NHS
Health Research Authority
Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group
18 April 2013 at 10:30 am at Skipton House, SE1 6LH

Present:

Name	Capacity
Dr Mark Taylor (Chair)	Lay
Dr Charlotte Augst	
Dr Tony Calland	
Dr Robert Carr (items 1-7)	
Mr Paul Charlton	Lay
Dr Patrick Coyle	
Professor Julia Hippisley-Cox (items 1-7)	
Mr Anthony Kane	Lay
Professor Jennifer Kurinczuk	
Ms Clare Sanderson (items 1-7)	
Dr Murat Soncul	
Mr C. Marc Taylor (items 1-7)	
Ms Gillian Wells	Lay
Mr Terence Wiseman	Lay

Also in attendance:

Name	Position (or reason for attending)
Ms Natasha Dunkley	Confidentiality Advice Manager
Ms Claire Edgeworth	Deputy Confidentiality Advice Manager
Mr David Evans	Expert advisor – Data Protection Act 1998
Mr Martin Frowd	Senior Business Support Officer
Ms Suzanne Lea (item 6 only)	Programme Manager, Information Governance Review, Department of Health
Ms Rebecca Stanbrook	Director of Confidential Advice – section 251

1. INTRODUCTION, APOLOGIES FOR ABSENCE AND CONFLICTS OF INTEREST

Apologies were received from Dr Tricia Cresswell, Dr Kambiz Boomla, Ms Madeleine Colvin and Dr Christopher Wiltsher.

Professor Julia Hippisley-Cox, Ms Clare Sanderson and Mr C. Marc Taylor declared potential conflicts of interest with item 8, the Clinical Practice Research Datalink report, and were not present for the discussion of this item.

The Chair welcomed Members to the first meeting of the Confidentiality Advisory Group (CAG) and set out his aspiration to continue to develop the CAG as a source of credible advice and high quality expertise, noting that significant amounts of work had taken place under the ECC and PIAG and therefore the aim was not to reinvent the wheel but to continue to deliver improvements. He noted the high calibre of Members and indicated that the advice to be provided was often not a crude balance of two public goods, research/other uses of patient information and confidentiality, but rather a contextually defined situation that could involve finely balanced considerations.

2. CAG ESTABLISHMENT

Ms Stanbrook delivered a presentation on the draft Terms of Reference for the Group and Terms and Conditions for Members for discussion.

Terms of Reference

The Chair clarified that the Regulations currently governing the work of CAG (the Health Service (Control of Patient Information) Regulations 2002) were laid under section 251 of the NHS Act 2006 (as re-enacted), but it was likely that changes to the Regulations would be made in future. Responsibility to advise the Secretary of State for Health on amendments to the Regulations had transferred from the National Information Governance Board to the Care Quality Commission (CQC), to be exercised by their National Information Governance Committee once appointed. There was no requirement for CQC to consult the Group, however, as the Health Research Authority via CAG would be the body responsible for advising on applications submitted under these Regulations, Members were clear that it would be of benefit for CAG to have some involvement in any proposed changes. Ms Stanbrook confirmed that discussions were ongoing between the CQC and the HR Department of Health sponsors to seek to find a relevant point of contact within the CQC in order to progress this aspect.

Members sought clarification on the process for choosing an alternative Vice Chair in the absence of the Chair or Vice Chair, and in whether the Chair, Vice Chair or alternate Vice Chair were required in order for a meeting to be deemed quorate. Members noted that an alternative Vice Chair could also be useful in the event that the Chair or vice-Chair were unavailable or had conflicts of interest. The Chair noted that Dr Patrick Coyle had acted as an alternative Vice Chair with respect to proportionate review applications in January-February 2013 while the Chair and Vice Chair had focused on transition related business, and thanked Dr Coyle for his support.

Members agreed that the preference was to have a named alternative Vice Chair and agreed to elect to this role via an email-based election process. This post would support the Chair and Vice Chair on relevant sub-groups and for proportionate review activities.

Action: Confidentiality Advice Team to arrange election by email for an alternative Vice Chair

The Group ratified the Terms of Reference subject to the amendment that the alternative Vice Chair would be a standing role elected by the Group as a whole, rather than chosen by Members present at a given meeting for the duration of that meeting only.

Other comments were provided on quoracy of CAG, which was confirmed as nine Members including the Chair/vice-Chair, and clarification was provided on the terms of appointment for transferring and existing Members.

Conflict of interest policy

The Chair presented the draft Conflict of Interest policy, highlighting the distinction between a general declaration of interest that would be provided by Members as part of joining the CAG and a specific declaration of interest. Specific declarations would require an assessment on handling. Specific declarations of interest were further divided into conflicting and competing interests. The purpose of this policy was to demonstrate transparency, provide public confidence in CAG operations, and to assist the Confidentiality Advice Team when allocating applications.

The Chair suggested that conflicting interests should always require the declaring Member's exclusion from the room and any discussion or advice, while competing interests would permit the Member to remain present and contribute to discussion, as long a declaration was made. Members welcomed a flexible and transparent approach to declaring conflicts, noting the perception of conflict could be as important as an actual conflict and therefore transparency was crucial. It was noted that declarations might need to reflect both individual and organisational interests and that conflicts might arise from past as well as current employment. Members noted that on occasion, a Member with a declared conflict against a specific application might also be the only source of specific information or expertise available to the Group, and agreed that in such situations, a declaring Member could still be asked specific questions by the Group before being excluded from the remainder of the discussion. It was agreed that the operation of this policy would need to be developed over time and that the final arbiter on any question of conflict of interest would be the Chair, or the Vice Chair if the conflict involved the Chair. Members were reminded that they were responsible for raising any potential conflicts in advance of meetings with the Advice Team and the Chair and Members would be welcome to propose suggested wording to reflect any conflict.

Members agreed to accept the Conflict of Interest Policy.

Standing Operating Procedures

Ms Stanbrook presented the Standard Operating Procedures for CAG, which had been designed through aligning Ethics and Confidentiality Committee concepts, processes and terms with those of the HRA's Research Ethics Committees. These included validation of applications, the role of the Confidentiality Advice Team, meeting structure, proportionate review processes and potential outcomes. It was emphasised that the Group was an advisory body, with final decisions on applications taken by the HRA for research applications or the Secretary of State for Health for non-research applications. As a result, it was imperative that new applications were correctly identified as research or non-research, and recorded accordingly for approval purposes. The Chair noted that where it was unclear whether an application should be defined as research or not, HRA guidance could be sought.

Members requested criteria for when it would be appropriate for an applicant to attend a meeting of the Group, and how Freedom of Information Act 2000 requests would be handled, including which elements of an application would be published. It was noted that the HRA has a Freedom of Information policy at the corporate level and therefore it was not necessary to include this separately in the Standard Operating Procedures. It was noted that FOIA requests would be handled by the responsible officer at the HRA, who would take the final decision on disclosure. Members agreed that most details of an application should be disclosable under the Act.

Members made a number of comments on the SOPs. The advice outcome section was discussed and Members agreed that the section should be amended to include further details in relation to the consequences of a particular outcome. Applicants would then be aware of the next steps and expectations when receiving an advice letter. Members considered that a flow

chart may be particularly helpful in demonstrating what further actions would be required by the applicant.

The ICO adviser noted that the ICO was not referenced within the summary pages and recommended that this be updated to reflect that the ICO had an expert advisor who sat on the committee.

