Item 2 – ECC 8-02/2010

Meeting held on Wednesday 1st December

Present

Members: Dr Andrew Harris (Chair), Mrs Pauline Brown, Dr Patrick Coyle, Dr Mike Catchpole (to item 4 H), Professor Carol Dezateux, Ms Stephanie Ellis, Professor Sir Denis Pereira Gray, Mr Michael Hake, Ms Sue Parroy (via teleconference), Dr Mark Taylor,.

In attendance: Dr Alan Doyle *(NIGB Director),* Ms Natasha Dunkley *(Approvals Manager),* Ms Claire Edgeworth *(Approvals Officer),* Ms Melanie Kingston *(Deputy Approvals Manager), Ms* Karen Thomson *(NIGB IG Lead)*

1. Welcome and apologies

Apologies were received from Dr Tony Calland, Dr Tricia Cresswell, Dr Fiona Douglas, Mr Paul Eveson (Department of Health), Mr Sean Kirwan (Department of Health),Professor Roy McClelland and Mr Terence Wiseman.

Mr Felix Ritchie attended from the Office of National Statistics for application 8-05(g)/2010, Research Use of the ONS Longitudinal Study.

Conflicts of interest

Dr Mike Catchpole declared an interest in agenda item 3b, Health Protection Agency (HPA) annual review [ECC 8-03(b)/2010], as an employee of the HPA.

Dr Mike Catchpole also declared an interest in item 5e, Integrating Strain Typing and Database Technologies in Research Service [ECC 8-05(e)/2010], as he worked closely with the HPA collaborators on the project and there was a possibility that he may take some responsibility for the data once collected.
He was not present for these items.

Professor Carol Dezateux declared an interest in item 3a, as some activities carried out within her department would be affected by the outcome of this discussion.
She did not take part in the decision.

2. Minutes of last meeting [ECC 7-02/2010] and matters arising

The minutes from the 28 September meeting were approved subject to minor amendments.

Matters arising

HQIP meeting

The Chair reported that a meeting had taken place between the Health Quality Improvement Partnership (HQIP), the Chair and Natasha Dunkley from the NIGB Office to discuss the future of the National Clinical Audits within HQIPs umbrella. It was agreed that the ECC should have a presence at an upcoming national audit meeting and it was agreed that the Chair would attend in April 2011.

Dr Andrew Harris appointed as Coroner for London Inner South

Members were informed that as of January 2011 the Chair had been appointed Coroner for London Inner South. Due to the increased time commitment this would bring the vice chair would now increase his ECC commitment and there would be a division of workload with the vice chair who would attend some NIGB meetings and chairing some Committee meetings. The Chair of the NIGB, Harry Cayton, would review this arrangement after a year.

Future of the NIGB

Alan Doyle provided an update to members on the future role of the NIGB and informed them that Paul Jones, NHS Chief Technology Officer, had been appointed as lead sponsor. Members noted that it was important that the Board retained its independence. The Chair advised that he had recently written a leader article that reflected this and members requested that this was circulated to them.

Action: NIGB Office to circulate article to members.

ECC Membership recruitment update

Alan Doyle provided an update on the ECC membership recruitment process. 41 applications had been received and 8 had been selected for interview. There was a very strong calibre of candidates and there were 3 posts to be filled.

2a. ECC Chair's Report [ECC 8-02(a)/2010]

The ECC Chair provided a report of the items discussed in the NIGB meeting on the 28 October 2010. These included:

- A report on NHS Data Loss Incident Reporting in England by Amanda Johashen, NIGB NHS Information Governance Lead.
- Briefing on the Arms Length Bodies review outcome.
- Information Governance in Social Care – a Caldicott Guardians view by Angela Dwyer, Assistant Head of Social Care (Transforming Social Care and performance), Portsmouth City Council.
- An annual update on the Care Record Guarantee
- A presentation on eHealth in the European Union by Michael Wilks, NIGB public member.

2b. NIGB Office Report [ECC 8-02(b)/2010]

a. Database Monitoring sub Group transition to the NHS Information Centre (NHS IC)

Members were provided with an update on the transition of the Database Monitoring sub Group (DMsG) to the NHS Information Centre. It had been the NHS IC's intention prior to the election in May that Members of the DMsG would be invited to be members of the NHS IC's Independent Advisory Group (IAG).

Since that time, the coalition government had imposed a recruitment freeze and efficiency measures on all government organisations and the NHS IC were impacted by the Arms Length Body review. These factors had hampered future arrangements as new structures could not be established until the functions and resources of the NHS IC were confirmed.

In order to be able to maintain business continuity, members were informed that an interim group had been established comprising of:

- Dr Mark Davies (as the NHS IC Caldicott Guardian)
- Clare Sanderson (as the NHS IC Director of Information Governance)
- Paul Eveson (given his expertise and previous advisory role to DMsG)
- Dr Patrick Coyle (as former chair of the DMsG)

This was not a permanent solution to replace the DMsG, but provided sufficient safeguards for an interim period until the future position concerning the NHS IC becomes clear. The NIGB would continue to have a role in overseeing information governance policies and practice of the NHS IC.

The NIGB Office held a handover meeting in November 2010 with the NHS IC to discuss any outstanding applications; it had been agreed that the NHS IC would take over responsibility for closing any applications that were approved in principle by DMsG but had not been fully approved yet, therefore the NIGB Office would have no more contact with the applicants.

The NIGB Office would continue to provide advice to the NHS IC about any applications that required section 251 support. It was noted that Patrick Coyle (ECC member) and Paul Eveson (Department of Health) would be part of the interim group providing further reassurance that data would not be released without section 251 approval being in place where necessary.

b. NIGB applications database

ECC members were informed that work on the new NIGB applications database was progressing well and was near to completion. Non-research applicants would be able sign up to the database via the NIGB website and fill in section 251 applications via this route. It would link directly with IRAS and research applicants would be able to submit their application on the IRAS system and it would be sent straight into the database.

Members would be able to log into the database via a web link. All existing approvals would have basic information migrated onto the database. This would allow the Office to track the progress of reviews more efficiently and ease the review process for members and applicants.

c. Security reviews

Members were informed that a team under the remit of Mr Phil Walker within the Department of Health had taken over responsibility for assessing system level security policies in relation to applications for section 251 support. Members were informed that some delays had been incurred in the processing of security reviews, and a meeting had recently taken place between the NIGB Director and the security review team in order to seek clarification over timescales for processing review documentation. The security review team agreed that reviews would be completed, or appropriate correspondence would take place with the applicant, within ten working days, however, there was a backlog to be managed.

d. NHS Information Centre (NHS IC) update on patient engagement

A condition of the section 251 support for Project Sutton (MIDAS) (ECC 2-04(b)/2010), Hospital Episode Statistics (ECC 2-05(b)/2010) and the Central Register (ECC 2-04(c)/2010) was that the NHS Information Centre (NHS IC) was required to develop its approach to patient engagement.

Members noted that the NHS IC had planned to implement an Independent Advisory Group and a Patient Reference Group which would improve patient involvement in the work of the NHS IC. These plans had also been discussed with the NHS IC Board who were supportive of the proposals. It had previously been agreed that terms of reference for both of the groups would be approved at a future board meeting once they had been developed. However shortly after that meeting the NHS IC became subject to stringent controls on resource recruitment as did all public sector organisations. As a result these activities had been curtailed.

Members were informed that significant progress was made on the Patient Reference Group (PRG) before the project had to be suspended. The Terms of Reference for the PRG were drafted and reviewed internally in anticipation of the group being established and an initial draft of the person specifications and job descriptions for the Chair and members of the planned PRG were drafted. In parallel, research had been conducted across the NHS IC to establish which services had already implemented patient engagement with patients in the development and operation of their products and services and examples of other patient groups outside of NHS IC (e.g. BMA) had been reviewed to establish a range of options for the approach to be adopted.

