NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

06 August 2015 at 9.00am – 3.30pm at Skipton House, SE1 6LH

Present:

Name	Capacity and items present for
Dr Mark Taylor (Chair)	
Dr Kambiz Boomla	
Dr Tony Calland MBE	Chaired items 2a and 4b
Dr Patrick Coyle	Chaired item 2b
Professor Barry Evans	
Ms Clare Sanderson	
Dr Murat Soncul	
Dr Miranda Wolpert	
Mr Anthony Kane	
Ms Hannah Chambers	

Also in attendance:

Name	Position (or reason for attending)
Ms Natasha Dunkley	Confidentiality Advice Manager, HRA
Ms Claire Edgeworth	Deputy Confidentiality Advice Manager, HRA
Ms Amy Ford	Senior Confidentiality Advisor, HRA
Mr Ben Redclift	Confidentiality Advisor, HRA

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Apologies

Apologies were received from Dr Kambiz Boomla, Professor Julia Hippisley-Cox, Mr Anthony Kane, Mr C. Marc Taylor, Dr Robert Carr (provided written comments on items 3c, 3d and 4a) and Ms Gillian Wells.

Declarations of interest

Professor Barry Evans declared an interest in items 2A and 3d as the applications either involved his employer, Public Health England, or requested data from them. It was agreed that this interest would not prevent Professor Evans from remaining in the room for the discussion.

2. AMENDMENTS TO APPROVED APPLICATIONS

a) BINOCAR [PIAG 2-08(e) 2002]

Background

From 1 April 2015 responsibility for providing the surveillance function undertaken by the BINOCAR registers transferred to Public Health England (PHE); as part of this transfer a number of staff previously delivering the registers had been transferred to PHE under TUPE arrangements. PHE had requested support in order to collect prospective data and transfer legacy data held by BINOCAR registers to PHE. Joint letters had been submitted to CAG from PHE and BINOCAR which confirmed the approach for the transfer of this legacy data.

Amendment request

An amendment request was submitted from BINOCAR in May 2015 which requested an extension to their support until 20 June 2016 and to allow linkages to ONS mortality and HES data from the Health and Social Care Information Centre (HSCIC). This request was to ensure that the research programme currently delivered by the BINOCAR registers could be continued, noting that the PHE application detailed surveillance purposes only.

The amendment detailed that once the linkages were complete the applicant intended to identify a third party (potentially the HSCIC) to retain identifiable data so that future linkages could be carried out without the applicant needing access to identifiable data items. It was suggested that identifiable data would need to be retained for 2 years.

A teleconference took place on 12 June 2015 and an extension to hold the current data was granted until 20 September 2015. The applicant was asked to submit a new application by this time and respond directly to the issues raised within the outcome letter.

Subsequently, the applicant confirmed that a full application to the August meeting would not be possible. It was therefore suggested that BINOCAR submit a document to address the specific points raised in the letter dated 19 June 2015 to the August meeting and submit a full application by 17 August 2015. Members were asked to consider the responses to the issues raised, comment on any further information required and confirm whether the full application could be considered by sub-committee once it was received. This would ensure that a further interim extension to the current support would not be required.

Confidentiality Advisory Group Advice

Members agreed that the submission addressed the concerns raised in the interim and that the full application, once submitted, could be considered via the precedent set route.

b) Life Study [5-05(b)2012]

This research application from University College London detailed a birth cohort study that aimed to track the growth, development, health, wellbeing and social circumstances of over 100,000 babies. The application detailed two different components; pregnancy and birth (previously maternity and national).

The pregnancy component would be undertaken by research midwives who would approach women within the maternity unit to invite them to attend a Life Study appointment. It was confirmed that the research midwives would split their time between clinical and research duties and would therefore be considered part of the clinical care team. This aspect would therefore not require support.

Amendment request

The current amendment request detailed Ipsos Mori writing to women following identification at the Health and Social Care Information Centre (HSCIC), rather than the HSCIC carrying out the invitation mail out. The applicant provided details of the discussions that had taken place in relation to the feasibility of the HSCIC carrying out the mail out.

Confidentiality Advisory Group advice

Members noted that due to ongoing development of the study and various changes the application had not yet received final approval.

Transfer of data to Ipsos Mori

It was noted that the correspondence from the HSCIC indicated that they were unable to carry out the mailing on the applicant's behalf. Members therefore noted that it would be necessary to engage a third party in order to carry out the mail outs and agreed that they were broadly supportive of the amendment.

Patient information

Members agreed that prior to providing a recommendation of support they would need to see the information provided to patients as part of the mail out, which should include details of how patients could object to receiving further letters in relation to the study. Members also queried how many times and how frequently patients would be contacted as part of the initial mail out if they did not respond.

Data retention

Members agreed that Ipsos Mori should not retain the data for any longer than necessary and sought assurances that this would be the case. Further information in relation to the retention of the data in identifiable form at Ipsos Mori in relation to those that did not respond or objected was requested.

Patient engagement

Members noted that a significant amount of patient engagement had taken place in relation to the previous approach via the HSCIC and that patients were supportive of this. Members queried whether patients had been engaged when amending the process and what the views in relation to the proposed amendment were.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, CAG advised that they would require further information prior to confirming a recommendation of support for the amendment. The applicant was asked to provide the following information. The information, once provided, would be reviewed by a sub-committee of members in the first instance.

Request for further information

1. Copies of patient information materials to be sent as part of the mail out.
2. Confirmation of how many times and how frequently patients would be contacted.
3. Confirmation of the data retention policy for data held by Ipsos Mori as part of the mail out.
4. Confirmation whether patients had been consulted in relation to the change in approach and what comments had been received in relation to this.

3. NEW APPLICATIONS – Research

a) Retrospective case note review of enteral tube related issues [15/CAG/0154]

This application from the University of Southampton aimed to review records of hospital admissions for enteral tube related problems to identify how often admission for tube related problems occurs and the reasons for admission. The study will also identify whether there are any patient characteristics which make hospital admission more likely. The study protocol was divided into two parts for clarity on the aspects requiring approval under the regulations.

