NHS
Health Research Authority
Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group

24 July 2014 between 10:00 and 17:30 at Skipton House, SE1 6LH

Present:

Name	Capacity
Dr Mark Taylor (Chair)	Lay
Dr Kambiz Boomla	
Dr Patrick Coyle (Vice Chair)	
Dr Tony Calland MBE (Vice Chair)	
Mr Anthony Kane	Lay
Mr C Marc Taylor	
Ms Clare Sanderson	
Ms Gillian Wells (Alternative Vice Chair)	Lay
Professor Julia Hippisley-Cox (all items, except 5a)	
Professor Jennifer Kurinczuk (for items 5-9)	
Professor Barry Evans (all items, except 6b)	
Dr Miranda Wolpert	
Mrs Hannah Chambers	Lay

Also in attendance:

Name	Position (or reason for attending)
Ms Natasha Dunkley	Confidentiality Advice Manager, HRA
Ms Claire Edgeworth	Deputy Confidentiality Advice Manager, HRA
Mr John Robinson	Confidentiality Advisor, HRA
Mr David Evans	Expert advisor – Data Protection, Information Commissioner's Office
Ms Carla Denneny	HRA Quality Assurance Auditor, HRA (observing)
Mr Gordon Harrison	Head of Communications, HRA (observing, item 5a only)

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Introductions

The Chair welcomed Ms Carla Denneny, HRA Quality Assurance Auditor, who was attending the meeting as an observer.

Apologies

Apologies were received from Dr Robert Carr, Dr Murat Soncul and Professor Ann Jacoby.

Professor Jennifer Kurinczuk attended from item 5 to the end of the meeting.

Declarations of interest

The following interests were declared:

Professor Julia Hippisley-Cox:

Declared a competing interest in relation to one of the applications discussed under item 5a, CAG 5-05(a)/2014 Southend-on-Sea integrated care pioneer, as a director of ClinRisk Limited who provided one of the risk prediction software tools referred to in the application. She did not receive the meeting papers and left the room during the determination of the Group's recommendations for this item.

Ms Clare Sanderson:

Declared a competing interest in item 5a [CAG 5-05(a)/2014] as she had been providing information governance advice, in her professional capacity, to one of the suppliers that provides risk stratification software to a number of clinical commissioning groups and NHS England. This interest was noted and it was agreed that this did not prevent Ms Sanderson from participating in the discussion of the item.

Professor Barry Evans:

Declared a competing interest in item 6b [CAG 5-07(b)/2013 due to his role at Public Health England. He did not receive the meeting papers and left the room during the discussion of this item.

Members did not declare any other competing or conflicting interests.

2. ANNUAL REVIEWS

a. Research to identify and publish measures of quality delivery of healthcare by provider or in some instances, by area (Dr Foster) annual review [PIAG 2-05(d)/2007]

The application from Imperial College London, which included research and non-research apects, received support in 2007 in order to process hospital administrative data (Secondary Uses Service data supplied through commissioning datasets from the Health and Social Care Information

Centre (HSCIC) to provide measures of quality of delivery of healthcare by provider or in some instances by area and to support a management information function for the NHS. Anonymised data would be provided to Dr Foster Intelligence for analysis purposes.

Access was requested to date of birth, date of death, postcode and NHS number. The following conditions were specified within the original approval:

1. Appropriate contractual arrangements being established with the organisation providing data.
2. That sensitive information such as sexual health information was filtered out prior to disclosure.
3. That the Imperial Unit undertakes its own user involvement rather than relying on that of Dr Foster Intelligence.
4. That data is pseudonymised on rolling 3 year programme.
5. Clarification of precisely what data is disclosed to DFI and assurance that it is effectively anonymised.

Confidentiality Advice Group advice

Public interest

The Group discussed the annual review report provided and noted their understanding that the activities carried out under the application provided a significant public benefit and a number of high-quality outputs. Members were highly supportive of the purposes of the application and agreed the public interest was in this activity continuing. However, further consideration identified core aspects that should be resolved in relation to this large scale data processing as indicated below.

Fair processing

It is a requirement of the Regulations that an application cannot be inconsistent with the principles of the Data Protection Act 1998 (DPA). The first principle of the DPA requires that reasonable efforts are made to inform data subjects of the use of their data.

Following comment from the Information Commissioner's Office, members advised that the information provided to patients in relation to the processing of data could be improved in terms of clarity and availability. It was noted that currently information was provided on the Imperial College website however it was agreed that this should include significantly more detail in relation to the processing. This should incorporate the data processed and the purposes it is used for. In addition, comments were raised that the fair processing information provided on Imperial College's website should be easily found and identified from other related sites such as Dr Foster Intelligence and the Health and Social Care Information Centre (HSCIC).

Members asked that the applicant consider how fair processing could be improved further and work with others, such as the HSCIC, to ensure an aligned approach. As this was a key requirement members asked for a report in relation to this aspect to be submitted within 2 months detailing the improvements made to fair processing information. If further advice was required in relation to this aspect the Information Commissioners Office should be contacted in order to discuss further.

Patient objection

Separate to but linked to the issue of fair processing, Members advised that it should be ensured that methods to record objections should be made clear within any fair processing information provided and that any objections must be respected.

Practicable alternatives and justification for ongoing support

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 and Regulation 7(1) (c) of the Health Service (Control of Patient Information) Regulations 2002.

A number of potential future practicable alternatives to allow the reduction of identifiable data had been specified within the annual review report and members were pleased to note that the applicant appeared to be proactively engaging with alternatives to the use of identifiable data.

Submission of an updated application form

Members reiterated the requirement to review the need to process identifiable data on a regular basis and agreed that as the applicant had considered a number of practicable alternatives which may be feasible in the future; further consideration should be given to these aspects as soon as possible. Due to the time since original approval (provided in 2007) members agreed that it would be appropriate for the applicant to submit a revised application in the near future to ensure that all purposes were clear, amendments since original application were included and the considered alternatives were detailed in full.

It was suggested that the applicant should engage with the CAG practicable alternatives working group in order to discuss alternatives when a revised application was complete and ready for submission. The working group is currently in the process of developing guidance in relation to technical practicable alternatives without consent and advised that they would welcome a discussion to support consideration of alternatives. Please contact me nearer to the time in order to facilitate discussions.

Sexual health data

Members requested clarification that sexual health data was fully anonymised prior to the disclosure from the HSCIC and that the applicant did not receive any identifiable sexual health data.

Risk Stratification

It was noted that the application detailed providing information back to GP practices in relation to individual patients and members advised that this type of activity had recently been reviewed as part of a national application for risk stratification (CAG 7-04(a)/2013). Members queried whether the risk stratification activities detailed within this specific application were captured within the national application.

Confidentiality Advice Group advice conclusion

As a whole, it was recommended that the approval in place for the purposes set out in the application should continue for a further 6 months until 7 February 2015 to enable assurances on fair processing and management of patient objection to be provided within 2 months, and for an

updated application form to be submitted. The continued recommendation for support was subject to the following conditions:

1. Further consideration of the ways in which fair processing could be improved. It was advised that an integrated approach with the HSCIC should be explored. Assurances in relation to improvements made should be provided within 2 months of this outcome, by 1 October 2014.

2. To ensure continuous approval, a revised application form must be submitted to the January 2015 CAG meeting (submission deadline 12 December). At this time the CAG practicable alternatives working group would welcome a discussion in relation to the potential alternatives and arrangements can be facilitated by the Confidentiality Advice Team.

3. Confirmation that sexual health data would be fully anonymised prior to the disclosure from the HSCIC.

4. Confirmation whether the risk stratification element of the application was detailed within the overarching national application for risk stratification from NHS England. (CAG 7-04(a)/2013)

3. RESUBMITTED APPLICATIONS

a. Critical Care Health Informatics Collaborative [14/CAG/1012]

This research application from University College London (UCL) detailed the establishment of a research database including clinical, laboratory and demographic data in relation to all patients admitted to Adult Critical Care Units across 5 NHS Trusts.

