NHS
Health Research Authority

Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group

3 October 2013 at 10 am at Skipton House, SE1 6LH

Present:

Name	Capacity
Dr Mark Taylor (Chair)	Lay
Dr Charlotte Augst	
Dr Kambiz Boomla	
Dr Tony Calland	
Mr Paul Charlton	Lay
Ms Madeleine Colvin	
Dr Tricia Cresswell (vice-chair)	
Mr Anthony Kane	Lay
Ms Clare Sanderson (from item 7a)	
Dr Murat Soncul	
Mr C. Marc Taylor	
Ms Gillian Wells	Lay
Dr Christopher Wiltsher	Lay
Mr Terence Wiseman	Lay

Also in attendance:

Name	Position (or reason for attending)
Ms Heather Dorricott	Quality Control Manager, Clinical Practice Research Datalink (items 5b-6a)
Ms. Natasha Dunkley	Confidentiality Advice Manager
Ms. Claire Edgeworth	Deputy Confidentiality Advice Manager
Mr David Evans	Expert advisor – Data protection (Information Commissioner's Office)
Ms Amanda Hunn	Patient and Public Engagement Project Manager, Health Research Authority (item 4)
Dr John Parkinson	Director, Clinical Practice Research Datalink (items 5b-6a)

1. INTRODUCTION, APOLOGIES FOR ABSENCE AND DECLARATIONS OF INTEREST

Apologies were received from Dr Robert Carr, Dr Patrick Coyle, Professor Julia Hippisley-Cox, Professor Jennifer Kurinczuk, and Ms Rebecca Stanbrook.

The following interests were declared:

- Mr C. Marc Taylor declared a competing interest in the Clinical Practice Research Datalink items (5b through 6a) and did not partake in the discussion.
- Dr Murat Soncul declared a conflicting interest in items 4a and 7f and left the room for the duration of these two discussions.
- Paul Charlton declared an interest in item 7a and left the room for the duration of the discussion.
- Mr Chris Wiltsher declared membership of the patient group consulted by the applicant for item 7b, but it was agreed that this did not constitute a conflict of interest and he remained present for the discussion.
- Dr Charlotte Augst declared that her children were part of the cohort for item 5a, but it was agreed that this did not constitute a conflict of interest and she remained present for the discussion.
- Dr Kambiz Boomla declared an interest in item 7c in that one of his colleagues had provided advice in relation to the application, but it was agreed that this did not constitute a conflict of interest and he remained present for the discussion.

2. MINUTES OF THE MEETING HELD ON 8 AUGUST 2013

The minutes were agreed as an accurate record, subject to minor amendments.

3. CAG OFFICE REPORT AND MATTERS ARISING

Matters arising

Members noted the forthcoming date for the information sharing workshop with the Information Commissioner's Office. It was agreed that the date would be circulated to Members to attend if wished.

Action: Office to circulate date of workshop to Members.

Members requested that when stating in the minutes whether a provisional approval had been provided, that the outstanding conditions of support are also articulated.

Action: Office to ensure that points of clarification or conditions are reflected clearly within minutes.

Chair update

The Chair provided an update following the meeting around Local Authority Public Health access to patient confidential data (PCD) that had been previously reported to Members. It was noted that the output from this meeting was still pending due to reduced capacity within PHE and the need to negotiate with the HSCIC on the feasibility and delivery of pseudonymised monthly HES extracts.

It was noted that work had been carried out to seek to establish observer status on the CQC's NIGC so that there would be potential to provide advice on potential new Regulations. This had been accepted in principle.

An update was provided on recent discussions between the Chair and Professor Roy McClelland, Chair of the Northern Ireland Privacy Advisory Committee (PAC), regarding CAG interaction with PAC. It was agreed that where a specific interface issue arose, then the office would liaise directly with the Chair of PAC or advise the applicant to do so. The Chair of PAC would also be invited to CAG away days where appropriate where more general issues would be discussed. It was suggested that this interaction should be included within the SOPs to document the interaction between CAG and PAC to ensure that good working relationships survived a change in personnel. . Broader R&D policy issues would be dealt with through the recently established links between HRA and the R&D Division of the Northern Ireland Public Health Agency.

Action: Office to amend SOPs to reflect CAG/PAC working arrangements.

For information

Secretary of State approval decisions

The DH senior civil servant on behalf of the Secretary of State for Health (SofS) agreed with the advice provided by the CAG in relation to the August 2013 meeting applications.

HRA approval decisions

The HRA agreed with the advice provided by the CAG in relation to the August 2013 meeting applications.

ECC 6-02(FT16)/2012 - CQC 2013 Maternity Survey CQC security breach

The CQC reported that a serious error was made when submitting the 2013 maternity survey sample for Pennine Acute Hospitals NHS Trust to the Survey Co-ordination Centre for checking. The initial file that was submitted to the Co-ordination Centre contained full names, address/postcode and NHS number of the women sampled for the survey. These details should have been removed prior to submitting the file, as outlined in the survey guidance manual. This was the second breach from this organisation and following the first, several assurances were made that mitigating actions were put in place to ensure that the incident was not repeated. The CQC wrote to the organisation to advise that they contact the ICO to report the breach and determine what further action is required. No further information had been received by the CAT from the NHS Trust at this stage.

At the June CAG meeting Members requested that the Confidentiality Advice Team contact the CQC for an update in relation to the Trust response. A letter of assurance from the Trust to the CQC was shared with CAG.

Members queried whether the issue had been reported to the Information Commissioners Office

Action: Office to confirm status of reporting and feed back to Members.

Operational and CAT advice updates

Linkage of HES and MHMDS data

A letter was received from the Chair of the Data Access Advisory Group (DAAG) at the Health and Social Care Information Centre (HSCIC) in relation to linkage of the Mental Health Minimum Data Set (MHMDS) to Hospital Episode Statistics (HES) data, which the HSCIC had recently carried out under direction from NHS England. Following this linkage, DAAG had received a request from the Care Quality Commission (CQC) for access to the bridging file in order to enable them to link HES and MHMDS data which they already held, and had requested CQC provide assurance that appropriate access controls would be in place. DAAG wished to reassure CAG that where a customer with existing support under the Health Service (Control of Patient Information) Regulations 2002 for access to identifiable HES data wished to link to MHMDS data, the request would be referred to CAG to ensure that any necessary amendments to existing support could be considered.

Publication of guidance on managing non-response

The guidance on managing non-response had now been published on the HRA website.

Information Governance Toolkit update

Following on from the update in the August office report, guidance in relation to the IG toolkit process had now been drafted and a revision of the FAQ document would follow shortly. Regular catch ups had been scheduled with the IG Toolkit team at the HSCIC to ensure that IG Toolkit assessments were carried out as efficiently as possible for CAG applicants and to identify any improvements that could be made to the process. The proposed improvements and regular catch ups had had a positive effect on processing times for IG Toolkit responses so far and had resulted in improved communication between CAT and the IG Toolkit team.

Update on recruitment

Progress had been made in relation to the current vacant post and it was anticipated that interviews for the Confidentiality Advisor role would take place over the week commencing 23 September. The Confidentiality Advisor role would include primary responsibility for proportionate review applications and supporting full meeting applications. In particular, the additional resource would enable the meeting schedule to move to a monthly frequency.

