Meeting held on Tuesday 30 March 2010

Present

Members: Dr Andrew Harris (Chair), Dr Tony Calland, Dr Patrick Coyle (DMsG Chair & ECC Member), Professor Carol Dezateux, Ms Stephanie Ellis, Professor Sir Denis Pereira Gray, Mr Michael Hake, Ms Ros Levenson, Professor Roy McClelland, Ms Sue Parroy, Dr Mark Taylor, Mr Terence Wiseman.

In attendance: Ms Natasha Dunkley *(Approvals Manager),* Ms Claire Edgeworth *(Approvals Officer),* Mr Paul Eveson *(Department of Health),* Ms Melanie Kingston *(Deputy Approvals Manager),* Mr Andrew Lall *(Deputy Approvals Manager),* Ms Zoë Lawrence *(NIGB Business Manager)*

1. **Welcome and format of meeting**

Apologies were received from Mrs Pauline Brown, Dr Tricia Cresswell and Professor Mike Catchpole.

2. **Minutes of last meeting [ECC 1-02/2010, 2-02/2010] and matters arising**

The minutes from the 2 and 3 February meetings were approved subject to minor amendments.

Matters arising

Care Quality Commission (CQC)

The Chair of the DMsG noted that whilst the Care Quality Commission (CQC) had statutory powers to obtain data, they brought their applications to DMsG for assessment as good practice. The Committee were informed that the CQC had offered to discuss their activities further with the DMsG. The DMsG thought that this would be of interest to the ECC and asked whether Members thought it would be of benefit to invite the CQC to attend a Committee meeting.

Members felt that there was some uncertainty over the purpose of the suggested meeting, and that although it would be helpful to discuss the statutory role of the CQC, especially considering the context of the recent application, Members were mindful that the primary focus of the Committee was to assess the increasing number of applications.

It was highlighted that the CQC were under a statutory obligation to consult with the NIGB when developing their code of practice on the handling of patient identifiable information, and therefore it would be more appropriate for this option to be explored further within the context of these discussions.

Action: NIGB Office to liaise with colleagues at the CQC.

ECC Chair's Report [ECC 3-02(b)/2010]

The Chair provided an update to the Committee on the following issues discussed at the National Information Governance Board meeting held on 24 February.

Guidance on release of patient data for screening programmes

A presentation had been made to the Board on behalf of the National Screening Committee. The paper introduced the NHS Health Check which was a new vascular risk screening programme, and the issues around capturing cohort information without consent. It had been highlighted that: the current system missed eligible people and there was a variance across general practices regarding the release of data to programmes. The Board had expressed concern about sharing data from general practices without consent and discussed the practicalities involved for general practices in obtaining consent, and the likelihood that independent sector providers would receive confidential information.

It was recommended that guidance for general practices would be developed in conjunction with the British Medical Association (BMA), General Medical Council (GMC) and National Screening Committee (NSC). A small working group would take this forward.

Enabling guidance for patients to access their electronic records

Guidance that had been presented last October had been revised and was reconsidered by the Board. The Board agreed that it needed further clarification for use by practitioners and suggested further changes.

Information Governance Framework (IGF) from the NHS Information Centre and Research Capability Programme

A paper was resubmitted to the Board that described the Information Governance Framework (IGF) that would provide assurance for those who processed patient data for secondary uses, such as Honest Broker Services and the pseudonymisation implementation project. This IGF was part of a wider initiative that took into account advice from a range of organisations. The Board had raised a number of queries around the IGF, including the independent audit process and the role of the NIGB in receiving assurance over the outcomes from these audits. It had been agreed that the NIGB office should continue to maintain dialogue with the Information Centre and the Research Capability Programme on NIGB engagement in the monitoring of the audit process and return to the Board with recommendations on an appropriate mechanism.

NIGB Implementation of recommendations to implement Care Quality Commission National Study on how healthcare organisations manage personal data

Dr Lesley Rogers advised that the NIGB should give priority to the development of data sharing agreements across health and social care. Another recommendation was for the NIGB to become involved in commentary on informational governance on Serious Untoward Incidents. The NIGB Director was to assess the capacity of the office to take forward one or more of the recommendations.

Research Database Working Group

The Board had approved the terms of reference of the Research Database Working Group. The NIGB welcomed the plan to have further discussions with the research community in a

"research session" to explore and develop mutual understanding of issues involved in these applications.

DMsG Chair's report [ECC 3-02(b)/2010]

Use of HES for marketing purposes

In one application, the Group had identified that it would be possible that the information obtained from HES would be used for a direct marketing purpose. The Group noted that this was not an acceptable use of HES data.

Consent and national databases

The Chair reported that DMsG was frequently asked for advice on the adequacy of consent. A number of consented applications were made which did not take into consideration organisational change, particularly in national databases. Others were made when studies were at an advanced stage or when recruitment was complete and researchers realised that information on mortality or cancer incidence was more easily obtained from the Medical Research Information Service (MRIS) rather than searching through records. The group had reached the view that national databases contained patient information derived from patient records, and therefore when the consent form permitted researchers to access information from medical records this would implicitly cover information in national databases. However, the DMsG agreed that if researchers wished to obtain data from national databases it would be best practice to explicitly state this within consent forms and patient information leaflets.