The application requested support under class 1, 2, 4 and 6 was received to allow access to data from hospital systems and Hospital Episode Statistics (HES) data from the Health and Social Care Information Centre (HSCIC). NHS number, date of birth, postcode and gender were requested in order to carry out linkages to HES data. The application specified a pilot activity only.

Resubmission background

This application was originally submitted to the 19 June 2014 CAG meeting where members were unable to provide a recommendation of support as the application raised a number of issues outlined within the outcome letter dated 30 June 2014. Further information was provided in a resubmitted application.

Confidentiality Advisory Group advice

Public interest

Members reiterated that they considered the application to be important and were highly supportive of the pilot 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.

Members discussed whether consent would be feasible, a number of issues were recognised which would mean that consent was not practicable, these included resource issues on units themselves, the large number of patients involved and the potential high levels of non-response. Members advised that lack of mental capacity would not constitute a reason to provide support under the Regulations in itself and that the applicant would need to consider whether it would be feasible to seek assent under the provisions of the Mental Capacity Act 2005. However, noting the other issues specified, members accepted that it would not be practicable to engage consent or assent in these circumstances.

Data linkage methodology

Members were pleased to note that the applicant had consulted with the HSCIC in relation to the data linkage methodology and that the data flow diagram indicated that data would be retained and linked in a pseudonymised format by UCL. However, members queried whether it would be possible for identifiable data from Trusts to be sent directly to the HSCIC and for the pseudonymisation algorithm to be applied to the clinical data which was sent to UCL prior to disclosure from Trust sites.

In addition, members requested confirmation whether the current proposed data flows meant that it would be possible for UCL to reverse the pseudonymisation process and re-identify records

Fair processing

It is a requirement of the Regulations that an application cannot be inconsistent with the principles of the Data Protection Act 1998 (DPA). The first principle of the DPA requires that reasonable efforts are made to inform data subjects of the use of their data. Members agreed that whilst consent was not considered to be feasible it may be possible to improve fair processing by including information in relation to the database within direct written communication with patients from hospitals following discharge.

Clarification over data controller responsibility

Members requested clarification regarding who would be considered to be the data controller for the database.

Disclosure of data to third parties

Members reviewed the additional clarity provided in relation to the disclosure of data to third parties and the processes in place to manage this. Members raised some concerns that there was potential to disclose data outside the science field as and indicated that they had reservations in relation to this as it was not clear who this referred to and for what purposes they may require access to data.

Patient and public involvement

Members indicated disappointment that further patient and public involvement had not been carried out to date. However, they reviewed the patient and public involvement plan provided and were pleased to note that a number of activities were planned in relation to this aspect. Members advised that the majority of activities in the report should be actioned as soon as possible.

Justification for identifiable data items

Members requested further information in relation to whether postcode was required in order to carry out linkages with HES data and asked that the applicant confirm with the HSCIC the minimum amount of identifiable data required.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, due to the issues highlighted above, further information would be required prior to confirming that the minimum criteria under the Regulations appeared to have been met. Members requested that the applicant provide further information in relation to the following points. Members advised that if useful a teleconference could be arranged with the applicant as they were supportive of the application in principle and were keen to engage with the applicant on the points raised.

1. Consideration of whether it would be feasible to send identifiers directly to the HSCIC, rather than via UCL, and whether it would be possible to pseudonymise the data at an earlier stage prior to disclosure from Trusts.
2. Confirmation whether it would be possible to reverse the pseudonymisation process detailed within the current approach.
3. Consideration of whether it would be feasible for Trust to send out patient information directly to patients in relation to the database to ensure that patients were aware of the processing.
4. Confirmation in relation to the data controller for the database should be provided.
5. Further confirmation in relation to the potential disclosure of data to third parties outside the science field.
6. Members requested that the majority of activities specified within the public and patient engagement plan be actioned as soon as possible.
7. Confirmation of whether postcode is required in order to carry out linkages at the HSCIC.

Principles of CAG Decision Making

Dr Miranda Wolpert requested further information regarding the precedent for decision making specifically with regards to expectations of applicants in seeking consent and interaction with Research Ethics Committees and CAG. Ms Natasha Dunkley suggested that the existing 'principles of decision making' document could be reviewed. Dr Wolpert agreed to work with Ms Dunkley to conduct this review.

Action: Ms Natasha Dunkley to follow up comments with Dr Miranda Wolpert and review the principles of decision making document.

b. Offender healthcare: Health Needs Assessment Project [CAG 5-03(b)/2014]

These service evaluation applications from NHS England set out the purpose of a review of service user health records, including referral information, clinical information recorded on the Prison Electronic Patient System and clinical presentations. Members considered the two activities together as both raised similar issues.

The aim of the Healthcare Needs Assessment project was to determine the population health issues, leading to agreed priorities and resource allocation and improving health and reducing inequalities.

The aim of the Escort and Bedwatch project was to carry out a review of clinical activity associated with referrals of service users to receive treatment within a secondary care setting. The review

would focus on a specific time frame to review the treatment and care of service user pathways to determine if the service user could have been more appropriately treated within an offender healthcare setting and what developments would be required to provide care closer to home.

A recommendation for classes 1, 5 and 6 support was requested to cover access to medical records onsite in order to extract pseudonymised information.

Resubmission background

These applications were originally submitted to the 19 June 2014 CAG meeting (CAG 4-05(b)/2014 and CAG 4-05(c)/2014) where members were unable to provide a recommendation of support as it appeared that there were potential practicable alternatives to the use of confidential patient information without consent. A resubmitted application was submitted for members consideration.

Confidentiality Advisory Group advice

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.

Members discussed whether it would be feasible for prison staff to carry out data extraction as suggested following the previous submission, the applicant's assertions that it would be important for healthcare professionals with specific clinical expertise to carry out data collection in order to ensure the correct context were recognised. Members agreed that it would be beneficial to ensure that the reviews were undertaken by appropriate individuals.

Consent

Members discussed the applicant's assertions in relation to problems of relying on consent for the data collection. It was agreed that due to the retrospective nature of the data collection, seeking consent from patients would be particularly difficult and infeasible in this instance. However, members advised that they could not accept similar assertions in relation to future audits and as the need was now identified it should be ensured that prisoners were fully informed and provided consent for future audit activities.

Patient information materials

Members noted that the applicant had committed to providing specific patient information posters and leaflets in relation to the audit and requested that these were submitted for comment. It was advised the applicant should ensure that these include details of methods to register patient objections.

Patient involvement

The applicant had confirmed that they would consult with groups involved with patients. Members requested that a specific patient and public involvement plan be provided with timescales and details of who would be consulted and how the feedback would be used. Members advised that some methods of involvement should be undertaken prior to data collection taking place.

Data access controls

It was noted that all individuals with access to data would be healthcare professionals and therefore owe a professional duty of confidentiality. Members queried how access to records would be audited and supervised and how any potential breaches would be picked up and acted upon.

In addition, members queried who would be the data controller for the data after the prisoner had been released and advised that if possible a note should be included on a patient's record which should indicate that the record had been accessed as part of the audit so that the patient could be informed.

Content of prison healthcare record

Members queried whether the prison record included GP record information in relation to treatment received outside prison and whether this would be accessible to individuals carrying out the audit.

Security arrangements

Members noted that data would be stored on memory sticks but that these would be encrypted. It was advised that it should be ensured that strict security measures were placed around the transfer of data from prison sites, even if the data was pseudonymised.

CAG advice conclusion

In line with the comments above, members agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending provisional support to the Secretary of State for Health, subject to further information being provided as outlined below.