The terms of reference for the Independent Advisory Group (IAG) had been drafted, a key element of which was the inclusion of escalation procedures. These would ensure that in the unlikely event that advice of the IAG conflicts with the view of the NHS IC on handling of a request for information there is a clear path for resolution of the conflict.

Finally, as a result of the White Paper: Equity and Excellence: Liberating the NHS the role of the NHS IC would be changing. This would be defined in the health bill which was due to have its initial parliamentary reading at the end of November. The NHS IC was currently undertaking a Privacy Impact Assessment (PIA), to consider the impact on patient privacy of the new NHS IC responsibilities. The NIGB Director had been invited to take part in the consultation. It was expected that the PIA will identify, amongst other measures to protect patient privacy, the need to implement arrangements for patient involvement and independent advice on governance arrangements.

The NHS IC had indicated that resource controls had resulted in the progress made to date being less than anticipated when plans were initially developed. However, the PIA in progress and which NIGB were being consulted on should provide the impetus needed to ensure approval for the appointment of the required resources and appointment of members to each of the planned groups.

e. Fast track applications

8-02 (FT1) 2010 - Emergency Stroke Calls: Obtaining Rapid Telephone Triage Phase 4A

The application from the University of Central Lancashire formed a part of larger research project that aimed to evaluate a training package for Emergency Medical Service (EMS) Dispatchers to improve the accuracy of stroke identification during a 999 call. It aimed to explore the association

between words used by the public during a 999 call and subsequent dispatch codes provided by the EMS dispatcher, and the final diagnosis in hospital. Section 251 support was sought to permit the researchers to listen to 999 calls (approximately 1000) over two one-week periods to cover the before and after stages following the introduction of the training package.

Members agreed that consent would be impracticable and that there was a high public interest in this activity taking place. However, Members felt that greater clarity was required on how diagnosis was to be extracted from the medical records, and in particular, by whom. Members agreed that they would be content to support this application in principle, subject to satisfactory clarification over how the diagnosis would be extracted, and revision of the responses demonstrating compliance with the Data Protection Act 1998. This application was reviewed by Sue Parroy, Pauline Brown and the Chair.

ECC 8-02 (FT2)/2010 - Predicting Response to Chemotherapy in Malignant Melanoma: The role of DNA repair genes.

This study from the University of Leeds set out to investigate the hypothesis that DNA repair genes are over expressed in melanoma tumours and the assessment as to why melanoma tumours are so resistant to chemotherapy. As such, the aim was to confirm the significance of DNA repair gene expression on response to chemotherapy in primary melanoma tumours in a larger sample set.

In terms of identification of potential participants, these would be identified using trial data centres at clinical centres by recruiting clinicians or by study coordinators at the University of Leeds for epidemiological studies. For those identified at trial centres, patient details would be sent securely to the clinician who recruited the patient to the trial allowing them to trace required tissue samples locally. Members noted that this study would provide essential biological insight into melanoma resistance to chemotherapy and potentially, genetic variations could be used to identify those patients who would respond to chemotherapy. As such, Members agreed that there would be a important public interest in this activity taking place.

A study design had been selected where the researcher would only obtain data with limited identifiers such as study number, date of birth and date of death. Stored samples would be relabelled by study number and laboratory number only at the centre of recruitment, prior to being sent to Leeds or being passed onto the research team in Leeds. Members were pleased to note that the identifiability of the requested data items would be reduced to age at diagnosis (for example) after data validation and analysis had taken place and that date of birth and date of death would be removed from the final dataset.

In assessing whether consent would be practicable, Members noted the reasons provided on page 10 of IRAS, and in particular noted that the median survival estimate was six months for stage IV melanoma and the estimate that less than 12% of the original participants would still be alive after 5 years. Members were of the view that in such an instance, consent was not deemed to be practicable and therefore support under section 251 could be justified. This application was reviewed by Fiona Douglas, Mark Taylor and the Chair.

8-02 (FT3) - Census of care in hospitals

The study from the University of Sheffield would examine the potential to improve care for people at the end of life by exploring need for, and provision of, palliative care at two hospitals in England. A census has been carried out of all inpatients present in the hospitals during a two week study period.

Twelve months after the inpatient census, a retrospective survey would be undertaken of all inpatients present in the two hospitals at the time of the censuses. Patients who had died in the 12 months following their hospital admission would be identified and the case notes of these patients would be examined in order to explore the care approach, requirements, and needs of these

patients. Section 251 support was requested to conduct this case note review of patients who had died.

Members were clear that although clinical data would be accessed, there would be minimal retention of identifiable data. It was considered that section 9 of the application had clearly addressed the issues of consent, demonstrated why it would not be feasible, and had offered evidence on skewing that would arise should a different approach be employed. This was considered to add weight to the public interest involved in this activity going ahead under the specified arrangements. This was reviewed by Michael Hake, Pauline Brown and the Chair.

ECC 8-02 (FT4) 2010 - Does adding a facilitated behaviour change intervention improve outcomes among people with recently diagnosed type 2 diabetes receiving intensive treatment in General Practice? The ADDITION Plus 5year follow-up study

This was an application from Addenbrooke's hospital that set out arrangements around a long-term follow-up of an existing trial cohort. Section 251 support was sought to permit the mortality tagging of half of the study participants (239 cohort size in relation to the clinically detected group), and the remaining half were already tagged under a previous application for section 251 support.

Members were not persuaded that reasons for not seeking consent had been sufficiently explored, and were unclear why the majority of patients who were being seen for 5-year follow-up could not be asked for their consent for the researcher to receive mortality information.

In line with this, Members were also concerned that there appeared to be a potentially implicit view that some of the cohort might refuse to provide consent. Members were also unclear as to why mortality data was considered to be of prime importance in terms of achieving the outcomes, and felt that a stronger justification to support this would be required. This was of particular concern as if a member of the cohort withdrew, then they would not expect any further data to be gathered about them.

In light of these concerns, this application could not be approved in its current form and the applicant was invited to consider the issues and provide a revised application. This application was reviewed by Mark Taylor, Pauline Brown and the Chair.

ECC 8-02 (FT6) /2010 - Caring for seriously ill older people on acute hospital wards

This application from the University of Nottingham requested support under section 251 in order to provide a legal basis for access to medical records of 30 patients following their death on the study wards. The application presented the view that the medical records would be an important source of data about the processes of decision making and communication between professionals and relatives regarding the care of patients with and without dementia. The information extracted from the records would be anonymised at the source, and no patient identifiable details would be recorded in the data base.

Members noted that the numbers involved were very small, and that there appeared to be opportunities to obtain a view from next of kin. In line with this, Members requested further clarification upon this aspect. Details were also missing on the extent of patient engagement, and further clarification was requested on the retention of identifiable information. Members were unable to recommend support under section 251 to the application in its current form. This was due to questions raised over scope, and the view that the reasons why a relative or carer could be approached had not been fully explored, particularly in light of the small numbers involved in the study. Members were supportive in principle, but felt that more detailed information would be required in order to provide sufficient justification for support under section 251. The applicant has been invited to address and submit a revised application. This application was reviewed by Michael Hake, Pauline Brown and the Chair.

ECC 9-02(FT1)/2010 ICONS: Identifying Continence OptioNs after Stroke Exploratory Trial

This application from the University of Central Lancashire set out to recruit stroke patients into a study designed to assess whether interventions (systematic voiding programme and supported implementation) helped patients become continent again following a stroke. Section 251 support was required for a research nurse to access patient identifiable data in order to keep a recruitment log of all potential participants admitted to the stroke unit with a diagnosis of stroke who met the trial inclusion criteria, and to collect information to facilitate comprehensive patient identification for the study.

