**Ethics and Confidentiality Committee Meeting - Monday 26 September 2011**

*Members:*

Professor Sir Denis Pereira Gray (*Deputy Chair, acting Chair*), Mrs Pauline Brown, Professor Michael Catchpole, Dr Patrick Coyle, Professor Julia Hippisley-Cox, Dr Tricia Cresswell, Ms Stephanie Ellis, Mr Michael Hake, Dr Colin Harper, Mr Stephen Hinde, Dr Jane Kaye and Mr Terence Wiseman.

*In attendance:*

Mr Steve Collins (*Department of Health - observer*), Dr Alan Doyle *(NIGB Director)* Ms Natasha Dunkley *(Approvals Manager),* Ms Claire Edgeworth *(Deputy Approvals Manager),* Mr Sean Kirwan (*Department of Health*), Rick Borges (*Deputy Operations Manager)*

## 1. Welcome and apologies

Apologies were received from Dr Andrew Harris, Dr Tony Calland, Dr Fiona Douglas, Ms Susan Parroy and Dr Mark Taylor.

The Chair welcomed the attendance of Mr Steve Collins who informed the Committee he was the Departmental sponsor for the National Information Governance Board and the NHS Information Centre, and was attending to observe proceedings.

### Declarations of Interest

The following interests were declared:

1. Professor Julia Hippisley-Cox was not present in the room for the discussion and decision on item 3b.

2. Professor Jane Kaye was not present in the room for the discussion and decision on item 5f.

3. Professor Sir Denis Pereira Gray declared an interest in item 4b, was not present in the room for the discussion and decision, and Dr Tricia Cresswell chaired the item.

## 2. Minutes of last meeting [ECC 7-02(a)/2011] and matters arising

The minutes from the meetings held on 28 July were approved as an accurate record, subject to minor amendments.

## 2a. Matters arising

<u>ECC membership</u>

The Committee were informed that following calls for continued membership, Mr Michael Catchpole, Mr Patrick Coyle, Ms Stephanie Ellis and Professor Sir Denis Pereira Gray would be leaving the Committee on 31 December 2011. Ms Susan Parroy had confirmed that she would be leaving the Committee with immediate effect. A limited recruitment campaign had taken place and recruitment

would be carried out with a panel consisting of Dr Andrew Harris, Dr Alan Doyle and a representative from the Appointments Commission (Mr Jit Jethwa), with the expectation that new members would be appointed from 01 January 2012.

Deputy Chair nominations

At the September 2011 strategy day it was noted that Professor Pereira Gray was currently Deputy Chair and that this position would become vacant upon his departure at the end of the year. Members had been requested to send their nominations to the NIGB Office, with a voting procedure to take place in the event more than one member applied.

The NIGB office reported that all current members had nominated Dr Mark Taylor, and no other nominations were received. In line with this procedure, the Committee ratified the appointment of Dr Mark Taylor as deputy chair from 01 January 2012, and extended their congratulations to Dr Taylor.

ECC report to NIGB

Mr Stephen Hinde provided feedback from the recent NIGB meeting, where members had requested more detailed reporting information on applications and issues considered by the Committee, in line with the ECC having received delegated authority from the NIGB to consider and advise on applications made under the Health Service (Control of Patient Information) Regulations 2002.

A suggested outline framework was provided for brief discussion. The Committee agreed it was entirely proper to be open and transparent with the Board, and commented that the detailed minutes would provide the most comprehensive information on all items considered by the Committee, but it was acknowledged that due to the timings of the Committee and Board, the Board would not receive a set of approved minutes, or they would need to be from an earlier meeting. It was agreed that the NIGB office would draft a report following this framework, and attend the NIGB meeting to ensure it was meeting reporting requirements. Professor Pereira-Gray also highlighted that any member of the Board could attend the ECC meetings as an observer and this would be encouraged and welcomed.

Security assurance requirements

It had previously been reported that following a DH policy directive, all those processing patient identifiable data would be expected to complete the NHS IG Toolkit assessment. A videoconference meeting took place subsequently between the Department of Health's information governance policy team, the NHS Information Centre, Research Capability Programme, the Wellcome Trust, the National Institute for Health Research, the NIGB Office and Ms Pauline Brown.

This introductory meeting clarified the overarching policy directive, and it was confirmed that the principle behind the change was accepted by all parties. The NIGB focus was to ensure that this process took place in a managed environment, with effective communications, guidance and support available to researchers and implications for existing applicants clearly articulated, as the security review process is managed independently by the Department of Health. A series of questions seeking advice on how the operational aspects would be managed have been provided to the DH policy team , along with a number of applicant names so that DH can trial the change and to feed into wider rollout. Progress will be reported as the plan progresses.

## 2b. NIGB Office Report [ECC 7-02(b)/2011]

The following sets out applications that were considered outside of the formal committee meeting schedule as they were either considered under the fast track criteria, or related to amendments that did not require full committee consideration.

**Fast Track applications**

1. **ECC 7-02(FT1)/2011 The effect of concomitant prescription with antidepressants upon the efficacy of interferon based treatment to treat chronic active hepatitis C**

This application from the University of Bristol detailed a study which aimed to investigate whether concomitant antidepressant prescription reduces effectiveness of interferon based treatment for chronic hepatitis C. A recommendation of support was requested to facilitate access to patient records held within the Department of Viral Hepatology at the Bristol Royal Infirmary, for patients treated between July 2006 and July 2011, by one researcher in order to extract anonymised data for analysis.

Members advised supporting this application as the minimum threshold of the Health Service (Control of Patient Information) Regulations 2002 had been met. This was subject to the following specific conditions of approval:

1. Where individuals were still in follow up at the hospital they should be approached for their consent prior to accessing their record as consent should be feasible.

2. Posters should be displayed within the hepatology department to inform patients that the research was taking place in line with fair processing requirements of the Data Protection Act 1998.

2. **ECC 7-02(FT2)/2011 – Defining the Long Term Consequences of Acute Kidney Injury (AKI): A pilot for the AKI risk in Derby**

This application from the Royal Derby Hospital detailed a study which aimed to determine the long term effects of AKI on the development and progression of chronic kidney disease, as well as the effects of AKI on patient survival. A recommendation of support was requested to allow the nephrology team to access contact details for patients who have suffered AKI, as well as those who were screened for, but did not suffer AKI, across all departments. It was expected that only 7.5% of these patients would have been cared for by the nephrology team and therefore they would not constitute part of the patient clinical care team. Contact details would be used to write to participants in order to obtain consent to review medical notes and request mortality data from the NHS Central Register. Members advised supporting this application as the minimum threshold of the Health Service (Control of Patient Information) Regulations 2002 had been met.

**Amendments**

1. **ECC 6-05 (b)/2010 - Abdominal Aortic Aneurysm Quality Improvement Programme Request to receive mortality data**

The original application from the University of Bristol had received a recommendation of support to access identifiable HES data in order to identify and validate missing local cases from the National Vascular Database (NVD), so as to feed back to Trusts and to drive up local completion rates.
The application required access to HES for a time-limited period (April 2012), and required access to NHS number, date of birth and gender.

The Committee had advised supporting the original application, subject to the following condition of approval:

1. The recommendation of support could not be used to permit validation of data using HES where the patient information had already been collected without consent. It applied solely to those details that were collected and held on the NVD with consent.

The amendment requested that the following data items be provided to the applicant from the Medical Research Information Service (MRIS): cause of death, date of death, GP registration and PCT exit data.

This amendment was processed via Chairs action where it was advised that the minimum threshold of the Health Service (Control of Patient Information) Regulations 2002 had been met.

