Ethics and Confidentiality Committee meeting - Thursday 28 July 2011

Members:

Dr Mark Taylor (Chair), Mrs Pauline Brown, Dr Tony Calland, Professor Michael Catchpole (*to item 4D*), Dr Patrick Coyle, Professor Julia Hippisley-Cox, Dr Tricia Cresswell (*to item 4D*), Dr Fiona Douglas, Ms Stephanie Ellis, Professor Sir Denis Pereira Gray, Mr Michael Hake, Mr Stephen Hinde, Ms Sue Parroy, and Mr Terence Wiseman,

In attendance:

Dr Alan Doyle *(NIGB Director, to item 4D),* Ms Natasha Dunkley *(Approvals Manager),* Ms Claire Edgeworth *(Deputy Approvals Manager),* Ms Vanessa Kaliapermall (*Department of Health*), Rick Borges (*observer - NIGB Business Support Manager)*

1. Welcome and apologies

Apologies were received from Dr Andrew Harris, Dr Colin Harper, Dr Jane Kaye and Mr Phil Walker (Department of Health)

Declarations of Interest

Dr Mark Taylor declared a potential conflict of interest in agenda item 5G and was not present for the discussion or decision. That item was chaired by Professor Sir Denis Pereira Gray.

Professor Julia Hippisley-Cox declared a potential conflict of interest in agenda item 4e and was not present for the discussion or decision. As Professor Cox was named in agenda item 3b she also declared a possible conflict, and therefore did not participate in that discussion or discussion.

2. Minutes of last meeting [ECC 5-02(a)/2011] and matters arising

The minutes from the meetings held on 01 June were approved as an accurate record.

2b. NIGB Office Report [ECC 5-02(b)/2011]

Change to security review arrangements

Review of security arrangements for applications is independently carried out by the Department of Health's security review team, managed by Mr. Phil Walker. Currently, applicants complete a system level security policy (SLSP) (template available on the website via http://www.nigb.nhs.uk/s251/forms). This process is carried out independently of any recommendations of support made by the Committee and satisfactory assessment is a mandatory requirement for any recommendations of support.

The Office has been recently been notified that version 9 of the IG Toolkit has been published that contains a new view for 'hosted Secondary Use Team/Project'. In particular, there is the addition of view 9-335 'Information security assurance', that specifically covers instances where organisations are carrying out research activities that have received support from the Committee.

https://nww.igt.connectingforhealth.nhs.uk/RequirementQuestionNew.aspx?tk=407156803834574&lnv=2&cb=cfd1cca7-77d7-40fe-a823-074f6239e262&sViewOrgType=22&reqid=2168&last=truet

The NIGB have been informed that it is the Department of Health's policy to enable all users of NHS patient identifiable information to be able to provide relevant information governance assurance through their adoption of the NHS IG Toolkit. Practically, this is likely to remove the need for applicants to provide system level security policies and assurance will be obtained via adequate completion of the Toolkit. The intent is for this change to be fully operational from 01 April 2012 with the option that early adopters will make use of the available Toolkit facility from now.

The Committee raised a number of queries over implications of this change, particularly to the academic community, and queried what support, training and consistent rollout arrangements would be in place in order to ensure it would be managed effectively throughout a transition period. It was agreed that the NIGB Director would engage with the Department to take forward concerns from the Committee, understand in greater detail the policy directive and report back at the next meeting.

Action: **NIGB Director to report back to next meeting to update on actions on changes to security review process, members to forward any queries.**

Fast Track applications

ECC 6-02(FT1)/2011 A pilot prospective study of the role of cerebral oximetry in predicting outcomes in inhospital cardiac arrest

This study from Southampton University NHS Trust aimed to determine the clinical effectiveness of a non-invasive monitoring system for the assessment of oxygen delivery to the brain during cardiac arrest in six hospitals that had decided to pilot its use as part of clinical practice. Section 251 support was required to allow a research nurse to access records relating to those patients who had died in order to collect anonymous data to determine the utility and effectiveness of cerebral oximetry in predicting survival, neurological and cognitive outcomes. It was noted that the clinical care team would approach living patients in order to obtain consent prior to a research nurse accessing their data.

Members considered this to be an important study which had the potential to generate significant new knowledge. It was agreed that trying to seek consent patients during a cardiac arrest would be impracticable and therefore consent from those who did not survive would not be possible. Members agreed to approve this application.

ECC 6-02(FT2)/2011 Study of suicide in the Falklands cohort

This application from the University of Bristol requested section 251 support in order to flag a cohort of Falklands veterans on the NHS Central Register to obtain cause of death to allow the Ministry of Defence to ascertain the actual number of suicides within the cohort. If an excess of suicide, or any other causes of death, were identified then this would trigger further targeted studies with the aim of influencing policy to improve support and services to veterans of this conflict. It was agreed that there was a high public interest in this activity being carried out, and a recommendation of support was provided subject to confirmation that full date of birth would be removed from the database once age had been calculated.

ECC 6-02(FT3)/2011 Diagnosis of dementia and relative cognitive decline

This application from Worcestershire NHS Trust requested section 251 support in order to access records held by five NHS memory clinics to extract anonymised data. The aim of the study was to explore whether there was a difference in the amount of cognitive decline that people with high levels of premorbid intellectual function must undergo before being diagnosed with dementia, when compared to people with other levels of premorbid intellectual function.

This application was originally forwarded to two members plus the Chair in line with the usual fast track procedure; however a number of queries and concerns were raised which led to further queries being sent to the applicant and the application being circulated to two additional members.

In conclusion members could not provide support to this application and advised that section 251 support could not be recommended for access to this highly sensitive data as they were of the view that the study could be undertaken prospectively with consent. (note resubmitted application 4D)

ECC 6-02 (FT4/BPSU)/2011 Autoimmune Addison's Disease of Childhood

This was an application from Sheffield Children's NHS Foundation Trust. Members noted that this was an important study into a serious condition with a very low incidence and therefore a requirement to obtain complete ascertainment. Members considered the identifiers requested; NHS number, sex, date of birth and partial postcode, to be reasonable to allow de-duplication of cases.

Members were concerned that the application did not fully demonstrate compliance with the Data Protection Act, particularly principle 1, the provision of fair processing information, and 6, processed in accordance with the rights of individuals. As approval under section 251 cannot be inconsistent with the principles of the DPA members requested that the applicant revisit their responses to the first and sixth principles. Members agreed to approve this application, subject to appropriate resolution over DPA compliance.

ECC 6-02 (FT5)/2011 the community/in-patient interface in adult mental health

This application aimed to map the patient journey from a variety of perspectives – the patient, patient's carer(s), staff (both in community and hospital) and records. A study of people involved in an episode of in-patient care for an adult patient with long term mental health problems receiving community care from and Assertive Outreach Team. Episodes would be chosen to cover either good or bad patient experiences. Identifiable data was required for the purposes of linking data from multiple sources and to seek consent from patients who were going to be interviewed. Identifiable data was considered necessary due to the way the data was organised and this would be pseudonymised as soon as linkages had taken place.

Members were concerned about the level of patient identifiable data the applicant proposed to collect, including complaint data which the patient may have understood was collected in confidence. Members were also unsure of the proposed outcomes of the study and could therefore not conclude that the study would be in the public interest. As such members agreed that they could not recommend section 251 via the fast track process and in this instance the application would require review by full committee.

The study was currently undergoing REC consideration; the applicant confirmed that there had been some issues raised by the REC and as a result changes would be made to the methodology. As the methodology was currently unclear the applicant advised that they will submit to a full committee meeting at a later date and **withdrew the application.**

ECC 6-02 (FT6)/2011 Maternal Hyperglycaemia, Ethnicity and Neonatal outcome Study. HENS.V1

This application from the University of Leicester detailed a study to clarify the influence of ethnicity on neonatal outcomes of diabetes in pregnancy and to provide current information about management of these infants. Section 251 support was requested to access patient records in order to identify a cohort of mothers and their babies, and extract identifiable data including full name, date of birth, sector level postcode, NHS number and hospital number. Identifiers were required in order to avoid duplication, link maternal and neonatal data and trace participants notes if incorrect information was extracted.

Members were supportive of this application in principle however they required further clarification before a decision could be made.

- Who would carry out the identification of the cohort, case note review and complete the data collection form. If not by the clinical care team then the reasons would need to be provided.
- Whether fewer identifiable data items could be used to carry out the linkage, for example would date of birth, hospital number and NHS number be sufficient.
- Confirmation that sector level postcode only will be collected.
- Confirmation that fair processing information would be displayed in view of patients within the hospital and that any dissent will be respected.

The applicant clarified these points and confirmed that both researchers accessing identifiable data would be members of the clinical care team for the patients involved and therefore have access to the requested data as part of their role. For this reason it was confirmed that section 251 would not be required.

ECC/BPSU 6-02(FT7)/2011 Hypocalcaemic Seizures Due To Vitamin D Deficiency In Children

This application from University College London detailed a study using the BPSU orange card methodology in order to provide the incidence of hypocalcaemic seizures due to vitamin D deficiency in infants and children in the UK and Ireland. NHS Number, hospital ID, date of birth, date of death and sector level postcode were required for de-duplication purposes and date of birth, date of death and sector level postcode would be retained for analysis purposes.

Members agreed this was an important study and that it was appropriate to use the BPSU methodology due to the low incidence level. However concerns were raised over the validity of a question within the questionnaire that requested clinicians to recall what clothing the mother of the child was wearing. Members agreed that the reliability of the data would be low as this information would not be included in the child's medical notes and would be based on what the clinician could recall from the consultation.

The applicant provided further detail to justify the retention of this question and that clinicians would be provided with an option to state that they were unsure. Members agreed that sufficient justification had been provided and were reassured that clinicians would be provided with the option not to answer the question if they could not accurately recall the data. This application was approved subject to REC approval being received.

