NHS
Health Research Authority
Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group

6 March 2014 at 10:00 at Skipton House, SE1 6LH

Present:

Name	Capacity
Dr Mark Taylor (Chair)	Lay
Dr Christopher Wiltsher	Lay
Dr Kambiz Boomla	
Dr Patrick Coyle	
Dr Robert Carr (items 2-9)	
Dr Tony Calland MBE	
Dr Tricia Cresswell (Vice-Chair)	
Mr Anthony Kane	Lay
Mr C Marc Taylor	
Ms Clare Sanderson	
Ms Gillian Wells	Lay
Professor Julia Hippisley-Cox (not present for item 6a)	

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 Stephen Robinson	Corporate Secretary, HRA (item 8)
Mr Gordon Harrison	Head of Communications, HRA (item 4)
Mr David Evans	Expert advisor – Data Protection, Information Commissioner's Office

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Welcome

Mr Stephen Robinson attended for item 8 in his capacity of approver for HRA research applications.

The Group noted that Dr Tricia Cresswell, Dr Christopher Wiltsher and Mr Terence Wiseman would not be seeking to extend their appointment past 31 March 2014. The Chair thanked for these members for their significant contribution to the Group, the NIGB Ethics and Confidentiality Committee and the Patient Information Advisory Group over the past years, with particular thanks expressed to Dr Cresswell who had been advising within this function since its inception in 2001.

Apologies

Apologies were received from Professor Jennifer Kurinczuk, Dr Murat Soncul, Dr Charlotte Augst, Ms Madeleine Colvin and Mr Terence Wiseman.

The Chair advised that he had received notification of Ms Madeleine Colvin resignation since the last meeting. Due to other commitments, Ms Colvin had resigned with immediate effect.

Declaration of interests

The following interests were declared:

- Professor Julia Hippisley-Cox did not receive CPRD papers and left the room for item 6a in order to avoid any perception of a competing interest given her role with QResearch.

2. MINUTES OF THE MEETING HELD ON 9 JANUARY 2014

It was noted that the circulated minutes did not include the discussion in relation to a proportionate review application – EPIC Norfolk [CAG 9-08(e)/2014] that had been referred to the meeting for consideration. The discussion and advice in relation to this application was noted and Dr Wiltsher advised that he would review the advice letter outside of the meeting and send separate confirmation to the Advice team. It was agreed that the final minutes incorporating the discussion of this application would be approved by the Chair.

The minutes were agreed as an accurate record subject to the inclusion of the discussion regarding the EPIC Norfolk application.

ECC 6-02(FT16)/2012 - CQC 2013 Maternity Survey - security breach item in the October 2013 meeting minutes

Members were advised that the security breach reported at the October 2013 meeting, which involved a disclosure of confidential patient information when the 2013 maternity survey sample for Pennine Acute Hospitals NHS Trust was submitted to the Survey Co-ordination Centre for checking, had not been reported to the Information Commissioners Office (ICO). The Trust specified that this was because the incident had been contained and the information was sent to and from secure NHS emails. Members highlighted that they would have expected this to be reported to the ICO. It was also noted that under the terms of the existing approval the applicant was the Care Quality Commission (CQC).

The ICO representative confirmed that the incident took place before the new arrangements for security reporting via the Information Governance Toolkit had been implemented and that he would review the internal case management system to identify whether there had been any recorded incidents.

It was advised that the concerns from the Group should be fed back to the applicant organisation, in this instance, the CQC, along with a reminder that security breaches could affect ongoing approval at annual review stage. Members requested to be advised of what actions the CQC had taken following the two breaches and whether the CQC handling of the breach was in line with established referral processes.

Security breaches under Regulation 2 and 5 approval

Members further discussed the role of CAG in relation to considering security breaches to an approved dataflow and noted that there were established incident reporting processes in place for such events and care should be taken to ensure that these were followed.

While not the CAG role to review security incidents members noted that it was important for any incidents around a dataflow operating under approval to be flagged to the CAG as it could impact on the approval status. Members agreed that further understanding around the current process for incident reporting and what constituted a breach would be required so that it would be clear what appropriate next steps would be under an approval and whether these processes meant that responsibilities were met under an approval.

It was agreed that there needed to be a system to flag any security breaches, and it was suggested that this be included as a question in the application forms and specifically at annual review stage.

Action: CAT to write to CQC in order to advise that all breaches and actions taken should be reported to CAG via the CQC and that breaches may affect ongoing approval.

Action: CAT to confirm process for reporting confidentiality/security breaches.

Action: Annual review template to be updated to request details in relation to any confidentiality/security breaches that have taken place over the previous review period, along with remedial actions.

3. OFFICE REPORT AND MATTERS ARISING

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 January 2014 meeting applications.

In relation to CAG 7-04 (a)/2013 (reported under *'update on previous applications'*), the approver requested explicit feedback on condition (j) and (k) at the 6-month review period. Further clarity was also sought on the specific number of commercial suppliers, acting as data processors on behalf of GPs, that would be covered by the support, prior to agreeing final approval. The numbers and type had been confirmed by NHS England as the following:

- Commissioning Support Units - 23
- Commercial third parties - 11
- Clinical Commissioning Groups (in-house processing) - 10

HRA approval decisions

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

Operational and Confidentiality Advice Team updates

Monthly meetings

Members were reminded that from April 2014 CAG meetings would be held on a monthly basis. Dates have been circulated to members and are available on the HRA website.

http://www.hra.nhs.uk/resources/confidentiality-advisory-group/confidentiality-advisory-group-cag-meeting-dates/

HSCIC data pseudonymisation review workshop

Ms Claire Edgeworth and Professor Julia Hippisley-Cox attended two workshops held by the HSCIC to explore the feasibility of applying pseudonymisation across HSCIC datasets, considering data flowing into and out of the HSCIC and any supporting data flows. One workshop had a business focus and the other technical. Ms Edgeworth provided a presentation detailing the role of CAG in advising on applications which requested identifiable data from the HSCIC and the importance of considering alternatives such as pseudonymisation as part of this advice. The workshops were held as part of a pseudonymisation review being carried out by the HSCIC which aimed to ensure that all aspects of the application of pseudonymisation were understood and that it is used appropriately within the HSCIC; balancing functionality, benefits, risk and costs associated with pseudonymising data, including pseudonymisation at source, and any potential impact to the onward flow of quality information.

Letter from Ms Rebecca Stanbrook to Max Jones

Ms Rebecca Stanbrook, previous Director of Confidential Advice, had written to Max Jones, Director of Information and Data Services at the HSCIC, in order to request that the HSCIC consider whether there was an alternative legal basis to process confidential patient information for national audits sponsored by the Healthcare Quality Improvement Partnership (HQIP). As a condition of continued support on the HQIP commissioned audits, the Secretary of State representative asked that this clarification be provided by the end of March 2014. A letter was received in response from Rob Shaw, Director of Operations and Technical Services and Senior Information Risk Owner at the HSCIC, who confirmed that the HSCIC hoped to have a response prior to the end of March deadline.

Practicable alternative working group

The practicable alternatives working group held a workshop on the 30 January. The workshop aimed to determine what practicable alternatives existed, to ensure that guidance is realistic and contemporary in relation to what alternatives exist to potential applicants. Attendees included representatives from the HSCIC, PHE, ONS, GP system suppliers and pseudonymisation software suppliers. The outputs from this Group form a part of the HRA actions listed in the Caldicott 2 review report, and would be reported to the Caldicott Implementation Monitoring Group.

Applications considered via proportionate review

CAG 10-03(PR1)/2014 Group B Streptococcal disease in infants less than 90 days of age

This research application from St George's, University of London set out a study using the BPSU methodology to investigate all cases of Group B streptococcus in infants aged under 90 days in England and Wales over a 13 month period, in order to assess incidence and mortality. It was estimated that there would be around 600 cases. Data would be processed by Public Health England. A recommendation for class 2, 4 and 6 support was requested to cover access to patient data from clinicians on a questionnaire and GBS isolates from microbiology laboratories. This application was considered under proportionate review criteria 5, 'applicants using British Paediatric Surveillance Unit (BPSU) methodology', and reviewed by Dr Mark Taylor (Chair), Dr Tricia Cresswell and Ms Madeline Colvin.

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

Confidentiality Advisory Group advice

Members agreed that the activity was important noting the assertions that “Group B Streptococcus (GBS) was the most common cause of serious bacterial infections (e.g. septicaemia, pneumonia) in the first week of life and of meningitis in the first three months of life” and that “approximately 10% of babies with GBS disease will die.”

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

It was noted that complete ascertainment would be essential to establish incidence and analysis by birth weight and gestation.

It was noted that two data sources were being linked so identifiers were required for linkage purposes. Members agreed that the identifiers required for linkage were justified (NHS number, hospital number and date of birth) and that date of birth, date of death, ethnicity, gender and hospital name and postcode would be required for analysis purposes.

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. With this in mind, members requested that paediatricians pass copies of leaflet to parents/carers of children included in the study to meet fair processing requirements. Members advised that leaflets should also include details of how an objection could be registered if required.

Members requested clarification regarding what identifiers would be retained within the web based analysis data set and that it would include those required for analysis only - date of birth, death, sex, ethnicity gender and assigned unique identifier.

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 recommended provisional support, subject to satisfactory responses to the further clarifications as set out below, and compliance with the specific and standard conditions 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.

Request for clarification

1. Confirmation of what identifiers will be retained within the web based analysis data set as this should be those required for analysis only.

Specific conditions of support

1. Confirmation that paediatricians would pass patient information leaflets to parents/carers where possible and that these will include details of how to object to the use of confidential patient information.
2. Favourable opinion from Research Ethics Committee
3. Confirmation of suitable security arrangements via IG Toolkit submission.