2. **ECC (HFEA) 5-04 (a) /2010 Are children born after assisted reproduction at increased risk of cancer? A population based linkage study.**

The original application from University College London had requested a recommendation of support to allow the comparison of cancer incidence among 130,000 children born after assisted reproductive technologies (ART) as recorded on the Human Fertilisation and Embryology Authority registry, with that of the childhood population as a whole as recorded on the National Registry of Childhood Tumours. In order to identify whether children conceived after ART might be at increased risk of cancer, access to HFEA data (130,000 records) of children born after ART (including 103,251 from non-donor cycles) from 1992 – 2006 would be linked to 14,343 cases of children diagnosed with cancer in the UK from 1992 – 2007.

This amendment requested access to the following items on the HFEA register for data matching purposes: maternal and paternal date of birth, treatment centre and treatment cycle date. It was noted that these data items were requested as the pilot study had identified that several cases could not be confirmed as a match based on the original identifiers. As this was an innovative process, it was agreed that it would be reasonable for the applicant to specify further identifiers to carry out the matching if the pilot proved that the original identifiers were insufficient, and that sufficient justification had been provided to warrant this amendment.

3. **ECC 8-02 FT3/2010 Census of care in hospitals**

This application from the University of Sheffield had previously received a recommendation of support to facilitate the collection of data from acute hospital notes where a patient had died within twelve months from admission. This amendment request detailed that often place and cause of death were not recorded in the hospital notes and requested that the MRIS service be used to confirm these details. As these data items were included within the initial application this amendment did not contain significant deviations from the original application, and was therefore considered to fall within the scope of the original recommendation of support.

4. **PIAG 2-05 (b)/2007 Disclosure and use of NHS activity data in relation to commissioning and specialist mental health services; <u>AMENDMENT</u> - Use of MIDAS (MRIS Integrated Database and Administration System) – the system developed within Project Sutton, to support the delivery of the Population Analysis Reporting System (PARS)**

This amendment request from the NHS Information Centre indicated that PARS has been a requirement of the BT SUS PDS service for the past three years. It stated that there had been a number of difficulties in delivering this, and the amendment request sought a recommendation of support to use MIDAS to provide data for the purposes of PARS. The intention would be for this

revised process to replace the service previously supplied by BT SUS and this amendment request related to England only.

It was noted that the use of patient demographic data to facilitate analysis and reporting for a range of users was already covered within the current recommendation of support within the secondary uses service application [PIAG 2-05(b)/2007]. Subsequent clarification also confirmed that the list of identifiers disclosed for PARS would not differ from those currently provided via the BT SUS recommendation of support. As this represented a change to data source, with access to no additional identifiers, this amendment received a recommendation of support, subject to appropriate security checks.

**Update on previous applications**

1. **ECC 6-05(c)/2011 Conservative Kidney Management Assessment of Practice Patterns (CKMAPPS)**

Members had considered this application from the University of Southampton at the July 2011 meeting and agreed that they were broadly supportive of this application in principle. However, as it appeared that a practicable alternative existed to the disclosure of patient identifiable data for linkage purposes it was indicated that this would need to be fully explored before the committee could advise recommending support to the Secretary of State for Health. Members had requested clarification on whether GPs would be able to provide the referral data required to researchers in an anonymised format, therefore negating the need for the researcher to seek a legal basis to process patient identifiable information.

Following the meeting the applicant provided further justification detailing why the above approach was not practicable. This was reviewed by members outside of the formal committee schedule and it was agreed that the applicant had justified the unfeasibility of using an alternative approach, and therefore the committee advised recommending support to the Secretary of State for Health, with the condition that name and postcode would not be collected.

2. **ECC 6-05(b)/2011 Evaluation of the new "Fit-Note", construction of a national database**

Members had considered this application at the July 2011 meeting and agreed that there appeared to be a practicable alternative to accessing identifiable data without consent and that these alternatives should be explored in order to ensure the minimum threshold of the Regulations had been met before considering advising support.

Following the advice provided in the meeting the applicant confirmed that the GP practices would carry out the deprivation scoring on behalf of the researcher and therefore only de-identified data would be accessed by the researcher. In line with the revised approach, it was confirmed that a recommendation of support would no longer be required as the applicant would be in receipt of pseudonymised data.

3. **ECC 7-04 (f)/2010 Improved Access to Psychological Therapies (IAPT)**

This application from the Department of Health and NHS Information Centre had received a provisional recommendation of support in September 2010, and the outstanding conditions of support were managed outside the formal meeting schedule. In reviewing the dataset, it had been noted that a British Military Forces indicator was included. This was queried and further justification provided.

The NIGB Office were subsequently informed in August 2011 that there is an agreement between the NHS and Ministry of Defence that all Defence Medical Services patient demographic data be de-militarised in order to ensure data does not associate a patient with current membership of the Armed Forces. As this reduced the extent of identifiability, this did not have significant impact upon the current recommendation of support, however, an internal review is intended to be carried out by connecting for Health to explore why the various bodies involved had not been aware of this policy directive, and what existing communications were in place to inform such bodies.

**4. Health Protection Agency (HPA) – annual review of specific support**

Following review of the early draft of the HPA annual review of support under the Regulations, it has been agreed that due to outstanding clarifications and lack of available HPA staff to review feedback in time for the September submission deadline, that the HPA will provide their report for consideration at the December 2011 meeting.

**5. ECC 3-04(e)/2011 – Q-Research Data Linkage**

This application had previously received a recommendation of support, however, following queries from the NHS Information Centre, the data controller and applicant worked further to refine the methodology to ensure only the minimum amount of identifiable data requested was necessary. This revised approach was provided to the original members who reviewed the application.

It was confirmed that the HES data extract would no longer include any identifiable data, that NHS number is pseudonymised and would not be disclosed either by the GP practice computer or by the NHS Information Centre; postcode would no longer be required and date of birth would berounded to year, would be required for quality assurance processes (e.g. to establish that matching is correct).

Members sought further clarification as to whether NHS number could potentially be decrypted by Q-research, and noting the response, agreed in the specific contextual arrangements, that this would be extremely unlikely. Members also queried, due to the richness of data obtained, whether there was a significant risk of inferential identification. It was agreed that in this specific context, the controls and governance measures in place meant that the risks were likely to be insignificant.

In line with the revised approach, it was confirmed that a recommendation of support would no longer be required as the applicant would be in receipt of pseudonymised data.

**6. Clinical Audit Support Unit - National Diabetes Audit**

It was noted that in the recent update report considered by the Ethics and Confidentiality Committee on its meeting on 28 July 2011, this specifically referenced the National Diabetes Audit (*paediatric*), and that a full application would be provided to the Committee for consideration by March 2012. As the National Diabetes Audit (*adult*) had already been considered by the Committee in March 2011, the paediatric audit was separate to the adult component in terms of any recommendation of support provided under the Health Service (Control of Patient Information) Regulations 2002.

It was not currently clear from records when the National Diabetes Audit was intended to cover two separate audits, and therefore there was no record presented to the Committee of the paediatric component and intention to submit a separate application, prior to the annual review submission. Additionally, as the report indicated that less than ten per cent of paediatric diabetes specialist services have access to a clinical IT system, it was important that a system level security policy be provided to reflect these arrangements. The applicant had been informed of the requirement to submit an application to cover the paediatric audit.

### 7. Confidential Inquiry into Maternal and Child Health

It has been previously reported that the Confidential Inquiry into Maternal and Child Health transferred to the NPSA. The Office has been recently informed that the Healthcare Quality Improvement Partnership (HQIP) is now the data controllers for this activity. A concern had arisen over the technical arrangements in place to manage the electronic submission process as this was recently implemented by the NPSA, however, a system level security policy (SLSP) had not been provided. A SLSP was submitted to the Office on 31 August, however, the data controller arrangements reverted to HQIP on 01 September and now require further revision to reflect HQIP arrangements, who are intending to sub-contract the data processing arrangements to a different organisation from the NPSA. As queries have arisen from NHS Trusts submitting data, the data controllers have been informed of the requirement to provide a SLSP as soon as possible to cover electronic submissions.