NIGB Office Report [ECC 3-02(c)/2010]

Members' Terms of Office

Members were informed that six members' term of office would come to an end in December 2010. The vacancies for members of the ECC would be nationally advertised and recruited by the NIGB.

Regulations

Members were informed that the Department of Health (DH) had arranged a meeting to discuss possible amendments to the regulations in order to encompass commissioning, honest brokers and consent for disclosure. The NIGB IG Lead would be attending the meeting as it was at an official level at this stage and did not remove the necessity for the DH to formally consult the NIGB on any changes. Members were to be kept informed of progress.

Annual Reviews

The NIGB Office had been working on ensuring that the register of approved applications was accurate and up to date. This had commenced by amending the current annual review template which had provided much clearer updates on applications. Additionally, the NIGB Office had been writing to all applicants that were due to submit an annual review to remind them of this statutory requirement

.

Fast Track applications

The following applications had been received and processed under the fast track procedure since the February Committee meeting.

ECC/BPSU 3-02 (FT1)/2010 – British Paediatric Surveillance Unit Study of Infants and Children who develop a Chylothorax

This study from University Hospitals Bristol NHS Foundation Trust was to establish how frequently chylothorax occurred and the instances of occurrence within differing groups of infants and children. The study followed the BPSU 'orange card' surveillance methodology.

Members considered this to be an important clinical issue and considered whether consent was practicable. Members concluded that although it might be possible to gain consent via the attending paediatrician or the relevant GP, this might be after the case had been discharged and therefore would require the paediatrician to contact the parents or for the consent form to be forwarded to the relevant GP. As such, Members concluded that in that specific instance it would involve a disproportionate effort compared to the relatively small risk of the data being collected.

This study had been reviewed by the Chair, Tricia Cresswell, Mike Catchpole and Mark Taylor and was approved.

ECC 3-02/2010 (FT2) Clinical Decision Making at the end of life qualitative study

This application from the University of York was considered by a smaller number of Members as it involved a deceased cohort, which was a criterion for the fast track procedure. This was a retrospective case note study to explore the process of decision making at the end of life. The information collected would aid in the identification of objective changes occurring in the final week of life which could be used to assist clinical staff to make decisions about care and treatment of patients.

Members considered this an important study which could help allow more people to exercise choice over how to spend their last days. It was agreed that it would not be practicable for the researcher to carry out the study using de-identified data. It was agreed that on this occasion it would not be appropriate to seek consent from the family members, but that members' suggestions about further consideration of user involvement were to be passed to the applicant.

This had been reviewed by the Chair, Mark Taylor, Tony Calland and Susan Parroy and was approved.

Extensions / amendments

ECC 2-06 (h)/2009 – Attribution Data Set

The Department of Health had provided notification that they had to cancel their previously approved application to receive data from the Personal Demographics Service (PDS) (ECC 5-07(g)/2009) due to logistical issues and data quality concerns. This application therefore requested permission to revert to obtaining the data from National Health Applications and Infrastructure services (NHAIS). As this application had previously been approved by full Committee, and the applicant had confirmed that the previously approved security arrangements were still in place, this application was approved by Chair's action.

PIAG 2-05(j)/2006 National Joint Registry extension

The National Joint Registry (NJR) had requested an extension to their current section 251 support to enable linkages to its dataset and the Hospital Episode Statistics (HES) and the Patient Episodes Database Wales (PEDW) service.

It was agreed that this extension was in the public interest and was approved by Chair's action.

ECC 5-02/2009 (FT3) Emergency department triage methods for suspected pandemic influenza

This application had been originally approved via the Fast Track procedure due to the nature of the swine flu pandemic. The original research protocol had stated that the applicant would prospectively identify cases by being alerted by the clinical care team when a case of pandemic influenza presented. They would then ask the clinical team to extract information for them and follow these cases up after 30 days. However due to the pandemic not materialising as they had envisaged the applicant had requested an amendment to identify the cohort retrospectively as they had not managed to recruit sufficiently via the prospective method.

This was considered by a smaller number of Members who advised that due to a number of changes and the current public interest, that consent should be sought via the members of the direct clinical care team involved in the care and treatment of the individual cohort, and that consent should be sought from the family of those who were deceased. The applicant agreed that this approach would be feasible, but indicated the possibility of a high non-response rate leading to bias that would render the outcomes invalid. They had also indicated that there was a lack of funding to cover this approach to allow their staff to continue, and that they had been informed that clinical teams were neither willing nor had the time to extract the data from clinical records. As such, the applicant had withdrawn their request to amend their activity.

<u>Update on previous February 2010 applications</u>

PIAG 4-05(k)/2007 Iron Deficiency Anaemia

Members were informed that a meeting had taken place between the applicant, the Chair, Tricia Cresswell, Carol Dezateux and the NIGB office. This had led on from the outcome in the February meeting where it had been agreed that a subsequent meeting take place.

