Meeting held on Thursday 29 July 2010

Present

Members: Dr Andrew Harris (Chair), Mrs Pauline Brown, Dr Tony Calland, Dr Patrick Coyle, Dr Tricia Cresswell, Professor Carol Dezateux, Dr Fiona Douglas, Ms Stephanie Ellis, Professor Sir Denis Pereira Gray, Mr Michael Hake, Ms Ros Levenson, Ms Sue Parroy, Dr Mark Taylor, Mr Terence Wiseman.

In attendance: Ms Janice Boucher *(NIGB Social Care IG Lead),* Dr Alan Doyle *(NIGB Director – to item 4),* Ms Natasha Dunkley *(Approvals Manager),* Ms Claire Edgeworth *(Approvals Officer),* Mr Paul Eveson *(Department of Health),* Ms Melanie Kingston *(Deputy Approvals Manager),* Ms Zoë Lawrence *(NIGB Business Manager),*

1. Welcome and apologies

Apologies were received from Professor Roy McClelland and Professor Mike Catchpole.

2. Minutes of last meeting [ECC 5-02/2010] and matters arising

The minutes from the 2 June 2010 meeting were approved, subject to minor amendments.

A conflict of interest was declared from Dr Tricia Cresswell in relation to agenda item 3a, and from both Dr Andrew Harris and Professor Carol Dezateux in relation to agenda item 5f. These Members did not participate in the decision for these items.

A discussion arose over formalising management of conflicts of interest, and it was agreed that a formal policy would be adopted.

ACTION 1: formal conflict of interest policy to be prepared

2a. ECC Chair's Report [ECC 6-02(a)/2010]

The Chair provided an update on the NIGB meeting attended on 23 June 2010. This report covered the following aspects:

- A presentation on information governance in a research context from the Medical Research Council
- The NIGB Strategic Plan and Annual Report
- Appropriate use of smartcards and liability when a smartcard was inappropriately shared
- Proposed changes to the Care Record Guarantee
- Progress on HealthSpace and Summary Care Record development

For further information on the NIGB Board meeting please see minutes published on the NIGB website.

2b. NIGB Office Report [ECC 6-02(b)/2010]

This report provided an update on applications previously considered, amendments, fast track applications and general updates from the NIGB Office.

a. ECC 6-06-(d)/2009 Seascale Births and Schools Cohort

Following the decision of the Committee concerning this resubmitted application in February 2010, the NIGB Office had received a letter from Professor Alex Elliot, Chair of the Committee on Medical Aspects of Radiation in the Environment. It appeared from the letter that the conditions of approval had been misunderstood as Professor Elliot was of the view that consent was to be sought and he was concerned that this would invalidate the study. The reply clarified that the conditions of approval under section 251 were research ethics committee approval and compliance with fair processing under the Data Protection Act through notifying the cohort of the study. In this instance, explicit consent was not required, although dissent should be respected, and the applicant was informed that further advice on the DPA should be sought from the Information Commissioners Office if necessary.

b. Public Health Observatories (PHO)

At the April ECC meeting and the May DMsG meeting an application from the PHOs for identifiable HES data was discussed. Following these meetings, it was agreed with the DH that the previous 'safe haven' arrangement with PHOs was no longer applicable and did not provide a secure basis in law for the use of patient identifiable information, and that PHOs should apply for support under section 251 to cover the future access to patient identifiable data for specified purposes. The NIGB Office met with PHO representatives and agreed a way forward. An application from PHOs would be expected later in the Summer. A decision would need to be taken on whether the application should be considered under class or specific support.

c. National Cancer Patient Experience Survey

The NIGB Office had been receiving a number of telephone calls from NHS Trusts seeking clarification on whether there was section 251 support in place for them to disclose patient identifiable information to Quality Health for the above national survey. Quality Health had been commissioned by the Department of Health (DH) to send questionnaires to cancer patients, and had requested data on cancer patients to do so (data items: name, address, postcode, NHS number, sex, ethnicity, year of birth, admission and discharge dates, admission type, ICD 10 codes, specialty code, and referring GP). The Office advised that as section 251 support was not in place, it was for Trust to decide whether they wanted to accept the risk and disclose the information. The Office also corresponded with Dr Reg Race of Quality Health to advise on the legal basis and to confirm that section 251 did apply for this survey. The correspondence was referred to the DH. DH officials met with the NIGB office and agreed that applications would be made for future surveys, and that consent would be sought by Trusts to disclose the remaining data to Quality Health, as section 251 support could not be provided to data already collected. Over 130 Trusts out of 153 had already submitted their data to Quality Health.

d. Honest Broker – Privacy Impact Assessment

The NHS Information Centre (NHS IC) is in the process of setting up a Privacy Impact Assessment (PIA) Project for Honest Brokers. The PIA forms part of the development process for any projects that have privacy implications. The PIA will include various consultation documents which would be shared with the ECC.

e. NCASP Audits

The contractual arrangements for these audits are currently under review. The majority of the audits will remain with the NHS IC, but six may contractually move to be within the National Institute for Clinical Outcome Research (NICOR). Currently NICOR is not a legal entity but is based within University College London, meaning that UCL would take contractual responsibility. It was indicated that there might be a risk that the contracts would not be in place in sufficient time for the audits to continue. The data is currently held by the NHS IC. If this is the case the approvals in place for these audits would need to be amended for the storage of patient identifiable data as when current arrangements expire this would not allow for further data to be collected out of contract.

f. Care Quality Commission (CQC) – Confidentiality Code of Practice

Section 80 of the Health and Social Care Act 2008 required that the CQC produce a Confidentiality Code of Practice in consultation with the NIGB. The NIGB Office has received a draft copy of the Code which has been shared informally at this point with a selection of ECC and NIGB members for their initial comments. The Code will be formally presented to the NIGB at its September meeting.