Amendments

PIAG 4-06(c)/2006 Long term sequelae of radiation exposure from computed tomography in children and adolescents

The following changes were requested by the University of Newcastle:

1. To extend the nested case-control study to include additional cancer cases, including lymphomas, brain, bone, thyroid, skin and breast tumours. These were not explicitly mentioned in the original protocol, however the amendment did not involve accessing any further patient identifiable data.
2. To include data from electronic images and reports transmitted digitally via Picture Archiving and Communication System (PACS) in Radiology departments using the system. It was confirmed that pseudonymised data would be extracted in line with the original security policies and noted that the original application detailed both paper and electronic record access.

As no additional data would be accessed this amendment was reviewed by the NIGB Office and noted against the application.

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PIAG 1-08(b)/2003 Breast Test Wales (BTW) and Cervical Screening Wales (CSW)

An amendment request was made to allow BTW and CSW to outsource the printing of negative results to a third party. The extension was approved via Chair's action, subject to satisfactory security arrangements being confirmed.

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

The original proposal from West Hertfordshire Hospital NHS Trust was to look at the rates of joint replacement surgery from two previous studies. It was noted that the Early Rheumatoid Arthritis Study (ERAS) was began in the early 1980's where 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 ERAN cohorts.

An amendment request was made via a letter dated 6 June to access data from the National Joint Registry, as well as HES database, on orthopaedic procedures that the ERAS and ERAN cohorts had undergone. This amendment request was considered by members outside of a Committee meeting and approved.

<u>Update on previous applications</u>

Q-Research [ECC 3-04 (c)/2011]

This application from the University of Nottingham was originally considered at the March 2011 meeting. Following a recommendation of provisional support, the NHS Information Centre had subsequently written to the Chair to query the extent of disclosure and concern over their compliance with the Data Protection Act (DPA) 1998. At the June 2010 meeting members briefly discussed the issue and agreed that it was entirely appropriate for data controllers to seek to reassure themselves over the arrangements in order to ensure their own compliance with the DPA. However, it was considered essential that dialogue be entered into between the applicant and data controller in order to resolve such issues and reach an agreed final position. Once this dialogue had taken place, the Committee noted that if an amendment were required it then could be considered further. It was agreed that the Chair would write to the applicant to confirm this position.

Subsequent to this response, an approach making greater use of pseudonymisation techniques has been agreed with the NHS IC. Following discussion with the Chair, the applicant has been asked to supply a letter (jointly signed with the NHS IC) confirming what details have been changed from the original application, whether the new approach poses greater or lesser security risks, and clarification over the extent of de-identification. This is intended to be reviewed by the Chair and a small group of members once received.

British Paediatric Neurosurgery Group audit ECC 3-04(t)/2011

This application from the Society of British Neurological Surgeons was considered at the March 2011 meeting where a recommendation of support under section 251 and its Regulations had been requested in order to provide a legitimate basis for the future processing of this dataset. The Committee had agreed that this was a very important data set with a large number of public interest outcomes, and they were keen to support this activity and aid the applicant in seeking to provide a legitimate basis for further use of this dataset. However, concerns had been raised over the statement that the Royal College of Surgeons of Edinburgh was not aware of the Data Protection Act. Subsequent to the response, the office was copied into a letter dated May 2011 that provided an apology from one of the named applicants to the Royal College; this stated that there was a misunderstanding over the wording of the application, and that they would be keen to work with the NIGB and Royal College to resolve the issue. No further contact has yet been made.

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

A letter had been received from Professor Michel Coleman from the London School of Hygiene and Tropical Medicine where the concluding part indicated that where linkages to other data sources had previously been required that subsequent requests had been made to the ECC for support, and that there was likely to be an increased number of linkages to other data sources over the next few years. The letter specified that continuing to seek support for access to each of the data sources, and to review/update the overall application each year was untenable and represented a significant amount of time and research resources. Analogies were drawn between the specific support provided to the Health Protection Agency and a meeting was therefore requested to manage this issue.

The office has written to the applicant and highlighted the requirement under Regulation 7 for all class support applications to provide an annual review to review the extent of identifiable information and that measures are taken to reduce identifiability where appropriate. This is a light-touch review and only where particularly contentious would it be referred to the full Committee. In terms of the request to waive seeking further support in relation to future unspecified linkages, the applicant has been advised that clarity is required in terms of what activities have been approved under the Regulations. They have been advised that such extension requests are not overly burdensome, and that the office would be happy to discuss such proposed linkages in advance of the requirement, and could advise on the best method to take forward. Clarity was also provided on the specific support provided to the HPA, their need to provide an annual review, and the difference between class and specific support. The applicant was also encouraged to liaise further with the cancer registries in order to progress their activities coming under their specific support. At present, a meeting has not been advised due to the need for class applications to comply with the framework of the Regulations

PILOT N-ALIVE: NALoxone InVEstigation – ECC 8-05 (h)/2010

This application from the Medical Research council was originally considered in December 2010 where the proposal had been 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 had been sought to request receipt of full death datasets within the age range. Members had previously requested clarification on the approach, in order to determine whether support would be required.

This application has now been halted on the grounds that the applicant has indicated that they are finalising other aspects of the application, and it is possible that they will only seek morbidity information for those participants where consent had been obtained. Until greater clarity is available, this application has been deferred.

Health Protection Agency Annual review

All actions related to specific activities contained within the 2010 Health Protection Agency have been successfully concluded. A meeting took place on 16 June 2011 between Professor Anthony Kessel, Dr Fortune Ncube, Thomas Bjorn, Antony Haworth and Sarah Perman from the HPA, and Dr Andrew Harris and the office in order to discuss reasons for changes in the annual review reporting requirements. The proposed framework for future reporting was discussed, clarifications provided over the responsibility of the Committee to advise the HPA, and suggestions made to improve joint working. It has been agreed that an annual report will be provided to the Committee for review at its meeting on September 2011.

Updates

1. Regulation and Governance of Medical Database Research in the United Kingdom – University of Sheffield

This event at the University of Sheffield was organised by Mark Taylor (ECC member) and attended by the NIGB office. The one day workshop discussed the future face of NHS Information Governance in medical database research. Details of the workshop are available at http://www.sheffield.ac.uk/law/research/clusters/sible/sibleworkshops/regulation

2. Knowledge development – Research Ethics Committees

In order to understand further the operation of research ethics committees, the NIGB office have approached NRES who have arranged a number of attendances at REC meetings in an observer capacity. A meeting is also scheduled to take place at the East Midlands REC Centre in August 2011 to gain an understanding of the operational aspects on how RECs manage research applications.

3 For consideration

3a ECC 1-06(c)/2009 National Clinical Audit Support Programme Review – interim review report

This interim report from the NHS Information Centre was provided in response to the outcome from the September 2010 Committee meeting, where a number of conditions of approval had been set out and are repeated below:

1. Detail of the role and input of the NHS Information Centre (NHS IC) to assist information about national clinical audit being provided at a local level.

2. For audits where NHS Number was not complete, to identify and specify how a strategy will be put into place, and for this strategy to be implemented.

3. For audits where NHS Number is almost or fully complete, to set out detailed steps of the identifiers and how these could be reduced in identifiability so that a pseudonymisation approach can be pursued as an exit strategy from section 251. These can be submitted on an incremental basis, preferably in suites, and this should be discussed further with the NIGB Office.

4. Conditions 2 and 3 should be fully completed and satisfactorily reviewed by the Committee by April 2012 at the very latest.

5. A focused report should provide specific updates on progress against conditions 1-3 for the audits so it can be considered at the Committee meeting on the 28 July

Outcome

Members welcomed this interim report detailing progress against conditions 1-3 and discussed it in detail; the key points arising from the discussion are summarised below:

1. **Detail of the role and input of the NHS Information Centre (NHS IC) to assist information about national clinical audit being provided at a local level**

The report requested that the condition for a more generic leaflet about the role of the NHS IC in relation to national clinical audit was put on hold. This was due to the uncertainty regarding the future state for national clinical audit.

Members recognised the difficulty in providing information relating to the national role of the NHS Information Centre given that future arrangements were not yet certain. When considering whether this aspect could be put on hold the Committee were mindful of the reason for implementing the condition, namely to mitigate the potential misunderstanding by patients that the NHS Information Centre was a local NHS organisation and to ensure that it was understood that the NHS IC managed a programme of audits. The Committee noted that currently the NHS IC provided audit specific leaflets which provided fair processing information for patients and stated that the NHS IC was an independent special health authority.

The Committee welcomed the NHS IC input in providing topic specific patient information leaflets and encouraging the use of posters and leaflets in clinics. In reflecting that this was considered particularly important in light of recent Government commitments to patients, such as ‘no decision about me without me’ the Committee requested further information, including how widely patient information leaflets were distributed, how they were distributed at a local level and what the NHS IC specifically were undertaking to encourage this distribution.

2. **For audits where NHS number was not complete, to identify and specify how a strategy will be put into place, and for this strategy to be implemented.**

The Committee were pleased to note the information within the report that the NHS number was now a mandated data item and were of the view that significant progress had been made to ensure this was collected. The Committee noted that the Cardiac Rehabilitation audit was the only audit that currently did not have complete use of NHS Number but that it was intended this should be mandated by 16 May 2012. It was noted that other audits where NHS ascertainment was not complete related to the cardiac audits and management of these audits had transferred to University College London.

3. **For audits where NHS Number is almost or fully complete, to set out detailed steps of the identifiers and how these could be reduced in identifiability so that a pseudonymisation approach can be pursued as an exit strategy from section 251. These can be submitted on an incremental basis, preferably in suites, and this should be discussed further with the NIGB Office.**

Members welcomed the detail provided in the appendix 2 of the report in relation to the pseudonymisation approach applied to the data and noted that as the ascertainment of NHS number was now 100% they would anticipate that the audits could reduce the amount of identifiable data collected.