The applicant was advised to attempt to carry out the study by using de-identified data which had been anonymised by the cancer registries and, if possible, to use an anonymised dataset from the GP databases. The applicant agree to investigate these options and to feedback accordingly.

ECC 6-06(p)/2009 Advancing Quality

This application from NHS Northwest had been rejected at the February 2010 meeting due to a number of concerns, and a meeting agreed to be arranged to discuss further options in order to aid the resubmission.

NHS IC- Honest Broker Pilots (ECC 2-04(b)/2010 and 2-04(c)/2010)

Members were informed that the NHS Information Centre (IC) did not intend to resubmit these applications in the near future.

ECC 5-07(i)/2009 – Testing of review criteria to selected NICE guidelines

The applicant had provided a letter setting out their position against the outcome of this rejected application. This letter had been assessed by the NIGB Office, Chair and Deputy Chair and the original decision upheld. The applicant had been informed that the only further option to them was to pursue an appeal via the NIGB.

3. Resubmitted applications for section 251 support

Count Me In [ECC 3-03(a)/2010]

This application from the Care Quality Commission (CQC) was originally considered under the fast track procedure, however, due a number of concerns raised by Members it was decided that the application would be considered by the whole Committee. These concerns included progress toward using de-identified data, a lack of clarity over the basis for not seeking a consent-based approach, the coming into force of the Mental Capacity Act, and the potential for inferential identification.

Section 251 was required to carry out a Census on a specified date in order to compare the outcomes with the data previously collected between 2005-2009. This would then form a basis for planning and implementing services which were appropriate and responsive. It also aimed to encourage all mental health and learning disability service providers to have in place an accurate and comprehensive ethnicity monitoring and record keeping procedures so that this type of data would always be available. The outcomes from the Census would provide information to help providers in achieving the strategic plan to tackle discrimination in mental health services.

The cohort to be studied consisted of all inpatients (approximately 35,000), informal and detained, in registered mental health and learning disability services, plus outpatients of these services who would be subject to the Mental Health Act.

The Committee welcomed the engagement from the CQC in attempting to resolve issues prior to the Committee meeting. Members also agreed that it was important for the Census to be completed considering that it was in its final year, and were therefore keen to ensure that all concerns had been satisfactorily resolved due to the sensitive nature of the data being requested.

Members discussed the CQC's powers as set out in the Health and Social Care Act 2008 and whether the Census could be considered as part of its regulatory functions. Members were of the view that in law, the Census was not a regulatory function, but an advisory or non-regulatory function of the CQC. As such, the Committee agreed that due to the nature of the activity and the level of sensitive data being collected, that it was entirely appropriate for the Census to be considered under section 251 and welcomed the CQC in continuing to seek section 251 support.

The Committee discussed the application at length. They agreed that the outcomes of the Census would provide a strong public interest. The Committee discussed the identifiers requested by the CQC and noted that the CQC had provided subsequent commitment to

removal of postcode during the submission encryption process so that it would not be received by the CQC, and the Committee welcomed this..

The Committee raised concerns regarding the high degree of potential damage to the interests of an individual if identification were possible. The Committee felt that identification of a patient with mental health or learning difficulties, coupled with experience of compulsory detention or particular sexual orientation, especially in ethnic minority communities, might seriously damage the interests of the individual.

The Committee welcomed the suggestion by the applicant to commit to a suppression policy at the level of five so that any cell containing five or less items would be suppressed It was understood that the applicant would not be publishing results until later in the year and it was indicated that the impact of such a suppression policy on the aims of the Census would be discussed. The Committee noted this and reiterated that such a suppression policy, together with the removal of postcode, would significantly mitigate against the risk of identifiability and agreed that the suppression policy should be reflected as a condition of approval and that any issues that arose from this could be discussed with the NIGB office at the earliest opportunity.

The Committee discussed the issue of the feasibility of gaining consent at length. Members discussed that a pseudonymised approach to data collection would be preferable as there were recognised to be some issues around gaining consent and that this may not be practicable. However Members were not convinced by some of the statements given in subsequent correspondence in relation to why consent could not be obtained by the applicant. In particular, Members were troubled by the statement that consent would not be required as the information would be collected in any event. Members noted that the collection of data by the CQC was for a purpose different from the original (regulatory) purpose of data collection, and therefore agreed that consent needed to be considered and that it was not valid to rule it out for these reasons.

Members noted the comment that as the activity was not research then it would not be considered to be intrusive and therefore the requirements under section 30-33 of the Mental Capacity Act would not apply. Whilst agreeing with this aspect, Members were of the view that this did not mean that data controllers did not need to consider the implications of releasing data of those without capacity for secondary use. Members agreed that providers should be alerted to their duty to consider if attorneys or deputies need to be consulted in any instances, for example, to avoid overriding dissent. Members considered that for future surveys, reasonable efforts should be made by providers to consult the various representatives in line with the general provisions of the Mental Capacity Act, so that their views would not be bypassed.