## 3 For consideration

### 3a Research Capability Programme transition arrangements

Mr Peter Knight and Ms Kerrie Woods attended to discuss the future hosting arrangements of the Research Capability Programme Health Research Support Service. The Committee welcomed this attendance and subsequent discussions, were clear that they continued to fully support the approach of the Health Research Support Service and emphasised that they would wish it to proceed within an appropriate and secure legal framework and with a continued high level of governance control. In particular, members highlighted that when the service was intended to go live, there could be an issue in that the Health Service (Control of Patient Information) Regulations 2002 are narrowly framed and the ongoing activities of the pilot programme past the pilot stage could potentially stretch the boundaries of the current Regulations too far. A view was expressed that the ideal situation would be to embed the activities in a proper statutory governance arrangement.

Mr Knight informed the Committee that the intention would be to site the programme within the Medicines and Healthcare Regulatory Authority, and to merge the service with the General Practice Research Database. Members noted that the research capability programme is a public asset and therefore needs to be publicly accountable, therefore the Committee queried the extent of transparency in the future over activities of the programme and whether all applications would be readily published.

It was understood that the intention was to return to the Committee in December 2011 to provide a lessons learnt report against the original pilots. This was also welcomed as members were keen to ensure that the lessons learnt would retain the good models already put into place.

Members set out several points for further discussion at the December meeting:

1. Some members were unclear on the precise linkages, for example, it was queried whether there would be onward linkages with police records.

2. A view was expressed that pseudonymisation at source could be further explored.

3. Members expressed their congratulations on the extent of patient and public involvement that had taken place, and were particularly keen to understand what changes had, or would take place, based on this engagement.

4. Committee experience had been that when an existing application moved to a different data controller, often there was a corresponding reduction in governance controls, and the committee sought reassurance on how this aspect would be managed.

**3b NICOR interim report - 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**

This interim report was provided in response to the final outcome letter dated 7 March 2011, where a number of conditions of support had been set out and a short interim report was requested detailing progress towards condition 1 and 2 detailed below:

Extract of specific conditions of approval

1. For those audits where NHS Number ascertainment is nearly complete, the expectation is to move towards pseudonymisation of data. Each relevant audit should be separated and the overall activity completed by 30 April 2012, with a short interim report on progress to be reviewed at the 28 July 2011 meeting. This should include 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.

2. For those audits where NHS Number ascertainment was not complete, a strategy to be set out to demonstrate how NHS Number ascertainment would be increased, and then subsequent moves towards pseudonymisation.

At the 28 July 2011 committee meeting, members had requested further detail of the pseudonymisation strategy detailed in section 4 of the report and were unsure whether the systems would result in fewer identifiable data items being submitted at a central level. Specifically members requested that information on how the proposed suppression of identifiers would reduce the amount of identifiers collected outside local care teams and the subsequent effect on the use and retention by NICOR of identifiable items should be provided for the September 2011 meeting.

Outcome

The Committee welcomed the additional information provided in relation to the pseudonymisation strategies utilised by the audits and thanked the applicant for meeting with the Office to clarify the report further. Members noted that the primary reason for asking for patient demographic data (name, postcode, date of birth) was in order to match to the NHS Central Register to obtain death data. Members were informed that demographic data was required because whilst a valid NHS number may be submitted for a patient at a local level, this was sometimes inaccurate e.g. another patient's NHS number may be submitted. This became apparent when matching with Central Register data took place and therefore to ensure accuracy of data, demographic details were used as a check.

Members commented that the solutions proposed in the current interim report specified methods to ensure there was a valid NHS number present and it was queried whether the suggested mechanisms for pseudonymisation were realistic unless they could check the accuracy of the NHS number, rather than just the validity. Members welcomed the applicant's commitment to exploring whether the Personal Demographics Service (PDS) could be used to verify the NHS number automatically upon submission, as suggested in the letter to the applicant from the NIGB Office on 18 August 2011. However it was noted that this would be dependent on agreement from Health Quality Improvement Partnership (HQIP), who were the data controller and funder of the audits.

Members reiterated the requirement section 251(4) that members are required to consider whether a practicable alternative to the disclosure of patient identifiable data without consent exists, taking into account the cost and technology available. In addition, the Health Service (Control of Patient Information) Regulations 2002, section 7(1) does not allow the processing of more confidential patient information than is necessary to achieve the stated purposes. This requirement is also in line with the third principle of the Data Protection Act 1998. With this in mind members considered that the apparent solution should be explored, in order to determine whether it was feasible as an alternative to enable the reduction of the confidential patient information currently being processed.

In line with section 7(1) of the Regulations, members requested that the applicant explore the extent of the inaccuracy of the NHS number when it came to matching with the NHS Central Register and what effect that would have on the audits. Members agreed that this analysis should be broken down into individual audits, in line with the condition of approval that separate applications would be required in April 2012. Without this information the Committee agreed that it could not make a decision whether the extent of confidential patient information requested was in fact necessary for the purposes of the audits.

In addition, it was noted that HQIP would have a significant role in the exploration of the alternative and members suggested that a meeting take place between HQIP and the Chair and deputy Chair of the Committee, Dr Andrew Harris and Professor Sir Denis Pereira Gray. The NIGB Office would contact HQIP separately to arrange this.

Members requested the following actions be completed as part of the review in April 2012:

1. Investigation into the proposed alternative that NHS number be validated automatically at a local level when the submission to the NICOR is made, for example by using the Personal Demographics Service. The Committee were of the view that this would negate the need for patient name and, in line with point 2 below, full justification should be provided if this requirement continues.

2. Significant movement towards the reduction of collection of identifiable data items by NICOR, in particular, the continued requirement of patient name and postcode would be considered, in detail, for each audit.

3. In relation to the NHS number ascertainment strategy, members were of the view that if the alternative in point 1 could be utilised then NHS number ascertainment would be greatly improved. If the alternative proved unfeasible members requested further justification that 100% ascertainment was required as it was noted that nearly 100% of cases had NHS Number submitted.

4. Information about the percentage of inaccurate NHS numbers following linkage with the NHS Central Register; this should be presented for individual audits as part of the separated applications.

**3c East Midlands Patient Experience Survey (EMPES) ECC 6-05 (d)/2010 Annual Review**

This application was considered after item 4a as that application raised broader strategic issues that were of relevance to this application.

This application from NHS Nottinghamshire set out the purpose of identifying and helping improvements in patient care and satisfaction. The information would be analysed and comparisons made across all PCTs. Information related to this would be made available in a suitable format to patients. A recommendation of support was requested to permit the disclosure of patient identifiable

information related to patients who had undergone a PROMs procedure to a third party (Quality Health). Quality Health would subsequently send the patient questionnaire to patients in order to seek their consent for their data to be linked to the PROMs data set.

The application requested access to name, address and NHS number, date of admission and discharge, provider organisation and site code, primary diagnosis and primary operative procedure code.

The Committee had advised recommending support for the one-off activity in July 2010 with the condition that a consent-based process should be introduced on a prospective basis. The annual review detailed that a consent-based process would not be feasible at this current time for the following reasons:

1. Patient feedback within focus groups and differences within survey response statistics had suggested that a number of patients were not receiving the PROMS questionnaire, this suggested that the EMPES survey would suffer similar decline if distribution was carried out by local clinical care teams.

2. The feedback obtained from the focus group suggested that patients were of the view that they are given too much information following hospital procedures and therefore do not pay attention to most. It was suggested that the current timing of the questionnaire was helpful and that they would be more likely to respond.

The annual review requested a continued recommendation of support to allow the activity to continue for the next twelve months whilst the stated decline in the distribution of the PROMS questionnaire was investigated and a practicable consent model designed.

Outcome

Members raised some concerns that the annual review moved away from the previously stated position that a consent based methodology would be introduced for the ongoing activity. However, members recognised the real practical difficulties experienced in the distribution of patient surveys by local NHS staff and the effect that this would have on the results of the survey. Members welcomed the commitment made to moving towards a consent based model and agreed that they would expect an update of progress within the next annual review.