Members agreed, in line with previous advice, that the pseudonymisation approach should be explored as an exit strategy from reliance upon section 251 support. Members noted that it was stated that identifiable data would be collected and stored within the NHS IC until the end of each audit, and although restricted access would be applied, this did not constitute an exit strategy from the use of section 251. The Committee therefore agreed that they would expect to see a movement towards the reduction of identifiable data collected/retained and with this in mind requested that the NHS IC consider decreasing identifiable data items collected for the audits where possible.

As NHS number ascertainment was now at 100% for all audits members were mindful that they may not be able to provide continued approval for all identifiable data items in future unless clear and detailed justification for each identifier was provided. As the understanding was that individual audit applications will be submitted for Committee review by April 2012, the Committee requested that further justification was provided in relation to the collection of all identifiable data items for each audit, in particular patient name and full postcode. It was recognised that some linkages to other datasets may require additional identifiers and that identifiers, such as date of birth, may be required to allow duplications to be removed; however members agreed that they would require full details of these subsequent linkages and purposes to ensure that the identifiers requested were the minimum necessary. Additionally members queried, given that the Exeter system would automatically validate NHS number within the National Bowel Cancer Audit and the Lung Cancer audit dataset, why name would then need to be submitted at a national level for these audits.

Members considered the justification provided for the use of patient name within the audits, it was noted that this was in order to validate patient NHS number. Members were mindful that section 251 (4) allows that a recommendation of approval can only be made where there is no practicable alternative to the disclosure of patient identifiable data without consent, taking into account the cost and technology available. Members queried why automatic validation at the point when the submission of data to the NHS IC was made, for example by using the Personal Demographics Service, could not be used to validate NHS numbers for all audits. The Committee were of the view that this would negate the requirement for full name to be submitted. Members agreed that this would appear to be achievable and would expect the alternative to be explored in further detail.

Additionally it was noted that there was variability between audits in relation to the data items collected and members queried the reason for this inconsistency. As members were mindful that best practice should be applied to all audits and therefore, where possible, the minimum amount of identifiers necessary should be collected, further details were requested as to why some audits required additional identifiers as this was not clear within the report.

Conclusion

1. The Committee agreed that whilst the requirement for the NHS IC to provide specific information leaflets in relation to their national and strategic role could be put on hold until the specific role of the NHS IC became clearer, this would only be on a temporary basis and did not negate the requirement to ensure patients were appropriately informed that the audits were carried out on a national level. It was noted that the NHS IC currently provided audit specific leaflets which provided fair processing information for patients.

2. The Committee requested further detail about the input of the NHS IC in the provision of patient information leaflets at a local level, including how widely patient information leaflets were distributed, the NHS IC's understanding on whether these are distributed at a clinical level, how the NHS IC is assured that this takes place and what the NHS IC specifically were undertaking to encourage this distribution.

3. The Committee agreed that, given that NHS number was now at 100% ascertainment, they would expect to see significant moves towards the reduction of collection of the other identifiable data items when the audits were reviewed in April 2012. In particular the continued requirement for full name and postcode would be considered for each audit and, if required, should be considered in detail.

4. The Committee queried why NHS number could not be validated automatically at a local level when the submission to the NHS IC was made, for example by using the Personal Demographics Service. As a potential alternative to the collection of name, the Committee requested that these alternatives were explored in detail.

Further actions

The following should be completed as part of the separated applications in April 2012:

1. Confirmation of the NHS ICs involvement in the distribution of local patient information leaflets, including how widely these were distributed, how they were distributed at a local level and what the NHS IC specifically were undertaking to encourage this distribution.

2. In order to achieve an appropriate exit strategy under these Regulations, significant movement towards the reduction of collection and retention of identifiable data items by the NHS IC, in particular the continued requirement of patient name and postcode would be considered, in detail, for each audit when each application is consequently submitted.

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

Members considered the strategic implications arising from consideration of these national clinical audits, and agreed that such issues should be raised to the NIGB. As the NIGB Chair, Dame Fiona Caldicott would be meeting with the NHS Information Centre, it was agreed that members would send their comments to the office to aid in the briefing.

Action: Members to send their comments on strategic role of national clinical audit to the office

3b ECC 1-06(d)/2011 – Application for transfer of responsibility for national cardiac audits to the National Institute for Cardiovascular Outcomes Research (NICOR) at University College London

This interim report was provided in response to the first specific condition of approval, detailed within the final approval letter dated 7 March 2011, where a short interim report was requested detailing progress towards condition 1 and 2 detailed below :

Extract of specific conditions of approval

1. For those audits where NHS Number ascertainment is nearly complete, the expectation is to move towards pseudonymisation of data. Each relevant audit should be separated and the overall activity completed by 30 April 2012, with a short interim report on progress to be reviewed at the 28 July 2011 meeting. This should include the purposes of each audit, required identifiers, linkages involved in each and an assessment of each item to identify where identifiability can be reduced and at what point.

2. For those audits where NHS Number ascertainment is not complete, a strategy to be set out to demonstrate how NHS Number ascertainment will be increased, and then subsequent moves towards pseudonymisation. The timescales specified above for the first condition apply to this condition

Outcome

Members welcomed this interim report detailing progress against the move towards pseudonymisation of data for those audits where NHS Number is almost complete (condition 1 above) and the NHS Number ascertainment strategy (condition 2) and discussed it in detail; the key points arising from the discussion are summarised below:

1. **For those audits where NHS Number ascertainment is nearly complete, the expectation is to move towards pseudonymisation of data.**

Pseudonymisation strategies

Members were mindful that it is a requirement of the current legal framework that an appropriate pseudonymisation approach should be explored as an exit strategy from reliance upon section 251. Members welcomed the detail provided in section 4 of the report in relation to the pseudonymisation strategy and agreed that the solutions presented theoretically appeared to provide a method to reduce the amount of identifiable data collected, and these were to be welcomed. However, it was not clear from the document whether any of these options were being actively pursued. The Committee could not see evidence of which approach was currently in operation and sought further clarity on this aspect as a priority as it did not appear that a suitable exit strategy was currently in place.

In addition Members queried the assertion included within the potential pseudonymisation options outlined in section 4 of the report, that where a valid NHS Number was available, upload of other identifiers could be dynamically suppressed or prevented from being entered. It was understood that the audits would require submission of identifiable data items where NHS Number was collected in order to validate NHS Number, therefore whilst the options detailed suppressing identifiers, NICOR would still be in receipt of the patient identifiable data. Members therefore requested further information about the systems detailed, the proposed suppression of identifiers and the subsequent submission and holding by NICOR of identifiable items.

As this was a key point members requested that clear details of this aspect were submitted to the NIGB office for review at the September 2011 Committee meeting.

Maximum de-identification and minimum information

A requirement of the Regulations is that, so far is practicable, identifiable items should be removed from the information which is not required for the purposes for which it is, or is to be, processed. With this in mind members reviewed the extent of identifiers used for each audit and the progressive steps taken to reduce the extent of identifiable information once collected.

Within the report and responses to office queries members noted that as it appeared that currently the pseudonymisation strategies detailed within section 4 were not yet operational, identifiable data

would be collected and stored within NICOR, and although restricted access would be applied, this did not constitute an appropriate exit strategy from the use of section 251 support. Members were mindful that recommendations under section 251 cannot be inconsistent with the Data Protection Act 1998 and in line with the fifth principle, personal data should not be kept for longer than is necessary for the purpose or purposes The Committee therefore agreed that they would expect to see a movement towards the reduction of identifiable data collected/retained and with this in mind requested that NICOR consider decreasing identifiable data items collected for the audits where possible. As NHS number ascertainment was nearing 100% for most audits, members were mindful that they may not be able to provide continued approval in future unless clear and detailed justification for all identifiers was provided. As the understanding is that individual audit applications will be submitted for Committee review by April 2012, the Committee requested that further justification was provided in relation to the collection and retention of all identifiable data items, for each audit, in particular patient name and full postcode and where NHS Number was present. It was recognised that some linkages to other datasets may require additional identifiers and that identifiers, such as date of birth, may be required to allow duplications to be removed; however members agreed that they would require full details of these subsequent linkages and purposes to ensure that the identifiers requested were the minimum necessary for the specified purposes.

Practicable alternative

Members considered the justification provided for the use of patient name within the audits, it was noted that this was in order to validate the patients NHS Number. Members were mindful that section 251 (4) allows that a recommendation of approval can only be made where there is no practicable alternative to the disclosure of patient identifiable data without consent, taking into account the cost and technology available. Members queried why automatic validation at the point when the data submission to NICOR was made, for example by using the Personal Demographics Service, could not be used to validate NHS Numbers for all audits. The Committee were of the view that this would negate the requirement for full name to be submitted. Members agreed that this would appear to be achievable and would expect the alternative to be explored in further detail.

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

Members considered the information provided in section 3 of the report in relation to the NHS Number ascertainment strategy and were pleased to note that NHS Number ascertainment was improving within all the specified audits.

Members noted the applicant's assertion that they could not require trusts to submit NHS Number and welcomed the information that trusts were encouraged to submit NHS Number by the submission system and subsequent report data being fed back to trusts. However, members were of the view that NICOR should seek to make the item compulsory within all data collections and reject data where NHS Number was not present. Where NHS Number was not available NICOR could seek the alternative detailed in section 1 above, by using automatic validation, if it was considered that 100% ascertainment was required.

In line with the above, the Committee considered the assertion that 100% ascertainment would be required to meet the purposes of the audits; members were of the view that a sample based approach could be pursued in order to meet the specified purposes of the audits. The Committee requested further detail regarding the requirement for data on all patients to be submitted as justification for NICOR being unable to mandate the NHS Number in the audit dataset, and why this was required in relation to the purposes specified within the application.

Conclusion

1. Members requested further detail of the pseudonymisation strategies detailed in section 4 of the report and were unsure whether the systems would result in fewer identifiable data

items being submitted at a central level. Specifically members requested that the following information was submitted for the September Ethics and Confidentiality Committee meeting, how the proposed suppression of identifiers would reduce the amount of identifiers collected outside local care teams and the subsequent effect on the use and retention by NICOR of identifiable items.