CAG 10-03(PR2)/2014 National Cancer Patients' Experience Survey 2014: Acute and specialist trust surveys of inpatients and day cases

This service evaluation application from NHS England as data controller set out the purpose of carrying out a survey of adult inpatients and day case patients with a primary diagnosis of cancer who have been admitted to an acute or specialist NHS Trust during September, October and November 2013. A recommendation for class 2, 4 and 6 support was requested to allow access to patient contact details in order to send out the National Cancer Patients' Experience Survey 2014. This application was considered under Proportionate Review Criteria 1 – participant recruitment.

This application was considered by Dr Mark Taylor (Chair), Dr Kambiz Boomla and Dr Tricia Cresswell.

Access was requested to name, address, sex, ethnic group, ICD10 code, admission and discharge dates, speciality code, referring CCG, admission type, NHS number, date of birth.

Confidentiality Advisory Group Advice

Members noted that this pilot was based on a similar methodology to the previously reviewed survey applications and noted that alternatives had been explored in detail with the applicant at this time and it had been agreed that the methodology was appropriate.

Members requested further information in relation to the separation of mailing and sample data and the applicant explained that sample data would be extracted from Trusts and then processed into individual send out files. The applicant stated that the send out files are used to generate the survey material.

Members sought clarification that identifiable data would be destroyed after the validation checks and survey fieldwork has been completed. The applicant confirmed that this is correct.

Members were content with the responses given.

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.

Specific conditions of support

1. The applicant must abide by the assurances in the letters to patients that names and addresses will not be linked to survey responses.
2. Confirmation of suitable security arrangements via IG Toolkit submission.

CAG 10-03(PR3)/2014 Piloting new approaches 2014 (patient survey)

This service evaluation 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. A recommendation for class six support was requested to cover access to a sample of consecutively discharged inpatients from twelve Acute and Specialist Trusts within two waves (December 2013 and February 2014). This application was considered under Proportionate Review Criteria 1 – participant recruitment. This application was considered by Dr Mark Taylor (Chair), Dr Tricia Cresswell and Dr Murat Soncul.

Access was requested to unique identifier code, title, first name, surname, address fields, postcode (where available), admission/discharge dates, main specialty on discharge, whether admission from Treatment Centre, route of admission, NHS Site code on admission and discharge, ethnicity, gender, year of birth.

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 this pilot was based on a similar methodology to the previously reviewed survey applications and noted that alternatives had been explored in detail with the applicant at this time and it had been agreed that the methodology was appropriate.

It was noted that identifiers would be required to send out the survey to the appropriate patients.

Members agreed that the mailing and sample data must be kept separated before they were issued to the mailing house and required that this was reflected in the guidance document**.**

Members stated that this application only applies to the pilot phase of the new approaches to the National Inpatient Survey. It was specified that further advice must be sought prior to any further rollout of these changes.

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.

Specific conditions of support

1. Support is only given for the pilot. CAG would require a further application with the key findings from the pilot, prior to any further roll out.
2. The survey guidance document should be updated to require the separation of the mailing and sample files before they are submitted to the mailing house (see guidance section 4).
3. Confirmation of suitable security arrangements via IG Toolkit submission for each of the survey companies.

CAG 10-03(PR4)/2014 Parents' Experiences of Neonatal Care

This application from the Picker Institute as data controller set out a survey of parent experience of neonatal care services in hospitals in England and Wales in 2014, to assess any improvements made since the 2011 survey. A recommendation for class 5 support was requested to cover access to name and contact information for 200 babies discharged from hospital, in order for questionnaires to be sent to parents. This application was considered via the proportionate review process under criteria 4 - Time limited access to undertake record linkage/validation and to pseudonymise the data and reviewed by Dr Mark Taylor (Chair), Dr Tricia Cresswell and Dr Tony Calland.

Access was requested to mothers name, address, postcode, date of delivery mother's ethnicity and hospital site.

Confidentiality Advisory Group advice

The methodology was determined as appropriate and had been supported for other questionnaire surveys, noting that evidence had been provided for the use of survey contractors rather than undertaking at trust level. The identifiers requested had been confirmed as the minimum required and mothers under the age of 18 would be excluded.

Members were pleased to note that there had been considerable involvement of parents and that appropriate checks were made to ensure that as far as possible questionnaires would not be sent when there had been a neonatal or maternal death.

Members queried whether the application was research or service evaluation, noting that the objective was to measure parents' experiences of neonatal services to understand how the quality of care can be improved, but that this had been presented as research. Members requested confirmation to ensure the appropriate approval route.

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

Request for clarification

1. Confirmation from NRES of whether the activity is considered to be research or service evaluation.

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission.
2. If research, confirmation of favourable Research Ethics Committee opinion.

CAG 10-03(PR5)/2014 2014 Accident and Emergency Department (A&E) Survey

This service evaluation application from the Care Quality Commission was for a recommendation of support for the transfer of patient identifiable data from acute and specialist trusts, to an approved survey contractor (Picker, Quality Health, Patient Perspective or CAPITA Surveys & Research) for the purpose of mailing out questionnaires for the 2014 A&E survey. The 2014 A&E survey will be the fifth carried out to date. All 147 eligible trusts will be asked to conduct the survey with preparations expected to begin in March 2014 and fieldwork is expected to start from May 2014. A recommendation for class 6 support was requested to allow access to patient contact details in order to send out the questionnaire. This application was considered under Proportionate Review Criteria 1 – participant recruitment. This application was considered by reviewed by Dr Mark Taylor (Chair), Dr Tricia Cresswell (vice-chair) and Ms Gillian Wells.

Access was requested to title, first name, surname, address, postcode, unique identifier code, date and time of attendance, NHS Site code, ethnicity, gender, year of birth and GP Practice Code (GPPC).

Confidentiality Advisory Group advice

Members felt the reasoning behind the change of approach incorporated within this application was both reasonable and justified.

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 this pilot was based on a similar methodology to the previously reviewed survey applications and noted that alternatives had been explored in detail with the applicant at this time and it had been agreed that the methodology was appropriate.

It was noted that identifiers would be required to send out the survey to the appropriate patients.

Members agreed that the mailing and sample data must be kept separated before they were issued to the mailing house and required that this was reflected in the guidance document.

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 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. Within the Survey Dissent document it is stated that Capita phone staff are specifically trained so that people are "helped to overcome objections." Confirmation that staff will be helpful rather than overly assertive is required.
2. The follow up letter draft refers to results coming out in "Winter 2012" and should be updated.
3. Some of the numbering on the questionnaire appears to be incorrect. For example, with Questions 23, 25, 27 and 28. If answered yes, the patient is directed back to the same question. Please review the questionnaire to ensure such issues are corrected.
4. Confirmation of suitable security arrangements via IG Toolkit submission for each of the survey companies.

Amendments to approved applications

ECC 6-02(FT4)/2012 Lifelong health and wellbeing of the 'Scotland in Miniature' cohort

The original research application from the University of Edinburgh and study protocol stated that if recruitment of the 6-day sample fell below 400, the 36-day ample members would be sent the 6-day invitation pack. Recruitment to June 2013 resulted in 137 participants joining the study out of 542 invitations sent (25%). To date, 135 participants refused to take part and 208 (38%) participants had not responded to the invitation. This amendment was reviewed by the Chair.

Amendment request

Support had not previously been sought to mail out an invitation to members of the 36-day sample in England and Wales. This amendment requested support to contact members in England and Wales for both samples rather than just in the 6-day sample.

36-Day sample members would be sent a smaller questionnaire rather than the existing questionnaire and testing kit for the follow-up study. An invitation would be made to members to ask if they would like to participate in a more detailed study, which would include home testing and a telephone interview.

Confidentiality Advisory Group advice

The amendment requested was forwarded to the Chair who stated that the amendment represented a proportionate way to address the low numbers that had been recruited to date.

Health Research Authority recommendation

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 a favourable opinion from a Research Ethics Committee.

ECC 5-05(j)/2012 Long term risk of cervical cancer following HPV infection

This research application from the London School of Hygiene and Tropical Medicine (LSHTM) requested access to patient identifiable data to follow up a cohort of approximately 50,000 women who were recruited between 1988-1993. At recruitment all women provided a cervical smear for routine cytology, from which a sample was retained for HPV testing. The study would compare HPV infection results to NHS central register cancer and mortality data to determine future risk of cervical cancer.

This amendment sought to link the cohort to HES data to obtain dates of any hysterectomies in the follow-up period. This link would be utilised to censor women undergoing a hysterectomy from the cohort analysis and thereby improve the estimate of the cumulative cervical cancer incidence rates. The amendment was reviewed by the Chair.

Confidentiality Advisory Group advice

The amendment requested was forwarded to the Chair who recognised that the addition of these dates was important to supplement the data already being held. The Chair noted that with the retrospective nature of the collections, together with the numbers involved, that consent was not a practicable alternative.

Health Research Authority approval decision

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

1. The amendment is approved, subject to compliance with the standard and specific conditions of approval.

Specific conditions of support

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

ECC 8-02(FT2)/2011 National Review of Asthma Deaths (NRAD)

This audit application from the Royal College of Physicians of London detailed a review of asthma deaths within the UK by an in-depth multidisciplinary confidential enquiry, with the aim of understanding the circumstances surrounding current asthma deaths. This was in order to identify avoidable factors and make recommendations for implementing changes to improve care and reduce the number of avoidable deaths. This amendment was reviewed by the Confidentiality Advice Team as there was no additional data or purposes specified.

Amendment request

This amendment requested a six month extension to the retention period of identifiable data (from April to September 2014, inclusive) to:

1) Complete the national report (due to be launched on 6 May)
2) Respond to any queries post-publication by stakeholders, the public and wider health community
3) Allow for post-publication journal papers to be written and quality improvement activities to be arranged
4) Take action/follow-up action on cases of concern regarding poor treatment that have been identified during the NRAD process
5) Allow for sufficient time for data to be archived and/or destroyed, as per our original section 251 application.

It was noted that the data would not be used for any new purposes beyond NRAD and identifiable data would be destroyed as stated in the original application.

Confidentiality Advice Team advice

As the data would not be used for any new purposes beyond NRAD and identifiable data would be destroyed as stated in the original application, the Confidentiality Advice Team noted the request for six month extension to the application due to resource issues.