Part 1

All patients undergoing enterostomy tube insertion in the year 2012 will be identified from the Patient Administration System in two acute NHS Hospital Trusts in England. Additionally all patients discharged with a nasoenteric feeding tube in situ in the year 2012 in the same Trust will be identified. Data will be extracted from the Inpatient Patient Administration System by a Clinical Informatics Database Manager in one Trust and authorised personnel in the other Trust. Data extracted will be anonymised by the use of a unique identifier prior to access by the chief investigator. Support would not be required for this aspect of the study.

Part 2

The dietetic records of all patients identified as having an enterostomy tube inserted in 2012 or discharged with a nasoenteric feeding tube in situ will be identified by the Nutrition and

Dietetics Department and their records reviewed by the researcher. Extracting data from the dietetic records will give the researcher access to patient identifiable information as the records are paper, although the researcher will not extract and record any information that will enable the patient to be identified. The researcher is also part of the normal care team for some patients in one Trust. Approval under the regulations would be required for access to the dietetic records by the researcher.

Data will also be extracted from Hospital Episode Statistics (HES) or the Secondary Uses Service (SUS) however this will be anonymised before the researcher receives it.

A recommendation for class 1 and 6 support was requested to allow access to date of birth, date of death and postcode for an authorised user for the process of extracting and anonymising the information.

Confidential patient information requested

Access was requested to date of birth, date of death and postcode. This application had been referred to full CAG review following initial consideration via the precedent set process. The application was referred because members had queried whether a practical alternative existing through effective the de-identification of records by the direct care team.

Confidentiality Advisory Group advice

Public interest

It was noted that this was research into an important field as the number of patients with enteral tube fitted had expanded in recent years. There was therefore strong public interest in this research topic.

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 were content to accept the arguments provided by the applicant around the unfeasibility of conducting this research on a consented basis and the impracticability of extraction and de-identification of records by those with pre-existing legitimate access to the records. There was lengthy discussion around this issue by the committee who agreed that access limited to the researcher was preferable. However the applicant was reminded that the reasons offered for not seeking consent from those who lack capacity could not be used as a justification for seeking approval under the regulations.

Patient Notification

Members queried whether there were opportunities to notify the patients about the study at routine clinical visits. It was felt that if opportunities arose to inform the patients about mechanisms for objection that these should be provided wherever possible.

It was therefore recommended that information be made available about objection mechanisms for secondary uses of patient data. Members agreed that, as a minimum, study information should be displayed within the trusts in order to ensure that the fair processing requirements of the Data Protection Act 1998 were met and to ensure that patients could register dissent in relation to the current activity or future activities if extraction and anonymisation had already taken place.

Scope of application

In reference to part 1 of the study, it was noted that data would be extracted from the Inpatient Patient Administration System (PAS) by a Clinical Informatics Database Manager in one Trust and authorised personnel in the other Trust. Members highlighted that although approval under the regulations was not required for this aspect of the research the applicant should be reminded that only those with legitimate basis to access the PAS should do so.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Reassurance should be provided by the applicant that data will only be extracted from the PAS by those with legitimate access to the data.
2. Study information should be displayed within the Trusts and patients informed of mechanisms to opt out of secondary uses of their data at every opportunity.
3. Favourable opinion from a Research Ethics Committee.
4. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

b) IVF Treatment and Child Health Outcomes: A Data Linkage Study [15/CAG/0162]

This application from the University of Manchester sets out the purpose to examine the effects of various culture media on IVF treatment pregnancy/live birth rates and the health of the resulting babies. Researchers from University College London collected information on culture media use throughout the UK by having sent out the National Culture Media

Questionnaire (NatCMQ) to all licensed fertility clinics within the UK. Information describing the cultural media used between January 2011 and December 2013 would be extracted from the NatCMQ (including name of culture media and brands) and linked with routinely collected IVF treatment and health outcomes retained within the HFEA register.

A recommendation for class 5 and 6 support was requested to allow access to an authorised user for the purpose of audit, monitoring and analysing patient care and treatment.

Confidential patient information requested

Access was requested to the HFEA Research Register to link with NatCMQ data which included the following data items: clinic centre of treatment, exact patient and partner age at embryo transfer, treatment date, exact birth weight, gestation length, treatment funding source and fertilisation rate.

Confidentiality Advisory Group Advice

Advice to HFEA

Members considered two aspects to this application:

1. Whether support wa required for applicant access to the National Culture Media Questionnaire (NatCMQ).

2. Advice recommendation to the HFEA on whether access to the HFEA Research should or should not be granted. The final decision on access to the Research Register would be taken by the HFEA under their statutory framework.

In considering the first aspect, the CAG advised the HRA that access to the NatCMQ dataset was not identifiable, and therefore support would not be required under the Health Service (Control of Patient Information) Regulations 2002.

In considering the second aspect, members reviewed the history of the development of the MoU and highlighted that, since April 2013, there had been a number of significant changes in areas such as organisational responsibilities, information governance approach and guidance and the introduction of the Health & Social Care Act 2012.

The CAG subsequently considered its remit to provide advice, in order to facilitate an approval recommendation for access to the HFEA Research Register, within the framework and exclusions of the MoU. On the basis of the information provided members advised that they could not provide specific advice on whether access to the register should be granted in the context of this application, however, it offered an opinion as the detail raised some critical points for consideration and to facilitate future advice provided to applicants.

Three aspects were discussed; whether the HRA, via the CAG, could advise the HFEA on access to the Register; the identifiability of the data requested and whether the consent provided was sufficient to grant access.

MoU Scope

Members noted that the MoU specified the following in terms of scope:

(2.2) Relevant applications are defined as research with a relevant medical purpose and a favourable ethical opinion where access relates to confidential patient information registered prior to 01 October 2009 held on the HFEA Research Register

Relevant to the CAG consideration is that data must be identifiable and relate only to data collected prior to October 2009. Members noted that the HFEA had provided information to set out their position that data was potentially identifiable. The application requested access to IVF treatment and health outcomes on the Research Register from January 2011 and December 2013. It was clear that the requested information related to data on the HFEA Research Register obtained post October 2009, where disclosure should be undertaken on a consented basis as specified in the exclusion criteria of the MoU. Members therefore advised that this was out of scope of the MoU, which framed the subsequent discussion.