2. The Committee agreed that, given that NHS Number was nearing 100% ascertainment, they would expect to see significant moves towards the reduction of collection of identifiable data items when the audits were reviewed in April 2012. In particular the continued requirement for full name and postcode would be considered for each audit and, if required, should be considered in detail.

3. The Committee queried why NHS Number could not be validated automatically at a local level when the submission to NICOR was made, for example by using the Personal Demographics Service. As this was a potential alternative to the collection of name as an identifiable data item, the Committee requested that the alternative were explored in detail and reported against in April 2012.

4. Members noted the assertions in section 3 of the report that NICOR could not require trusts to submit NHS Number or reject data where NHS Number was not present as audits required 100% ascertainment of cases. Whilst members agreed that the proposed solution in point 3 above may result in 100% ascertainment of NHS Number, if this approach proved not to be feasible and data was to be collected without NHS Number members requested further justification that 100% ascertainment of cases would be required.

Further actions

The following should be completed for submission to the September 2011 Ethics and Confidentiality Committee meeting:

1. Further detail of the pseudonymisation strategies detailed in section 4 of the reports, this should specifically detail how the proposed suppression of identifiers would reduce the amount of identifiers collected outside local care teams,

2. the subsequent effect on the submission of and retention by NICOR of identifiable items and how this assists an appropriate exit strategy to the requirement for section 251 support,

As part of the formal report to be provided by April 2012, this should include the following

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

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

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

Action: NIGB Office to arrange meeting with applicant to discuss outcomes

3c ECC 7-02(FT1)/2010 European Urban Health Indicators System Part Two (EUROHIS 2): Urban Health Monitoring and Analysis System to Inform Policy AMENDMENT

The application set out the purpose of studying trends in population health for urban areas across nine EU countries. This population based survey set out to query whether it would be possible to obtain information on urban health indicators to produce tools for policy makers at local, national and international level. The survey period would last 8 weeks and requested support under section 251 to permit access to NHAIS in order to obtain name, GP registration, date of birth, full postcode, gender and telephone number. The data was required for the sampling frame to be able to stratify by age and gender. It was noted that all partners would be using similar population registers and therefore it was considered essential to use the Exeter system so as to allow comparability with the other partners.

This application had originally been considered via the fast track process and had received a recommendation of support, therefore the discussion focused solely on the amendment request in relation to the conditions of approval.

Amendment request

The amendment request was in relation to the following:

1. In response to the Committee's condition of approval that due to the particularly intrusive nature of the study an additional safeguard in the form of suitability checks by GPs was required; confirmation of a change in methodology was received which detailed that telephone calls and house visits would not be carried out for the remaining PCTs where mailings had not been started.

2. The letter from the applicant suggested that GPs were sent a final letter, asking them again to check the suitability of their patients for inclusion in the study; and informing them that if no response was received from GP practices by the 15 August then mailings would begin.

3. In response to the Committee's suggestion that another GP practice could be approached where the applicant found that a GP would not carry out suitability checks; assertions were made by the applicant that there would be potential for bias if the methodology was changed to a purposive sampling strategy and may result in an over representation of the less deprived. Additionally the applicant confirmed that almost all GP practices in the area had been contacted.

Due to the substantial change in methodology, where GPs would not carry out suitability checks or had not been approached yet, the Committee agreed that postal surveys could go ahead without the requirement for these suitability checks. This was subject to the conditions of approval below.

Conditions of amendment

1. That prospectively no house or telephone visits would take place, regardless of whether GP suitability checks had been carried out or not.

2. Confirmation whether an amendment to the current REC approval would be required for the amended methodology.

4. Resubmitted applications for section 251 support

4a. ECC 8-05(g)/2010 Research Use of the ONS Longitudinal Study

This application had previously been considered by the Committee at the December 2010 meeting where the previous application set out a proposal to provide access to the Longitudinal Study by Approved Researchers within the Virtual Microdata Laboratory (VML). There was a question over the extent of identifiability of information to be provided to researchers, and as there was the potential for the information to be considered identifiable, section 251 support was sought to enable this disclosure. At this time Mr Felix Ritchie had attended the meeting and discussion indicated that the applicant was of the view that section 251 support could be provided to permit delegated authority to disclose identifiable patient information. The Committee confirmed that section 251 support could not be used to provide this delegated permission, but welcomed the applicant engagement and caution over the disclosure of potentially identifiable data. The following was reported to the applicant in the outcome letter:

1. From what was understood, much of the use of data appeared to be managed in a controlled environment, and this was to be commended. However, further evidence would be required to support this aspect.

2. The Committee was not in a position at the meeting 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 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 this should be comprehensively addressed. It was assumed that these controls were generally good, but there was limited information available and therefore there was sufficient evidence on which to reach a conclusion.

4. Before the Committee could reach a decision on this specific application, as noted in the meeting, 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 these 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 clarity for both parties in terms of the remit of section 251 support and where it would be required.

Members noted the resubmitted application suggested that all researchers accessing the VML would be required to apply for section 251 support. The application detailed the data security procedures for all onsite users and requested that as governance arrangements would remain the same for all researchers accessing VML the application should be taken as a baseline for security arrangements and that details of specific researcher access would be added as an addendum to this application.

Outcome

The Committee considered the additional information and evidence provided around the governance procedures and access controls which researchers using the VML were subject to. Members were pleased to note that previous concerns about the lack of clarity over the governance arrangements had been addressed within the application.

The Committee discussed the applicant's assertion that all researchers accessing the VML system would be required to make an application for section 251 support. It was agreed that whilst this seemed a particularly cautious approach, the VML would hold many sensitive data items which may lead to identification and the Committee were not aware of other data individual researchers

may have access to which could render the information identifiable. Therefore the suggestion that all researchers, in the first instance, would need to apply to the ECC was supported, but Members agreed that they envisaged most would be suitable for processing via the fast track procedure.

Members suggested that whilst the approach outlined above would be of benefit it would be necessary to review the arrangements on a continuing basis and proposed that a sub-group of members be established to provide recommendations on the types of application which may require support, and those which may not, once applications commenced. Mrs Pauline Brown and Dr Patrick Coyle were nominated to form the sub-group. Members also noted the template provided that would be used by each individual researcher, and suggested that this would also need to be reviewed by the sub-group once applications were received to ensure key information for the Committee was being provided.

Conclusion

Members were reassured by the additional information provided by the applicant in relation to the VML governance arrangements. It was agreed that this application could be approved as a baseline application to which addendums would be added for separate researcher access requests under section 251, which would require consideration by the Committee. Members considered that due to the nature of the requests it would be possible to process these via the fast track system in the first instance, with the caveat that in the initial stages, ratification might be required from the full Committee whilst the process is standardised. These arrangements would undergo a continuous review by a sub-group of members in order to ensure that applications for section 251 support were only made where necessary.

4b. Resubmission: ECC 5-04(j)/2011 Colorectal Cancer Screening Equity Audit for Coventry and Warwickshire

This application from NHS Coventry proposed an equity audit of uptake of colorectal screening in Coventry and Warwickshire, in order to inform a social marketing campaign which would specifically target localities and social groups with a low uptake. Section 251 support was requested to receive the following identifiable data items for patients invited for colorectal cancer screening in 2008/2009 – 2010/2011: address, full postcode and GP practice, as well as details of the invite to screening and uptake. Full postcode was required in order to utilise social segmentation software to generate an accurate profile of the target population for the marketing campaign.

Application history

This application was originally considered at the Committee meeting held on the 1 June. At that meeting the Committee had noted that the project appeared to have beneficial outcomes but there was fundamental information missing with the application form. In particular the Committee highlighted that they could not identify specific data flows, the size of the cohort, the overall purpose of the activity, the justification for the use of postcode and address for analysis purposes and why the organisation currently holding the data could not carry out the analyses. Members raised further concerns that patients had not been engaged with in relation to the activity and requested further consideration be given to this aspect. Members agreed that due to insufficient information they were unable to recommend section 251 support at that time.

Resubmission grounds

The resubmitted documentation set out a number of points, and these points and the Committee's assessment is summarised below. The Committee considered that the application comprised a far more complete version than the previous submission and noted that there had been some

confusion over what documents the Committee reviewed and as such a lot of information had been included in the system level security policy, which was not reviewed by the Committee.

Outcome

1. Practicable alternatives

The resubmission detailed that the data would be requested from the NHS Cancer Screening Programme, who would be unable carry out the analysis required as it did not fall within the remit of the organisation and staff would not have the epidemiological expertise or appropriate software to carry out the activity.

Members noted the applicant's assertions that the current data holder would be unable to undertake the analysis required and additionally were not in possession of the relevant software to process the data in the manner required. Whilst members understood that they may not be in the position to undertake the analysis of the data, queries were raised over why the socio-demographic mapping could not be carried out by the Cancer Screening services, and in doing so negate the need for postcode data to be disclosed. It was discussed that look up tables could be obtained and used fairly easily and therefore Members were not convinced that there was a need for specialist knowledge to undertake this part of the activity. It was advised that this alternative should be fully explored in order to demonstrate and evidence that there is no other reasonable alternative by which this activity can be undertaken.

2. Cohort size

It was confirmed that NHS Warwickshire invited 112, 085 individuals and NHS Coventry invited 45, 062 individuals for bowel cancer screening over the three years for which data was required. Members noted the large numbers involved in the study and agreed that consent would be difficult to obtain even on a prospective basis given that one of the key outcomes was to assess the socio-demographics of those who would not have been in contact with clinical teams as part of screening. However this part of the population would require particular justification for use of their data given that they had not opted in to be part of the cancer screening programmes when given the opportunity, and may have the least expectation that their data would be used in this way.