1. Provision of the patient information leaflet and poster.
2. Provision of a public and patient involvement plan, including timescales for completion.
3. Confirmation of whether if it would be feasible to include a note within the patient record which indicates that the record has been accessed as part of this audit activity.
4. Confirmation whether the prison record included GP record information in relation to treatment received outside prison.

4. NEW APPLICATIONS – Research

a. Retrospective Observational Study to Describe Treatment Patterns and Health Care Resource Utilisation Associated with Anti-Tumour Necrosis Factor (TNF) Therapy in Patients Diagnosed with Crohn's Disease (CD) or Ulcerative Colitis (UC) [14/CAG/1011]

This research application was made by Optum on behalf of Takeda Pharmaceuticals International (TPI), Inc. and detailed Barts Health NHS Trust as the applicant. The application was for a review of clinical activity associated with patients with Crohn's Disease (CD) who received their first dose of Anti-Tumour Necrosis Factor (TNF) between 01 June 2009 and 01 June 2011 and patients with Ulcerative Colitis (UC) who received their first dose of anti- TNF between 01 June 2009 and 01 June 2013.

The aim of this study was to provide real-world evidence of treatment patterns, health care resource utilisation (HCRU), and associated health care costs in adult patients who have initiated anti-TNF therapy for the treatment of CD or UC.

The application set out the purpose of accessing deceased patient data to supplement the data collected from consented living patients as part of the above study and data access during 'for cause' monitoring by Optum. A recommendation for class 1, 2 and 6 support was requested to cover access to extract deceased patient data and to enable the auditing and monitoring of the study site data. Access was requested to a dataset including date of death and ethnicity.

Confidentiality Advisory Group advice

Members reviewed the response from the applicant following the no advice letter issued on the 4 July 2014 which requested clarification as to who would collect date of death and ethnicity information from deceased patient records and how this would be stored and transferred out of the EEA. Clarification was also sought as to how many deceased patients may be included within this activity and whether a member of staff with legitimate access to confidential patient information could instead access and anonymise the data.

Clarification of application scope

Members commented that the data flows specified within the application were not entirely clear. It was confirmed that the following was understood in relation to data flows and the requirements for disclosure of confidential patient information without consent:

1. Initial identification of patients would be undertaken by the local clinical care team and this would not require support as there was no disclosure of confidential patient information.
2. Access to data in order to carry out audit activities only required access by Optum.
3. Access to data in relation to the living by individuals carrying out audits would be fully consented.
4. Support under the Regulations was requested to access data in relation to deceased individuals as consent would not be in place for this access.
5. It was proposed that data, including date of death, a potential identifier, would be extracted and sent to TPI. Members stated that the dataset should be considered as confidential patient information if date of death was included.

Members were unclear with which organisations the data collected in this research would be shared. It was noted that "business partners" had been specified and members requested clarification as to the companies/organisations likely to be included within this group

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.

When considering whether a consent based approach was feasible, members recognised the applicants assertions that it was not appropriate to contact relatives of deceased patients due to the potential distress this could cause.

Members considered whether it would be possible to use pseudonymised or anonymised data and noted that the response from the applicant dated 11 July 2014 which specified that study site personnel would be involved in the case report form data collection. It was unclear to members why members of the direct care team of the deceased patient could not complete this data collection, especially if only a small number of deceased patient records would be included. If access to the record was required members requested that the applicant consider whether it would be feasible for the researcher to be provided with hard copies of such records with the identifiers redacted so that patient confidential information would not be disclosed.

Members were concerned that the data being collected had been referred to throughout the application as pseudonymised although the full date of death, a potential identifier, would be included.

Justification of identifiers

Members were not convinced as to the justification for collecting full date of death rather than month and year of death and requested further information in relation to this requirement.

Publication of results

In order to ensure transparency of finding, members requested further information in relation to how the findings of the study would be made available.

Transfer of data outside of the EEA

Members agreed that the applicant would need to ensure that adequate protection was provided if the transfer of date of death outside the EEA was required. This should be ensured by appropriate contractual obligations with the disclosing organisations, Optum and Takeda Pharmaceuticals International, Inc.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, due to the issues highlighted above, further information would be required prior to confirming that the minimum criteria under the Regulations appeared to have been met. Members requested that the applicant provide further information in relation to the following points.

1. Confirmation as to whether the summary included within application scope was accurate.
2. Further justification regarding why full date of death rather than month and year of death being collected was required.
3. Please consider whether it would be possible, given the small number of deceased patients, to provide hard copy records for the purposes of the audit and manually redact identifiable data items.
4. Clarification as to how the findings from this study would be shared and made available.
5. Confirmation that adequate protection if the transfer of date of death outside the EEA was required. This should be ensured by appropriate contractual obligations with the disclosing organisations.

Precedent set criteria – transfer out of EEA

Members agreed that transfer of confidential patient information outside the EEA should be added as an exclusion criterion for Precedent Set review.

Action: Confidentiality Advice Team to amend Precedent Set criteria to exclude transfer of confidential patient information outside the EEA.

Vulnerability of HTTPS SSL implementations to the 'heartbleed' exploit

Members noted that the applicant for the above application relied on a website protected by SSL and requested further guidance in relation to the vulnerability of existing SSL implementations following the 'heartbleed' exploit.

Action: Confidentiality Advice Team to request further information from the Health and Social Care Information Centre in relation to the vulnerability of existing SSL implementations following the 'heartbleed' exploit.

b. A feasibility study of case-finding strategies for the detection of Hepatitis B and Hepatitis C in Primary Care [14/CAG/1013]

This application from the University of Surrey set out the purpose of a study which aimed to compare three testing strategies compared to usual viral hepatitis testing practice in primary care (GP practices).

A recommendation for class 1, 4 and 6 support was requested to cover access to confidential patient information from GP practice records by a researcher in order to help with patient identification for the study. MIQUEST queries would be set up to allow the extraction of pseudonymised data for follow up purposes only and a researcher may require access in order to set this up. This would be undertaken only where necessary and requested by GP practices and where possible only pseudonymised data would be provided to the applicant.

Where GP practices required help from the researcher to follow-up patients after tests had been completed, it was confirmed patients that would be informed of this and asked for consent. This would be by written or verbal consultation between the GP and patient.

Confidentiality Advisory Group advice

<u>Practicable alternatives</u>

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.

When considering whether consent was feasible, members noted that consent would be received from participants to allow a researcher to access follow up data where required. Members recognised that it was likely that GP practices would require assistance in order to carry out the invitation process and noted that access would be restricted to one researcher only.

Members considered whether anonymised or pseduonymised data would suffice and in was noted that confidential patient information would be required to allow access to identifiable data in order to invite participants to take part.

<u>Application scope</u>

Members noted that the application sample size was relatively small and some queries were raised in relation to the representativeness, however it was recognised that this particular application was for a feasibility study only.

Research Ethics Committee opinion

Members advised that it was a condition of any approval for a research application that a favourable Research Ethics Committee opinion be provided. It was advised that although advice had indicated that REC review was not required for this specific project, an application should be submitted on a discretionary basis to ensure that the appropriate REC approval was in place. This would be required prior to final approval to access confidential patient information being confirmed.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met, and that there was a public interest in research of this nature being conducted, and therefore advised recommending conditional support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee
2. Confirmation of suitable security arrangements via IG Toolkit submission.

5. NEW APPLICATIONS – Non-research

a. Southend-on-Sea integrated care pioneer [CAG 5-05(a)/2014]

This non-research application from the Department of Health sought support to extend and build upon the NHS England risk stratification application (reference: CAG 7-04(a)/2013) to enable the linkage of social care data with risk stratified commissioning data sets as part of integrated care. This set out the purpose of planning and assessing care interventions across health and social care needs for individual service users.