REC/CAT interaction

Ms Claire Edgeworth held a training session at Manchester REC centre in relation to the role of CAG and CAT in order to raise awareness of CAG and encourage closer working; dates were also scheduled for sessions at the London, Newcastle and Bristol REC centres. As reported in the August office report a guidance document outlining interaction between REC staff and members and the CAT had been drafted and was now awaiting final approval within the HRA. This document would continue to be updated to reflect any issues that might arise.

Monthly meetings

Members were advised that from April 2014 it was anticipated that CAG would move to monthly one day meetings. Dates were currently being finalised and would be shared with Members at the earliest opportunity.

Some concern was raised about the level of work that additional meetings would create. Members were informed that the intention to move towards monthly meetings had been agreed at an early

stage in the transition to the HRA and that when established it was likely that there would be fewer items for consideration at each meeting and therefore the intention was that the volume of work would not significantly increase.

Internal audit

An internal audit of the administration of CAG application would take place in November by the Quality Assurance team within the HRA in preparation for the ISO accreditation process next year.

Working Groups update

Practicable alternatives working group

The second meeting of the practicable alternatives working group took place in September. This meeting included further discussions around the scope and presentation of guidance along with plans to ensure that relevant stakeholders were consulted with and informed. Actions arising from this meeting included holding two stakeholder workshops in October/November 2013 (precise dates still to be confirmed at the time of writing). The working group members and CAT were beginning to draft guidance and algorithms and a report would be circulated to CAG members prior to the November meeting.

Marc Taylor provided an update and explained that the group were looking to establish three aspects:

1. Consolidation of information and guidance provided by the Ethics and Confidentiality Committee and CAG and exploration into what alternatives existed for those seeking to process confidential patient data without consent.
2. Consolidation of existing definitions of what constitutes identifiable and pseudonymised data.
3. Establishment of a risk matrix for CAG use to establish a consistent approach to establishing risk factor of re-identification of a dataset.

External meetings and events

Meeting with Dr Beth Thompson, Wellcome Trust

Ms Natasha Dunkley and Ms Claire Edgeworth met with Dr Beth Thompson, Policy Adviser at the Wellcome Trust, to receive an update in relation to the draft European Data Protection Regulation and to discuss the guidance produced in conjunction with the ICO in relation to non-response. Dr Thompson suggested some improvements to the guidance to increase understanding which were incorporated into the final version. It was agreed that CAT would keep Dr Thompson informed of any opportunities to comment on guidance in future.

Applications considered via proportionate review

CAG 6-03(PR1)/2013 - The QUEST Study

This research application from Luton & Dunstable University Hospital Foundation NHS Trust set out the purpose of assessing the effectiveness of the current sepsis care pathway and the impact of adding an additional clinical test (the procalcitonin point of care test) to the pathway. A recommendation for class 1, 5 and 6 support was requested to cover access to data on 100 deceased adult patients across two chosen sites (50 per site) who had attended A&E with suspected sepsis. Access was requested to date of birth, date of death, postcode, gender and ethnicity. This application was considered via the proportionate review process under criteria 2, *access to data of deceased patients.*

Members noted that the cohort in question would be deceased and agreed that it would not be appropriate to seek assent from legal representatives in order to undertake the specified access to data. It was noted that consent would be sought from those patients who were alive. Members noted that whilst the number of patient records to be reviewed was low, resource constraints meant that it would be difficult for the clinical care team to undertake the anonymisation processes. Whilst Members deliberated whether it would be possible to try and utilise additional resource for this process, it was agreed that on balance, taking into consideration the risk, they could recommend support for a researcher to access data on site in order to carry out anonymisation.

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and therefore advised recommending support to the Health Research Authority.

CAG 6-03(PR2)/2013 - Retrospective analysis of reversible myocardial dysfunction in ICU

This research application from Oxford University Hospitals NHS Trust set out the purpose of a retrospective analysis of repeated heart ultrasound outcomes performed in general ICU population in order to characterise the natural history and outcomes of patients experiencing heart impairment. The study aims to develop a greater understanding about whether the condition affects wider critically ill patients. A recommendation for class 1, 4 and 6 support was requested in order for the research team within John Radcliffe Hospital to identify patients who had serial heart ultrasounds whilst in the ICU and assess changes in heart function during the course of critical illness. Access was requested to the ICU patient monitoring database, local data collected for national ICU audit programme (ICNARC) and the heart ultrasound database. The ICU patient monitoring database would be extracted for all patients admitted to the ICU from January 2008 to June 2013 and linked to the ultrasound database. Where patients were identified as having serial ultrasounds clinical data would be extracted from the patient monitoring database and local ICNARC data. Access was requested to name, date of birth, hospital number and gender. This application was considered via the proportionate review process under criteria 4: *time limited access to undertake record linkage.*

Members agreed that the research aims would be of benefit in terms of improving medical support to patients. It was asserted that consent would not be feasible because of the retrospective nature of the study and the high mortality rate in ICU patients. Members agreed that this reason would result in it being difficult to obtain consent from the cohort. Members noted that anonymised or pseudonymised data would not be suitable for this study as identifiers would be required in order to carry out the requested linkages. Members noted that multiple identifiers might sometimes be necessary for the purposes of linkage, but encouraged use of only the minimal number of identifiers possible.

Members noted that a patient information leaflet had been produced which was provided to in-patients and included information about the use of their data for research purposes. Members suggested that the information leaflet should also include clear details in relation to how patients could opt out of the use of data in research. In addition, Members discussed whether there were any opportunities for activity specific information to be provided to patients and suggested that the applicant could explore the possibility of including a notice on the hospital website in relation to the project.

Members noted that question 15-2 of the application form specified that the research was discussed at a public meeting and requested further information in relation to the attendees at that meeting.

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *conditional* support to the Health Research Authority, subject to confirmation that patient information materials relating to this specific activity would be made available to living patients; confirmation that these patient information materials would give patients a clear opportunity and mechanism for objection if they did not wish their data to be included in the study; and

provision of more details concerning patient and public engagement with respect to this application, including details of the public meeting mentioned in the application.

CAG 6-03(PR3)/2013 - Impact of overweight on prognosis of diabetes mellitus

This research application from the University of Hull set out the purpose of establishing a research database which would be used to assess the relationship between obesity, cardiovascular disease and mortality in diabetes mellitus and address issues that might have accounted for inconsistent results in previous studies. A recommendation for class 1, 4 and 6 support was requested to cover access to a database including approx. 12,000 patients' data held at the diabetes out-patient clinic at Hull and East Yorkshire Trust for the purpose of data extraction and linkage to ONS mortality data. Access was requested to name, NHS number, date of birth, date of death and postcode. This application was considered via the proportionate review process under criteria 4: *time limited access to undertake record linkage and pseudonymise the data.*

Members agreed that the study outcomes specified within the application would be of public benefit. Members noted that, due to the size of the retrospective cohort, consent was considered not to be feasible. It was noted that research data would be pseudonymised once linkages had taken place and Members agreed that this should be a condition of support.

Members advised that the applicant make further efforts to improve their patient and public involvement strategy to raise awareness of the processing, for example by producing patient information materials. Any patient information should also include information in relation to mechanisms for patients to register objections.