Identifiability

Accepting the nature of the application meant that the data was out of scope of formal CAG advice, in assessing the question of identifiability members noted that there had been a number of broader changes in information governance guidance, positions and definitions since April 2013, with more layers of granularity than previous opposite positions of 'anonymised' or 'identifiable'. The CAG therefore wished to offer an opinion as to how identifiability could potentially be assessed so as to establish a clearer mutual understanding when the HFEA assessed criteria of identifiability as this would support future relevant advice requests.

The view was considered as to whether the data was identifiable and members advised that the HFEA firstly should seek a view from the Information Commissioner's Office (ICO) in their capacity as regulator for issues over the Data Protection Act 1998 (in the context of whether it is personal data as defined within the DPA 1998). Noting that the information requested was more than would be published routinely by the HFEA, members noted that no personal identifiers were present however it probably rested at the limits of confidentiality due to the presence of dates; it was also unclear whether small numbers would be an issue. It was noted that the HFEA assessment had provided information referencing back to 2010 and also referenced Connecting for Health guidance. In light of more recent changes and organisational abolition, the opinion was given that a review of questions of identifiability could usefully be undertaken to assist the HFEA in its disclosure decisions, so as to strike a balance between protection and appropriate dissemination for research purposes.

Members considered the dataset in the context of the 'Caldicott2' Review report and noted that if disclosure of the data could mean a risk of re-identification, then consideration could be given to the context in which the recipient would be holding the data. In practice, this would involve identifying the risk against defined criteria and putting in place controls around the disclosure. With suitable controls, data could be considered 'anonymised in context'. It was advised that the HFEA may therefore wish to consider disclosure if

appropriate terms and conditions are in place. It was also recognised that this approach had been adopted in light of the Caldicott2 report by bodies such as the Health & Social Care Information Centre and the Clinical Practice Research Datalink service. In the latter instance in particular, criteria was developed with a 'peer review' function supported by CAG.

Members therefore advised that it could not confirm that the data was or was not identifiable, as this is an initial assessment to be undertaken by the data controller in light of existing legislation and policy/guidance. It was also agreed that work should be undertaken so that there is an agreed understanding of identifiability between the two groups as the different approaches were noted and it was strongly emphasised that if progressing this approach, then the package of terms and conditions and controls should usefully be discussed with the ICO as the first step.

It was clarified at the meeting that a further meeting would take place in mid-September with the HRA to discuss this outcome and support progression as appropriate.

Consent

Members noted the consent forms provided and were unclear on whether the HFEA considered the consent to be sufficient to cover the proposed access, as the data requested covered dates where consent was expected to be in place. The consent was considered broad but a view expressed that this was an ethical issue outside of the CAG remit. It was noted that the applicant asserted that consent could not be sought, however, members queried whether the HFEA had assessed the consent directly in their capacity as data controllers and had reached a view as to sufficiency.

Members noted that the MoU clearly specified data collected after 01 October 2009 is excluded from the advice recommendation on the grounds that consent is expected to be in place to allow access for research purposes. While sympathetic, members concluded that they were unable to advise on this aspect.

In conclusion, the CAG agreed the following points:

- It was unable to provide advice to the HRA on whether access to the Research Register should be granted as the data related to information excluded within the MoU (post-2009 data). A recommendation as to identifiability could not be provided due to different understandings and as CAG were of the opinion that this could be assessed in light of more recent guidance and though working with the ICO.

- The CAG would welcome development of a mutually agreed understanding of identifiability and criteria used and would be happy to support appropriately.

- The opinion was offered that the HFEA may wish to revisit the previous advice and to consider the significance of context and controls so as to consider recognising information as 'anonymised in context' if not considered suitable for publication (this is analogous to the concept of 'de-identified data for limited access' as specified in the 'Caldicott2' review report.

c) Risk Modelling in the Critically Ill [15/CAG/0163]

Purpose of application

This application from the Intensive Care National Audit & Research Centre (ICNARC) set out the purpose of conducting an epidemiologic study to understand the risk factors for, and the consequences of critical illness leading to improvement in risk models used to underpin national clinical audits for adult general critical care, cardiothoracic critical care and in-hospital cardiac arrest by utilising data linkage with other routinely collected data sources. The patient cohort would include patients admitted to an adult critical care unit or experiencing an in-hospital cardiac centre in NHS Hospitals in England and Wales for the period between 1st April 2009 to 31st March 2015.

The applicant was seeking support in order to disclose confidential patient information to the Health and Social Care Information Centre (HSCIC) and also for the HSCIC to carry out data linkage activity to link datasets from Case Mix Programme (CMP), the National Cardiac Arrest Audit (NCAA), National Diabetes Audit, UK Renal Registry and National Adult Cardiac Audit with Mortality data from the Office for National Statistics and also HES Data from the HSCIC.

A recommendation for class 2, 4 and 6 support was requested to allow access to an authorised user for the purpose of obtaining and using information about past or present geographical location and to link patient identifiable information obtained from more than one source.

Confidential patient information requested

Access was requested to NHS Number, date of birth, gender, ethnicity, postcode and date of death for patients admitted to an adult critical care unit or an in-hospital cardiac centre within NHS Hospitals in England and Wales for the period between 1st April 2009 to 31st March 2015.

The dataset will also include date of admission, all other dates within the dataset and hospital names which will all be anonymised in the subsequent dataset.

Confidentiality Advisory Group advice

Public interest

Members agreed that this was a medical purpose as defined within the s251 (12) NHS Act 2006. Members agreed that the activity carried out would likely to provide a significant public interest due to the need to understand the risk factors for, and the consequences of

critical illness to improve adult general critical care, cardiothoracic critical care and in-hospital cardiac arrest.

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 consent would not be feasible due to the size of the cohort and the data which was to be utilised were from previous data collections with its own s251 support. Members noted that confidential patient information was only to be used for disclosure to HSCIC to carry out data linkage activity and to pseudonymised the dataset.

Members noted that the method taken to pseudonymise the data and data flows were appropriate and effective.

Justification of identifiers

Members agreed that the use of identifiers appears to be appropriate and necessary to carry out the data linkage activity.