Members noted that the process for discussing issues with NRES should be updated to ensure that the Director of Confidential Advice – s251 was kept informed, as well as the REC Operations Manager.

Members suggested updating the SOPs to include criteria where applicants might be expected to attend a meeting, to ensure that this could be referenced when requests to attend were received.

The process for co-opting experts to give specialist advice was noted and it was suggested that this should be updated to reflect that written advice, as well as attendance at meetings, could be requested by CAG.

Members suggested the annual review template should include a question on dissent and specifically whether any patients had dissented, and highlighted that the question on evidence of funding for an application might be problematic as some funders might only confirm funding once an application was approved.

Ms Stanbrook presented the process by which applicants dissatisfied with the advice given by the Group, or the final decision, could make representations via the HRA or the Department of Health as appropriate. Where a representation was made, the Group would be asked to consider whether there was any change to the advice originally given. It was confirmed that the HRA, or the Secretary of State in the case of non-research applications, retained the right to take a final decision different to that recommended by the Group's advice, but it was considered very unlikely that this right would be exercised. Members suggested that this might give rise to a conflict of interest, or perception of such, by the Secretary of State or Department of Health if a representation was received from the Department of Health itself against advice given by the Group on a non-research application submitted by the Department. It was noted that the Secretary of State remained subject to judicial review in the event of any conflict or perceived conflict, and that the final approval process for non-research applications was the same as had been in place during the lifecycle of the National Information Governance Board and its Ethics and Confidentiality Committee, prior to the Group's establishment. Members suggested that improving transparency and external confidence in the Group would decrease the likelihood of representations against advice. Ms Stanbrook confirmed that the Standard Operating Procedures would reflect the relationship between the Group and the Human Fertilisation and Embryology Authority once the Memorandum of Understanding had been finalised.

The Chair highlighted a need to consider methods for appointing the future Chair and Vice Chair and incorporate these into the Standard Operating Procedures, noting that final authority on the appointment of the Chair would continue to rest with the HRA. Members suggested that the departure of the Chair and Vice Chair at the end of their term should be staggered in order to improve continuity, and noted that the alternative Vice Chair, once elected, could act as Vice Chair if necessary during a transition period. It was confirmed that the Establishing Chair was eligible to reapply following the end of his term. The Chair noted that Dr Tricia Cresswell had been elected Vice Chair by the Ethics and Confidentiality Committee at their February 2013 meeting, and asked the Group to reaffirm this election outcome for the duration of Dr Cresswell's one year term. **The Group unanimously ratified the previous election of Dr Tricia Cresswell as Vice Chair for one year.**

Action: Terms of reference and Standard Operating Procedures to be updated and published

Regulation 3 remit.

Following the issue of Directions (not available at time of discussion) that established the Health Research Authority as an approving organisation for research applications, and subsequent conversations with the Department of Health, there had been a change to the CAG's role on the application of Regulation 3.

Under the Directions, the CAG would advise on Regulation 2, 5 and 3(4). Under Regulation 3, the bodies that can process identifiable information for the defined purposes are already specified so no further approval would be required on this aspect, nor CAG advice. Regulation 3(4) however does requires an approval mechanism as it does not permit access, but requires data controllers to provide information. Members noted that the application of Regulation 3(4) had never been invoked beforehand as the Regulations had generally been utilised in a permissive manner.

Members noted that this new understanding of Regulation 3 could lead to practical difficulties as a key component of this Regulation was operating under the definition of "other risks to public health". These had not been defined, therefore Members were concerned that while undefined this could potentially enable a large number of activities to be processed under this unclear definition. Mr Phil Walker had stated that he would provide a short paper to CAG as it would be important for CAG to have an agreed and mutual understanding of what fell within and without this definition. This would be essential for the Confidentiality Advice Team so that they could advise applicants accordingly and/or know where to direct applicants. Members also noted that the ECC had provided a safeguard in that there was a light tough oversight and it was unknown what new oversight would be in place. Considering the move of public health activities to local authorities, Members queried what safeguards were in place to ensure that those operating under this support could be sure that they were processing information under the right legal provision, and to be clear when they would be moving outside this. Members confirmed that CAG would support any new interpretations and would be willing to work with relevant partners so that those operating under the Regulations were clear on their responsibilities.

In the interest of time, the HRA induction for Members was deferred to the June meeting.

3. MINUTES OF THE ETHICS AND CONFIDENTIALITY COMMITTEE (ECC) MEETINGS HELD ON 6-7 FEBRUARY 2013

The minutes of the final ECC meeting were agreed as an accurate record.

4. MATTERS ARISING

Transfer into Public Health England

Ms Natasha Dunkley advised Members that Public Health England had notified the ECC in December 2012 that specified functions with existing support under the Regulations would be transferring into Public Health England. Due to the issue around Regulation 3 that had been recently identified, this would have an impact on the communicable disease surveillance activities currently carried out by the Health Protection Agency, however, as some of the named functions were class applications approved under Regulation 5, the CAG would have remit to advise on these aspects. The transferring functions were confirmed as follows:

1. National Cancer Registry Databases (*Regulation 2*)
2. Communicable Disease Surveillance and Control (*Regulation 3*)
3. Congenital Anomalies Register (BINOCAR) (*Regulation 5*)
4. Contacting National Health Applications & Infrastructure Services (NHAIS) data subjects for Cancer Screening Programmes in England (*Regulation 5*)
5. End of Life Care Repository(*Regulation 5*)
6. National Drug Treatment Monitoring System (*Regulation 5*)

Members clarified that of seven existing congenital anomaly registers, only two would be transferring into Public Health England's direct control, and that the Department of Health had confirmed the Healthcheck programme would not come under Regulation 3.

Action: Confidentiality Advice Team to write to Public Health England and transferring functions to seek clarity on transfer arrangements.

Changes to the Central Register and management of class applications

Ms Claire Edgeworth advised Members that the Health and Social Care Information Centre's NHS Central Register application (ECC 2-04(c)/2010) had been extended for one year to allow time for around 150 separate studies currently covered under this approval to submit separate applications for support. It was agreed that these studies should be reviewed initially by the Confidentiality Advice Team under the proportionate review process as they already had support in place as part of a wider application. A truncated application form would be used for this purpose and a draft of the application form and accompanying guidance was submitted and approved by members.

Guidance on Data Protection

The Chair advised Members that data protection guidance had been revised with the assistance of the ICO. The intent would be for the question specific guidance on IRAS to be updated to include this aspect once the facility to change text within the HRA had gone live. It was agreed that the Central Register class application process would present an opportunity to gain feedback on the amended guidance and should be provided to applicants.

NHS Mail

Ms Dunkley reminded Members that NHSmail email addresses had now been put in place for all Members who did not already have secure organisational email addresses, and the aim was for all future email correspondence with relevant Members to be via those new addresses. Members asked whether the new addresses would facilitate downloading attachments, and Ms Stanbrook undertook to review the policy on downloading emails.

Date of death follow-up discussion

The Chair tabled a draft paper on date of death following on from the February 2013 discussion item (ECC 9-03/2013), and invited Members to join a sub group to develop the paper further. Members suggested that date of death, while not confidential in itself, might become so if linked with other identifiers, but also emphasised a need to avoid implying that the aim was to make information that was already public confidential. Professor Julia Hippisley-Cox, Mr Anthony Kane, Mr Tony Calland, Ms Clare Sanderson and Ms Gillian Wells agreed to join the sub group.