3. Purpose of the project

Further detail was provided that the purpose of the project, specifically the proposal to use ACORN and MOSAIC software to perform a social segmentation analysis to assign individuals into 5 categories and then further into subcategories, would lead to better informed targeting of resource. Members noted the intention to use this data to identify those less likely to take up offers of screening and use this to target resources through marketing. Members queried whether this information was already available at a national level and whether this particular project would add any additional understanding to the work already done to identify those who were less likely to engage in screening services. Additionally members were of the view that the audit part of the activity could be undertaken using data already collected by the Cancer Screening Programmes and therefore queried how the requirement of the specified software, ACORN and MOSAIC, would further inform the audit question posed.

4. Requirement for postcode and address

The application provided confirmation that only postcode would be required for the analysis to be undertaken. Members were pleased to note that the applicant had confirmed they no longer required address. However in line with the comments above, members queried why the full de-identification of data could not be undertaken by the current data holder, providing only an anonymised dataset for analysis.

5. Patient involvement

The application confirmed that future plans for the consultation of a local patient group could be undertaken on the advice of the Committee. The Committee noted that although plans had been made to engage with the patient population this requirement had not been fully addressed and patient views had not yet been sought. Members reiterated that this is a key consideration and that advised that they would expect any application to specify a clear plan for patient engagement activities.

6. Data Protection Act 1998 (DPA) principles

Further information was provided specifying the applicant's compliance with the Data Protection Act 1998 (DPA).The Committee noted that whilst additional information had been provided the responses still did not reflect how patients would be informed of the uses of their data (in line with the first principle of the DPA) or how individuals would be given provision to register dissent over processing of their personal data (in line with the sixth principle) in certain circumstances.

7. Research or local audit

Members queried whether this proposal fell strictly within the parameters of local audit or whether it could be considered research (in to the use of a specific social marketing tool to identify groups of low responders). Members suggested that applicant should seek the advice of a research ethics committee. However this issue was not considered to be as significant as the concerns in relation to practicable alternatives to disclosure of full postcode detailed above.

Conclusion

The Committee were of the view that the super output area could be calculated by the data holder (Cancer Screening Programmes) with relative ease and therefore negate the requirement for postcode data and allow a fully anonymised dataset to be released for analysis. Additionally Members agreed that whilst the further information provided allowed clarity over some of the issues raised they were still of the view that they could not identify the additional benefit this activity would have, given that it appeared the analysis was available on a national level.

Members were mindful that section 251 (4) allows that a recommendation of approval can only be made where there is no practicable alternative to the disclosure of patient identifiable data without consent. Members considered that the audit question outcomes could be met using previously collected data or data generated at a national level, which could then be used to inform the marketing programme. Such options should be fully explored prior to any subsequent resubmission.

4c. Resubmission: ECC 5-04(d)/2011 Integrated Drug Treatment System (IDTS) Evaluation

This application from Kings College London detailed an evaluation of the national IDTS programme. The study considered whether IDTS clients who left prison whilst still receiving a stable dose of oral methodone or buprenorphine medication were less likely to die in the 16 weeks after release, compared with IDTS clients released after receiving full opiate detoxification. Section 251 support was requested to allow access to prison health records in order to extract name, date of birth and ethnicity and allow mortality data to be obtained from the NHS Central Register.

This application was previously reviewed at the June 2011 meeting. The Committee were unable to provide support at this time as it was noted that the application suggested that the study had

been following a consented methodology and that section 251 support had been requested as administrative issues had lead to a loss of resource to complete the activity. Members had noted that it was not appropriate to recommend approval where the primary reason was that of administrative resource, and that recommendations of support could only be made where there were no practicable alternatives. In this case, Members were of the view that consent had previously been practicable and therefore could continue, albeit at a slower pace than required. Members also asked the applicant to consider whether some of the study aims could be met using a smaller cohort size.

Resubmission grounds

The resubmission requested that the Committee reconsider the request to recommend section 251 support to allow access to prison health records and NHS Central Register data. The covering letter and amended application confirmed that consent had not been planned as part of the methodology from the outset, but that attempts to undertake consent had led to the identification of the impracticality of the approach and therefore the requirement for section 251 support to undertake the study had arisen. It was also detailed that prisons were unable to operationalise taking consent within the IDTS programme or the day to day running of the prison. This had led to only 1 in 3 prisons being able to adopt the study, which could potentially lead to bias in the results of the study. The letter detailed that at the current rate of recruitment the study would need to run for 6-8 years, rather than within the 4 year timescale required and that due to the nature of the study, the large numbers specified were required in order to provide the required outcomes.

Outcome

The Committee considered the revised and additional information provided and commented that the response was helpful and clearly thought through. A summary of the discussion is below:

Consent methodology and prisons being unable to operationalise consent processes

It was noted in particular the previous misunderstanding that the study had been designed and implemented using a consent methodology when in fact this was not the case and some prisons had never been able to operationalise the consent mechanisms. Members were also mindful of the difficulties faced when attempting to gain consent amongst the prison population, who may be difficult to engage. However Members wished to make clear that the duty of confidentiality owed to prison patients was no less than that owed to any other patient and therefore any decision would be taken with this in mind.

Public interest

Members are required by the Regulations to consider the public interest in the activity being carried out and agreed that in this instance it was exceptionally high, taking into consideration the high death rate amongst the study population. Members agreed that such an evaluation was timely due to a current lack of evidentiary understanding on whether acute detoxification programmes were successful in their intended aims. It was also considered important to be able to understand the benefit of the implemented system and that members expected any programme that sought to change patterns of care to be fully evaluated.

Fair processing

Members reviewed the fair processing information and opt out provisions provided to patients. There was concern that there was a high rate of illiteracy in prisons and therefore the applicant was asked to consider how they would communicate the uses of data and the option to opt out to those who were unable to read the information provided. As section 251 cannot be used to override dissent members were particularly concerned that all patients should have a right to understand and opt out of the study process.

Conclusion

Members agreed that the information included within the resubmission clarified the reasons leading to an application for section 251, which were previously misinterpreted. Further to this and the overwhelming public interest in the activity going ahead, the Committee recommended approval to this resubmission subject to the following specific conditions of approval:

1. That the applicant consider how those unable to read will be informed about the study and given the opportunity to opt out. Details of the proposed method should be provided to the NIGB Office.

4d. Diagnosis of dementia and relative cognitive decline

This application requested support in order to access records held by five NHS memory clinics to extract anonymised data. The aim of the study was to explore whether there was a difference in the amount of cognitive decline that people with high levels of premorbid intellectual function undergo before being diagnosed with dementia, when compared to people with other levels of premorbid intellectual function.

This application was originally processed via the fast track procedure as it was noted that no identifiable data would leave the NHS site on which it was legitimately held. Following this review an outcome was provided on the 14 June which detailed that members were unable to provide a recommendation of support due to concerns over the level of access required to highly sensitive data, compliance with the third principle of the Data Protection Act 1998 and the identification of a practicable alternative to carrying this out without consent by undertaking on a prospective, consented basis.

The resubmitted information provided clarity on the following areas:

1. Access to highly sensitive data

It was confirmed that the applicant would only access the data of those who had solely attended medical clinics and would exclude medical files of individuals who had had any previous contact with secondary or tertiary mental health services.

2. Compliance with the third Data Protection Act principle

The third principle of the Data Protection Act requires personal data shall not be excessive in relation to the purpose or purposes for which they are processed, and the Committee had previously raised concerns that a greater number of records than required were to be accessed. The applicant identified guidance (Coaley, 2010) to inform how many records would be required for review; the guidance had indicated that access to 500 records would be sufficient and it was confirmed that this would be the minimum amount in order to obtain accurate norms for the population size.

3. Prospective consent based approach

It was confirmed that from November 2010 it was no longer mandatory to record a patients pre-morbid IQ. As this was a central factor to achieving the aims of the research study it was stated that it would not be possible to carry this out on a prospective basis.

In reviewing the responses, Members considered this to be an important study with a high level of public interest in ensuring that dementia was identified as soon as possible. It was also agreed that the extent of user involvement was to be commended and the Committee agreed that the applicant had provided sufficient reassurance over their previous concerns. It was noted that it would not be possible to carry this out prospectively if the data was no longer recorded and that the applicant had considered how best to maintain patient confidentiality as far as possible by only accessing 500 records of those who had attended solely memory clinics. Members also agreed that consent would not be feasible for a retrospective cohort as contact details were likely to be out of date. However, where it was identified that an individual was still in follow up in the memory clinic members agreed that they should be approached for consent prior to the researcher accessing their records.

Based upon the above considerations the Committee agreed to a provisional recommendation of support to the details provided within the application and resubmitted documentation, subject to the following specific and standard conditions of approval:

Specific conditions of approval

1. That where individuals were still in follow up at the memory clinic they should be approached for their consent prior to accessing their record.

4e. Resubmission: ECC 5-04(b)/2011 Data Linkage between electronic primary care records (THIN) and Hospital Episode Statistics (HES) using the Sapior Enhanced Trusted Third Party (eTTP) service

This application from Sapior Ltd detailed a methodology for the de-identification and pseudonymised linkage of medical records from the Health Improvement Network (THIN) with patient records held by the NHS Information Centre (NHS IC).The linkage would be carried out using the HES-ID and the Vision ID. Section 251 support was requested to facilitate a trained operative to visit a single representative site for each health data record format and access identifiable data to allow configuration of the eTTP service.

Application history

This application had originally been considered via the fast track process as it involved one representative from Sapior accessing data at a single representative site. However queries had been raised by members about the purpose and potential risk of identification of the resulting dataset and members requested that it be considered at the full Committee meeting held in June. Following this meeting an outcome letter was sent which raised questions regarding the extent of disclosure of the merged dataset, the potential for re-identification and purposes for the linkage taking place. A meeting with the applicant was suggested. Following the subsequent meeting with a sub-group of Committee members the following requests for clarification were made (applicant response in bold):

1. Provision of detail of the costs involved for the GP system provided to establish the extraction and encryption of the data fields automatically.
   Confirmation that this extract service would cost around £5000 and would not be available until the beginning of 2012.
2. Provision of details and costs involved for the NHS IC to provide a look up table containing HES ID and vision ID.
   Confirmation that the NHS IC could provide the two required fields and that access to HES records would not be required.