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *conditional* support to the Health Research Authority, subject to provision of plans to raise awareness of the activity; provision of patient information materials; and confirmation that identifiable data would be retained separately from clinical information and that identifiers would be kept no longer than necessary once linkages had been established.

CAG 6-03(PR4)/2013 - Comparing psoriasis treatments and care pathways using routine data

This research application from the University of Surrey set out the purpose of a study to describe the effect of formulation, combination, and sequence of primary and secondary care therapy for psoriasis on health service utilisation and costs using data routinely collected as part of clinical services in primary and secondary healthcare service. A recommendation for class 1, 4 and 5 support was requested to cover access to data of 23,000 adult patients, across three CCG areas, with a GP diagnosis of psoriasis. Access was requested to name, NHS number, date of birth, postcode and gender. This application was considered via the proportionate review process under criteria 4: *time limited access to undertake record linkage and pseudonymise the data.*

Members agreed that the study outcomes would have potential public benefit, including better management of psoriasis and potential savings for the NHS, and were supportive of the application in principle. Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

Members noted that the linkage methodology had previously been approved in relation to other applications under the Regulations. However, Members queried whether there were now other practicable alternatives that could now be considered, for example utilising existing linked datasets, such as CPRD, or undertaking linkage of datasets within the HSCIC. Members queried whether the applicant had considered any of these alternatives and requested further information in relation to why these would not be suitable. Members considered the extent of confidential patient information that

would be accessed by the applicant and noted that NHS number ascertainment would appear to be near to completion. Members requested that the applicant consider and provide further information in relation to the whether linkages could be undertaken using NHS number only.

Members discussed the clinical data that would be required for the study and agreed that it was unclear whether any sensitive data would be included within the relevant clinical data, in particular whether any mental health data would be required. It was noted that the application specified that relevant clinical data would be extracted but it was not clear how relevant data would be determined. Members requested further information in relation to how this was determined and requested a complete list of data items to be extracted.

Members requested that the applicant provide further information in relation to the arrangements for carrying out linkage between primary and secondary care data. It was noted that a data flow diagram had been referenced within the application but had not been submitted and Members agreed that this should help ensure that the data flows were clear within the study documentation. The diagram should include details of who will have access to data at each stage of the process and clarity over data sources for secondary care datasets.

It was a requirement of the Regulations that an application could not be inconsistent with the principles of the Data Protection Act 1998 (DPA). The first principle of the DPA required that reasonable efforts be made to inform data subjects of the uses of their data. With this in mind, Members queried how long posters would be made available within GP practices before data extraction took place. Members noted that the patient information leaflet mentioned opt-out and suggested that this should be amended to state clearly that this referred to actions to take if individuals did not wish their data to be included within the study as the term opt-out might not be familiar to all patients. Members queried whether there would be any future uses of the linked dataset that were not currently specified within the application and advised that if this was the case, further information in relation to access control would be required.

Members recommended to the Health Research Authority that the decision with respect to this application be deferred, subject to clarification of any exploration of alternatives; clarification as to whether linkages could be undertaken using NHS number only; clarification in relation to how clinical data required for the study was determined, including a complete list of data items to be extracted; provision of a data flow diagram; confirmation of how long posters would be displayed in GP practices; and clarification as to whether there would be any future uses of the linked dataset, with details relating to access control if the dataset were to be made available outside the research team.

CAG 6-03(PR5)/2013 - CQC 2013 Inpatients Survey

This service evaluation application set out details of the transfer of patient identifiable data from acute and specialist trusts to defined survey contractors for the purpose of mailing out questionnaires for the 2012 acute inpatient survey. The application was considered at an office level as it was noted that this was a repeat of the 2012 acute inpatient survey and therefore fell within proportionate review criteria 14: *repeat projects*.

The cohort would relate to inpatients aged 16 years or over who were discharged from acute and specialist NHS hospitals in June, July or August 2012 (earlier for smaller trusts), who had had one overnight stay in hospital. Inpatients treated for obstetrics/maternity or psychiatric reasons, private patients, current inpatients, those without a full UK postal address, and those who are found to be deceased prior to the start of the mailings would not be included in the cohort. Such checks would be carried out locally by the Trusts. A recommendation of support was requested to cover the transfer of patient identifiable information (as listed within the application) from trusts and the subsequent processing of this information by specified contractors. It was indicated that that NHS trusts would be

advised to employ the service of one of the specified 'approved contractors' to reduce the cost, burden and risk in the provision of survey data.

The applicant confirmed that the methodology and sampling frame were identical to those used for the 2012 acute inpatient survey. It was noted that ICD10 code would be included within the data submitted from trusts for the 2013 survey in the sample file, that anonymised data would be shared with NHS England and the Department of Health for specific purposes and that the completion of the questionnaire on-line would be piloted. It was confirmed that Patient Perspective, Quality Health, Picker and Capita Surveys and Research would be the specific contractors used to administer surveys.

The amendment to include information in relation to ICD10 codes was forwarded to the Vice Chair for consideration. It was agreed that support could be recommended for the inclusion of ICD10 code within the sample file. However, it was advised that where small numbers of cases were generated by the inclusion of ICD10 code this would be potentially disclosive and should not be included within the sample file. The Vice Chair agreed that the sharing of de-identified data with NHS England and the Department of Health could be supported for the specific purposes outlined within the application.

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *conditional* support to the Secretary of State for Health, subject to exclusion of small numbers generated by rare diagnoses from the sample file sent to survey contractors.

Amendments to approved applications

PIAG 4-08(b)/2003 - National Confidential Enquiry into Patient Outcome and Deaths (NCEPOD)

This audit application from the National Confidentiality Enquiry into Patient Outcome and Deaths had support in order to carry out a number of studies with the aim to review clinical practice and identify potentially remediable factors in the practice of anaesthesia, surgery and other invasive medical procedures including primary care.

The amendment request detailed extending support to allow collection of data for a lower limbs amputation study. It was confirmed that the existing NCEPOD methodology would be used.

The amendment was forwarded to the Chair who queried whether it would be possible to ask local care teams to anonymise patient notes prior to submission to NCEPOD. In response to this specific point, the applicant asserted that whilst the anonymisation at a local level could be encouraged this was often carried out insufficiently and resource issues prevented this from being practicable. It was agreed that this should continue to be encouraged so that anonymisation took place where possible.

The Chair agreed that the minimum criteria under the Regulations appeared to have been met and therefore advised recommending support to the Secretary of State for Health, subject to confirmation that anonymisation of case notes prior to submission to NCEPOD would be encouraged where possible.

ECC 3-04(f)/2011 - SLAM IG Clinical Dataset Linking Service

This research application from the South London & Maudsley NHS Foundation Trust set out the purpose of investigating the associations between specific mental disorders in secondary mental health care (schizophrenia, schizoaffective disorder, bipolar disorder and dementia) and physical illness. This would use a new linked dataset containing health records for patients with these disorders from the SLAM BRC Case Register Interactive Search (CRIS) and general hospital records

from the English national Hospital Episode Statistics (HES) database. Review of this application was sought so as to provide a legitimate basis for the processing of this patient identifiable information; to effectively test this 'honest broker' capability and to permit the linkage and subsequent anonymisation. This required access to name, date of birth, sex, address, postcode and NHS Number.