It was noted that no identifiable data would be removed from the hospital sites without consent, that access would be limited to one research nurse and that the recruitment log would form part of the hospitals record. Members agreed that the research nurse would have a similar duty of confidentiality as that of a health professional and that the risks from disclosure were minimal. They therefore agreed to recommend support under section 251. This application was reviewed by Fiona Douglas, Stephanie Ellis and the Chair.

f. Extensions

ECC 8-02 (FT5)/2010 - Southall And Brent REvisited. Ethnic differences in risks and outcomes of the cardiometabolic syndrome (SABRE STUDY)

This application from Imperial College London was for an extension to application reference PIAG 2-05 (FT1)/2008 and section 251 support was sought in order to permit access to Hospital Episode Statistics and cancer registration data in order to link to mortality data (for which section 251 support was already in place).

Members agreed that there was a high public interest involved in the activity, and the outcomes would provide benefit to future patients. Members also agreed that there was a substantial difference in linking cancer and HES data compared with linking solely mortality data in terms of content/potential sensitivity, and therefore this aspect required detailed scrutiny. Members raised a number of concerns over consent, the handling of non-responders, use of postcode, and clarification over the actual linkage process and how this would operate, and consideration of how to reduce identifiability. Based on these concerns, Members were unable to approve the application in its current form, and the applicant had been invited to resubmit the application. This application was reviewed by Patrick Coyle, Tricia Cresswell and the Chair.

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

This application had already received approval under section 251 to permit linkages between its own database and HES and Patient Episode Database Wales (PEDW) for the purposes of analysis as part of the NJR's annual report, and to use HES-linked data for the purposes of surgeon outlier analysis.

This particular extension requested the use of HES and PEDW data in order to support an audit of revisions not reported to the NJR. The reason to support this extension was namely that the number of revisions might not be accurate, and therefore an audit was required of all revisions contained within the combined dataset but missing from the NJR. This audit would aim to establish whether the procedure had been a genuine revision or a mis-coded re-operation rather than a revision, and this would be achieved through contacting the revising surgeon for each case. The

HES data required would comprise provider codes (5 and 3), local patient identifier, spell start and end dates, surgeon date and procedure fields.

In considering this request, it was agreed that mis-coded HES records could pose a potential patient safety issue, and therefore the balance between improving patient care and the potential benefit to the public weighed in favour of providing section 251 support to this activity. This was approved by Chair's action.

ECC 2-05 (a)/2010 – Hospital Episode Statistics – change to security arrangements

The NHS IC had set out a proposal to extend the processing capacity to include the in-house environment (referred to the Data Managed Environment - DME) to replace the functions currently carried out remotely in the Northgate environment. It was noted that the DME would only be used for the purposes currently agreed under the above referenced application. Once the data linkage had been carried out that the copy of HES held within DME would be removed entirely. The system level security policy around the DME has been reviewed and approved by the DH Security Review Team.

PIAG 1-05 (g)/2007 HES and STATS19 one to one matching project

This application from the Department of Transport had already received approval under section 251, and as a condition of this approval, the Committee had suggested investigating the feasibility of the NHS Information Centre (NHS IC) carrying out the data linkages. This investigation was subsequently carried out and agreement obtained in principle that the NHS IC would be able to carry out the matching activity.

A revised application form reflecting the data flows, and changes to security arrangements had been reviewed and approved by the DH Security Review Team.

PIAG 4-05(f)/2008 - Sudden Arrhythmia Death Syndrome (SADS) audit

This application from the NHS IC had previously been reported at the September meeting, where it was indicated that there had been issues over continued funding and the subsequent status of approval under section 251. This annual review report provided notification that it was expected for funding to continue via HQIP until March 2011. In particular, discussions over continuation of the audit would take place within the next 2 months with the aim of either agreeing the extension of the audit or closure after 31 March 2011.

g. Update on previous applications

Integrated Patient Care System "Stratify" [ECC 7-04(d)/2010].

This application submitted to the September meeting from Redbridge PCT had been rejected as the purposes and access were unclear to the Committee, however the applicant had been advised to clarify and resubmit. The application had been through a number of iterations since that point and at present, the NIGB Office has been informed that the system is fully automated and therefore no identifiable data would be accessible to PCT staff. Members were informed that the NIGB Office continued to seek clarification and assurance over this aspect.

3. Items for consideration

3a. Section 251 and the NHS Trusts and Primary Care Trusts (Sexually Transmitted Diseases) Direction 2000 [ECC 8-03(a)/2010]

Members were presented with a paper which outlined an issue in relation to the interaction between section 251 and its supporting regulations and the NHS Trusts and Primary Care Trusts (Sexually Transmitted Diseases) Directions 2000 The issue had arisen following advice received from the Department of Health that section 251 and the Health Service (Control of patient information) Regulations 2002 only permitted the common law duty of confidentiality to be set aside and did not apply to other specific provisions provided by Parliament. The Sexual Health Directions 2000 require PCTs and NHS trusts to restrict the disclosure of identifiable sexually transmitted infection data to medical practitioners or those acting on their behalf for the purposes of treatment or to prevent the spread of infection. The paper stated that this not only restricted disclosure to these purposes but also sets aside the common law duty to permit such disclosures without the requirement for section 251 support.

The Committee had previously acted in good faith and section 251 had been provided in relation to applications that involved identifiable sexually transmitted disease data. It was noted that the decision taken would affect some previously approved applications.

The Committee were asked to consider key issues relating to the directions in order to determine to what extent section 251 could be applied. The issues discussed were:

1. The scope of what activities may be included within prevention: The Directions appeared to define “prevention” in relation to professional actions for the benefit of individuals. It was not clear whether or not it was within their scope to include, for example, the preventive actions of organisations for the benefit of populations, or for preventive care policy or audit of a screening programme.
2. How data sets with multiple purposes should be dealt with, such as testing for HIV in pregnant drug users.
3. The scope of what constitutes STI data.
4. To which organisations the Sexual Health Directions apply: It was noted that the Directions only applied to NHS Trusts and PCTs. However, this was thought to be against the intended spirit of the Directions and members were asked to consider whether they should be taken to apply to all STI data irrespective of the source and that section 251 could not permit disclosure from other sources. With the move from Primary Care Trusts to Foundation Trusts, the Committee recognised that there was further uncertainty.
5. The general approach to be taken to both new and previously approved applications.
6. The approach that should be taken in relation to previously approved applications, in particular it was noted that some of the Health Protection Agency activities involved identifiable sexual health data and that the annual review for their specific support was on the agenda.

The Committee could not be certain of the extent to which the Directions displaced the common law duty of confidentiality, nor their scope. They noted that correspondence with the Department of Health had taken place over the Directions and they were of the view that further legal advice should be sought from the NIGB’s Departmental Sponsor as it was important for the Directions to be interpreted consistently throughout the NHS and not just in relation to section 251 approvals. It would be appropriate to refer to the Department of Health for a lead on this. Members also noted that as the scope of the Directions was limited they may need revising to reflect the current landscape of healthcare. Members agreed that after receiving this advice they could then be clear on the implications for section 251 approvals.

Action: Letter to be sent to the Department of Health seeking legal opinion on interpretation of Sexual Health Directions 2000.

3b. Health Protection Agency annual review [ECC 8-03(b)/2010]

The annual review from the Health Protection Agency (HPA) had been reviewed by members at the July 2010 meeting; however, concerns had been raised over the clarity of activities that could fall within the specific support that was provided to the HPA. It was noted that there was a number of diverse activities that were carried out by the HPA and were detailed within the review. The HPA had been asked to clearly distinguish between those activities which fell within Statutory Instrument 2002 No. 1438, The Health Service (Control of Patient Information) Regulations 2002, and where research activities were involved make a separate application under class support.

The Committee considered the report in detail and discussed which activities could fall within the HPA specific support and which would need individual review. The Chair had prepared a draft paper as a basis for discussion to aid the Committee.

Chlamydia Testing Dataset

Members agreed that this activity engaged the Sexual Health Directions, however, they were of the view that this activity fell within the broader definition of prevention in the Directions and therefore there were no issues around this activity in relation to these Directions. It was therefore agreed that this activity fell within the Regulations made under section 251 and was therefore within the scope of normal activities carried out by the HPA.