Action: Confidentiality Advice Team to arrange sub-group meeting

5. CAG OFFICE REPORT

Secretary of State approval decisions

The DH senior civil servant on behalf of the SofS agreed with the advice provided by the ECC in relation to the February 2013 meeting applications.

Organisational transfer update

HSCIC application closures

Following the enactment of the Health and Social Care Act 2012, it was noted that a number of applications from the Health and Social Care Information Centre (HSCIC) would no longer require support under the Health Service (Control of Patient Information) Regulations 2002, as the HSCIC would have their own statutory powers to process confidential patient information. It was confirmed that the following applications would not require support and therefore be marked as expired and formally closed from the 1st April 2013:

1) ECC 2-04(c)/2010 NHS Central Register (support would continue for class support applications aspect as detailed within the 2013 annual review)
2) ECC 2-05(a)/2010 Hospital Episode Statistics
3) ECC 2-04(b)/2010 MIDAS (MRIS Integrated Database and Administration System) – the system developed within Project Sutton
4) ECC 7-04(f)/2010 Improving Access to Psychological Therapies
5) ECC 3-04(b)/2011 Disclosure and use of NHS activity data in relation to community services
6) ECC 3-04(c)/2011 National Dementia and Antipsychotic Prescribing Audit
7) ECC 8-05(c)/2011 Diagnostic Imaging Dataset (DID)
8) ECC 6-05(a)/2012 Use of patient identifiers from the MHMDS to facilitate linkage to HES in order to test the provision of a regular routine linked data extract containing anonymised record level mental health and HES data (A further report was requested within the outcome letter)

Following correspondence, it was indicated that it was unclear whether a number of national audit applications commissioned by the Healthcare Quality Improvement Partnership (HQIP) would fall within the HSCIC's new statutory powers and that legal advice was currently being sought by the HSCIC in relation to these. It was agreed that support under the Regulations would continue to be provided until this was confirmed by the HSCIC.

Cancer Registries interim annual review of specific support

At the December 2012 meeting, ECC Members discussed how assurance would be provided for those functions with existing support that would transfer into the governance arrangements of Public Health England (PHE). It was agreed that PHE would provide a full report at the October CAG meeting including confirmation that there were appropriate governance controls in place to ensure that the information was processed in line with the agreed purposes. The cancer registries had provided a short interim report that confirmed the following:

- In terms of transfer, the report confirmed that in April 2013 the cancer registries and the NCIN would transfer into PHE and both aspects would be under the management of the Chief Knowledge Officer (CKO). The functional areas of registration and analysis had been formally split, and were now each accountable to a different deputy director of the CKO. The perspective was that the formal split of roles should further strengthen the differentiation between the data that was needed to undertake registration and that which was needed for analysis. The report acknowledged that there were outstanding questions to be answered but clarity would only be obtained as PHE developed.

- The continued migration of the disparate cancer registry systems to ENCORE to constitute a single system was progressing well and completion was expected by June 2013.

- The new Cancer Outcomes and Services Dataset had been approved by the Information Standards Board and had been mandated for data collection from January 2013.

- There had been a review of national cancer audits to ensure value for money. Work was taking place with the Healthcare Quality Improvement Partnership's existing and future audits in order to utilise the new data management and quality assurance infrastructure

that the ENCORE system provided. There were already plans in place for the HQIP funded National Prostate Audit to use the ENCORE system and the other audits were out for tender.

- The report highlighted new sources of cancer registration data and the Systemic Anti-Cancer Therapy (SACT) dataset. The SACT implementation programme was part way through its 2-year plan to establish electronic recording of chemotherapy drugs administered to patients in secondary care across all Trusts in England. The dataset flowed to a specialist intelligence unit based within the Oxford registry, staffed by a small team of registration and clinical experts, who provided initial quality control checks on the data and worked with clinical teams to improve the quality of this complex data. There was keen external interest in utilising this resource and currently any access to identifiable or potentially disclosive information would operate under the Registries' existing data access rules.

Separate to this interim report, a draft proposal was received by the HRA via Sir Alex Markham. This proposal set out various challenges to research use of cancer registration data and proposed a system of access. As this proposal was at an early stage, they were advised to seek input from the cancer registries in developing this potential access regime, liaising with the advice team at the appropriate time.

Legal advice / guidance update

Legal advice in relation to accessing patient data generated outside the NHS context

A request for advice in relation to application ECC 6-05 (b)/2012 HES Linkage to Private HES was submitted to Department of Health lawyers in November 2012. The advice sought was in relation to whether data which was not generated within an NHS context could fall within the remit of the Regulations. The application was considered at the December 2012 meeting and Members agreed that due to the nature of the application a final recommendation could not be made until this advice had been provided. The legal advice had now been received and indicated that the Regulations would apply to patient information generated outside an NHS context, i.e. private healthcare data. The applicant had submitted further information in relation to the requested clarifications and this would be considered outside a meeting by Members who reviewed the application in the first instance.

Sexual health directions

It had previously been advised that where patient data fell within the NHS Trusts and Primary Care Trusts (Sexually Transmitted Diseases) Directions 2000 (Sexual Health Directions), i.e. where patient data was collected in relation to the treatment of a sexually transmitted disease by a Primary Care Trust (PCT) or NHS Trust or Foundation Trust, identifiable data could only be disclosed where one of the exemptions within the Directions was in place. The exemptions were where the disclosure would be supporting the treatment or the prevention of sexually transmitted diseases. Where an exemption was in place the disclosure would take place under the Directions and an application for support under the Health Service (Control of Patient Information) Regulations 2002 would not be required. However, where an exemption did not apply the Directions prohibited the disclosure of identifiable data, even with an application for support under the Regulations.

The Department of Health had confirmed that from 1 April 2013, following the abolition of PCTs and Strategic Health Authorities, the Directions would apply only to NHS Trusts and NHS Foundation Trusts. Once Health and Social Care Act 2012 amendments to the NHS Act 2006 were fully implemented, the relevant power for the Secretary of State for Health to make regulations and directions (section 8 of the NHS Act 2006) would be amended to apply only to Special Health Authorities. The intent was, therefore, to revoke the Directions as they would no longer had legal effect from this point. However, all providers of health and social care services would be legally obliged to have regard to the new Code of Practice on sharing patient identifiable information, once this was developed by the Health and Social Care Information

Centre. While the CoP does not currently cover STI services in the context of the revocation of the Regulations, it will provide an opportunity over the coming months to develop guidance, which would be binding on the NHS and local authorities. The CoP and new Guidance will be an important means of reaffirming the importance of keeping information about a person's use of NHS STI services, detached from their other NHS care records. The guidance will also reflect the importance of being able to share this information with other healthcare professionals where the individual had expressly consented to do so.

Members were therefore advised that the Sexual Health Directions would shortly be revoked and data that would have fallen under the Directions would no longer be prohibited from being disclosed and would therefore fall within the remit of the Regulations.

Anonymisation standard for publishing health and social care data

This standard had been approved by the Information Standards Board for Health and Social Care. The publication of this standard and supporting implementation guidance would assist Health and Social Care services to meet their legal responsibilities for protecting patient/service user information from unlawful disclosure, more specifically, when required to publish more information in line with the Government's Transparency agenda. It also aimed to provide organisations with an agreed and standardised approach, grounded in the law, for distinguishing between identifying and non-identifying information, and to specify a set of standard tools for ensuring, as far as was reasonably practicable to do so, that any information released or published could not identify individuals.