This amendment requested that the Hospital Episode Statistics (HES) data extract provided to the SLAM IG Clinical Dataset Linking Service be expanded to include date of death and cause of death. It was noted that both of these data items had previously been accessed under class support.

The amendment requested was forwarded to the Alternate Vice-Chair who agreed that it was reasonable for the HES extract to include date of death and cause of death as these identifiers had already been covered by class support. It was emphasised that full date of death must not be disclosed onward to researchers.

ECC 4-03(b)/2012 - Locality-wide integrated end of life care project – stage 1

This service evaluation application from Pilgrim's Hospices in East Kent set out details of a pilot to develop a navigation centre/coordination service to ensure those at end of life were provided with the right care at the right time. The activity also intended to analyse the quality of care provided by the NHS, social care and third sector organisations. A recommendation for class 1, 4, 5 and 6 support was requested to provide a legal basis to access deceased person's data to enable linkages to social care/third sector data to provide a baseline to support the overarching Invicta project. The application requested access to name, postal address, date of birth and death, NHS number, gender, diagnosis and service ID. Information retained for analysis would consist of patient clinical commissioning group, (preferred) place of death, diagnosis and gender.

The amendment asserted that uptake by GP practices, with respect to seeking patient consent on behalf of the study, had been lower than expected with only 10% of the potential patient cohort covered, and that at the current rate of uptake it was extrapolated that no more than 20% of patient deaths amenable to end of life care would be included by the end of 2013. This level of ascertainment was stated to be insufficient to permit valid comparisons to be made or trends to be identified in local improvements to end of life care. An extension to the existing support under the Regulations was therefore sought in order for Pilgrim's Hospices staff to view patient identifiable information relating to all persons who died between 1 January 2013 and 31 March 2013 and, from January 2014, those who died in the period 1 October 2013 to 31 December 2013.

The amendment request was forwarded to a sub-group of CAG Members who agreed that it had been demonstrated that it was not practicable to seek consent for the whole cohort in 2013. Members agreed to recommend an extension of support to cover *retrospective* access to the records of patients who had died between 1 January 2013 and 31 March 2013, and with effect from January 2014, *retrospective* access to the records of patients who had died between 1 October 2013 and 31 December 2013.

It was reiterated that *prospective* access to patient records should be done through gaining the patient's consent for inclusion on the end of life register, in line with the original approval, and therefore it was envisaged that support under the Regulations would not be provided for future cohorts. Members agreed that they would not expect there to be any need for further extension to retrospective data collection.

Updates on existing applications

CAG 5-07(a)/2013 National Chronic Obstructive Pulmonary Disease (COPD) Audit Programme

This application was recommended for conditional support at the August CAG meeting. One of the conditions requested that the applicant pilot consent at the pilot data collection stage. The applicant asserted that there were a number of reasons why consent could not be piloted for this activity. This response was forwarded to the Chair who agreed that the applicant had provided adequate justification for not piloting the consent based approach for this aspect of the pilot. This condition was therefore withdrawn.

CAG 4-08(b)/2013 Fragility Fracture Secondary Prevention Audit

This application was considered at the June CAG meeting and members agreed that the application should be deferred due to a number of clarifications that were required. Following the meeting the applicant responded and it was agreed that the application could be partially approved, to allow access to confidential patient information from fracture liaison services and from GP practices who undertook data extraction themselves or explicitly consented to the automated extraction of data for the fragility fracture audit.

The aspect of the application which detailed the automated extraction from GP practices where opt out was in place was deferred, pending a response from the Information Commissioner's Office in relation to compliance with the Data Protection Act. Some concerns were raised over the automated data extraction and how this process would ensure that the GPs were able to comply with their fair processing responsibilities under the DPA. The applicant was asked for further information in relation to the contracts in place with GP practices in relation to the automated data extraction and whether it would be possible for GPs to provide some indication that they were aware of the audit prior to the automated data extraction taking place.

Further discussion in relation to the issue of carrying out automated data extraction from GP practices took place under item 7b, National Chronic Obstructive Pulmonary Disease (COPD) Audit Programme - Primary Care Clinical Audit Dataset Pilot Extraction.

3a. IG assurance tool equivalency review report

This discussion took place under any other business at the end of the agenda when Ms Clare Sanderson was present. Following discussion at the June CAG meeting, the HSCIC via Ms Claire Sanderson agreed to write a paper setting out specific alternatives to the IG Toolkit, for endorsement by CAG and then approval by the DH.

The paper of potential options and a report following the assessment of IG assurance tool equivalency which included an assessment of the Welsh equivalent, Caldicott: Principles into Practice (CPIP), was presented to the Group.

Wales

Members noted that the IG Toolkit was not completed as a matter of course by Welsh organisations but a Welsh equivalent was in place (CPIP); thus Welsh organisations applying for support under the Regulations were required to complete both the IG Toolkit and the Welsh counterpart, potentially duplicating work. In particular, the IG Toolkit was mandated within England but not Wales. It was noted that CPIP had been assessed to be an adequate alternative to the IG toolkit, but that further discussions would be required with the Department of Health prior to its formal adoption as an alternative.

It was highlighted that a number of annual reviews had been received from Public Health Wales, who had completed CPIP but had not completed the IG Toolkit and that it was crucial that advice was provided in relation to the assurance that would be considered adequate for these applications as soon as possible. It was agreed that as long as an approved System Level Security Policy was in place which covered the current processing and that a high score on CPIP had been achieved, this would be acceptable and there would not be a requirement to complete the IG toolkit.

Options for assurance

It was agreed that the office should work with the HSCIC to consider when the alternatives contained within the HSCIC paper would be suitable to provide assurance in particular circumstances where disclosure was not particularly high risk. For example, where a lone researcher required access to data on NHS sites, or required access for a very limited time period to a dataset that did not contain particularly sensitive data. It was noted that following approval by CAG, this would need a final policy decision to be made by DH prior to adoption.

Action: Office to work with HSCIC to establish circumstances where potential options for security assurance would be acceptable.

4. HRA PATIENT AND PUBLIC ENGAGEMENT PROJECT

Ms Amanda Hunn presented a report on the Health Research Authority's patient and public engagement project.

Dr Cresswell queried whether the results provided had been checked against the previous consultations undertaken by the DH and whether there had been a change in perception. It was noted that what constitutes the 'NHS' had changed over time so it would be interesting to understand what the patient perception was of the NHS.

5. ITEMS FOR CONSIDERATION

5a. SLAM IG Clinical Dataset Linking Service – project-specific children amendment [ECC 3-04(f)/2011]

The original research application provided approval for research to be carried out on the linked dataset to enable the investigation of associations between specific mental disorders seen in secondary mental health care (*schizophrenia, schizoaffective disorder, bipolar disorder and dementia*) and physical illness. This would use a linked dataset containing health records for relevant patients from the SLaM BRC Case Register Interactive Search (CRIS) and general hospital records from the Hospital Episode Statistics (HES) database. In effect, it was intended to pilot an 'honest broker' activity within the Trust.