Support was requested until 31 March 2015 to cover the following activities:

1. Baseline application for one 'Pioneer' site (Southend) and supporting Commissioning Support Unit (CSU) and other data processor to receive information so as to undertake the indirect care element of risk stratification with future intention for remaining 'Pioneer' sites to be added once arrangements in place.
2. The existing Risk Stratification application (CAG 7-04 (a)/2013), from NHS England, enables the flow of a specified list of health datasets for risk stratification purposes with limited access to NHS numbers through an Accredited Safe Haven. This request seeks to extend this approach and to allow access to additional datasets based on consent (where practical) and fair processing with opt out arrangements.

The following links to pre-existing applications were noted:

a) CAG 7-04 (a)/2013 in that similar controls were indicated to be applied, and

b) Linked to data approved under CAG 2-03 (a)2013 '*transfer of data from the Health and Social Care Information Centre (HSCIC) to commissioning organisation Accredited Safe Havens (ASH)*'

Confidentiality Advisory Group advice

It was agreed that this was an important activity and there was a clear public interest in the overarching aims along with an appropriate medical purpose. This integration was also considered to be an extremely important development. The CAG expressed its thanks to the applicants for their attendance as this was found to be extremely useful in exploring further the detail of the activity. The discussions clarified that this was effectively a pilot activity that would be a baseline for further similar submissions for the remaining pioneer sites.

It was noted that a sub-group of the CAG had met in advance of the meeting with the applicants to provide informal advice prior to the formal submission. It had been advised that the application be clearly separated from the NHS England 'risk stratification' application where feasible, however, member feedback on the documentation was that the Department of Health application seemed more closely aligned than expected to the NHS England risk stratification application, and discussions indicated that this separation had proven difficult to achieve. This was highlighted as the NHS England application was due for further review and clarification at the August CAG meeting, with the potential consequence that until clarifications were satisfactorily addressed by NHS England, this may prevent other applications progressing where they seek to use that application as the baseline. Members also noted that due to similarity of purpose and core data items that the current application under consideration would need to comply with all of the conditions of approval in place for CAG 7-04 (a)/2013.

<u>Fair processing</u>

In particular, members noted that the pause around care.data had potentially changed the plan to utilise this campaign as the vehicle for suitable fair processing information provision. In light of the fact that any approval cannot be inconsistent with the provisions of the Data Protection Act 1998, members indicated that there should be a clear and consistent approach to satisfying this obligation in light of the issues experienced over care.data. Discussions indicated that there had been efforts to engage with stakeholders and HealthWatch, some engagement with GPs and leaflets were being developed to provide to patients via GPs. It was advised that discussions should take place with the Information Commissioner's Office (ICO) to assess whether the proposed approach was likely to be consistent with the provisions of the Data Protection Act 1998, and the final opinion of the ICO provided back to the CAG. This was considered important as the understanding of the CAG was that only a small proportion of patients attend their GP so it was queried what steps would be taken to ensure knowledge of the activity reached the relevant population.

<u>Patient objection</u>

Separate to, but linked to the issue of fair processing, members queried what information on patient objection would be provided to patients; responses indicated that this was the responsibility of GPs however members felt that greater assurance should be provided that suitable mechanisms were in place. As this application was presented as a pilot, members agreed that this should be explored and a consistent approach applied with clearer information provided in the resubmission. Members also queried how patient objection would be managed if recorded at GP level, and how this would translate across into the social care environment with the resubmission addressing this aspect.

Information provision

Members raised a number of questions on the patient leaflet, including how patients would be aware of the identity of the third party; attendees confirmed that this name had not been included due to potential re-tender in future, and it was advised that the public participation group should be approached to ascertain what could be appropriate.

Discussions on the practice letter confirmed that practice participation would be voluntary and members raised questions on the information that had been provided to practices. Concerns were raised over the phrasing of "national restrictions" that were understood to refer to the seeking of approval under the Health Service (Control of Patient Information) Regulations 2002. Members advised that this was not an accurate representation and requested review of this aspect. The letter to practices also did not explain what data would be collected nor explain the extent of the datasets. Discussions indicated that a 'black box' technological methodology would be utilised where it would be pseudonymised upon landing and there would be no human intervention; it was advised that this letter be updated to make clear the precise scope of what was being requested and subsequent handling. It was also confirmed that GPs would be able to review social care data but social care workers would not be able to access GP data, and these restrictions should be specified within the refined information. Members advised that while clearly some GPs were enthusiastic the letter would benefit from amendment in order to ensure that GPs were fully informed, that the upload would be understood along with the benefits, and to help discharge the GP responsibilities as data controllers. It was strongly advised that the LMC be engaged with to avoid any potential issues arising at a later date considering the extent of the data involved.

Data controller relationships

The ICO representative provided feedback that it would be advisable to map out explicitly within the application the data controller relationships for GPs so that there would be no confusion or questions as other Pioneers join. It was indicated that there may be issues of joint data controllership so these should be clarified and set out for the avoidance of doubt. The ICO also provided feedback that the contract provided did not appear to meet the requirements of the seventh Data Protection principle, and advice should be sought from the ICO to ensure that it is likely to be compliant and a final corrected version submitted as part of the application.

Information items

Members noted that the dataset involved access to a greater number of data items than those set out in the NHS England applications. Discussions confirmed the rationale for this which members indicated should be updated within the application; CAG also noted that the extent of data items clearly extended the proposals set out in the 'Caldicott2' Review Report in relation to commissioning activities so a clear justification should be specified in reflection of the discussions. Members also queried the scope of the datasets and it was confirmed that some of the datasets were national, while others were local; it was advised that these should be specified within the application, with clear separation on what was considered to be health and separate social care datasets.

Social care data

Linked to the information items point, members also queried which of the information items specified related to social care data, which was understood to be fully consented for the purposes specified within the application. This point of consent should also be clearly specified within the

application; explaining when and how it was obtained and detail on what it covered. Members queried whether it explicitly covered the purposes specified within the application and requested that this be made explicit. Members also expressed uncertainty on how broad the definition of social care data was within the application; discussions clarified that social care data did not include activity data and data would be extracted from one source, therefore members advised that the resubmission should refine this section to capture the discussions, including, for example, confirmation that free text data would not be included.

Confidentiality Advisory Group conclusion

In line with the comments above, the CAG agreed that they were currently unable to provide a recommendation. It agreed to defer providing final advice to the Secretary of State for Health to enable the actions specified above to take place via further submission so as to enable the minimum threshold in the Regulations to be achieved.

The following advice was also agreed to be provided back to the applicant to aid in the refined future submission:

1. The CAG strongly supported the purposes of this activity and encouraged development of the application in line with the comments above to enable it to be reconsidered at the earliest applicant opportunity.
2. The link to the NHS England risk stratification application was noted. The applicants were encouraged to continue to work closely with NHS England due to the conditions of support applied to CAG 7-04 (a)/2013. Where clarifications and actions linked to the risk stratification application were identified to require a national solution, this should be explored; where solutions can reasonably be undertaken locally, in the absence of a national solution, these should be specified.
3. Members advised that there should be better engagement with public and patient involvement within the application detail.
4. There should be a better articulated integration of the health and social care environment and benefits from the patient perspective as it appeared to be focused from a social care perspective.
5. The importance of transparency was highlighted as an overall theme in that the application should make clearer to the patient what is covered, particularly in relation to the fair processing leaflet.
6. The discussion elicited a number of points of clarification from the applicants and these should all be incorporated into the revised application form.
7. References to the standards that would be applied was noted; members advised that these should be explicitly set out within the application due to evolving definitions and standards and to ensure this aspect was clear in future as the baseline application.

b. AMENDMENTS

a. British Regional Heart Study (Men) [PIAG 1-07(d)/2004]

This research application from University College London (UCL) Medical School set out a study which aimed to determine both established and new risk factors responsible for the considerable variation in ischaemic heart disease and stroke in Great Britain. It was also concerned with the effects of risk factor changes and their impact on cardiovascular disease events. The present aim was to continue to collect CVD-related incident morbidity for prevention and the promotion of a disability-free life in older men aged over 65 years. The study sought to trace and contact those

patients lost to the original cohort of 7735 who agreed to take part in the original study, but who had since moved.