In conclusion Members agreed that the only valid reason provided for not seeking consent was the need to have full ascertainment so as to remove bias and ensure results were not rendered meaningless, and agreed that this allowed sufficient justification for support to be provided under section 251.

This application was provisionally approved subject to the following conditions of approval:

1. Postcode to be removed during the encryption process at submission by the provider so that it will not be received by the applicant.

2. A suppression policy would be implemented to suppress numbers of 5 or less in publication.

3. If carried out in the future for the applicant to notify providers that whilst section 251 approval had been given they should consider whether appointed deputies or attorneys in any instances need to be consulted.

Action: NIGB Office to notify applicant of Committee decision

International Cancer Benchmarking Project [ECC 1-05(a)/2010]

This application from the London School of Hygiene and Tropical Medicine had originally been considered at the Committee meeting in February via a letter and supporting papers. However, Members had requested that a full application be submitted to the March meeting to allow the Committee to reach a fully considered decision; taking into account all relevant information. This application was an extension to an existing section 251 approval; Linkage of National Cancer Registry data to national Hospital Episode Statistics (HES) data (PIAG 1-05(c)/2007).

This application set out the purpose of investigating why cancer survival was lower in England than in other countries. The application also included a paper setting out justification for use of full date of birth, diagnoses and death. The cohort would be all patients (aged 15-99 years old) who were normally resident in the territory covered by the contributing cancer registry in England and Wales when diagnosed with cancer of the breast, colon, rectum, lung and ovary during the period 1995 – 2007. The primary outcome measure would be to examine relative survival proportion and the excess hazard ratio.

Members agreed that this was an important international comparative study and that the results were likely to have a strong public health value and there would be a strong public interest in the outcomes of the study. Members noted that some comparable data would be received from Northern Ireland and from other jurisdictions, some outside of the European Economic Area, and that it would be the applicant's responsibility to ensure that the appropriate approvals had been obtained from the relevant jurisdictions as this fell outside of the remit of section 251. Members noted that patient identifiable information would not be transferred overseas and were therefore satisfied with the applicant's response to this aspect.

Members agreed that consent would not be feasible due to the large numbers involved. Members assessed the identifiers requested and agreed that these were reasonable and minimal for the purpose; in particular, it was noted that it would be necessary to have full date of birth as survival calculation required precise dates. Members discussed that although there was an acceptably low risk of inferential identification, due to the nature of the cancers being studied, the lack of geographical identifiers and the context of the study, there was still an expectation by patients to know what their personal data was being used for. As such, Members agreed that meaningful user involvement should be carried out by the applicant and reported in the annual review.

Members discussed at length whether there were any alternatives to the applicant carrying out the linkage activity so as to minimise the transfer of identifiable data. Members were concerned that the Cancer Registries did not appear to be in a position to carry the linkage part of the activity due to inconsistencies in coding and noted that this was a key reason why the activity needed to be carried out by the applicant in one setting. However the committee were advised that there was a technical statistical reason that this analysis needed to be done from one data set, in order to preserve accuracy of data and calculate confidence intervals. Members recognised that it would not be within the applicant's remit to influence the capacity of Cancer Registries. But it continued to consider that the use of registries for analysis was a practicable alternative to extracting untransformed data from each and should normally be

followed. Advising that this application should be covered by section 251 was wholly exceptional.

Members noted that the applicant had stated that the data would be retained until March 2011, at which point any further requests to retain data for a further period would be made to the Committee. Members agreed that this would be reasonable in the context of this activity.

The application was provisionally approved subject to the following conditions:

1. Patient engagement and consultation to be carried out by the applicant and reported in the next annual review. .

2. The approval did not cover any data generated outside of England and Wales as this fell outside of the remit of section 251.

Action: NIGB Office to inform applicant of Committee decision.

Action: Chair to contact Cancer Director, who facilitated the application, to discuss the role and capacity of cancer registries

NCASP 8-month review [ECC 1-06 (c)/2009]

This review report was submitted by the NHS Information Centre (NHS IC) for the National Clinical Audit Support Programme (NCASP). The application had originally been approved in March 2009 for a 4-month period. At the July 2009 Committee meeting, approval was subsequently provided for a further 8-month period, after which point a review report against the conditions of approval had been requested. Members noted that although provisional support had been provided in July 2009, final support was not provided until December 2009 as not all system level security policies had been provided until this point.

At the July meeting, the Committee had requested that progress be provided in 8-months on the three conditions of approval; an update on the exit strategy from section 251 support, information on clearer opt-out provisions, and information on how patients had been involved in the audits. The Committee were asked to consider the NHS IC's progress and provide further advice as necessary. In the interim period, the NIGB Office had been informed that the audits would potentially be put out for tender and therefore there might be a change in data processor.

Members welcomed the documentation provided and appreciated that a significant amount of work had taken place in order to produce the review report. Members also noted further correspondence that indicated that six cardiac audits would be transferring to the National Institute for Clinical Outcome Research (NICOR) once contractual and transition arrangements had been finalised.

