Health Research Authority

Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group

28 November 2013 at 10:30 am at Skipton House, SE1 6LH

Present:

Name	Capacity
Dr Mark Taylor (Chair)	Lay
Dr Charlotte Augst	
Dr Kambiz Boomla	
Dr Tony Calland	
Dr Robert Carr	
Mr Paul Charlton	Lay
Dr Patrick Coyle	
Dr Tricia Cresswell (vice-chair)	
Professor Julia Hippisley-Cox	
Mr Anthony Kane	Lay
Professor Jennifer Kurinczuk	
Ms Clare Sanderson (item 4 onward)	
Dr Murat Soncul	
Mr C. Marc Taylor	
Ms Gillian Wells	Lay
Dr Christopher Wiltsher	Lay
Mr Terence Wiseman	Lay

Also in attendance:

Name	Position (or reason for attending)
Mr Richard Driscoll	Director of Development, British Society of Gastroenterology (item 4)
Ms. Natasha Dunkley	Confidentiality Advice Manager
Ms. Claire Edgeworth	Deputy Confidentiality Advice Manager
Mr David Evans	Expert advisor – Data protection (Information Commissioner's Office)
Ms Beth George	Programme Manager, NHS England (item 7b)
Mr Stephen Robinson	Corporate Secretary, HRA (observing)
Mr Tom Smith	Chief Executive, British Society of Gastroenterology (item 4)
Ms. Rebecca Stanbrook	Director of Confidential Advice – section 251
Ms Ming Tang	Director of Data and Information Systems, NHS England (item 7b)

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Apologies were received from Ms Madeleine Colvin.

The following interests were declared:

Professor Julia Hippisley-Cox did not receive CPRD papers and left the room for items 5a and 5b in order to avoid any perception of a competing interest given her role with QResearch. Professor Julia Hippisley-Cox also declared a competing interest in item 7a as a Director of ClinRisk Limited who provided one of the risk prediction software tools referred to in the application. She attended to provide expert advice to Members on the capabilities of the software, and highlight related issues, but did not participate in the advice given by the CAG for this item.

2. MINUTES OF THE MEETING HELD ON 3 AND 4 OCTOBER 2013

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

3. CAG OFFICE REPORT AND MATTERS ARISING

For information

Secretary of State approval decisions

The Secretary of State for Health (SofS) noted the CAG recommendation of deferral in relation to the Invoice Validation application [CAG 7-07(a)/2013] briefly considered at the October CAG meeting. However, due to early discussion with the applicant and CAG willingness to comment on a detailed resubmission outside of the formal meeting schedule, the SofS agreed that the deferral outcome had been superseded and therefore refrained from providing a decision on the first deferral recommendation.

The Department of Health senior civil servant on behalf of the SofS agreed with all other advice provided by the CAG in relation to the October 2013 meeting applications.

HRA approval decisions

ECC 3-04(f)/2011 - SLaM Information Governance Clinical Dataset Linking Service: Project-specific children inclusion amendment

At the October 2013 meeting, CAG had recommended provisional support to the HRA, subject to satisfactory responses to clarifications around how the patient leaflet would take full account of children's understanding, how any objections would be managed once the child reached adulthood, and confirmation that the protocol had been reviewed by the Oversight Committee. The HRA decided to defer the decision on grounds that the issue was significant enough to warrant a clear response from the applicant before indicating an outcome. The applicant provided satisfactory responses to these clarification and CAG recommended provisional support. The HRA accepted this decision.

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

Changes to Approver based on jurisdiction

Following legal advice, Members were advised of the following approval arrangements:

1. For research activities where patient confidential data (PCD) was generated in England – HRA was the approving body utilising CAG recommendation
2. For research activities where PCD was generated in Wales only – SofS was the approving body utilising HRA advice
3. For research activities where PCD was generated in England and Wales – HRA and SofS would approve utilising CAG recommendation
4. For non-research activities where PCD was generated in England and/or Wales – SofS was the approving body utilising CAG recommendation

This change led to a small delay in one approval decision, however, this issue has been addressed and future delays are not anticipated.

Operational updates

Monthly meetings

Members were advised that from April 2014 it was anticipated that CAG would move to monthly one-day meetings. Dates had been shared with Members and were located online at http://www.hra.nhs.uk/resources/confidentiality-advisory-group/confidentiality-advisory-group-cag-meeting-dates/.

Northern Ireland DHSPSS

The Confidentiality Advice Team (CAT) had recently been contacted around any known issues on access to social care data from Northern Ireland as the Northern Ireland authorities were seeking to establish their own equivalent of 'section 251' Regulations and were considering options for the future sharing of patient information for purposes other than the direct care of the individual ("secondary uses") in Northern Ireland. The requestors had been directed to the Social Care REC in the first instance to gain an understanding of how this REC handled social care requests.

Information Standards Board (ISB)

It had been identified that since 1 April 2013, ISB / ISMS had been unclear on who had taken on the previous NIGB function of providing information governance advice against information standards; some of which had received approval under Regulation 5. Following detailed correspondence CAG responsibilities had been made clear and it had been agreed that the Health and Social Care Information Centre (HSCIC) would take the lead on general IG issues. It had also been agreed that Ms Dunkley would continue to liaise with ISB and the HSCIC and would flag any issues proactively while these processes continued to embed.

NHS England applications

Prospective application - Learning Disabilities – Case Management

Members were informed that CAG received late notification of an application that was originally intended to be considered at the November 2013 meeting. Despite efforts by the advice team, the applying organisation was unclear and application author had not been established at time of the request. Advice was subsequently provided on an initial draft by Ms Dunkley that indicated the scope was unclear and the distinction between direct and indirect care needed clarification, along with details of alternatives and DPA compliance. A meeting subsequently took place two days before the agreed submission deadline where it was agreed, following this feedback, that the application was not sufficiently comprehensive to enable a recommendation to be provided and that significant work would need to take place to enable the application to be considered further. Further timescales were established to enable consideration at the January 2014 meeting.

Application handling

Following the instance above, Ms Stanbrook made clear to NHS England that the current handling of application submission did not enable NHS England to present its applications in the best possible way. NHSE had identified a programme manager who would be responsible for ensuring NHSE communications were aligned and consistent. It was agreed that a detailed training session would be held with relevant stakeholders within NHS England in January to aid in further submissions as the first step, with the CAT to ensure that the programme manager would take proactive responsibility for managing internal NHSE applications.

CAT transfer to Operations

The Confidentiality Advice team would be moving into the Operations Directorate and reporting to Joan Kirkbride, Director of Operations at the end of December 2013. The team had started providing updates to Ms Kirkbride as part of the transition and she was expected to attend the January CAG meeting. Members were also reminded that Mr Martin Frowd would be leaving the team on 20 December 2013, and Mr John Robinson would be commencing employment with the HRA as a Confidentiality Advisor from 06 December 2013.

External guidance referencing CAG

Following Member comment, it had been identified that the HSCIC Confidentiality Guidance and Reference document implied that CAG provided an approval function rather than its advisory role. The HSCIC had responded indicating that this would be rectified in the next iteration of the document. The CAT also received an enquiry from an MP who had located joint NHSE and HSCIC guidance on the NHS Choices website which in a FAQ made incorrect reference to CAG approving activities. The HSCIC and NHSE had both responded positively and quickly to these errors, and sought advice from the CAT on accurate phrasing.

Freedom of Information request

The team had recently received a FOIA request seeking details of the numbers of approved and non-approved applications, with a breakdown by geographical split and number of patient records involved. All information held was provided, except for precise number of patient records involved as this information was not consistently recorded by applicants and would have exceeded the cost and fees threshold to identify whether the information was held.

Human Fertilisation and Embryology Authority Memorandum of Understanding development

The HFEA MoU had been rewritten to more explicitly reflect the advice and approval arrangements under the HRA and CAG, and to set out the anticipated timescales for responses. This MoU was currently with the HFEA under their internal approval processes and was expected to be ratified by the end of November. In the meantime, new points of contact had been identified since staffing changes, and a relationship was undergoing development.

HRA Advice line integration

There were plans for all written requests for advice to be received via the one portal of the HRA advice line which would be subsequently allocated with the final response going out via this portal. Following some discrepancies in approach and requests for clarification going via this portal, it had been agreed that the CAT would continue to maintain the handling of requests directly in order to provide a streamlined service. This position would change once software was procured to enable a more integrated correspondence management system.

Applications to establish registries with consent

It had been agreed in principle that CAT would advise on a panel considering requests to establish registries to increase patient participation. This had arisen from an external need for an ‘approval’

from the HRA and formed part of the potential HRA assessment work. Information would be provided as it developed.

Withdrawal of application – Candesic

This application from a Trust entailed the establishment of a case management system. In effect, the HSCIC would carry out the data linkages and the applicants (a commercial body operating on behalf of the Trust) would receive an anonymised dataset. Numerous letters of support were received, including from MPs, however, all support letters and documentation indicated that the applicant would be processing identifiable data. The applicant was advised by Ms Dunkley that these letters could not be accepted as valid as they provided support to an activity that had not been requested, and the application would need to be re-written. No further contact from the applicant had been received, despite formal notification that the application would be withdrawn from potential consideration.