Fast Track applications

a. 6-02 (FT1)/2010 Spotlight

This prospective observational study from the London School of Hygiene and Tropical Medicine set out the overarching purpose of investigating the measurement of delays into admission to Intensive Care, through assessing duration of survival following this admission. The cohort, consisting of a sample of 9000 patients, would comprise patients evaluated on the ward by critical care outreach teams, and subsequently admitted to critical care. The time period between this evaluation and subsequent admission would be assessed to investigate whether this delay had affected survival. Patient survival would also be determined at 90 days through using the Medical Research Information Service.

The study required access to name, NHS Number, date of birth, and postcode (unit level) for linkage/validation purposes, and date of death, gender and ethnicity would be retained for analysis purposes.

This application was reviewed by Members and the Chair outside of Committee and approved subject to the following conditions:

1. Consent should be obtained where reasonably practicable if units remain in contact with patient's if/when they regain capacity.

2. The fair processing information should be signposted in the relevant community languages where feasible.

b. ECC 6-02 (FT2)/2010 Confidential Inquiry into premature deaths of people with learning disabilities

This application from the University of Bristol set out the purpose of a confidential inquiry being carried out in the Avon area. It was noted that this would likely to be extended into Gloucestershire in year 1, and then in year 2 in an area with a high ethnically-diverse population. The inquiry was likely to run for a period of 3 years which was predicted to cover 160 reviews and access to information related to controls.

Section 251 support was required to permit access to contact details so that the team could identify the relevant healthcare services, the provision of information about the circumstances of death to the team, and to make contact with families of the deceased where appropriate. Access to patient identifiable data included name, NHS number, date of birth and postcode.

This application was reviewed by Members and the Chair outside of Committee and approved subject to the following conditions:

1. Provision of justification to support retention of unit level postcode, consideration as to whether district level postcode would suffice and if not, to consider the earliest opportunity unit level postcode can be destroyed

2. Incorporation of a privacy risk of harm assessment to take into account increased risk of inferential identification

Amendments to existing applications

a. ECC 2-06(o)/2009 Suicide in the Criminal Justice System

This application from the University of Manchester sought to extend the existing approval to enable the collection of secondary mental health care data for subsequent linkage to the Police National Computer (PNC). This data would be identified from consultant psychiatrists for living control participants who were sampled as part of the National Study of Suicide in the Criminal Justice System in England and Wales. Where identified, the responsible consultant would be sent a single questionnaire and asked to provide sensitive information regarding the cohort which would include the following identifiers: name, NHS number, date of birth, date of death, postcode and gender.

This amendment was reviewed by Members and the Chair outside of Committee and approved.

b. PIAG 4-05(e)/2007 IMS Health and HES Data Linkage

This application outlined an amendment to the approved activity so that authorised NHS IC staff could access the identifiable data fields in both the HES extracts and the prescribing data provided by the NHS Trusts. This amendment was approved.

3. FOR CONSIDERATION ITEMS

3a. Health Protection Agency (HPA) Annual Review [ECC 6-03(a)/2010]

This annual report set out progress of the HPA activities carried out under the Health Service (Control of Patient Information Regulations) 2002 (the 'Regulations'); specifically those related to communicable disease and other risks to public health. The purpose of the annual review was to review at intervals not exceeding 12 months the need to process confidential patient information, and the extent to which it is practicable to reduce the confidential patient information which is being processed. This also includes a review of the scope of the approval, security and confidentiality arrangements, and to check that the activities were progressing as planned. Members assessed the annual review report and subsequent information provided to support the review.

Members noted the extremely important public health activities carried out by the HPA, and welcomed this annual review submission. In particular, Members were mindful that a number of

statutory changes have been and will be taking place, and therefore assessment of the specific support provided under section 251 was reviewed within this context.

It was highlighted that the Committee strongly welcomed the activities of the HPA and considered them to carry out a hugely important and essential function. Members noted that the report contained a large amount of information, and included an update on structures, processes, specific issues arising throughout the previous year, and appendices. In particular, Members noted that Public Health Wales (PHW) was no longer covered by the specific support under the Regulations, and therefore expected that an application would be forthcoming so that the appropriate legal support would be in place to provide a continuing legitimate basis for the PHW public health activities.

Members firstly noted that research activities did not form a part of the specific support under which the HPA operates in terms of its section 251 approval. It was agreed that clarity was required over this aspect and for those aspects that were definitively research activities there should be a separate application made for each to the respective approval bodies. This concern arose particularly from sections 4-6 of the annual review report as Members felt that on the face of the report there appeared to be some blurring between those activities clearly covered within the scope of the Regulations, and those that appeared to be research activities. Members emphasised this point as they were keen to maintain a clear boundary between those activities that clearly fell within the Regulations, and those which did not.