In assessing progress against the conditions of approval, Members noted that, in terms of an exit strategy, it would not be immediately feasible to move forwards with specific regulations due to the political environment. However they welcomed the fact that progress on drafting the Regulations was underway.

Members discussed in detail the information provided on opt-out provisions and raised concerns over the consent to treatment analogy contained within the documentation as this had been cited to explain why consent would not be feasible in some instances. Members queried how far implied consent could be stretched, and agreed that if the activity formed part

of direct care for a patient then consent could reasonably be implied. However, in line with General Medical Council guidance, then once the activity goes beyond direct care, such as through establishment of a national database, then consent, pseudonymised data, or another statutory basis would be required in order to legitimately process the data. As such, Members felt that it would be inappropriate to apply implied consent for secondary use purposes. In particular, Members noted the assertion that where heart failure has been experienced then consent cannot be obtained. The documentation indicated that up to 50% would be readmitted therefore Members were unclear as to why there appeared to be an opportunity to obtain consent that would not be taken. This should be explored in any further submitted documentation. Members also noted the commitment that any new audits would be fully consented where feasible, and therefore queried whether a pilot could be carried out and reported against to add evidence to any difficulties cited.

The Committee emphasised that they were of the view that a duty of confidentiality exists between a doctor and a patient, and therefore the disclosure of confidential information was a harm in itself as it could lead to a loss of trust in the medical relationship and the NHS. As such, it would be essential to obtain consent where feasible, use pseudonymised information where practicable, and seek another statutory basis in all other instances.

Members discussed comments made about the disenfranchised, and emphasised again that they felt that this sub-cohort would be hard to reach, but not impossible. The challenge that presented itself was the investigation of different methods that could be used to approach this group. Members also disagreed with the assumption that those from BME communities would automatically be hard to reach and felt that the subtleties involved had not been explored. Members were of the view that this aspect should be significantly investigated with an appropriate level of expertise as it did not accept these blanket assertions. Members also noted the lack of reference to the Mental Capacity Act (MCA) within consent considerations and did not accept some of the examples presented by the applicant as reasons for not obtaining consent. Members noted the NHS IC's statement that they intended to develop guidance around the Mental Capacity Act in the context of NCASP, but were of the view that the principles of the MCA were already in place and therefore should be fully taken into consideration within the audits.

Whilst Members were in agreement that consent would be difficult due to the large numbers involved they queried why a sampling technique could not be used and why full ascertainment was required. Members felt that the applicant should explore this route and provide evidence why this was not feasible.

Members noted that due to the indicated transitional arrangements there would be difficulties in providing established plans in terms of engaging patients and moving forward with consent aspects, however Members were disappointed in the lack of detail provided in terms of timescales. As such, whilst generally supportive of the actions set out in the documentation, the Committee were unable to comment further due to the lack of detail. The Committee stated that in future they would wish to see definitive commitments around specific actions in order to enable the Committee to reach a considered decision.

Members discussed the application moving forward and an initial query was made regarding whether it would be feasible for the relevant information to leave clinical teams in a pseudonymised format using NHS Number or another pseudonymised identifier as the key linkage item. While section 251 support would be required for the initial transfer of data, pseudonymisation would be acceptable as an exit strategy from section 251 support. Members appreciated that the NHS Number had limitations as a reliable identifier, and whilst aware that although the use of NHS Number had now been mandated, some legacy datasets did not contain NHS Number. Members also considered using NHS Number for the cardiac audits and

whether its absence could lead to bias. Members agreed it was for the relevant data processor to make their case on any practical issues in line with the conditions of approval set out below. The Committee agreed that it would look for progress to be made by the NHS Information Centre or any subsequent data processor to address this issue.

Members raised concerns that section 251 was originally meant to be a temporary measure for this application whilst efforts for consent and/or pseudonymisation were pursued. Members appreciated that section 251 was currently in place only for those audits where consent was not in place. However, Members agreed that significant attempts should be made to reduce the identifiability of data once received. In line with this and where consent had been demonstrated not to be feasible, Members recommended that the audits needed to be divided into separate applications, as they had varying exit strategies and could be best handled separately in future considerations by the Committee.

Members discussed the audits which had 100% ascertainment of NHS Number. It was agreed that for this group of audits, efforts should be made to reduce the identifiability of the data items and progress should be reported against this. For those audits where 100% of NHS Number had not been achieved, the applicant was advised to separate these out and submit individually back to the Committee under the relevant data processor at the time.

Members were mindful of the important of the audits and they agreed to provide approval for a further 6 months, with the expectation contained within the documentation that the transitional arrangements would have been finalised. Members also emphasised that until any subsequent data processor had received approval under section 251 to hold the data relating to NCASP, that under no circumstances should any data relating to the NCASP audits be transferred onwards. This was a provisional approval subject to the following conditions:

1. NHS IC to proactively engage the NIGB Office in terms of the status of the audits and their transitional arrangements.

2. No data from NCASP audits to be transferred to any other organisation following successful contract award, until the next organisation had received full and final support under section 251. The NHS IC would be notified by the NIGB Office when this situation occurred.