External meetings and events

Information sharing workshop with the Information Commissioner's Office

An information sharing workshop took place in October 2013 with the ICO audit team and Mr David Evans. The purpose of this session was to provide an understanding of the Health Research Authority, the legal framework underpinning CAG considerations, a detailed review of handling requests for advice and applications at the office level, and exploring the lessons learnt through such assessment. It also aimed to identify potential synergies between the different organisations. A suggestion was made for a potential link to the ICO audit function for those activities that were potentially 'high-risk' which could be identified at time of annual review, and this would be explored further in due course.

Information sharing Workshop - Wales

Members were reminded that a similar information sharing workshop to be hosted by the CAT was scheduled for 2 December with Welsh colleagues from the NHS Wales Informatics Service. This would be more focused on non-research activities and would also cover the legislative background, request handling and issues unique to non-research. Members were invited to attend.

Public Health England meeting

Ms Stanbrook and Ms Dunkley met with Public Health England on 1 November to discuss the outcome of the PHE annual review and to receive a general update on activities. The importance of following CAT advice at the initial stages was emphasised and progress on the annual review discussed. It was noted that an Information Governance Toolkit (IGT) submission had not been provided in line with anticipated timescales, which was preventing a final approval letter being issued. It was also noted that delays to the IGT submission were impacting on the novated applications in that the Advice Team could not confirm to applicants that approval was continuing. The plans to establish in-house expertise on handling requests were still under development, and it was noted that internal correspondence on 'section 251' were sometimes incorrect which had been flagged through applicants seeking advice via the CAT. It was agreed to continue these meetings on a monthly basis.

Applications considered via proportionate review

CAG 8-03(PR1)/2013 - Prospective evaluation of the diagnostic efficacy of the 2010 United Kingdom National Institute for Clinical Excellence Guidelines on Chronic Heart Failure

This audit application from Leeds Teaching Hospitals NHS Trust set out the purpose of a follow-up study on an existing cohort of 3,691 patients in the Leeds area who had received a N-terminal pro-B-type natriuretic peptide (NTproBNP) blood test in the period between 1 May 2012 and 1 May 2013

and were subsequently admitted to hospital. A recommendation for class 6 support was requested to cover access to Hospital Episode Statistics data on hospitalisation and Office for National Statistics data on mortality, both held by the Health and Social Care Information Centre (HSCIC), in order to assess patient outcomes following the blood test, the usefulness of the blood test as a predictor of subsequent outcomes, and the overall effectiveness of the national heart failure pathway. Access was requested to date of admission, date of diagnosis and date of death. It was noted that the existing dataset already included name, NHS number and date of birth which were gathered in the course of providing care and treatment. 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.* This application was considered by Dr Mark Taylor (Chair), Dr Robert Carr and Ms Madeleine Colvin.

Public interest

Members agreed that there was a strong public interest in this study.

Practicable alternatives

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

It was noted that consent for the large number of patients included in the retrospective dataset would be impracticable. Members also noted that the existing dataset, collected in the process of providing care, already included identifiable data and requested that the applicant pseudonymise patient information once linkages have taken place.

Fair processing

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

CAG advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *provisional* support to the Secretary of State for Health, subject to confirmation that data would be pseudonymised following linkages, reasonable efforts would be made to inform the cohort about the processing and any objection would be respected.

CAG 8-03(PR2)/2013 - UK Register of Fatal anaphylactic reactions

This service evaluation application from Central Manchester University Hospitals NHS Foundation Trust set out the purpose of a study to review deaths from anaphylactic reactions, evaluating whether treatment was given, if so what treatment and why it was ineffective. A recommendation for class 2, 4 and 6 support was requested to cover linking data on an existing locally held database of deceased patients with data held by coroners. Access was requested to date of birth, date of death and cause of death. 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 criteria 2 – *Access to deceased patients' data.* This application was considered by Dr Patrick Coyle, Ms Clare Sanderson and Mr Terence Wiseman.

Public interest

Members agreed that there was a strong public interest in this study and noted that severe anaphylaxis was an increasing problem with high mortality.

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 all of the patients in the cohort were deceased and therefore consent would not be feasible in this instance.

Research purposes

Members were of the view that the application appeared to be seeking to establish a research database and with this in mind queried whether the applicant had applied for a research ethics committee opinion, both for the current and existing database. Members were of the view that a REC opinion should be obtained if the database was to be established for research purposes and the IRAS form should be completed to ensure that all relevant questions could be addressed.

Existing database

The status of the existing database was unclear and Members asked for further details regarding what was included within the current dataset.

Identifiable data items requested

Members requested clarification regarding what patient identifier was referred to within question (i) of the application form. In addition Members queried what patient identifiers would be used to contact the Coroner.

Data sources

It was noted that the application form specified that information would be collected from various sources. Members queried what the various sources were, whether the patients clinical care team would provide this information or whether researchers would be accessing patient records and which identifiable fields would be submitted from each source. In addition Members queried if the database would be national and which regions had currently submitted data.

Retention of identifiable data

Members were unclear why identifiable data needed to be retained throughout the life of the registry. In particular, they queried whether date of birth could be changed to age and date of death be changed to age at death or month and year only. If there was justification for retaining any other identifiers in full Members asked for this to be provided for each individual identifiable data item. If identifiable data items were required, Members queried whether it would be feasible to pseudonymise the linked data and retain identifiers on a separate, secure database that holds no clinical data?

Contact with family Members

Members noted that question (n) specified that contact would be made with family Members of the deceased to gather any missing information. Members requested further information in relation to how this would be managed considering the potential distress this could cause relatives of the deceased.

Future use of the database

Members commented that any third party researchers seeking to use the database should be given access to anonymised data only and that access to identifiable data should be subject to a further application.

CAG advice conclusion

The CAG advised that the minimum criteria under the Regulations had not been met, and therefore advised recommending to the Secretary of State for Health that the application be deferred, subject to clarification of identifiable data items held in the existing dataset; clarification of the definitions used for "patient identifier" and "patient identifiers sufficient to contact the coroner"; provision of a complete list of data sources, data flows and collection methods, including any regional limitations; provision of further information on whether researchers intended to contact relatives of deceased patients and how this would be managed without causing distress; and justification of why data should be retained in identifiable form throughout the lifetime of the registry, rather than pseudonymised and if necessary re-identified through retention of identifiers on a separate secure database containing no clinical data.

It was noted that any disclosure of identifiable data from this dataset to third party researchers would require a separate application for approval under the Health Service (Control of Patient Information) Regulations 2002.

CAG 8-03(PR3)/2013 - HipLink: Registry-retrieval linkage study of over 1000 metal-on-metal hip arthroplasties

This research application from the Royal National Orthopaedic Hospital NHS Trust sought to establish a comprehensive database on metal-on-metal hip arthroplasties, in order to more fully understand mechanisms of failure. A recommendation for class 4 support was requested to allow linkage of the London Implant Retrieval Centre's existing database with that of the National Joint Registry. Access was requested to name, NHS number, hospital number, date of birth and gender. 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 criteria 7 – *Validity of consent.* This application was considered by Dr Patrick Coyle (chairing), Mr Anthony Kane and Professor Jennifer Kurinczuk.

Members considered the sample consent form provided within the application protocol and found that the processes within the application and stated purposes for seeking the data were consistent with the grounds under which consent was originally obtained. Members noted that the wording of the original consent had included access to "any of my medical notes" and considered as a result that the National Joint Registry data would reasonably fall within the scope of the original consent.

It was noted that data would be pseudonymised as soon as linkage had taken place, and that there was ongoing engagement with and participation by patient representatives.

Confidentiality Advisory Group advice conclusion

The CAG agreed that an application for support would not be recommended as consent appeared to be in place.

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

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

criteria 3 – access on site to extract anonymised/pseudonymised data. This application was considered by Dr Patrick Coyle (chairing), Mr Paul Charlton and Dr Christopher Wiltsher

A related application, CAG 8-03(PR5)/2013, Targeted case finding for COPD in Primary Care (TargetCOPD) V4.0, was submitted at the same time as this application.

Members raised a number of queries in relation to the application which were addressed by the applicant in a teleconference on the 9 October 2013. A summary of this teleconference was provided to Members, which confirmed that; patients had already been contacted where possible and response rates were around 40%, pseudonymised data only would be extracted from GP practices in relation to those who had not provided consent, data would be transferred using an encrypted memory stick, programme managers who have honorary contracts with confidentiality agreements included would carry out data extraction and HES data would only be accessed for those patients who had provided consent. Further information, including a copy of patient information materials, was also submitted by the applicant, and it was agreed that the majority of the queries had been answered satisfactorily.

It was confirmed that the majority of patients from whom it was intended to seek consent from had already been contacted, and the application now requested time limited access to identifiable data on GP practice sites in order to set up an automated extraction of anonymised data for those patients who had not responded to the request for consent. It was agreed that information in relation to those patients who had actively refused to take part should not be accessed.