In line with the considerations above, the Confidentiality Advisory Team 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.

CAG 5-07(d)/2013 National Emergency Laparotomy Audit (NELA)

This amendment request from the Royal College of Anaesthetists to this audit application detailed a change in purpose to enable anonymised audit data to be disclosed for further research or audit purposes. The amendment was specifically in relation to the used of anonymised data in the EPOCH Trial, Enhanced Peri-Operative Care for High-risk patients.

Confidentiality Advice Team advice

The email received from the applicant provided confirmation that the disclosure of anonymised data would remain within the general purposes of the audit, in particular it was noted that the EPOCH study group will work closely with NELA to evaluate the long-term effects of the quality improvement intervention in participating hospitals. Updated patient information leaflets covering the additional purpose were forwarded and it was confirmed that pseudonymised data only would be provided for the purposes of the EPOCH trial. The need to continually refine and respect any expressed patient objection was acknowledged.

The information was reviewed by the Confidentiality Advice Team and it was agreed that a recommendation of support to the Secretary of State for Health could be provided for this purpose following the provision of this information.

Secretary of State decision

Following advice from the CAG, the Secretary of State for Health agreed to approve the application, in line with the conditions and clarifications highlighted by the CAG.

ECC 5-05(a)/2012 Clinical Practice Research Datalink Service 12_160 protocol

This research amendment request detailed CPRD linkage with the Midlands and North West Bowel Screening Programme Hub in order to provide a pseudonymised dataset to the University

of Edinburgh to carry out a study titled “The influence of a negative FOBT on the response of screening invitees and healthcare providers to symptoms of colorectal cancer”. The linkage to the Midlands and North West Bowel Screening Programme Hub data was specified within the overarching CPRD application. The amendment therefore requested support to allow the disclosure of a dataset at PCT/CCG area level only. The CPRD application specified that CPRD would only disclose regional identifiers to a minimum population of about 1 million, and disclosure of data at PCT/CCG level would involve disclosure at a lower level than this. This amendment was reviewed by Dr Mark Taylor (Chair), Dr Tricia Cresswell and Professor Jennifer Kurinczuk.

Confidentiality Advisory Group advice

Members agreed that the study was important as demonstrating a negative impact of screening (people not attending with symptoms) would change the risk/benefit balance of carrying out the screening programme.

Members requested confirmation that identification of individual GP practices would not be possible. It was confirmed that pseudonymised CPRD GP practice ID only would be disclosed, which could distinguish whether the practice was located in the Cumbria or Trafford Primary Care Trust area but would not identify individual GP practices. Members agreed that this was satisfactory.

Members advised that this recommendation did not set a precedent and the amendment was for the purpose of this study only. The overarching CPRD application would not be affected and disclosures at a lower geographical level than a population of 1 million would continue to be considered on a case by case basis.

Members agreed that the minimum requirements of the Regulations appeared to be met and agreed to recommend support to the Health Research Authority, as the application related to English data only, to allow the disclosure of PCT/CCG level data to University of Edinburgh for the specified study only.

Health Research Authority decision

Following advice from the CAG, the Secretary of State for Health agreed to approve the application, in line with the conditions and clarifications highlighted by the CAG.

PIAG 4-08(b)/2003 NCEPOD

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 amendment request detailed extending support to allow collection of data for the Gastrointestinal Haemorrhage study. It was confirmed that the existing NCEPOD methodology would be used.

Confidentiality Advisory Group advice

The amendment was forwarded to the Chair who noted that the requested identifiers seemed appropriate and that anonymisation would take place within 2 months. The Chair agreed that there was a clear public interest in the results of the study.

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

Secretary of State decision

Following advice from the CAG, the Secretary of State for Health agreed to approve the application, in line with the conditions and clarifications highlighted by the CAG.

ECC 5-02(FT7)/2012 National Cancer Survivorship Initiative – patient Reported Outcome Measures survey of survivors of cancer of the ovaries, cervix, uterus and bladder

This service evaluation application, originally from the Department of Health (DH), detailed an expansion to the pilot Patient Reported Outcome Measures survey, which was completed in 2011 and the longitudinal follow-up survey of 2012. (ECC 8-05 (b) 2010). The application detailed that following this pilot a policy decision had been made to extend the survey to 4 pelvic cancer groups – ovary, cervix, uterus and bladder and colorectal and prostate cancer patients. Identifiable data including name, address, sex, ethnic group, year of birth, NHS number, ICD10 code, speciality code and date of diagnosis for each patient would be provided from the cancer registries to a contractor who would administer the survey on DH's behalf. Mortality checks would be made with the Demographic Batch Service checks to ensure that the patient was alive before sending the survey. This was reviewed by the Confidentiality Advice Team.

Amendment request

An amendment request was received on 5 December 2013 setting out a change in data controller from the Department of Health to NHS England and seeking an extension in support under the Regulations to June 2014, on the grounds that the transition to NHS England had delayed internal financial approvals and therefore data collection had not yet taken place. It was envisaged that data collection would take place in early 2014. A refreshed application form was submitted in support of the change of data controller, and it was asserted that the data collection methodology, data processor and data protection standards would not change from those in the original application.

Confidentiality Advice Team advice

The amendment was considered at an office level by the Confidentiality Advice Team as the only requested changes were to the data controller and the period of data collection. It was noted that no new identifiers had been requested and there would be no changes to the identifiability of the data or data flows.

In line with the considerations above, it was agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and a recommendation of support was submitted to the Secretary of State for Health.

Secretary of State decision

Following advice from the CAG, the Secretary of State for Health agreed to approve the application, in line with the conditions and clarifications highlighted by the CAG.

ECC 2-03(c)/2012 National Paediatric Diabetes Audit (NPDA)

The amendment from Royal College of Paediatrics and Child Health on behalf of HQIP request to this audit application detailed enabling anonymised audit data to be disclosed for further research or audit purposes.

Advice was provided in relation to this request in a letter dated 22 October 2012. This sought a summary of the purposes of this audit and confirmation that the disclosure of anonymised data would remain within the general purposes of the audit; sight of updated patient information leaflets covering this additional purpose and a commitment to continually improve processes and to refine granularity so as to ensure proper respect for any expressed dissent. This amendment was reviewed by the Confidentiality Advice Team.

Confidentiality Advice Team advice

The subsequent letter received from the applicant on the 5 December 2013 confirmed that the data would be disclosed in an anonymised format only and that the disclosure would be in line with the general purposes of the original application. The need to continually refine and respect any expressed patient dissent was acknowledged. Updated patient information leaflets were forwarded which included the following information:

> The information collected will occasionally be shared with non-commercial organisations with a legitimate interest in diabetes research. Again, none of this information will contain NHS Numbers or any other information that can be used to identify your child. For a list of third parties using this information, please contact npda@rcpch.ac.uk.

It was agreed that a recommendation of support to the Secretary of State for Health could be provided for this purpose following the provision of further information.

Secretary of State decision

Following advice from the CAG, the Secretary of State for Health agreed to approve the application, in line with the conditions and clarifications highlighted by the CAG.

ECC 1-03(c)/2012 National Head & Neck Cancer Audit

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. This amendment was reviewed by the Chair.

Amendment request

This amendment request, received on 30 January 2014, detailed linking data collected as part of the National Head and Neck Cancer Audit to data from Hospital Episode Statistics (HES), Cancer Registries Radiotherapy (RTDS) and Systemic Anti-Cancer Therapy (SACT) datasets.

Further information was requested in relation to the specific data items requested as part of the amendment. A list of HES data items requested was received. It was confirmed that data linkage would take place using NHS number but where NHS numbers were missing linkage would take place using diagnosis date and treatment start date. The complete list of RTDS fields used depended on the analyses being undertaken and the data quality within the item and normally a reduced extract of the RTDS specifically generated for the audit would be used. SACT data would not be requested until 2015. It was agreed that confirmation of the specific data items required should be forwarded once available and any changes to this could be notified within an annual review.

Confidentiality Advisory Group advice

The amendment was forwarded to the Chair who supported the proposed changes and 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.

Secretary of State decision

Following advice from the CAG, the Secretary of State for Health agreed to approve the application, in line with the conditions and clarifications highlighted by the CAG.

PIAG 2-05(d)/2007 Research to identify and publish measures of quality delivery of healthcare by provider or in some instances, by area and to provide a management information function for the NHS.

This audit application from Imperial College London received support in order to use hospital administrative data in form of HES, PEDW and data supplied through SUS to provide measures of quality if delivery of healthcare by provider or in some instances by area and to support a management information function for the NHS. Anonymised data was provided to Doctor Foster Intelligence for analysis purposes. This amendment was reviewed by the Chair.

Amendment request

An amendment request was received on 02 December 2013 which detailed linking to PROMs and NJR data. A list of data items for inclusion was provided by the applicant on 13 December and the request was forwarded to the Chair for their consideration.

Confidentiality Advisory Group advice

The Chair agreed that the request for inclusion of NJR and PROMS data was justified noting the list of purposes provided within the letter detailing the request and the strong publication record which suggested that the applicant would make good use of the data. The Chair recommended support for the amendment, noting the controls in place to ensure that data was pseudonymised on a rolling 3 year basis and that identifiable data would not be disclosed to Doctor Foster Intelligence**.**

Secretary of State decision

Following advice from the CAG, the Secretary of State for Health agreed to approve the application, in line with the conditions and clarifications highlighted by the CAG.

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.

ECC 8-02(FT5)/2010 SABRE (Southall and Brent Revisited)

This research application from University College London set out the purpose of examining the association between insulin resistance and cardiovascular risk in people of European, South Asian and African Caribbean origins who were living in West London.

A recommendation for class support was requested to cover continued access to mortality data from the NHS Central Register, maintained by the Data Linkage Service (DLS) at the Health and Social Care Information Centre (HSCIC). A cohort of 4,858 patients was flagged at the DLS.