In line with the considerations above members advised continuing the recommendation of support for a further twelve months, subject to the following conditions:

1. Progress made in moving towards a consent based model.

2. Reporting how the information collected from the patient survey had been used and what improvements have been made.

## 4. Resubmitted applications

### 4a. National Cancer Outpatients' Experience Survey ECC 6-05(d)/2011

This application from Cancer Research UK, on behalf of the Information Prescriptions Consortium and Quality Health, set out details of an outpatient patient survey to evaluate the effectiveness of the Information Prescriptions Programme. The application detailed working with 30 selected NHS acute trusts to collect and use data of up to 30,000 cancer patients in two cohorts, each of 15,00 patients.

A recommendation of support was requested to allow Quality Health to access confidential patient information in order to identify the cohort and write to them with a questionnaire. On return of that questionnaire the patient would provide consent to Quality Health processing their data for the specified purposes.

Confidential patient information requested

Access was requested to the following confidential patient information; name, address, NHS number, sex, ethnic group, year of birth, attendance dates, admission type, ICD10 code, speciality code, radiotherapy and chemotherapy status flags and cancer staging at diagnosis.

Application history

This application had been considered at the July 2011 meeting when the Committee was unable to provide a recommendation of support as it appeared that a practicable alternative existed. The Committee requested that the applicant explore whether a fully consented approach would be feasible, in line with previous advice provided following similar applications, and that further evidence would need to be provided that this would not be a feasible approach before a recommendation of support could be made.

Resubmission grounds and outcome

The resubmitted application provided further evidence for the assertion that a methodology which required prior consent to sending out the questionnaire would result in systematic flaws and bias.
Members welcomed the additional information included within the resubmission and thanked the applicant for providing these. Members agreed that they were highly supportive of the purpose of this activity and it was important that it should go ahead. However they advised that it is necessary to ensure that the minimum requirements under the Regulations are met in order to provide a recommendation of support, taking into account the legal framework around access to confidential patient information, including the common law of confidentiality, Data Protection Act 1998 and the Human Rights Act 1998.

The following issues were raised in response to the suggestion of the pursuit of a fully consented approach:

1. Impracticality and sample bias of the prior consent model

The resubmitted application stated that it would be a significant burden on clinical staff to distribute surveys. Evidence resulting from the PROMS survey was provided to support the assertion that where NHS staff had been requested to distribute surveys in the past they had only sporadically distributed these.

Members commented that ideally the leadership, management and ownership of the proposed survey at a local level would allow this survey to succeed. However, members accepted the assertions that distribution of surveys would present a real burden on local NHS staff and agreed there would be a detrimental effect on the success of the survey.

2. Sample bias introduced by staff selection of patients

Evidence provided within the application form and annexes detailed previous surveys in which NHS staff prejudices in distribution had influenced the completion and results of patient surveys.

In considering this potential bias issue, it was agreed that this may present a real issue for the validity of survey results. Additionally members commented that if a patient had had a bad experience, they would be less likely to respond to the survey if the questionnaire was provided directly from that clinical care team.

3. Issues with suggested practicable alternative, i.e. staff distributing survey to all cancer patients

The Committee were informed that the timing of the survey was essential and that it was required that this was distributed at the end of a patient's treatment. Additionally, information was provided within the application form and the annexes that evidence existed that low response rates had been experienced in previous surveys undertaken with the suggested distribution methodology and that postal reminders would not be sent which would lead to distortions in the response data.

The Committee noted the assertion of the importance of timing of the survey distribution and agreed that it would be difficult to manage this within local NHS staff.

A joint letter from Professor Sir Mike Richards, National Cancer Director, Harpal Kumar, Chief Executive of Cancer Research UK and Ciarán Devane, Chief Executive of Macmillan Cancer Support was also submitted in support of the resubmitted application.

The Committee agreed with the statement in this joint letter "*we recommend that there needs to be an agreed method in the NHS of undertaking such important surveys of patients in order to test the effectiveness of health intervention and information"*. However, the Committee was concerned that legitimising the activity under the current legal framework may not be the appropriate route. The Committee asked the Chair, at the time the Committee's deputy Chair, to consider this point in reply to the additional letter of support.

When taking into account the assertions within the resubmitted application, and, whilst it was reiterated that the statement "no decision about me, without me" would suggest that consent should be in place, the Committee were of the majority view that the suggested practicable alternative would not be feasible and would present serious issues that would affect the results of the survey. As there was currently no other legal basis for the disclosure of confidential patient information for national surveys, members concluded that the minimum criteria under the Regulations had been met, and therefore advised providing a favourable recommendation to the Secretary of State for Health. However, as members were of the view that national patient surveys were a fundamental factor in improving quality of care, a view was expressed that there needs to be a better way to legitimise these activities, and this point would be raised with the National Information Governance Board.

**4b. History of Presentation of cervical cancer in young women in England' study ECC 5-04 (c) /2010**

This application from Kings College London set out the purpose of studying the extent and determinants of delays to treatment in young women diagnosed with cervical cancer. Invitations would be sent to all young women aged 18-29 who had been diagnosed with cervical cancer in England in the past six months.

A recommendation for support was requested to provide a legitimate basis to access confidential patient information from the Trent Cancer Registry, the national registry for this disease, in order to write to women for consent to participate in the study.

The application requested access to name, address, postcode and date of birth, as well as name consultant name and hospital in which the women were being treated in order to ask the clinical care team if it was appropriate to approach the patient first.

The Committee had previously considered this application at the June 2010 meeting where a practicable alternative had been identified to the disclosure of confidential patient information. Members had suggested that the consent process could be undertaken within the Trent Cancer Registry, who had access to confidential patient information for their defined purposes; recruitment of the cohort could then be undertaken without a recommendation of support.

Resubmission grounds

The resubmitted application included a cover letter which detailed that the suggested methodology had been trialled by the applicant since April 2011. The following issues had arisen which had affected the level of uptake and were likely to result in the study failure:

- Poor data quality due to the current method involving passing data through multiple people,
- A delay of up to two months in contacting potential participants,
- Confusion about who participants and the clinical team needed to contact in relation to the study
- The study lead spending a disproportionate amount of time coordinating the study.

Responses to queries from the NIGB Office detailed that original estimations had predicted that approximately 40% of the eligible cohort would need to be contactable and agree to be interviewed to meet the study target of 187 women in one year. In reality, the study had been recruiting for over 4 months and 30% of eligible women had been contacted, of which 36% of these had agreed to be interviewed (18 participants) and 32% (16 participants) had been already more than six months from diagnosis due to the specified delays and therefore not suitable for inclusion.

Outcome

Members considered the assertions presented within the cover letter and the responses to the NIGB Office queries. It was agreed that the applicant had adequately trialled the suggested alternative and that the results of this had provided evidence that this was not feasible. Members therefore agreed that the minimum requirements under the Regulations had now been met and therefore advised recommending support to the Secretary of State for Health. This recommendation was subject to the following conditions:

**Conditions of support**

1. Confirmation from a research ethics committee that an amendment had been approved or that an amendment would not be required as a result of the change in methodology.

## 5. New applications for section 251 support

When the Committee advises recommending support to the Secretary of State for Health, these applications are always subject to adherence to standard conditions of support, confirmation of satisfactory security arrangements by the Department of Health's security review team, and where it is medical research, a favourable opinion from a relevant research ethics committee.

## 5a. ECC 7-05(a)/2011 - Investigating factors influencing the infant mortality rate in Lincolnshire (case control study)

This application from the University of Nottingham set out details of a case control study to investigate factors affecting the infant mortality rate within premature babies in Lincolnshire, in response to NHS Lincolnshire raising concerns over the infant mortality rate within the county over the last few years.