External events

HRA training event

Dr Mark Taylor and Ms Claire Edgeworth presented at two HRA training days held in February and March which covered uses of Personal Data in Research. Topics included the legal issues a researcher was required to consider when using confidential patient information with or without consent and the role of CAG.

REC training event

Ms Claire Edgeworth attended London City & East Research Ethics Committee on the 7 March to provide a presentation on the use of identifiable patient data in research. The presentation included an overview of the legal framework of the use of identifiable patient data without consent and the role of CAG.

Information Governance Toolkit presentation

Ms Natasha Dunkley delivered a presentation at the Information Governance Toolkit (IGT) for Clinical Research and Education Departments that was hosted by the NHS-HE forum (in conjunction with the NIHR CRN Coordinating Forum). The aim of the presentation was to provide views on the Information Governance Toolkit in the context of applications from both the NIGB and the HRA perspectives. Attendees consisted of the Associate Director-Collaboration and Development from the HRA, a number of existing applicants, representatives from academic and higher education communities, and Sir Alex Markham. As the NIGB had recently published its consultation response on the IGT, there was significant discussion on challenges faced by applicants in completing the IGT; there were also case studies from applicants who had undergone the Toolkit process. Unfortunately the Department of Health representative was unable to attend on the day. However, the event provided a valuable opportunity to listen to concerns and discuss possible solutions. In the short term, the aim was to work with the IG Delivery team to initially refine guidance to make clearer the process.

Operational

Staff transfer

Following the abolition of the NIGB on the 31st March 2013, the ECC team within the NIGB had transferred to the HRA and had been renamed the Confidentiality Advice Team to more accurately reflect the remit.

Changes to meeting deadlines

Ms Claire Edgeworth confirmed that the meeting deadlines had been adjusted from those originally issued to Members. Meeting dates remained unchanged. The meeting dates and deadlines were listed on the HRA website.

Advice provided to the Human Fertilisation & Embryology Authority (HFEA)

The National Information Governance Board developed an agreement with the HFEA for the NIGB (via the ECC) to provide advice to the HFEA on whether access to its Research Register should be granted. As the HFEA remained the data controller for this register, ECC advice was provided directly to the HFEA as no approval was required from the Secretary of State. The HFEA had requested that this advice service be continued under the HRA and had developed a revised Memorandum of Understanding. This had been agreed in principle with the HRA, subject to internal checks for consistency, therefore the CAG would also continue to advise the HFEA on access to the research register.

HRA stakeholder events

The HRA carried out two stakeholder events in Manchester and London in January 2013 in order to obtain views from stakeholders on the HRA establishment of CAG and to listen to any concerns from attendees. It included presentations from Dr Janet Wisely, Dr Mark Taylor and Ms Natasha Dunkley and was attended by a number of interested stakeholders including academics, government departments and independent patient charities. Attendees posed a number of questions and the Confidentiality Advice Team had responded to these. The questions and responses had been published on the HRA website.

Media Activity

The NIGB received a Freedom of Information Act request from medConfidential for the documentation submitted by NHS England that was considered on 14 March 2013. Due to the impending abolition of NIGB, this was processed and completed on 28 March. This had arisen from an article published in the Health Service Journal (HSJ) and all information was disclosed, including minutes and supporting correspondence. A separate letter was also sent to the Chair from medConfidential, Big Brother Watch and Privacy International expressing concerns over the potential application. This letter was included in the papers for the NHS England submission. There had also been recent press activity over the NHS England article via the HSJ and Pulse.

Applications considered via proportionate review

CAG 1-06(FT1)/2013 Hounslow and Richmond Community Healthcare NHS Trust – Community Nursing Survey

This service evaluation application from Hounslow and Richmond Community Healthcare NHS Trust detailed sending a survey to patients that had been seen by the community nursing survey between 1 October and 31 December 2012. The application detailed that the size of this cohort was not likely to exceed 1,000 patients. The application detailed that name and address details would be sent to NHS Quality Health in order to send surveys to patients. Date of birth and NHS number were requested in order to carry out mortality checks using DBS. No clinical information apart from the fact that the patient has received treatment from community nursing

would be submitted to Quality Health. This application was considered under proportionate review criteria 1: *applications to identify a cohort of patients and subsequently to seek their consent.*

Support was recommended in order to access data from DBS. Support was not deemed necessary for Quality Health to access contact details in order to disseminate surveys, as it was noted that they would be acting as data processor for one NHS Trust in this instance.

CAG 1-06(FT2)/2013 HES Cancer Extract

This audit application from the National Cancer Services Analysis Team requested support to hold a database of hospital episodes and cancer registration records related to cancer services in England, to link databases together and to share processed HES data, and linked data with the Cancer Registries in England. The data would be used to support cancer policy development, cancer service reconfiguration, and to support the National Cancer Program, both centrally and in the form of Cancer Networks, NHS service providers and commissioners of cancer services. This application was considered via Chair's action under proportionate review criteria 8: *Amendments to approved applications.*

This application consolidated the following 3 applications:

1. 1-08(l)/2003, Data analysis of existing data sources to demonstrate variation in cancer service provision in England
2. 4-09(e)/2003, Inter-comparison of data collected by ONS on cancer registration, and held as part of the HES database of hospital admissions by ONS
3. 1-07(p)/2004, Collaboration with cancer registries to share work carried out by the NatCanSAT using HES and NSTS data, with Cancer Registration Data

A combined application had been requested as all three applications referred to the same data extract, however they had been submitted separately over a number of meetings. As it had been indicated that funding was likely to move to NHS England from April 2013 it was agreed that one resubmission should be made to cover all three applications to ensure clarity in future. The application was forwarded to the Chair who noted that the purposes remained the same as the original applications. It was noted that the previous application had not explicitly stated that cancer audit data would be accessed; however the Chair agreed that this could be supported given that the processing would be in line with the original purposes, and was of the view that this would not raise any new issues.

CAG 1-06(FT3)/2013 ETPOS European Transfusion Practice and Outcome Survey: An observational outcome study of transfusion practice in surgical patients (excluding cardiothoracic surgery) throughout Europe

This research application from the Royal Free London NHS Foundation Trust detailed a European study of pre-operative transfusion practice with the aim of describing difference in transfusion practices throughout Europe and correlating with perioperative outcomes. Support was requested to allow data to be collected on all patients over the age of 18 years undergoing elective or emergency surgery who received one or more units of packed red blood cells during the intraoperative period. Each patient would be followed up at 30 days by the local principal investigators who would be consultant anaesthetists. Anonymised data would be extracted on a case report form and sent to the Chief Investigator. This application was considered via the proportionate review process under criteria 3; *where applications are accessing data on NHS sites to extract anonymised or pseudonymised data*.

Members agreed that the study was important and noted that there was a huge variation in the use of blood during surgery. Members commented that the study was well constructed and the quality of the data that could be obtained would be likely to outweigh the minimal risk to patient confidentiality from local Principal Investigators accessing confidential patient information. The assertions made about the difficulty of consenting patients were noted and Members agreed that this would mean that consent would not be feasible in this instance. Members noted that the application referenced patient notices being put up in hospitals and requested that a copy of

this be forwarded to the Confidentiality Advice Team. Members noted that the application made reference to using the NHS data linkage service if 30 day outcomes were not known by local hospitals. Members commented that in their view the surgical team should be able to provide information in relation to the mortality of a patient at 30 days and agreed that further justification would need to be provided if access to NHS Central Register data was required. A recommendation of support was provided, subject to confirmation of REC favourable opinion and confirmation of satisfactory security arrangements.