Confidentiality Advice Team advice

It was noted that support had previously been in place for this activity in order to link to Hospital Episode Statistics (HES) and cancer registration data via the DLS. Support to collect mortality data had previously fallen under the NHS Central Register application (ECC 2-04(c)/2010) but that approval reference had expired as the legal basis for the HSCIC to collect and process this information was provided within the Health and Social Care Act 2012. It was therefore recommended that support for the disclosure of mortality data continue under the application reference specified above.

Confidentiality Advice Team advice conclusion

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.
In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations continued to be met, and therefore advised recommending *conditional* support to the Health Research Authority for continued access to mortality data, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

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

CR2/2014 Whitehall II Study (Stress and Health Study)

This research application from University College London set out the purpose of a study to explore the relationship between socio-economic status and cardiovascular disease by examining the inter-relationships between contextual, biological, psychosocial and behavioural factors. Measures included blood pressure, blood sugar, blood lipid levels, height, weight, cardiovascular tests, walking speed, lung function, questions about diet, and five tests of mental functioning.

A recommendation for class support was requested to cover continued access to mortality data from the NHS Central Register, maintained by the Health and Social Care Information Centre (HSCIC). A cohort of 10,308 patients was flagged at the HSCIC.

Confidentiality Advice Team advice

Further information was requested in relation to content of consent forms and these were provided by the applicant on the 16 October 2013. It was confirmed that all participants would have provided consent to inclusion in the study from the outset and that the original consent requested permission to obtain sickness record from the patient's employer and details of serious illness their GP. It was confirmed that mortality data would not be collected where a patient had withdrawn from the study.

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. It was noted that the applicant continued to contact participants directly and advised that continued efforts were made to inform participants that information in relation to mortality would be accessed from the HSCIC.

Confidentiality Advice Team advice conclusion

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.

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

Specific conditions of support

1. Continue to inform and remind participants that information in relation to their mortality is accessed on an ongoing basis
2. Support will not extend to situations where a participant has objected to their data being processed as part of the study.
3. Favourable opinion from a Research Ethics Committee.
4. Confirmation of suitable security arrangements via IG Toolkit submission.

CR3/2014 Forty year follow up of the Cambridge Cohort of open spina bifida

This research application from St George's, University of London set out the purpose of a study to assess survival and quality of life in a complete cohort of consecutive cases of treated open spina bifida followed up from birth.

A recommendation for class support was requested to cover continued access to mortality data from the NHS Central Register, maintained by the Health and Social Care Information Centre (HSCIC). A cohort of 117 patients was flagged at the HSCIC and it was confirmed that following review in 2013 there were 40 living patients.

Confidentiality Advice Team advice

Further information in relation to the original consent provided was requested and it was confirmed that the consent form included the following statement: *I understand that my medical notes may be looked at by the researchers and I agree that they can have access to my GP or hospital records.* It was confirmed that all living participants were contacted as part of the 40 year follow up.

Identifiable data would be retained in order to ensure that data could be linked to other personal data collected with consent.

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. It was advised that continued efforts were made to inform participants that information in relation to mortality would be accessed from the HSCIC and this information should be included within any future planned contact.

Confidentiality Advice Team advice conclusion

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

Specific conditions of support

1. Continue to inform and remind participants that information in relation to their mortality is accessed where possible on an ongoing basis.

2. Favourable opinion from a Research Ethics Committee.
3. Support will not extend to situations where a participant has objected to their data being processed as part of the study.
4. Confirmation of suitable security arrangements via IG Toolkit submission. Confirmation has been sought from the IG toolkit team that the toolkit return is satisfactory.

CR4/2014 Asbestos Workers Survey

This application from the Health & Safety Laboratory set out the purpose of a study to monitor the long-term health of asbestos workers and help to determine whether the 1969 Asbestos Regulations were effective in reducing the risk of asbestos-related ill-health.

A recommendation for class support was requested to cover continued access to mortality and cancer data from the NHS Central Register, maintained by the Health and Social Care Information Centre. A cohort of approximately 100,000 patients as at 2006 had been flagged at the HSCIC. It was noted that the cohort size was projected to continue to grow by approximately 2,000 per year but that participants from 2006 onwards had provided consent and were therefore not included within the request for support. The application was reviewed by Dr Patrick Coyle, alternate Vice Chair.

Access to mortality and cancer data including name, address, date of birth and NHS number was requested.

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 at the time of initial recruitment, members of the cohort were asked to complete a questionnaire and medical examination and therefore the Health and Safety Laboratory retained identifiable data for these purposes. The large, retrospective nature of the cohort meant seeking consent from all pre-2006 patients to obtain data from the HSCIC would not be feasible; however consent would be sought where patients attended medical examinations.

It was confirmed that it would be necessary to retain identifiable data in order to link to questionnaires completed at medical examinations where consent would also be sought. It was noted that around 25% of the cohort had currently provided consent in this way.

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. Further information in relation to how efforts could be made to inform the cohort was requested

The applicant was informed that an opinion would need to be sought from an NRES research ethics committee as this was a requirement of the Regulations.

It was not clear why it would be necessary to retain identifiable data in relation to patient who were found to be deceased and further clarification in relation to this point was requested.

Further information in relation to the data items that would be available for analysis purposes and what access controls were in place around identifiable data was requested.

Confidentiality Advisory Group advice conclusion

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.
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 Secretary of State for Health, subject to satisfactory response to the request for clarification and compliance with the specific and standard conditions of support.

Request for clarification

1. Confirmation of how reasonable efforts will be made to inform the cohort that data in relation to their mortality and cancer data will be accessed
2. Confirmation as to why it is necessary to retain identifiable data in relation to patients who are deceased
3. Confirmation of what information will be required for analysis purposes and how it will be ensured that access to identifiable data will be kept to a minimum.

Specific conditions of support

1. Consent should continue to be sought in order to access cancer and mortality data from those individuals attending medical examinations.
2. Favourable opinion from Research Ethics Committee.
3. Confirmation of suitable security arrangements via IG Toolkit submission.

CR8/2014 South London Stroke Register

This research application from King's College London set out the purpose of a register of first stroke events occurring in residents of a defined area of South London corresponding to northern Lambeth and northern Southwark.

A recommendation for class support was requested to cover continued access to mortality data from the NHS Central Register, maintained by the Data Linkage Service (DLS) at the Health and Social Care Information Centre. A cohort of 4,800 patients was flagged at the DLS. It was noted that the cohort was projected to continue to grow by approximately 250 patients per year.

Confidentiality Advice Team 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.

Identifiable data was held by the applicant with consent and support was requested to obtain mortality data from the HSCIC only. It was confirmed that consent to collect mortality data would be feasible from participants recruited in future and for those patients attending follow up interviews (around 50%). However, support was required for those individuals who did not respond to requests for interviews and had completed a consent form which did not make explicit reference to obtaining mortality data from the HSCIC.

The applicant was advised that in order to ensure that mortality data was collected on a consented basis prospectively the consent form should be amended to include the wording specified by the HSCIC and consent should be sought from individuals attending follow up appointments.

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 pursue a pseudonymised approach for those patients who were alive as the research team would continue to contact individuals for the purposes of the study with their consent.

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. In line with this, it was advised that continued efforts should be made to inform participants that information in relation to mortality would be accessed from the HSCIC and this information should be included within any future planned contact.

Confidentiality Advisory Team advice conclusion

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

Specific conditions of support

1. Continue to seek consent from patients attending follow up appointments for their mortality to be accessed from the HSCIC. Correspondence with patients who do not attend appointments should remind patients that mortality data will be accessed from the HSCIC.
2. Confirmation of suitable security arrangements via IG Toolkit submission.
3. Confirmation of favourable REC opinion.

Update on previous applications

CAG 7-04(a)/2013 Disclosure of commissioning data sets and GP data for risk stratification purposes to data processors working on behalf of GPs

This application was originally considered on 4 October 2013 and the Secretary of State decided that the application should be deferred pending resubmission in line with CAG advice. This resubmission was considered on 28 November 2013 and a decision of provisional support was provided in the letter dated 09 January 2014. Following additional liaison with the ICO, final conditional support was provided on 23 January 2014. Details of the provisional approval and final approval decision are set out below.

Application scope

This application from NHS England on behalf of the relevant data controllers sought support for the activity of risk stratification to be used by clinical commissioners to target specific patient groups and enable clinicians with the duty of care for the patient to offer appropriate interventions. The stated aim of risk stratification was to reduce hospital readmissions through ultimately targeting clinical interventions to high risk patients. A recommendation for class 1, 4, 5 and 6 support was requested to support the disclosure of commissioning data sets (ref CAG 2-03(a)/2013) from the Health and Social Care Information Centre (HSCIC) and GP data from GP systems, to data processors working under the instruction of GPs as data controllers; to support disclosure of patient confidential data to enable the indirect care element of risk stratification, namely for the preliminary processing to combine and process primary care and secondary care data; and also to provide a legal basis to enable the Health and Social Care Information Centre (HSCIC) to transfer this information onwards to the relevant data controllers for this purpose.

Confidentiality Advisory Group advice summary

Due to a need for greater specificity on scope, consideration of practical issues around providers and the need to clarify the dataset, the application had received a deferral decision from the Secretary of State for Health following the October 2013 meeting. A teleconference subsequently took place with a CAG sub-group prior to the resubmission in November 2013 and further discussion identified that definitive consideration by CAG outside of the formal meeting schedule would not be manageable due to the complexity and the timescale for NHS England to complete actions, which had increased as this complexity was explored.

Members noted that considerable work had been completed by NHS England; the interim development work had enabled the application to be much clearer and appropriately detailed. This was strongly welcomed as it enabled focus on aspects specific to CAG consideration.

Members agreed that this activity was a medical purpose as defined within section 251(12) of the NHS Act 2006.

In assessing the balance of where the public interest lay, members noted that this was a significant data flow involving the **majority of all primary and secondary care health records** and questioned whether this was a proportionate data flow balanced against the anticipated benefits. It was noted that risk stratification was not currently following an evidence-based standard although there was an understanding that risk stratification enhances care. It was also noted that NHS England was seeking to put in suitable controls through developing specifications and data flows for named and current risk stratification suppliers as a precursor to developing a consistent national approach. The CAG was informed that the definition of risk stratification and tools had previously been developed in an *ad hoc* manner. The future intent was to develop a national and consistent approach and support under Regulation 5 would enable NHS England to work with risk stratification suppliers and relevant organisations in order to develop these national definitions and standards.