Patient notification and patient opportunity to opt-out

Members noted the limited effort to provide information regarding patient notification and patient opportunity to opt-out. Members understood that this was deemed as secondary fair processing, however, advised that the applicant should enhance the current patient notification on the ICNARC website and also ensure that patient notification was available for access on the websites of the other organisations involved within this project.

Onward disclosure of patient level data

Members discussed the onward disclosure of patient level data to researchers and the risk of potential re-identification and the applicant safeguards which were in place. Members noted that the applicant was to ensure compliance in line with the MRC 'Good Practice Principles for Sharing Individual Participant Data from Publically Funded Clinical Trials' and to incorporate these principles within the applicant's standard operating procedures for all requests to access patient level/anonymised data. Members advised that it was important that the data was disclosed appropriately for the public good but was appropriately safeguarded to ensure patient privacy. With this in mind, the members requested the applicant to forward the disclosure policy and associated documentation.

Separate to consideration of this application, members suggested that a future education item to cover the work and guidance of the Medical Research Council.

Action: CAT to obtain copy of MRC draft good practice guidance.
Action: CAT to add MRC to proposed education item schedule

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information

1. Enhance patient notification on ICNARC website and the other organisations involved within the project.
2. Provide onward disclosure policy and associated documentation.

Specific conditions of support

1. Patient Notification on ICNARC website and on the websites of the other organisations involved within the project.
2. Favourable opinion from a Research Ethics Committee.
3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

d) A case study of spatiality in advanced presentation gastroesophageal cancer [15/CAG/0165]

Purpose of application

This application from University of Hull describes a case study of cancer of the gullet (gastroesophageal cancer, GOC). GOC presents an interesting case for study, as certain attributes are very commonly associated with sufferers, such as advancing age, male gender, smokers and those with higher alcohol intake, as well as those from lower socioeconomic groups. This project will use a case study approach to map and analyse patients' environments against these common attributes, so that maps can be produced according to underlying population demographics and to analyse how the environment plays a part in stage of presentation.

A search of the disease register database held by the National Cancer Intelligence Network (NCIN) at Public Health England will be undertaken to yield all patients with histologically confirmed GOC who presented to the Queens Centre Castle Hill Hospital, during the period 1999 2010. ONS lifestyle survey data from this period will be used to develop the weighted map of the region. ONS population data from 2010 census will be used to determine age and sex of postcode level data, so that incidences may be weighted accordingly. Data from the Environmental Systems Research Institute, the geographical underpinning map

datasets, will be used for the purposes of cartography and mapping the appropriate geographical catchment area.

All data will be held within the geographic information system for purposes of analysis. This will be stored in an encrypted format and only accessible to the researcher and her academic supervisors.

A recommendation for class 2 support was requested to cover access to confirmed GOC diagnosis, histological type, Interventions, GP registration, patients Date of Birth, age, gender, date of presentation to cancer specialist services and date of death where this has occurred.

Confidential patient information requested

Access was requested to confirmed GOC diagnosis, histological type, Interventions, GP registration, patients Date of Birth, age, gender, date of presentation to cancer specialist services and date of death.

Confidentiality Advisory Group advice

Patient notification

The issue for CAG, separate to that of Data Protection compliance, was ensuring that there was appropriate information provided so as to increase public confidence in uses of data where this takes place without consent. The applicant was asked to ensure that information in relation to the study, including details in relation to registering objections, was displayed on relevant websites to ensure that efforts were made to inform patients about the processing.

Justification of identifiers

It was noted that application was unclear on the requirement for retention of identifiers beyond 5 years post PHD and on what might be done to reduce primary risks post collection. The applicant was asked to clarify what conversion into a less identifiable form could take place prior to analysis, for example converting date of birth into age, and what the applicant intended to do to reduce identifiability of data prior to publication? It was noted that the dataset had potential for further use and the applicant was asked to provide reassurance that this would be used in an anonymised format to reduce primary risks post collection.

Members also noted that the researcher used the Sweeney K definition of anonymous data and referred to quasi – anonymous data throughout the application. Clarification would be required from the applicant that this represented the Information Commissioners Office (ICO) definition of anonymous data.

Additional points

The applicant was requested to clarify that this is a multi-centre study and the sites involved.

It was noted that data was to be held on a password encrypted memory stick and members sought assurance that this met security standards required for NHS organisations in line with the Information Governance Toolkit. The applicant was asked to ensure that this was the case.

Confidentiality Advisory Group 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 satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below. Specific conditions of support

1. The applicant was requested to clarify that this is a multi-centre study.

2. The applicant was requested to clarify the retention of identifiers beyond 5 years post PHD and what could be undertaken to reduce primary risks post-collection.

a) What conversion into a less identifiable form can take place prior to analysis?

b) The applicant was asked to confirm how they intended to reduce identifiability of data prior to publication.

3. Increased patient notification. What can the researcher do to encourage NCIN for increased notification on the website.

4. The applicant should address what definition of anonymous data is being used (Sweeney K and quasi anonymous data).

5. Favourable opinion from a Research Ethics Committee.

6. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

e) Role of Surgical Centralisation on Renal Cancer Survival [15CAG0169]

This application from the University of Cambridge set out the purpose of a research study which aimed to link data from HES, ONS and Cancer Registries in order to answer five specific questions. First, how has nephrectomy practice in England evolved in the past few years in response to regionalisation? Second, what role does service reconfiguration play in changing renal cancer outcomes? Third, what is the relationship between case volume and outcome in nephrectomy, from short to long term and how does treatment in a high volume centre alter an individual's outcome compared to treatment in a lower volume centre? Fourth, what are the interactions between treatment setting, patient background and tumour characteristics in predicting renal cancer survival and mortality? Finally, how does

understanding the volume outcome relationship in nephrectomy change the current paradigm on renal cancer service and risk prediction model?