In February 2013, an amendment had been submitted which sought to extend the scope of the type of research to be carried out using the linked dataset into mental disorders occurring in childhood and adolescence, personality disorders in adults and unipolar/ bipolar affective disorder. Alternative uses of HES such as receipt of maternity care data to identify pregnancy in order to explore the health outcomes of women with a history of psychotic disorder who become pregnant was also provided as an example of the potential broadening of scope. At the time, members were supportive in principle but had advised that the proposed amendment involved a significant deviation from the details of the original application in that all mental health diagnoses would be open to potential research. Members had indicated at the time that they were supportive, in principle, of the widening of research into children and adolescents as these are under-researched areas of the population, however this would

need to be addressed separately due to consideration of sensitivities. The applicant subsequently withdrew their request for the inclusion of children and noted they would return at a later date to cover this aspect

Members reviewed the detail of the protocol titled '*Does exposure to pro-convulsant psychotropic treatment predict epileptic outcomes amongst children with Autistic Spectrum Disorders?'* This project would investigate the prevalence and incidence of epileptic disorders for children with Autistic Spectrum Disorders, and how associations between Autistic Spectrum Disorders and epilepsy outcomes might be influenced by clinical profile and potentially modifiable factors, such as psychotropic medication treatment. It was noted that the details and methodology of the original application had already received a recommendation of support and the protocol did not involve any new data collection or linkages.

Members advised that there was a clear and strong public interest in this research being undertaken, and agreed that the rational for linkage was well articulated and provided a clear example of the type of activity the original application was approved to deliver. In terms of children, Members raised questions over whether the patient leaflet adequately covered the needs of children, and queried the situation on whether children would be given the opportunity to register an objection to the processing at the relevant competent age.

Members agreed that they were highly supportive of this activity, agreed that there was no other practicable alternative and that the minimum requirements of the Regulation appeared to have been satisfied. The CAG therefore agreed to provide a *provisional* recommendation of support to the Health Research Authority, subject to confirmation that the patient information leaflets could be tailored to meet the needs of parents and children; that there had been consideration of how patient objections could be managed once children reached a competent age; and clarification whether this proposal had undergone satisfactory review by the Oversight Committee.

5b. CPRD risk rating assessment documentation review [ECC 5-05 (a) 2012]

The original research application had received approval in February 2013, subject to a number of conditions of support, one of which was the provision of an update report to each CAG meeting for the first year to enable CAG Members to understand the processes used and decisions taken by the Independent Scientific Advisory Committee (ISAC).

Following update reports to the April, June and August meetings of the CAG, a teleconference had been held between a subset of CAG Members and representatives of CPRD on 18 September 2013, to further discuss ISAC and one of the outputs of that discussion was a review of CPRD's risk rating assessment processes.

Members welcomed the updates that had been made following the helpful teleconference, and found that these were broadly in line with what had been suggested. Members noted that revised extracts had been provided and requested that there be full revision and provision of original documentation once finalised as it had been noted at the teleconference that some of the documentation was pending an overall update as processes matured, and Members agreed that it was important to establish these definitively as soon as possible. It was also noted that the documentation supplied in the application and narrative report had been superseded and it would be important to update original documentation and ensure a definitive version was supplied to support the approved application.

Members also requested that the assessment process should be written and form part of the overall application so that there was clarity for all parties on the interaction between CAG and ISAC and considerations that determined this. This would include aspects related to the management of the assessment process such as how application types were reviewed and in what instances it was

escalated. This should be a complete suite of documents supporting the process that could be appended to the main application.

Members reviewed the complicating factors as amended and agreed that clear progress had been made which was also welcomed. As this was the first iteration Members as a whole felt that further discussion would be required on unpicking these complicating factors further and expressed the view that often risk depended on the nature of the information requested, in addition to the number of datasets involved, and felt that the risk assessment did not explicitly cover the aspect of qualitative assessment and it would be important to reflect this in the complicating factors. The CAG would welcome further discussion on this matter to reach a final position.

As a whole, Members agreed that positive progress had been made and there was now greater clarity on how levels of risk were assessed, although further discussion to refine this further in terms of qualitative factors would be required. It was also agreed that all relevant information as indicated above should be updated/developed with clear dates and version controls as there was a risk of confusion over which version would be applicable to this support.

Members therefore advised that a further discussion take place with CAG and ISAC with regards to the qualitative aspects of the risk assessment process, and that CPRD provide a complete suite of revised documents covering all aspects of the ISAC decision-making process to form part of application support.

5c. Review of ISAC disclosures [ECC 5-05(a)/2012]

The original research application had received approval in February 2013, subject to a number of conditions of support, one of which was the provision of an update report to each CAG meeting for at least the first year to enable CAG Members to understand the processes used and criteria utilised by the Independent Scientific Advisory Committee (ISAC) when assessing the risk of deductive disclosure.

Members had previously been unable to review the report in detail as the underlying considerations were still undergoing development; however consideration of the updated risk assessment documentation at the meeting meant that the Group was able to review this in a more informed capacity.

Members agreed that as there was now evolving clarity on the risk and decision-making processes that the report helped to demonstrate that ISAC had been implementing the process that the teleconference had elucidated. Members felt that the report showed the quantitative risk factors but did not explicitly demonstrate the qualitative risks and agreed to follow up this aspect through separate consideration of the risk assessment documentation.

In conclusion, Members agreed that they were broadly satisfied with the format of the report, welcomed its continuation and requested that future reports be presentationally sorted into High, Medium and Low risk categories to aid focus on the key issues.

5d. CPRD – 'high' risk protocol 13_017 and establishment of proportionate review criteria [CAG 6-05(d)/2013]

CPRD had identified a protocol that potentially fell into the 'high-risk' category based on the revised documentation considered separately by the CAG under application reference ECC 5-05 (a)/2012. This protocol was titled: Protocol 13_017R: Variation in the care of patients with bowel and blood

cancers at the end of life: a feasibility study evaluating the potential of data linkage in the National Cancer Data Repository.

CPRD had identified and presented to CAG the following risk areas:

1. Return of linked data to the data controller who might have access to identifiable data
2. Use of a data field that had a potential risk for re-identification
3. Small or specific population with risk of small cell counts based on rarity of outcomes or exposures & proposed stratifications

CPRD had subsequently proposed the following mitigations to manage the risk:

1. Acceptance, as a condition of the license agreement, that the privacy enhancing methodology was appropriate and adequate to prevent the facility to map the dataset against the original and enable re-identification, and notification of potential future audit to check compliance by CPRD.

2. Identification that a number of data fields had been atypically requested and that 'place of death' would be obtained from the Cancer Registry in this instance. It had been noted that place of death in its raw form would identify individual establishments, but the data included for this study would be a derivation of type of place of death (described as 1 home, 2 care home, 3 hospital, 4 hospice and 5 other).

3. Emphasis that when reporting the researcher should ensure that no cell should contain less than 5 events.

These conditions had been accepted by the researcher.

This protocol was considered in the context of the evolving decision-making documents undergoing separate consideration by Members at the meeting (item 5B). It was agreed that in the context of the evolving considerations underpinning the risk assessment process and the proposed controls for the data items requested as stated, that the disclosure and controls in place should be sufficient to render the data to be de-identified, and that a full application for support under the Regulations would not be required in this instance.

Members also discussed the feasibility of development of proportionate review criteria covering similar applications and were supportive of this in principle. It was agreed that the underpinning considerations and finalisation of documents would need to be in place and agreed before moving toward finalising the proportionate review criteria, and the Group would be happy to establish this from that point.