Members expressed concern that while the data flows involved the majority of all patient records, the main purpose of risk stratification was to re-identify only a small percentage of the population for enhanced care. It was therefore noted that strong justification would be required for the processing any identifiable information. It was also agreed that consent would not be practicable as the current models require data on the total population to be processed in order to subsequently identify the target risk groups/individuals.

In assessing the viability of practicable alternatives, the capability of delivering pseudonymisation prior to landing was discussed and indications were given by NHS England that there were currently technological constraints, a need for re-identification for case management purposes, and in particular, issues over the HSCIC current capacity to deliver. The discussions highlighted that the capacity position had not been definitively explored with the HSCIC and endorsement of this position from the HSCIC had not been provided with the application, therefore members advised that any such evidence that this practicable alternative could not be applied should be evidenced by the HSCIC.

In terms of Data Protection compliance, members questioned what fair processing materials would be made available, and sought clarification on where data controller responsibilities would lie, particularly in relation to the integrated dataset, and requested clearer information on retention agreements. It was agreed that NHS England would liaise directly with the Information Commissioner's Office to address all data protection aspects, and a final agreed position would be fed back to CAG as part of the final approval conditions.

Noting that any approval should be time-limited, it was questioned whether it would be more appropriate for NHS England to work on the exit strategy options rather than seeking support so support would not be needed. However, the CAG noted that it was important that local organisations currently commissioned to deliver risk stratification were able to identify a legal basis for the activity to take place now.

Members noted that pseudonymisation prior to landing or an exit strategy relying on linkage by the HSCIC with the HSCIC controlling re identification were not further explored in the application.

As a whole, members were unclear on the precise timescale for moving towards the options and requested clarity on these and timescales so a clear plan for moving away from Regulation 5 support would be in place. NHS England confirmed that providers had been engaged and the option they would move towards was currently being collated.

After detailed discussion, Members indicated that further work would need to be carried out to demonstrate an acceptable exit strategy. The exit strategies for risk stratification for commissioning purposes and risk profiling of a population that seem feasible and are likely to be acceptable involve:

- HSCIC undertaking risk stratification **or**
- Pseudonymisation (including pseudonymisation of NHS number) prior to landing at the risk stratification supplier.

For both options, the key to re-identification will only be made available to those responsible for providing direct care.

Confidentiality Advisory Group advice conclusion

Noting the significant amount of work that would need to take place to effect the cultural and practical changes required for the final 'end state', members recommended providing a positive recommendation to enable risk stratification to be delivered while the appropriate exit strategies were developed and achieved.

Members recommended support for a **six month** period, commencing from date of the final approval letter (23 January 2014), subject to the following **specific conditions:**

a. Compliance with the Data Protection Act 1998, particularly clarification of data controller and fair processing responsibilities to be established in conjunction with the ICO, with final position to be provided to CAG as soon as agreed. Support would not come into effect until the ICO had confirmed satisfaction with the responses.
    i. Confirmation was received on 23 January 2014 from the Information Commissioner's Office that subject to the agreed actions, they were generally satisfied with what had been agreed.
    ii. NHS England confirmed that the data controllers for GP data would be GPs and this data will only be released by agreement of the GP. When this data is linked with Secondary Uses Service (SUS) data it is understood that GPs will be data controllers in common with the HSCIC.
    iii. NHS England confirmed that CCGs, CSUs and any relevant commercial third parties will be acting as data processors on behalf of and as directed by the GP.

b. Risk stratification suppliers to meet the necessary security and assurance standards in place for all applications approved under Regulation 5, and to achieve compliance with all conditions established by the HSCIC (or relevant bodies) before information under this application can flow. Such approaches and conditions to be agreed with the relevant parties.

c. Support applies only to named and existing risk stratification suppliers and existing contracts; new suppliers should have in place the to be agreed final option(s) as this is in line with the overarching approval provided to NHS England [CAG 2-03 (a)/2013]

d. A list of named risk stratification suppliers operating under this current support and the data flows to be published by NHS England / HSCIC.

e. Support is only provided to named and existing providers which operate the following:

i. Data is received “de identified for local access” (NHS number) or is pseudonymised on landing
ii. Processing is within a “closed box” with strict role based access
iii. Re-identification is solely for the purpose of direct care and is available only to those with a direct clinical care relationship with the patient.

f. Review of supplier specifications to be assessed by the applicant against these conditions and progression towards exit strategy.

g. Position over clarification of retention period of data to be held by existing risk stratification suppliers to be included with consideration of potentially different retention periods for the small percentage who go onto receive interventions from the large numbers of low risk patients who do not need further care.

h. Detail on how right of patient objection will be managed.

i. The proposed list of conditions to be excluded from the full patient GP record was acknowledged to be incomplete. The current iteration allows highly sensitive information (i.e. rape, incest, domestic violence or drug treatment for sensitive conditions) to be collected. This list should be updated and finalised with the relevant exclusions removed to avoid the risk of inadvertently transferring inappropriate information.

j. **Documented engagement with the HSCIC to maintain and enhance the development of the appropriate exit strategies, in particular pseudonymisation prior to landing or reliance on HSCIC for the linkage for the entire risk stratification process.**

k. **Due to time taken from provisional to final support, this condition is amended to require a report on progress to be provided to the CAG meeting in May 2014 to confirm:**
- the risk stratification standards
- the exit strategy.
- Provision of other information in line with the comments above.

Matters Arising

Practicable Alternatives

The Chair expressed his thanks to all members of the Practicable Alternatives work group.

Mr Marc Taylor (Chair of the working group) advised that the definitions document was being reviewed and that the initial guidance would be finalised shortly. It was noted that further work would be required to complete the management of risk work stream and in relation to determining the appropriateness of seeking consent. It was confirmed that consent would currently fall outside of the scope of the working group. The Group recognised that the aim of the work group was not to increase the number of questions for applicants to answer but to provide guidance of what information should be included with applications.

The Group noted that a further progress report will be made at the April 2014 meeting, and would focus initially on guidance provided to applicants prior to making an application.

Dr Christopher Wiltsher, who chaired the recent workshop for system and service suppliers, outlined the outcome of the workshop meeting in terms of establishing feasibility and limitations of utilising particular services for linking data sources in a pseudonymised or anonymised format.

The Chair thanked the working group for the workshop report and it was advised by the Group that there should be an annual review of pseudonymisation methods and developments and the workshop should be repeated at this stage. Members noted in particular that it would be useful to

understand ONS processes and requested that this be added on to the list of education items for future CAG meetings.

The Group noted that the Health and Social Care Information Centre (HSCIC) were currently undertaking a review of the potential use of pseudonymisation, which the Group would review once finalised. Members requested that an update be requested from the HSCIC in relation to timescales for the review.

It was suggested that following the completion of the current work streams, the Group review the consistency of risk factors and potential mitigating actions and requirements for application Annual Reviews. The Chair suggested that the Group emphasise what methods applicants could consider to evidence a review of practicable alternatives.

Action: CAT to include ONS in planned future education items.

Action: CAT to request timescales for publication of pseudonymisation review from the HSCIC.

National Audits

Further to the letter detailed above from Ms Rebecca Stanbrook to Max Jones (Director of Information and Data Services, HSCIC) it was noted that clarification was being sought and NHS England were currently reviewing an alternative legal basis to process Patient Confidential Data for national audits. Members were informed that HSCIC were due to respond by the end of March 2014.

The Group stated that further discussions may also be required in order to ensure that General Practitioners were aware and had consented to automated data extractions for national audit purposes. This would ensure that they were able to adhere to the fair processing requirements as part of their role as data controller. It was noted that a meeting and further information had been requested in relation to this from the HSCIC and the HSCIC had indicated this would be provided with the response due at the end of March in relation to the above issue. Members advised that further attempts to engage with the HSCIC in relation to this issue should be made and consideration should be given to whether this should be raised with the Secretary of State Representative.

Action: CAT to write to HSCIC to request further information in relation to automated data extractions.

Action: CAT to draft letter to SofS in relation to ongoing automated data extraction from GP practices.

Recruitment of members

Members were informed that recruitment for new members was in progress and that interviews would take place the next day.

The Chair also advised that in order to maintain continuity of expertise and to align with future recruitment schedules it had been agreed that Ms Gillian Wells, Professor Julia Hippisley-Cox and Dr Tony Calland MBE had agreed to extend their membership within the Group until March 2016. He Chair thanked these members for their continued voluntary service.

Proportionate Review process

The Group were advised of a proposed change to the Proportionate Review process, which included a schedule of meetings to ensure the regular review of applications, which allowed members one week to complete their review. A proposed rota of members would be developed and circulated for members to mitigate any potential issues with their availability.

Ms Claire Edgeworth advised that further information would be circulated to members for comment and that it was intended to pilot the new process from April 2014. Members requested a copy of the Proportionate Review criteria.

Action: CAT to circulate proportionate review process and proportionate review criteria for comment.

The Chair provided a brief update on amendments to the Care Bill and the potential new role for the CAG. It was noted that this was at a very early stage and that any changes would be subject to an understanding of scope and appropriate resourcing.

4. MEDIA HANDLING [CAG 10-04/2014]

Mr Gordon Harrison, Head of Communications, HRA provided a presentation on media handling. Members discussed the key stakeholders within the scope of the Group's work and how awareness of the Group could be raised especially in relation to encouraging consent to be sought. These comments would be fed into reputation and media planning approaches.

It was noted that members might be approached by the media for comment in their capacity in other roles. Members were informed that If speaking in a personal capacity this must be made explicit. Any media requests for information on the CAG or HRA must be agreed by the Chair and HRA in advance.

