NHS
Health Research Authority
Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group

16 May 9.00 at Skipton House, SE1 6LH

Present:

Name	Capacity
Dr Mark Taylor (Chair)	Lay
Dr Kambiz Boomla	
Dr Patrick Coyle (Vice Chair)	
Dr Robert Carr	
Dr Tony Calland MBE (Vice Chair)	
Mr Anthony Kane	Lay
Mr C Marc Taylor	
Ms Gillian Wells (Alternative Vice Chair)	Lay
Professor Jennifer Kurinczuk	
Professor Barry Evans	
Mrs Hannah Chambers	Lay
Professor Julia Hippisley-Cox (item 5 only)	

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

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Apologies

Apologies were received from Dr Miranda Wolpert, Professor Ann Jacoby, Ms Clare Sanderson and Dr Murat Soncul. Professor Julia Hippisley-Cox sent apologies for items 1, 2, 3 and 4.

Declarations of interest

No declarations of interest were received.

2. MINUTES OF THE MEETING HELD ON 10 APRIL 2014 AND MATTERS ARISING

Members requested that the minutes be updated to reflect discussion in relation to the Access to MIDAS for the What About Youth? 2014 survey application [CAG 1-06(d)/2014], it was noted that a pilot survey had taken place and was reported within the submission and members had queried whether confidential patient information had been disclosed for this activity and if so under what legal basis.

Pending the above amendment, the minutes were agreed as an accurate record, subject to minor changes.

An update was provided in relation to the actions arising from the minutes.

Review of annual review requirements

It was noted that a project group would be established to undertake a review of the annual review requirements arising from approved applications. Ms Gillian Wells had agreed to chair the project group with members consisting of Dr Murat Sincul, Ms Clare Sanderson, Mr Tony Kane and Professor Julia Hippisley-Cox. The intent would be to review the requirements and how information is gathered and assessed, with a view to providing final recomemndations to the CAG in its August meeting. The Chair thanked Ms Wells for taking on this work and emphasised the importance of the review at this time.

HSCIC Pseudonymisation Steering Group

Ms Dunkley had attended the first meeting of this group as an observer and provided a short update to the Group. It had been agreed that Dr Kambiz Boomla would attend as the CAG observer representative with Mr C. Marc Taylor attending when Dr Boomla was unavailable.

Professor Julia Hippisley-Cox was also a member of this group but was not attending or contributing from a CAG perspective.

The purpose of the CAG having an observer presence was intended to provide insight into actions of group as pseudonymisation could be an exit strategy from support under the Regulations, however, it was emphasised that care would need to be taken that there would be no indication of the CAG providing endorsement to the actions taken within the activity, in light of the proposed new role of the CAG. The potential tension was acknowledged and the limitations of an observer capacity, while appropriate, were highlighted. It was confirmed that the CAG could not be drawn into a decision-making process and the position would be reviewed and issues raised as the steering group progressed if the CAG position became difficult.

Applications for activities similar to care.data programme

Following points raised by the Group following discussion of CAG 1-06 (a)/2014 in the March 2014 meeting, Ms Dunkley confirmed that the representative of theSofS had been approached for views on handling applications that raise issues similar to 'care.data, while public confidence in 'care.data' was being re-built. Feedback had been provided that confirmed the CAG was right to raise this issue, and it was recommended that Eve Roodhouse, Programme Director for care.data be approached to identify whether she would be willing to provide an update on care.data to the CAG.

Major Internet Security Threat – 'Heartbleed'

It was confirmed that the Confidentiality Advice Team had raised this issue with the local NHS.net administrator to determine whether any action was required by members and it was confirmed that no further action was required at this stage.

National Child Development Study The 1958 British Birth Cohort Study [CAG 1-03(PR2)/2014]

The Chair highlighted that the issue of indefinite retention of data for long term cohorts had arisen in the context of this application

Members queried the issue of indefinite retention and requested further assurance as, for example, funding may not be in place in future years and the status of retaining information would need to be considered in this context.

Members did note that the CAG would need to approach this issue of long-term retention in a considered manner as certain studies will generate real historical records that would need to be retained for a potentially indefinite time period. It was advised that there should be consideration of what falls into a true historical records and it was agreed that this would be an action to include on an away day as part of the business improvement programme.

Action: categorisation of historical records and retention requirements to be included as part of business improvement.

3. 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 April 2014 meeting applications.

HRA approval decisions

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

Operational updates

Booking process

In order to ensure sufficient time is provided for thorough consideration of applications, members were informed that CAG will consider up to 8 new applications at each meeting. This number had been identified as the maximum to ensure that each application receives an appropriate level of scrutiny. In order to manage this, from 1 May 2014 applicants would be required to book an application onto the next available CAG meeting prior to submission. Applications would be booked on a first come first served basis.