Additionally, Members raised queries over section 8 of the report and the activities of the research consortium. It was not clear to Members whether this comprised a joint activity between Oxford University and the HPA, and were of the view that if the University was involved then it was possible that a separate application would be required to cover their involvement. At present, the level of information provided was not considered sufficient for a decision to be taken on this aspect, therefore further detail was requested on the membership and activities of this group so that this could be taken forward appropriately.

Members noted that there was a specific request for advice in terms of data sharing in acute emergency situations. Members raised the point that the HPA covers a number of functions, and queried whether some of the specified examples could be considered to form part of the HPA's statutory functions in its role as a category 1 responder. If this was the case, and if these could be specified, it would be possible that those activities would not require endorsement under section 251 as they would already be covered within the original legislative purpose of the HPA. Members requested that this aspect be explored further. In particular, Members expressed the concern that the request for advice, as currently phrased, could be perceived as the Committee providing a 'blank cheque' to cover the scenarios. It was appreciated that this aspect was at an early stage of development within the HPA, and therefore Members agreed that they were not in a position at present to provide definitive advice on this matter until the general statutory obligations and general business of the HPA had been explored within this context.

Due to this necessarily wide variety of activities contained within this report, Members expressed the view that the current format did not altogether assist the reader in understanding the diverse nature of activities, and convey the complexity of issues around activities and changes to legislation that might impact on the approval provided under section 251. As such, Members agreed that the current summary format was not sufficient to reflect the changing and diverse nature of the activities, and therefore significant revision would be required.

It was recommended that the applicant engage with the NIGB Office in order to establish the level of detail required for this annual review. Suggested areas for division of the report were legislative changes and impact, organisational changes and impact, updates and/or changes to previous activities; where future activities were indicated, to provide further detail such as purpose, timescales, outputs and any data sharing arrangements. These should also be clearly defined as to whether they were research, or fell under the Regulations. A section on governance structures should be clearly set out and any cross-referencing to other applications that had section 251

support should provide the relevant reference number. Additionally, in terms of compliance with the Data Protection Act (DPA), the report should show how compliance with the fair processing was being achieved as approval under section 251 could not be inconsistent with the DPA.

In line with the above details, the Committee were unable to take a decision at the July meeting and deferred reaching an outcome. Instead, they requested that the review report be substantially revised, with advice from the NIGB Office on required format, and that this report should be submitted to the September Committee meeting. Members wished to highlight that they strongly supported the work of the HPA under section 251, but felt they did not have sufficient clarity of information to enable them to take an informed decision.

ACTION 2: NIGB Office to meet with HPA to discuss outcome and provide advice

3b. Children and Adolescent Psychiatric Surveillance System [ECC 6-03 (b)/2010]

The Child and Adolescent Psychiatric Surveillance System (CAPSS) is an initiative developed by child and adolescent psychiatrists in conjunction with the Royal College of Psychiatrists (RCPsych) and the Royal College of Paediatrics and Child Health (RCPCH). These papers arose from a request from CAPSS for their methodology to be formally adopted by the Committee as being suitable for the Committee's fast track procedure. As CAPSS closely reflected the methodology involved in surveillance systems followed by the BPSU, this was initially discussed at the November 2009 meeting, and a number of requirements set out to enable formal adoption of this approach. Further documentation related to this aspect was provided and discussed at this meeting.

Members discussed in detail the request for applicants carrying out CAPSS surveillance studies to be handled as per the current British Paediatric Surveillance Unit (BPSU) system for processing applications requiring section 251 approval. The Committee welcomed the effort that had been involved into producing the documentation, and noted that CAPSS would not be in receipt of any patient identifiable information themselves. Members also welcomed the confirmation that they would expect the minimum amount of identifiers to be collected to avoid duplications, and that these data would be retained for a period of two years.

Members noted some inaccuracies within the documentation provided, and particularly those in relation to correct citation and abbreviation of the Committee and the NIGB , and requested that these should be rectified and information updated where appropriate where this information was in the public domain. Members also raised queries over the general governance and sought clarification over collection of data related to third parties.

Members also noted that user involvement was not strongly covered due to cited reasons of insufficient funding. It is a principle of the Committee's decision-making that research activities should generally seek to engage patient representation, and debated whether they were prepared to accept this lack due to funding issues. As a whole, the Committee agreed to maintain its view that patient engagement was integral to applications, and should be explored where reasonable opportunities are present, having due regard to cost. In particular, it was noted in the context of this review that individual researchers would seek to apply for support under section 251 under the CAPSS methodology, and therefore the extent of user involvement would be assessed individually for each application.

Subject to the above amendments being carried out as soon as possible, the Committee agreed that it would be appropriate to initially review such applications under the fast track procedure. The practical effect of this agreement would be that any application to the Ethics and Confidentiality Committee, made by a researcher seeking to carry out a study under the CAPSS methodology, and would initially be processed outside the normal Committee meeting schedule by a smaller

number of Members. The caveat to this agreement would be that applications seeking to significantly deviate away from the principles under this methodology, or those that raised significant concerns might require scrutiny within a full meeting.