5. THEMES FROM CAG AWAY DAY NOVEMBER 2013 [CAG 9-05/2013]

The current status and proposed timescales of the actions from the CAG away day were tabled at the meeting. In addition, further papers in relation to CAG principles in assessing feasibility of consent for audits, revised IRAS question specific guidance text, demonstrating an equivalent duty of confidentiality to that of a health professional and the emergency research process that were circulated.

The Chair requested that members review the circulated documents and feedback any comments to the Confidentiality Advice Team (CAT) in relation to the proposed timescales for development.

Members were asked to review the circulated audit paper for this to be discussed at the April 2014 Group meeting.

Ms Claire Edgeworth advised that updates are required to the guidance on how to use IRAS and increasingly so as a new version of the system would be established in 2015. It was noted that some guidance had already been updated to remove references to the National Information Governance Board (NIGB) however this had not yet been implemented into IRAS.

Action: CAT to circulate documents for comment.

6. ITEMS FOR CONSIDERATION

a. ECC 5-05 (a)/2012 Review of ISAC decision-making documentation

The list of disclosures was noted. As an annual review had not been provided according to the review schedule, members) discussed the anticipated provision of the annual review and advised on aspects the applicant should report against.

1. <u>Impact of care.data on CPRD fair processing mechanism</u>

   It was noted that CPRD are intending to rely on the care.data information communications to satisfy its own fair processing obligations within the Data Protection Act 1998 under this approval. The pause around care.data will impact on satisfying this

obligation under the approval therefore members requested that assurance be provided from the Information Commissioner's Office (ICO) that he is satisfied with the current arrangements in place to ensure that the activity is compliant with the provisions of the Data Protection Act 1998. The applicant should liaise directly with David Evans from the ICO.

2. Mechanism for handling patient objection

It was understood that a 'Type 1 objection' covers the flow of data to the HSCIC however the read code currently lists this objection as '*dissent from secondary use of GP patient identifiable data'.* It is known that work is ongoing elsewhere on the management of read codes however members noted that under the conditions of this approval, any pre-existing or subsequent patient objection must be respected and where applicable this information not included within the scope of this approval.
In light of this condition of support, the applicants should provide a clear, non-technical description on how CPRD, in conjunction with the HSCIC, ensure that patient objection is currently managed, and how it is anticipated to be managed in light the 'type 1 and 2 objections'.

3. Processing of protocol consented datasets

The 'Linkage Master Dataset' includes protocol consented datasets and member understanding is that these cover situations where patients have explicitly consented to data linkage within the CPRD environment.

The CAG confirmed that these protocol consented datasets offer clear opportunity for consent to be provided by the patient/data subject, and subsequent receipt and linkage of this data into the CPRD/HSCIC environment is not included within the scope of the approval. The applicants would be asked to confirm explicit understanding of this position and provide descriptive examples of how consent is obtained for each scenario of this subset (separate example for clinical trials, PROMs and ASLPAC). An updated linkage master dataset should also be provided with these items removed.

4. ISAC decision making

Members reviewed the current iteration of the ISAC decision-making process.
It was noted the neither CAG nor the HRA/SofS have approved this document as it is the responsibility of the applicant to ensure that the criteria is sufficiently robust. The work over the previous 12 months with the CAG has been to work with the CPRD to help facilitate a document that is clear on situations where the disclosure raises risks of potential identifiability and therefore escalation to the CAG.

Members noted that the criteria did not include an assessment of the purpose of the proposed disclosure, and requested this inclusion. It was also advised that the assessment should be explicitly linked to the ICO Anonymisation Code of Practice and this should also be documented.

While not a condition, members commented that it may be prudent to ensure that more than two persons review all protocols, particularly in relation to the potential disclosiveness of the dataset to the recipient, in the first instance to ensure that there is suitably robust scrutiny prior to any decisions being taken or referral to the CAG.

5. Information Publication

It was noted that the CPRD is a flagship research institution and is therefore expected to follow the highest standards of governance and transparency. This is particularly important as the support in place is provided to enable data controllers to provide identifiable information to the HSCIC (in their capacity as data processors on behalf of

CPRD) without being in breach of the common law duty of confidentiality. In line with this, it was advised that the following should be published on the CPRD website

a. ISAC decision-making process (subject to the amendments above)
b. Terms and conditions provided to recipients of data
c. Up to date list of all disclosures provided to recipients (as provided to the CAG)

A final version of (a) should be provided to the CAG along with links to (b) and (c).

6. Public benefit

The purpose of the annual review is to demonstrate there is a continued need for processing and to provide justification for the common law duty of confidentiality to be lifted. Members advised that a summary of benefits that would otherwise not have taken place without this support being in place should be provided. It is noted that many disclosures have been in relation to drug safety, clinical epidemiology and health outcomes so the specific benefits that have arisen from a sample of these activities should be provided e.g. inclusion within peer reviewed publications and/or outcomes.

7. Pseudonymisation review

It is known that the HSCIC is due to shortly complete a review into pseudonymisation. Once published, CAG advised that they would reserve the right to seek further information from the CPRD in relation to the processing taking place under this approval. This advice would be sent to the applicant so that the annual review would fully address these points.

b. CAG 7-07(a-c)/2013 Invoice validation – amendment

The original non-research application from NHS England, approved in November 2013, sought support to enable the correct commissioner to be identified to enable payment for treatment. This was requested as an interim measure and would form a part of NHS England's 'managed change' process. The application had been presented as three separate applications to reflect the different environments and controls and to primarily set out the mechanism to allow data to flow to Clinical Commissioning Groups (CCGs) and Commissioning Support Units (CSUs) to support invoice validation in the short term. This would allow business continuity while strategic options to reduce or remove the need for personal confidential data (PCD) were explored.

The first application (7-07(a)/2013) was intended to explore the extent of access to PCD as part of this managed change process. Applications (b) and (c) reflected that this could not happen immediately and that support was needed immediately to enable appropriate payments within the system.

Amendment request

A refined amendment request was provided on 11 February 2014 following withdrawal of the inclusion of Welsh data by NHS England due to the need for further information on equivalency measures before this aspect could be considered by the CAG.

The amendment scope covered an additional data flow of 'weakly pseudonymised' data set (with one strong identifier) from the CEfF to the ASH aligned with the Commissioner. Where necessary the ASH would provide a 'weakly pseudonymised' data set (with one strong identifier) to the aligned CEfF.

The amendment confirmed that it would remain applicable to those bodies specified in the applications referenced (a) –(c) and the purpose of submission was intended to support the testing and development of new ways of working as part of the 'managed change'

programme. This reciprocal data flow would support the co-ordination of work and the development of systems necessary for the change process. The CEfF would retain a weakly pseudonymised data set (with one strong identifier) to support this co-ordination and testing.

Confidentiality Advisory Group advice

Detail of the original CAG advice was provided in the letter dated 22 November 2013. This amendment did not require further detailed review of the normal CAG considerations due to its nature, and as these had already been addressed through the original review as set out in the original final approval outcome. In reviewing the request, it was noted that the amendment would reduce unnecessary data flows, which was welcomed by the Group, and this was considered to be a positive measure as it supported the move away from reliance on unnecessary data flows and items.

Members were aware that, following comment from the Information Commissioner's Office (ICO) review, clarification over retention of data needed to be finalised and reported against in the May 2014 CAG meeting. In light of this need for clarity, members noted that currently the retention period was until June 2014 to allow for a challenge period and there was an expressed intention to seek to reduce this. Members therefore sought a definitive timescale on the maximum challenge period for invoice validation and payment as this would enable assessment at the May 2014 meeting in terms of progression towards this aim.

Members noted the reference to 'weakly pseudonymised' data, noting that it had been cited previously in the above referenced applications. Members agreed in light of external work taking place on definitions, and noting that 'weakly pseudonymised' is not a standardised term, future information provided to CAG should no longer reference this phrase. Instead, members requested that any future information should make clear the precise identifiable data items/data set that is referred to avoid any future ambiguities.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the amendment was in line with the stated aims of the application to reduce an refine data flows, and therefore advised recommending *provisional* support to the Secretary of State for Health, subject to a satisfactory response to the clarification request and compliance with the specific and standard conditions of support as set out below.

Request for clarification

1. Clarification of the maximum time period by which invoices can be challenged in light of concerns over retention. This will allow assessment of the position at the CAG meeting in May 2014. Please note support for this amendment will not come into effect until a satisfactory response is received and a final approval letter issued.

Specific conditions of support

1. All of the existing application clarifications and conditions of support set out in the letter dated 22 November 2013 remain applicable.

2. All further correspondence that refers to 'weakly pseudonymised' data should no longer be used as this is not a standardised terms with a clear meaning. In future, the precise identifiers should be specified / make explicit the relevant identifier(s) or datasets. In this application and amendment context it is understood to refer to NHS Number or postcode.

c. CAG 8-06(b)/2013 National Chronic Obstructive Pulmonary Disease (COPD) Audit Programme - inclusion of primary care audit to existing secondary care audit dataset – response to previous deferral

This amendment from the Royal College of Physicians of London set out the purpose of collecting the primary care clinical audit dataset to inform the National COPD Audit. This was an amendment to the main audit application which included collection of secondary care clinical audit data.

The audit aims included:

1. To enable the improvement of the quality of care for COPD delivered in primary care settings, through the provision of high quality longitudinal data.
2. To enable providers of acute hospital care for COPD to improve the quality of care provided in these settings, through the provision of high quality time–limited data collections.
3. To enable providers of pulmonary rehabilitation for COPD to improve the quality of care provided in these settings, through the provision of high quality time–limited data collections.
4. To enable COPD care providers to improve the integration and management of their COPD services, through the periodic provision of organisational data.
5. To explore the potential for Patient Reported Experience Measures to be included in the national COPD audit programme in the future.

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

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

Background

This amendment request had been considered on the 9 January 2014 and further information had been requested. Members queried whether a pseudonymised solution could be adopted immediately for some GP system suppliers or, if this is not possible immediately, how this could be adopted as a future exit strategy from the use of confidential patient information from GP practices without consent.