6. New applications – Research

6a. CPRD - processing of free text information [CAG 6-06(a)/2013]

This research application from the Medicines and Healthcare products Regulatory Agency (MHRA) Clinical Practice Research Datalink (CPRD) function was submitted to enable CPRD to process free text data in order to subsequently anonymise this information upon receipt. Access was not requested to specific identifiers although identifiers were likely to be present within free text data being received. Support was therefore requested to provide a lawful basis to enable CPRD to receive and anonymise incidentally received identifiable data contained within the free text.

Public interest and benefit

It was acknowledged that free text information was particularly sensitive, and while all efforts were made to anonymise the information, it was important to recognise that while the information may not be identifiable, it was extremely personal and reflected a life history. This high level of sensitivity therefore set an equivalent standard in terms of access to free text data without consent, and ensuring all reasonable steps were taken to retain public trust.

Members noted that the application indicated that free text data was of important research use but had not justified this explicitly. Members requested more specific examples to demonstrate the benefit including numerical data on, for example, the percentage out of 100 approved applications that required free text data. It was also suggested that the applicants could expand upon and articulate within the application form what the consequences would be should free text not be available, and this would be important to evidence the broader public interest in this activity taking place.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of free text information without consent existed, noting that free text fields typically held the most sensitive information about patients. Members also discussed the options of pseudonymisation at source and whether CPRD could act as a data processor on behalf of GPs.

Reiterating the point raised in the sub-group meeting, Members requested an explicit response to the question on whether there was a mechanism in place to enable parts of 'free text' to be extracted e.g. could the text be extracted and not the letters, as the understanding of the Group was that it would be possible to extract information in a hierarchical approach, so the applicant would need to work through each option, indicate if it was feasible and then explain for each option why it was necessary and relevant for each part to be extracted into CPRD.

Data Protection compliance and fair processing

It was noted from the discussion that CPRD were seeking to progress solutions and were in discussion with those leading on the care.data mechanism. As transparency and clear provision of information were essential and part of the broader government policy direction, Members noted that the leaflet supplied was developed in 2008, referred to GPRD and was out of date in terms of progress made within GPRD and CPRD since initial leaflet development.

It was understood that the intent was to utilise the care.data mechanism as part of the broader high level approach to fair processing, therefore Members agreed, while welcoming this progression, that until this situation was resolved support could not be recommended at the current time as it is a statutory requirement that approval is not inconsistent with the provisions of the Data Protection Act 1998. While care.data involves the provision of high-level information, Members requested an updated version of the patient leaflet (which also covered the overarching CPRD activity)

Members noted the statement that there was no intention to seek further ethical review on the basis that when GPRD merged into CPRD a protocol had been provided to the East Midlands Derby REC that indicated free text fields would be accessed. Members highlighted that the detail contained within this section was brief and the legal basis for the processing of free text data would have been unclear at this time as free text processing was not included within the overarching CPRD (or GPRD) approval; noting that the CPRD application provided only for the processing of anonymised data without consent by the MHRA. Additionally, the East Midlands Derby REC would not have had the benefit of reviewing a detailed application which set out in full the issues around the processing of free text patient information.

Following discussion with HRA colleagues, it was agreed that this new application should receive separate ethical review as it was separate to the overarching CPRD approval, not an amendment, and it was a requirement of the Regulations that research applications receive a favourable opinion from a REC.

Exit strategy

Linked to the issue of practicable alternatives, Members sought further clarity on the anticipated arrangements to move away from the proposed support, such as exploring further pseudonymisation at source and other technological and operational arrangements to reduce the need for identifiers to be incidentally received by CPRD. Information was provided within the application but Members indicated that these needed to be fully explored so that there was a clear pathway articulated to moving away from approval. Members also sought clarity on what happened to letters scanned into the system but not used by CPRD following discussion of retrospective cleansing of data.

Members noted the responses and indicated that a significant operation such as CPRD should undertake strong patient and public involvement and wider engagement. Members agreed that this was particularly important and that lay involvement should be broader than those groups involved in the approvals processes, so any plans for future strengthening of this important aspect should be incorporated within a revised application.

CAG advice conclusion

The CAG agreed that the minimum criteria under the Regulations did not currently appear to be met, and therefore advised recommending *deferral* to the SofS and the Health Research Authority, to enable the following actions to take place to bring the application within the framework of the Regulations:

a. Fair processing actions to be progressed in conjunction with the Information Commissioner's Office; assurance and approved patient information materials to be provided at the relevant time before any final approval could come into effect.

b. Revision of the application form to fully incorporate responses to the issues set out above. This was to include a cover paper to clearly show which sections reflected these responses within the application.

c. A favourable ethical opinion to be provided from a Research Ethics Committee on the revised application to be considered by the CAG.

d. A satisfactory level to be achieved within the IG Toolkit before any final approval could be provided; this could be carried out in parallel to CAG consideration of the application.

7. New applications – Non-research

7a. Enhanced quality assurance process of the provision of NHS-funded care for people with a learning disability or autistic spectrum disorder [CAG 6-07(a)/2013]

This service evaluation application from NHS England set out the purpose of two distinct activities which formed part of the actions arising from the national review of events at Winterbourne View Hospital, as published in 'Transforming care: A national response to Winterbourne' (Department of Health, December 2012), and its supporting concordat. A recommendation for class 1, 4, 5 and 6

support was requested, firstly to support triangulation of data on NHS funded care for patients with a learning disability or autistic spectrum disorder, and secondly to carry out a review of a random sample of care reviews carried out by local health and care commissioners to ensure that these reviews were properly conducted.

Public interest

Members noted that there was an obvious and significant public interest in this activity taking place, and strongly supported the purposes of the activity; noting that patient involvement also appeared to be good.

Triangulation activity

In reviewing the data flows, Members were unclear whether all of the data streams presently existed. It was agreed that, subject to clarifying this question, there appeared to be no other way to carry out this activity and it was appropriate for NHS number to be the sole identifiable data item used to link the data sources.

Members noted that a practicable alternative to this activity taking place under this support would be via Directions but the application stated that the time this could take could jeopardise the timescales for the activity. Members were disappointed to note this and proposed that in this specific instance only, due to the high public interest, that this explanation could be reluctantly accepted, and that future similar activities would be planned to enable this alternative legal basis to be utilised. The application also asserted that the HSCIC did not have the capacity to deliver this work alongside the Learning Disability audit: however, Members noted that the application did not provide evidence of this. Members requested that a written statement confirming these assertions should be provided from the HSCIC directly to evidence that there was no other practicable alternative.

Enhanced Quality Assurance Process

Members were also supportive of this safeguarding activity and noted that it appeared to be following a confidential enquiry methodology. Members also agreed that there was a high public interest in this aspect taking place and were therefore supportive of a positive recommendation. This was subject to the provision of specific detail on whom the EQAP team would consist of as it would be important to know to whom approval was intended to cover, and to receive assurances on arrangements to ensure the team understood the terms of the proposed approval.

Members noted that section (o) indicated a practicable alternative, but did not explain why this would not be a suitable approach. Members requested that this be refined and a detailed response provided to demonstrate that there was no other practicable alternative to achieving this aspect in this way.