Compliance with the Data Protection Act 1998

It was a requirement of the Regulations that an application must not be inconsistent with the principles of the Data Protection Act 1998 (DPA). Further information was submitted by the applicant on the 25 October which included consent forms and information leaflets provided to the patients. Members noted that the information and consent form provided requested explicit consent from patients to access healthcare records. Guidance from the Information Commissioner's Office (ICO) was sought in relation to compliance with the Data Protection Act 1998 and it was indicated that, where a data controller had previously relied on explicit consent as a schedule 3 condition to process sensitive personal data, they could not then rely on another condition, such as a medical purpose. Therefore, as an attempt for consent to process patient information had been made in some instances and no response had been received, processing data as specified within the application might not satisfy a schedule 3 condition under the Data Protection Act.

In order to ensure that the DPA requirements were met, Members advised that the applicant contact the ICO representative to discuss further options for those patients who had already been contacted and had not responded. For those patients who had not yet been contacted and from whom consent would be sought, advice should be sought from the ICO to ensure that any patient information materials did not preclude further access to data in relation to those patients who might not respond.

CAG advice conclusion

The CAG recommended that the application be deferred, pending further discussion with the ICO in relation to compliance with the DPA.

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

This research application from the University of Birmingham set out a cohort study covering 76,608 GP patients in the West Midlands region who were aged 40 to 79 and had a history of smoking but had not been diagnosed with chronic obstructive pulmonary disease (COPD). Assistance had been sought from GP practice staff to identify eligible patients and make contact with these in order to seek consent for inclusion in the study on behalf of the applicant. Aims of the study included assessing the comparative benefits of a targeted approach versus routine practice in COPD case identification, and the effectiveness of an active approach via a questionnaire. The study was correspondingly divided into routine and targeted arms. A recommendation for class 1, 2 and 6 was requested to allow a

researcher to access GP records in order to set up a MIQUEST query to extract anonymised data and postcode and address data in relation to the routine care arm to identify patients by household. Access was requested to name, NHS number, address and postcode. This application was considered via the proportionate review process under *criteria 3 – access on site to extract anonymised/pseudonymised data.* This application was considered by Dr Patrick Coyle (chairing), Mr Paul Charlton and Dr Christopher Wiltsher.

A related application, CAG 8-03(PR4)/2013, the Birmingham COPD cohort study v2.0, was submitted at the same time as this application.

Members raised a number of queries in relation to the application which were addressed by the applicant in a teleconference on the 9 October 2013. A summary of this teleconference was provided to Members which confirmed that; patients had already been contacted where possible (except for the routine arm) and response rates were around 40%, pseudonymised data only would be extracted from GP practices in relation to those who had not provided consent, data would be transferred using an encrypted memory stick, programme managers who have honorary contracts with confidentiality agreements included would carry out data extraction and HES data would only be accessed for those patients who had provided consent. Further information, including patient information materials, was submitted by the applicant, and it was agreed that the majority of the queries had been answered satisfactorily. It was confirmed that the majority of patients from whom it was intended to seek consent from had already been contacted, and the application now requested time limited access to identifiable data on GP practice sites in order to set up an automated extraction of anonymised data for those patients who had not responded and who had not been contacted (targeted care arm). It was agreed that information in relation to those patients who had actively refused to take part should not be accessed.

Targeted care arm

It was a requirement of the Regulations that an application must not be inconsistent with the principles of the Data Protection Act 1998 (DPA). Further information was submitted by the applicant on the 25 October which included the consent forms and information leaflets provided to the patients. Members noted that the information and consent form provided requested explicit consent from patients to access healthcare records. Guidance from the Information Commissioner's Office (ICO) was sought in relation to compliance with the Data Protection Act 1998 and it was indicated that, where a data controller had previously relied on explicit consent as a schedule 3 condition to process sensitive personal data, they could not then rely on another condition, such as a medical purpose. Therefore, as an attempt for consent to process patient information had been made in some instances and no response had been received, processing data as specified within the application may not satisfy a schedule 3 condition under the Data Protection Act.

In order to ensure that the DPA requirements were met, Members advised that the applicant contact the ICO representative to discuss further options for those patients who had already been contacted and had not responded. For those patients who had not yet been contacted and from whom consent would be sought, advice should be sought from the ICO to ensure that any patient information materials did not preclude further access to data in relation to those patients who might not respond.

Routine care arm

Members agreed that support could be recommended to carry out data extraction in relation to those patients within the routine care arm. It was noted that posters would be displayed within GP practices that would inform patients that data extraction would take place and that access to identifiable data would be time limited.

CAG advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *conditional* support to the Health Research Authority, subject to provision of fair processing information in relation to the study, including a clear mechanism to enable

patient opt out of any data collection. It was reiterated that this recommendation applied only to those patients in the routine care arm, and also excluded patients who had actively refused to take part, and the applicant was encouraged to contact the ICO to ensure DPA compliance in relation to patients within the targeted arm who had been contacted.

CAG 8-03(PR6)/2013 – IOSwean

This service evaluation application from Guy's and St Thomas's NHS Foundation Trust set out the purpose of an international observational study of critically ill patients who were ventilated in an intensive care unit for more than 24 hours during a specified two week period, to assess variations in the process of weaning patients off ventilation and any impact on the patient outcome. The study included 25 sites in the UK with ten patients per site. A recommendation for class 1 and 5 support was requested to cover access to patient data. Access was requested to month and year of birth, date of death and gender. This application was considered via the proportionate review process under *criteria 2 – Data of deceased persons.* This application was considered by Dr Patrick Coyle (chairing), Dr Charlotte Augst and Mr Anthony Kane.

Public interest

Members agreed that there was a clear public interest in comparing practice in critical care ventilation across different locations.

Practicable alternatives

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

It was noted that consent would not be feasible in this circumstance as all patients in this study would be critically ill and undergoing ventilation at the time of inclusion in the study.

Justification of identifiers

Members agreed that the age and gender of subjects were clearly important to the research and the date of death was an important data item in order to be able to calculate total time on invasive mechanical ventilation prior to death.

Members queried whether full date of death would be required to be sent to the site in Canada and advised that the applicant consider what the minimum data items required were and where possible ensure that de-identified data only was transferred outside the EU. If identifiable data was required, then a full justification for this should be provided.

Scotland and Northern Ireland

Members noted that the application form stated research sites might include Scotland and Northern Ireland, and noted that the remit of the CAG only covers England and Wales.

CAG advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *provisional* support to the Secretary of State for Health, subject to clarification of the need, with clear justification, to disclose full date of death outside the EU.

CAG 8-03(PR7)/2013 - Analysis of Routine Outcomes Relating to TAVI through Computational Algorithms (AORTA)

This service evaluation application from Newcastle upon Tyne Hospitals NHS Foundation Trust set out the purpose of a project to compare and validate data held locally on patients who had undergone transcatheter aortic valve implantation or surgical aortic valve replacement procedures against data on the same held by the Hospital Episode Statistics (HES) and National Institute for Cardiovascular Outcomes Research (NICOR) databases. A recommendation for class 1, 3, 5 and 6 support was requested to cover access by a researcher to 500 patient records at Newcastle upon Tyne Hospitals NHS Foundation Trust in order to extract pseudonymised data for linking with the already pseudonymised HES and NICOR datasets. Access was requested to partial postcode, sex, age and ethnicity. 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*. This application was considered by Dr Patrick Coyle (chairing), Dr Tony Calland and Mr Terence Wiseman.

Public interest

Members agreed that there was a valid medical purpose and public interest in evaluating the benefit of surgical procedures.

Practicable alternatives

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

Members agreed that it would be disproportionate in this instance to seek consent from this group of patients, many of whom could be expected to be in poor health. It was noted that only pseudonymised data would be extracted from local records. Members queried whether full postcode would be required and the applicant confirmed that partial postcode only was requested.

CAG advice conclusion

The 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.

CAG 8-03(PR8)/2013 – DIAMOND-Lewy Work Package 1, version 1.0

This research application from the University of Cambridge set out the purpose of a study to improve the recognition and diagnosis of Lewy Body Dementia (LBD) through development of a new assessment tool, and to improve patient management and outcomes with respect to the same condition through development of an evidence based toolkit for clinicians. A recommendation for class 1, 3 and 6 support was requested to cover access to the records of 1,800 adult patients at NHS Trusts in North East England and East Anglia with a diagnosis of dementia or Parkinson's disease, in order to screen these records for LBD and contact the subset of patients with LBD to seek consent for inclusion in further research. It was expected that this subset would be approximately 480 patients. Access was requested to name, NHS number, hospital number, date of birth, address, postcode, telephone number and gender. This application was considered via the proportionate review process under *criteria 1 – Consent for consent.* This application was considered by Dr Patrick Coyle (chairing) Dr Murat Soncul and Ms Gillian Wells.

Public interest

Members agreed that there was a strong public interest in improving diagnosis of Lewy Body Dementia and care of patients with this serious condition.

Practicable alternatives

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

It was noted that this group of patients might have reduced capacity to give consent due to the nature of their condition, but consent would still be sought from patients meeting the LBD criteria (expected to be approximately 480 patients). It was noted that access to identifiable data would be required in order to contact patients to seek consent to inclusion in further research. Following extraction, data would be pseudonymised with identifiers held in a separate database.

Patient information materials

Members requested sight of the patient information sheet and letter.