A recommendation for class 1, 5 and 6 support was requested to cover access to confidential patient information from Public Health England in relation to patients undergoing a nephrectomy between 1998 and 2013 (approx. 112,000 patients)

Confidential patient information requested

Access was requested to a dataset including date of death and date of birth.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Further efforts should be made to inform patients about this specific use of data by ensuring that information was displayed on the University and other relevant websites and that consultation with patient groups takes place.
2. Action taken to ensure that identifiers are destroyed at the earliest opportunity.
3. Confirmation that the scope of the application was as described above.
4. Favourable opinion from a Research Ethics Committee.
5. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

4. NEW APPLICATIONS – Non- Research

a) UK Shunt Registry [UKSR] [15CAG0166]

This application from University of Cambridge set out the purpose of the UK Shunt Registry (UKSR) for hydrocephalus and other disorders of the circulation of cerebrospinal fluid was established in 1994 with the support of MHRA and relevant charities. The current paper-based system held data on over 35,000 patients. The future aims of the Shunt Registry include:

- defining the current state-of-the-art in terms of long term management of different groups of patients with disorders of the CSF circulation and related venous disorders [‘hydrocephalus’] using shunts, endoscopic third ventriculostomy, choroid plexectomy and cranial venous stenting in order to inform best practice,

- providing an accurate picture of the use of different types of shunt,

- identify, in collaboration with the UK Shunt Evaluation Laboratory, substandard shunt systems,
- monitor in real time the outcomes of different groups of patients with 'hydrocephalus' achieved by type of operative intervention (shunt, endoscopic third ventriculostomy, choroid plexectomy, venous stent), type and manufacturer of implant, hospital and multidisciplinary team, and highlight where these fall below an expected performance in order to allow prompt investigation and to support follow-up action,
- inform patients, carers, clinicians, providers and commissioners of healthcare, regulators, and implant suppliers of the outcomes achieved in surgical interventions for 'hydrocephalus',
- provide independent data for a key CQUIN (shunt infection within 30 days of insertion),
- enhance patient awareness of outcomes after surgical interventions for 'hydrocephalus' to better inform patient choice and patients' quality of experience through engagement with patients and patient organisations,
- support evidence-based purchasing of 'hydrocephalus' – related 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.

In order to meet these aims the UKSR would collect data on all surgical interventions for all groups of patients with disorders of the CSF circulation and related venous disorders in England, Wales, Scotland and Northern Ireland. From 2015 UKSR was in transition to the ORION cloud-based platform (Outcome Registry Intervention and Operation Network) and would seek patient consent for prospective data inclusion, the application specified that this would only take place where local policies required this.

A recommendation for class 1, 4, 5 and 6 support was requested to allow the disclosure of confidential patient information from Health and Social Care Information Centre (HES and ONS mortality data), Neurosurgical National Audit Programme (NNAP) and local hospitals to University of Cambridge in relation to all surgical interventions for all groups of patients with disorders of the CSF circulation and related venous disorders in England and Wales.

<u>Confidential patient information requested</u>

Access was requested to name, postcode, NHS number, date of birth and date of death in the retrospective historical data, collected via a paper based system, in order to carry out linkages with NNAP, HES and ONS mortality data.

Access was requested to NHS number, date of birth and date of death only for prospective data from 2015 submitted from Hospitals and linked to NNAP, HES and ONS mortality data.

Confidentiality Advisory Group advice

Public interest

Members agreed that the aims of the registry appeared to be in the public interest and were supportive of the application in principle.

Practicable alternatives

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

Members noted that consent would not be feasible for the legacy data collected. In relation to the prospective data, the applicant had confirmed that consent would be sought; however this would be dependent on whether local hospital policy required this. Members advised that, in line with other registries, consent mechanisms should be in place across all hospitals and that, whilst support could be provided where consent was 'not recorded', consent should be the primary legal basis for the disclosure of prospective data from Hospitals, HSCIC and NNAP.

Members recognised that a period of support may be required whilst the applicant moved towards the implementation of consent and agreed that support should be recommended for a period of one year. Following this, members advised that consent mechanisms should be in place and that support should only be provided where consent was not recorded.

Members asked that the applicant provide details of the consent process to be put in place as soon as possible, this should be developed in conjunction with all data controllers disclosing data for the purposes of the registry.

Justification of identifiers

In relation to the prospective dataset, members requested that the applicant clarify the requirement for both NHS number and date of birth. Members agreed that where possible linkages should be undertaken using NHS number only where possible and that complete date of birth should only be accessed where NHS number was not sufficient or available.

In relation to the retrospective dataset, members requested that the applicant consider how long all identifiable data would be retained for and whether it would be possible to reduce the identifiers held within the dataset. For example, by adopting a pseudonymised approach to future data linkage or taking steps to ensure that NHS numbers within the dataset were accurate.

Retrospective dataset – legal basis

Members discussed the retrospective dataset and, whilst noting that consent would not be feasible, asked the applicant to explain their understanding of the current legal basis for the retrospective dataset. Members agreed that this would need to be clarified before support was confirmed.

Application scope

The application specified linkage with “other datasets as the requirement arises”, members advised that it would not be possible to recommend support for unspecified datasets and that the applicant would need to submit an amendment request if the requirement arose.

Patient notification

Members advised that further efforts should be made to inform the cohort about the data collection and requested that details of these efforts be submitted to members. In particular, it was advised that patient information must include details of how to object to inclusion within the registry. Members recommended that information was displayed on ORION and Trust websites and that the applicant ensure that the patient information provided was acceptable by way of consultation with a patient group.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in this activity being conducted, and therefore advised recommending support to the Secretary of State, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Support for prospective data collection would be provided for a period of one year from final approval, following this a consent based approach should be adopted in line with other registries and support would be provided where consent was ‘not recorded’ only.
2. Provision of the details of the consent based approach should be provided as soon as possible and by annual review stage.
3. The levels of instances where consent was ‘not recorded’ would continue to be monitored at annual review stage.
4. In relation to the prospective dataset, where possible linkages should be undertaken using NHS number only, rather than NHS number and date of birth. Complete date of birth should only be accessed where NHS number was not sufficient or available.
5. In relation to the retrospective dataset, the applicant should consider how long all identifiable data would be retained for and whether it would be possible to reduce the identifiers held within the dataset in line with the comments above.
6. Confirmation of the legal basis for current processing of retrospective data should be provided.
7. The approval relates to those datasets specified within the application only.

8. Further information should be provided in relation to efforts to inform patients in line with comments under patient notification above.

9. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

b) National Head and Neck Cancer Audit (HANA) [15/CAG/0170]

Purpose of application

This application from Saving Faces, the Facial Surgery Research Foundation sets out the purpose of conducting a commissioned audit on behalf of the Healthcare Quality Improvement Partnership (HQIP). The HANA database was to assess and improve the quality of services and the outcomes achieved by head and neck cancer treatments across the NHS. The data would provide comparative information to patients, commissioners and regulators of healthcare professionals. HANA will collect data on pre-operative health status and co-morbidity, details of the treatments provided and the principle healthcare professionals responsible, and also the development of any recognised complications following surgical and non-surgical treatments delivered within NHS hospitals.

The applicant was seeking support in order for confidential patient information to be disclosed to Dendrite Clinical Systems Ltd for the purpose of data linkage, retaining the linked datasets (including identifiers) as part of a database for audit purposes, and to anonymise the data for Saving Faces to analyse.

The applicant was seeking support in order to disclose NHS numbers to the Health and Social Care Information Centre (HSCIC) for the purpose of checking mortality data to determine whether the patient was deceased and the associated cause of death.

The applicant was also seeking support in order for HSCIC to disclose the DHANO historical data set, which includes confidential patient information, to Dendrite Clinical Systems Ltd, for the purpose of data linkage and retaining the data within the database.

A recommendation for class 1, 4, 6 support was requested to allow access to an authorised user for the purpose of extracting and anonymising and linking patient identifiable information obtained from one or more source.

Confidential patient information requested

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

Confidentiality Advisory Group advice

Public interest

Members agreed that this was a medical purpose as defined within the s251 (12) NHS Act 2006. Members agreed that the activity carried out would likely to provide a significant public interest due to the need to assess and improve the quality of services and the outcomes achieved by head and neck cancer treatments across the NHS.

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 currently obtaining consent from patients would not be feasible due to the size and geographical locations of the cohort, which would reduce consistency coverage across all providers. Members advised that s251 support could not be provided where lack of capacity was the primary reason not to seek consent.

Members noted that exit arrangements from this potential support under the Regulations had not been provided within the application. Members suggested that moving forward the applicant may consider prospectively obtaining consent from patients via the clinicians within the hospitals. It was understood that s251 support may be advised for retrospective legacy data and also where consent was not recorded within the hospital. Members requested that an exit strategy should be submitted for review.

Justification of identifiers

Members agreed that the use of identifiers appeared to be appropriate and necessary, with the exception of name. Members noted that the applicant would have access to NHS number and were unsure as to the reasons why the applicant would also require access to name. Members requested the applicant to justify the need to utilise name.

Members noted that within the application, the retention period was specified as ten to twenty years. Members requested clarification and justification to retain the identifiers for that period of time.

Inclusion of Public Health England Cancer Registry Data

Member noted that Public Health England (PHE) cancer registration data had not been included within the application. Members advised that utilising cancer registry data could prevent the duplication data flows as data may already be available within the registry. Members requested the applicant to consult with Public Health England and to provide feedback.

Patient and Public Involvement

Members noted that there was a planned patient and public involvement workstream. Members requested further information as to when the workstream would be implemented.

Patient Notification

Members advised that the patient information sheet could be simplified and that the process was not clearly laid out. Members requested the applicant to review and improve the patient information materials and to incorporate information to enable patient objection where appropriate.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that this application would be deferred and further information would be required from the applicant in order for a recommendation under the Regulations to be provided.

Further information required

The following information should be provided to allow the CAG to continue their consideration of the application:

1. Submit an exit strategy for member review.
2. Provide justification for the need to utilise name.
3. Clarification and justification of retention period.
4. Applicant to consult with Public Health England and to provide feedback.
5. Further information as to when the Patient and Public Involvement workstream would be implemented.
6. Review and improve the patient information materials and to incorporate patient opt-out.

5. MINUTES OF THE MEETING HELD ON 09 July 2015

The minutes of the meeting held on 9 July 2015 were approved.

6. CAG OFFICE REPORT

For information

Secretary of State approval decisions

The DH senior civil servant on behalf of the Secretary of State for Health (SofS) agreed with the advice provided by the CAG in relation to the July 2015 meeting applications.

HRA approval decisions

The HRA agreed with the advice provided by the CAG in relation to the July 2015 meeting applications.

Operational and CAT advice updates

CAG Standard Operating Procedures

CAG members were advised that the latest version (v1.2) of the Standard Operating Procedures had been published online. Following earlier email correspondence, the Chair reminded members that the quorum for CAG meetings was seven members including the Chair, and this had moved from the terms of reference to the SOPs as quoracy was an operational issue best sited within the SOPs; the change had been made to reflect consistency with the research ethics committees quoracy requirements. Members noted that they had previously been aware of this.

A governance document for CAG was currently being drafted by Mr Bill Davidson and would incorporate CAG terms of reference. This would be provided to members in mid-September for comment. Members requested that a summary of changes be included with the document that outlined any changes made to the original terms of reference. It was advised that following approval by the Operational Management Group (OMG) this document would be submitted to the HRA Board for approval.

Action: CAT to circulate draft guidance document to members with summary of changes.

Update on existing applications

Community Mental Health Survey CAG 9(PS1)/2014

Two Trusts, Cumbria Partnership NHS Foundation Trust and Lincolnshire Partnership NHS Foundation Trust reported that they had submitted a sample file, which included no identifiers but more sensitive data such as mental health care cluster code, to the contractor, rather than the co-ordination centre. The correct process is that the contractor receives the mailing file only (which contains name and addresses) and the co-ordination centre receives only the sample file, which contains more sensitive data but is anonymised.

The files were immediately deleted without being opened at the co-ordination centre. Reports were submitted from both Trusts detailing the breach, which in both cases appeared to have been caused by human error, actions taken and steps to ensure that this did not re-occur. The information was provided to the Vice Chair in line with the SOPs to determine if any further clarification was required. It was noted by the Vice Chair that the

breach involved no disclosure of identifiable information as the sample file only was submitted in error and deleted as soon as possible.

ACTION: CAT to provide formal advice letter for the relevant approver and send to the applicant.

