ambulance services. User involvement was also considered to be good. Members noted that approximately 50% of the cohort would not have NHS Number attached, and therefore it would be reasonable for the transfer of relevant data items to enable the TDLS to carry out tracing. Members reviewed the request for use of GP registration for the purpose of linking to primary care data in approximately 18 months. This was a secondary aim of the study and the application indicated that linking to primary care data was a new area and that it would take time to develop the methods and determine data sources. Members highlighted that the Committee must be clear on what it was advising against, and due to the stated and understandable level of ambiguity, agreed that they were not currently in a position to advise support to this aspect. They advised instead that this aspect be

excluded from the current consideration, and an extension to the current application should be submitted nearer the time once data sources had been investigated and confirmed. Following on from this, Members sought clarity over the retention of data as it appeared to be held to meet the secondary aims of the project.

As a whole, Members were very supportive of this activity, and agreed to recommend support to the Secretary of State for Health, pending clarification on fair processing information given to participants in line with the Data Protection Act 1998; the proposed lifetime of the study, excluding linkage to primary care; the revised data retention period in light of the Committee's recommendation regarding linkage to primary care; and potential issues around respecting dissent, if a patient's dissent was recorded within hospital notes but not ambulance service notes. Members reiterated that the arm of the study relating to linking to primary care data in approximately 18 months was excluded from this advice and provisional approval, and encouraged the applicant to submit a separate application at the relevant time to cover this aspect in the future.

3e. Mitogent study [3-03(e)/2012]

This application from University College London's Institute of Child Health detailed a case control study investigating whether the genetic variant contributes to hearing loss in babies of less than thirty one weeks. Support was requested for research nurses to have access to identifiable patient information in order to identify eligible participants (cases and controls). In particular, access was requested to name (child and parent), NHS Number, hospital ID, date of birth, date of death and full postcode. Members appreciated that there was a very high public interest in this activity being carried out, and that it was a well-thought out study. They noted that essentially that the study was looking for a very small proportion from a very large population and cases would require multiple ascertainment. The importance of identifying highly matched controls based on date and demographics was highlighted; therefore the Committee was mindful of the need to have access to various sources for this complex activity. As this application related to the 'consent for consent' issue, Members agreed that access to patient identifiable information would be required due to a situation of multiple ascertainment. In discussing whether there was a practicable alternative, Members queried whether this activity could be better placed under the BPSU methodology where information could be sent to clinicians who could check for amino glycoside exposure and send de-identified information back to the research team. However, it was agreed that this would be difficult and therefore not practicable.

While broadly supportive of this activity, Members queried the role of Professor Marlow and whether it was appropriate for a cover letter to go out in his name rather than a clinician in the relevant unit. It is a principle of the Committee that initial contact should be made by someone 'known' to the patient, therefore Members specifically requested that a cover letter should go out in the name of the paediatrician within the relevant unit. Members also noted the retention period was vague within the information leaflet, but that information would be retained for a longer period should a further research project be identified. Members agreed that the information leaflet should make clear, in line with the application form, the precise nature of retention so that the information was clearly retained with consent. In conclusion, the Committee agreed to provide a recommendation of support to the Secretary of State, subject to the above changes.

3f. Mycobacterium abscessus in Cystic Fibrosis [3-03(f)/2012]

This application from Papworth Hospitals NHS Foundation Trust set out to investigate the biology of the organism *mycobacterium abscessus*; to identify whether there was a clinical correlation between its genetic makeup, how it appears in the laboratory and disease patterns. In particular, it was being investigated as it was emerging as a cause of infection in patients with inflammatory lung disease, and in this instance, patients with cystic fibrosis. Support was requested in order to provide a legitimate basis for the researcher to extract patient identifiable data; name, NHS Number, hospital and laboratory ID. Members noted that the study involved a relatively small cohort size of 600 patients, and in considering the methodology, noted that it involved one researcher travelling to multiple units in order to extract information. Members queried why the units could not extract the relevant identifiers as this seemed feasible, and cited the example of the BPSU methodology whereby local or treating clinicians identify

relevant cases and extract relevant information, and de-identified information is then transferred to the researcher using a unique study ID. Members considered that this methodology could be applied here without any breach of confidentiality and therefore advised reviewing the methodology via the BPSU website (http://www.rcpch.ac.uk/bpsu) and adapting it in line to meet the needs of the study. Members noted that the Committee's remit applies only to England and Wales, not Northern Ireland, and highlighted a need for significant improvements in order to meet the fair processing requirement of the Data Protection Act 1998 through providing relevant information via clinicians to the cohort.

In conclusion, the Committee advised that they would not currently be able to recommend support to the Secretary of State for Health as a different methodology could reasonably be employed, following a similar version of the BPSU approach, that would not involve a breach of confidentiality. It was advised that the applicant engage with the BPSU team to discuss how their methodology works, and to adapt it to these specific circumstances.