However, Members requested clarification on the following aspects:

1. Members sought clarification on the scope of consent obtained when the screening is initially carried out. In line with this, the view was expressed that an exit from continued reliance upon section 251 could be via updating the original consent to cover screening and subsequent use of data. As Members were unable to locate consideration of an exit strategy, they requested further clarification upon this aspect.

2. Members sought clarification on whether it would be practicable to manage without use of full postcode of residence in order to achieve the activity. Members were also unclear on the retention of postcode and when or whether it would be destroyed once mapping to PCT/lower super output area had taken place. Members therefore requested a response to this aspect to provide reassurance that full postcode was necessary.

National Tuberculosis Strain Typing Module

Members agreed that the scope of this activity fell within the activity of surveillance and consequently clearly lay within the Regulations under section 251. Whilst Members were generally satisfied with the details of the activity, further clarification was requested on the following aspect:

1. The publication of results is described as suitably anonymised, however, Members were of the view that TB is relatively rare and small numbers might enable identification. Whilst anecdotally the Committee agreed that the HPA was likely to have robust policies in place, on the basis of the information provided further clarification was requested on how this aspect would be managed to ensure suitable anonymisation

The Survey of the Prevalence of Abnormal PrP using Appendix Tissue (Appendix Survey)

Members noted that notification of this activity had been provided in the 2009 annual review. In particular, it was noted that consent from next of kin of the deceased was obtained. Members were broadly satisfied with this activity however, requested confirmation over the following aspects:

1. Please provide a copy of the information provided to next of kin

2. As access to tissue samples is governed by the Human Tissue Act, Members sought reassurance that the provisions of this Act were adhered to in this activity. A brief summary of how compliance is achieved in this context should therefore be provided

Occupational Exposure to Spongiform Encephalopathy

Members agreed that this was clearly within scope of the Regulations under section 251 and noted that the monitoring would be consented. However, Members sought clarity on the following aspect:

1. Members were unsure whether the review examination of the records would also be covered by this consent. A view was expressed that the numbers involved were likely to be relatively small, and therefore the expectation would be that this aspect would be consented.

Provision of clinical samples to the National Institute for Biological Standards

Members noted in the June 2010 report this activity stated that samples might be received where it is unknown whether consent had been obtained, and that it would be handled according to Caldicott principles.

1. Members felt that further clarity would be helpful on this aspect as they were unclear on whether consent would be sought if it were not already in place.

Genitourinary Medicine Clinic Activity Dataset (GUMCAD2)

It was noted that the previous GUMCAD application had been referenced in the 2007 annual review. Members also noted that a previous decision taken in relation to SHRAD had determined that specific activity involved non-identifiable data.

Members as such queried whether this dataset was rendered more identifiable from the previous GUMCAD dataset. In the meeting, further correspondence had been provided to Professor Mike Catchpole which sought to provide further clarity over the extent of identifiers in comparison to previous decisions, however, unfortunately the Committee did not have the benefit of reviewing this in advance.

Members therefore requested further clarification over the dataset so as to confirm whether this was more identifiable. If not, then the Sexual Health Directions would not be engaged.

In line with this, Members therefore sought further clarity over the following:

1. Please provide written confirmation over the requested identifiers and whether there have been further additions to the original GUMCAD dataset
2. Due to the sensitivity of the dataset, Members requested further clarification over how small numbers would be managed as Members expressed concern over small rural practices and reporting against small populations

3. Members noted the stated that "*some reports and indicators are publically available on the website, while others which provide greater granularity of data, are only available to nominated public health professionals across a secure web portal*". Members sought further clarity over the data sharing arrangements and in particular:
    a. Please clarify what is meant by greater granularity of data in this context

    b. In terms of reporting, Members queried whether reporting would be made at service provider level

    c. Members queried how management of disclosive risk would be managed
4. Members discussed the scope of the activity and queried the extent to which is fell clearly within surveillance as a view was expressed that the activities appeared to be broad. Further clarity on this aspect was therefore requested.
5. Clarity was requested over why consent was not deemed to be feasible as the understanding was that the datasets originated from a consultation with the patient. Members also queried whether there would be scope for the patient to dissent to this use of data

Separate applications

The following lists those activities which the Committee considered required an individual application.

Survey of Chlamydia Prevalence in England

Members noted that this activity would be reviewed by a research ethics committee and that it appeared to have features of both research and surveillance. In particular, Members highlighted that there would be ethical issues involved in sending unsolicited letters to women where there might be religious or cultural norms. Based upon this sensitive issue, and that it did not clearly appear to fall within the Regulations, Members agreed that a separate application should be submitted for review.

The Children's Infection Linkage Project (CHILP)

Members were unclear as to whether this was research or whether it was within scope of the Regulations and as such, raised the following points:

1. Clarity over why consent was not deemed to be practicable

2. How the fair processing notification required under the Data Protection Act 1998 would be achieved

3. Clarity over the governance arrangements to establish how anonymisation would be achieved and further assurance over management of inferential risk in publication.

4. Details provided on the data items being processed so reassurance is provided that the minimum necessary information is being processed.

As Members were unclear on the nature of this activity, but were broadly supportive in principle, it was agreed that a separate application should be submitted to the Committee for review.

Health care associated infections – research consortium

This activity was set out in the July 2010 annual report, and subsequent correspondence had also been received in relation to this aspect. This correspondence indicated that an application would be made to the Committee, therefore Members agreed that a separate application should be submitted.

Conclusions

For those activities the Committee considered to fall within the Regulations and where clarification has been indicated, it is advised that each point should be responded to in a letter. Once received, these responses would be reviewed by the Chair and a smaller number of Members.

Future annual reviews

The Committee appreciated the time taken to produce the annual report, and noted that they would wish to streamline the process so that the Committee would be provided with appropriate reassurances over the activities carried out by the HPA under the authority of the Regulations. Members were clear that historically, the HPA tended to have a strong record in maintaining appropriate governance structures regarding the handling of confidential patient information, and it was agreed that the current report format did not necessarily aid in providing this reassurance.

As such, members suggested that there would be potential to develop a report on the information governance arrangements within the HPA. This would cover the core requirements set out under Regulation 7 and would therefore provide confirmation of use of minimal identifiers, access controls, risk assessment and prevention of inferential identification. This could also include reasons for not obtaining consent, management of dissent and user views. It was agreed that development of future annual reviews would be managed by the Office in conjunction with the Chair.

Action: NIGB Office to inform applicant of Committee decision

4. Resubmissions

4a. Children's National Services Framework (NSF) Data Sets [ECC 704(e)/2010]

This application set out the details of the Children's NSF data sets (a. Maternity, b. Child Health and c. Child and Adolescent Mental Health Services (CAMHS)) which would provide a source of data to support the planning of children's services in the future. Data would flow from Trusts to the data warehousing solution to form a profile of the care events and associated demographic detail. The solution would pseudonymise patient data before it is stored in the reporting data warehouse, so that data users would not be able to identify individual patients.

Section 251 support was required to provide a legal basis to permit the flow of identifiable data, patient demographics, observations, appointments, admissions & interventions from Trusts to the data warehouse (SSD) prior to data being pseudonymised.

This application had been originally considered at the 28 September meeting, however due to a number of concerns the Committee were unable to approve the application at that time.

Members considered the resubmitted application and agreed that, as a whole, it appeared that progress had been made in seeking to address and resolve the issues highlighted by the Committee. In particular, the linkages and data flows had been satisfactorily articulated and Members understood that identifiable data would only be accessed at the point of absolute necessity when discrepancies within the data submitted could not be rectified those providing the data.