As such, Members agreed to support this request.

4. RESUBMITTED APPLICATIONS FOR SECTION 251 SUPPORT

4a. CAPSS survey of childhood–onset non-affective psychosis [ECC 5-04 (k)/2010]

This application from the University of Durham set out the methodology around a monthly postal survey whereby Consultant Child and Adolescent Psychiatrists would be asked to report children younger than 14 years of age they have encountered with schizophrenia or a related psychosis. For each case the reporting clinician would be sent a brief questionnaire establishing basic clinical details about the cohort. At one year a follow-up questionnaire would be sent. In addition, in order to assess sensitivity of the surveillance study at the end of the first 13 months a brief telephone survey would be conducted. This would involve contacting all the Consultant Child and Adolescent Psychiatrists within one health region and asking whether they had encountered a case of schizophrenia (or related disorder) in under 14-year olds in the last year. This "double-capture approach" would be used to estimate the effectiveness of the survey methodology. The survey was intended to identify this population and assist in finding more effective ways to meet their needs.

This application was initially considered via the fast track procedure as it appeared to follow the BPSU methodology, which is an ‘approved methodology’ for consideration of section 251 applications, however, due to a number of concerns raised, it had been referred to a full Committee meeting in June. In the June meeting, Members were of the view that the concerns had not been adequately addressed and requested that the application be resubmitted to the July meeting, taking fully into account the concerns raised.

Members reviewed the concerns that arose in their initial consideration of this application at its June meeting, and therefore focused their discussion on whether the concerns had been adequately addressed. Members noted the clear applicant engagement with the queries posed and welcomed the steps taken to address these in detail. This included the clarification over a two-year retention period, and that follow-up would be achieved via a unique study code that would be issued with the original card. Together with age, gender and ethnicity this was stated to be sufficient to achieve follow-up. In particular, Members noted the point about removal of references to opt-out on the public information leaflet. The Committee noted that section 251 support could not be used to override active dissent, in line with the standard conditions of approval, and that such instances should be handled in line with the requirements of the Data Protection Act 1998.

As the applicant had fully addressed the concerns raised, the committee agreed to recommend support under section 251 to this study.

5. NEW APPLICATIONS FOR SECTION 251 SUPPORT

5a. Greater Manchester Drug related Deaths Early Warning Surveillance System [ECC 6-05(a)/2010]

This application was originally considered under the fast track procedure as the cohort related to deceased persons. However, during this assessment Members raised a number of concerns;

these were considered to be substantial and therefore it was agreed that a decision could not be taken via fast track and the application was referred to full Committee.

This was an application from the Greater Manchester Public Health Practice Unit to develop a drug related deaths confidential inquiry protocol and to develop a database for monitoring drug related deaths in drug treatment service users. Additionally, the intention was to develop an early warning system to enable inter-agency information sharing, and it was indicated that there would be a service audit component to the activity.

A large number of patient identifiable data items were requested; including NHS Number, ethnicity, date of birth, date of death, coroner's inquest report, toxicology reports, drug use status, HIV status, GP treatment history, mental health and prison history. It was noted that the activity would require linkage of data items across a number of sectors.

Members noted that the applicant had engaged with the NIGB Office in order to attempt to resolve some of the core issues raised by Committee Members. The detailed concerns raised by the Committee during its original fast track review had been provided to the applicant and reflected much of the discussion that took place at the Committee meeting. Members agreed that this appeared to be a valuable activity with significant public interest considerations, however, the fundamental issues raised were so significant that the Committee was unable to approve the application in its current form.

The key considerations, which should be read in conjunction with the initial concerns raised by Members are set out below:

1. Members expressed significant concerns over the multitude of purposes contained within the application. While it appeared that one purpose was to provide evidence on aspects of the care of drug users who had died as a result of their drug habit and how this might be improved, it also appeared to include others, some of which were not articulated. It could be inferred that the purposes included ascertaining contributory factors to death, service monitoring to identify system failures, identification of changes in pattern of drug usage, identifying habitual location of drug users, discovering areas in which organizational partnerships might improve efficiency, improving coding of deaths, to performance monitor drug teams, measuring the number of unidentified drug deaths, and comparing different organizational perceptions on individual cases. However, this very breadth of purposes had not been fully explored. The methodology also appeared to include both surveillance and a confidential inquiry methodology. Members with research experience commented that the usual range of skills and experience expected for confidential enquiries was not evident and the selection process had not been well defined. The view was that without greater clarity about purposes it is not possible to determine if the methodology is appropriate. Members also felt there was a misunderstanding of the principles of surveillance. An understanding of these is crucial for the Committee to determine whether the balance of public interest and individual detriment was in favour of public interest and whether there was a practicable alternative to s251.