A recommendation for classes 1, 2, 4 and 6 support was requested to provide a legitimate basis to access neonatal and obstetric records relating to 73 cases and 289 controls.

Confidential patient information requested

This application requested access to neonatal and obstetric records for babies born between two gestational ages within Lincolnshire, or born outside of Lincolnshire where the mother would usually be resident in the county.

Date of birth, date of death, deprivation score and gender of baby, and ethnicity of baby and parents would be extracted for analysis purposes.

**Outcome**

Members agreed that this was an important issue which would require further investigation and discussed the application at length; a summary of the discussion is below.

Established methodology

It was noted that this activity was being undertaken on direction of NHS Lincolnshire. Members discussed the methodologies already established to investigate infant mortality cases through the national confidential enquiry now run by the Centre for Maternal and Child Health Enquires (CMACE). The predecessor organisation, the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI) had conducted a number of investigations including a case control study on antepartum stillbirth.

The Committee was unsure why these methodologies were not being utilised by NHS Lincolnshire in this instance. The Committee noted that initial attempts had been made to request anonymised information from trusts with trust clinical staff completing the anonymisation. Trusts had not complied. However the approach to trusts appeared to have been from the researchers. The Committee (mindful of the serious issue) was of the view that an investigation under the umbrella of clinical governance, with the Director of Public Health leading the investigation and trusts being represented on the steering group could require trust compliance with the provision of anonymised data, in keeping with the original methodology.

Practicable alternatives

Members are required to consider under section 251 (4) whether a practicable alternative to the disclosure of patient identifiable data without consent exists, taking into account the cost and technology available.

- Feasibility of consent

Members were sympathetic to the reasons specified within the application for not gaining consent from those patients whose babies had died. However, in considering whether there may be another practicable alternative to a recommendation of support, members were of the view that consent may be possible from those parents whose babies had survived. However use of anonymised data would be preferable.

- Use of anonymised/pseudonymised data

In line with the points raised above regarding established methodologies, it was noted that it was a requirement of all NHS trusts to participate in clinical governance investigations. Trusts had in the past complied with the case control studies run by CESDI. Therefore anonymisation by trust staff was feasible. Members were of the view that an appropriate approach to trusts appeared not to have been made. Members were of the view that it was practicable to take this issue forward through clinical governance routes, with appropriate leadership. The trusts would then provide anonymised data to the researchers.

**Conclusion**

In conclusion, the Committee was mindful that an established methodology was in place to provide anonymised data and that trusts had provided anonymised data previously to CESDI. It appeared that a further approach could be made to trusts as part of this important clinical governance issue.

In line with the considerations above, the Committee was mindful that the minimum criteria under the Regulations had not been met as there appeared to be an established alternative to the disclosure of confidential patient information without consent and therefore they could not provide a recommendation of support to the Secretary of State.

**5b. ECC 7-05(b)/2011 Homicide by patients with schizophrenia: a case control study**

This application from the University of Manchester set out details of a case control study which would compare those patients with schizophrenia who kill and those who do not. The study would look for difference in demographics and also in the treatment that was received. The methodology would utilise data from the National Confidential Inquiry into Suicide and Homicide (NCISH) for cases, which had previously received a recommendation of support [PIAG 4-08(d)/2003].

A recommendation for classes 4, 5 and 6 support was requested to provide a legitimate basis to access Hospital Episode Statistics (HES) data on 750 controls, matched by age and sex to cases. HES data would be used to identify consultants in order to send questionnaires relating to the patient's care and treatment.

<u>Confidential patient information requested</u>

The application requested access to HES data including local patient ID, NHS number, sex, date of birth, admission date, discharge date and consultant code. A questionnaire requesting information on the patient's demographic characteristics, clinical and forensic history and aspects of their care and treatment would then be completed by the relevant local care team.

**Outcome**

Members noted that the data requested was of a particularly sensitive nature; however they agreed that the public interest in the activity taking place was particularly high and would provide significant benefits to the population as a whole.

Practicable alternatives

In considering under section 251 (4) whether a practicable alternative to the disclosure of patient identifiable data without consent exists, taking into account the cost and technology available, the Committee made the following points:

- Feasibility of consent

Members discussed whether consent for the access to control data would be feasible. They noted that the cohort would be retrospective in nature dating back to 1997 and that consent would pose a significant burden on NHS staff. The alternative of researchers accessing patient contact details would result in more confidential patient information being disclosed than necessary for the purposes of the study. Members agreed that the impracticalities caused would make consent unfeasible to obtain.

- Use of anonymised/pseudonymised data

Members considered whether an alternative existed which would negate the requirement for the use of confidential patient information. Discussion took place around whether it would be possible for consultants to be asked to identify patients themselves, complete anonymised questionnaires and submit these to the research team. However, given the retrospective nature of the study, members agreed that this was unlikely to be a practicable alternative.

Extent of confidential patient information requested

The Health Service (Control of Patient Information) Regulations, section 7 (1) does not allow the processing of more confidential patient information than is necessary to achieve the stated purposes. This requirement is also in line with the third principle of the Data Protection Act 1998. With this in mind members considered the extent of confidential patient information requested for the purpose. In particular, Members queried whether the questionnaire would be returned in an identifiable format. It was considered that, following identification of controls, identifiable data would not be required and therefore the completed questionnaire should be completely anonymised at the point of return. Members also noted that the study aimed to utilise data collected by NCISH under PIAG 4-08(d)/2003 and requested clarification whether this data would be used in an identifiable format.

Data Protection Act 1998 principles

Section 251 (7) specifies that recommendations of support cannot be inconsistent with the provisions under the Data Protection Act 1998 (DPA).

- First principle

The first principle of the DPA requires personal data to be processed fairly and lawfully, which determines that reasonable effort should be made to inform the data subject of the uses of their data. This is of particular importance when processing confidential patient information without consent.

Members advised that in order to comply with the above principle reasonable efforts should be made to inform the control population of the activity, for example where patients were still in contact with services they should be provided with patient information leaflets about the study. Members

requested clarification on the procedures that would be in place to inform data subjects about the use of their data.

- Fifth principle

The fifth principle of the DPA specifies that personal data should not be kept for any longer than is necessary for the purposes specified. With this in mind members considered the retention period for identifiable data specified within the application and queried whether the six year retention period related to identifiable information as this was thought to be excessive in this context.

- Sixth principle

The sixth principle of the DPA requires data to be processed in line with the rights of the data subject. Where confidential patient information is being processed without prior consent it is important that the patient is given reasonable opportunity to register objection to the processing of data where it is likely to cause, or is causing significant damage or distress. In line with the Committee's standard conditions of support a recommendation of support cannot be used to override patients' objections and therefore where dissent is registered this should be respected.

Members raised concerns that the application had indicated a route for clinicians to opt out of the completion of the questionnaire but did not specify a method to inform patients and allow them the right to opt out. In line with the discussion outlined in relation to compliance with the first principle, members indicated that where an individual patient dissented from the use of their data for the purposes of the study, the questionnaire should not be completed and any data held on the patient by the University should be destroyed.

Members agreed that responsibility for achieving compliance with the DPA requirements remained with that of the applicant but as a recommendation could not be inconsistent with the DPA the applicant would need to evidence the provisions made for compliance.

Conclusion

The Committee were supportive of the application in principle and recognised that there was no practicable alternative to the methodological approach. However, in line with the considerations above, the Committee were mindful that a recommendation of support could not be inconsistent with the provisions of the DPA. Members agreed that they would need further information regarding the compliance with these principles before advising the Secretary of State for Health that the application should be supported.

In line with the issues raised above under the Data Protection Act principles section, the applicant was requested to:

1. Provide information on how reasonable efforts would be made to inform patients at a local and national level of the activity.

2. Confirm that the provisions of the sixth principle of the DPA would be adhered to.

3. Clarify how long identifiable data would be retained.

4. Clarify whether NCISH data would be required in an identifiable format, and if so to confirm that researchers accessing the data had legitimate access for the purposes of the NCISH application (PIAG 4-08(d)/2003).