Precedent set applications

Members were informed that the proportionate review process was renamed to precedent set from the 28 April 2014 and the website had been updated to reflect this change.

Practicable alternatives working group

Members were informed that a secondment from the Medical Research Council, who developed the HRA decision tools, had been approved to develop an online guidance tool to present the practicable alternatives work. It was anticipated that this would be ready for piloting by end June 2014.

Applications considered via Precedent Set review

Understanding age inequalities and inequities in the cancer pathway [CAG 2-03(PR1)/2014]

This research application from the University of Leeds set out the purpose of a study which aimed to use routine health data to quantify and understand the influence of age on the incidence,

tumour characteristics, diagnosis, treatment, survival and outcomes of a number of cancers at a population level.

The application detailed linking a number of datasets; cancer registry, HES and pathology and treatment information, at the NCRS Northern and Yorkshire offices. It was confirmed that any datasets taken off site would be fully anonymised.

A recommendation for class 2, 4, 5 and 6 support was requested to cover access to date of birth, date of death, postcode and NHS number. All identifiers would be removed once all linkages had taken place. This application was considered via the proportionate review process by Mark Taylor (Chair), Marc Taylor and Robert Carr, under criteria 4; time limited access to undertake record linkage/validation and to pseudonymise the data.

Confidentiality Advisory Group advice

Members agreed that the subject was important, and that the research would add to improving cancer outcomes in the UK.

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 the large retrospective nature of the cohort and agreed that individual consent would not be feasible in this instance.

Identifiable data would be required in order to carry out data linkage only and the dataset would be anonymised prior to analysis. It was noted that the research team would require access to identifiable data in order to carry out linkages, cross checks and to seek additional detail if necessary.

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 queried whether efforts were already made to inform the cohort about the work of the Cancer Registry and whether a description of the new linkages and their purpose and benefits could be added to this information.

Members sought assurance that those processing identifiable data were under an appropriate duty of confidentiality.

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 recommending provisional support to the Health Research Authority, subject to compliance with the specific and standard conditions of support and request for further clarification as set out below.

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following the application is conditionally approved, subject to compliance with the standard and specific conditions of approval.

Request for clarification

1. Confirmation of what efforts can be made to inform the cohort in line with the comments outlined above.
2. Confirmation that those processing identifiable data are under an appropriate duty of confidentiality.

Specific conditions of support

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

Mental Disorder & Cancer care: a data linkage study in south London II [CAG 2-03(PR3)/2014]

This research application from Kings College London sought to link cancer registry data held with data held by SLAM, HES and mortality data which were all linked via existing approvals. The resulting pseudonymised database would be used to investigate whether people who have had a mental disorder have delayed presentation of cancer, trajectories of their cancer treatments and other incidental conditions compared to those who do not have a mental disorder.

A recommendation for class 4 and 6 support was requested to cover access name, NHS number, date of birth and postcode by the Health and Social Care Information Centre (HSCIC). A dataset including date of death and a pseudonym would be disclosed to the applicant to allow linkage to existing datasets. This application was considered by proportionate review by Mark Taylor (Chair), Jennifer Kurinczuk and Clare Sanderson under category 4 – time limited access to carry out linkages and pseudonymise data.

Confidentiality Advisory Group advice

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 agreed that the large retrospective nature of the cohort meant that seeking consent to carry out data linkage would not be feasible.

Members noted that the transfer and processing of identifiers would be kept to a minimum and that linkage would take place using pseudonymised data only. Identifiable data would be required by the HSCIC to identify relevant patient notes only.

It was confirmed that data would only be used by those researchers named within the application.

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.

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following the application is conditionally approved, subject to compliance with the standard and specific conditions of approval.

Specific conditions of support

1. Support was for the specified linkage only and additional applications should be made for support for further linkages.
2. Confirmation of satisfactory security arrangements via confirmation of a satisfactory IG toolkit submission.
3. Favourable opinion from a Research Ethics Committee.

COPD audit programme - pulmonary rehabilitation clinical audit pilot [CAG 2-03(PR3)/2014]

This audit application from the Royal College of Physicians set out the purpose of a pilot for the pulmonary rehabilitation audit, commissioned by the Healthcare Quality Improvement Partnership, which would provide a snapshot audit of service delivery and quality. The audit aimed to enable providers of pulmonary rehabilitation for COPD to improve the quality of care provided in these settings, through the provision of high quality time–limited data collections.

A recommendation for class 1, 5 and 6 support was requested to cover access to data including NHS number, date of birth and postcode, no data linkages would take place at pilot stage. This application was considered via proportionate review by Mark Taylor (Chair), Tony Calland and Tony Kane, under criteria 4: time limited access to undertake record linkage/validation and to pseudonymise the data.

Confidentiality Advisory Group advice

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 noted that the application depended on obtaining data from a multiplicity of public and some private service providers, and therefore members were of the view that pseudonymisation at source could not be considered as an alternative for this aspect of the audit at present.