3. Assertions around engaging with the “disenfranchised” were to be explored and difficulties explicitly teased out and explained.

4. Those audits where 100% ascertainment of NHS number had not been achieved should be submitted to the Committee at the earliest opportunity, in order to explore in detail options for consent/pseudonymisation, The applicants should provide a timetable to the NIGB Office to be reported at the June Committee meeting.

Action: NIGB Office to notify applicant of Committee decision.

NCASP Hip Fracture Database [ECC 2-05 (c)/2010]

This application from the NHS Information Centre sought support under section 251 for a change in purpose to the previously approved National Hip Fracture Database (NHFD) within the NCASP audits. This application sought activity level data from the Secondary Uses Service (SUS) to be linked to clinical data from the NHFD. The application proposed that the NHFD would generate a report by PCTs on a periodic basis, detailing whether the patient was in receipt of best practice care or not. PCTs would subsequently use this report to link to SUS activity data.

This application had originally been considered at the February Committee meeting, however due to a number of incomplete sections the Committee had been unable to approve the application and had asked the applicant to fully complete the application and resubmit.

The Committee were pleased to note that the application had been fully completed and the requirements set out from the February outcome letter had been clearly set out and achieved. In particular, the Committee welcomed the steps taken towards pseudonymisation where all patient identifiers were removed and replaced with a single anonymised identifier and this number was then made available to NHFD administrative and hospital staff to allow cross-checking of relevant records without revealing patient information.

In noting that it was important that complete coverage was ascertained for the purposes of the audit, Members drew attention to the statement made in section (o) of the application where it was stated that some of the cohort may develop acute confusional states. Members highlighted that the Mental Capacity Act had not been considered and reiterated that its provisions should be applied where necessary.

This application was provisionally approved subject to the following condition:

1. The approval would last for one year, should the activity need to continue beyond this one year period the applicant should engage with the NIGB Office in good time.

Action: NIGB Office to notify applicant of Committee decision.

Prospective analysis of bruising in children [ECC 2-06/2009]

This application from Cardiff and Vale NHS Trust was originally for the purpose of investigating the extent and pattern of bruising of children who have been physically abused as compared to children who experience bruising due to inherited bleeding disorders. This was originally considered by the Committee in March 2009, however, the application had been rejected and a resubmission advised as Members felt that there was a lack of clarity around the scope and specific activity for which section 251 support was required. The Committee also agreed that any resubmission should clarify the scope of the activity, provide further information on testing the acceptability of using patient identifiable information without consent, provide a clear justification on why consent was not feasible and clarification as to why pseudonymised data would not suffice.

Members discussed this resubmitted application at length and welcomed the clarification provided that section 251 was sought for the retrospective group of children where there had been a suspicion of physical abuse and an accidental cause was subsequently established. Relevant information would be obtained via a case note review. Members agreed that this activity was in the public interest and appreciated that there may be difficulty getting consent from parents for research relating to this sensitive area, and that this meant it would be extremely difficult to carry out this study in another manner. Members also considered that by not seeking consent, this would in effect not be overriding the dissent of the patient, but that of the parent(s). It was also appreciated that the validity of the results may be affected if a consent based approach was pursued. Members took all these considerations into account when assessing whether section 251 should be provided.

Members also noted that the extraction of anonymous data would be carried out by one research nurse and therefore the breach would be minimal as the data would remain within the NHS. The public interest in carrying out this activity was discussed at length by Members and it was agreed that it would provide benefit to clinicians and raise awareness when analysing

bruising patterns in future. As such, Members agreed that the public interest to the child was so great that it could justify the breach of confidentiality in this instance and that it was one of a few examples where consent could not be obtained.

This study was provisionally approved subject to the following condition:

1. Approval was solely for access to relevant information contained within medical records, and did not confer approval to multi-agency records.

Action: NIGB Office to inform applicant of Committee decision.

Cambridge Stroke Audit [ECC 6-06(o)/2009]

This application from Addenbrooke's Hospital required section 251 support in order to create a research database to determine stroke outcomes through recording clinical information on acute stroke patients. This would be carried out retrospectively on the previous five year period, and continue on a prospective basis. Identifiers requested included Hospital ID and unit level postcode. The outcome of this would be to attempt to identify factors that determine stroke outcomes with and without treatment.

This application had originally been submitted to the November 2009 Committee meeting and had been rejected as the Committee had not been provided with sufficient justification to explain why consent was not feasible. Additionally, Members had raised a number of queries around the purpose of the database, retention of data and the criteria around the onward disclosure of identifiable data.

Following correspondence outside the Committee meeting between the applicant and the NIGB Office, it had been established that those holding honorary clinical contracts would have access to identifiable data for the purpose of extracting and anonymising the data. It had also been agreed that only partial postcode would be collected and that hospital ID would not be stored on the database.