## 5c. ECC 7-05(c)/2011 Non-Hodgkin Lymphoma in Young Adults

This application from the University of Manchester set out details of a prospective cohort study with the aim to collect diagnosis, treatment and outcome data on every 15 to 29 year old diagnosed with non-hodgkin's lymphoma (NHL) over a 3 year period with the aim of establishing the incidence of each NHL type, document treatments and record readmission and cure rates.

A recommendation for class 4, 5 and 6 support was requested to provide a legitimate basis to access confidential patient information to collect notifications, link information from different sources and to audit, monitor and analyse current treatment.

Confidential patient information requested

The activity requested access to name, NHS number, GP registration, date of birth, date of death and postcode from pathologists making the diagnosis of the patient and from the young adult cancer registry, located within the North West Cancer Intelligence Service (NWCIS). Follow up data would then be requested from treatment centres for each case to 2 years from diagnosis and patients would be flagged for mortality on the NHS Central Register for 5 years.

Practicable alternatives

Members are required to consider under section 251 (4) whether a practicable alternative to the disclosure of confidential patient information without consent exists, taking into account the cost and technology available.

- Feasibility of consent

Members noted that the application estimated that there would be around 600-650 cases of NHL diagnosed within England, Wales and Scotland who were within the specified age range over a 3 year period and were of the view that pursuing a consent based approach for a cohort of this size would be feasible.

The application provided evidence that consent had proved particularly difficult to obtain within the cohort group in past studies. However, members noted that the evidence appeared to detail intervention trials rather than studies involving the use of patient data only, and were of the view that the differences between the two methodologies would be significant when a participant was considering inclusion into a study.

Members also raised a concern over the assertion within question 9-2 of the application form which stated that "*NIGB have advised that individual informed consent is not required",* and wished to reiterate that the assertion was not correct and queried in what context this had arisen.

- Use of anonymised/pseudonymised data

The Committee considered that as Cancer Registries have specific support under the Health Service (Control of Patient Information) Regulations 2002 to collect information in relation to the diagnosis and treatment of cancer patients, the lead cancer registry in this area could provide the information required in an anonymised format without a further breach in patient confidentiality. It was noted that confidential patient information was requested primarily to allow linkage of data sources. Members therefore advised that if consent proved not to be feasible, the applicant should

explore the possibility of Cancer Registries providing anonymised information for the purposes of the study.

Data Protection Act principles

Section 251 (7) specifies recommendations of support cannot be inconsistent with the provisions under the Data Protection Act 1998 (DPA).

The sixth principle of the DPA requires data to be processed in line with the rights of the data subject. Where confidential patient information is being processed without prior consent it is important that the patient is given reasonable opportunity to register objection to the processing of data where it is likely to cause, or is causing significant damage or distress. In line with the ECC standard conditions of support a recommendation of support cannot be used to override patients' objections and therefore where dissent is registered this should be respected.

Members welcomed the patient involvement undertaken in relation to the study, however they highlighted that the requirements of the DPA in relation to the sixth principle and noted that although the consulted patient group had advised that details of the opt-out provision should be removed from the patient information leaflet, there was still a requirement under the DPA to provide the opt-out provision. Members were of the view that data controllers should make this explicit to all potential study participants to ensure that they are aware of their rights as a data subject.

Patient involvement

The Committee consider that where confidential patient information is to be used without consent the study should seek a representative view from a relevant patient group or directly from a sample of patients themselves in order to test the acceptability of using identifiable data without consent. Members welcomed the patient involvement undertaken by the applicant, and noted that the small patient group had indicated that they were supportive of the collection of confidential patient information.

Conclusion

Whilst supportive in principle of the purpose of the activity, in line with the considerations above the Committee were mindful that the minimum criteria under the Regulations had not been met as it appeared that practicable alternatives to the disclosure of confidential patient information existed. As such, they were unable to advise recommending support to the Secretary of State for Health at this time.

**5d. ECC 7-05(d)/2011 Cancer waiting times and effect on survival**

This application from the University of Bristol detailed a study to investigate the impact and potential preventability of socio-economic and ethnic inequalities in cancer care. The study objectives were to determine the contribution of waiting times to inequalities in cancer survival, to explore reasons why inequalities in waiting times arise and to investigate potential interventions to reduce waiting times in patient care pathways.

A recommendation for classes 5 and 6 support was requested to provide a legitimate basis for a researcher from the University of Bristol to access linked GPRD, HES and Cancer Registry data. In particular, the application set out access to a linked dataset including patient date of birth and death for patients diagnosed with breast, colorectal, prostate and lung cancers and Non-Hodgkins lymphoma, between 1996 and 2010.

Outcome

Members considered that the outcomes of the study would have a significant public interest. Members wished to highlight that date of birth and date of death are considered identifiable data items, as the application made many references to the use of an anonymised dataset. Members are required to consider whether an application has satisfied the minimum threshold of the regulations, in line with this they discussed the following:

Practicable alternatives

Members are required to consider under section 251 (4) whether a practicable alternative to the disclosure of patient identifiable data without consent exists, taking into account the cost and technology available.

- Feasibility of consent

Members agreed that the large numbers involved within the application would mean that consent would not be a practicable alternative to seeking a recommendation of support.

- Use of anonymised/pseudonymised data

Members discussed whether it would be possible to use anonymised data for the purposes of the study. The assertion made within the application that full dates of birth and death were required to calculate survival time in terms of days and to accurately calculate age at each stage was noted. Further to this, members queried whether the applicant had approached the Cancer Registries to undertake interval calculations in days on their behalf. As the Cancer Registries had an existing legal basis for access to confidential patient information, this would not require a recommendation of support.

Extent of confidential patient information requested

The Health Service (Control of Patient Information) Regulations, section 7 (1) does not allow the processing of more confidential patient information than is necessary to achieve the stated purposes. This requirement is also in line with the third principle of the Data Protection Act 1998.

Members confirmed that, in line with the point raised above, the feasibility of the Cancer Registry calculating intervals should be fully explored. Members discussed the justification provided for full dates of birth and death, if the alternative proved not to be feasible. Members agreed that precise survival times would be required and recognised that this should be in terms of days. However, they were not convinced that full date of birth would be required for patients, as it was noted that the entire cohort would be adult and therefore were unsure why calculation of age in days would be necessary.

Data Protection Act principles

Section 251 (7) specifies recommendations of support cannot be inconsistent with the provisions under the Data Protection Act 1998 (DPA).

The third principle of the DPA requires that personal data should be adequate, relevant and not excessive for the purposes for which it is being processed. Members considered the extent of confidential patient information that would be accessed for the purposes of the application. In line with the points made above, members reiterated that further justification for the disclosure of date of birth would be required if a recommendation of support was required.

Patient involvement

The Committee consider that where confidential patient information is to be used without consent the study should seek a representative view from a patient group or directly from a sample of patients themselves in order to test the acceptability of using identifiable data without consent. Members noted that no patient involvement had been undertaken in relation to this activity and agreed that they would expect reasonable consultation to be undertaken with a representative patient group.

Conclusion

In line with the considerations above, the Committee requested clarification on whether the applicant had approached the Cancer Registries to determine whether it would be possible for them to undertake the calculation of intervals, negating the requirement for researchers to access confidential patient information.

If evidence was provided to demonstrate that an alternative methodology would not prove feasible, the Committee agreed that the minimum criteria under the Regulations would have been met, and pending this clarification advised providing a favourable recommendation to the Secretary of State for Health. This support would be subject to the following conditions:

1. Month/year of birth only should be collected, unless further justification is provided to the Committee that only full date of birth would suffice.

2. Potential patient involvement should be reconsidered and details of a plan to involve patients forwarded to the NIGB Office.