2. Members noted that data required from the medical records, the inquest and police files were hugely sensitive. For example it might include not only drug usage, but offences, prison terms, history of violence, risk behaviours, sexuality, HIV and alcohol and mental health information. The application listed a long list of identifiers without justification, which would be necessary to enable to the Committee to ascertain whether these would be necessary. Members agreed that in many of these cases, the family would be traumatised and might wish for the details of the drug or criminal activities to be kept confidential. The application appeared to seek to collect an extensive set of highly sensitive data based on model data collection templates that were specified in DH Guidance for Drug Action Teams on developing local confidential enquiries. Members were mindful of the statutory prohibition of processing confidential patient information no more than is necessary for the purpose, and therefore Members agreed that neither the application nor the guidance

provided a clear justification for why and how these sensitive data items would be used in any analysis or how it was thought that remedial actions will be informed through their collection, to preserve privacy and reduce the risk of inferential identification. For example the use of the initials of the deceased suggests that the adequacy and techniques of pseudonymisation were not appreciated. As such, Members considered this section was not sufficiently well-defined to justify the obtaining of all of the items without consent.

3. The application also argued that consent would not be required because the data related to deceased individuals, and also implied that it was not required because access to fully identifiable information would be restricted to a small team. However, the DH Guidance (which dated from 2003) recommended that "*active consent should be obtained from a personal representative of the patient" (or that alternatively the enquiry should be conducted "solely on information in the coroners' records*") which suggested these records were in the public domain, and it was understood that the full record would not be made available. The application also did not fully consider that that disclosure of the personal details of the deceased to a wide range of agencies that might have had contact with the deceased could of itself be a disclosure of confidential information. As such, the view was that an adequate justification had not been provided to justify this aspect.

4. Members appreciated that much of the application was based upon Department of Health guidance, however, it was noted that this document had been published prior to the Health Service (Control of Patient Information Regulations) 2002 SI 1438, and therefore its principles did not reflect nor was consistent with the current requirements on information governance and management. It was therefore unfortunate that the application was based upon an outdated piece of guidance as this necessarily had implications for the application. Members were also of the view that there was inadequate evidence of suitable patient engagement in this activity, nor the use of focus groups to advise on the most appropriate approach and design. Members were of the view that such an approach would have led to significant improvement of the application.

5. A document from the Greater Manchester Police on information sharing arrangements relating to this surveillance system was provided, in which it is stated that the data sharing schedule was made in compliance with the DPA, the Common Law, and the Crime and Disorder Act. Members noted that the legislation referred to might well be permissive to the disclosure of data to the police for the purposes of a criminal investigation, but they should not be seen to permit health investigations. As such, Members queried the statutory basis for this activity and felt that there was a misunderstanding of relevant powers as they related to sharing of personal information for health purposes, among partner agencies, and requested clarification on this aspect.

Due to the summary of reasons cited above and the more detailed queries, the Committee was unfortunately unable to recommend support under section 251 for this application in its current form. It would welcome this activity taking place in the appropriate form and with the necessary controls, however, the concerns were so fundamental that it would be necessary for the points made to be explored in detail and resolved by the applicant should the wish be to resubmit this application. The applicant was advised to clarify the purposes of the activities and if necessary split the application. Advice was given about engaging with suitable methodologies such as Child Health Death Reviews or national confidential enquiries, about the value of seeking advice from a REC and the role of the office in facilitating an amended application.

5b. Abdominal Aortic Aneurysm Quality Improvement Programme [ECC 6-05 (b)/2010]

This application from the University of Bristol required access to 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.

Members noted that there was a variation in outcomes and there had been incomplete returns of data, and that initially non-identifiable data had been used to attempt to resolve the issue, but now identifiable data items were required in order to identify discrepancies. Members agreed that as a whole there was a public interest in completing this activity. Members also agreed that it would not be reasonably practicable to seek to obtain consent on a retrospective basis, and they welcomed the confirmation that consent would be sought on a prospective basis to populate the NVD from the first week of August 2010.

As such, whilst Members were supportive in principle of the request to access HES data utilising section 251 support, they were mindful that support under section 251 could not be used to provide retrospective legal support to patient identifiable information collected without patient consent in the first instance. It was understood that for some of the cohort details held on the NVD that consent was obtained for some, but not for all patients. As such, the support provided under section 251 could only be used to validate details of those patients for whom consent had been obtained in the first instance.

5c. International Study of Incident Cancer (ISICA) Breast Cancer & Diabetes [ECC 6-05 (c)/2010]

This was an application to establish a registry of diabetic patients diagnosed with breast cancer since January 2008. This would be used to ascertain whether there was a risk of breast cancer associated with particular medications in patients with diabetes using a case control methodology. This study would be funded by Sanofi-Aventis and the National Cancer Research Network had expressed their support for this study, provided that section 251 support could be obtained to permit access to patient identifiable information by the 'research monitors' specified in the application.

These monitors would carry out the identification of breast cancer patients using pathology records or discharged diagnosis listings. Potentially diabetic patients would be identified from patient records. Section 251 support was requested to permit these monitors to identify and extract information about potential participants, prior to their consent to participate being obtained.

Members appreciated the efforts by the applicant to seek to resolve issues by the NIGB Office, and agreed that generally there would be a public interest in the outcomes. Members also assessed the comments received by two local trusts who had indicated that they would welcome the resource of the monitors in carrying out the activity.

Members highlighted that section 251 support could only be provided where there is no other feasible option, such as consent, where anonymised data could be used, or of particular relevance in this instance, where the local clinical care teams are able extract the relevant information and provide only pseudonymised or consented data to external researchers.