Members highlighted that whilst pseudonymisation was not deemed to be feasible at this stage for this aspect and this option should be continued to be explored as part of an exit strategy from the use of confidential patient information without consent. It was advised that provider organisations were encouraged to ensure NHS numbers were at the highest possible levels to facilitate this.

Members discussed whether consent would be feasible. Some views were raised that consent appeared to be difficult and may be too onerous in terms of resources and time and therefore have a detrimental effect on the pilot project. Members did note that the inclusion criteria meant that patients would attend an appointment during the pilot phase and recommended that the applicant pilot consent at this stage in order to provide evidence to inform any further application. Members agreed that this should be a condition of support and that the expectation would be that the applicant could collect sufficient information in the pilot stage to determine whether consent could be pursued as a potential exit strategy from support and how long it may take to establish this.

Members noted that NHS number, postcode and date of birth had all been requested as these would be data items required to carry out linkages within the full audit application. Members requested that the applicant test the requirement for all these identifiable data items prior to submission an amendment to the full application. For example, it was queried whether linkages could be undertaken using NHS number alone. If linkages could be undertaken using NHS number only members queried why date of birth and postcode were required.

It was noted that identifiable data items would be destroyed within 2 months of completion of the pilot. Members agreed that this was reasonable.

It was advised that the final statement ‘For more information please ask a member of the hospital COPD team for a leaflet’ include a reference to opt out, for example ‘or ‘if you want to opt out’ or ‘chose not to participate’. In addition, members commented that the poster should include further information about the potential benefits of the audit.

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 recommending conditional support to the Secretary of State for Health, subject to compliance with the specific and standard conditions of support as set out below.

The Secretary of State for Health, having considered the advice from the Confidentiality Advisory Group as set out below, determined that the application was conditionally approved, subject to compliance with the standard and specific conditions of approval.

Specific conditions of support

1. The patient information poster should be amended to make opt out more explicit in line with comments above.
2. A consent based approach should be piloted so further information can be provided in any future submission about the feasibility of consent and whether this could be adopted as an exit strategy.
3. The applicant should consider whether linkages could be undertaken using NHS number only and provide evidence of the requirement for postcode and date of birth within any future application, this should include results of a pilot to determine whether linkage on NHS number alone has proved to be feasible.
4. Confirmation of suitable security arrangements via IG Toolkit submission.

1970 British Cohort Study [CAG 2-03(PR4)/2014]

This research application is for the 1970 British Cohort Study, which is the third of Britain's world renowned national longitudinal birth cohort studies. It follows all those born in a particular week in 1970 throughout their lives, charting the effects of events and circumstances in early life on outcomes and achievements later on. The study is run by the Centre for Longitudinal Studies (CLS), at the Institute of Education, University of London and funded by the Economic and Social Research Council.

Since 1970 there have been eight attempts to gather information from the whole cohort. Over time, the scope of enquiry has broadened from a medical focus at birth, to encompass physical and educational development at the age of five, physical, educational and social development at the ages of ten and sixteen, and then to include economic development and other wider factors at ages 26, 30, 34, 38 and 42. Future sweeps of the study will take place every 4-5 years.

The ongoing success of the study depended on maintaining contact with as many study members as possible. The purpose of this application is to request Section 251 support for two activities which would support this endeavour.

1. To supply the HSCIC with lists of 'untraced' cohort members in order that they can be matched with GP registrations and new addresses supplied. These matched individual would then be contacted and invited to continue their participation in the study.
2. Receive notifications from the HSCIC which inform us of deaths, embarkations (i.e. emigrations) and exits/entry from the NHS which are used for both tracing and research purposes.

A recommendation for class 2, 3, 4 and 6 support was requested to cover access to HSCIC data for the above purposes. This application was considered via the proportionate review process by Mark Taylor (Chair), Clare Sanderson and Gillian Wells, under criteria 1 and 2 – patient recruitment and access to deceased patient data.

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

Confidentiality Advisory Group advice conclusion

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

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 support to the Secretary of State for Health, in line with the conditions and clarifications highlighted by the CAG.

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission.

Amendments

NCEPOD [PIAG 4-08(b)/2003]

This audit application from the National Confidential Enquiry into Patient Outcome and Death set out the purpose of a study to review clinical practice and identify potentially remediable factors in the practice of anaesthesia, surgery and other invasive medical procedures including primary care. A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover access to patient data.

Access was requested to name, address, NHS number, hospital number, age, date of birth, date of death, date of admission, date of ICU admission, date of procedure.

Amendment request

The Applicant requested to use a prospective method and stated that sepsis was not well coded, therefore there was a need to identify patients as they are diagnosed in intensive care or by an outreach team. In addition, patients would be identified in the emergency department via positive blood cultures. Once identified databases will be populated and sample of patients randomly selected to obtain case notes and questionnaires retrospectively.