3. Confirmation that the encryptions levels used would not allow the NHS number to be seen in an identifiable form by Sapior.
   Confirmation and detail that the encryption design would not allow Sapior staff to use any of the details in an identifiable form was received.
4. Provision of the confidentiality agreements signed by members of Sapior staff accessing GP/HES records.
   Confidentiality documents provided.

These responses were considered by the sub-group of members in the first instance. Sub-group members were pleased to note that as a result of discussions access to HES records was no longer required, were satisfied with further detail over the purpose of the application and reassured that the software developed by Sapior would only transmit, in an encrypted form, vision ID and NHS number. However a question was raised whether a cost of £5000 and a delay of six months could in this instance be used as justification for recommending section 251 support to access patient identifiable data in one GP practice. Sub-group members advised that this point would require a decision by the full Committee at its meeting on 28 July.

Outcome

The Committee considered whether the alternative to access of GP records by a Sapior representative was reasonable, taking into account that the disclosure was of quite a low level.

Members were mindful that section 251 (4) allows that a recommendation of approval can only be made where there is no practicable alternative to the disclosure of patient identifiable data without consent, taking into account the cost and technology available. Members discussed that in this instance £5000 would not be considered an unreasonable amount and that section 251 support could not be provided for the reasons of mitigating the cost of this technology.

When considering whether section 251 support can be applied the Committee must also take into account the public interest of the activity taking place balanced against the level of disclosure. Members therefore considered whether the public interest in the activity taking place was such that a six month delay would be of detriment to the overall activity or would prevent the medical purpose of the activity being fulfilled. Members agreed that they could not identify justification that a six month delay would be of significant disadvantage to the aims of the application. The Committee therefore agreed that they could not recommend section 251 as a practicable alternative had been identified which appeared could be pursued without harming the public interest.

Conclusion

Members were therefore unable to recommend section 251 support given the identification of an alternative to the access to patient identifiable information. In considering whether section 251 could be applied, members advised that they would need to be provided with strong evidence that the six month delay would cause detriment to the medical purpose of the activity.

5. New applications for section 251 support

5a. ECC 6-05 (a)/2011 - Do Children Born After Assisted Reproduction Have A Higher Mortality Than Those Born After Spontaneous Conception? A Population Based Pilot Linkage Study

It has been agreed that the Human Fertilisation and Embryology Authority (HFEA) will delegate the handling and assessment of all applications with a medical purpose under the Human Fertilisation and Embryology (HFE) Act 1990 to the National Information Governance Board Ethics and

Confidentiality Committee (ECC). Under this delegated authority, the ECC has remit to consider and recommend to the HFEA whether to grant or refuse permission to use identifiable register information (or to impose conditions upon its use). As data controller of the Register, the HFEA will take a final decision based upon this recommendation, and then if disclosure is permitted will work with the applicant(s) to enable use of the dataset. In terms of disclosure of patient information not contained in the HFEA register, the ECC will take the final decision under section 251 of the NHS Act 2006 and its Regulations.

This application from University College London (UCL) set out a pilot study that sought to compare death rates amongst non-donor children born after assisted reproductive technology (ART) in 2001 as recorded on the HFEA Register. This would be compared against death rates of the childhood population as a whole as recorded by the Office for National Statistics (ONS). It was noted that the named UCL researchers would not receive access to identifiable information; instead, the disclosure would relate to the dataset being transferred to ONS by the HFEA and ONS's subsequent processing of the Register data. It was noted that ONS already have legal authority to process information under its own recommendation of support via section 251 and Regulations, and under the Statistics and Registration Services Act 2007, however, this specific purpose is considered to fall outwith of its current support.

The aim of the pilot study would be to investigate whether there is any potential health risks associated with ART for children. A number of previous studies had been carried out but these had been limited by small sample size, therefore this study represented the largest cohort to date in this field of research.

Outcome

Members agreed that this was a clearly constructed application, and that a strong case for the wider public interest had been made due to the importance of the research question. In reviewing whether consent would be feasible, it was noted that a substantial campaign had taken place when the Register was opened as a research resource, that provided opportunities for dissent to be registered. It was also noted that the HFEA did not hold addresses on its Register, therefore in order to seek consent the applicant would need to be provided with extended access to identifiable data, which was not considered proportionate in this instance. In line with this, it was agreed that due to the numbers involved (approximately 8,000), consent would not be feasible in this instance. Members also agreed that there would be a requirement for access to identifiable data by ONS in order to provide the matching and linkages, and therefore pseudonymised data would not be sufficient to achieve the aims of the linkage activity.

In reviewing the methodology, it was also agreed that this was proportionate and that the controls in place were appropriate to reflect the sensitivity of the dataset. Members also considered the point made that the data obtained from accessing the birth records at ONS was to be securely transferred back to the HFEA. The purpose of this would to update and resolve discrepancies in the HFEA registry dataset, and it was noted that the HFEA already have legal support under its own powers to obtain this data. Members were unclear on whether a recommendation of support under section 251 and its Regulations would be required to mandate this aspect, however, it was agreed that should this be the case, then the Committee would be content to provide a recommendation of support to this aspect as well.

In reviewing the extent of requested identifiers, the Committee was satisfied that the minimum amount of items were being requested to achieve the purpose. It was noted that the request to utilise father's name had been excluded from the details of this application, but if required in future would need to be the subject of an amendment. Additionally, in reviewing the expected cohort size, members highlighted that the predicted numbers could potentially be less than stated in the applications as there would be a requirement to ensure that those who had registered dissent would not be included within the study.

In line with the details above, the Committee agreed to provide a recommendation of provisional support to the HFEA to inform their own decision.

5b. ECC 6-05(b)/2011 Evaluation of the new "Fit-Note", construction of a national database

This application from the University of Liverpool detailed the establishment of a national database to record details of patients issued with a "Fit Note" within a specified period. The database would then be used to address the lack of evidence relating to factors associated with certified sickness outcomes. Study specific outcomes included the identification of patient, GP and practice factors associated with a range of sickness absence outcomes and to estimate the effectiveness of the new Fit Note in reducing periods of incapacity compared to the previous MED3. In the broader context the database would contribute to early interventions aimed at identifying patients/claimants at risk of long-term incapacity. Section 251 support was requested to allow access to patient postcode by researchers at the University of Liverpool to allow deprivation score to be calculated.

Outcome

The Committee agreed that the evaluation of this new medical statement would be beneficial and that it was important that it was undertaken. A summary of the discussion is below:

Medical Purpose

When discussing this application members were mindful that the Regulations made under section 251 specify that the purpose must fall within a medical purpose as defined within the NHS Act 2006 (section 251(12)). Members discussed the justification for collecting the data in the summary provided within the IRAS form and the applicant's response to the NIGB office query around the medical purpose of the activity. Whilst some views were raised that the purpose would not be of a specific medical benefit, the Committee as a whole concluded that there would be some benefits to the patient population in undertaking the activity. It was noted that one of the stated aims was to "contribute to creating new perspectives on health and work, and improve awareness and understanding of work for good health", as well as a broader aim to contribute to early interventions aimed at identifying patient at risk of long term incapacity. Based upon this information, the Committee concluded that this activity fell within a medical purpose as defined within the Act.

Consent based methodology

Section 251 (4) allows that a recommendation of approval can only be made where there is no practicable alternative to the disclosure of patient identifiable data without consent. In this instance it was noted that the patients would be attending the GP practices in order to obtain their Fit Note and the Committee were of the view that at this time consent, or at the very least fair processing information, could be implemented. Members discussed the applicants assertions that bias would be created if a consent or opt out methodology was pursued, they were however mindful that no specific evidence had been provided to inform this argument and queried whether the large numbers stated would be required or whether a sampling technique could be applied. The Committee were therefore not persuaded that significant bias would arise or affect the activity and advised that the consent option should be piloted to evidence assertions of significant bias before a judgement could be made that consent would not be reasonably practicable.

The Committee also highlighted that recommendations of support under section 251 cannot be inconsistent with the provisions of the Data Protection Act 1998; therefore members advised that at the very least reasonable fair processing information, for example patient information leaflets, would need to be provided to patients along with the option to opt out of this particular data use.

Based upon the considerations above, the Committee were currently unable to provide a recommendation of support until the minimum threshold of the Regulations framework had been achieved.

5c. ECC 6-05(c)/2011 Conservative Kidney Management Assessment of Practice Patterns (CKMAPPS)

This application from the University of Southampton aimed to determine the practice patterns for conservative kidney care management (CKM) of older patients with stage 5 Chronic Kidney Disease (CKD5). It also set out the intention to inform service development and design of a future prospective multicentre study to evaluate the effectiveness, cost effectiveness and appropriateness of CKM compared to dialysis for treatment of elderly patients. Identifiable data including name, address, postcode, NHS number, GP registration and date of birth were requested in order to allow linkages of laboratory and renal IT system files by the UK Renal Registry to define the location of kidney care at initial diagnoses, subsequent referral and any use of dialysis. Additionally patient names were requested to allow cases to be referred to when GP interviews took place.

Outcome

Members were supportive of the purposes of this application, agreed that this was an important study and that the outcomes would be in the public interest.

Practicable alternatives

When considering whether section 251 support can be provided members are required to be assured that there is no other practicable alternative to the processing of patent identifiable data without consent. Members were therefore mindful of whether the specified purpose of the data linkage could be achieved using existing data sources. A view was raised that as GP practices would store blood test results on their systems, they may be able to provide a dataset that reflected who had been diagnosed with CKD5 and also who had been referred as a result of this. The Committee requested that the applicant explore this alternative and provide justification why this would not be feasible, prior to a recommendation being made.