3. Once intervals have been calculated date of death should be removed from the dataset.

4. The database should be archived within the Cancer Registry at the end of the study.

**5e. ECC 7-05(e)/2011 - Bridge Project: Evaluating two models of transitional care**

This application from the University of Warwick set out details of a project which aimed to compare two models of transitional care between child and adolescent mental health services (CAMHS) and adult mental health services by undertaking a retrospective case note review and tracking care pathways, treatment and support offered to a cohort of young people making a transition from Sandwell and Coventry CAMHS who did not respond to requests for consent in order to extract anonymised information. In addition a sample of young people would be invited to take part in an interview.

A recommendation for classes 1, 5 and 6 support was requested to provide a legitimate basis to access case notes for those that did not respond to letters from CAMHS requesting consent to partake in the study.

Outcome

Members noted that this was an important activity that would produce valuable outcomes and welcomed the fact that real attempts at gaining consent were being made. Members are required to consider whether an application has satisfied the minimum threshold of the regulations, in line with this they discussed the following.

Practicable alternatives

Members are required to consider under section 251 (4) whether a practicable alternative to the disclosure of patient identifiable data without consent exists, taking into account the cost and technology available.

- Feasibility of consent

Members noted that the application would only require a recommendation of support for those patients who did not respond to the consent form and follow up telephone call as the consent process would be undertaken by members of the CAMHS team. Members were mindful of the requirements of the Regulations and that a recommendation of support could only be provided where consent was not practicable. Members agreed that the methodology detailed within the application indicated that proceeding on a consent based approach would be feasible and, whilst noting the low response rates within previous studies, the applicant would still expect reasonable response rates to allow interviews to take place.

Additionally it was noted that patients would currently be in contact with CAMHS services and members queried why consent could not be obtained from the patients in person at an appointment with the services. The application asserted that the clinical CAMHS team could not undertake this; however a view was raised that the CAMHS managers, who would be carrying out the mail out of consent forms, could potentially approach participants for consent.

Conclusion

In line with the considerations above, the Committee were mindful that the minimum criteria under the Regulations had not been met, and a consent based approach could be utilised. Therefore they could not advise providing a recommendation of support to the Secretary of State for Health. Members advised that if the consent based approach proved not to be feasible a resubmission should be made detailing the attempts made and the results.

**5f. ECC 7-05(f)/2011 Post Intensive Care Risk adjusted Alerting and Monitoring (PICRAM)**

This application from the University of Oxford detailed the establishment of a research database, which would comprise of three existing intensive care databases across three hospitals; John Radcliffe, Churchill and Royal Berkshire Hospitals. The study aimed to identify patients at most risk of death or mishap following discharge from the Intensive Care Unit (ICU) at the point which they left the ICU, allowing concentration of resources on those most at risk.

A recommendation for classes 4, 5 and 6 support was requested to provide a legitimate basis for access to confidential patient information by researchers in the “CareVue” database, local Intensive Care National Audit Research Centre (ICNARC) database and Patient Administrative system.

Confidential patient information requested

In order to link the specified databases, access was requested to NHS number, hospital ID, date of birth and postcode.

Outcome

Members considered the activity to have significant outcomes that would aid improvement of patient care. In considering whether an application has satisfied the minimum threshold of the Regulations, in line with this they discussed the following.

Practicable alternatives

Members are required to consider under section 251 (4) whether a practicable alternative to the disclosure of patient identifiable data without consent exists, taking into account the cost and technology available.

- Feasibility of consent

Members agreed that due to the large number of patients, and the retrospective nature of the database (more than 8000 admissions over the last 13 years in John Radcliffe and Churchill Hospitals and 3000 over the last 6 years in Royal Berkshire Hospital) consent would not be feasible.

- Use of anonymised/pseudonymised data

Members noted that identifiable information would only be required in order to link the three databases and the combined database to be retained by the University would be anonymised.

Extent of confidential patient information requested

The Health Service (Control of Patient Information) Regulations, section 7 (1) does not allow the processing of more confidential patient information than is necessary to achieve the stated purposes. This requirement is also in line with the third principle of the Data Protection Act 1998. With this in mind members considered the extent of confidential patient information requested for the purpose. It was noted that NHS number, hospital ID, date of birth and postcode were requested for linkage purposes. Members queried how many patients could be matched on NHS number or hospital ID alone and agreed that where linkages could be carried out using only these data items, date of birth and postcode should not be used.

Additionally members queried what data items would be available to researchers as it appeared there was some inconsistency within the form. Question 11A specified data items held within the data records and included a greater number of personal identifiable items than question 3B, which specified those data items required for linkage. Members requested confirmation of which data items which would be accessible by researchers.

Additional points

Members noted that the confidentiality clause specified within question 12-1A of the application and commented that there was no penalty included within the clause. Members advised that this would be expected in order to highlight to staff the seriousness of a breach in confidentiality, and would aid in meeting the equivalent standard of confidentiality expected from that of a healthcare professional.

It was noted that the application specified a generic favourable opinion from a research ethics committee was being sought to allow other research to be undertaken using the resulting database. Members reiterated that further projects should be completed using anonymised data and that the advisory recommendation of support sought from the Ethics and Confidentiality Committee would be for access to confidential patient information in order to establish the database, in line with the purposes specified within the application, and did not include onwards disclosure in an identifiable format.

**Conclusion**

In line with the considerations above, the Committee agreed that the minimum criteria under the Regulations had been met, and therefore advised providing a favourable recommendation to the Secretary of State for Health. This recommendation was subject to satisfactory clarification of what data items would be accessible by researchers accessing data on NHS sites.

Any recommendation of support would be subject to the following conditions:

1. Where possible linkages should take place using only NHS number and Hospital ID. Postcode and date of birth should only be accessed where a match cannot be established using these administrative identifiers.

### 5g. ECC 7-05(g)/2011 The Trauma and Research Network (TARN); collection of patient identifiers to allow linkages of SUS and TARN

This application from the University of Manchester set out details of an activity which would allow PCTs to link SUS activity data to TARN data. TARN data provides an assessment of injury severity of patient injuries, seniority of clinicians treating the patient, time to transfer for non-emergency referrals for specialist care and presence of a prescription for rehabilitation. It was noted that the collection of confidential patient information for these purposes was included within a separate application, PIAG 3-04(e)/2006. The datasets would be linked at PCT level in order to support the implementation of the Best Practice tariff for trusts receiving major trauma and continue monitoring standard of care across the country.

A recommendation for classes 4, 5 and 6 support was requested to provide a legitimate basis for TARN to access NHS number and date of birth for the purpose of facilitating linkage at PCT level and of providing PCTs with a method to link TARN data to SUS activity data.

Outcome

Members agreed that the activity would facilitate Best Practice tariffs and this in turn would encourage best practice within the NHS. Members are required to consider whether an application has satisfied the minimum threshold of the regulations, in line with this they discussed the following.

Practicable alternatives

Members are required to consider under section 251 (4) whether a practicable alternative to the disclosure of patient identifiable data without consent exists, taking into account the cost and technology available.

- Feasibility of consent

Due to the large numbers and condition of patients involved in the activity, it was agreed that consent would not be feasible in this instance.

- Use of anonymised/pseudonymised data

It was noted that the linkage activity would require the specified patient identifiable data.

Extent of confidential patient information requested

The Health Service (Control of Patient Information) Regulations, section 7 (1) does not allow the processing of more confidential patient information than is necessary to achieve the stated

purposes. This requirement is also in line with the third principle of the Data Protection Act 1998. With this in mind members considered that the application had justified the requirement for NHS number and postcode in order to facilitate the linkage activity.

Data Protection Act principles

Section 251 (7) specifies recommendations of support cannot be inconsistent with the provisions under the Data Protection Act 1998 (DPA).

The fifth principle of the DPA requires that personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes. In line with this members queried why identifiable data would need to be retained by TARN for a period of 3 years. Additionally, members could not identify how long PCTs would retain the linked information in an identifiable format. Clarification was requested on these two points.