Mechanisms for registering objection

Members asked for more information on how objections to processing of confidential data would be handled given the potential for patients in this group to have reduced capacity to consent.

Justification of identifiers

Members questioned whether full date of birth was necessary and whether month and year of birth would suffice for the stated purpose of comparing outcomes in patients with and without LBD. It was agreed that the other identifiers requested were appropriate for identifying and contacting the LBD cohort to seek consent.

SDHS Training

Members requested further information on the training required by individual staff of the Secure Data Hosting Service (SDHS) prior to receiving approval from the Clinical Trials Unit (CTU) to access sensitive personal data.

Patient and public involvement

Members praised the extensive patient and public involvement work cited in the application as having taken place.

CAG advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *provisional* support to the Health Research Authority, subject to clarification whether full date of birth would be necessary or could be reduced to month and year of birth; clarification how objections from patients to the processing of their data would be managed, with particular regard to patients who might have reduced capacity to consent; provision of the patient information sheet and letter; and provision of further information on the training required by staff of the Secure Data Hosting Service prior to receiving approval from the Clinical Trials Unit to access sensitive personal data.

CAG 8-03(PR9)/2013 – National Prostate Cancer Audit: analysis of existing datasets

This audit application from the Royal College of Surgeons of England referred to a collaborative prostate cancer audit which was part of the Healthcare Quality Improvement Partnership programme looking at treatment and outcomes for all patients. The application detailed the linkage of the HES dataset already held by the Royal College of Surgeons (PIAG 2-07(i)/2004 Audit of outcomes after surgical procedures using linked HES data and ONS mortality data) to cancer registry data held by Public Health England using the HSCIC's date linkage service. This application was considered by proportionate review under criteria 4: *time limited access to undertake record linkage and to*

pseudonymise the data. This application was considered by Dr Mark Taylor (Chair) and Dr Patrick Coyle.

Public interest

Members agreed that there appeared to be a substantial public interest to the activity taking place as the outcomes could lead to more effective and efficient management of a very common cancer.

Practicable alternatives

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

Members noted that the numbers over the retrospective period of the audit would be large and consent was considered not to be feasible and that identifiers were being used to a minimal extent for linkage and that identifiers were being removed at the earliest opportunity.

Fair processing information

Members noted that fair processing information would only be provided via a website. It was agreed that this may be the only suitable option for this retrospective audit. However, Members commented that for any prospective data collections, further efforts should be made to inform patients that their data would be included within the audit.

CAG advice conclusion

The 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.

CAG 8-03(PR10)/2013 – Database of Twins with Inflammatory Bowel Disease in the United Kingdom

This research application from Chelsea and Westminster Hospital NHS Foundation Trust set out the purpose of an existing national research database of twins where one or both twins were affected by inflammatory bowel disease, which was originally collected via consent. A recommendation for class 3 support was requested to cover access to Hospital Episode Statistics (HES) data in order to provide a legal basis for access to the database and to trace patients who were no longer in contact with the applying organisation, for the purpose of seeking renewed consent from these patients. Access was requested to name, NHS number, hospital number, date of birth, date of death, address, postcode, gender, ethnicity and GP registration. This application was considered via the proportionate review process under criteria 1 – *Consent for consent.* This application was considered by Dr Patrick Coyle (chairing), Mr Paul Charlton and Dr Murat Soncul.

Background

An earlier iteration of this application had been considered by the Confidentiality Advisory Group's precursor, the Ethics and Confidentiality Committee of the National Information Governance Board (NIGB ECC), in 2012. The ECC had not recommended support at that time, but had been supportive in principle of the proposal to re-contact patients included in the original consented database in order to obtain consent for further use of their data.

The ECC advice provided in June 2012 identified several areas for clarification or further action. These were provision of a clear consent form; provision of details of how initial contact would be managed, including details of the format and reminder methods; provision of details on how non-response would be handled; provision of details in relation to how objections would be managed; confirmation of restrictions in place to limit onward use of the data; confirmation of which data fields

would be retained within the administrative database and separate from the research database; and, given the age of the database, clarification on how checks would be carried out to ensure details were accurate and up to date and deceased persons would not be inappropriately contacted.

Resubmission

Confidentiality Advisory Group Members noted changes made to the new iteration of the application as a result of the advice given by ECC to the applicant in June 2012.

Consent form

A revised consent form had been provided as part of the new application and Members agreed that this was now sufficiently clear.

Initial contact

Members noted the information provided by the applicant and emphasised that it should be ensured that letters should not be sent inadvertently to deceased patients or to former addresses of patients. It was advised that this information should be sought via the HSCIC to ensure that patients were not inappropriately contacted. Members strongly advised that the applicant consult with the HSCIC to consider options.

Non-responders

Members noted that a maximum of three attempts would be made to contact patients, in line with the applicant's local policies, and agreed that this was a reasonable approach as long as it had been ensured that the data in relation to addresses had been updated.

Management of objections

Members noted that the response letter and revised consent form made clear that the wishes of patients who objected to the processing of their data would be respected.

Restrictions in relation to onward use

Members noted the assertion that further research would be limited to the treatment of patients with inflammatory bowel disease, but emphasised that any onward disclosure of data from the database must be fully de-identified and comply with HSCIC rules on small numbers that might otherwise render the data re-identifiable. Should any third party investigators seek access to this database for further research, a further application for support under the Regulations should be made.

Pseudonymisation of research data

Members advised that successful pseudonymisation would require the establishment of an administrative database to hold identifiers, which would be separate from the clinical database which would contain only clinical data and a single linkage key field. Members requested clarity on which identifiers would be retained on the administrative database and confirmation that none would be retained on the clinical database. In addition, Members advised that access to the identifiable data should be strictly limited.

Accuracy of data

Members noted the intention to check status of patients via the local care teams and, in line with the comments above, suggested that this information should also be sought via the Health and Social Care Information Centre to ensure that patients were not inappropriately contacted.

Application form

Members requested that the application form be updated to include the details of pseudonymisation and disclosure protocols in place.

CAG advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *provisional* support to the Secretary of State for Health and Health Research Authority, subject to consultation by the applicant with the HSCIC to consider options in relation to updating databases to ensure participants would not be inappropriately contacted; confirmation of which identifiers would be retained on the administrative database following pseudonymisation of the data, including assurance that no identifiers would be retained on the clinical database and details of access restrictions to identifiable data; confirmation that no identifiable data would be disclosed onward to any third party without a further successful application under the Regulations and that de-identification would be mindful of risks of re-identification arising from small numbers; and provision of an updated IRAS application form including details of pseudonymisation and disclosure protocols and how objections would be managed.

Amendments to approved applications

CAG 8-03(PR11)/2013 – Hip Fracture Audit [formerly ECC 3-04(s)/2011]

This audit application was originally submitted by the Health and Social Care Information Centre and received approval by the Secretary of State for Health on 11 April 2011. The application set out aims to use case-mix, process and outcome data together with quality standards to improve the quality of care. A recommendation for class 1, 3, 4, 5 and 6 was requested to cover linkage with Hospital Episode Statistics (HES) data. Access was requested to NHS number, date of birth, date of death and postcode. This application was considered via proportionate review under criteria 8, *amendments to approved applications.* This application was reviewed as an amendment by the Chair, Dr Mark Taylor.

An amendment request to the original application ECC 3-04(s)/2011 was received on 30 August 2013, following prior discussions with the Confidentiality Advice Team, to change the data processor for this application to the Royal College of Physicians of London. Details of resultant changes to data flows were provided. Healthcare Quality Improvement Partnership (HQIP) would remain data controller.

The amendment requested was forwarded to the Chair who was generally supportive of the change to a new data processor. The Chair noted that the completion rate for NHS number was only 97% and that this had not changed in the two years since the original application, and therefore requested that the applicant provide a report at annual review stage on the steps taken to improve this completion rate and move away from the need for other identifiers for linkage or validation of NHS number.

Due to the change of data processor, a new reference number was issued for this application, but the annual review due date remained as the anniversary of final approval of the original application.

PIAG 2-05(j)/2006 – National Joint Registry

This audit application from the Healthcare Quality Improvement Partnership (HQIP) sought support for the collection of data on hip, knee, ankle, elbow, and shoulder replacement procedures carried out in England, Wales, and Northern Ireland, in both the NHS and independent healthcare sectors. The underlying aims for which this data was collected were to:

- Monitor in real time the outcomes achieved by brand of prosthesis, hospital and surgeon, and highlight where these fall below an expected performance in order to allow prompt investigation and to support follow-up action.

- Inform patients, clinicians, providers and commissioners of healthcare, regulators, and implant suppliers of the outcomes achieved in joint replacement surgery.
- Evidence variations in outcome achieved across surgical practice in order to inform best practice.
- Enhance patient awareness of joint replacement outcomes to better inform patient choice and patients' quality of experience through engagement with patients and patient organisations.
- Support evidence-based purchasing of joint replacement implants for healthcare providers to support quality and cost effectiveness.
- Support suppliers in the routine post market surveillance of implants and provide information to clinicians, patients, hospital management and the regulatory authorities.