Amendment request

An amendment request was received which detailed accessing data in relation to the cohort from the Health and Social Care Information Centre's (HSCIC) Mental Health Minimum Dataset (MHMDS). The applicant was asked to specify which conditions would be of particular interest and it was confirmed that dementia was the primary concern – which included Alzheimer's disease and vascular dementia and their main subtypes and symptoms. It was also confirmed that the applicant would need to take account of other mental health diagnoses which could be early manifestations of a dementia outcome or mask the diagnosis (e.g. depression).

Confidentiality Advisory Group advice

Extent of data requested

Members discussed the request and noted that the applicant had confirmed that only data in relation dementia related outcomes would be requested. Members were pleased to note that the request had been reduced and agreed that they would require a definitive list of conditions and data items requested from the MHMDS with justification.

Managing data in relation to non-responders

The amendment requested was forwarded to the Information Commissioner's Office representative to provide advice in relation to the access of data for those who were living and had not responded to requests for consent. The ICO advised that in these circumstances, where consent had been sought but not provided, it would not be compliant with the Data Protection Act 1998 (DPA) to continue to collect further data.

Therefore, as the request would not be compliant with the DPA, it was advised that those 305 patients whose consent had been requested but not gained were not included within this amendment. The ICO took the view that consent could be requested one further time from this sub-set, but that no further processing should take place without this consent.

It was advised that the applicant ensure that only the minimum amount of data required was from the HSCIC and that data in relation to conditions that were not of interest should not be retained for any longer than necessary.

Practicable alternatives and justification for ongoing support

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 queried whether the applicant had considered whether it would be feasible to move to a pseudonymised approach in future if the data would be received from the HSCIC only and requested that the applicant discuss the feasibility of this approach with the HSCIC.

Health Research Authority recommendation

Following advice from the CAG, the Health Research Authority agreed to recommend conditional support to the Secretary of State for Health, in line with the conditions and clarifications highlighted by the CAG.

Specific conditions of support

1. The amendment request was not supported for the 305 non-responders.
2. Confirmation and justification in relation to which data items would be required with the extract from the MHMDS should be provided.
3. Please explore whether a pseudonymised approach to data linkages could be adopted which would mean that identifiable data would not be required, an update in relation to possible alternatives should be provided within the next annual review report.

Non-response guidance

Members suggested that the non-response guidance should be promoted as widely as possible and queried whether it would be appropriate to include in the CAG stakeholder event planned for late 2014.

Action: Confidentiality Advice Team to consider inclusion of non-response guidance at CAG stakeholder event.

b. UK National Screening Committee Hepatitis B in Pregnancy Audit [CAG 5-07(b)/2013]

This audit application from University College London and the UK National Screening Committee set out a national clinical audit of the management of pregnant women with hepatitis B and their babies over a 12 month period. The audit would measure current practice against the NHS Infectious Diseases in Pregnancy Screening Programme standards with respect to referral of all women screening positive for hepatitis B or with a prior diagnosis, and evaluate specialist and perinatal management of hepatitis B positive women and their infants.

A recommendation for class 4, 5 and 6 support was requested to cover access to data from maternity services on around 3000 pregnant women screening positive for hepatitis B or with a prior diagnosis of hepatitis B. NHS number would be requested in order to carry out data linkages. Month and year of birth of mother would be used to help de-duplication. Date of birth of infant would be used to establish timing of interventions in relation to delivery.

Access was requested to NHS number, date of birth of infant, month and year of birth of mother. An additional request for hospital number and partial postcode was received on 31 October 2013. Hospital number was requested to further assist de-duplication and improve data quality, and partial postcode to enable women to be allocated by London borough. It was confirmed that neither item would be retained for analysis purposes.

Amendment request

An amendment request was received which detailed two aspects:

1. The retention of NHS number from the UK National Screening Committee Hepatitis B in Pregnancy Audit and link with PHE data on infant vaccination and infection status.

2. Access to the following data in relation to low risk women:
   - pregnancy outcome, i.e. termination of pregnancy, miscarriage, live birth or stillbirth

- date of pregnancy outcome
- NHS number for live born infants
- receipt of infant vaccination at delivery for live born infants

Confidentiality Advisory Group advice

Data flows

Members noted that the additional data would be provided by Public Health England and requested further information in relation to the nature of the data set and the data flows that would take place in order to allow data linkage.

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. Members noted that the request to retain NHS number was in order to carry out further linkages and members requested clarification regarding whether the applicant had considered whether a pseudonymised approach to data linkage would be feasible whereby the NHS number was pseudonymised using the same algorithm in both datasets.

Requirement for new application

Due to a number of clarifications and the extent of the amendment request, members asked that a new application be provided in relation to the new activity. An IRAS or non-research application form should be completed, depending on how the activity was classified. It was noted that the retention of NHS number would be required in the interim and CAG agreed that support could be recommended for the retention of NHS numbers in whilst an application form was completed and submitted. The applicant was advised that the new application should take into consideration possible alternatives such as pseudonymisation as outlined above.

Classification of activity

Members queried whether the specified amendment meant that the activity would be classified as research. It was explained that this had already been queried with the applicant by the Confidentiality Advice Team and confirmation had been provided that the applicant considered this to be service evaluation. Members requested that the applicant seek advice from the Health Research Authority and complete the decision tool available on the HRA website to provide further evidence.

Members discussed the research decision tool in general terms and were advised that any comments in relation to this should be provided to the Confidentiality Advice Team.

Action: Members to forward any comments in relation to the HRA decision tool to the Confidentiality Advice Team

Confidentiality Advisory Group conclusion

In line with the considerations above, CAG agreed that the minimum criteria under the Regulations appeared to have been met for part of this amendment, to allow retention of NHS number for 36 months following delivery, and therefore advised recommending support to the Secretary of State

for Health. CAG agreed that they would be unable to recommend support for the other aspects of the amendment and that a new application should be submitted.

c. MINUTES OF THE MEETING HELD ON 19 JUNE 2014

The following changes were noted:

Item 5b and 5c - CAG 4-05(b)/2014 Improving Offender Healthcare: Health Needs Assessment Project and CAG 4-05(c)/2014 Improving Offender Healthcare: Escort and Bedwatch Audit

- Emphasising that members were of the view that patients could easily be located and therefore contacted for consent.
- Emphasising that the extent of the potential disclosure was significant and that an auditor would have access to the entire record as there were no controls within the system to limit this.

There were no other changes suggested and the minutes were agreed as an accurate record.

d. CAG OFFICE REPORT

For information

Secretary of State approval decisions

The DH senior civil servant on behalf of the Secretary of State for Health agreed with all advice provided by the CAG in relation to the June 2014 meeting applications.

HRA approval decisions

The HRA agreed with all advice provided by the CAG in relation to the June 2014 meeting applications.

Meetings

'Future role of CAG'

A meeting took place on 25 June 2014 in follow-up to the first meeting that took place on 28 April 2014. It was attended by Mark Davies, David Knight, Peter Knight, Monty Keuneman, Bill Davidson, Anne Luciw, Christine Holmes and Jennifer Bryom (the Department of Health); Richard Wild (IIGOP); Janet Wisely, Joan Kirkbride and Natasha Dunkley (the Health Research Authority) and Dr Mark Taylor (HRA CAG);.

Led by the Department of Health, the aim of the meeting was to discuss the Care Act Regulations which will set out the factors and matters to which the CAG must have regard when advising the HSCIC and potentially HRA and SofS. Such criteria may include the purposes for which the data is to be used, whether anonymised data could be used or consent practicably obtained, and potentially a 'one strike and you're out' rule.'