Extent of identifiable data

Members noted the intention to disclose patient names to a researcher from the University of Southampton in order for them to provide a reference to GPs when discussing why some patients were referred to secondary care and why some were not. It was intended that these names would make discussions with GPs easier and more productive. Members understood that the purpose of the interview was to get a better understanding of the reasons for non-referral and as this is qualitative research, a large, representative complete sample would not be required. Members were of the view that GPs would be able to recall patients details using only NHS number and therefore suggested that NHS number could be used to identify specific cases. The researcher would therefore have no requirement for any further identifiers for this purpose.

If data regarding referrals could be provided from the GPs in an anonymised format, as detailed in point 1 above, further justification would need to be provided that it would be crucial to identify patients within discussions to GPs, as identifiers would then only be need for this specific activity.

Members discussed that there was a considerable amount of identifiable data requested. It was agreed that if the data required could not be obtained in an anonymised format from GP systems the applicant should reconsider the extent of identifiers requested for linkages and provide full justification for each item.

Additional issues

Members queried whether the referral data might identify any health issues for particular patients, for example those who had not been referred and should have been, and requested information on how this would be handled if this was the case.

Conclusion

Members agreed that they were broadly supportive of this application in principle. However as it appeared that a practicable alternative existed to the disclosure of patient identifiable data for linkage purposes this would need to be fully explored before a recommendation under section 251 could be made. Members therefore asked that the following points be considered:

1. Whether GPs would be able to provide the referral data required to researchers in an anonymised format, therefore negating the requirement for section 251 support for the data linkage activity.

If the above alternative is not found to be achievable further clarification was also sought over the following points:

1. The extent of identifiable data required for linkage purposes and full justification provided for each data item requested.

2. Clarification that only NHS Number will be used to identify patients when carrying out GP interviews.

Depending upon timings, it was agreed that responses could be considered by members outside of the formal meeting schedule when received

5e. **ECC 6-05(d)/2011 National Cancer Out Patients' Experience Survey 2011-12: Surveys of Outpatients in elected Acute and Specialist Trusts participating in the Information Prescriptions Programme.**

This application from Cancer Research UK, on behalf of the Information prescriptions consortium and Quality Health, sought approval to work with 30 selected NHS acute trusts to collect and use data of up to 30,000 cancer patients in two cohorts, each of 15,000 patients. Data collected from Trusts would include patient name, address, sex, ethnic group, year of birth, ICD10 code, date of last attendance, speciality code, referring PCT, admission type and NHS number. The first cohort would be selected from outpatient attendees in June-July 2012 and section 251 support was requested until September 2012. The Committee discussed this application at length, and also referred to previous applications that had sought support for patient survey activities.

<u>Feasibility of Consent and Extent of Disclosure</u>

Members are required to consider whether there is a practicable alternative to the disclosure of each item of confidential patient information without prior consent. It was noted that previous applications detailing similar methodology and disclosure to Quality Health had been approved. Support under section 251 is, however, always conditional upon appropriate exit strategies being pursued wherever possible toward either consented or de-identified use of patient information, so as to remove any continued need to rely upon section 251 as a legal basis for the processing of confidential patient information without patient consent.

The Committee had advised, in relation to previous similar activities, that further work be undertaken to explore how far it is possible for consent to be given for the patient experience survey at one of the many consultations in the typical patient's journey. It is desirable that patients know and understand how their data are being used, and the Committee had previously indicated that they would expect this work to be undertaken to evidence any continued need to rely upon

section 251, or, ideally, to reduce the need for reliance upon section 251 as legal support, and to focus upon a consent-based approach.

Members noted the response to the NIGB office query in relation to this which detailed changes to the wording of consent, rather than exploring the feasibility to gain consent prior to the disclosure of data to Quality Health. Members also noted the concerns regarding the bias that alternative methodologies might introduce. While the Committee accepted that the concerns of bias might be well-founded, there was insufficient evidence presented to the Committee that the levels of bias introduced by any alternative methodology would be sufficient to undermine the integrity of the research. In particular, it was questioned whether alternative methodologies could be adopted that reduced the level of identifiable data disclosed to Quality Health prior to consent. Members were concerned that section 251 support was in effect being sought to mitigate against the need to seek to develop appropriate information provision and/or consent mechanisms. This was considered particularly important in light of recent Government commitments to patients, such as 'no decision about me without me', and therefore the Committee were keen to ensure that an appropriate mechanism to inform patients, rather than seeking to use section 251 support on a regular basis, would be put into place.

In line with this, members agreed that they would expect further exploration of alternatives to be undertaken by the applicant in order to inform the assertions that unacceptable levels of bias may be generated by pursuing alternative methodologies based upon consent or relying upon fewer confidential data items being disclosed without consent. Based upon the information provided, the Committee were not persuaded that sufficient evidence had been provided to justify the claim that unacceptable levels of bias would be introduced by alternative methodologies which reduced the extent of disclosure prior to consent being given.

Members appreciated the large numbers involved in the survey and that consent to send the survey may be difficult to obtain via Trusts. However, in relation to this some members queried, for example, why questionnaires could not be distributed to every patient within reception areas in clinics and reiterated that the patient's choice to return the questionnaire to Quality Health would constitute valid consent to take part. The Committee noted that, without further work, such as a pilot study, providing evidence of the relative public interest merits of alternative methodologies, it could not recommend section 251 be used to support the activity.

Public interest

Members agreed that the public interest in the activity taking place was particularly high and would provide significant benefits to the patient population being studied. The Committee agreed that in principle it was highly supportive of the purpose of this activity and that it was important that it should go ahead under an appropriate basis.

Consent model

Additionally members discussed the new consent model that was to be used on the front cover of the cancer outpatients' survey. Members were of the view that the consent taken was very broad with little detail of purpose and queried its validity due to this. Members advised that the consent taken should give patients the option to opt in and out of particular aspects of future data access, rather than giving one broad approval, and should clearly detail future opt out provisions.

Conclusion

Members agreed that, in line with previous advice, that a consent based approach, to be implemented at some point within the patient journey, should be explored as an exit strategy from reliance upon section 251. The Committee queried, for example, whether questionnaires could be distributed to all cancer patients within outpatient clinics and consent to take part provided once the questionnaire was returned to Quality Health. Without evidence (e.g. pilot results) that alternative methodologies involving lower levels of disclosure (including nil disclosure) of identifiable patient

information without consent were impracticable, the Committee were not able to support this application. If such evidence were to be provided, then the Committee would welcome a revised application.

5e. ECC 6-05(e)/2011 Dietary fibre and cardiovascular disease in the UK Women's Cohort Study

This application from the University of Leeds detailed a study to explore dietary fibre intake and fibre from different food sources in relation to the risk of cardiovascular disease (CVD). Section 251 support was requested to allow the disclosure of pseudonymised Hospital Episode Statistics (HES) data for patients with specified ICD10 codes. Initial consent for the study was obtained in 1995 and specific reference had not been made to either the HES database or the NHS Information Centre as a source of data. This application and consent form had previously been considered by the NHS Information Centre's Data Access Advisory Group who advised that the consent form was not sufficient to allow the release of HES data and that section 251 support would be required for the disclosure of data.

Outcome

Consent form

The Committee noted that the initial consent for this study had been obtained in 1995 and at the time it was not a requirement to complete consent forms. The Committee agreed that they were sympathetic to these types of historical studies and understood requests for section 251 to enable a secure legal basis for the disclosure of this data.

Practicability of gaining further explicit consent

Members discussed whether further explicit consent could be obtained by the applicant and agreed that given the low level of sensitivity of the data requested, the original consent taken and the historical nature of the cohort, it would be disproportionate to require the applicant to re-consent all participants. However members agreed that if, in future, there was a requirement to approach participants again consideration should be given to taking consent for access to national databases. At this time the NHS Information Centre should be approached to determine suitable wording. In considering the questionnaire which contained the consent provisions, whilst views were raised that this could be considered as adequate consent for the disclosure of HES data; as a whole the Committee understood the hesitation to allow the data to be released without section 251

Conclusion

As re-consenting the cohort was deemed unfeasible in the circumstances, and given that all participants had initially consented to the original study which had detailed follow up of the cohort using medical records, the Committee agreed that a recommendation of support could be provisionally made.

5f. ECC 6-05(f)/2011 Psychotropic medication prescribing patterns in English prisons

This application from the University of Manchester detailed a study which aimed to describe psychotropic medication prescribing rates in medium security prisons, and compare them with rates in the community. Section 251 support was requested to run the cross-sectional prescribing

survey without consent to allow the collection of anonymised demographic, prescription and diagnostic data from patient's clinical records.

Outcome

Members agreed that this activity would be of benefit to the study population and were highly supportive of the aims of the study. The Committee noted that previously members of the direct healthcare team at each prison site had been trained to collect the data. However, the quality, completeness and reliability of the data collected had been insufficient and had led to the requirement for one trained researcher to carry out the data extraction across all sites.

Impracticability of consent

Members considered whether a consent based methodology could be pursued and agreed that this would be complicated due to combination of the requirement of the study to obtain data on a given census day and the transient nature of the prison population. The applicant also asserted that it would not be possible to predict which patients would be prescribed psychotropic medication on any given day and that often the prescriptions were for seven days or less. The Committee therefore agreed that obtaining consent would not be feasible. However Members wished to make clear that the duty of confidentiality owed to prison patients was no less than that owed to any other patient and therefore any decision would be taken with this in mind.

Compliance with the Data Protection Act 1998

Section 251 support cannot be inconsistent with the principles of the Data Protection Act 1998 (DPA), as consent would not be practicable for this study members considered the fair processing information (the first principle) given to patients and discussed whether reasonable attempts had been made to inform data subjects of the uses of their data. Members noted that posters would be provided within prisons, detailing the data collection and also the opt-out provisions (the sixth principle). However members queried whether there could be any further efforts made to engage with the prison population, particularly the high level of prisoners who were illiterate. The applicant was asked to consider how they would communicate the uses of data and a mechanism to register dissent to those who were unable to read the information provided. As section 251 support, where provided, cannot be used to override dissent members were particularly concerned that all patients should have a right to understand and simple facility to be in place to register objections to the processing of the data.