In discussing this application in detail, Members assessed the view that clinical teams should not carry out the identification for bias reasons, and queried whether this was sufficient to justify that there was no other reasonably practicable method by which to carry out the activity using the research monitors. It was noted that some Trusts had indicated they did not have a resource, but that some did. As the Committee was presented with information that indicated that some Trusts would be willing to carry out the activity using their local clinical care teams, Members considered that sufficient justification had not been provided to permit support under section 251. Members were therefore of the view that the activity could be carried out using the local clinical care teams in

the first instance, and in this situation, section 251 support would not be required. In the subsequent event that there is a failure to recruit further Trusts who are prepared to use local resources, then the Committee would accept a further application which would need to provide significant evidence that there was insufficient local resource.

As such, the Committee was unable to provide support under section 251 to the application at present, as it appeared that there would be a reasonably practicable alternative to carrying out the activity using the methodology (local clinical care teams) within the study. Should after a period of time there be evidence to suggest that the applicant is unable to recruit sufficient Trusts, and have explored fully the local resources, then the Committee would welcome a further application providing this evidence.

Should the applicant decide to resubmit in the future so as to permit the external research monitors access to patient identifiable information, then Members highlighted the following points:

1. Ethical review by a research ethics committee. This opinion should be obtained in any event and if resubmitting, a copy of the outcome letter should be provided to the NIGB Office.

2. Members were of the view that user involvement within the context of section 251 and research activities had been misunderstood and suggested following the link to INVOLVE that is available via the NIGB website www.nigb.nhs.uk
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3. Members queried why the UK Cancer Registries could not carry out this activity and requested that this be explored further.

4. If resubmitting, the Committee requested to see a copy of the contract of employment. This was in line with the requirement under section 7(2) of the Regulations which states that "*No person shall process confidential patient information under these Regulations unless he is a health professional or a person who in the circumstances owes a duty of confidentiality which is equivalent to that which would arise if that person were a health professional*".

5. Members also expressed concern that the GPs were not fully informed about the study, and would welcome the research ethics committee's views on this aspect.

6. Members queried what would occur with the results of the study and what would be published as it was unclear whether the results would be published in the UK.

7. Members requested that more UK involvement was required in the study, and that the applicant should identify and engage a NHS clinical academic collaborator. Members also understood that it would be a research ethics committee requirement as part of research governance that a contract must be held with the NHS (which could be achieved via this clinical academic collaboration). It was recommended that this aspect be discussed further with the research ethics committee.

5d. East Midlands Patient Experience Survey (EMPES) [ECC 6-05(d)/2010]

This application from NHS Nottinghamshire County set out the purpose of identifying and driving forward improvements in patient care and satisfaction. The information would be analysed and comparisons made across all PCTs. Information related to this would also be made available in a suitable format to patients.

Section 251 support was requested to permit disclosure of patient identifiable information related to patients who had undergone a PROMs procedure to a third party (Quality Health). This third party

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, full postal address and NHS Number, date of admission and discharge, provider organisation and site code, primary diagnosis and primary operative procedure code. The PCT would compile an identifiable list of patients which would be sent to Northgate Information Services. Northgate would finalise the mailing list through using the Demographic Batch Service to identify those who had moved or were deceased. This final list would be transferred to Quality Health who would then dispatch the invitation letters. Responses would be returned to Quality Health, which would transfer this information back to Northgate, who would then link the consented data to PROMs.

In assessing this application, Members agreed that there had been a good standard of user involvement, and that the responses given to demonstrate compliance with the Data Protection Act had been clearly articulated. Members also agreed that there would be an extent of public interest to the patients in this activity being carried out.

Members initially queried why the PCTs could not carry out the activities themselves, as this would be the ideal situation that should not involve any disclosure of patient identifiable data to a third party. In discussing this issue, Members noted in particular that section 251 support was specifically requested to enable the project to continue, and also to allow sufficient time to establish a mechanism by which the activity is carried out with explicit patient consent.

The Committee noted that the application provided a clear pathway in moving away from support under section 251, and highlighted the following in the briefing document

> *"The longer-term approach would be to develop and implement a consent model that would obtain patient consent at the first point of patient contact within the hospital. This would allow the project to progress into future stages which could include all inpatient activity in acute care and even other areas of care provision."*

Members welcomed this commitment to moving towards consent, and this was the key consideration affecting the decision taken in relation to this outcome as this was a finely balanced decision. Members agreed that consent would not be feasible retrospectively, but would expect for plans to be in place for future similar activities.

As such, the Committee agreed to recommend support under section 251 for this one-off activity, subject to satisfactory resolution of the following request for clarification.

Request for clarification

1. In assessing the requested access to information, Members queried the rationale for diagnosis code. They understood that it was required for linkage purposes, however, they were unclear on why procedure code was not sufficient. As such, they requested justification on the need for diagnosis code.

5e. Cambridge Centre for Ageing and Neuroscience (Cam-CAN) study [ECC 6-05 (e)/2010]

This application from the University of Cambridge set out the purpose of examining the effects of ageing on cognitive ability. Section 251 support was requested in order to permit researcher access to PCT lists to access name, GP registration, date of birth, address (sector level) and postcode. This would be for the purpose of identifying and sampling the cohort, at which point potential participants would be written to in order to seek consent to participate in this study.