Security assurance

Members noted that the arrangements must be proportionate to the sensitivity of the information, and it was agreed that this application covered extremely sensitive information. The application indicated that NHS England would not have an IG Toolkit submission until end March 2014: however, all applicants were required to typically receive a satisfactory level before any final approval could come into place. Members noted that this was a high priority activity and that it would be important to ensure that suitably appropriate and robust arrangements were established. Due to the fact that it was likely an IG Toolkit submission would not be in place, it was understood that the applicant had been liaising with the HSCIC IG Delivery Team to explore alternatives. Members requested specific written detail on what had been agreed, and confirmation of the approach from the HSCIC IG Delivery Team.

Fair processing

Members noted that they would need to understand how information about the activity would be provided to the relevant cohort, including patient right of objection, and that this would need to be reflected within the application.

CAG advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *provisional* support to the Secretary of State for Health, subject to compliance with the specific and standard conditions of support and further clarifications as set out below.

1. Clarification on which of the data sources are currently in existence

2. Specification of the composition of the team (e.g. organisation and role) and details on how it would be ensured that they were abiding by the terms of the proposed approval, under the remit of NHS England as the applying organisation.

3. Under section (w) there was a list of information that NHS England could collect but would not (e.g. union representation). Members requested that this be refined to include only those items that were intended to be collected to achieve the purpose.

4. Clarification of a precise retention period as the current approach appeared unclear. Members advised that a retention period be no longer than a defined time.

5. Detail of and clear undertakings on how security of information would be managed throughout the process. If an alternative to the IG Toolkit submission had been agreed, details to be provided.

6. Provision of statement from the appropriate person at the HSCIC to demonstrate that the relevant practicable alternatives were not feasible.

7. Revision of section (o) to expand upon the EQAP practicable alternative.

8. Clarification on fair processing and transparency arrangements.

7b. National Chronic Obstructive Pulmonary Disease (COPD) Audit Programme - Primary Care Clinical Audit Dataset Pilot Extraction [CAG 6-07(b)/2013]

This second audit application of a series from the Royal College of Physicians of London specified a pilot activity in order to test the submission of primary care clinical audit dataset to inform the National COPD Audit. The audit aims included:

1. To enable the improvement of the quality of care for COPD delivered in primary care settings, through the provision of high quality longitudinal data.
2. To enable providers of acute hospital care for COPD to improve the quality of care provided in these settings, through the provision of high quality time–limited data collections.
3. To enable providers of pulmonary rehabilitation for COPD to improve the quality of care provided in these settings, through the provision of high quality time–limited data collections.
4. To enable COPD care providers to improve the integration and management of their COPD services, through the periodic provision of organisational data.

5. To explore the potential for Patient Reported Experience Measures to be included in the national COPD audit programme in the future.

A recommendation for class 1, 5 and 6 support was requested in order for the Health and Social Care Information Centre (HSCIC) to access and extract audit data from GP practices in relation to all patients over 35 with a diagnosis of COPD on primary care registers. Access was requested to NHS number, postcode and date of birth.

Public interest

Members agreed that there was a substantial public benefit in the aims of the main audit activity given that COPD was a particularly prevalent condition with a high mortality rate.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

Members discussed whether consent might be feasible for this aspect of the process. It was noted that the applicant asserted that as complete as possible a dataset was required for the purposes of the pilot. Members were informed that the applicant had been asked to pilot consent for a previous application to extract data from a secondary care setting and that satisfactory justification had been received for this not being feasible. However, Members noted that this was a different care setting and queried whether it might be feasible to gain consent for some patients. Members agreed that they were cautious about presuming that consent would not be feasible for large national audits and that they would need to take into account the specifics of each activity and the conditions of care specified to determine whether consent was feasible. With this in mind, Members noted that it would be clear to GPs who would be included within the audit as data was requested in relation to those patients diagnosed with COPD only. Members requested that the applicant consider whether consent could be piloted in relation to this data collection.

- Use of anonymised/pseudonymised data

Members noted that identifiable data would be required for linkage purposes but that a pseudonymised data only would be provided to the Royal College of Physicians.

Automated data extraction from GP practices

Members noted that it was proposed that the Apollo systems would be used where installed to automatically extract data from GP practices. GPs would be given the opportunity to opt out but in some circumstances would not be asked to explicitly opt in. Members noted that this was a similar issue to that currently being discussed in the context of the Fragility Fracture Secondary Prevention Audit (CAG 4-08(b)/2013) and advised that further information would be required prior to making a recommendation in relation to this aspect. Members noted that a letter from the HSCIC had specified that the agreement in place with Apollo was that consent agreements between the Apollo client and GP practices would differ for each data extraction and it was agreed that CAG needed to understand the explicit agreements in place with GP practices around the data extraction for both the FLS and COPD audit. Therefore, whilst recognising that there may not be a current solution that would allow opt in rather than opt out, the Group were unsure whether this would contradict the current agreement with Apollo and whether all GP practices would be aware that data could be automatically extracted using this method. The Group requested further information in relation to the agreement in place

around this specific data extraction and confirmation that extraction without GP consent would be consistent with the agreement between the GP practices and the Apollo client.

Patient information

Members noted that the patient information submitted was for a secondary care setting and advised that a separate information sheet should be developed and made available via GP surgeries. Members requested a copy of this document.

CAG advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *partial conditional* support to the Secretary of State for Health, in relation to the pilot activity only, and subject to provision of the updated patient information materials and confirmation that the feasibility of piloting consent for this data collection had been considered. The aspect of the application which detailed the automated extraction from GP practices where GPs had not explicitly opted in to the use of this system was not included in the recommendation.

7c. National Clinical Audit & Quality Improvement Programme for Chronic Kidney Disease in Primary Care [CAG 6-07(c)/2013]

This audit application from Informatica Systems Limited set out the purpose of a national primary care CKD audit covering all GP practices in England and Wales and the interfaces between primary and specialist secondary care. This activity aims to improve the diagnosis and recording of chronic kidney disease (CKD) in primary care, to audit primary care management against NICE quality standards and understand and map the variation of patient care in this setting. A recommendation for class 1, 4 and 5 support was requested to enable patient information regarding all patients with relevant Read codes to be extracted from participating GP practices using a tool developed by the applicant and linked to Hospital Episode Statistics (HES) and Office for National Statistics (ONS) data. Access was requested to NHS number, date of birth and postcode.

Public interest

Members agreed that there was a public interest in the audit taking place and were supportive of the activity in principle.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

Members discussed whether consent would be feasible for this audit, taking into account the data requested and the conditions of care. It was noted that CKD was often not diagnosed and for this specific audit data would be collected in relation to patients with a number of different read codes, and not just those diagnosed with CKD. For this reason Members agreed that it would be difficult for consent to be obtained, given that it might not be clear which patients would be included within the audit.

- Use of anonymised/pseudonymised data

It was noted that identifiable data was requested in order to carry out data linkages.

Retention of identifiable data

It was noted that the application specified that data would be retained for the duration of the project. Members queried why this would be necessary for all patients, particularly why identifiable data would need to be retained in relation to patients who had died.

Patient information materials

Members reviewed the fair processing information provided and noted that the information leaflet specified that address data would not be submitted. However, postcode had been requested as part of the dataset detailed within the application. Members requested that the applicant ensure that the patient information leaflet was accurate and submit an amended version.