The Committee were unable to recommend support under section 251 to include items related to sexual health data. A query had risen as to the interaction between section 251 of the NHS Act 2006 and the NHS Trusts and Primary Care Trusts (Sexually Transmitted Diseases) Directions 2000.The outcome of this could have wide-ranging implications for the NHS, therefore, this issue

was to be raised with the Departmental Sponsor and Department of Health legal advice was to be sought as it would be essential that a precise view was reached. Until a clear position has been reached, the Committee were unable to take a decision on this aspect at present and was therefore obligated to exclude it from its consideration. Members discussed that due to the potential implications of this advice the data relating to sexual health should be completely anonymised and form a stand-alone dataset to ensure this was the case.

Members raised concerns that a right of opt-out had not been put into place and noted that in compliance with the first principle of the Data Protection Act 1998 those processing personal data are under an obligation to ensure that the data subjects are informed of this processing. Additionally, data subjects have the right to request that processing of their personal data ceases under certain circumstances, and therefore were of the view that this aspect had not been satisfactorily addressed.

In order to meet the fair processing requirements the Committee was clear that without provision of information to patients about the use of their information and right of opt-out, there would be no basis for implying consent for use of this data. In particular, one of the Committee's principles is that consent cannot be implied for secondary uses and therefore it would be important for this point to be managed. Members suggested that further detail should be provided by the applicant around this aspect.

In conclusion the Committee agreed that the majority of points had been satisfactorily addressed, except for the provision of a mechanism to manage opt-out. It was agreed to recommend approval for this application under section 251 subject to the following request for clarification and condition of approval.

Request for clarification:

1. Clarification of the arrangements to be in place around the secure holding of the pseudonymisation key, and measures that would be taken to ensure confidentiality and appropriate access.

Specific conditions of approval:

2. Clarification and receipt of information to be provided to patients detailing their right to opt-out.

3. That sexual health data would not be included within the approval.

    a. However, the exception to this was that the Committee agreed that in relation to maternity dataset where the offer of screening was universal to all women, was a part of routine care and most crucially, not an indicator of risk, then this could flow in identifiable form. This would include the offer and acceptance of a test, the date of the test and the fact that the test had produced a valid result. This principle should be adopted where applicable. The actual result could not currently flow in identifiable form.

Action: NIGB Office to notify applicant of Committee decision.

4b. Revised submission of the National Community Child Health Dataset for Wales (NCCHD) [PIAG 1-07(b)/2004]

This application from NHS Wales required section 251 support for the NCCHD, a statistical database which provided NHS activity on children in Wales to support the NHS in Wales, the NHS Wales Department of the Welsh Assembly Government and other government departments. The

dataset would be used for provision of maternal and child health information, provision of immunisation information, production of analyses to support epidemiology and performance management, supporting the development and evaluation of governmental policies, and provision of extracts and analyses to support research.

This application had originally been considered at the Committee meeting in April 2010, at which point it was agreed to recommend support under section 251 for a period of six months. This time period was provided to allow the applicant to seek to address a number of issues raised at this meeting.

The Committee welcomed the provision of an updated application form and details provided on the action plan following the previous conditions of approvals. Members appreciated the amount of work that had taken place in order to address their concerns.

The Committee considered the data flows outlined within the application and the proposed method of pseudonymisation and were of the view that date of birth and postcode appeared to be retained with limited moves towards reduction of identifiability. In particular, the Committee queried whether retention of full date of birth would be required once age-based derivations had taken place and requested further clarification over this aspect. The long-term retention of full postcode was also queried as members were of the view that this could be reduced to lower super output area and then destroyed. It was requested that further consideration be given to this aspect as well.

Previously Members had indicated that they would require an update on movement towards an appropriate exit strategy and consideration of consent where feasible. Members noted the view within the resubmitted application form that consent was not thought to be an appropriate exit strategy as 100% ascertainment was required as one of the key purposes of the database was to monitor the whole of Wales, regional and small area trends in relation to births, maternity and immunisation uptake. The Committee queried whether 100% ascertainment was necessary, but were of the view that they did not have sufficient information by which to judge whether this was the case, and requested further justification to support this view. It was agreed that while pseudonymisation would be an option, it should not be taken to negate that fact that consent should be pursued where feasible.

Members raised concerns in relation to the potential onwards disclosure of the dataset, particularly as there might be rare disorders which would increase the identifiability and inferential risk. Members also queried the support letter provided with the application and the statement contained within it that *“there is no direct access to data outside of the team providing the NCCHD service and any requests for the data are carefully considered”.* The Committee were unclear from this statement as to whether the requests for data originated from outside the NCCHD team, and also sought clarification on the specific measures taken around small number suppression and requested further clarification on this aspect.

In the application presented at the April meeting, Members had been concerned that there appeared to be no opt-out mechanism available. In the resubmitted application it was explained that the applicant organisation had a mechanism by which individuals could write in to explain why the processing could cause damage or distress. However, the detail clarified that there was no mechanism by which consent could be withdrawn. The Committee agreed that, whilst there was not an automatic right for consent to be withdrawn arbitrarily, that a mechanism by which individuals could withdraw their consent to the processing of their personal data should be in place in line with the sixth principle of the Data Protection Act (DPA) 1998.

It was noted that a small proportion of data processed by NHS Wales Informatics Service (NWIS) was identifiable, and the perspective was taken that in being akin to the consent issue, that such an opt-out would be disproportionate. Members disagreed with the analysis of this point and were strongly of the view that if processing personal data, then compliance with the principles of the DPA would be required, in line with guidance issued by the Information Commissioner’s Office.

Members requested that the opt-out provision aspect be revisited and revised to move into line with the principles of the DPA. The Committee reiterated the importance of this aspect as any section 251 approval is required to be in line with the DPA provisions.

In relation to user involvement, it was noted that the intention was to develop the NCCHD Steering Group to include lay and/or patient representatives. Members were of the view that as the purpose of the Steering Group was to consider the impact and requirements of the NCCHD on stakeholders and the public it was considered essential to have suitable patient representation. Members were disappointed to note that it appeared there had not been significant progress on this aspect, and were of the view that such an important dataset would benefit from appropriate patient engagement, which would also be of benefit in assisting in moves towards compliance with the DPA. Members were of the view that this issue had been outstanding for a significant period of time, and therefore would have expected to see concrete moves towards suitable engagement, and requested a clear progressive update on this aspect.

In conclusion members agreed the approval under section 251 could continue but that further development would be required on the following aspects of the application:

1. Exit strategy of consent: In line with the comments above, further justification to be provided over the importance of 100% ascertainment. Applicant to also consider contexts where consent might be feasible.

2. Exit strategy of pseudonymisation: provide progress report towards pseudonymisation. In particular, detailed consideration of reduction of postcode and date of birth.

3. Provision of the documented controls to manage onward disclosure and management of inferential risk; how access would be managed and details of the small number suppression policy in place.

4. Progress against compliance with the first and sixth data protection principle, with emphasis on compliance with the fair processing aspect and mechanism to manage dissent.

5. Definitive progress report against patient involvement, with timescales and constraints.

In line with the above, the Committee requested a short and comprehensive report to be provided on these aspects at a future Committee meeting.

Action: NIGB Office to notify applicant of Committee decision.

5. New applications for section 251 support

5a. Processing and use of data from the Mental Health Minimum Dataset (MHMDS) [ECC 8-05(a)/2010]

This application from the NHS Information Centre required section 251 support to provide a secure legal basis for Systems and Service Delivery (SSD) to provide patient identifiable data to NHS commissioners, and to get agreement in principle for information to be held for onward disclosure under controlled conditions. It was noted that currently pseudonymised or de-identified data were used to achieve the commissioning activities, and therefore this represented a fundamental change to current data sharing arrangements.

Members considered whether sufficient justification had been provided for section 251 support to be provided in this instance and focused upon the legislative framework of section 251 of the NHS Act 2006 and the Health Service (Control of Patient Information) Regulations 2002 in reaching its decisions. The Committee advises the Secretary of State for Health on whether support under section 251 can be provided to permit the common law duty of confidentiality to be set aside so

that information which identifies patients can be used securely without their consent. The Committee does not provide a regulatory function, but fulfils an advisory and supportive role in legitimising essential activities, within the framework of the current legislation.