A recommendation for class 1, 4, 5 and 6 support was requested to cover continued access to patient data where consent had not been recorded on the data collection form, and continued permission to link National Joint Registry data to Hospital Episode Statistics (HES), Patient Episode Database Wales (PEDW) and Patient Reported Outcome Measures (PROMs) datasets. It was noted that the National Joint Registry had been a mandatory data collection for the NHS since April 2011. This application was reviewed as an amendment by the Chair, Dr Mark Taylor.

Confidential patient information requested

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

An amendment request was received seeking to aggregate several separate existing applications, the oldest dating from 2006, where support under the Regulations was already in place for collection of data for the purposes listed above. The request included continued linkage with the HES, PEDW and PROMs datasets.

The amendment request was considered by the Chair who recommended that support under the Regulations should continue to apply only to patients where consent status was not recorded. The consolidation of a number of different amendment requests to ensure an accurate record of the approval was welcomed.

It was noted that the current consent form gave assurances that: "Data in the NJR may only be used for medical research in orthopaedic and scientifically-related studies. We do not pass on patients' personal details to researchers'" The Chair commented that this could lead to patients being unaware that their data could be shared using support under the Regulations.

The Chair also highlighted that the information sheet specified that "It is not possible for anyone other than your surgeon to identify you as an individual" and advised that this statement did not appear to reflect accurately the submission of identifiable data to the NJR, although it was noted that this was included within the consent form. In addition, the only linkage referred to was the linkage of different joint operations in order to measure time between operations to "find out problems with implants or surgeons", which did not appear to reflect the extent of data linkages and purposes described within the application form.

In line with the comments above, the Chair advised that the information sheet and consent form be revised to ensure that those patients who consented to being included on the NJR were aware of how their data would be used.

The Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health subject to provision of a revised consent form.

ECC 3-04(o)/2011 - NHS Abdominal Aortic Aneurysm Screening Programme

This service evaluation application from Gloucestershire Hospitals NHS Trust set out the purpose to allow NAASP to receive the whole of England cohort (men in their 65th year registered with a GP) prior to full rollout of the screening programme in 2013. Once included in the screening programme, consent would be obtained and support under the Regulations would no longer be necessary. Access to NHS number, Name, Date of Birth, Date of Death, Address and Postcode, Registered GP Practice was requested. This information was required at this stage in order to obtain accurate numbers in order to inform the full roll out, which would prevent GP practices being missed from programme areas if a new practice is opened and also allow more timely notification of deaths which would prevent invites being sent to men who are deceased. This amendment was considered by the Chair, Dr Mark Taylor.

An amendment to this support was requested to allow linkage of all patients invited for screening by NAAASP in 2013/2014 with HES and ONS data obtained from the Health and Social Care Information Centre (HSCIC) in order to determine outcomes. Pseudonymised data only would be provided to the University of Leicester for analysis purposes.

The amendment request was forwarded to the Chair who noted the steps taken to ensure that pseudonymisation of datasets took place at the earliest opportunity and agreed to recommend support to the application.

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

ECC 3-03(f)/2012 - Mycobacterium abscessus in Cystic Fibrosis: genetic variation, intracellular Behaviour and Clinical Correlation

This research application from Papworth Hospitals NHS Foundation Trust set out to investigate the biology of the organism *mycobacterium abscessus*; to identify whether there is a clinical correlation between its genetic makeup, how it appears in the laboratory and disease patterns. In particular, it is being investigated as it is emerging as a cause of infection in patients with inflammatory lung disease, and in this instance, patients with cystic fibrosis. A recommendation for class 1, 4 and 6 support was requested in order to provide a legitimate basis for the researcher to extract patient identifiable data; name, NHS Number, hospital and laboratory ID. This request was assessed by the Confidentiality Advice Team.

An amendment request was received on 25 October 2013 to change the datasheet to include all medications received by patients at the time of their first positive sample, rather than only specified medications. A revised data sheet (version 2) was submitted in support of this change. It was noted that there were no changes to identifiable data items or data flows, and therefore an amendment to the original decision under the Health Service (Control of Patient Information) Regulations would not be required.

It was noted that the change to medication items recorded might require an amendment to the existing ethical approval and confirmation of a favourable opinion for the amendment should be submitted.

ECC 6-02(FT11)/2012 – Complete Kawasaki Disease National Survey

This research application from University Hospitals Bristol NHS Foundation Trust detailed a surveillance study using the BPSU methodology which would collect information in relation to the epidemiology, clinical outcomes and current clinical management of Kawasaki disease in patients under 16 within the UK and Ireland. A recommendation for class 1 and 6 support was requested to allow duplications to be removed. Access was requested to date of birth, hospital number, NHS number, partial postcode (first four digits) and date of death. Month/ year of birth and death only would be used for analysis purposes. This amendment was considered by the Vice-Chair, Dr Tricia Cresswell.

An amendment request was received seeking to expand data collection to include incomplete as well as complete Kawasaki disease in order to improve overall ascertainment, and to extend the period of data collection for one further year. A revised protocol was submitted on 9 October 2013 to support this change.

The amendment requested was forwarded to the Vice-Chair who was supportive of the justification for improving ascertainment and the extension to the data collection period, noting the methodology for the study remained unchanged, and provided a recommendation of support.

ECC 5-05(d)/2012 - Prevention of neural tube defects in ethnic communities in the UK

This research application from University College London detailed a study which aimed to calculate the prevalence of neural tube defects (NTDs) within different ethnic groups, to map the natural history of NTD pregnancies and to assess pre-pregnancy knowledge, attitudes and behaviour of women with a previous NTD affect pregnancy. Confidential patient information including name, NHS number, date of birth and postcode was requested to allow the Health and Social Care Information Centre (HSCIC) to access data from BINOCAR registers in order to link HES, BINOCAR and ONS data and provide pseudonymised data only to the applicant. The HSCIC would provide the Department of Health (DH) Abortion Statistics Manager with identifiable demographic data in order to allow them to identify the cohort and provide pseudonymised data to the applicant. This amendment was considered by the Confidentiality Advice Team.

An amendment request was received on 12 September 2013 for inclusion of 2011 data, which was not yet available at the time of the original application, and inclusion of a consanguinity field which was already collected by one of the congenital anomaly registers. The request cited a link between consanguinity and birth defects which had not been extensively explored in relevant literature to date. It was also clarified that identifiable patient data from BINOCAR registers would not be linked to HES, ONS and DH datasets, and that all identifiable data would be destroyed at the end of the study rather than archived as had been originally proposed.

The amendment requested was considered by the Confidentiality Advice Team as there was no significant increase in the identifiability of the data, and a recommendation of approval was submitted to the Health Research Authority and the Secretary of State for Health.

PIAG 2-08(e)/2002 - BINOCAR

The BINOCAR audit application from Queen Mary University of London (QMUL) had approval to collect identifiable data on all cases of congenital anomalies within the population of England and Wales. A number of regional and disease specific registers of congenital anomalies provided continuous epidemiological monitoring of the frequency, nature, cause and outcomes of congenital anomalies. Confidential information including mother and baby name, address, postcode, NHS number, date of birth and baby date of death were collected from a number of NHS organisations and other outcome datasets. This application was considered by the Confidentiality Advice Team.

A previous amendment request, received in June 2013 and approved by the Secretary of State for Health in an outcome letter dated 16 July 2013, detailed allowing a member of Department of Health (DH) staff access to National Down Syndrome Cytogenetic Register (NDSCR) data for 2011 in order to compare with DH notification data for the same year. The aim of the activity would be to try and match each termination recorded in the NDSCR with that recorded by DH and determine whether the case had been correctly notified to DH. Cases would be matched using postcode and date of birth of mother. All matching would take place at the Wolfson Institute at the University of London on an encrypted DH laptop and NDSCR data would be removed from DH laptops following the matching process.

A further amendment request was received on 4 October 2013 and sought to extend the existing support to cover NDSCR data for 2012 as well as 2011 and enable comparison with DH data for the same year. This was to compare the two years and assess whether there had been any improvements in data quality, following a Care Quality Commission investigation of paperwork at abortion clinics in 2012 and a subsequent letter from the Chief Medical Officer to all such clinics to remind them of their obligations with respect to notifications.

The amendment requested was reviewed at an office level by the Confidentiality Advice Team as the only change requested was an extension of the period for which data was to be collected, and a recommendation of approval was submitted to the Health Research Authority and the Secretary of State for Health.

ECC 2-02(c)/2011 - PARAMEDIC: Prehospital Randomised Assessment of a Mechanical compression Device In Cardiac arrest

This research application from the University of Warwick set out the intent to carry out an assessment of the LUCAS device used by paramedics during CPR for patients who suffer out of hospital cardiac arrest. This would be for the purpose of assessing the survival rate of patients in comparison to standard manual compression. A recommendation for class 2, 3, 5 and 6 support was sought to permit the transfer of patient identifiable information to the research team so that they could send out the initial contact letters to be sent by the research team. Section 251 support was also sought to permit the flagging of patients on the Central Register so as to ascertain survival status. In particular, access to the following information was requested: name, NHS Number, date of birth, date of death, postcode and telephone number. For analysis purposes, date of birth, date of death and gender were specified. This application was reviewed by the Confidentiality Advice Team.

An amendment request was received on 6 June 2013 seeking to access data centrally from Hospital Episode Statistics (HES) rather than locally from each hospital site and informing CAG that the cohort had been extended from 3675 patients to 4344 patients.