CAG 1-06(FT4)/2013 A Pilot Study to Inform a MultiCentre Randomised Controlled Trial of an Impedance Threshold Device (ITD) – the ResQPOD, in Cardiac Arrest

This research application from Newcastle Upon Tyne Hospitals NHS Trust detailed a pilot randomised control trial to test the long term benefits of the ResQPOD impedance threshold device. This would inform and test the feasibility of a larger, adequately powered study. Support was requested to allow a research paramedic to be assigned within the North East Ambulance Service who would collect information on patients following the intervention and use this to obtain follow up details about the patient's treatment. Where a patient survived and was admitted to hospital, identifiable data would be collected to allow consent, or assent from relatives where the patient lacked capacity, to be obtained within 48 hours of admission. No identifiable data would need to be retained if it was established that a patient had died prior to admission. This application was considered via proportionate review under criteria 1; *applications to identify a cohort and seek consent* and, where a patient is deceased, under criteria 2; *applications to access deceased patient's data*.

Members noted the assertions that consent would not be possible at the time of the intervention due to the emergency nature of the situation and that consent would be sought as soon as possible from those who did survive. Members agreed that consent would not be feasible in a situation where a patient was in cardiac arrest and noted that identifiable data would be required in order to link the patient through recovery and administer consent. A recommendation of support was provided, subject to confirmation of REC favourable opinion and confirmation of satisfactory security arrangements**.**

CAG 1-06(FT5)/2013 Investigating the Safety of Medication Use in Primary Care

This research application from the University of Hertfordshire detailed a study which aimed to carry out a review of patient notes within six GP practices and pharmacies in order to review prescribing errors and meet the following objectives:

- To characterise existing systems of error identification, reporting and recording at PCT and primary healthcare organisation (general practice and community pharmacy) levels,
- to assess the safety culture of primary healthcare organisations,
- to develop primary care definition of prescribing errors and their categories,
- to determine prevalence and types of prescribing errors in general practice, and to assess dispensing accuracy in community pharmacies, and
- to design, implement and evaluate a practical error preventing intervention for primary healthcare organisations, in the UK.

The applicant requested support to allow a researcher to access 600 patient records within GP practices and 2000 prescribing records from community pharmacies in order to extract de-identified data only. This application was considered via the proportionate review process under criteria 3: *Where applicants are accessing data on-site to extract anonymised or effectively pseudonymised data.*

Members agreed that seeking individual consent for this activity would be impracticable given the retrospective nature of the records being reviewed and noted the potential benefit of the outcomes to patients. Members discussed that the completed IRAS form indicated that NHS number would be required in order to carry out linkage or validation. Members requested that the applicant provide further information in relation to whether NHS number would be recorded and if so for what purpose. In addition, Members queried how pharmacy records would be identified. It was noted that whilst the patient information poster detailed that the University

would be involved in the study it was not explicit that University staff would have access to patient records. Members requested that the applicant update the poster to reflect this.

Members agreed that the minimum requirements of the Regulations appeared to have been met and agreed to provide a recommendation of approval for this activity, subject to confirmation of whether NHS number would be recorded by the researcher and if so for what purpose, and details of how identification of pharmacy records would be carried out. Any approval would also be subject to a favourable REC opinion and confirmation of satisfactory security arrangements.

CAG 1-06(PR6)/2013 AMICABLE Airway Management in Cardiac Arrest Study V1.1

This research application from London Ambulance Services NHS Trust detailed a study to evaluate the influence of airway management strategies on survival and quality of life where successful pre-hospital resuscitation had taken place. Support was requested to allow a researcher, employed by London Ambulance Services NHS Trust, access to contact details and survival status in order to contact the patient and seek consent and complete quality of life questionnaires. This application was considered via proportionate review under criteria 1: *Applications to identify a cohort of patients and subsequently to seek their consent.*

Members agreed that the proposal to access confidential patient information in this instance was reasonable, given that consent would not be possible at the time of treatment and that identifiable data would be required in order to identify which heart attack centre patients were admitted to. Members queried whether the researcher would have legitimate access to the required London Ambulance Service (LAS) data as part of their role within the Trust and requested further clarification in relation to this. Members discussed that it was unclear whether any clinical information would be extracted from LAS data prior to consent. It was noted that a researcher would require access to demographic data in order to request survival data from heart attack centres, however further clarification was requested in relation to whether any clinical data would be accessed from LAS prior to determining survival status. Members requested clarification in relation to what information would be required from the LAS if a patient was found to be deceased, in order to include the patient in the study. Members agreed that the minimum amount of data possible should be accessed prior to consent or survival status being known.

It was noted that the primary aspect of the application included approaching patients for their consent. Members requested further information in relation to how data would be used where a patient could not be contacted or did not respond to the request for consent as this was not clear within the application form. Members noted that the application specified that data would be stored in an anonymised format but would include NHS numbers. Members advised that where NHS number was included in a dataset the data would not be effectively anonymised and therefore where feasible a unique reference number should be attached to individual level data, which would not allow identification in itself. Members reviewed the patient information materials provided and commented that the information seemed particularly technical. It was noted that a REC favourable opinion in relation to the materials had been obtained, however Members requested that the applicant ensure that information in relation to dissenting from the study was presented clearly within the information sheet. Members emphasised that the request for consent should be accompanied by an introductory letter from the clinical care team. It was noted that this was also a requirement of the REC favourable opinion. Members noted the intention to contact patients via telephone and suggested that telephone contact was particularly intrusive where no consent for such contact had been given. Members suggested that it might be feasible for the patient's clinical care team to call the patient to introduce the study or that a telephone number could be obtained from a public record as an alternative to disclosing this data.

Members sought clarification on whether the researcher would have legitimate access to the database and all data accessed at LAS NHS Trust as part of their role within the Trust, and what clinical information would be accessed at LAS NHS Trust, prior to ascertaining survival status and seeking consent. Members also requested clarification in relation to the information required in order to include deceased patients in the study, and asked how data from those who

had not provided consent or could not be contacted would be managed. Members requested clarification on how long such data would be retained in an identifiable format and confirmation of the process to be used for anonymising the data, particularly given Members' advice that a dataset containing NHS numbers would be considered identifiable.

A recommendation of support, pending satisfactory responses to the request for clarification was made. Any final recommendation would be subject to a favourable REC opinion; confirmation of satisfactory security arrangements; amendment of the patient information materials to include clear reference to informing patients how they could opt out of their data being used in the study; and confirmation that the initial approach to patients would include a cover letter from the clinical care team or, if by telephone, would be by the clinical care team.