Conclusion

In line with the considerations above and subject to satisfactory resolution of clarification points, the Committee agreed that the minimum criteria under the Regulations had been met, and therefore advised providing a favourable recommendation to the Secretary of State for Health. This recommendation was subject to satisfactory responses to the requests for clarification above.

### 5h. ECC 7-05(h)/2011 CRANE Epidemiology Register

This application from the Royal College of Surgeons of England set out details of a register of birth and demographic data in relation to all children born in England, Wales and Northern Ireland with the congenital abnormality of clefting of the lip/and or palate. It was noted that the Committee's remit was solely in relation to English and Welsh generated data.

A recommendation for classes 4, 5 and 6 support was requested to provide a legitimate basis to access hospital ID, NHS number, date of birth and date of death for all children born in England and Wales in order to eliminate duplicate records and to remind centres to obtain consent.

Outcome

Members noted that this application was made in order to collect limited identifiers for surveillance purposes and that consent would be sought for the longer term CRANE treatment outcomes database. In considering whether an application has satisfied the minimum threshold of the regulations, members discussed the following.

Practicable alternatives

Members are required to consider under section 251 (4) whether a practicable alternative to the disclosure of patient identifiable data without consent exists, taking into account the cost and technology available.

- Feasibility of consent

Members noted that the surveillance activity required limited identifiers in as timely a manner as possible in order to meet its fundamental aims, i.e. to ensure that there is an up to date register of all children with cleft lip and/or palate and to monitor the frequency and incidence of clefting in the population. Members welcomed that consent would be obtained via the clinical care teams for the

collection of further detailed outcome data and that if an individual registered their dissent the information would be anonymised.

- Use of anonymised/pseudonymised data

Members agreed that identifiable information would be required to allow de-duplication and to facilitate consent processes.

Public interest test

When considering whether a recommendation for support can be made the Committee must also take into account the public interest of the activity taking place balanced against the level of disclosure necessary. Members agreed that the public interest in the activity taking place was particularly high and the outcomes would provide a significant public health benefit.

Conclusion

In line with the considerations above, the Committee agreed that the minimum criteria under the Regulations had been met, and therefore advised providing a favourable recommendation to the Secretary of State for Health.

**5i. ECC 7-05(i)/2011 CRANE Treatment outcomes**

This application from the Royal College of Surgeons of England set out details of a treatment outcomes database which would audit and report on the quality of care for patients with cleft lip and/or palate. The database would aid work with the Craniofacial Society of Great Britain and Ireland (CFSGBI) to improve the delivery of cleft care in the UK and work in partnership with Specialist Commissioning Groups (SCGs) to inform commissioning of cleft services.

A recommendation for classes 4, 5 and 6 support was requested to provide a legitimate basis to collect name, hospital ID, NHS number and date of birth, cleft type, and hospital name. It also included access to treatment outcome information at 5 years including weight and height, number of decayed, filled and missing teeth and index of facial growth.treatment and outcome data at 5 years of age for those children who were born prior to the introduction of the current consent model in 2008, whilst the consent re-verification process took place.

Outcome

Members noted that this application was to collect treatment outcome data for those babies that had been born prior to the current consent model and agreed that it was likely consent would have been given in some form for many of these patients.

Practicable alternatives

Members are required to consider under section 251 (4) whether a practicable alternative to the disclosure of patient identifiable data without consent exists, taking into account the cost and technology available.

- Feasibility of consent

Members noted that consent would eventually be obtained for the use of confidential patient information in this instance. However, the delay in re-verifying consent for the retrospective cohort would affect the timely and meaningful reporting of the national outcome statistics. Members

advised that a recommendation of support would be suitable for a one year period as they were of the view that this should provide adequate opportunity for consent to be re-verified by the treatment centres.

- Use of anonymised/pseudonymised data

Members agreed that identifiable information would be required to allow the treatment outcomes to be matched accurately to patient's original registration records.

Conclusion

In line with the considerations above, the Committee agreed that the minimum criteria under the Regulations had been met, and therefore advised providing a favourable recommendation to the Secretary of State for Health to cover a 12 month period. Any extensions to this time period would require evidence to justify an extension.

### 5j. National Pulmonary Hypertension Database Review: Service evaluation of Portopulmonary Hypertension ECC 7-05(j)/2011

This application from Newcastle Upon Tyne Hospitals NHS Trust, on behalf of the National Pulmonary Hypertension Consultant Forum, detailed a retrospective observational service evaluation of the national pulmonary hypertension database, which would specifically look at the disease condition portopulmonary hypertension. The activity was requested by the National Pulmonary Hypertension Consultant Forum and involved a review of databases at ten treatment centres (one in Dublin and therefore outside the remit of the Committee) to form a national view of treatment.

A recommendation for classes 1, 5 and 6 support was requested to provide a legitimate basis for access to local databases by a nominated individual in order to extract anonymised information.

Confidential patient information requested

Access to patient databases held at nine treatment centres was requested; where data was incomplete hospital numbers would be used to identify patient notes in order to complete the dataset (approximately 30-50 patients in each centre). A nominated individual would carry out data collection in all treatment centres.

Outcome

Members are required to consider whether an application has satisfied the minimum threshold of the regulations, in line with this they discussed the following.

Practicable alternatives

Members are required to consider under section 251 (4) whether a practicable alternative to the disclosure of patient identifiable data without consent exists, taking into account the cost and technology available.

- Feasibility of consent

Members noted that whilst the database would contain large numbers, confidential patient information would only be required for those suffering from portopulmonary hypertension, which was

estimated to be around 30-50 patients at each site. Members noted the retrospective nature of the cohort, and discussed that many may be dead and that consent would therefore not be an option. However, members were of the view that where patients were alive they were likely to be in contact with treatment centres and that consent may be obtained for these patients via the local care teams for those patients.

- Use of anonymised/pseudonymised data

Members noted that only anonymised data would be extracted at a national level, but that hospital number would be required from local databases at each site in order to locate patient records when required.

Patient involvement

The Committee consider that where confidential patient information is to be used without consent the study should seek a representative view from a patient group or directly from a sample of patients themselves in order to test the acceptability of using identifiable data without consent. Members were concerned that no direct discussion had been undertaken with patient groups in relation to access of confidential patient information for these purposes and highlighted the importance of the perspectives of patients.

Additional points

Members noted that the answers to some questions were brief and reiterated that when considering whether to make a recommendation of support, members must be provided with sufficient information to provide evidence that the minimum requirements under the Regulations had been met. In line with this, it was advised that any future applications should be completed in full with this in mind.

Conclusion

In line with the considerations above, the Committee agreed that the minimum criteria under the Regulations had been met for part of the cohort (deceased patients), and therefore advised providing a favourable recommendation to the Secretary of State for Health for those who were deceased or not able to be traced by treatment centres. For those who were alive and in contact with local clinical care teams, members requested that consent should be obtained via a clinician responsible for the care of the patient.

**Specific conditions of support**

1. This recommendation was for access to data in England and Wales only.

2. This recommendation was for access to deceased person's data and those who could not be traced by the clinical care teams for consent; where patients are in contact with local care teams consent should be obtained via a clinician responsible for the care of the patient.

3. A patient group should be engaged with in order to seek input into the study and represent the interests of patients. The applicant was asked to provide details in relation to plans for patient engagement to the NIGB office.

**6, Any other business**

Definitions of the clinical care team

Members discussed two papers that had been provided by Professor Pereira Gray and Mr Wiseman. Members agreed that they found these documents useful and agreed the following conclusion. A member of the clinical care team could reasonably be defined as fitting all of the following criteria:

- Someone who is reasonably recognised as such by the patient
- A person who administers care and treatment to the patient
- A person who makes a decision in relation to specific care of the patient (a registered healthcare professional)
- A person who has a contractual obligation of confidentiality