Confidentiality Advisory Group advice

The amendment was reviewed by the Chair who was content to support the amendment on the basis of there being no methodological changes to the approved application.

Confidentiality Advisory Group advice 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.

The Secretary of State for Health, having considered the advice from the Confidentiality Advisory Group as set out below, determine that the amendment was approved, subject to compliance with the standard conditions of approval.

Validation of risk assessments for patients from MSS (VoRAMSS) [ECC 6-06(b)/2009]

This research application from the University of Manchester set out a prospective study that aimed to validate and assess the reliability and utility of recently developed risk assessment instruments in a group of 560 patients across 38 medium secure units in England and Wales with a diagnosis of Schizophrenia. A recommendation for class 1, 2, 4, 5 and 6 support was sought in order for the research group to access patient medical notes at 6 and 12 months to link with information on the Police National Computer. Identifiers requested were name and date of birth.

An amendment request was received on 15 November 2013 seeking an extension of support under the Regulations until September 2016, on the grounds that the original study had identified a higher number of discharged patients returning to prison than had been expected. There was therefore an interest in finding out why this might be through evaluating the factors influencing the decision to return to prison rather than choosing a health or social care pathway and identifying what healthcare those discharged to prison received while in prison and following release. This would involve a more detailed follow-up of those already discharged to prison and identification of new discharges from medium secure psychiatric facilities, including consideration of additional discharges in order to generate an accurate picture of why more people than expected were transferred back to prison and what happened to them. A refreshed version of the study protocol was supplied to support the amendment.

Confidentiality Advisory Group advice

The amendment request was forwarded to the Chair who was supportive of the request on the grounds that the findings of the study could not have been expected at the time of the initial application, and agreed that there was a clear public interest in following up the initial findings. 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. The Chair recommended that the

applicant ensure that information in relation to the study was made available in line with the requirements of the first principle of the Data Protection Act 1998.

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.

The Secretary of State for Health, having considered the advice from the Confidentiality Advisory Group as set out below, determined that the amendment was approved, subject to compliance with the standard conditions of approval.

Specific conditions of support

1. The applicant was asked to ensure that fair processing information was made available in line with the requirements of the Data Protection Act 1998.
2. Confirmation of suitable security arrangements via IG Toolkit submission.
3. Confirmation of a favourable opinion from a Research Ethics Committee.

UK Renal Registry [PIAG 1-07(c)/2004]

This audit application from the UK Renal Registry (UKRR), part of the Renal Association, was established to report on Established Renal Failure service provision, management and outcomes in the UK. The UKRR collects data on all patients with Established Renal Failure (ERF) in the UK. This information is subsequently analysed and published in a publically accessible annual report and plays an important role in improving the care and outcomes for patients with advanced kidney disease. Data is sent quarterly by renal units to the Registry using a secure electronic method. The UKRR currently has an established link with NHS Blood and Transplant to allow information regarding renal transplantation to be shared between the two organisations.

Amendment request

The amendment request submitted detailed extending the current support to include further data items and patients with any and all forms of acute kidney injury (AKI) from renal units and laboratory systems. AKI patients would be identified using an algorithm provided by NHS England based on serum creatinine changes over time. Access was requested to patient name, address, postcode, date of birth, NHS number, hospital number and date of death.

Confidentiality Advisory Group advice

Members noted the assertions made within the application that data from laboratory systems using older, legacy systems may not utilise the NHS number and therefore additional data items were required to link individual patient care. In addition, if a patient moved from a renal unit or had been identified by a laboratory system which recorded the NHS number to a system which did not, the continuity of the record would be lost. Additional identifiers were therefore requested to ensure that the patient could continue to be followed up. Address data was requested as the postcode provided was often incorrect. It was advised that identifiable data items collected for verification purposes should be destroyed as soon as possible.

Confidentiality Advisory Group advice conclusion

CAG agreed that the minimum criteria under the Regulations appeared to have been met and therefore advised recommending support to the Secretary of State for Health, subject to compliance with the specific and standard conditions of support.

The Secretary of State for Health, having considered the advice from the Confidentiality Advisory Group as set out below, determined that the amendment was approved, subject to compliance with the specific and standard conditions of approval.

Specific conditions of support

1. Retention of each identifiable data item should be for the minimum time necessary and should be deleted when possible. Please confirm timescales prior to final approval.
2. Confirmation of suitable security arrangements via IG Toolkit submission.

Central Register class support applications

These are historical, pre-existing approved applications which have previously fallen within the NHS Central Register application (ECC 2-04(c)/2010) and now submitted on an individual basis. This is because the overarching NHS Central Register application is no longer required by the HSCIC following powers provided to them within the Health and Social Care Act 2012. These applications are considered by proportionate review by the Confidentiality Advice Team, following agreement from the Confidentiality Advisory Group, under criteria 15 – access to mortality, cancer or GP registration data from the NHS Central Register - class support study.