As such, in order to advise the Secretary of State for Health on whether section 251 support should be provided, the Committee must be satisfied that the statutory requirements are met. These include the need for sufficient evidence that:

- It fulfils a medical purpose as defined in the NHS Act 2006;
- The purpose must not be principally for care or treatment;
- The purpose is necessary or expedient in the interests of improving patient care or in the public interest;
- There is no other reasonable practicable alternative i.e. neither consent nor anonymised data are practicable;
- The use must not contravene the Data Protection Act 1998;
- There is maximum de-identification and only the minimum necessary use of patient information.

The Committee considered the requirements in turn:

Medical purposes

Medical purposes include health and social care services management. The purported uses of the data for commissioning and care of the patients would therefore fall within medical purposes and therefore this statutory requirement had been satisfied.

Exclusion for care and treatment purposes

In reviewing the support letters provided, Members noted that the letter from Mr David Arrowsmith highlighted that one of the stated reasons for receiving patient identifiable data would be to enable management of clinical risk, and in particular, to enable identification of high risk patients. Members were unclear about how much of the purpose of receiving confidential patient information would be to direct or review treatment at specific individuals. This was of concern to the Committee as section 251 (6) states that "*Regulations under subsection (1) may not make provision for requiring the processing of confidential patient information solely or principally for the purpose of determining the care and treatment to be given to particular individuals*". This is because consent is needed for examination and treatment and hence falls outwith section 251 which only pertains to the secondary use of confidential patient data. As such, it was not clear how much of the stated purpose for this change would be outwith the scope of section 251 support. Members agreed that further clarity over this aspect should be sought. Whilst a significant concern, this was not a critical issue in the overall decision.

Public interest

Under section 251 (1), applicants are required to demonstrate that the proposed activity is in the interest of improving patient care or is in the wider public interest. For all applications there is a need, as a public body, to apply the Human Rights Act 1998, and thus consider whether the interference with people's privacy is in accordance with the law, necessary for one of the prescribed derogations and proportionate. It was not clear how the purposes fit within the prescribed derogations, but additionally the Committee needed to consider whether the interference was proportionate, weighing the conflicting interests and their benefits and risks. Members noted that damage to public trust by not seeking consent is a potential harm considered in all applications, and the remit of the Committee is to consider the actual and potential risks and harm to the individual from the use of the data, and to balance that with the benefits of the proposed unconsented use of data.

Members were clear that it was entirely proper that payments should be allocated correctly and that the system of payment by results was a proper component of healthcare commissioning and recognised this as a benefit. What was not clear, given that this has been undertaken to date using pseudonymised data, was whether there was sufficient justification to use identifiable data. Additionally, and as a lesser point, the potential risks of inadvertent disclosure of sensitive data, the fears generated by public knowledge of the unconsented use of such data and the damage caused to their trust in the custodianship of their records, on which trusting professional consultations rely were viewed as proportionately greater harms. Article 8 of the European Convention on Human Rights was incorporated into UK law by the Human Rights Act 1998 and therefore the Committee must consider implications of this when reaching decisions. The Committee considered that this Act was likely to be engaged both for the disclosure to SSD and if ever there was any inadvertent disclosure of identifiable information or identification by inference.

It was noted that insufficient evidence had been provided to justify the substantial change to using patient identifiable data as opposed to the current system of using pseudonymised data. Indeed this was felt to be a retrograde step in information governance terms, where data flows should be moving towards using pseudonymised data for commissioning and other secondary purposes and therefore robust justification was needed to warrant this change. In line with this, the Committee was unable to conclude that the balance of the public interest would be best supported through recommending support under section 251 as the case was currently presented.

Practicable alternative

In reviewing the application, the Committee had due regard to section 251(4) of the NHS Act 2006 which states that support cannot be recommended "*if it would be reasonably practicable to achieve that purpose (otherwise than pursuant to such regulations), having regard to the cost of and the technology available for achieving that purpose*."

In particular it must be demonstrated that the purpose cannot be achieved using de-identified data and that seeking consent for the use of identifiable data was not practicable.

There was no evidence that the Committee could identify in the application exploring the possible alternatives, and no evidence to support the claim that the requirement of patient identifiable data was absolutely essential for commissioners. No alternative methods of fulfilling the requirement of commissioners to be able to check the residence of a mental health patient, for payment purposes were considered in the submission. Indeed, nor were the challenges of adopting alternative ways of apportioning costs for mental health services, without using patient identifiable data, considered. The Committee agreed that there was insufficient evidence within the application to enable them to conclude that all options had been explored, such as use of pseudonymised data.

Compliance with the Data Protection Act 1998

In providing recommendations under section 251, the Committee is bound by section 251 (7) which states "*Regulations under this section may not make provision for or in connection with the processing of prescribed patient information in a manner inconsistent with any provision made by or under the Data Protection Act 1998*". The Committee must follow this requirement and so always seeks evidence that applicants have carefully considered this Act and responded appropriately to its requirements.

The Committee could not identify sufficient evidence within the application that all of the principles of the Act were being complied with. In particular, there was insufficient evidence provided that the sixth Data Protection principle was being honoured. This principle indicates that personal data must be processed in accordance with the rights of the data subject and includes a right to object to processing that is causing or likely to cause damage or distress.

Additionally, the Committee raised concerns over compliance with the first Data Protection principle. Due to the sensitivity of the dataset, it was important that attempts would be made to inform the data subjects of the use of this data, thus ensuring compliance with the fair processing aspect of the Data Protection Act 1998.

Maximum de-identification and minimum information

Members reviewed the particularly sensitive items and identifiers required to achieve the stated purpose. While it was clear that a 'fit for purpose' dataset would be required and was reasonable, the extensiveness of the data set and the addition of patient identifiable items would seem to be disproportionate and require justification in the context of disclosure to SSD and risk in relation to third party disclosures.

In conclusion, whilst the Committee were mindful of the benefits of the activity, members are obliged to operate within the legal framework provided and agreed that the application did not currently provide sufficient evidence to enable them to conclude that the criteria had been met for section 251 protection. It was noted that the potential loss of trust of a very vulnerable group of the public in the confidentiality of their information would be very serious if the section were applied without clear legal justification.

As a whole, the Committee were supportive of this important activity in principle, but were unanimously unable to recommend support to the Secretary of State for Health under section 251 of the NHS Act 2006 due to insufficient justification contained within the application to meet the legal requirements.

Members were conscious that this decision would cause some difficulty; however, they were clear that the detail of the application did not enable the Committee to recommend support as the threshold for reaching the framework of the legislation had not been achieved. It was recommended that a meeting take place with the applicant to discuss the outcomes further.

Action: NIGB Office to inform applicant of Committee decision.

5b. National Cancer Survivorship Initiative [ECC 8-05(b)/2010]

This application from the Department of Health and Quality Health sought support to cover the pilot phase of a proposed national survey of cancer survivors, which was intended to last until June 2011. The purpose of the activity was to aim to improve understanding of quality of life outcomes for cancer survivors and was intended to support the DH National Cancer Survivorship Initiative (NCSI). The activity would build upon the current national Cancer Patient Experience Survey Programme (CPESP) 2010 which focused on the experience of care of cancer patients.

Section 251 support was sought to enable the legitimate transfer of patient data from the Cancer Registries to Quality Health, and for Quality Health to liaise with cancer centres so that patient questionnaires would be sent to patients on appropriate cancer centre letter headed paper. A sample would also be identified from the cancer registries. To carry out the activity, Quality Health would require access to name, address, sex, ethnic group, year of birth, NHS number, ICD10 code, speciality code, date of diagnosis and Trust NACS code for most recent treatment spell.