The meeting moved on to cover practicalities of actually undertaking the work and volumes involved as the scale of the proposed activity had not yet been quantified. It was indicated that it

may involve up to 400 applications. It was noted that the HSCIC had not been directly represented and it would be important for this level of practical knowledge to be clearly established so that capacity and resourcing implications could be planned for.

It was agreed that Mark Davies would have a follow up discussion with Max Jones at the HSCIC together with CAG members (Mark Taylor, Natasha Dunkley possibly others if appropriate) shortly to consider the review of recent HSCIC data releases and the subsequent quarterly updates and use them to develop a view of the desired practical scope of CAG's roles in relation to the HSCIC and what it would mean for resources.

The group discussed the scope and application of the regulations, including whether they should apply to the advice given by CAG to the HRA and SofS, and noted that, if the regulations were to apply to all three recipients of CAG's advice, they would need to be suitable to cover this wide range of purposes. The DH agreed to undertake this. It was also agreed that the draft regulations as they currently stood would be circulated to the CAG. A possible workshop for interested parties to attend to help develop the regulations was suggested. DH agreed to organise this. A further meeting was scheduled for 25 July 2014.

Applications considered via Precedent Set review

The following applications were considered by sub-group under the precedent set process. Details of the Chair and members of the sub-group are included for each application.

Why do people with autism fare so differently in adult life? [CAG 5 (PS2)/2014]

This research application from Kings College London set out the purpose of obtaining up to date address from the Health and Social Care Information Centre (HSCIC). The address information would then be used to write to the cohort to invite them to participate in further stages of the study. A recommendation for class 3 and 6 support was requested to cover access to address and mortality data from the HSCIC. Access was requested to name, date of birth, date of death and address. NHS number, name, date of birth and postcode held by the applicant would be provided to the HSCIC in order to identify the cohort**.**

This application was considered via the precedent set process under criteria 1 – application to identify a cohort of patients and subsequently to seek their consent - by Dr Patrick Coyle (Chair), Professor Jennifer Kurinczuk and Dr Kambiz Boomla.

Confidentiality Advisory Group advice

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. Members noted that identifiable data would be required in order to seek consent from the cohort and that all subjects or their carers would have previously given consent, and would therefore not be surprised to be approached again by the study team.

Telephone contact

Members noted the applicant's proposal to telephone the subjects one week after they had received their letter to ask if they had any further questions before deciding whether or not to take

part. Whilst noting that the telephone number was not part of the request for confidential patient information, members asked for assurance that a script was in place for the researcher to use which ensured that the telephone call was to answer any questions the participants may have, and would not apply pressure on the participant to consent.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised the Health Research Authority to provide a recommendation of provisional support to the Secretary of State for Health, subject to compliance with the specific and standard conditions of support as set out below.

Health Research Authority recommendation

As the application scope covered information generated in both England and Wales a joint approval decision would be required from the Health Research Authority (England) and the Secretary of State for Health (Wales). CAG advice would be provided to the HRA who would provide a recommendation to the SofS in relation to Welsh data.

Following advice from the CAG, the Health Research Authority agreed to recommend provisional support to the Secretary of State for Health, in line with the conditions and clarifications highlighted by the CAG.

Specific conditions of support

1. Assurance whether script was in place for the researcher to use which ensures that the telephone call would not apply pressure on the participant to consent.
2. Confirmation of a favourable Research Ethics Committee opinion.
3. Confirmation of suitable security arrangements via IG Toolkit submission.
4. Please provide a signed copy of the IRAS form.

Neonatal Exchange Blood Transfusion (EBT) [14/CAG/1010]

This research application from Central Manchester University Hospitals NHS Foundation Trust set out the purpose of utilising the British Paediatric Surveillance Unit (BPSU) methodology to collect and analyse data relating to explore the use of neonatal exchange blood transfusion (EBT) and other therapeutic options within the context of fewer transfusions now being performed.

A recommendation for class 1, 2, 4, 5 and 6 support is being requested to extract and anonymise information, obtain and use information about past and present geographical location, link patient identifiable information obtained from more than one source, auditing, monitoring and analysing patient care and treatment.

This application was considered via the precedent set process under criteria 5 – applications utilising the British Paediatric Surveillance Unit (BPSU) methodology by Mr Mark Taylor (Chair), Professor Julia Hippisley-Cox and Mr Anthony Kane.

Confidential patient information requested

Access is requested to NHS number, hospital number, date of birth, date of death, hospital, ethnicity, gestational age and birth weight.

Confidentiality Advisory Group advice

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.

When considering whether consent would be feasible, members accepted that a complete case ascertainment was necessary to avoid the risk of bias in the analysis.

Justification and retention of identifiers

The necessity of the identifiers was recognised to undertake the analysis and identify duplicates to avoid errors. Members were unclear from the application as to the how long identifiable information such as hospital number, NHS number, sex, ethnicity and date and time of birth would be retained. Clarification was sought regarding how long identifiable information would be retained. The applicant stated that they would wish to keep this until data collection was complete but would reduce the identifiable data items for analysis.

Additional points

Members noted that the submitted application form did not confirm that objections from parents to being included within this study would be respected. The applicant advised that objections would be respected within the BPSU. If parents raised a concern with the BPSU through the contact details provided in the information sheet, the BPSU would remove the data from the collection.

Members noted that the applicant had already gained REC approval on the 15 February 2013 and sought confirmation that data collection had not already commenced. The applicant confirmed that no data collection had taken place and that the study had not started. The applicant had submitted an annual review report to the REC as required.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in research of this nature being conducted, and therefore advised recommending provisional support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. The provision of a listing of the retention period for all identifiers.
2. Confirmation that participant objections will be respected and how this will be performed.
3. Favourable opinion from a Research Ethics Committee.

4. Confirmation of suitable security arrangements via IG Toolkit submission for Section 251 purposes.

Retrospective Observational Study to Describe Treatment Patterns and Health Care Resource Utilisation Associated with Anti-Tumour Necrosis Factor (TNF) Therapy in Patients Diagnosed with Crohn's Disease (CD) or Ulcerative Colitis (UC) [14/CAG/1011]

This research application described a study being undertaken to describe the treatment patterns of anti-TNF use among patients diagnosed with Ulcerative Colitis (UC) and Crohn's Disease (CD) in clinical practice. The treatment patterns would be used to categorise patients into primary responders/non-responders and secondary loss of response to anti-TNF therapy in normal clinical care.

The aim of this study was to provide real-world evidence of treatment patterns, health care resource utilisation (HCRU), and associated health care costs in adult patients who have initiated anti-TNF therapy for the treatment of CD or UC.

The study would be carried out in the gastroenterology departments of NHS general hospitals. Patients with CD who received their first dose of anti-TNF between 01 June 2009 and 01 June 2011 and patients with UC who received their first dose of anti-TNF between 01 June 2009 and 01 June 2013 (the Eligibility Period), will be considered for study participation.

This application was considered via the precedent set process under criteria 2 – access to deceased person's data by Professor Julia Hippisley-Cox, Dr Mark Taylor (Chair) and Mr Anthony Kane.

This application from Optum on behalf of Takeda Pharmaceuticals International, Inc. set out the purpose of accessing deceased patient data to supplement the data collected from consented living patients as part of the above study. A recommendation for class 1, 2 and 6 support was requested to cover access to extract deceased patient data and to enable the auditing and monitoring of the study site data. Access was requested to date of death and ethnicity.

Confidentiality Advisory Group conclusion

The Precedent Set sub-group Confidentiality Advisory Group were unable to give advice due to a number of significant points that were identified from the review of this application. These points are listed below. The application has been referred to a full review at the Confidentiality Advisory Group meeting on 24 July 2014.

<u>Practicable Alternatives</u>

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.