Haemostatic Factors of Coronary Heart Disease [CR13/2014]

This application from the Royal Free & University College Medical School set out a long term prospective study aimed at improving the identification of men at high risk for heart attack.
A recommendation for class support was requested to cover access to mortality data from the NHS Central Register, maintained by the Data Linkage and Extract Service (DLES) at the Health and Social Care Information Centre. A cohort of 3,052 patients was flagged at the HSCIC.

Confidentiality Advice Team advice

The Confidentiality Advice Team 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 noted that identifiable data was currently held by the applicant with consent and support was requested to obtain mortality data from the HSCIC only.

Identifiable data was held by the applicant with consent, support was requested to obtain mortality data from the HSCIC only. It was confirmed that it would not be possible to remove all identifiable data in relation to participants as information in relation to diabetes and non-fatal myocardial infarction was requested and future linkages to MINAP or hospital admissions may occur. It was advised that this recommendation of support did not cover access to future linkages other than to HSCIC mortality data and a further application should be submitted if support was required for any additional linkages.

It is a requirement of all applications that data processing is not inconsistent with the Data Protection Act 1998. The first principle requires that reasonable efforts are made to inform data subjects of the uses of their data. In line with this, it was advised that continued reasonable efforts were made to inform participants that information in relation to mortality would be accessed from the HSCIC, for example including this information on relevant websites.

It was advised that NRES confirmed that they do not have a record of the application and as such the approval may have elapsed. Confirmation from NRES that the approval remains valid was requested prior to final confirmation of support.

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.

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 recommending provisional support to the Health Research Authority, subject to compliance with the specific and standard conditions of support and further clarifications as set out below.

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.

The Secretary of State for Health, having considered the recommendation from the Health Research Authority as set out below, has determined that the application was approved, subject to compliance with the standard and specific conditions of approval.

Specific conditions of support

1. Reasonable efforts to inform patients of ongoing data collection should be made in line with the requirements of the Data Protection Act.
2. Confirmation of suitable security arrangements via IG Toolkit submission.
3. Confirmation of favourable REC opinion in line with comments above.

Updates to previous applications

The Birmingham COPD cohort study v2.0 [CAG 8-03(PR4)/2013]

This research application from the University of Birmingham set out a cohort study covering 2,500 GP patients in the Birmingham and Black Country area who were aged 40+ and had a diagnosis of chronic obstructive pulmonary disease (COPD). Assistance had been sought from GP practice staff to identify eligible patients and make contact with these in order to seek consent for inclusion in the study on behalf of the applicant. A recommendation for class 1 and 6 support was requested to allow a researcher time limited access to NHS number in order to establish a query using the MIQUEST system and extract pseudonymised data in relation to those patients who had not responded to requests for consent.

Further information

Further information was provided by the applicant on the 28 February, the applicant confirmed that the following process would be followed:

1. GP practice staff would remove from view any patient identifiable data from the master linking spreadsheet, and any patient identifiable data from data outputs prior to disclosure to researchers. It was confirmed that as this was a relatively simple task and not as time-consuming as the other processes, practice staff were agreeable to this.
2. Much of the linkage could be performed using local ID numbers which would not be identifiable to researchers.
3. An automatic tool had been developed which would allow the extraction and linkage of data to study IDs without the operator viewing any patient identifiable data.

Confidentiality Advisory Group advice

As it had been confirmed that researchers would have no access to identifiable data the vice-Chair (Dr Patrick Coyle) confirmed that an application for support under the Regulations would not be recommended in these circumstances. Staff within GP practices should ensure that patient identifiable data was not accessed or removed from GP practice sites.

Targeted case finding for COPD in Primary Care (TargetCOPD) V4.0 [CAG 8-03(PR5)/2013]

This research application from the University of Birmingham set out a cohort study covering 76,608 GP patients in the West Midlands region who were aged 40 to 79 and had a history of smoking but had not been diagnosed with chronic obstructive pulmonary disease (COPD). Assistance had been sought from GP practice staff to identify eligible patients and make contact with these in order to seek consent for inclusion in the study on behalf of the applicant.

Aims of the study included assessing the comparative benefits of a targeted approach versus routine practice in COPD case identification, and the effectiveness of an active approach via a questionnaire. The study was correspondingly divided into routine and targeted arms.

Further information

Further information was provided by the applicant on the 28 February, the applicant confirmed that the following process would be followed:

1. GP practice staff would remove from view any patient identifiable data from the master linking spreadsheet, and any patient identifiable data from data outputs prior to disclosure to researchers. It was confirmed that as this was a relatively simple task and not as time-consuming as the other processes, practice staff were agreeable to this.
2. Much of the linkage could be performed using local ID numbers which would not be identifiable to researchers.
3. An automatic tool had been developed which would allow the extraction and linkage of data to study IDs without the operator viewing any patient identifiable data.