Members were generally supportive of the aims of this activity. However, concern was raised that little information had been provided about Quality Health who would be accessing the data within the patient letter. Members noted that the letter would be provided on headed paper from the relevant cancer centre, however members discussed that it might be more appropriate if the letter was on GP practice headed paper and requested that the applicant consider this possibility. Additionally members agreed that the letter could be more appropriately worded to reflect that the data was going to be sent to Quality Health and that further information about them should be provided.

Members considered the response to Office queries which set out reasons why the cancer registries could not carry out the activities themselves. Members noted that the reasons cited could be seen to be anecdotal and therefore requested that the applicant provide full justification as to why it was not feasible for the cancer registries to carry out the activity. In particular the Committee requested that this justification should originate from the cancer registries themselves so that there was a clear and evidenced based explanation as to why this would not be feasible.

Members agreed that there was a public interest in the activity taking place, but were concerned that engagement with patients had not taken place. It was suggested that the applicant could obtain views from the cohort population in order to add weight to providing support under section 251.

The Committee agreed to provisionally approve this application subject to satisfactory clarification of the following:

1. A detailed justification should be provided from the cancer registries detailing why they could not carry out the activity themselves; this should cover the issues of cost, resource, and any other information to add weight to the perspective that they would be unable to carry this out.
2. A plan detailing the involvement of patients within this activity should be provided to the NIGB office.
3. Consideration of the feasibility of sending information on letters headed from GP practices.

Subject to satisfactory resolution of the clarifications above, approval would be based on the following conditions:

1. A copy of the participant information leaflet and questionnaire to be provided to the NIGB office for review by relevant members.
2. Formal confirmation of a lead cancer registry. It was understood that the next meeting of the UKACR Executive would be on the 8/9 December where this issue would be discussed.
3. Written confirmation to be provided from the appropriate Caldicott Guardians.

Action: NIGB Office to inform applicant of Committee decision.

5c. Risk Stratification Project [ECC 8-05(c)/2010]

This application from NHS East Riding of Yorkshire required section 251 support to put into place a process to manage risk stratification through utilising a tool that would incorporate data from Hospital Episode Statistics (HES) admission, outpatient, A&E and GP Practices to calculate a patient risk score.

Section 251 support was sought to enable extraction of data from three GP systems which would include practice name, NHS Number, sex, date of birth, diagnosis code and date of diagnosis. This data would be transferred to United Health UK, a healthcare management information company.

Members noted that one justification for accessing patient identifiable information was to enable the identification of patients who were at risk, and it was considered essential that GP practice staff were provided with the necessary information to support the delivery of timely interventions in an efficient and effective manner. This activity seemed to fall outside the medical purposes of section 251 and therefore members advised that either a consent or pseudonymisation based approach should be utilised. Members also discussed whether the risk score could be applied directly to GP systems.

Additionally members were concerned that there appeared to be no fair processing information provided to patients.

Members discussed whether it would be proportionate to carry out this activity using the level of patient identifiable data that would be transferred to United Health UK. They also considered whether the data items required were the minimal amount required and whether they were necessary. The Committee were ultimately of the view that they could not identify a clear justification for the transfer of patient identifiable data to United Health UK, and were of the view that pseudonymised data should be utilised in the first instance. Once those at risk had been identified, then only those patients should have their details "reverse-pseudonymised". Members noted that this was similar to the PARR tool process and were of the view that a similar approach could be followed here.

As the Committee were of the view that a pseudonymisation approach could be utilised there was insufficient justification to warrant recommendation of support under section 251.

Action: NIGB Office to inform applicant of Committee decision.

5d. Orthopaedic Intervention of Rheumatoid Arthritis: A retrospective analysis of cumulative incidence, prognosis markers, outcomes and cost effectiveness over a 20 year period [ECC 8-05(d)/2010]

This application from West Hertfordshire Hospital NHS Trust required section 251 support to examine rates of joint replacement surgery from two previous studies. It was noted that the Rheumatoid Arthritis Study (ERAS) was begun in the early 1980's when consent requirements were different. Section 251 support was sought to enable access to all orthopaedic procedures from HES based on OPCS and ICD10 codes, and to match these with the ERAS and ICD10 codes, and to match these with the ERAS and ERAN cohorts.

Members debated whether this could be considered to be audit or research as it appeared to be a combination of both. Members were of the view that orthopaedic procedure was seen as a proxy for structural damage to the joint, so in that sense it could be considered to be research as the longer term outcome of the use of more modern medication was not known.

Members noted that ERAS had commenced in 1986 and that there was no written evidence of consent as this was not a requirement at the time. Members were sympathetic to the situation and agreed that it would be against the public interest to "lose" the data to a change in rules since the activities started. Members were satisfied that this was a one-off situation and would not reoccur. The Committee also agreed that patient involvement was good, and that any further attempts to strengthen this would be welcomed.

In reviewing the extent of requested identifiable information, Members agreed that the use of identifiers was minimal in that NHS Number would be used where it was known, and that name and date of birth would be used if NHS Number were not available. The committee agreed that this was reasonable in these circumstances.

In assessing whether consent would be feasible, Members agreed that the seeking of consent would be impracticable as it was expected that a number would be deceased or lost to follow-up and that there appeared to be limited evidence of dissent. However, members were of the view that some of the cohort would be followed up and in contact with the service and those that were should be provided with fair processing information.

The Committee agreed to provide section 251 support to the study subject to satisfactory clarification on the following:

1. Clarification over the number of the cohort where NHS Number was missing.

2. Clarification regarding the number of records that would be involved in the matching process, and the overall size of the cohort.

3. Confirmation whether an amendment or application would be required from a research ethics committee in relation to this specific activity.

Any approval would be subject to the following conditions of approval:

1. Provision of a favourable opinion from a research ethics committee (if applicable).

2. Where the cohort were to be followed up and in contact with the service, efforts should be made to notify them of this activity.

3. The provisional approval would be related to the one-off activity. Any further actions that might require support under section 251 would be subject to a further application.

Action: NIGB Office to inform applicant of Committee decision.

5e. Integrating Strain Typing and Database Technologies in Research Service [ECC 8-05(e)/2010]

This application from Oxford Radcliffe Hospital NHS Trust required section 251 support to carry out an investigation into ways in which new technologies could improve infection control service delivery through studying three pathogens and to determine whether detailed genomic information about these pathogens would be useful.

Section 251 support was sought to enable access to patient identifiable data from those potentially infected with the relevant healthcare acquired infection. The application requested access to routinely collected hospital data, name, NHS Number, hospital ID, GP registration, date of death, postcode and SHA area.

Members agreed that this was a detailed application and that consent would not be practicable due to the large numbers and timings of the activity. It was also agreed that there would be a clear public benefit to this activity taking place.

However, members were unclear whether the application detailed what would amount to a covert overriding of dissent. However, following review of the REC letter, there was the implication that patients would receive information about the study in a hospital information leaflet so dissent would be possible and permissible,

Members also noted the extent of user involvement and noted that, whilst small, it was acceptable at this point. However, it was agreed that attempts should be made in the future to strengthen this aspect and that this should be reported upon in the next annual review. Finally, the Committee noted that it appeared samples would be collected, and were clear that this would fall under the terms of the Human Tissue Act.

The Committee agreed to recommend provisional support under section 251 for the activity. This provisional support was subject to satisfactory clarification of the following:

1. Clarification over who would be accessing names to check clinical utility in phase 2 of the study.

If the clarification request were to be satisfactorily resolved, approval would be subject to the following conditions:

1. Provision of a favourable opinion from a research ethics committee.
2. A mechanism to allow dissent to be in place.
3. User involvement should be strengthened and reported against in the next annual review.

Action: NIGB Office to inform applicant of Committee decision.

5f. A National Neonatal Research Database [ECC 8-05(f)/2010]

This application from Chelsea and Westminster NHS Foundation Trust sought section 251 support to enable the establishment of a national neonatal research database for subsequent use as a research resource. Section 251 support was required to enable routinely collected patient identifiable data to be populated on this research database. In addition to routinely collected clinical data, the application also included requested use of NHS Number, hospital ID, date of birth, date of death, postcode, gender, ethnicity, maternal NHS number and ethnicity and postcode of infant at two years old.