The amendment requested related only to a change in data source and therefore was reviewed at office level. It was noted that 95% of the patient cohort would be deceased. A recommendation of approval was submitted to the Health Research Authority and the Secretary of State for Health.

ECC 4-03 (c)/2012 – Clinical Outcome Review Programme Child Health Reviews UK CHR-UK

The Healthcare Quality Improvement Partnership (HQIP) had indicated that they would potentially like to utilise the data for further research activities, rather than progressing to full anonymisation as originally anticipated. However, plans for use of the data had not yet been established. It had been agreed via Dr Tricia Cresswell that the data could be temporarily retained in an identifiable form to enable the applicants to submit an application to the April 2014 meeting; if clear plans for future use had not been established by that point then the information would need to be anonymised in line with the original application details.

<u>Updates on existing applications</u>

ECC 5-05 (f)/2012 MBBRACE-UK – Delivering the Maternal, Newborn and Infant Clinical Outcome Review Programme (MNI-CORP).

The Confidentiality Advice Team were provided with notification that the 2013 topic chosen by the Independent Advisory Group, as part of the commissioned programme of themed topic reviews of stillbirths and serious infant morbidity, will be Congenital Diaphragmatic Hernia (CDH). The amendment notification and subsequent conversation confirmed that the Leicester TIMMS team would not be processing identifiable data for the purposes of this enquiry, and that the methodology would be following the details provided in the original approval. As this involved no change to the

existing approved methodology and involved no changes to data items or purpose, this was noted by the Confidentiality Advice Team; no formal approval decision was required.

CAG 6-07 (a)/2013 - Learning Disabilities (Winterbourne)

This application received a provisional approval outcome from the SofS in October 2013, subject to clarifications and confirmation that the practicable alternatives would not be feasible. Work on the clarifications by the applicant had been progressing relatively slowly. However, in parallel, it had been noted that there had been a delay in seeking evidence from the HSCIC on whether the practicable alternative they could offer was or was not feasible. This had been due to identifying the correct persons within the HSCIC who were authorised to provide this assurance. The Confidentiality Advice Team would continue to meet with the HSCIC on a monthly basis and it had been mutually agreed that there was a need to establish a process to cover these situations. The process was anticipated to be refined by end December 2013.

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

This application was considered at the June CAG meeting and Members agreed that the application should be deferred due to a number of clarifications that were required. The application had been previously supported in part, pending further information in relation to the agreement in place around the automated extraction of data from GP practices without explicit consent. The issue of automated extraction was discussed further at the October CAG meeting in relation to the COPD [CAG 6-07(b)/2013]. Members requested further information in relation to the agreement in place with APOLLO and noted that consent agreements between the Apollo client and GP practices would differ for each data extraction. The Group agreed that they needed to understand the explicit agreements in place with GP practices around the data extraction for both the FLS and COPD audit. Further information was provided by the applicant following the meeting and considered by all members via correspondence.

<u>Agreement in place with APOLLO</u>

It was noted that there was no specific agreement in place with GP practices that used the Apollo software which specified data would be extracted for the purposes of audit without explicit GP consent. Members advised that it was important to ensure that GPs were aware in general terms that data could be extracted automatically. As there was no agreement in relation to the consent processes for carrying out automatic extracts from GP systems in place, Members advised that this omission should be corrected before new extractions took place and there should be a clear agreement in place which specified whether or not GP practices agreed to the extraction of data from their systems without explicit consent.

<u>Future data extractions</u>

Members agreed that GP practices must be provided with adequate notification of any specific audit to meet their responsibilities as data controllers. Consistent with what appeared to be current practice, Members advised that this should involve at least two separate direct communications with individual practices, ideally via different methods of communication, for example post or email. This would ensure that relevant information to be passed on to patients was provided and also give GP practices an opportunity to opt-out of the extraction.

<u>CAG advice conclusion</u>

Following review of the applicant's response, Members agreed that the minimum requirements of the Regulations had been met for the application and conditional support was recommended for the automated data extraction from GP practices, subject to amendment of the terms and conditions of

the use of the Apollo system before new automated extractions take place; establishment of a clear agreement to specify whether GP practices agreed to the extraction of data from their systems without explicit consent; and provision of a minimum of two different forms of direct communication with GP practices prior to a new extraction taking place.

Members queried whether there was any update in relation to this. It was confirmed that it was anticipated that the HSCIC would submit further information; however at the time of the meeting this had not yet been received.

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

CAG considered this application at their August 2013 meeting and 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 a number of clarifications in relation to data flows, confirmation of NHS number ascertainment and confirmation that date of birth and postcode would be destroyed once conversions had taken place. An amended data flow diagram was forwarded and it was noted that the ascertainment of NHS number was found to vary between 90% and 100% across NHS trusts. It was asserted that this variance would bias the results of the study if only patients with a recorded NHS number were included. Confirmation that date of birth and postcode would be destroyed once conversions had taken place was provided.

The response was forwarded to the Chair, Dr Mark Taylor, and a recommendation of support was provided subject to provision of a letter of support from the Caldicott Guardian or equivalent, provision of the audit specific patient information leaflet and confirmation of how this would be made available to patients. It was noted that these conditions had now been satisfied.

Matters arising

Training requirements

The Confidentiality Advice Team informed members that it was a requirement for Members to undertake the online training in equality and diversity and also attend one training day a year. It was confirmed that the CAG away day would count as one day training and members would receive certificates of attendance for this.

Members queried whether undertaking equality and diversity within their own employing organisations would be sufficient.

Action: CAT to liaise with HRA to determine whether equality and diversity training undertaken within Members' own organisations was sufficient.

Julia Hippisley-Cox wins John Perry prize

The chair congratulated Professor Hippisley-Cox on winning the John Perry prize for her work developing the Open Pseudonymiser tool.

Managing differences between advice and decisions by HRA/SofS

It was highlighted that the current version of the CAG SOPs did not explicitly include the process to adopt if the decision from HRA or Secretary of State differed from the advice provided by CAG. Members advised that this be revised as soon as possible to ensure clarity in procedure when a different decision to that advised by CAG was taken. It was expected that should there be a change in position that the approving body would liaise with the Chair to discuss the issues, as they would be likely to be mutual learning arising from such situations

Action: CAT to review SOPs to include process in situations where differences between CAG advice and decisions by HRA/SofS arise.

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

The CQC reported that a serious error was made when submitting the 2013 maternity survey sample for Pennine Acute Hospitals NHS Trust to the Survey Co-ordination Centre for checking. The initial file that was submitted to the Co-ordination Centre contained full names, address/postcode and NHS number of the women sampled for the survey. These details should have been removed prior to submitting the file, as outlined in the survey guidance manual. This was the second breach from this organisation and following the first, several assurances were made that mitigating actions were put in place to ensure that the incident was not repeated. The CQC wrote to the organisation to advise that they contact the ICO to report the breach and determine what further action is required.

At the October CAG meeting Members queried whether the issue had been reported to the Information Commissioners Office. It was confirmed that Pennine Acute Hospitals NHS Trust had chosen not to report this to the ICO. The ICO representative confirmed that this incident would be recorded.

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

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

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

Resubmission background

This application was originally considered at the October CAG meeting, Members agreed that they were cautious about presuming that consent would not be feasible for large national audits and that they would need to take into account the specifics of each activity and the conditions of care specified to determine whether consent was feasible. Members advised that in this instance it appeared that consent would be feasible as they were of the view that the patients in question would be regularly seen by clinicians. Members highlighted to the applicant that there would be many advantages in requesting consent in this instance and would ensure that any further requests for research would be on a consented basis and would not have to rely on further applications under the Regulations.

Resubmission grounds

The applicant requested that CAG reconsider the advice provided. A resubmission document was submitted which detailed a number of issues in utilising the consent based approach as suggested by CAG from the outset. It was confirmed that consent would eventually be feasible, but a 3 year period where approval under the Regulations was in place was requested to allow the establishment of the Registry.

Research purpose

The applicant confirmed that they would not use the Registry data for any research purpose until consent is in place.

Difficulties in seeking consent and effect on initial implementation of Registry

There were a number of issues which were highlighted in relation to seeking consent from the cohort which led to the conclusion by the applicant that whilst consent might be a long term objective, it could not be achieved in the short term. It was asserted that many clinicians viewed consent as being an unmanageable addition to clinical contact time and that whilst some centres had resources to carry this out, others had stated that they did not. In addition, it was confirmed many patients would visit a clinician only annually and that hospitals were increasingly introducing virtual follow-up.

There would be a potential impact in having to seek consent from an early stage on the initial implementation of the project and on the integration of the Registry system with the National IBD Audit. In particular, it was stated that securing future income depended on the ability to demonstrate that the project was viable within a limited time period. This included demonstrating that the data collection, reporting and linkage systems worked and could produce valuable data and that hospitals would participate in the Registry. A grace period of three years was therefore requested at the start of the project where data could be used without consent.

Future plans for consent

Further information in relation to how future plans for consent would be implemented was included.