The applicant provided a response to this request for consideration at the CAG meeting on the 6 March.

Confidentiality Advisory Group advice

Members considered the further information provided which specified that it would not be possible to adopt a pseuduonymised methodology due to the additional burden on GP practice staff. It was suggested that an effective pseudonymisation at practice level approach for national audit would require a dedicated national programme to systematically roll out the pseudonymisation process across England and Wales. GPES was identified as a long term exit strategy from reliance of support.

Members reiterated that they considered the activity to be important, noting that the condition was very serious and required a large amount of NHS resources.

Members were advised that at least two GP system suppliers had already implemented software to allow pseudonymisation at source and noted that the HSCIC was currently carrying out a review in relation to the feasibility of adopting pseudonymisation at source.

Members therefore requested that the applicant provide further information in relation to the particular difficulties experienced in pursuing a pseudonymised approach in order to ensure that there was no alternative. For example, details of the additional burden this would be on GP

practice staff and exploration into whether the GP system suppliers were able to do this routinely. Members suggested that the applicant could obtain statements from suppliers in relation to the additional burden to provide evidence that the approach would not be feasible.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, CAG recommended that the amendment be deferred pending further information being submitted in line with the request for clarification outlined below.

Provision further details of the additional burden that a pseudonymised approach would place on GP practice staff and explore whether the GP system suppliers are able to do this routinely. Members suggested that the applicant could obtain statements from suppliers in relation to the additional burden to provide evidence that the approach would not be feasible.

Adopting a pseudonymised approach for national audits

Members agreed that the pseudonymisation review being carried out by the HSCIC would be crucial in indicating whether a pseudonymised approach could be adopted as standard for national audit data extractions. Particularly where extractions were taking place from GP practices where systems may be equipped to pseudonymise data.

Members agreed that once the pseudonymisation review report was available further discussion should take place with NHS England, the Healthcare Quality Improvement Partnership and HSCIC in relation to the practicality of a pseudonymised approach for national audits.

Action: CAT to contact NHS England, HQIP and HSCIC to arrange meeting with CAG members once pseudonymisation review is published.

7. NEW APPLICATIONS – Non-research

a. NHS Blood and Transplant Potential Donor Audit and Referrals Database [CAG 10-07(a)/2014]

This application from NHS Blood and Transplant set out the purpose of utilising donor referral information in an identifiable format to allow audit activities to take place using the data. The application enhanced the Potential Donor Audit System (PDA), PIAG 4-05(e)/2008, which received support to allow collection of data in relation to potential donors attending emergency departments. The current application requested an extension to the amount of information collected and requested access to data in relation to all patients referred for possible donation.

A recommendation for class 4, 5 and 6 support was requested to cover access to referral information in relation to all patients referred for possible donation and linkage to ACORN data using postcode.

Access was requested to date of death and postcode.

Confidentiality Advisory Group advice

Members agreed that the purposes outlined in the application were of public benefit, noting that assessing barriers to organ donation with a view to improving donations was very important.

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.

In considering whether consent would be feasible, members noted that patients would be in critical care and therefore too unwell to be approached for consent. Members agreed that it would not be practicable to approach family members at this time given the sensitivity of the situation.

In considering whether pseudonymised/anonymised data could be used, members noted that the identifiers requested appeared to be appropriate to allow linkage to take place to the ACORN software to determine demographic information.

Members raised concerns that there appeared to have been no patient consultation in relation to the activity. Evidence of patient involvement can help to demonstrate the public interest of an activity taking place and provide an opportunity to test the acceptability of the use of and access to confidential patient information without consent. Members noted that it may be possible to consult with the Solid Organ Advisory Group and advised that the applicant pursue this option and provide further information in relation to public involvement undertaken at annual review stage.

Members requested that the applicant confirm which aspects of the flow of data required support, it was noted that statistical and clinical studies may require identifiable data and members requested confirmation that this was the only aspect which required support.

Members queried how it would be ensured that access to identifiable data would be restricted to the minimum numbers of individuals necessary.

Members noted that section l of the application specified that free text would be included in an extract of referral data and requested confirmation of what sort of information this would be likely to include.

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

Request for clarification

1. Confirmation that support is only requested in order to access data for the purposes of statistical and clinical studies.
2. Confirmation of how it will be ensured that access to identifiable data is kept to the minimum number of individuals possible.
3. Confirmation of what sort of information will be included within free text data.

Specific conditions of support

1. Postcode should be deleted from the dataset as soon as possible.
2. Patient involvement should take place and feedback should be reported at annual review stage.
3. Confirmation of suitable security arrangements via IG Toolkit submission.

b. NICOR registries/audits [CAG 10-07(b)/2014]

This application from the University College London set out the purpose of carrying out three new audits in relation to the following procedures:

1. Percutaneous Mitral Valve Repair: a catheter-based device which is used to repair heart valves, providing an alternative to open heart for those patients who are clinically appropriate

2. Left Atrial Appendage Occlusion: a device used to prevent stroke in patients with atrial fibrillation (irregular and rapid heartbeat)
3. Patent Foramen Ovale Closure in Adults: a procedure to close a hole, or potential hole, between the upper chambers of the heart, to prevent stroke

A recommendation for class 4, 5 and 6 support was requested to allow access to patients undergoing the procedures. Data would be collected from NHS organisations undertaking procedures, the Health and Social Care Information Centre (Hospital Episode Statistics) and the Office of National Statistics.

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

Confidentiality Advisory Group advice

Members agreed that the activity was in the public interest and that it was important that the procedures were evaluated.

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 considered whether consent would be feasible. Members noted the assertions within the application that the evaluation stage required complete ascertainment in order to ensure that there was no potential bias within the small cohort. The application specified that consent may be feasible from individuals in future if the procedures were considered suitable for routine care and the audit was continued.

Members considered whether it would be feasible to use anonymised/pseudonymised data. It was noted that identifiable data would be required in order to carry out data linkages but that this would be deleted at the earliest opportunity once data linkage activities had been completed. In particular, members noted that name would only be retained until NHS number had been validated by the HSCIC and postcode would only be used to link to grid reference data.

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 considered the patient information leaflet provided. It was noted that this leaflet had been provided in conjunction with other applications for support, however, members advised that there was potential to improve the patient information further. Members suggested that the 'what we do with the information' section could be streamlined and improved by specifying what data items would be disclosed to NICOR. It was suggested that a layered approach to fair processing could be adopted by signposting a website which would include more details about the purposes of processing data.

Members also requested that the patient objection provision be made more prominent within the leaflet and include mechanism to object via email and phone.

Members queried whether the devices were part of the Medicine and Healthcare products Regulatory Authority licensing scheme and requested further information in relation to how the specified activity was related to mandatory surveillance data and the licensing scheme.

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 activity of this nature being conducted, and therefore advised recommending *provisional* support to the

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

Request for clarification

1. Confirmation of how the specified activity is related to the MHRA licensing scheme.

Specific conditions of support

1. An amended version of the patient information leaflet should be forwarded in line with the comments above.
2. A letter of support from the sponsor organisation must be submitted.
3. Confirmation of what data items are included within the audit dataset.
4. Confirmation of suitable security arrangements via IG Toolkit submission. **Confirmed**

c. 2014 Child Inpatient and Day Case Survey [CAG 10-07(c)/2014]

This service evaluation application from the Care Quality Commission detailed the first iteration of a national children's survey conducted as part of the national NHS patient survey programme. The survey was developed to incorporate the views of children and young people into existing national patient surveys.

A recommendation for class 5 and 6 support was requested to cover access to contact details of patients (children aged 0-17) who had been admitted as an inpatient or received treatment as a day case patient in June 2014. Approximate 850 patients per trust would be included.

Access was requested to name and address of patient and the patient's parent/carer.

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 were supportive of the application in principle and agreed that seeking children's views was important. However, members raised concerns that, as the survey cohort were children, they were potentially vulnerable and were concerned about the disclosure of child addresses to a third party on a large scale. With this in mind, members agreed that there would need to be a particularly strong justification to balance the disclosure of this data and noted that in some instances Trusts would undertake the survey themselves. Members advised that as this approach was feasible, there appeared to be a practicable alternative to the disclosure of confidential patient information without consent and this should be pursued in all instances.

Members advised that if a resubmission of the application was made, the following points should be taken into consideration:

1) Section k specified that the statistical dataset would be used for a 'wide variety of purposes'; members advised that this needed to be narrowed and defined more closely. In addition, the application should specify which other national organisations the data would be shared with.

2) Confirmation of how it will be ensured that free text responses will not be identifiable when provided to hospitals should be provided.

3) The response to the eighth Data Protection Act principle should be reviewed to ensure that it is fully demonstrated how this principle has been met.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations had not been met as it appeared a practicable alternative to the disclosure of patient information without consent existed and therefore advised that the Secretary of State for Health that the application should not be supported.

NEW APPLICATIONS – Research

a. Partnerships in Care Research Database [CAG 10-08(a)/2014]

This application from Partnerships in Care, an independent service provided, detailed the creation of a research database to use for research studies to inform treatment and the planning of services.

A recommendation for class 4, 5 and 6 support was requested to cover access to link records collected in relation to 935 patients from medium secure units to Hospital Episode Statistics (HES) and mortality data from the Health and Social Care Information Centre (HSCIC).

Access was requested to name, address, date of birth and date of death.

Confidentiality Advisory Group advice

Members queried the legal basis for Partnerships in Care holding the existing dataset in relation to the patients and sought confirmation that all patients had been treated by Partnerships in Care. Members advised that they would need to be assured of the legal basis to hold the existing dataset prior to providing a recommendation of 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 considered whether consent would be feasible. Members noted that consent had not been obtained from patients originally and that some patients may have died or be difficult to trace so consent would be difficult to obtain at this stage. In addition, the applicant had provided further information in relation to the difficulties in seeking consent in response to queries which detailed that consent would not be feasible as participants might not respond to requests.