Confidentiality Advisory Group advice

As it had been confirmed that researchers would have no access to identifiable data the vice-Chair (Dr Patrick Coyle) confirmed that an application for support under the Regulations would not be recommended in these circumstances. Staff within GP practices should ensure that patient identifiable data was not accessed or removed from GP practice sites.

Piloting new approaches 2014 – security breach [CAG 10-03(PR3)/2014]

This application from the Care Quality Commission (CQC) set out the purpose of trialling new approaches to the National Inpatient Survey to increase the frequency and granularity of the survey. It is anticipated that the survey will be run up to four times a year. The increased frequency of this survey should provide more accurate survey data for the data packs used in CQC inspections. Increased granularity provides a benefit to obtaining performance data for sub-units within trusts and enable greater precision in targeting poor performance.

The CQC reported that Heatherwood and Wexham Park Hospitals NHS Foundation Trust submitted patient identifiable data along with sample file information to the coordination centre who should only receive sample file information with limited demographic and clinical data. The CQC wrote to the Trust on 14 March 2014 in order to request information in relation to actions taken. At the time of writing this report the response from the Trust is outstanding.

4. NEW APPLICATIONS – RESEARCH

Impact of earlier diagnosis of intracranial tumours in children [CAG 2-07(c)/2014]

This application had been moved from the agenda on the 15 May due to time constraints.

This application from the University of Nottingham set out the purpose of a study to investigate the role of a symptom awareness campaign (Headsmart) in reducing delays and improving outcomes. An evaluation of the impact in population health would be undertaken by examining annual changes in survival in children and young adults with intracranial tumour and investigating the relationship between diagnostic delay, survival and prevalence of functional deficits such as vision impairment.

A recommendation for class 4, 5 and 6 support was requested to cover access to data from the cancer registry in relation to patients aged 0-24 who had been diagnosed with an intracranial tumour. This data would then be supplemented with data on primary (CPRD) and secondary care presentations, specialist referrals, neuroimaging and vision impairment. Data would be processed at the London School of Hygiene and Tropical Medicine (LSHTM).

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

<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.

Members discussed whether it would be feasible to seek consent and agreed that the retrospective nature and size of the cohort would mean that this would not be possible.

Identifiable data was required in order to carry out data linkage and carry out quality-control checks on the linked dataset to check for inaccurate linkages.

Compliance with Data Protection Act

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 discussed that some efforts should be made to inform the cohort in line with this requirement. It was recognised that this responsibility would more appropriately sit with the cancer registries rather than individual organisations carrying out specific studies, however Members advised that some efforts should be made at a study level, such as displaying information on relevant organisation websites.

Patient and public involvement

It was noted that the application detailed patient and public involvement at a cancer registry level, rather than in relation to this specific study. Members agreed that this was appropriate, however they queried whether there might be an opportunity to carry out further patient involvement via the Teenage Cancer Trust. This would also help promote the study in line with the comments above in relation to making reasonable efforts to inform.

Data linkage methodology

Members requested further information in relation to how data linkage with CPRD data would be achieved.

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 and further clarifications as set out below.

Request for clarification

1. Please confirm the process for linking to CPRD data.

Specific conditions of support

1. Favourable opinion from a research ethics committee
2. Confirmation of suitable security arrangements via IG Toolkit submission for those organisations processing identifiable data.

a. ARTISTIC [CAG 3-02(a)/2014]

This research application detailed the ARTISTIC trial which aimed to compare cytology with and without HPV testing among 24,510 women attending for routine cervical screening in 2001-04. This project is an epidemiological follow-up based on their history of HPV infection and cytological abnormality, irrespective of their initial random allocation. Women were followed to 2009 through the two local participating cytology laboratories for cytology and histology. Additional linkages to Open Exeter and pathology reports were now required in order to obtain complete cytological follow-up by linkage to NHS cervical screening call-recall records.

A recommendation for class 1, 4, 5 and 6 support was requested to link cytology records, to confirm coded diagnoses and to identify women who have had a hysterectomy performed. Support was also requested to allow continued access to cancer and mortality data from the NHS Central Register, maintained by the Data Linkage Service (DLS) at the Health and Social Care Information Centre. Linkages would be undertaken using NHS number and date of birth.

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 consent had been obtained from the whole cohort to take part in the original study and that this was an extension to follow up this cohort. It was agreed that consent would be difficult to obtain given the historical nature of the cohort and the levels of non-response that may be experienced.

It was noted that identifiable data was requested in order to carry out linkages only and that personal data was already held by the applicant with patient consent. The dataset would be pseudonymised prior to analysis.