It was unclear to members who would extracting deceased patient data at each site and whether Optum would be involved in this initial collection of data or whether this would be performed by member of staff at the site who has legitimate access to such patient records.

It was suggested that if a small (less than 20) number of patients may have died consideration should be given to whether a member of staff within the Trust with legitimate access to this information could extract it. Otherwise, a justification should be provided as to why this is not possible.

Members noted inconsistencies with in the IRAS regarding access to confidential patient information outside of the patient's care team and requested clarification as to which organisations would have access to identifiable information, including data of death.

Additional points

Members noted that date of death was a potential identifier and were unclear of who would be extracting this information, where the dataset may be stored, how it would be used and whether it is intended that potential identifiers such as date of death would or may be transferred out of the United Kingdom.

Confidentiality Advisory Group advice conclusion

Members were unable to provide a recommendation of support at this time and due to a number of issues highlighted above requested that the application be referred to the July CAG meeting.

Request for clarification

1. Members understood that the application included a request to permit study monitors to access to deceased patient data. The applicant was asked to advise how date of death and ethnicity, would be collected from deceased patients records. This included who would be extracting this data, where it would be stored, how it would be used and whether it was intended that potential identifiers such as date of death would be transferred out of the United Kingdom.
2. Confirmation regarding how many patients at each site may have died. Confirmation of the relationship site staff had to the deceased patients whose data would be viewed and extracted. Consideration should be given as to whether, if a small number of patients may have died, it would be possible for a member of staff with legitimate access to this confidential patient information to extract the dataset.
3. Confirmation that no confidential patient information would be accessed outside the care team without prior consent at any stage including identification of potential participants.

The subsequent further discussion in relation to this application is noted in agenda item 4a.

Millennium Cohort Study [14/CAG/1006]

This research application from the University of London set out the purpose of carrying out tracing via the Health and Social Care Information Centre for the Millennium Cohort Study (MCS; a continuing, multi-disciplinary, longitudinal study of some 19,000 subjects born in 2000/2001. A recommendation for class 2, 3, 4 and 6 support was requested to cover access to mortality and address information from the HSCIC.

This application was considered via the precedent set process under criteria 1 - application to identify a cohort of patients and subsequently seek consent by Ms Gillian Wells (Chair), Professor Barry Evans and Ms Clare Sanderson.

Confidentiality Advisory Group advice

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. Members noted that identifiable data would be required in order to trace cohort details in relation to address and mortality with the HSCIC.

Members noted that the application included references to the use of the School Pupil database to trace cohort members that the study had lost contact with. Members advised that where it was possible to trace an individual's contact details using the school pupil database this should be used, rather than seeking access to confidential patient information.

Retention of confidential patient information

Members requested confirmation in relation to how long identifiable data would be retained.

Linkage with additional datasets

Members noted that the protocol made reference to linkage to routine health records and data held by Department of Work and Pensions (DWP) and that these linkages could prove useful in the event of non-response. Members queried under what circumstances these linkages would be made, to what datasets and advised that linkages should only be undertaken with consent.

Data Protection Act compliance

It is a requirement of the Regulations that an application cannot be inconsistent with the principles of the Data Protection Act 1998 (DPA). The first principle of the DPA requires that reasonable efforts are made to inform data subjects of the use of their data.

Members advised that the applicant should ensure that the cohort was kept informed (through annual letters, website, and other means) about follow up of address and data of death with clear means of registering any objection.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised the Health Research Authority to provide a recommendation of 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.

Health Research Authority recommendation

Following advice from the CAG, the Health Research Authority agreed to recommend provisional support to the Secretary of State for Health, in line with the conditions and clarifications highlighted by the CAG.

Request for clarification

1. Confirmation of how long identifiable patient information will be retained.

2. Question 50, page 23 of the IRAS form, referred to the sharing of some sensitive data items under 'special licence'. The applicant was asked to confirm the number of such licences issued to date, the type of sensitive data shared under 'special licence' and examples of data/staff security required for such licences.

Specific conditions of support

1. Confirmation that parents and children were informed (through annual letters, websites or other means) about follow up of address and data of death with clear means of registering any objection.
2. Tracing via the HSCIC should take place only where individuals could not be traced using the pupil database.
3. Linkage to DWP data should only take place with specific consent from individuals.
4. Confirmation of suitable security arrangements via IG Toolkit submission.
5. Confirmation of a favourable Research Ethics Committee opinion letter.

An investigation into the role of the pharmacy team in reducing avoidable hospital readmissions [14/CAG/1007]

This research application from the University of Huddersfield & Calderdale and Huddersfield NHS Foundation Trust (CHT) detailed the development of an evidence base for pharmacy interventions in reducing hospital readmissions. A request for support under the Regulations was received to allow a researcher to access the Trust's Health Informatics Service (THIS). Pharmaceutical and readmission risk information would be collected from the Trust's records (e.g. drug history from medical notes, prescription details from drug chart) and electronic patient administration system (PASWEB). NHS number only would be used for linkage purposes. A recommendation for class 1, 4, 5 and support was requested to allow access to patient records and to extract NHS number to carry out data linkage.

This application was considered via the precedent set process under criteria 4 – time limited access to undertake record linkage/validation and to pseudonymise the data by Ms Gillian Well (Chair), Dr Tony Calland and Professor Barry Evans.

Confidentiality Advisory Group advice

Practicable alternatives

Member agreed that consent would not be feasible as the request detailed accessing retrospective data. Members noted that identifiable data requested was restricted to NHS number only with one hospital employed researcher having access.

Patient objection

Members requested that the applicant ensure that the patient information leaflet included instructions describing how to register an objection to the use of confidential patient information and that this must be respected.

Additional points

Members made the following comments in relation to the application but indicated that these did not form part of CAG advice under the Regulations but were points of general advice. Members

advised that statistical advice could be obtained in relation to the sample size and queried whether it would be beneficial to determine those patients who had died during or after the hospital visit in order to remove those patients from the analysis. This did not impact the CAG assessment of whether the application met the minimum threshold of the Regulations and was provided as additional comment only.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in research of this nature being conducted, and therefore advised recommending conditional support to the Health Research Authority, subject to compliance with the specific and standard conditions of support and further clarifications as set out below.

Specific conditions of support

1. Confirmation of the sample size.
2. Confirmation that the patient information leaflet will include details of how to register a patient's objection to the use of data.
3. Favourable opinion from Research Ethics Committee
4. Confirmation of suitable security arrangements via IG Toolkit submission

Amendment to existing applications

Adults with histiocytic disorders in the Northeast region (Previously - Pilot study to assess patient services involved in treating adults with histiocytic disorders in Newcastle) [ECC 8-05(e)/2011]

This application from Newcastle University detailed a study into the occurrence and treatment of histiocytic disorders in Newcastle in order to describe the treatment and services received and assess how many had died. The results of the study aimed to encourage co-operation and planning of treatments and services for patients both in the Newcastle region and further afield and would potentially inform a national study.

A recommendation for class 4, 5 and 6 support was requested to provide a legitimate basis to identify cases from the pathology database, and then collect further information from treating clinicians and the Northern Region Young Person's Malignant Disease Registry. Identifiers were requested to link data from all sources.

Amendment request

The applicant sought to extend the study end date because of delays to the research approvals for the study meant that data collection had been slow. The researchers had therefore not been able to complete the study by the original end date of 30 June 2014.

Confidentiality Advisory Group advice

The amendment requested was forwarded to the Chair who was content to suggest the extension of this application based on the above justifications.

Confidentiality Advisory Group conclusion

In line with the considerations above, the Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health.

Specific conditions of support

1. Confirmation of a favourable opinion from a Research Ethics Committee.

National Oesophago-gastric Cancer Audit [ECC 1-06(c)/2011]

This audit application from the Health and Social Care Information Centre provided details of a follow-on audit of the National Oesophago-gastric (OG) cancer audit, due to commence in April 2011. The Audit would examine the quality of care received by patients with oesophago-gastric cancer in England and Wales. Linking with the first Oesophago-gastric Cancer Audit would allow for results to be published on a longitudinal basis and so highlight areas where care had improved and where improvement was still needed.