3g. The PAINTED study [3-03(g)/2012]

This application from the University of Sheffield set out details of a prospective observational cohort study of patients attending emergency departments with suspected pandemic influenza so as to evaluate existing triage methods, identify clinical predictors of adverse outcomes and to develop new triage methods. The application comprised two specific aspects: the transfer of identifiable data to research nurses for a pilot phase of the study, to take place between June 2012 and May 2013, and a pre-emptive application in the event of a pandemic in Autumn 2013. The application requested access to NHS Number, hospital ID, date of birth and date of death by a research nurse. Members indicated that the application detail focused primarily on a future, unspecified pandemic situation, and a smaller aspect on the requirement for a pilot phase to test data capture and collection. Following review, the pilot phase formed the main part of the Committee's consideration.

Members noted that a similar application had previously received a recommendation of support in 2009 [ECC 5-02(FT3)/2009]. However, they highlighted that the 2009 application had received a recommendation of support via fast track as there was a current and real urgency to have the application considered due to the level of risk the pandemic influenza A/H1N1 might have presented. Members considered the situation to be different at this time as there was no current or pressing risk of pandemic. In terms of providing support for an as yet unspecified date when an influenza pandemic might be in operation, having taken advice, the Committee noted that they were unable to provide a recommendation of support to that specific aspect. The reason for this was that the process to lift the common law duty of confidentiality might have significantly changed by the time the pandemic could potentially be in place, and as the NIGB would no longer be administering the function after 31 March 2013, the Committee determined that they could not provide advice for events taking place significantly after that time. Members therefore advised they were unable to advise support to this specific aspect. Once arrangements for the future administration for such applications were confirmed, these would be communicated by the relevant organisations.

In reviewing the pilot phase, it was noted that this was being carried out as the 2009 project had been undertaken in response to the emerging pandemic and could not incorporate a pilot phase. The current proposal set out the opportunity to undertake a pilot phase in 2012-13 to ensure that some of the problems encountered in the 2009 project were pre-empted prior to a possible future pandemic. In relation to this aspect the Committee agreed that this was laudable and entirely appropriate that methods for testing the process were carried out, and that it was an essential part of pandemic management to plan for such events and this was to be commended.

As the majority of the application appeared to be focused on an actual pandemic situation, Members indicated that the information presented for consideration might not be truly reflective of what the pilot stage was intending to achieve. While Members agreed that consent during an actual pandemic would not be feasible, they were mindful that this related to a pilot phase. The implication was therefore that the potential cohort would be significantly smaller and as there would be no risk of pandemic, that considerations over feasibility of consent would differ. Members suggested amending the form and information to make clear that this was a pilot to test the process that would be used in a real pandemic

situation. Appreciating that the application did not provide explicit detail on the pilot activity, Members however concluded that the predicted small numbers and lack of pandemic situation meant that consent should be feasible. As this represented a reasonably practicable alternative to breaching confidentiality, Members advised that a consent based approach should be pursued for the pilot phase.

3h. Chlamydia Screening Mailout to 18-24 year old men in North of Tyne [3-03(h)/2012]

This application from Newcastle Upon Tyne Hospitals NHS Foundation Trust (chlamydia screening programme) set out the aim of increasing the uptake of chlamydia screening in men and women aged between 20 and 24 as these are considered a high-risk group, so as to reduce onward transmission. It also set out the aim of measuring return rates and identifying prevalence within this population. Support was specifically requested so as to enable access to the cohort's contact details from the PCT, and for the transfer of these details to a third party, so as to enable the third party to send out chlamydia testing kits on behalf of the Trust for this one-off activity covering 5000 persons. Completed tests would be sent to the Health Protection Agency. To enable the information to be sent, access was requested to name, full postal address, age and gender.

Members noted that the service was originally managed within the PCT, but due to various changes it was now based within the acute setting, and therefore the Trust would need to access the contact information held by the PCT as local advice had indicated that there was no longer a legitimate relationship to enable the Trust to have default access to the contact information. In essence, support was requested to enable access by Newcastle upon Tyne Trust to the PCT datasets, which would subsequently be transferred to a data processor who would send out the relevant information. While sympathetic to the situation and appreciating why an application had been made in order to seek clarity over the issue, it was indicated that to advise support in this instance could set an unhelpful precedent in terms of applying support. Support under these Regulations is a measure of last resort in order to carry out essential NHS activities when there is no other practicable alternative. The primary reason for this application had arisen due to organisational changes occurring within the PCT and Trust, and a subsequent change in a 'legitimate relationship'. As organisational changes were expected to be extensive in the future, Members agreed that to recommend support in this instance would be to set a precedent that would not be productive in aiding the NHS to manage such changes.