CAG 1-06(PR7)/2013) Secondary Prevention of Burns and Scalds in Children

This research application from the University of Cardiff described a study which aimed to evaluate a risk assessment tool designed to assess childhood burns and direct to appropriate care. The application was for a pilot study only. The application followed on from previous PIAG approval which was obtained in order to establish the risk assessment tool, PIAG 4-05(i)/2008 Thermal injuries in children - Version 1. This application was considered via the proportionate review criteria under criteria 4: *Time limited access to undertake record linkage/validation and to pseudonymise the data.*

The application requested approval to access data in relation to patients under the age of 16 who had presented with scalds and non-scald burns at emergency departments over a 4 week period at 3 hospitals. Clinical staff would complete a data collection form on behalf of the research team who would then use identifiable details to request further information from other services such as health visitors, social workers, school nurses and children centres. Name, hospital or NHS number and date of birth would be collected in order to carry out linkages. Identifiable data items would be removed from the database once linkages were complete. It was noted that this application utilised the same methodology as the previously approved application referenced above.

Members agreed that this project detailed valuable outcomes which would be of considerable benefit, and considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed. Members agreed that issues around obtaining consent where there was a risk of injuries being non-accidental had been considered in relation to previous applications and noted that consent had been considered not to be feasible in many instances. Members noted that identifiable data would be used to carry out linkages only and would be destroyed once all data had been collected. Members noted the international element of the protocol and sought reassurance that no confidential patient information would be transferred to other countries.

The Group agreed that the minimum criteria under the Regulations appeared to have been met, and advised recommending provisional support to the Health Research Authority, subject to confirmation that no confidential patient information would be transferred to other countries in an identifiable form, confirmation of a favourable REC opinion and satisfactory security arrangements.

Amendments to approved applications

PIAG 2-05 (b)/2007 - request for extension of existing section 251 application for the Secondary Uses Service Data Flows from the HSCIC to CSUs/CCGs

NHS England submitted an amendment request to the existing national approval that allowed the Health and Social Care Information Centre (HSCIC) to release Secondary Uses Service (SUS) data in identifiable form to Primary Care Trusts (PCTs). the intent was to extend this to allow the HSCIC to release the same data for the same purposes to Commissioning Support Units (CSUs) as part of NHS England or Clinical Commissioning Groups (CCGs) (or their contracted data processors) for a 3 month period from 01 April 2013. Following formal receipt

of this request on 22 March, Members considered this on an expedited basis, requested clarifications by 25 March and provided formal advice to the Secretary of State on 27 March that there was insufficient information to provide a recommendation within the requested timescales. Following this letter and subsequent discussions with the Chair, it was agreed that the applicant should provide further clarifications in order for a recommendation to be provided to the Secretary of State by 5 April. Responses from the applicants were received on 3 April and circulated to all Members via email so consideration could take place on an exceptional virtual basis.

Members formally noted that the submission of the documentation for this critical activity had been provided at an extremely late stage considering the known deadline for these significant changes to be in place. While responses to clarifications had been responded to quickly, where the information was available, the short notice given to enable the provision of robust and credible advice had placed the Members in a difficult position. As Members were keen to facilitate and support appropriate activities, it was anticipated that any future significant changes requesting legal support would take place with appropriate planning and the involvement of the CAG at an early stage.

Members were provided with assurance that identifiable data would only be used for the same commissioning purposes as was previously permitted and that disclosure to CCGs and CSUs would be no more extensive than previously permitted to PCTs. Data recipients would be required to notify the HSCIC how they would handle the information by the end of the three-month period; that identifiable data would be pseudonymised, destroyed, or accounted for by seeking approval at the end of this time. Members were clear that the onus was on any organisations seeking section 251 support as an exit strategy from this interim state to submit an application to the published meeting timescale as there would be sufficient time for them to plan accordingly.

Members had expressed concern over compliance with the Data Protection Act 1998 and the ICO had commented that the current Data Sharing Agreement (DSA) should be transformed into a Data Sharing Contract and a plain English Data Sharing Agreement written to supplement it. Members supported this approach and agreed that any support should be conditional upon the plain English DSA being in place before the Data Sharing Contract was signed as this would provide greater clarity over local responsibilities when processing information under support. Members were not persuaded that maintaining essential business continuity across this interim period would require access to the past three years' data. Members could not identify any evidence that business planning or trend analysis would be significantly affected if historic data was not available for this interim period. The recommendation was that support should only be provided, at this time, for disclosure of data necessary to support current commissioning purposes and this should only extend to information for the past financial year. Any further extension could be covered in the main application to be considered by the CAG in April. Members concluded that while this was not an ideal situation, essential NHS activity should continue on an interim basis while the full application was developed. Members were clear that there were a number of aspects where progress would need to be made, or where this was not feasible a plan for progress with appropriate milestones and deadlines would need to be in place, before Members could recommend ongoing support. This recommendation for 3 months support was subject to a satisfactory review by the IG Delivery team to ensure that all relevant technical standards and local information governance policies were in place prior to any data transfer; production of a plain English version of the Data Sharing Agreement before signing of the Data Sharing Contract; and confirmation that all those processing data under this approval must have suitable contracts of employment in place establishing a duty of confidentiality equivalent to that of a health professional. It was reiterated that this recommendation covered access to data for the previous financial year only, in order to maintain essential business continuity, and any extension to the data to be accessed should be covered in the subsequent application. This amendment request was approved by the Secretary of State.

ECC 3-02(FT2)/2011 Person based resource allocation – linking PDS to the HESID index

This service evaluation application from the Health and Social Care Information Centre (HSCIC) sought support under section 251 to use Personal Demographics Service (PDS) data for the purposes of linkage to the HESID Index. It was noted that the linkages had previously been carried out by the Centre for Health Economics at York University. The HSCIC already had permission to access PDS for defined purposes; however, as this was for a different purpose, further support under section 251 was required. The Person Based Resource Allocation (PBRA) project required linkage of information on hospital activity to a population based view of all people within a given area to be linked to the HES ID Index. This linkage would be undertaken by the Trusted Data Linkage Service at the HSCIC. The output would be a pseudonymised extract provided to the Nuffield Trust who were undertaking this work on behalf of the Department of Health (DH). The amendment request detailed an update to the application to allow the specified linkage to be repeated for 2010/2011 and 2011/2012 data. As this was a repeat project with identical processing arrangements and purposes this was considered by the Confidentiality Advice Team. An annual report update was requested. Following receipt of the update it was noted that this was intended to be a one-off project and that identifiable data would be deleted within one month of completion of linkages. Support was therefore recommended for this repeat activity.

A query was raised in relation to whether data regarding membership of the armed forces was being requested from PDS as stated within the application. As the Confidentiality Advice Team had been informed that there was an agreement between the NHS and MoD that all Defence Medical Services patient demographic data should be de-militarised in order to ensure data did not associate a patient with current membership of the Armed Forces, confirmation was requested from the applicant whether there was an intention to process this data. It was confirmed that data in relation to a patient's military service would not be accessed.

ECC 2-02(e)/2012 The Loss of Consciousness Key (LOCK) scale – version 1

This research application from the Royal Free Hospital NHS Trust detailed a study which aimed to develop a scale (LOCK) which would improve the diagnosis of episodes of transient loss of consciousness. The LOCK scale would be applied retrospectively to the medical records of 100 patients referred to the neurology department of the Royal Free Hospital and prospectively to 100 patients presenting at the emergency department. The validity of the scale would be evaluated after 12 months, which would require access to records held either by the Royal Free Hospital or by GP practices. Support was requested for a research nurse to apply the LOCK scale to records held at the Royal Free Hospital Emergency Department and to access GP record data to confirm diagnosis after 12 months. The amendment request detailed increasing patient numbers from 200 patients to 500 in total for both the prospective and retrospective stage; this was in order to increase the statistical power. In addition, follow up data would be requested from GPs at 6 months, rather than 12.