Outcome

As a whole, Members considered this application to be clearly articulated, the study design to be sound, and the potential benefits in the public interest. In considering whether there would be another practicable alternative to the researchers accessing patient identifiable information, Members noted that the size of the study (3000 individuals to be consented in the first phase) and the limited number of practices (6) from which these were to be drawn, would seem to pose a significant workload for the GPs concerned if each subject had to be telephoned to obtain consent, and be assessed for mental capacity. Members also agreed that the level of information disclosed prior to consent was limited, and the invitation letters appeared to be clearly written.

Based upon the points made above, Members were generally content to provide support under section 251 to permit researcher access to identifiable information for the purpose of inviting patients to participate in the study. However, Members expressed significant concerns about the issue of visiting patients at home if they had not responded to the invitation to participate.

In discussing the proposal that members of the research team would visit the homes of subjects if they had not responded to the initial letter within 3 weeks, Members noted that they did not have information to confirm whether patients were informed that there would be a home visit if they did not respond to the participation request. In the event that this was not present, Members were concerned by this aspect.

Members felt that this was a potentially vulnerable cohort with possible capacity issues, and therefore were of the view that exceptional justification would be required for this approach. It is a principle of decisions taken under section 251 that initial approaches for research activities should come, or appear to come, from a treating clinician or someone known to the patient, therefore Members welcomed the fact that the invitation would appear to come from the GP, which is in line with this principle.

However, Members were concerned that the patient would be visited by the researcher, who they do not know, who would then seek to answer questions about the study and obtain consent. The Committee thought that there could be a potential perception of coercion in visiting the patient's home without having received confirmation in advance that this would be acceptable to the patient. Whilst Members considered this to be primarily an ethical issue, the Committee was of the view that it had a responsibility in this area as where section 251 support is provided, it permits access to specific patient identifiable data items for defined purposes. At the meeting, Members were not persuaded that providing access to information for this specific purpose would be acceptable for the issue stated above, and therefore requested the research ethics committee perspective on this aspect, as at present, they were not content to provide access to patient identifiable information for this aspect of the methodology.

In addition, when this methodology was previously queried via the NIGB Office, it was noted that this methodology of visiting patients where they had not responded to the request to participate had been used in previous studies. In order to inform justification to support this issue, Members requested further detail on this aspect, to include details of the studies, approvals process, and rationale for approaching this type of cohort with potential mental capacity issues. Members also requested confirmation as to the training received by the specified research interviewers on seeking to obtain consent from those with mental capacity concerns.

Excluding the issue of home visits, the Committee agreed to provide provisional support under section 251 to this study, however, this did not include the provision of information to facilitate the researcher visiting patients if no response had been received. However, Members agreed that if there was an exceptional justification, they would be happy to review this aspect of the methodology if further information was provided. As such, a number of clarifications were requested.

Request for clarification

This provisional approval was subject to the following clarifications being successfully resolved:

1. Provision of all final versions of documents assessed by the research ethics committee, in particular, those related to patient contact and participant information sheets.

2. Clarification of the nature and approvals process for those studies cited where potential participants had been visited at home prior to obtaining consent.

3. Clarification over the statement "*due to the hypotheses of the study we must use the same approach for all participants*". It would be helpful if you could explain why the study must follow the same approach in order to achieve the hypotheses.

ACTION 3: NIGB Office and Members to follow-up on issue of home visits with applicant

5f. A clinical, economic and operational evaluation of the pilot Women's Enhanced Medium Secure Services (WEMSS) [ECC 6-05 (f)/2010]

This application from the University of Manchester sought to evaluate the WEMSS in order to identify benefits and usefulness in treating the cohort, and to identify its impact in comparison to non-WEMSS NHS and independent sector services. The cohort would consist of all 42 WEMSS women and 84 controls, and consent would be obtained from 10 WEMSS women and all controls to carry out the qualitative aspect; consent would not be obtained for the quantitative aspect. It was for the latter aspect that support under section 251 was required.

Members agreed that this was an extremely important activity with a high public interest for those in marginalised groups. Members were also mindful that it would generate important qualitative information that would ultimately evaluate a service.

The Committee's primary concern was that the application stated that section 251 support was explicitly sought to override dissent as it was known that a proportion of the cohort would be likely to not provide consent. Members were sympathetic to the view taken that it would be important to obtain 100% ascertainment in order to fully evaluate the service, however, it is principle of decisions taken under section 251 that it cannot be used to override dissent.

In addition to discussing the fundamental point above, Members additionally requested further clarity on the following aspects:

1. Members were not clear on precisely which identifiers were required for linkage, and the analysis purposes, and requested further clarity on this issue

2. Members also requested justification on why each identifiable item was required, particularly those within the modified clinical bundle.

3. Clarification was requested at the point the data would be anonymised

4. The view was that there would be an inferential risk of identification due to the small numbers and the sensitivity of the outputs, and information was requested on what steps would be taken to manage this risk in publication.