Privacy impact assessment

It was noted that the application confirmed that a privacy impact assessment would be carried out and Members commended this and requested that a copy of this be submitted once available.

Data extraction from GP practices

Members noted that Informatica Systems Limited's Audit+ solution would be used to extract data from GP practices and, in line with the discussion in relation to automated data extraction from GP practices within application CAG 6-07(b)/2013), sought confirmation that GPs would be asked to explicitly opt in to the data extraction.

CAG advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *provisional* support to the Secretary of State for Health, subject to clarification of the necessity for retaining data for all patients for the duration of the project, particularly in relation to those who had died; confirmation that GPs would explicitly opt in to the data extraction; provision of a copy of the privacy impact assessment; and provision of a copy of the updated patient information leaflet.

7d. Inflammatory Bowel Disease Registry [CAG 6-07(d)/2013]

This audit application from the British Society of Gastroenterology set out the purpose of establishing a national IBD Registry which would feed into national service development planning and fulfil national audit, IBD standards and quality improvement benchmarks. The application also detailed using the registry to allow patients to be identified for research purposes and for the Health and Social Care Information Centre (HSCIC) to write to patients on behalf of the applicant. A recommendation for class 4, 5 and 6 support was requested in order to access data, including NHS number, date of birth and postcode in relation to all patients in the UK who had been diagnosed with IBD. Data sources included HES, ONS, Bowel Cancer audit, cancer registries, IBD Registry patient management system and data collected via a web portal system. Data would be collected by the HSCIC and only pseudonymised data would be disclosed to the British Society of Gastroenterology for analysis purposes. Access was requested to NHS number, date of birth and postcode.

Public interest

Members agreed that there was a public interest in the registry being established and were supportive of the activity in principle.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

Members discussed whether consent would be feasible for this activity and noted that the intention was to establish a registry which would be used for both audit and research purposes. Members agreed that they were cautious about presuming that consent would not be feasible for large national audits and that they would need to take into account the specifics of each activity and the conditions of care specified to determine whether consent was feasible.

Members were of the view that there would be many advantages in requesting consent in this instance. This would ensure that any further requests for research would be on a consented basis and would not have to rely on further applications under the Regulations. It was noted that the patients in question were likely to be seen regularly by clinicians and therefore consent might be feasible. Members noted the assertions that the consent process would take between 5-10 minutes per patient and advised that the applicant explore simplified methods of obtaining consent. Members commented that the current patient information leaflet was quite long and could be simplified in order to ensure that those who wanted to take part were provided with the key information. This could then be followed with more detailed information when requested.

Additional points

- Research use of registry

Members advised that the stated research purposes would be excluded from the application and these would require specific applications to be submitted to both CAG and to the REC if the consent based approach specified above was not undertaken.

- Security requirements

It was advised that if an application under the Regulations was required, the Information Governance Toolkit should be completed for the British Society of Gastroenterology and that this might be required in any case by the HSCIC. The applicant was advised to contact the HSCIC to discuss requirements.

CAG advice conclusion

The CAG agreed that it appeared that consent would be feasible and therefore could not currently provide a recommendation of support.

7e. Assessment of the impact of infecting organism and approach to surgery upon the outcome of revision knee replacement performed for infection [CAG 6-07(e)/2013]

This service evaluation application from Newcastle University set out the purpose of a study to determine how the approach to and the type of infecting organism influence the rates of re-infection and re-revision following first time revision total knee replacement performed for infection, and to determine the geographical variation in the rates of revision for infection and the types of infecting organism encountered. A recommendation for class 4 and 6 support was requested to cover access by researchers at Newcastle University to data held by the National Joint Registry (NJR) and Public Health England to carry out data linkage. Access was requested to NHS number.

Public interest

Members agreed that the application outlined a worthwhile project and were supportive of the activity in principle.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

Members noted that the application requested information in relation to a geographically dispersed population and that contacting individuals for consent would be difficult. In addition it was noted that in order to seek consent a higher level of disclosure would be required.

- Use of anonymised/pseudonymised data

It was noted that NHS number would be required in order to link the datasets. However, the applicant proposed a pseudonymised approach to data linkage in which the National Joint Registry (NJR) would provide a list of NHS numbers and corresponding NJR numbers to Public Health England (PHE). PHE and the NJR would then provide the dataset to the researcher who would link the data using NJR number only. Members agreed that this method would be less disclosive than linking using NHS number and advised that the applicant pursue this methodology.

Classification of activity

Members discussed whether the activity would in fact be classified as research and requested confirmation from the applicant regarding whether this aspect had been considered. Members advised that if research the activity would need to be reviewed and given a favourable opinion by a research ethics committee. The applicant was advised to use the HRA decision tool as soon as possible for an opinion in relation to whether the activity was research.

Patient and public involvement

Members noted that the application did not include any details in relation to public and patient involvement. It was noted that the application specified that it might be feasible to consult patients using the national joint registry's patient network to gain insight into public and patient views in relation to the activity. Members requested that details of this consultation be provided.

National Joint Registry consent form

Members advised that the NJR should ensure that their consent form covered this type of activity in the future given that the NJR obtained consent for processing for the majority of patients.

CAG advice conclusion

The CAG agreed that they were supportive in principle of the application but required confirmation, prior to providing a final recommendation, of whether the activity would be classified as research, and encouraged the applicant to test this using the HRA online decision tool.

7f. CRIS Lambeth DataNet [CAG 6-07(f)/2013]

This service evaluation application from South London and Maudsley NHS Foundation Trust set out the purpose of a study aiming to utilise linked datasets in three projects investigating healthcare services provided to patients and identifying social characteristics associated with severe mental illness in the Lambeth GP patient population. A recommendation for class 4 and 6 support was requested in order to link the SLaM Biomedical Research Centre Clinical Record Interactive Search (CRIS) dataset, a pseudonymised case record system, and LDN - a local primary care database containing information from GPs in one of South London and Maudsley's four catchment boroughs. Data collected from LDN included a problem list summary of each consultation, each long term condition, all medication prescribed and all clinical values (blood test results and other investigations). Access was requested to year of birth, date of death and GP registration.

Public benefit

Members agreed that the application outlined a worthwhile project and were supportive of the activity in principle.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

It was noted that consent would not be feasible due to large numbers involved within the activity.

- Use of anonymised/pseudonymised data

It was noted that the data linkage activity would use the standard methodology adopted by other SLAM applications using the CRIS system and that most identifiers would be destroyed prior to linkages taking place.

Patient information materials

Members noted that the patient information materials provided were not specific about the current activity and the sharing of identifiable data for this purpose. Members advised that further patient information materials should be developed or current information leaflets should be updated in order to ensure that the cohort were made aware that there might be disclosure and linkage of datasets for purposes such as those specified within the application.

Further use of dataset

Members specified that support would only be recommended in relation to the use of the linked dataset for the specified projects within the application. Any further use would be subject to additional applications.

CAG advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *conditional* support to the Secretary of State for Health, for the specified projects only, subject to provision of the updated patient information leaflets. It was reiterated that any additional use of the dataset would require further applications for support.

8. ANY OTHER BUSINESS

There was no other business to transact and the meeting came to a close.