The applicant confirmed that there would be no further changes to the protocol and it was noted that support was provided to access demographic data in order to seek consent from patient and access data on deceased patients. A REC favourable opinion was requested and forwarded on 29 January 2013. The Confidentiality Advice Team noted that there would be no changes to the established methods and the amendment was approved by the Secretary of State for Health.

PIAG 4-07(v)/2002 – The Neonatal Survey

This amendment to an audit application detailed collecting data from MBRRACE-UK in relation to stillbirths and deaths on labour ward for infants of 22 to 32 weeks gestation born within the East Midlands & Yorkshire (plus Northern for the EPICE study). The data collected from MBRRACE-UK would be all the data items collected via the Maternal and Newborn portal, including identifiers. The amendment would allow data to be accessed and used within the EPICE study - Effective Perinatal Intensive Care in Europe - Translating knowledge into evidence-based practice. Members noted that the only additional data requested was obstetric

data and that the primary change was in relation to the data source, where data would be collected from MMBRACE-UK, rather than via local research nurses. Members agreed that this aspect could be recommended for support as the data flow had previously been agreed. A geographical amendment was also included and Members noted that this would be required in order to allow a greater range of comparisons to be made between regions and also countries.

Updates on existing applications

ECC 2-02(b)/2012 North West Strategic Health Authority (NWSHA) data warehouse Amendment to PIAG 1-05(d)/2006 Analysis of attendances at hospital, GP surgeries and emergency ambulance journeys in the NWSHA

This audit application from the Clatterbridge Cancer Centre NHS Foundation Trust detailed an extension to an existing audit application (PIAG 1-05(d)/2006 Analysis of attendances at hospital, GP surgeries and emergency ambulance journeys in the NWSHA). Cancer registry data was requested for the purposes of evaluating an advertising campaign within the NWSHA, "Don't be a Cancer Chancer". In addition it was proposed that confidential patient information would be used to create a pseudonymised data warehouse in order to provide data for analysis for future projects and added to where necessary. This had been considered by the ECC in March 2012.

In order to ensure that the database could be added to where necessary it was proposed that NHS number; date of birth and postcode would be retained separately with a pseudonymous link to clinical data. The applicant was asked to provide further information in relation to a number of areas relating to practicable alternatives, extent of data being requested and governance arrangements. Responses from the applicant were received and forwarded to Members who originally reviewed the application for their comments. Members agreed that most of the points had been addressed in adequate detail. It was noted that GP data was currently not required and therefore this should be removed from the current request. Members noted that the applicant had assured the Group that they would look into the alternatives as outlined in point 6 above. Members commented that as well as the alternatives outlined above the Trusted Data Linkage Service (TDLS) at the Health and Social Care Information Centre (HSCIC) could possibly carry out linkages on the applicants behalf. Members agreed that exploration into this and other alternatives should be explored and that progress should be reported at annual review stage.

Members discussed the further information provided in relation to details of the established processed and governance arrangements. Some concerns were raised that the proposed data acquisition, retention, use and disposal policy would perpetuate dependence on one individual, which was an issue highlighted when the application was originally considered. Members advised that the policy should be in line with established Clatterbridge NHS Trust policies and agreed by the Caldicott Guardian and Trust information governance committee. In addition, the document should include clear lines of accountability, including data controller and data custodian responsibilities.

Members were pleased to note the commitment in establishing a log of data sources, however it was requested that this be in place as soon as possible and forwarded prior to any final approval. In relation to making changes to the data sources, Members advised that the process should be documented and clear and if possible include an assessment by a Trust IG representative who was not part of the NATCANSAT team. Members requested that the applicant provide a revised copy of the data acquisition, retention, use and disposal policy and current log of data sources.

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

This amendment request to a research application from the South London & Maudsley NHS Foundation Trust had been considered by the ECC at the February 2013 meeting. The amendment sought to extend the scope of the type of research to be carried out using the linked dataset e.g. mental disorders in children and adolescents. Examples were provided on how the

scope could be broadened, and could potentially include mental disorders occurring in childhood and adolescence, personality disorders in adults and unipolar as well as 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. Members had been supportive in principle but requested further refinement of the overall scope, practicable alternatives, how dissent would be managed and fair processing information updated. The applicant's responses were considered outside the formal meeting schedule and Members agreed that the applicant had satisfactorily addressed the points of clarification and provided a clear information leaflet. Members recommended that there be a more explicit statement on the right of opt-out, although this was not a condition of support. The applicant rescinded their request to extend the scope of the research to include children, although Members indicated that they would be supportive of this if this came back to the Group in due course.

ECC 8-04(d)/2013 A comparison of fenestrated endovascular aneurysm repair (fEVAR) with alternative treatment strategies

This research application from the Royal Liverpool University Hospital detailed a retrospective cohort study of all patients who underwent aneurysm repair in the Cheshire and Merseyside region between 1 April 2006 and 31 March 2008 (approximately 200 patients) to compare the outcomes of three different types of operation for abdominal aortic aneurysms. Support was requested to allow a researcher to identify patients by accessing various hospitals and theatre databases and consulting with surgeons themselves. Once a full list had been prepared CT scans and case notes for each patient would be accessed and reviewed. Following the ECC meeting in February 2013, the applicant was asked to confirm whether the researcher was a medical student. It was confirmed that the researcher was not a medical student but a qualified doctor working as a research fellow at the Royal Liverpool University Hospital. It was noted that data would need to be accessed at a number of hospitals.

The applicant was also asked to confirm whether it would be feasible to seek consent from those patients whose current status was known to the clinical care team. The applicant asserted that in order to identify patients it would be necessary to interrogate many sources of information, mainly from hospital coding and theatre lists, firstly of all patients who had an aneurysm repair, then to identify those to be included in the study by reviewing hospital records and scan results. As the inclusion criteria were very specific, including the use of specialised software to view CT scans, this would need to be carried out by the research team. Members agreed that this response was acceptable and the minimum requirements of the Regulations appeared to have been met. Members agreed to recommend support for the activity subject to a favourable REC opinion and satisfactory security arrangements.

ECC 8-04(e)/2013 Mortality study of UK hard-metal workers

This research application from the Institute of Occupational Medicine aimed to identify all workers that had worked at two hard metal manufacturing facilities since 1950 and assess whether their mortality patterns were higher than normal and whether this might be associated with increased exposure to substances in the hard metal manufacturing process. Support was requested to allow access to mortality data (date and cause of death) from the NHS Central Register. Members asked for clarification whether the applicant intended to flag the current working population on the NHS Central Register, and if so why it would not be feasible to seek consent from this cohort. The applicant confirmed that they intended to flag current workers on the NHS Central Register and reiterated that they would carry out presentations and provide information to the current work force, along with opportunities to opt out of the study. In addition it was explained that seeking opt in consent might result in a poor response rate which would then create bias in results. The applicant provided confirmation that a dataset including date of birth and death would be forwarded to the University of Pittsburgh. Members agreed that the justification was sufficient for not seeking opt in consent for current workers and that the condition to collect data on the retrospective cohort only could be removed. Members noted that the applicant provided reassurances that only pseudonymised data would be disclosed to

the University of Pittsburgh. However, it was also detailed that date of birth and death would be transferred; Members reiterated that these data items were considered to be potentially identifiable and therefore should be reduced as far as possible. It was agreed that the condition of approval would be amended to reflect this requirement.