Members recognised that it may be difficult to seek consent from those individuals that were no longer in treatment; however members advised that the applicant should explore whether consent from those who were in treatment would be feasible. Further information was requested in relation to this as it appeared an alternative to the use of confidential patient information existed for at least some of the cohort. Members advised that the questions in relation to consent (part a, question 29-3) should be completed in full.

In considering whether anonymised/pseudonymised data would suffice it was noted that identifiable data would be required in order to carry out linkage to HES data.

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, even if consent would not be feasible from those patients who were not in treatment, efforts should be made to inform patients in line with the DPA, for example by displaying information on websites or in patient areas.

The fifth principle of the DPA specifies that personal data must not be kept for longer than is necessary; members noted that the applicant had specified that data would be retained

indefinitely to allow historical information to be collected and requested further information in relation to why indefinite retention was necessary. It was advised that a review of the requirement to retain identifiable data within the research database was carried out at regular intervals. Members also requested further information in relation to what arrangements were in place to plan for changes in legacy if the dataset was to be retained indefinitely and advised there should be clear protocols to manage this.

Members advised that the applicant revisit the Data Protection Act question within the IRAS form (part B, question 12) to ensure that all the requirements were fully met and that this was evidenced.

Members requested further information in relation to what steps would be taken if a patient objected to the use of data.

Members requested that the applicant submit the HES data item request form so that the data items were clear. Members queried whether the request for support was a one off data collection from HES or whether the applicant intended to collect data in relation to patients over a number of years.

In addition, members commented that the data items specified as being required for carrying out linkages were potentially excessive as the HES dataset did not include name and requested clarification in relation to the exact data items that would be provided to the HSCIC.

The intention to disclose data to researchers was noted; members requested further information in relation to the scope of purposes that data could be disclosed to third parties for and asked for specific confirmation that no identifiable data would be disclosed without a further application for support. In particular, members advised that the applicant should ensure that small numbers would not lead to the identification of individuals, noting that the applicant had specified a cell size limit of 3 when 5 was usually advised to ensure confidentiality was maintained.

Confidentiality Advisory Group advice conclusion

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.

In line with the considerations above, the CAG agreed that they were unable to provide a recommendation of support to the Health Research Authority at this time and advised that the application should be resubmitted with the following information:

1. Confirmation of what legal basis Partnerships in Care currently process sensitive personal data in relation to the cohort.
2. Details of exploration into whether consent could be obtained from those patients who are still in treatment in line with the advice above.
3. Confirmation of what efforts can be made to inform patients of the processing in line with the DPA, for example by displaying information on websites or in patient areas.
4. Confirmation why indefinite retention of identifiable data is necessary and whether regular review of this requirement will be undertaken.
5. Evidence of consideration of legacy planning for the database if identifiable data is to be retained and policies to manage this.
6. Revision of the Data Protection Act question (part b, question 12) within the IRAS form.
7. Confirmation of what actions will be taken if a patient objects to the use of their data.
8. Confirmation of the scope of the application, including HES data items and years requested.
9. Confirmation of the minimum number of identifiable data items required for data linkage.

10. Details of the scope of purposes that data could be disclosed to third party researchers for.
11. Definitive confirmation that no identifiable data will be disclosed to third party researchers.

b. Building Blocks 2-6 [CAG 10-08(b)/2014]

This application from Cardiff University set out the purpose of following up a cohort of 1562 women and children until child reaches age of 6 in order to assess whether Family Nurse Partnership (FNP) reduces maltreatment of children.

A recommendation for class 4 and 6 support was requested in order to carry out linkage of Hospital Episode Statistics data to assess BB 0- 2 data which includes FNP data. Cardiff University would provide demographic data only to the Health and Social Care Information Centre (HSCIC) who would use this data to select relevant clinical records. Clinical data including the unique ID would be passed to Health Information Research Centre (HIRU) and linked using Secure Anonymised Information Linkage (SAIL). Cardiff University will provide the BB trial data to HIRU with the same unique ID. The linked dataset will be stored at HIRU.

Follow up data would be extracted at the child's 4th and 6th birthday.

Name, NHS number, GP registration and postcode would be provided in order to carry out linkages.

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.

In considering whether consent would be feasible, members agreed that obtaining consent would be difficult to obtain for a number of reasons. In particular, members noted that due to the sensitivity of the child protection focus of the study, the mobility of the cohort and the consequent introduction of non-ascertainment bias on sample representativeness, consent did not appear to be feasible in this instance.

Members considered whether anonymised/pseudonymised data would suffice and noted that identifiable data would be required for linkage purposes only and would be accessed for a short period of time until data was pseudonymised for analysis purposes. The linkage process detailed within the application appeared to be robust.

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.

A draft patient letter had been included within the application and members advised that information in relation to the intended data processing should be as clear as possible. Members discussed whether information in relation to potential future linkages should be included within the current patient letter, for example linkage to social care data. It was advised that the applicant would need to ensure that patients were informed of the extent of access to their personal data at some stage prior to further linkages taking place.

Members requested that final copies of all patient information be submitted once available to ensure that the fair processing requirements of the DPA were met.

Members noted that the application referenced further linkages to GP and social care data and advised that the current support did not include this. An amendment to the application should be made once details of further linkages are known.

Members advised that the applicant should ensure that clear instructions for registering were provided.

Members noted that an independent group of young people would be established to help advice researchers and queried whether it would be possible to include patients that were engaged with FNP but not currently part of the study.

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. Submission of final copy of patient information letter once available.
2. Confirmation whether it would be possible to include patients that were engaged with FNP but not currently part of the study.
3. Favourable opinion from a Research Ethics Committee.
4. Confirmation of suitable security arrangements via IG Toolkit submission. The HSCIC have been asked to confirm the toolkit submission is satisfactory.

c. Intergenerational and lifecourse influences on health and mortality [CAG 10-08(c)/2014]

This application from the Institute of Education at the University of London set out the purpose of carrying out further follow up in longitudinal study examining the influence of indicators of health and growth in one generation on the health and growth of the preceding or subsequent generation.

A recommendation for class 4 and 6 support was requested to cover access to details of cancer registration and mortality from ONS for 18,454 parent cohort members. The cohort members had already been flagged at ONS.

Access was requested to cancer registration and mortality data from ONS including name, NHS number, date of birth and date of death.

Confidentiality Advisory Group advice

Members requested further information could be provided in relation to the benefits in the research taking place to ensure that the public interest in the access to data could be evidenced.

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 for the activity would be feasible. Members noted that patients had provided consent to participate in the study in the first instance. The applicant asserted that it had been a number of years since the last point of contact, that the majority of parent cohort members would be deceased and current contact details are not held. Members agreed that obtaining explicit consent would be difficult but queried what efforts the applicant could make to inform the cohort about continued processing in line with the comments below in relation to compliance with the Data Protection Act.

Members considered whether anonymised/pseudonymised data would suffice and noted that identifiable data would be required in the first instance to allow linkages to be made to data already held by the applicant.

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 further efforts needed to be made to ensure that this requirement was met and asked the applicant to consider ways in which awareness could be raised, for example by informing cohort members who were being contacted and displaying information on relevant websites. The information provided should also include instructions to register objections to data processing.

Confidentiality Advisory Group advice conclusion

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.

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 further clarifications as set out below. compliance with the specific and standard conditions of support and

Request for clarification

1. Further information in relation to the benefits in the research taking place to ensure that the public interest in the access to data is evidenced.
2. Confirmation of what actions will be taken to ensure that awareness of the activity will be raised, for example by informing cohort members who were being contacted and displaying information on relevant websites.

Specific conditions of support

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

d. UCL Infection DNA Bank [CAG 10-08(d)/2014]

This application from University College London for the establishment of a new tissue bank to undertake research in the field of infectious disease, the primary research interest of the applicants is virology, however this resource will be used more widely and it is likely that research will encompass a range of human diseases. The tissue bank will include residual diagnostic samples, which will be held anonymised/linked with a unique identification number (UIN), in addition to prospectively consented samples. The collection of patient identifiable data will be limited to circumstances where further sampling is required. Support was requested to locate and invite a patient prior to consent into a project. Class 3 and 6 support was requested.

Access was requested to clinical data, name, address, date of birth, gender and hospital number.

Confidentiality Advisory Group advice

Members were unclear about what samples and data were currently held. Concerns were raised that it appeared that retrospective samples were not fully anonymised as there were references to storage of personal data, and as such researchers may be able to link to this

and identify samples to individual patients. Members therefore queried whether describing the samples as anonymised was accurate as linkage to full identifiers was required within the protocol. It was advised that the fact that the identification key was held separately from the samples did not render them anonymised as the researcher appeared to be retaining the key to this personal data.

Members noted that residual diagnostic samples would be accessed and would be "*frozen with the intention of nucleic acid extraction and without cryoprotection, from which intact cells cannot be recovered*" and sought clarification whether the arrangements in place would ensure that the requirements of the Human Tissue Act were met or would mean that the Act was not applicable.

In particular, members commented that if samples did fall within the HTA at any point of access by researchers, it should be ensured that the samples and corresponding data were managed in line with the requirements of the Human Tissue Act. Members requested that the applicant seek confirmation from the Human Tissue Authority in relation to this point.

Members were unclear whether retrospective samples were currently held with consent and requested further information in relation to this. Members queried whether it would be possible to obtain consent from patients retrospectively if consent had not been obtained from the outset.

Members were unclear as to who would be writing to patients in order to seek consent prospectively. The Group specified that the hospital where the samples originated from should contact the patients rather than a bank administrator. Members requested confirmation that consent would be obtained for the prospective stage of the tissue bank and advised that this would not require CAG review as long as consent was obtained via clinical care teams and the samples were anonymous to researchers (see points advised on information anonymous to the researcher above).

Members noted that there were references to disclosing identifiable data to third parties and queried how this access would be governed.

The Group commented that further clarification would be required in relation to the scope and purposes of the tissue bank as this was unclear and would be required to ensure that the medical purpose and public interest in recommending support could be defined.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations did not appeared to have been met, and therefore advised the Health Research Authority that this application should not be supported.

8. ANY OTHER BUSINESS

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