A recommendation for class 3, 4, 5 and 6 support was sought to collect data on all patients aged 18 and over who had been diagnosed with oesophago-gastric cancer between 1 April 2011 and March 2014 in England and Wales. Support was also sought to permit linkage with the first National OG audit in order to carry out longitudinal analyses, and to extend the cohort in April 2012 to include patients in England and Wales diagnosed with High-Grade Dysplagia. In particular, the audit requested access to NHS Number, postcode, sex, and date of birth. Linkages would be carried out with death data, HES, PEDW and the Casemix Programme within the ICNARC datasets.

Access was requested to NHS number, date of birth, sex and postcode.

Amendment request

An amendment request was submitted on the 2 May 2014 and detailed the following:

1. Support to link to Systemic Anti-Cancer Therapy Dataset (SACT) dataset from the cancer registry
2. Inclusion of place of death
3. Inclusion of surgeon General Medical Council (GMC) code.

Confidentiality Advisory Group advice

The amendment request was forwarded to Dr Tony Calland, Vice-Chair under the precedent set review process. It was noted that the specified amendments included key additional data and the additional linkage to SACT had been approved in relation to other audits. It was agreed that the amendment requests should be recommended for support. The Vice-Chair requested that the applicant confirm what data items would be extracted from the SACT once known.

Confidentiality Advisory Group conclusion

In line with the considerations above, the Vice-Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health.

National Lung Cancer Audit [ECC 1-03(e)/2012]

This audit application from the Health and Social Care Information Centre set out the purpose of collecting data on head and neck cancer patients in order to assess the effectiveness and appropriateness of treatment received by this patient group from specialist services. A recommendation for class 1, 4, 5 and 6 support was requested.

Access was requested to NHS number, date of birth, date of death and postcode.

Amendment request

This amendment request, received on 2 May 2014, detailed the following:

1. Linkage to:
    - Systemic Anti-Cancer Therapy (SACT) data
    - Diagnostic Imaging Dataset (DID)
    - Hospital Episode Statistics (HES) data
2. Access to mortality data including place and date of death.
3. Inclusion of surgeon GMC code
4. Use of data at Clinical Commissioning Group (CCG) level as part of CCG outcomes indicator set

Confidentiality Advisory Group advice

This amendment request was forwarded to Dr Tony Calland, Vice-Chair who agreed that the proposed linkages would have significant benefits to the audit. It was noted that the additional linkage to the SACT data and HES had been approved in relation to other audits The Vice-Chair agreed to recommend support, subject to further information in relation to the data items to be accessed from all datasets being provided once known to ensure a complete record of the audit dataset is held.

Confidentiality Advisory Group conclusion

In line with the considerations above, the Vice-Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health.

National Bowel Cancer Audit [ECC 1-03(d)/2012]

This audit application from the Health and Social Care Information Centre set out the purpose of collecting data in relation to bowel cancer patients in order to assess the effectiveness and appropriateness of treatment received by this patient group from NHS services. A recommendation for class 1, 4, 5 and 6 support was requested.

Access was requested to name, NHS number, date of birth, date of death and postcode.

Amendment request

This amendment request, received on 2 May 2014, detailed the following:

1. Linkage to:

- National Radiotherapy dataset
- Systemic Anti-Cancer Therapy (SACT) data
- Diagnostic Imaging Dataset (DID)
- National Emergency Laparotomy Audit (NELA)
- Inflammatory Bowel Disease database

2. Access to mortality data including place and date of death.
3. Inclusion of surgeon GMC code

Confidentiality Advisory Group advice

This amendment was forwarded to Dr Tony Calland, Vice-Chair who noted that the proposed linkages would have significant benefits to the audit. It was agreed that, whilst supportive in principle, further information should be provided in relation to the linkage with NELA and Inflammatory Bowel Disease database once known. The Vice-Chair agreed to recommend support, subject to further information being provided in relation to the linkage process with NELA and the Inflammatory Bowel Disease database once known. Details of the data items to be accessed from all datasets should also be provided once known to ensure a complete record of the audit dataset is held.

Confidentiality Advisory Group conclusion

In line with the considerations above, the Vice-Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health.

Small Area Health Statistics Unit (SAHSU) Health Database [ECC 2-06(a)/2009]

The original application from Imperial College London requested support to process a number of datasets; ONS data relating to births and stillbirths, cancer, mortality, NCAR and HES data. This was for the purposes of advice provision, development of methodology to interpret health outcomes for small areas and to act as a centre of expertise. The data was to be held for a period from 5 years up until April 2014. It had been agreed previously that future linkages between datasets should be considered via the proportionate review process as amendments to the original application.

The amendment request was consider by Dr Mark Taylor (Chair), Dr Tricia Cresswell and Dr Chris Wiltsher.

Amendment request

The submitted amendment request was for a study titled ‘Possible reproductive and other health effects associated with Municipal Solid waste Incinerators (MSWIs) in England and Wales’ and included a request for SAHSU to access National Community Child Health Dataset data.

The data requested from NCCHD included:

- Postcode
- Sex of baby
- Birth status (live/still)
- Birth weight
- Gestational age
- Age of mother at birth

- Birth date (baby)
- Number of babies (single/multiple)
- Ethnic group
- Delivery method
- Socio-economic status
- ID/NHS number of child

Confidentiality Advisory Group advice

The amendment was forwarded to members who agreed that the work of SAHSU was important and required linkage of large datasets with retention of some identifiers for linkage and then for analysis, including geographical identifiers. This was an established principle agreed within the overarching application.

Members noted that the specified study was in the public interest and were agreed that the methodology seemed appropriate and would require the use of confidential patient information but would restrict access to identifiers as far as reasonably possible.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised the Health Research Authority to recommend conditional support to the Secretary of State for Health, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Confirmation of favourable opinion from a Research Ethics Committee.
2. Confirmation of satisfactory Information Governance Toolkit score.

Patient Outcomes Registry [ECC 4-03(e)/2012]

This application from University College London set out details of the establishment of a research database derived from national cardiac audit data that would link care across pathways. The aim was to develop further the research potential of audit data to understand better the causes of coronary heart disease, timing and evolution of risk, and the interplay between biological, interventional and environmental factors.

Amendment request

The original approval specifically excluded the inclusion of Transcatheter Aortic Valve Implantation (TAVI) audit data and the applicant was advised that a separate application for this audit should be submitted. This application was submitted to the August 2013 CAG meeting and approved (CAG 5-07(c)/2013). The amendment request detailed including the TAVI audit data in the patient outcome registry.

Confidentiality Advisory Group advice

The amendment request was forwarded to Dr Patrick Coyle, Vice-Chair, who confirmed that the amendment was supported, noting that data would be processed as detailed within the original

application and that the Ethics and Confidentiality Committee were supportive of the inclusion of the TAVI audit initially.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the Vice-Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health.

e. ANY OTHER BUSINESS

Sub-group rota and member availability

The Chair requested that members check the review allocations for forthcoming Precedent Set sub-group meetings and advise the Confidentiality Advice Team (CAT) if there were any conflicts.

Change of Secretary of State from Health representative

It was advised that there had been a change in Secretary of State Representative. Rebecca Chaloner, Deputy Director, Innovation, Growth and Technology Directorate at the Department of Health, would now be approving non-research applications and would attend a CAG meeting in the near future.

Consultation – Protecting Health and Care Information

The Chair thanked members for their contribution to the CAG response to the Department of Health consultation; Protecting Health and Care Information, a consultation on proposals to introduce new Regulations. It was confirmed that the consultation response would be prepared and submitted by the HRA.