Confidentiality Advisory Group advice

Discussion with applicant

Members welcomed Mr Richard Driscoll, Director of Development, and Mr Tom Smith, Chief Executive, from the British Society of Gastroenterology, who were attending the meeting to answer queries relating to the resubmission of this application.

The applicants provided a brief presentation which confirmed the professional support for the activity and explained the background and steps already taken in establishing the Registry. The issues in relation to seeking consent from the outset were reiterated. In particular, it was highlighted that the applicant was committed to seeking consent from patients in the long term. However, it was recognised that there were particular cultural and practical issues that both clinicians and the BSG faced which might prevent this in the short term.

Members reiterated that the activity would present significant potential benefits to patients. Members queried why a period of 3 years had been identified as a realistic period before consent was sought. Members were of the view that if any support was recommended, it would be for a limited time period and it should be ensured that it would be practical to move toward consent in this time to ensure that an extension would not be necessary.

It was explained that there would be a period of take up for patient management systems within hospitals as not all would be able to adopt this straight away and therefore the period of 3 years was proposed to reflect this.

Members recognised that consent may be difficult to obtain during consultations and a number of suggestions were made in relation to how consent might be managed outside the clinical consultation. Members suggested that the applicant ensure that fair processing information was provided to patients in relation to the activity in advance of seeking consent. The actual consent process did not need to be face to face at a clinical appointment, but it should be ensured that the patient received the information prior to giving consent and that sufficient time and information was provided to allow the

patient whether to consent or not. Members agreed that there should be a set timescale during which patients were included on the registry prior to consent being obtained and 18 months appeared to be appropriate given clinical follow up times. In addition, some views were raised that this could be carried out on an opt out basis, however Members agreed that an opt in method should be explored.

Members requested that the applicant document the process to seek consent to ensure that the process and timescales in place were clear and recorded.

Some views were raised that it might be possible to seek consent at the patient consultation and that this could take place prior to any upload of data onto the Registry. Further assurance was sought that this would not be possible.

It was confirmed that it had been widely accepted that consent was important. However, in establishing the project, it was important that initial uptake in the Registry was high to ensure success and to enable retrospective data to be included. Once established, consent could then be implemented.

Members sought confirmation that information would not be included in relation to those patients who chose to object.

CAG discussion

Following the discussion with the applicant, Members agreed that a recommendation of support should now be provided for a limited time period only to allow the establishment of the Registry; consent should then be obtained within a set time following the patient's entry onto the Registry, and it was suggested that this time period should be 18 months. It was noted that opt out had been discussed; however Members were of the view that as opt in consent appeared to be feasible this option should be pursued.

As a condition of the recommendation, Members requested that the applicant forward the consent process, timescales and patient information materials for review and confirm that patient objections would be respected. In addition, Members requested a report at annual review stage which included details of the number of patients who had been approached for consent to monitor progress in the movement to a fully consented basis.

CAG advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending *provisional* support to the Secretary of State for Health, subject to provision of details of the consent process, timescales and milestones for movement toward a fully consented approach, patient information materials, and confirmation that patients who registered objections would not have their data included on the Registry. It was reiterated that details of the number of patients who had been approached for consent should be included in the first annual review report.

5. ITEMS FOR CONSIDERATION

5a. Clinical Practice Research Database (CPRD) – Review of ISAC disclosures [ECC 5-05(a)/2012]

Members noted the latest update on ISAC disclosures.

5b. CPRD – 3 additional datasets for linkage: Mental Health Minimum Data Set, Patient Reported Outcome Measures and IMS Health Hospital Prescribing [ECC 5-05(a)/2012]

This amendment sought approval under Regulation 5 of the Health Service (Control of Patient information) Regulations 2002 to include three datasets within the terms of the existing Clinical Practice Research Datalink application. This application set out arrangements for the identifiable data to flow directly to the Health and Social Care Information Centre (HSCIC) as the HSCIC would act as the 'trusted third party' on behalf of CPRD and carry out all linkages on identifiable data, before transferring a pseudonymised dataset to CPRD under agreed arrangements. These datasets were:

1. Mental Health Minimum Data Set (MHMDS) - contains record-level data about the care of adults and older people using secondary mental health services.

2. Patient Reported Outcome Measures (PROMS) – assesses the quality of care delivered to NHS patients from the patient perspective.

3. IMS Health Hospital Prescribing - collection of pseudonymised hospital prescribing data from participating NHS Trusts which is pseudonymised and linked.

Confidentiality Advisory Group advice

It was understood that CPRD would not receive personal confidential data linked to these datasets; the identifiers would continue to be processed by the Health and Social Care Information Centre and this would be in line with the terms of the original approval.

Members advised that inclusion of these datasets would be in line with the purposes of the approved application, and therefore agreed to recommend support to the approving bodies.

6. NEW APPLICATIONS – Non-research

6a. Linkage of NN4B, ONS birth registration and HES data [CAG 8-06(a)/2013]

This audit application from the Royal College of Obstetricians and Gynaecologists (RCOG) set out the purpose of creating a linked dataset containing NHS Numbers for Babies (NN4B), Hospital Episode Statistics (HES) and Office for National Statistics (ONS) birth data, in order to generate better performance indicators for maternity care. A recommendation for class 3, 4, 5 and 6 support was requested in order to access to all birth records at NHS Trusts in England over 2002-2013 (via HES) and linking with NN4B and ONS to capture births outside of NHS hospitals (England only). Confidential patient data would be held by the Royal College of Surgeons (RCS). Access was requested to baby's date and time of birth, baby's sex, postcode and place of birth.

Confidentiality Advisory Group advice

<u>Public interest</u>

Members agreed that there was a significant public interest in the audit taking place.

<u>Practicable alternatives</u>

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

Members noted that the number of patients included within the required datasets was particularly large and therefore consent would not be feasible. It was noted that certain identifiable data items would be required in order to carry out data linkage. Assurances were provided that identifiable data items would be reduced at the earliest opportunity. For example date of birth would be converted to day of birth.

<u>Fair processing information</u>

It was a requirement of the Regulations that an application could not be inconsistent with the principles of the Data Protection Act 1998 (DPA). The first principle of the DPA required that reasonable efforts were made to inform data subjects of the use of their data. Members noted that the applicant would display information on the RCOG website and that copies of an information leaflet would be disseminated to all CCGs to display in GP practices.

Members requested that the applicant submit a copy of patient information materials as a condition of support.

Clarification of data flows

Members agreed that it would be beneficial to see a data flow diagram which included data items, to ensure that the extent of data flows was fully understood and to act as a record for future reference. Members requested that this be submitted by the applicant as a condition of support.

Patient involvement

Members were pleased to note that a good level of patient involvement had been undertaken in relation to the activity.

Additional points

Members noted that the applicant intended to obtain NN4B data from the HSCIC and advised that the applicant should ensure that this data would be available via this route. Members requested that the applicant ensure that they clarify this with the HSCIC prior to providing the data flow diagram requested above.

CAG advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending provisional support to the Secretary of State for Health, subject to provision of a data flow diagram and patient information leaflet.

6b. National Chronic Obstructive Pulmonary Disease (COPD) Audit Programme - Secondary Care Clinical Audit [CAG 8-06(b)/2013]

This audit application from the Royal College of Physicians of London (RCP) followed a successful secondary care audit feasibility pilot (CAG 5-07(a)/2013) and sought support for the full secondary care audit element of the programme. A recommendation for class 1, 4, 5 and 6 support was requested to collect data via a web-based audit tool from every eligible organisation in relation to consecutive cases identified prospectively from February 2014 to May 2014, comprising approximately 200 NHS Trusts. Access was requested to NHS number, postcode, date of birth and date of death.

Confidentiality Advisory Group advice

Public interest

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

Practicable alternatives

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

Members noted that patients would be particularly unwell at this stage of treatment and that the applicant had indicated that whilst consent may be possible when patient's condition improved. It was agreed that it did not appear to be feasible to seek consent for data to be submitted from secondary care services; however Members would expect that any future submissions to collect data in relation to patients at a later stage in their treatment would include efforts to seek consent. It was noted that identifiable data would be required by the HSCIC in order to identify patients and that data would be linked in a pseudonymised format at British Thoracic Society (BTS). Pseudonymised data only would be used at RCP for analysis purposes.

Patient information materials

Members commented that the patient information poster provided did not mention opt out. However, it was noted that the applicant was implementing a layered approach to fair processing and providing a patient information leaflet for patients to refer to, which did include details of how to opt out. Members commented that further efforts could be made to improve fair processing and encouraged the applicant to ensure that all reasonable efforts were made to inform the cohort.

Access by local audit teams

Members noted that in some instances local audit teams would carry out data entry. It was discussed that this would be appropriate in these circumstances given that local audit teams would have legitimate access to patient data in order to carry out local audit activities.

CAG advice conclusion

The 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.

7a. Invoice validation [CAG 7-07(a-c)/2013]

These resubmitted applications had been considered by the entirety of CAG members outside of the formal meeting schedule for exceptional reasons, following consideration of original documentation at the October 2013 meeting. The following is reported as an update on the advice provided by the CAG members outside the formal meeting schedule, and was not discussed at this meeting.