Compliance with the Data Protection Act

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. Whilst members agreed that consent would not be feasible, they requested that the applicant make reasonable efforts in line with the DPA to publicise the collection of additional follow up data. Where contact with patients was planned, this should include details of follow up data and information should be made available on the study website.

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 conditional support to the Secretary of State for Health, subject to compliance with the specific and standard conditions of support:

Specific conditions of support

1. Confirmation of what efforts will be made to inform participants in line with the comments above.
2. Confirmation of suitable security arrangements via IG Toolkit submission.
3. Confirmation of a favourable opinion from a research ethics committee.

Development of precedent set criteria

Members discussed that this application could have been suitable for review under the precedent set process and that a new criteria should be created for applications which engaged large

historical cohorts, had consent from participants for inclusion into the original study and requested additional data linkages for the same purposes of original study.

Action: Amend PS criteria to include applications which engage large historical cohorts requesting additional linkages for same purposes of original study which was consented.

b. West Yorkshire Cardiac MR Outcome Study II [CAG 3-02(b)/2014]

This application from Leeds Teaching Hospitals NHS Trust set out the purpose of expanding a database which included patients who had a cardiac MRI scan in Leeds Teaching Hospitals NHS Trust from 1995 onwards. Studies in relation to clinical cardiology and cardiac MRI would be carried out using database.

A recommendation for class 4, 5 and 6 support was requested to cover access to follow up data from hospital records held by Leeds Teaching Hospitals NHS Trust and GP records in relation to patients who were unable to be contacted for consent and who underwent MRI scans prior to 2009.

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

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 applicant had attempted to seek consent from a sub-set of this cohort and had experienced a significantly high level of non-response. It was confirmed that consent would be sought from patients on a prospective basis.

Members recognised that identifiable data would be required in order to obtain follow up data in relation to patients.

Access to identifiable data

It was noted that 3 research group members and a limited number of future members of the research group would have access to identifiable data; members queried why it would be necessary for a number of individuals to have access to identifiers and whether this number could be reduced.

Disclosure of information from research database

The application specified that all disclosures would be reviewed by the applicant, Professor Greenwood. Members requested further clarification in relation to the protocols that were in place to manage decisions in relation to the disclosure of data, including what would be considered to be anonymised data

Retention of identifiable data

Members requested further information in relation to the retention of identifiers and whether identifiable data would need to be retained within the research database following the death of a patient or after 5 years given that no further follow up data would be required at this stage.

Data Protection 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 noted that the cohort was retrospective and dated back to 1995; however members advised that some efforts should be made to inform patients generally about the database and advise them how to object to inclusion, for example, it was suggested that information could be displayed on relevant websites.

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 and further clarifications as set out below.

Request for clarification

1. Why will it be necessary for 3 members of the research group to have access to identifiable data and could this be restricted to fewer individuals?
2. Please confirm what protocols are in place to manage decisions in relation to the disclosure of data, including what would be considered to be anonymised data.
3. How long will identifiers be retained within the research database and why has this period been identified as necessary.

c. Prescription Of analgesia in Emergency Medicine (POEM) [CAG 3-02(c)/2014]

This application from Royal Berkshire NHS Foundation Trust set out the purpose of a study to determine the factors that lead to failure to assess pain and provide timely pain relief and to assess the adequacy of pain management in consecutive patients presenting to emergency departments within the Thames Valley with confirmed breaks or dislocations to either the arms or legs. The data may highlight factors associated with failure to provide timely pain relief in the population.

A recommendation for class 1, 2 and 3 support was requested to cover access to data in relation to patients from emergency departments within 4 hospitals over 26 consecutive weeks who had a radiograph of a long bone (approximately 6000 patients).

Data including postcode would be transferred to the University of Reading in order to carry out deprivation scoring. This process required access to postcode for a total of 48 hours. Access was requested to hospital ID and postcode.

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 agreed that it would be difficult to seek consent noting that this may influence both clinician and patient behaviour which would have a significant impact on the results of the study.

Members noted that the applicant had asserted that it was important that postcode conversion to deprivation score was undertaken at the University of Reading by trained individuals and that this would require postcode to be retained by the University for a period of 48 hours only. On balance, taking into consideration the level of sensitivity of the data requested, members agreed that the applicant had justified the disclosure of postcode for this very brief time period.

Justification of identifiers

Members requested confirmation of whether hospital ID would need to be removed from hospital sites and agreed that further justification should be provided if this was the case.

Equivalent duty of confidentiality

It is a requirement of the Regulations that those accessing confidential patient information owe an equivalent duty of confidentiality to a health professional. Members queried how it would be ensured that all individuals accessing data under the Regulations had confidentiality contracts with sanctions for any misuse of confidential patient information in place, were acting under the supervision of an appropriate clinician within the hospital and had undergone sufficient training.