Members agreed that this application set out a worthy purpose, would provide a number of benefits and the additional clarity provided following office queries was welcomed. In particular, the Committee noted that user involvement had been very good and that the continued engagement was to be commended.

Members agreed that as a whole, consent would not be practicable due to the large numbers involved (60,000). However, the Committee was mindful that decisions taken under section 251 could not be inconsistent with the Data Protection Act (DPA) 1998. In particular, members focused upon compliance with the fair processing aspect of the first principle of the DPA. Whilst section 251 could permit access to patient identifiable information without consent, Members were clear that the parents of the cohort should informed where reasonably possible, thus fulfilling compliance with the fairness aspect of the first principle of the DPA. In addition, the Committee noted that the sixth principle permitted a number of rights, one of which was the right for data subjects to request that the processing of personal data should cease if demonstrated to cause damage and distress. As such members agreed that all applicants should have a mechanism in place to manage dissent and requested details on how this would be managed within this application. It was suggested that those involved in patient engagement could be consulted to aid in the development of an appropriate mechanism.

Members noted that some good user involvement had been detailed but that some was planned in future and noted that they would expect to see the results of the involvement and how this had affected the study.

Members highlighted that a principle of the Committee was that there should not be a long-term retention of identifiable data without consent. Members could not identify a clear justification to support this long term data retention, and requested that this issue be investigated by the applicant to enable reduced identifiability. In particular, members queried why the HESID could not be used as the key identifier once linkage with HES data had been carried out. However a view was raised that it might be helpful to retain encrypted NHS number to allow future linkages that may be unforeseen at this present time.

Members also noted the onward disclosure aspect of the study and queried what controls would be put in place to ensure that recipients would not seek to render the information more identifiable. Members expected that a data access policy would be in place to handle this situation and requested sight of this, and any other controls in place.

The Committee agreed to recommend provisional approval under section 251 for this study, subject to satisfactory responses to the following points of clarification:

1. Exploration of options to reduce identifiability of information in line with Committee's views on long-term retention of identifiable data without consent. It was recommended that the applicant might wish to contact the NHS Information Centre to explore further options.
2. Provision of the relevant documentation to support any onward disclosure to the NIGB Office.

If the above were to be satisfactorily resolved, any approval under section 251 would be subject to the following conditions:

1. Provision of a favourable opinion from a research ethics committee.
2. Provision of fair processing information to inform parents about the activity and to facilitate a mechanism to permit dissent to be registered and managed.

Action: NIGB Office to inform applicant of Committee decision.

5g. Research Use of the ONS Longitudinal Study [ECC 8-05(g)/2010]

This application from the Office of National Statistics set out a proposal for the provision of access to the Longitudinal Study by researchers who had been granted Approved Researcher status. There was a question raised over the extent of the identifiability of information to be provided to researcher, and as there was the potential for the information to be considered identifiable, section 251 support was sought to enable this disclosure.

Members welcomed the attendance of Mr Felix Ritchie at the meeting, and the attendance of Mr Ritchie and Ms Suzanne Fry earlier in the week, and welcomed this commitment.

Members commended the fact that potentially anonymised data was being treated as if it were identifiable. Members noted that there would be around 20-30 applications a year for the data and that it would only be accessible from ONS offices. However, in reviewing the application, members found it difficult to carry out a comprehensive review under section 251 as some of the current arrangements were slightly unclear.

Members discussed the nature of the historical approval for the Longitudinal Studies, and were of the view that the original support provided under section 251 covered the way ONS used the data for its internal use, but it appeared from this application that the subject was predominantly about disclosure of potentially identifiable information to third parties.

The discussion indicated that the applicant was of the view that section 251 support was in place to permit the delegated disclosure of identifiable information to third parties, however, the Committee confirmed that this was not their understanding. The Committee was mindful that some time had passed since the original provision of approval and that there was no record of a recent annual review being provided. It was essential that the current picture was clear so that both parties had an agreed understanding of the terms of the support provided under section 251. As such, members requested that an application covering the current arrangements would need to be submitted before any further consideration could take place around the details of the current application.

In line with the comments above, the Committee agreed the following outcomes:

1. Much of the data appeared to be managed in a controlled environment, and this was commended. However members requested further evidence detailing the environment that the data was managed within.
2. The Committee agreed that they were not in a position to recommend support under section 251 to the application as greater clarity was required over the current arrangements.
3. Members were unclear on the specifics of the internal governance arrangements over the management of the data; to include the current data access procedures, the appropriate selection of data items, and the audit controls that were in place, and were of the view that these should be comprehensively addressed. It was assumed that these controls were generally good, but there was limited information available and therefore there was insufficient evidence on which to reach a conclusion.

4. Members noted the lack of patient engagement in the application and commented that it would be important to incorporate this into any approval.
5. Before the Committee could reach a decision on this specific application, members requested that a separate application be presented to the Committee so it was clear what the current arrangements were. It was agreed that this was an appropriate approach to take as there was a lack of clarity over the present arrangements, and members were of the view that they needed to fully understand the current situation before determining whether section 251 support would be appropriate for any further activities. This would also aid in providing further clarity for both parties in terms of the remit of section 251 support and where it would be required.

Action: NIGB Office to inform applicant of Committee decision.

5h. PILOT N-ALIVE: NALoxone InVEstigation [ECC 8-05(h)/2010]

This application required section 251 approval for the Medical Research Council to carry out a clinical trial of the effectiveness of a drug in the event of an overdose in people recently released from prison. Section 251 support was sought to request receipt of full datasets within the age range.

In reviewing this application, members were slightly unclear on some aspects; in particular whether section 251 support would be appropriate for this activity. The Committee understood that whilst the majority of the cohort would provide consent, the plan would be to look at more general death data and therefore consent could not be obtained from all the other names contained within the dataset. The Committee were of the view that this would be acceptable in principle. However, members also noted that there was a significant possibility that aliases would be used, and therefore queried how this would be managed. Members agreed that the user involvement undertaken was commendable.

Members agreed that the overall activity could be potentially of benefit, and whilst supportive in principle, felt that there may be ethical issues arising from the activity and therefore requested to have a copy of any deliberations and favourable opinion letter from the research ethics committee before reaching a final decision. Members were also unclear on whether a flagging system could be used, and therefore requested that greater clarity be provided on the practicalities of the approach outlined in the application.

Action: NIGB Office to inform applicant of Committee decision.

5i. Dental Age Assessment: Setting International Standards [ECC 8-05(i)/2010]

This application from Kings College Hospital was to create a Reference Dataset that would aid in determining the accuracy of dental age when applied to small groups of children of known chronological age. This would aid in meeting a number of purposes.

In reviewing this application, Members noted that there was some disparity over the definitions used for anonymised and pseudonymised data and the Committee emphasised that where data of birth was included, this would render the information identifiable. As such, members felt there was some confusion within the application as to the extent of identifiable held. Members also queried why the response to the question that sought clarification over retention stated that this was not necessary. As date of birth was retained, members disagreed with this conclusion. Additionally, members agreed that this response to question 15-1 misunderstood the nature of user involvement in the context of this application. Members also noted that a response had not been provided in relation to how a patient's right to dissent from their personal data would be managed.

However, following assessment of the purposes, members were of the view that the overarching purposes appeared to have a forensic focus, rather than a medical purpose. Following review of

the relevant legislation and regulations the Committee concluded that the purpose seemed to fall outside of the remit of section 251 as it did not fall within any of the defined medical purposes. As such section 251 could not be provided to this application.

Action: NIGB Office to inform applicant of Committee decision.

6. Any other business

No other business was discussed.

Future meeting dates

2-3 February 2011
28-29 March 2011
1-2 June 2011
27-28 July 2011
26-27 September 2011
1-2 December 2011