Members raised concerns that the application had not sufficiently demonstrated that the stated data items to be extracted were the minimum necessary to provide an answer to the research question. In line with the third principle of the DPA, only the minimum amount of data necessary for the specified purposes should be used. Members raised concerns that the data items, although containing no identifiers, could have an inferential risk of identification in conjunction with other data sets. In addition members were unclear what amount of highly sensitive data would be available to the researcher when accessing records for the purpose of data extraction. Members asked that the applicant fully justify all data items to be extracted, including clinical items and detail how they would ensure that access to records would be kept to the minimum necessary.

Practicable alternatives

Section 251 (4) allows that a recommendation of approval can only be made where there is no practicable alternative to the disclosure of patient identifiable data without consent. With this in mind members questioned whether it would be possible to design a query to run on prison healthcare systems that would allow only the required anonymised data to be extracted. This would negate the requirement for researcher access to identifiable records and the need for section 251 support. It was understood that the majority of prison systems use Systmone and members requested that the applicant explore using the search engine built into Systmone

alternative in detail (including contacting the system supplier TPP), setting out any issues in pursuing this approach such as cost and timescales

Patient involvement

Members commented that the application detailed some interesting user involvement, but noted that patients at HMP Kennett had only been consulted in relation to members of the clinical care team extracting anonymised data. Members queried whether any further consultations with prisoners were proposed given the change in methodology.

Conclusion

In conclusion, the Committee was unable to provide a recommendation of approval at this time as it appeared that a practicable alternative existed that had not yet been explored. The Committee therefore requested the following:

1. That the applicant investigates the feasibility of the prison healthcare system provider designing a query which could be run on prison systems to extract an anonymised dataset for analysis. If this is possible then section 251 may no longer be required to access the specified dataset.

2. To also consider the inferential risk of identification in the extracted dataset and provide confirmation that this would not be used in conjunction with other datasets and that sensitive data items would be destroyed as soon as they are no longer required.

If this alternative is determined as unfeasible then evidence of this should be provided along with clarity over the following points:

1. Detail on how the uses of data and the option to register dissent will be communicated to those who are unable to read the information provided.

2. Full justification for all data items to be extracted, including clinical items and detail how access to records would be kept to the minimum necessary.

It was agreed that these responses would be forwarded to the Chair plus a smaller sub-group of members for consideration outside a Committee meeting in the first instance to determine if a recommendation of section 251 support could be made.

5g. ECC 6-05(g)/2011 Defining, modelling and mapping frequent use of paediatric patients in the emergency department

This application from the University of Sheffield detailed a study to define if the concept of frequent attendance occurs in paediatric populations presenting to the Emergency Department, and to define the population characteristics of frequent users of the Emergency Departments. Patient identifiable data would be removed by a member of the clinical care team prior to disclosure of data to the researcher; however the application requested section 251 support to allow access to postcode data for the purposes of deprivation scoring and calculation of distances to the hospital from patients' homes.

Outcome

Members were supportive in principle of the aims of this study and recognised that it was important to determine socio-demographic factors associated with paediatric attendance at emergency departments. When considering whether a recommendation of support could be provided, members discussed the following:

Impracticability of consent

The Committee noted that the study would utilise a large amount of individuals (65000) data over four emergency departments on a retrospective basis; therefore, the Committee agreed that it would not be feasible for the clinical care team to obtain consent for disclosure.

Practicable alternatives

Section 251 (4) allows that a recommendation of approval can only be made where there is no practicable alternative to the disclosure of patient identifiable data without consent. Members therefore queried whether it would be possible for a member of the clinical team within the hospital to undertake distance mapping and deprivation scoring on the applicants behalf. It was noted that look up tables for deprivation scoring could quite easily be obtained and used. The applicant was requested to explore the feasibility of this approach before further consideration could be made. If this approach was possible then section 251 support would not be required, therefore members strongly encouraged investigating this alternative approach.

If the above was not practicable members queried why it was necessary for the postcode data to leave the hospital sites and requested that the applicant consider carrying out the deprivation scoring and distance mapping on NHS sites, rather than extracting patient identifiable data.

Compliance with Data Protection Act 1998 principles

Section 251 support cannot be inconsistent with the principles of the Data Protection Act 1998 (DPA). As consent would not be feasible for this study, members looked for attempts to make the cohort aware of the use of their data, in line with the first principle which requires reasonable efforts to be made to inform data subjects of this use. In this instance members could not find evidence of fair processing information being provided and advised that this would need to be readdressed before a recommendation of section 251 support could be made. Additionally as there was no fair processing information the Committee queried whether any provisions had been made for the data subjects to opt out of their personal data being processed under certain conditions, for these purposes, in line with the sixth principle of the DPA.

User involvement

Members wished to reiterate that where patient identifiable data is to be used, and explicit consent from the cohort is not to be obtained, it is of particular importance that a patient representative view is sought in relation to the study, and in particular views on the use of identifiable data by a researcher without consent. This was considered important as it provides a check to the use of patient identifiable data without consent and is a key principle of the Committee. Members therefore advised that plans for patient engagement should be further considered by the applicant. Further advice on engagement with patients can be found within information provided by INVOLVE http://www.invo.org.uk/pdfs/InvolveExploringImpactSummary3.11.09final.pdf.

Duty of care to patient

Members raised some concern that in carrying out the study of frequent attendance, particular individuals may be identified as attending more frequently than others. Members queried whether the researcher would be able to identify an individual across different episodes of attendance and what action would be taken if they suspected non-accidental injury had taken place.

Conclusion

Members concluded that they were supportive of the purposes of the application but at present they would be unable to make a recommendation of section 251 support as it appeared that a practicable alternative could be identified. The applicant was therefore requested to explore the feasibility of the following approach:

1. Whether it would be feasible for the clinical teams, or someone with legitimate access to postcode data, within the hospital to undertake the distance mapping and deprivation scores on the researcher's behalf.

If this approach is not considered feasible then evidence should be provided along with consideration of the following:

1. Fair processing information should be provided in emergency departments to make reasonable attempts to inform patients that research was being undertaken and inform the cohort who to approach to register their dissent.

2. Please confirm whether it would be possible to undertake distance mapping and deprivation scoring on hospital sites.

3. Details whether a researcher would be able to identify an individual across different episodes of attendance and what action would be taken if they suspected non-accidental injury had taken place.

Once available, responses to these considerations would initially be considered by the Chair to determine whether a recommendation of support under section 251 could be made.

6. Any other business

Appointment of vice-Chair

The Committee noted that the current vice-Chair, Professor Sir Denis Pereira Gray, was scheduled to leave the Committee on 31 December 2011, therefore nominations to replace him in his capacity was requested.

Action: members to send nominations to the office

ECC strategy day

The Committee had met the day beforehand for a strategy day to discuss a number of issues around principles and process and to aid in development of general service improvement. This included a presentation from the NHS Information Centre. A summary of key points are set out below.

NHS Information Centre presentation on changes to processing and infrastructure – HES

Ms Clare Sanderson and Andrew Frith attended to provide a presentation. The focus of the discussion was that the contract with Northgate was coming to an end and it was stated that it was critical for new arrangements to be put into place as per details of an advance briefing paper. It would take approximately 18 months to complete the transition, and would necessitate two systems running concurrently. Advice was sought on how the Committee would need to be engaged, and at what points. In particular, it was indicated that where there was a need for identifiable HES information to be provided in a linked dataset, this must be drawn from the Northgate environment and placed into the Data Management Environment (DME). Instead of removing the HES identifiable data after each linkage the NHS IC indicated the need to persist the data in the secure DME environment with access restricted to authorised 'linkage processing' personnel.

The details of the current approved application (ECC 2-05 (a) 2010) states that once linkage has been completed, a copy will not be retained and the identifiable information would be deleted. The Committee were clear that such a change to indefinite retention would vary the current terms of the support provided under the Regulations, and a formal application for amendment would need to be made at the appropriate time; noting that the purpose of the discussion was not to request an amendment at this specific point. In particular, a query was raised by the Committee on whether indefinite retention would place the NHS IC in the position of carrying out an honest broker function, and whether the Regulations were sufficiently broad so that this activity could legitimately fall within the Regulations as currently phrased. Members were also mindful that the retention of data would need to be justified in the context of the Data Protection Act 1998 and the need to ensure that personal information would be retained for the minimum time necessary in order to achieve defined purposes. Members queried the justification and purpose of the need for indefinite retention, and specifically what it would enable the NHS IC to achieve that it was not currently in a position to manage at present. It was understood that in the short term this would lead to a more efficient process, and the intention would be to improve turnaround of speed of requests and to carry out auditing more effectively.

In terms of moving forwards and supporting the NHS IC in its transitional arrangements, it was agreed that it would not currently be appropriate for representatives of the Committee to sit upon the IG assurance group as specified in the briefing paper, as it could lead to a conflict of interest and need for the Committee to remain independent when taking decisions over applications for support. Instead, it was advised that the NIGB Director and office arrange a series of regular meetings in which to support the transition in the first instance. This approach would ensure that the Office is kept fully appraised, advice can be offered where appropriate, and agreements made on when information should be presented back to the Committee.

Terms of Reference

It was noted that NIGB terms of reference had been undergoing revision and the most recent version had been provided to the Committee for their comment. Queries were raised over the role of the sponsor in removal of the Chair, and clarification was sought that as the Committee was responsible for providing advice to the Secretary of State for health (SoS), that it would be more appropriate constitutionally for such direction to come from the SoS. The Chair also noted that he would seek advice from the DH lawyer on this aspect, and that this would be included in his discussion with the NIGB Chair.