1. CAG 7-07(a)/2013 - Application for transfer of data from the HSCIC to commissioning organisation accredited safe heavens: inclusion of invoice validation as a purpose within CAG 2-03 (a)/2013
2. CAG 7-07(b)/2013 - Invoice validation within Clinical Commissioning Groups (CCGs) controlled environment for Finance
3. CAG 7-07(c)/2013 - Invoice validation within NHS England within the Commissioning Support Units controlled environment (for Finance) on behalf of Clinical Commissioning Groups

This resubmitted non-research application from NHS England 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 was presented as three separate applications, as listed above, to reflect the different environments and controls and primarily set out the mechanism to allow data to flow to CCGs and CSUs to support invoice validation in the short term thus allowing business continuity while strategic options to reduce or perhaps remove the need for personal confidential data (PCD) are 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.

Confidentiality Advisory Group advice

Applicability of Regulation 5

Following discussions that had taken place at the October 2013 CAG meeting, it had been agreed that the application would be considered, on an exceptional basis, via virtual review by Members as Members understood that this was a high priority activity. Members had been provided with a further briefing via Mr Phil Walker that confirmed Regulation 5 could support the activity of invoice validation, that there was currently no other legal basis under which this activity could proceed, and that this activity was compliant with the Data Protection Act 1998. Although the original legal advice had not been provided, Members provided the recommendation below in good faith in light of that briefing.

Application clarifications

Members carried out an extensive review of the documentation and noted that the applicant had clearly spent a significant amount of time in producing the documentation; this was welcomed and appreciated.

Consideration of the application and subsequent discussion with the applicant highlighted a number of clarifications, so the CAG recommendation was based on the following refined position.

a. The first application (7-07(a)/2013) was intended to support the development, testing, and roll out of the information systems that would be in place in the 'end state' post March 2014. The other two applications related to processes that it was recognised were necessary in the interim as NHS England was not yet in a place where invoice validation could be done without PCD going to commissioners. CAG 7-07 (a)/2013 was to support work to develop methods for pseudonymised invoice validation: to develop the final-state with minimal data flows travelling from HSCIC to support invoice validation.

b. Support was intended to be applicable to those organisations that had achieved what was currently termed ‘ASH stage 1 accreditation’. This was clear in the first application but less so in the latter two.

c. NHS Shared Business Services was not intended to receive PCD for the purposes of invoice validation for NHS patients, so references to transfer outside the EEA were no longer applicable to these applications

d. Application 7-07 a)/2013 was not intended to permit access to the Personal Demographics Service for those carrying out the purposes specified in this application and it was confirmed that the details and controls would reflect those specified under CAG 2-03 (a)/2013 with the difference that invoice validation had been added as an additional purpose.

e. There was no intention to allow financial auditor access to PCD. Any such access should be the subject of a separate application.

f. In terms of data protection and schedules to legitimise processing, consent would not be relied upon.

g. Members noted that there was some differentiation between the terms used and expressed concern that ‘weakly pseudonymised data’ was being used to describe a fully identifiable dataset. It was also mindful that the term ‘ASH’ was currently evolving so it was important to specify what each phrase meant in the context of the applications.

h. A spreadsheet was also submitted providing details of the backing dataset supporting the invoice validation data flows that was currently in development. An accurate and up to date spreadsheet of data items and flows and their justification for use should be provided in the next update report

i. The Information Commissioner's Office (ICO) provided confirmation (20/11/2013) that they were generally satisfied with the proposed arrangements, subject to publication of a privacy impact assessment to be provided to the ICO no later than 6 December 2013. The ICO had also confirmed that they would expect to see a review of retention periods and also a review of the data items to ensure they were not excessive, which should be provided to CAG as part of the first update report.

Due to these clarifications and to avoid any potential for future confusion, it was advised that the applications be refined to reflect the understanding obtained through these separate email clarifications, and these should be provided no later than 19 December 2013.

As a whole, Members agreed that there was a strong public interest in this activity proceeding appropriately, and noted that the purpose of the application was to maintain essential business continuity while instigating a complex cultural and operational change. In particular, Members understood that the purpose of CAG 7-07 (a)/2013 was to test the feasibility and reduction of PCD in the future, and agreed, based on the application and subsequent clarifications, that a positive recommendation would be provided to the approving body. This was subject to the following recommended conditions of support.

CAG recommended conditions of support

1. Revision of the application forms to reflect the accurate position as indicated above, to be provided no later than 19 December 2013

2. 6 monthly reports on progress toward exit/ final state. To include: milestones/progress on progress implementing CAG 7-07 (a)/2013; report on service user engagement; any data breaches; outcome of audit (covering points 3 & 4 below, also see point 6)

3. Separation of staff/processes with access to PDS for invoice validation from others with access to other data for different purposes; there should be a separate controlled environment in which this work would be undertaken and specific statements regarding confidentiality clauses in employment contracts of those processing patient confidential data.

4. The same security assurance requirements as previously applied to the overarching application that must be approved by the HSCIC prior to any disclosure.

5. Clarity to be provided on how NHS England and relevant parties would demonstrate compliance for applications CAG 7-07(a)/2013, CAG 7-07(b)/2013 and CAG 7-07(c)/2013 respectively.

6. External audit of information governance and compliance with conditions 3 and 4 at least once within a 12 month period.

7. Actions specified by the Information Commissioner's Office (privacy impact assessment submission direct to the ICO and review of retention and data items in the CAG update report) to be provided in line with agreed timescales.

8. Any future issues around Data Protection compliance should be proactively raised with the Information Commissioner's Office and must be satisfactorily resolved to enable the support to remain valid.

9. PCD was not to be shared with NHS Shared Business Services for the purposes of invoice validation for NHS patients.

10. Any disclosure for purposes of financial audit should be subject to a separate application.

11. An up to date backing dataset and supporting information flows/justification should be reported against at the time of the first report.

12. This was a complex programme of change, therefore NHS England should work with DH colleagues and other relevant stakeholders to best identify how the different organisations with responsibility in this field should be expected to contribute collaboratively.

7b. Risk Stratification [CAG 7-04(a)/2013]

Context

Purpose of application

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.

Confidentiality Advisory Group advice summary

Members welcomed the attendance of Ms Ming Tang and Ms Beth George and found the discussions helpful in seeking to provide a recommendation.

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 SofS following the October 2013 meeting. A teleconference subsequently took place with a CAG sub-group 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.

Medical purpose

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

Public interest

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.

Members were concerned 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

Consent

It was agreed that consent was not practicable as the current models require data on the total population to be processed in order to subsequently identify the target risk groups/individuals.

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.

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.

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 moving enabling approval.

Exit strategy

It was questioned whether it would be more appropriate for NHS England to work on the exit strategy options so support would not be needed. However, 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.

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 done 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.

CAG advice conclusions

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 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 does not come into effect until the ICO has confirmed compliance with the Data Protection Act 1998.

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 between 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. A report on progress to be provided to the CAG meeting in March 2014 to confirm:
   - the risk stratification standards
   - the exit strategy.
   - Provision of information in line with the comments above

8. Health Check [CAG 8-08/2013]

Members received a briefing paper submitted by Public Health England. The briefing paper set out the context that Public Health England had a leadership role to advise local authorities on how to increase GP participation in NHS Health Checks. It was indicated that a current barrier to improving uptake was reluctance of GPs to participate due to information governance concerns over the selection and invitation process (as the Health Check itself would be carried out under a consented basis) on grounds that this might represent a breach of confidentiality.

The paper set out two suggested options to manage the process and Public Health England had specifically requested confirmation as to whether the CAG agreed that the options presented would not represent a breach of confidentiality. Additional advice was also requested on further options, in the event that an application might be made to cover these in due course if the main approaches did not significantly improve uptake.

Confidentiality Advisory Group advice

Members considered this paper in detail and noted that advice had been sought from the Information Commissioner's Office on aspects specific to data protection.

It was noted that Public Health England sought to identify whether utilising a data controller/data processor relationship would be a sufficient mechanism to manage any potential breach of confidentiality. Members advised that such questions were typically decided on the facts of an individual case and this appeared to be a request for legal advice on this matter. It was advised that the CAG was not constituted to take this legal decision.

It was commented that the approaches set out might represent a practicable alternative to seeking support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002, if appropriate agreements were established in such a way so as to protect confidentiality. However, whether this was or was not the case was considered to be unclear based on the reviewed information. Members therefore advised that PHE should firstly seek and obtain legal advice on potential contractual arrangements should there be intent to pursue this position further. Should an application be subsequently made, CAG agreed that it would be happy to review an application to determine if an approach as indicated in the briefing paper, supported by PHE legal advice, would represent a practicable alternative to seeking support under Regulation 5.

CAG advice conclusion

In conclusion, Members advised that, in the absence of legal advice provided to support the briefing paper, the circumstances did not make clear whether the proposed approaches did or did not constitute a breach of confidence. If legal advice was provided by Public Health England in support of a formal application, the CAG would be happy to consider at that point whether the proposed approach would represent a practicable alternative to support under Regulation 5. If an application was intended to be submitted, Members indicated that this could be considered under the CAG proportionate review process, details of which were available on the HRA website. Public Health England were encouraged to contact the CAT if the intent was for an application to be submitted.

9. ANY OTHER BUSINESS

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