Amendments to approved applications

Cancer risks in the British rubber manufacturing industry- CAG 5-08(d)/2013

This research application from the Institute of Occupational Medicine, on behalf of the University of Bristol, set out a study to determine whether specific chemicals used within the rubber manufacturing process increase the risk of cancer.

A recommendation for class 1, 4 and 6 support was requested in order to flag approximately 40,000 workers, who were aged 35 or over in 1967 and worked in the rubber industry, on the NHS Central Register and receive updates from the Health and Social Care Information Centre (HSCIC) in relation to cancer and deaths. The Institute of Occupational Medicine (IOM) would receive data from the Health and Safety Executive in relation to workers who took part in an original study undertaken by the HSE predecessor in 1967. They would then pass demographic data to the HSCIC who would use this to trace the cohort and provide identifiable data to IOM.

Access was requested to central register data including name, NHS number, date of birth and date of death to allow linkages to take place.

Amendment request

A notification was submitted to the Confidentiality Advice Team highlighting a change to the Chief Investigators organisation and that the analysis of pseudonymised data would now take place at the University of Bristol rather than the University of Manchester. It was noted that a condition of the original approval was that the dataset disclosed to the University of Manchester should include month and year of birth and death only. It was confirmed by the applicant that on transfer to the University of Bristol the data would be anonymised in the same way. Therefore there would be no amendment to organisations having access to confidential patient information under the Regulations.

Confidentiality Advice Team conclusion

In line with the considerations above, the Confidentiality Advice Team agreed that the minimum criteria under the Regulations appeared to have been met and therefore advised recommending support for the amendment to the Health Research Authority.

ALTER-10 study-14/CAG/1002

This application from Newcastle Upon Tyne Hospitals NHS Foundation Trust detailed a study to identify the significance of a minimally abnormal result of a liver blood test and to identify if this abnormality was associated with an increased risk of mortality due to liver disease of cardiovascular disease at 10 years. In addition, the study hoped to identify

whether a minimally abnormal result of a liver blood test was associated with an increased incidence of significant liver disease, type 2 diabetes and cardiovascular disease.

A request for class 5 and 6 support was received in order to access confidential patient information from a 2003 audit of liver function tests and seek further information in relation to mortality and clinical data from GP records in relation to a sample of those who are alive.

Name, NHS number, date of birth and date of death would be used to carry out data linkage. Date of birth and death would be retained for analysis purposes.

Amendment request

An amendment request was submitted to extend the duration of the study until 31st December 2015. It was noted that due to unexpected delays data analysis will not be complete before the original annual review date of 31st July 2015.

Confidentiality Advice Team advice

The amendment requested was considered by the CAT who recommended support to extend the duration of the study until December 2015.

Confidentiality Advice Team conclusion

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

Longitudinal Study of Young People in England (LSYPE) - CAG 1-03(PR3)/2014

This application from Centre for Longitudinal Studies at the Institute for Education, University of London, sets out the purpose of a longitudinal study, previously managed and funded by the Department of Education (DfE) from 2004 until 2012. In 2013, the Economic and Social Research Council (ESRC) took over the funding of the study and management transferred to the Centre for Longitudinal Studies (CLS).

The aim of the study is to examine how health, wealth, education, employment and attitudes are linked, how they change over time and how they can vary between different people, at different points in time.

A recommendation for class 2, 3, 4 and 6 support was requested to cover access to:

1. GP registrations and addresses from the Health and Social Care Information Centre (HSCIC) so that individuals could be contacted and invited to continue participating in the study.
2. Notification from the HSCIC of deaths, embarkations (i.e. emigrations) and exits/entry from the NHS

Amendment request

It was noted that one external supplier had been appointed as data processor to carry out the survey fieldwork and associated mailings for the LSYPE Age 25 survey. The National

Centre for Social Research (NatCen) had been contracted to carry out: (1) Email and postal mailings to LSYPE cohort members about the study. (2) Interviews with LSYPE cohort members. Upon completion of these activities, the data files will be securely deleted from NatCen systems. Note: These activities were covered in the original application, but the Data Processor had not been appointed at that time.

An amendment was submitted to request an additional data processor (NatCen) with no change to the purposes, data sources, data items or data flows.

Confidentiality Advice Team advice

The amendment requested was considered by the CAT who noted the submission of a satisfactory IG toolkit for this application.

Confidentiality Advice Team conclusion

In line with the considerations above, it was agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Updates on existing applications

Research to identify measures of quality and safety of healthcare 15/CAG/0005

This application from Imperial College London set out the purpose of the establishment of two databases. The first database would include a monthly and annual pseudonymised extract of Hospital Episode Statistics (HES) from the Health and Social Care Information Centre (HSCIC) on English NHS hospitals for the purpose of research. Data from this database would be provided to the Dr Foster Unit at Imperial College in a pseudonymised format.

The second database would hold a limited set of identifiable fields including NHS number and local patient ID to allow acute provider trusts to identify their own patients contributing to mortality alerts or other quality and safety alerts for the purpose of case note audits and mortality reviews.

A recommendation for class 4 and 6 support was requested to cover disclosure of confidential patient information from the Health and Social Care Information Centre (HSCIC) to Imperial College London.

Confidential patient information requested

Access was requested to monthly and annual extracts of HES, including Hospital Consultant Code, General Practitioner Code and Referring Practitioner Code and NHS number, Local Patient ID (LOPATID) and date of death (these three data items would be included on the second database only)

The application was partially approved following advice at the January and March 2015 CAG meetings, below is an extract from the specific conditions of support:

It should be ensured that historical data processed under PIAG 2-07(d)/2007 is irreversibly pseudonymised in line with this application. This should be carried out as soon as possible, please confirm when this is complete. New identifiable data processed under CAG [15/CAG/0005] should be retained for a maximum of three years after which it should be destroyed or irreversibly pseudonymised on a rolling basis.

The applicant confirmed on 10 July 2015 that the historical data had now been anonymised in line with this condition of support.

7. (A) STRUCTURE FOR FUTURE BUSINESS

An update was provided that, following the public recruitment campaign, a number of applications had been received and interviews would take place over the next six days.

A short paper was provided by the Chair to trigger discussion on how the business would be managed when CAG moved to two meetings per month in London and Manchester and when began to provide advice to the Health and Social Care Information Centre (HSCIC) under the Care Act 2014. Member written comments received in advance were discussed as part of this conversation.