The Committee welcomed the efforts made by the applicant to effectively pseudonymise the data that was to be held on the database; thus reducing the risk of any identifiable data being onwardly disclosed. Members agreed that although there were some issues about determining whether this was research or audit, they were content to class it as research as the database was being created for the purposes of research and there would be onward disclosure for research purposes.

Members assessed the nature of the staff who would have access to the data and those extracting the information. They noted that although the applicant had not been directly involved in the care and treatment of the entire cohort, they had been for some and they were directly employed in the relevant clinical speciality on an honorary clinical contract with current responsibility for treating patients. The Committee discussed that often honorary clinical contracts involved clinicians being an integral part of any care team and that there was a definite distinction between an honorary clinical and an honorary research contract. Due to this the Committee were content to confirm that there would be no breach in confidentiality involved in the applicant extracting pseudonymised data. In particular, as only pseudonymised data would be held on the database, there would be no breach of confidentiality involved in any onward disclosures.

Members commented that patient involvement could be improved upon and advised that the applicant should work towards gaining a broader patient view and input into the activity.

Members noted that initially the applicant had not intended to seek consent on a prospective basis and recommended that consent should be obtained where feasible.

Due to the above considerations, the Committee concluded that in this specific instance, as the applicant would have legitimate access to patient records, section 251 support would not be required in order to carry out the activity.

Action: NIGB Office to inform applicant of Committee outcome.

Functional Capacity Testing in cardiovascular patients [ECC 1-04 (e)/2010]

The aim of this study carried out by the University of Essex was to determine normative values for treadmill and shuffle walking test performances in cardiac patients prior to and receiving cardiac rehabilitation. This involved collating data on patients that was normally collected as part of their routine clinical care. The application requested support under section 251 in order to access health records related to cardiac patients over 24 months at four NHS Trusts in order to extract anonymised information.

This application had originally been considered at the February 2010 Committee meeting, however, it had been rejected at that meeting as Members considered that the anecdotal reasons cited, such as administrative burdens and insufficient funding, were not sufficiently compelling reasons to justify the provision of section 251 support.

Members were provided with further information from the applicant including results from a pilot of consent that was carried out which suggested a low response rate with the majority responding consenting to take part in the study. Members noted the large numbers of consent forms they would have to send out in order to obtain sufficient responses. The applicant also included views of patients who had been approached about the study and who had reflected a positive response to their information being disclosed. Members were given two letters from two Trusts stating that the extraction of anonymised data by clinical care teams would not be feasible and would be content for the researchers to complete this task.

Members were mindful of the similar wording of the two letters; however they were sympathetic to this application and considered that it would be an important piece of research in the public interest. Members also agreed that consent would not be practicable as in order to contact the patients more identifiers than requested for the study would be required, therefore constituting a greater breach of confidentiality.

This application was provisionally approved, subject to a review of the applicant's security arrangements.

Action: NIGB Office to inform applicant of Committee decision.

Audit of outcomes after surgical procedure using linked HES data and ONS mortality data [PIAG 2-07 (i)/2004]

This application from The Royal College of Surgeons was originally given section 251 support in 2004 for the applicant to obtain Hospital Episode Statistics (HES) data which had been linked with Office of National Statistics (ONS) mortality data in order to audit outcomes after surgical procedures. This extension request requested an additional identifier: baby's date of birth for living babies. The baby's date of birth was required in order to assess and evaluate issues concerning conditions that were defined in relation to a baby's age at the time of surgery, and outcomes concerning days of the week on which the surgery took place.

This application had originally been considered via Chair's action in consultation with a small number of Committee members. However, it was decided that whereas the original application involved access to identifiers of a deceased cohort, the current application involved access to identifiers of a living cohort and therefore issues of whether it was practicable to obtain consent required assessment by the full Committee.

Members noted that the applicant had not previously received any full identifiers directly from HES, however, utilising date of birth could theoretically render the information identifiable through linkage to the ONS mortality data. Members did agree that age in babies would need to be more accurate than in adults and date of birth would be essential in order to place the babies requiring surgery into small age bands.

As a whole, Members agreed that there was a significant public interest to this activity, and that consent would be impracticable due to the large numbers and the number of conditions which would be included in the audits, which would mean that consistency in the feasibility of gaining consent across all audits would be low. However Members considered the reasons given in the application for not following a consent based process to be unjustified and felt that just because HES data was collected for other purposes it should not necessarily be assumed that consent cannot be obtained for a further secondary purpose such as the one presented in this application. However Members were of the view that due to large numbers and logistical reasons across audits consent would be impracticable and therefore the concern focused upon the potential inferential risk of identification.

The Committee discussed whether there was a potential to gain less identifiable fields from HES whilst maintaining sufficient level of detail in order to carry out the audits. Members queried whether it would be possible to obtain date of operation and baby's age in days from HES without needing the actual date of birth. If so, this would mean that the current request for baby's date of birth would not be required and in utilising this approach Members were of the view that the researchers should be able to establish day of the week from the operation date. Members agreed that there was significant public interest to this activity, however they asked that the applicant explore the above option and were not able to provide section 251 support.