Noting that the selection of the cohort was not based against any clinical information and was in effect a random sample, Members considered that the transfer of confidential patient information to the Trust could be resolved locally through the PCT in its role as the data controller by establishing formal data processing agreements with the relevant parties. Risks of disclosure should be assessed by the PCT in line with its internal procedures. It was therefore strongly recommended that the relevant parties work together to establish a coherent arrangement under the framework of the Data Protection Act 1998.

The Committee therefore advised that support should not be provided as a reasonably practicable alternative existed at a local level, and the transfer should be managed locally without seeking this form of statutory support.

4. For consideration items

4a. National Audit for Cardiac Rehabilitation [ECC 3-04 (a)/2012]

This application from the Health and Social Care Information Centre (HSCIC) detailed the National Audit for Cardiac Rehabilitation which aimed to collect comprehensive audit data to improve local cardiac rehabilitation services to patients, in terms of access, equity, quality and clinical outcomes. This application was provided in response to the outcome from the September 2010 Committee meeting, where conditions of approval had been specified in relation to the national audits processed by the Health and Social Care Information Centre. For audits where NHS Number was almost or fully complete, the applicant had been asked to set out details of the identifiers required and how identifiability could be reduced so that a pseudonymisation approach could be pursued as an exit strategy from the approval. The applicant had also been asked to provide evidence of continued progress against reduction in collection and retention of identifiable data items, in particular the continued requirement for

patient name and postcode. Finally the applicant had been asked to investigate the proposed alternative that the NHS number be validated automatically at a local level when the submission to the NHS IC was made, for example by using the Personal Demographics Service, in order to negate the need for patient name, and provide full justification where this was not deemed feasible.

Members noted that name was only used at a local level in order for clinical care teams to write to and identify their patients. The application and query responses confirmed that name was not used by the HSCIC but was currently available to HSCIC staff. In further responses to NIGB Office queries, the applicant confirmed that by the end of June 2012 patient identifiable data would no longer be available to HSCIC during routine administration. Members noted that the Demographic Batch Service would be used to validate NHS number and it appeared that this did not require HSCIC access to identifiable data. As a whole, Members welcomed the progressive steps towards pseudonymisation and commended these. In line with this, Members agreed to advise recommending support to the Secretary of State

It was confirmed that data continued to be managed in line with the arrangements outlined in the SLSP for the original NCASP approval; ECC 1-06(c)/2009 Clinical Audit Support Unit (CASU) – formerly National Clinical Audit Support Programme (NCASP), and therefore another review would not be necessary at this time. It was detailed that the NACR would in future be moved from this platform to the HSCIC's new Clinical Audit Platform (CAP) and that the NIGB Office would be advised when this took place.

4b. Future of the ECC

The Committee discussed and considered in detail the development of a draft paper that could potentially be submitted to the independent Information Governance Review. It was agreed that Dr Tricia Cresswell would review the current draft in line with Member comments and circulate to all Members for comment.

Action: Dr Cresswell to provide revised draft to Members.

5. Any other business

Information Governance Review

Dr Alan Doyle and Mr Richard Wild updated the Committee on the most recent developments concerning the Information Governance Review, including publication of the Review's terms of reference and membership panel. The current timescale for activities included a national series of themed stakeholder evidence gathering events, a first draft report in November 2012 and a final report in February 2013. It was noted that the Review arose from the NHS Future Forum recommendations, had a remit covering England only and the Review Chair – who was also the NIGB Chair – was accountable to the Secretary of State for Health. Mr Richard Wild was now Director of the Review. Evidence would be gathered from a variety of stakeholder groups including from patients and the voluntary sector and the Review panel would identify priorities based on input during the evidence process.

The Committee welcomed the independent Information Governance Review, and noted that there appeared to be no statement of values and principles framing the terms of reference. It was indicated that without this, it would be difficult to understand the approach that would be undertaken in terms of achieving appropriate outcomes. It was also noted that the terms of reference included the caveat that not all aspects would be able to be looked at equally due to the tight timescales for production.

Members also queried that the terms of reference seemed to restrict appropriate information sharing to primary purposes (direct patient care) only, excluding all secondary purposes. Dr Alan Doyle advised that the Committee could feed into the Review through the Committee's July meeting and that existing correspondence between the Committee and the Secretary of State had already been submitted to the Review as evidence.

Information Governance transition

Dr Alan Doyle updated the Committee on the latest staffing and governance changes within the Department of Health including the arrival of Charlie Massey as Director General of External Relations and Mark Davies as his deputy, and the formal establishment of an Information Governance Management Group chaired by Bill McAvoy of the NHS Commissioning Board Authority, including representatives from Public Health England, the Care Quality Commission, Monitor, the UK Council of Caldicott Guardians and local and regional NHS information governance leads, and supported by a dedicated transition manager. Members welcomed the opportunity for input into the IG Management Group, but highlighted a need for a whole system approach to ensure a balance of interests between decision making bodies and advisory bodies. Dr Doyle also advised the Committee that further supporting documentation of the NIGB Transition Guidance was in development and would shortly be published on the website.