5. Members were not clear on whether there would be follow-up or whether this would be a one-off activity

6. In noting the sensitivity of the data, the view was that there was a high risk to privacy and therefore the justification for access needed to be specific within this context

Members discussed various ways in which to resolve this issue such as the potential of working with local clinical teams or possibly reframing as a local audit. Members emphasised that they would be keen to progress this activity and would like to facilitate its completion, therefore in order to progress this application, Members thought that it would be helpful to offer a meeting with the applicant, and it was agreed that the NIGB Office would facilitate this meeting.

ACTION 4: Meeting to be arranged with applicant and feedback to be provided in next ECC meeting

5f. Health Care Needs Assessment: Vulnerable Groups with Long Term Conditions [ECC 6-05 (g)/2010]

The Deputy Chair chaired this agenda item.

The stated purpose of this Health Care Needs Assessment from Tower Hamlets PCT was to understand the health and social care needs of vulnerable groups in Tower Hamlets with long term conditions (LTCs). The importance of this was to ensure that unmet needs could be addressed, and to ensure the appropriate services could be provided.

Members noted that the application required access to NHS Number, date of birth, gender and condition codes, and that NHS Number was required so as to quantify whether the vulnerable groups lived in nursing or residential care or at home, and if they lived at home, whether this was alone or with a carer. It was noted that NHS Number would be matched to the Unique Property reference number (UPRN). The UPRN database linked property data to social care data via a previous exercise which had already been carried out through collaboration with social services.

Members discussed the various linkages in detail, and felt that further clarity was required over the data controllers for each source. Members were also unclear on the specifics of the clinical effectiveness group, and were of the view that it appeared a potential outcome was to re-identify a de-identified database. Members thought it would be helpful to explore this aspect further as they were unsure as to the arrangements and current legal bases for the holding of patient identifiable information in the first instance.

As the Committee felt that further clarity was required over the purposes, the governance arrangements and the relevant legal bases for the data sources, they were unable to approve the application in its current form. However, the Committee were keen to address these issues and therefore queried whether it would be helpful to arrange a meeting by which to resolve these concerns. It was agreed that the NIGB Office would facilitate a meeting between Members and the applicant.

ACTION 5: Meeting to be arranged with applicant and feedback to be provided in next ECC meeting

5h. Improving the effectiveness of multidisciplinary team meetings for patients with chronic disease [ECC 6-05 (h)/2010]

The purpose of this application from University College London was to assess a number of multidisciplinary team meetings (MDMs) to identify good practice, the effectiveness of decision-making, and to provide recommendations for future MDMs. Section 251 support was required in order to enable researcher observation of 10 MDMs and to permit examination of medical records. The application requested access to name, NHS Number, Hospital ID, date of birth, postcode and gender.

In discussing this application, Members wished to commend the applicant on the extent of user involvement, and found this to be particularly impressive. Members also noted the responses provided to the queries, which set out the reasons to justify researcher access to patient identifiable information, and noted the perspective that the local teams did not have the capacity to carry out the linkages.

Whilst generally supportive of this application, in reviewing the requested identifiers, Members agreed that a case had not been made to justify use of full postcode, and queried whether full postcode was necessary to achieve the stated aims. As such, Members requested further clarification on this point before a decision could be taken on providing support to the use of full postcode under section 251.

Members also queried the arrangements over retention, and requested clarification over the retention period of the patient identifiable data as it appeared this had not been covered within the form.

As such, and based upon a consideration of the public interest, the Committee recommended provisional support under section 251, subject to satisfactory resolution of the requests for clarification and acceptance of the conditions of approval.

Request for clarification

1. Members were not clear on why full postcode was required, and therefore requested that a justification be made to support this use under section 251.

2. Clarification of the retention period for the retention of patient identifiable information, and the reasons behind this retention period.

5i. A randomised stepped wedge trial comparing the effects of an integrated electronic "TrackandTrigger" system ECC 6-05 (i)/2010

This application from Oxford Radcliffe Hospitals Trust set out the purpose of comparing electronic hand-held devices with their paper-based equivalent. This would be achieved through studying whether an electronic "Track and Trigger" would improve the outcomes of trauma patients and hasten recovery, in comparison to the scores assigned via the equivalent paper-based system. Section 251 support was sought to permit external research nurses access to and extraction of patient identifiable information for the purposes of this study.

As a whole, Members considered this to be a clearly-articulated application, and Members agreed that it would not be feasible to seek consent from the outset due to the nature of the cohort. In assessing whether consent would be feasible at a point within the care pathway, the Committee welcomed the statement from the applicant that a consent for 'access to medical records' form would be introduced as part of the process. Whilst the Committee were pleased to see this, they expressed concern over contacting the patient via telephone if a response had not been received. They were not persuaded that this would be appropriate and therefore requested that contact remain via the postal system.

As such, and based upon the clear public interest inherent in the application outcomes, the Committee agreed to recommend approval under section 251, subject to the following conditions of approval.

Conditions of approval

This provisional approval was subject to the following conditions:

1. Provision of a favourable opinion from a research ethics committee

2. Confirmation of satisfactory security arrangements

3. Consent to be sought for access to medical records via post. Telephone contact should not take place if consent had not been received.

6. Any other business

No further business was discussed.

Dates of future meetings

Wednesday 1 December 2010
Thursday 3 February 2011
Tuesday 29 March 2011