Should the option be explored and prove not to be feasible or to be impractical then the applicant should provide written information provided back to the Committee to this effect. Depending upon the response the Committee agreed that a final decision could potentially be reached via Chair's action rather than returning to full Committee.

Action: NIGB Office to notify applicant of Committee decision.

5. New applications for section 251 support

Children's Health and Well-being Data Linkage Project ECC 3-04 (a)/2010

This project initially sought approval to link three datasets: Sportlinx, The National Child Measurement Programme (NCMP), and The Healthy Schools Bus with the aim of addressing issues surrounding the longitudinal persistence of a high Body Mass Index and distribution of childhood obesity, overweight and underweight across Liverpool.

Section 251 support was sought to link the three datasets where the original consent for the collection of the datasets had not covered the linkage activity, i.e. the NCMP prior to amendment of consent form dataset, and the Healthy Schools Bus dataset. It was noted that prior to the Committee meeting the NIGB Office had advised that the Healthy Schools Bus dataset had no legal basis as the original consent form implied that patient identifiable data

would only be used for surveillance purposes. Following that the application was amended and section 251 support was sought for linkage between the Sportlinx dataset and the NCMP dataset collected prior to amendment of the consent form.

Members raised concerns over whether the wider public interest had been sufficiently articulated and justified as they did not consider that this activity was in the overwhelming public interest sufficient to justify the proposed breach of confidentiality. Members were also not clear about how the study would add value to the knowledge already available on childhood obesity.

Members discussed the data requested for the project and felt that it would be clearly identifiable to the applicant as they would have access to school information and unit level postcode. It was noted that the applicant had already moved from using date of birth to age, however the Committee queried whether it would be possible to reassess use of unit level postcode through moving to a less identifiable use of postcode at district level.

Members agreed that it would be likely that consent would not be practicable due to the numbers involved and the retrospective nature of data collection. However Members were concerned about the nature of the consent already taken and whether this had misinformed participants that their data would not be used in the way proposed in the application and that there was some conflict in the consent forms about what information would be shared and what would be held as confidential. Members requested that clarification be provided around this issue. Members were also not entirely clear about the data flows involved in the activity and felt that some aspects were confusing and requested further reassurance.

Members expressed concern that service user involvement had not been particularly well developed and were of the view that this aspect could be significantly strengthened through proactively seeking opportunities to engage members of the public and/or service users and demonstrating how their input had influenced the proposed activity.

Members were unable to provide section 251 support for the activity due to a number of outstanding concerns. They advised that a fully revised resubmission be made to the Committee, taking into account all the points made and incorporating all information.

Action: NIGB Office to inform applicant of Committee decision.

Teenage and Young Adult Cancer Survivor Study (TYACCS) ECC 3-04(c)/2010

This application from the University of Birmingham was to establish a research database to provide a resource for studies investigating fatal and non-fatal adverse health outcomes for individuals aged 15 to 39 diagnosed with cancer between 1971 and 2006.

Support under section 251 was requested in order to provide linkages of patient identifiable data between the National Cancer Intelligence Network (NCIN) and the Welsh Cancer Registry combined with HES data, the Myocardial Ischaemia National Audit Programme (MINAP) and Patient Episode Database Wales (PEDW). The application also covered flagging on the National Health Service Register (NHSCR).

The Committee discussed this application at length and considered the activity to have a significant public value and noted that section 251 support had been requested in order to carry out the linkage activities. However Members raised a number of queries and felt that further clarification was required around the activity before a final decision could be reached.

1. Members considered the service user involvement to be relatively limited considering the wider importance of the activity, and therefore requested that further consideration be given to taking advantage of the opportunities already in existence to the applicant and develop this further. The Committee requested a plan to show how this patient involvement could be taken forward within the context of the study.

2. Members requested clarification as to the longer-term intent of the study, and the proposed strategy for the use of data in future.

3. Members felt that further clarification was required around what identifiers would be destroyed as indicated within the application.

4. Members understood the GPRD to be an anonymised database, therefore they requested clarification on how the GPRD would be linked via the NCIN and MINAP.

5. Members were concerned about the issue of onward disclosure, and therefore recommended that the applicant establish a Publication Committee to consider protocols for onwards disclosure. Members were concerned that if there were any disclosures at patient level then it must be ensured that there is minimal possibility of re-identification. Members also requested reassurance that data would be released in as aggregated form as possible and the role of a Publications Committee should be to ensure this.

6. Members were not entirely clear on who would be carrying out linkages and requested that further details be provided on this aspect in relation to all of the data flows.

Action: NIGB Office to notify applicant of Committee decision.

6. Any other business

Improved decision making

Members were provided with a paper setting out potential aspects of work in order to clarify decision making. This would serve to aid the Committee in its decisions. Members were asked to volunteer to prepare discussion papers according to areas of expertise so that the aspects could be discussed at the away day in June.

7. Dates of future meetings

Tuesday 27 April 2010
Wednesday 2 June 2010
Away day – 17 June 2010
Thursday 29 July 2010
Tuesday 28 September 2010
Wednesday 1 December 2010