Patient information posters

It was confirmed that posters were being designed for display within emergency departments and members requested that the applicant ensure that these provide details to patients in relation to registering objections to the use of their data and that these were submitted these once finalised.

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 and further clarifications as set out below.

Request for clarification

1. Confirmation regarding whether it would be necessary to include hospital ID within the dataset provided to the University and if so justification for this.
2. Confirmation that research nurses and assistants have appropriate contracts and training in place and are acting under the supervision of a clinician in line with the comments above.
3.

Specific conditions of support

1. Copies of posters to be submitted once available.
2. Favourable opinion from to be obtained from a Research Ethics Committee.
3. Confirmation of suitable security arrangements via IG Toolkit submission.

d. Acanthamoeba Keratitis Study [CAG 3-02(d)/2014]

This application from Great Western Hospitals NHS Foundation Trust set out the purpose of a study to identify the total number of cases of Acanthamoeba Keratitis in the United Kingdom through a central reporting system British Ophthalmological Surveillance Unit (BOSU).

A recommendation for class 2 and 6 support was requested to cover access to cases which would be identified through a report card system, whereby an ophthalmologist would notify cases via BOSU. The clinician would then send a questionnaire which will ask for clinical details.

Access was requested to gender, age, ethnicity and hospital ID for a small number of patients (approx. 60 in total).

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.

It was agreed that consent would not be feasible due to the potential bias that this may cause. It was noted that the methodology followed a very similar process to the British Paediatric Surveillance Unit (BPSU) and it had been agreed that consent would not be feasible for this methodology.

Members queried whether the applicant had considered whether the requested dataset could be reduced at all. For example, whether county of residence would be sufficient rather than first half of postcode and whether another method of de-duplication could be used to negate the requirement for hospital ID. For example, to ask the two consultants who notified the apparently duplicate cases to have a conversation about which cases they have notified and for them to check if it was the same patient. It was agreed that this should be explored and, if required, further information in relation to the justification for these data items should be provided for member's consideration.

Members discussed whether the dataset would be considered confidential patient information if it was determined to be possible to remove hospital ID and reduce demographic data items to year of birth, sex, ethnicity and county only. It was agreed that, whilst the dataset was not publishable, if sufficient governance controls were in place around the processing of the dataset which meant that re-identification was not possible, an application for support would not be advised. The dataset should not be taken out of the controlled environment as there was still a risk of re-identification should this occur.

Compliance with Data Protection Act

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 efforts

should be made to inform patients about BOSU activities generally, rather than specific information being provided in relation to this study.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that they were supportive of the application in principle but requested further information as outlined below:

Request for clarification

1. Please consider whether county of residence would be sufficient rather than first half of postcode and whether another method of de-duplication could be used to negate the requirement for hospital ID.

Development of precedent set criteria

Members agreed that, following the requested clarification, if an application was determined to be necessary, future BOSU applications could be processed via the precedent set process as long as they followed the standard methodology.

Action: If support is determined to be necessary, the BOSU methodology should be defined and included as a PS criteria.

5. ITEMS FOR DISCUSSION

a. Registering patient objection

Members discussed a paper provided by the Chair in relation to registering patient objection and media attention paid to care.data and to the possibilities for patient opt-out. The paper was presented for comment and to help establish whether the CAG needed to take further action, or whether this was for the purpose of an internal guidance tool. It was highlighted that while objection codes are implemented electronically, it requires system suppliers to establish the rules for the system. It was also noted that there were a multiplicity of codes and the number involved was causing confusion at a local level. Members agreed that it was important to understand the implications of this for CAG business.

Members agreed that whilst the issue was significant, the responsibility of ensuring that objection was respected for the purposes of support provided under the Regulation would be the responsibility of the applicant and the data controller disclosing the data, and it would be for the applicant to ensure that the body disclosing data has an appropriate mechanism in place to respect objection.

This led to further discussion in relation to what actions should be taken where it appeared that there had been a breach of the conditions of support. It was agreed that this should be considered as part of the annual review assessment.

Action: Breach of conditions to be considered as part of annual review assessment
Action: Escalate issue of risk stratification opt-out with IIGOP, NHS England, the Secretary of State representative and Health Research Authority.

b. CAG statutory powers

Further information was provided to members in relation to CAG's statutory powers provided in the Care Act 2014. Members were informed that the scope and practical considerations of the advice to be provided to the HSCIC would be developed within a series of workshops to be undertaken by the HRA.

The Chair informed members that he would be seconded to the HRA on a part time basis from September in order to help determine the future role of CAG in line with the new statutory powers. It was confirmed that he would remain an employee of the University of Sheffield and would not be an employee of the HRA, this was important as Regulation requirements specified that members could not be employees of the HRA. Members queried how this would operate in practice and what assurances would be in place to ensure that the position of the Chair was not compromised. The Chair confirmed that the situation would be handled through complete transparency.