Group discussion took place over the proposed chairing arrangements and it was agreed that it would not be practically feasible for one Chair to chair all meetings, and chairing should be distributed amongst the chair team; noting that every effort would be made to ensure that the same officer remained the chair for each specific application lifecycle to ensure continuity. It was concluded that there was confidence in the chair team to manage any potential issues of consistency and continuity, with support from the advice team. Members agreed that it would be important for there to be a consistent Chair for the Manchester-based meetings for the initial meetings so as to support new members and to ensure consistency of approach within meetings. It was agreed that chairing for the London-based meetings would be undertaken by another member of the chair team, noting that due to previous involvement, the Chair would seek to continue to be involved in consideration of the commissioning applications.

Existing members had been asked earlier in the year whether they wished to attend any of the Manchester-based meetings. Members advised that it would be important to ensure that existing experience was present within both sets of meetings and all members should have the ability to cross-cover all business and have the option to attend both meetings to ensure that the geographical locations did not impact the consistency of CAG advice. This was agreed, with the caveat that no member would be expected to attend more than one CAG meeting per month.

It was noted that new members should attend a certain amount of CAG meetings prior to being asked to take on precedent set reviews. It was advised that a similar process to that which had previously taken place would be followed where members would ‘shadow’ precedent set-reviews prior to formally undertaking a review.

Action: CAT to establish and issue dates for London and Manchester meetings to ascertain member availability.

7 (B) Handling of potential breaches

The Chair advised members that two letters had been received from a third party in relation to two national applications that claimed a potential breach of the conditions of support for that application. Members were asked for their views on the process in relation to considering these types of situations.

There was a robust discussion in which a number of options were discussed such as automatic referral to the applicant or automatic referral to all CAG members as soon as received, prior to any handling. The CAG concluded that it would not be appropriate to automatically refer the issue to the applicant in every case nor to automatically send the issue on receipt to CAG members. Members agreed that where a potential breach in conditions had been reported the process outlined within the standard operating procedures (SOPs) should be followed in the first instance.

The following process was discussed and agreed in principle, subject to further discussion and agreement with the HRA:

1. The CAG Chair or alternative chair team member to consider the issue in conjunction with the Confidentiality Advice Team in the first instance.
2. An assessment of the credibility of the issue and strength of evidence would be undertaken; also whether the issue was one relevant to the CAG remit e.g. it may relate to a data protection issue where the ICO would be better placed to respond.
3. An element of flexibility in handling would be required. If credible and relevant to remit, options would include referral to the applicant to respond. Alternatively, referral to the SofS or HRA approver to seek their decision on how they wish to proceed.
4. If the allegation is found to lack sufficient foundation or be outside remit, this will be reported to the next CAG meeting.
5. If credible and within remit, the relevant applicant or approver response (once available) together with initial complaint would be presented to the next CAG meeting for consideration.

6. If applicant response (rather than decision-maker response) has been presented to CAG for consideration, then CAG will recommend whether to refer to SofS or HRA approver (as under 3. Above).

7. If approver response has been presented to CAG for consideration, then CAG may comment upon response (without invitation) or recommend to the approver any next steps, or could be asked by the approver to assess the issue (with invitation)

The CAG also emphasised the following principles when looking at potential breaches:

- CAG is an advisory committee of the HRA and does not take the final approval decision; therefore CAG can only recommend action as it would be for the approver to take the final decision on how an issue should be handled.
- It was important for the CAG to remain independent when assessing any potential breaches as it was not a regulator nor should it be seen as an external mechanism for issues to be inappropriately raised.

It was noted that while this was the process discussed this would need to be agreed with the HRA.

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6. ANY OTHER BUSINESS

a) Care Quality Commission Event – feedback

Ms Hannah Chambers and Ms Clare Sanderson provided feedback to the committee in relation to an event they had attended run by the CQC looking at secondary uses of the care.data programme.

b) National Audit sub-group minutes

In December 2013 the then Director of Confidentiality Advice at the HRA wrote to the Health and Social Care Information Centre (HSCIC) following advice from the Secretary of State representative to query whether the HSCIC were able to undertake audit activities under Directions under the Health and Social Care Act 2012, which allowed NHS England to issue Directions to the HSCIC. The Healthcare Quality Improvement Partnership (HQIP), HSCIC and NHS England have provided reports to CAG in relation to the feasibility of adopting this approach.

A meeting took place between CAG members, HQIP, NHS England and HSCIC in May 2014 to discuss the alternatives and a further meeting took place on 7 July 2015. Members were provided with a summary of this meeting and noted that the following future actions were agreed.

1. Undertake detailed analysis of data flows for one audit and consider options for each data flow, e.g. where Directions could be applied, where support under the Regulations would be required and where alternatives to the use of confidential patient information could be adopted. This information should be presented to CAG with an estimated timescale of pursuing Directions or alternatives in this scenario. This would allow high level principles to be developed in relation to the practicality of alternatives.
2. Ascertain data flows into and out of each clinical audit at individual project level to establish a baseline from which to plan next steps for each audit, alternatives for each audit would be assessed in detail at the annual review stage using the high level principles established.
3. Continue to work with the HSCIC on their strategy and the place of national clinical audit therein, provide estimated timescales for HSCIC to provide linkage element of activity only for clinical audits once point 1 and 2 above have been addressed.

A further report should be provided in 6 months (22 December for January CAG meeting) including information requested in point 1 and 2 and reporting progress in relation to point 3.

c) Reducing the disclosure of confidential patient information - guidance changes

A number of text changes were proposed to the guidance tool currently published as consultation in use on the HRA website. The changes were proposed following feedback received from users of the tool. Members noted and agreed the changes.

d) Confidentiality Advice Team changes

Members noted that Ms Amy Ford's secondment would conclude at the end of the week and thanked her for her hard work and expertise in supporting the CAG role. Members also expressed their thanks and gratitude to Ms Claire Edgeworth who would be leaving in September. Members wished to formally record their thanks for the support provided by Ms Edgeworth since the NIGB Ethics and Confidentiality Committee and wished her every success in the future.