ECC 8-04(f)/2013 Scottish Air Pollution and Mortality

This research application from the University of Manchester detailed a study which aimed to investigate the lagged relationship between exposure to air pollution and non-accidental mortality. In order to achieve this HES and mortality data would be linked with the UK Air Quality Archive. Support was requested to allow access to mortality data regarding all deaths from cardiovascular, respiratory, digestive causes, lung cancer, diabetes and other related deaths. Information relating to deaths between 1998 and 2011 in Manchester, Newcastle and Leeds would be accessed (approx. 191,000 deaths). Identifiable data would be required in order to link with air pollution data from DEFRA's UK Air Quality Archive. HES data in relation to all hospital attendances recorded on the HES database would be requested and would include date of death and sector level postcode.

Following their initial review, Members requested that the applicant consider the feasibility of the Health and Social Care Information Centre linking datasets on the applicant's behalf and providing a de-identified dataset to the applicant. Further information was received from the applicant in relation to the feasibility of this request and it was confirmed that the complexity of the data manipulation and matching required to be undertaken was such that it would not be feasible for the HSCIC to undertake the linkage and provide the applicant with an anonymised dataset. It was proposed that sector level postcode would remain within the dataset provided by the HSCIC and that hospital admission and mortality data would be provided separately with a subject level anonymous unique identifier to facilitate linkage. Members agreed that the complexities of data linkage would mean that the applicant would require access to the level of data specified and that the proposed approach appeared to be acceptable. It was advised that the applicant approach the HSCIC for their confirmation that they agreed with the above approach, as data controller for HES. Members agreed to recommend support, subject to a favourable opinion from a REC and confirmation of satisfactory security conditions.

6. PRESENTATION: CALDICOTT 2 RECOMMENDATIONS

Ms Suzanne Lea presented an overview of the key themes from the "Caldicott 2" Information Governance Review on the commissioning aspects alone. This had arisen as the CAG would be considering the NHS England application the following day and it was thought useful to have an initial understanding of the report recommendations. This presentation was delivered on an embargoed basis due to the formal delay to publication of the Caldicott 2 review report. Members thanked Ms Suzanne Lea for her thoughtful presentation and confirmed that they found it very useful.

7. PRESENTATION: TRUSTED DATA LINKAGE SERVICE

Ms Clare Sanderson presented an update on the HSCIC's Trusted Data Linkage Service (TDLS), which was based on the earlier Medical Research Information Service (MRIS, in operation since the 1960s) and Hospital Episode Statistics (HES) linkage service (in operation since 2011). The role of the TDLS was to match and combine datasets, for medical purposes only, in a secure environment. All TDLS customers were required to agree to refrain from carrying out further linkage on TDLS-linked data, agree to constraints on sharing and publication and to obfuscation of small numbers, have Information Governance Toolkit, ISO27002 or equivalent security assurance, and submit to audits by the HSCIC or their designated third party auditors.

Members noted the HSCIC's new powers under the Health and Social Care Act 2012 included mandatory data collection when directed by the Secretary of State for Health, NHS England, Monitor, the CQC or the National Institute for Health and Care Excellence. These mandatory

data collection activities would not require section 251 support as another legal basis was in place to enable the flow of information to the HSCIC. Collection of identifiable information on behalf of any other organisation would require support.

Ms Sanderson presented different process models used by the TDLS depending on whether the data sought was held by one source or multiple sources. . It was confirmed that linkage could only be for medical purposes, but was not necessarily restricted to medical data. The HSCIC was required under the Health and Social Care Act 2012 to assess the data quality of all incoming data and advise source organisations, and was beginning to publish annual data quality reviews for all major data flows.

8. REVIEW OF CLINICAL PRACTICE RESEARCH DATALINK (CPRD) DISCLOSURES (ECC 5-05(a)/2012)

This application had received a recommendation of support in February 2013. As part of the approval conditions, the applicant had been requested to provide a review of disclosures at each Confidentiality Advisory Group meeting for an initial 12 month period; with review of the process at 6 months. The purpose of this was to ensure that any risks involved over onward disclosures were minimised, and so that Members would have a clear understanding of the criteria the CPRD took into account when classifying whether a disclosure would be potentially identifiable or not.

Members welcomed this report and considered it alongside the previous 'narrative' provided for consideration at the February 2013 Ethics and Confidentiality Committee (ECC) meeting. Members clarified that the primary purpose of requesting a report on this area was to gain a clear understanding, in the broader external context of potential changes to information governance practices, of the decision-making process of ISAC underpinning an assigned risk score, and to receive on-going assurance that the decision-making process was robust so as to prevent the disclosure of identifiable information to third parties.

Members reviewed the documentation to identify whether there was sufficient information to understand the ISAC decision-making and risk-assessment processes. It was noted that the previous narrative report provided in February 2013 set out a summary of the risk categorisation, in that the risk rating of low, medium or high appeared to rely on the number of datasets being linked. The report provided for consideration listed only 'low' risk proposals. Members were of the view that the number of datasets to be linked was potentially a blunt instrument, as some datasets could involve rare conditions that would increase the potential identifiability through being linked with only one other dataset. It was appreciated that ISAC was an established group and that CAG was not yet familiar with the considerations of ISAC. It was considered important for CAG, in the context of the approval in place, to be provided with information of the considerations and process in place for ISAC review so that it could advise the Health Research Authority it was sufficiently assured all reasonable measures were taken to prevent inappropriate disclosure.

It was agreed that the information provided was not currently comprehensive enough to achieve these aims. As this was an evolving and learning process involving a unique resource, Members requested the following specific information to be provided to the June 2013 CAG meeting so as to gain a clear understanding of the ISAC decision-making process and reasoning:

1. To provide two clear case studies that explicitly and separately covered two applications where a low and medium risk score rating was identified.
2. If a medium risk score rating had not yet been considered, an example of the considerations that would be taken into account should be provided so that the CAG was clear how ISAC distinguishes between risk thresholds.
3. The case studies should be presented in a standalone format without reference to previous documentation.

4. Each case study should list the dataset, the data sets to be linked and provide a narrative (if extracts from minutes were not available) on the precise considerations that ISAC took into account in allocating the risk rating.
5. The narrative should cover, in a clear and succinct format, the process for consideration and set out the reasons why that particular risk rating was decided upon. Existing checklists or guidance would be accepted.

Methodological research

Members agreed that sufficient information had been provided to enable a recommendation that this category should be included within the approval.

Inclusion of additional datasets

CAG agreed that the list of specified national clinical audits contained within the additional data linkages spreadsheet should be included within the approval. With regards to the NHS Dentistry data, it was agreed that there was currently insufficient information to identify what would be covered within this data set, and it was understood from a previous conversation that the data itself needed to be reviewed to see if it was suitable to enable linkages with other datasets. Until clarity is obtained on the quality of the dataset and confirmation as to what is included, Members recommended that this should be excluded.

The Chair noted that Ms Rebecca Stanbrook had a potential conflict of interest with CPRD as she was employed part-time by the Medicines and Healthcare products Regulatory Agency which was also CPRD's host organisation. Consequently, any future research applications or amendments submitted by CPRD would not be considered by Ms Stanbrook but by the Chief Executive of the HRA.

9. ANY OTHER BUSINESS

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