NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group (CAG)

11 May 2017

Present	
Dr Kambiz Boomla	
Dr Anthony Calland	Vice-Chair
Ms Hannah Chambers	Lay member
Dr Patrick Coyle	Vice-Chair
Professor Barry Evans	
Mr Anthony Kane	Lay member
Ms Kim Kingan	
Dr Harvey Marcovitch	
Ms Diana Robbins	Lay member
Dr Mark Taylor	Chair

Also in attendance

Ms Jennifer Donald (observer to item 5d)	NHS Digital
Ms Natasha Dunkley	Head of Confidentiality Advice Service, HRA
Ms Rachel Heron (item 3a)	Confidentiality Advisor, HRA
Mr Stephen Robinson (item 5a–e)	HRA Corporate Secretary, HRA

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Introductions

The Group welcomed the attendance of Ms Jennifer Donald, NHS Digital Senior Business and Operational Delivery Manager, Data Approvals Owner. Ms Donald was attending in the capacity of an observer as part of understanding more about the operation of the CAG. It was noted that conversation had taken place with the Confidentiality Advice Team as part of this understanding. It was noted that Ms Donald may receive relevant applications considered by the CAG where relevant to NHS Digital, and this declaration was noted for the minutes.

Mr Stephen Robinson attended in his capacity as the decision-maker, on behalf of the Health Research Authority, for the research items considered by the CAG.

Apologies

Apologies were received from Ms Gillian Wells.

Declaration of Interests

Dr Kambiz Boomla declared a potential interest in item 5C 17/CAG/0072. It was declared that he was involved in the original IRIS study as it involves collaboration between the University of Bristol and Queen Mary University London. This had been notified in advance so Dr Boomla had withdrawn from acting as a reviewer for this application. It was agreed in the meeting that the declaration would be noted, Dr Boomla would remain in the room, and if there were questions of fact he could respond to these but otherwise would not contribute to the discussion or advice recommendation.

Dr Taylor noted that item 5E 17/CAG/0076 had been submitted by the University of Sheffield which was Dr Taylor's employing organisation. It had been arranged in advance for Dr Calland to chair this item. This declaration was noted for the minutes and Dr Taylor did not participate in the discussion or final advice recommendation.

No other interests were declared.

2. APPROVAL DECISIONS

The following decisions were taken in relations to the relevant CAG recommendations.

Secretary of State for Health approval decisions

The Department of Health senior civil servant on behalf of the Secretary of State for Health agreed with the advice provided by the CAG in relation to the non-research applications considered on 06 April 2017.

Health Research Authority approval decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the research applications considered on 06 April 2017.

3. REFERRAL FROM PRECEDENT SET

a. 17/CAG/0070 NHS Adult Inpatient Survey

Context

Purpose of application

This non-research application from Picker Institute Europe, CQC and NHS England set out the purpose of carrying out the 2017 NHS Adult Inpatient Survey, using standardised methodology to build up a national picture of patient experiences. A set of aggregated statistical data was produced which was shared with individual Trusts, CQC, NHS England and the Department of Health and used to monitor and compare the performance of trusts, and to drive improvements.

This survey would be the 15th carried out to date. The methodology was well established and had been approved by the CAG via Precedent Set Sub-Committee.

Participating trusts identified the sample in line with the inclusion/exclusion criteria, and disclosed names and addresses to approved contractors for the purpose of mailing out the surveys (this data was held in a mailing file along with the unique identifying code which is printed on the survey itself). Demographic information for each potential participant was collected in a separate sample file, linked by the identifying code.

Picker Institute was commissioned to manage and coordinate the surveys under the title of the Patient Survey Coordination Centre, carrying out checks across the samples submitted by trusts and disseminating aggregated results (identifiable information was not received by the Patient Survey Coordination Centre).

This application was escalated from the Precedent Set review to the CAG meeting due to the addition of a new approach to be piloted with up to 10 of the Trusts: - sending SMS reminders to potential participants after the 1st and 3rd mailing of the survey (where the patient had not responded to the survey). As this was a new element where precedent advice had not been set, the advice of the CAG was sought.

If the pilot were successful, the applicant intended to request support for a roll-out of this approach as standard across the survey programme, citing reduced costs as the main benefit of text messages as opposed to postal reminders

Confidential patient information requested

Access was requested to data from participating trusts in relation to inpatients aged 16 years old or over who were discharged from acute and specialist NHS hospitals in July 2017 having had one overnight stay in hospital (various exclusions were listed in the application including deceased patients and those who had registered their dissent).

The mailing file sent to contractors would contain the following information:

- Trust code – included in the unique identifier, below.
- A standardised unique identifier code (application listed full details of how this was constructed)
- Title (Mr, Mrs, Ms, etc.)
- First name
- Surname
- Address Fields
- Postcode (where available)
- Mobile telephone number for those patients included in the pilot, from a total of up to 10 trusts

The following approved contractors would be used:

- Picker Institute
- Quality Health
- Patient Perspective
- Capita
- Membership Engagement Services
- The SMS provider Firetext

The sample data file (used to link demographic data to the survey responses, to aid analysis and to enable checks to be carried out for any errors in how the sample was drawn) would contain non-identifiable data (listed in the application).

The two sets of information would be submitted by trusts to approved contractors as one file. Approved contractors split the data out before sharing the sample file with the Coordination Centre (to enable centralised checks on the appropriateness of samples drawn).

Confidentiality Advisory Group advice

Public interest

Members considered whether this threshold had been met. The overall aim of the survey - to investigate patient experience to monitor the performance of individual Trusts and to enable them to reflect upon the results – was agreed to be an important one.

It was observed that the response rate for the surveys was currently 47% and had decreased recently; this low return increased the risk of bias in the responses that were received. Strong support was voiced for the aim of the pilot: to investigate whether text message reminders could improve the response rate. There was evident public interest in improving the results of the survey overall.

Responses to text messaging could be varied and could introduce further bias into the survey responses (for example younger patients might be more receptive than older patients); therefore the use of a pilot to investigate the effectiveness of the approach was praised by the CAG. It was agreed that the results of the pilot should be reported back to the CAG.

Members acknowledged that the use of text message reminders was becoming widespread within clinical care, although there were still members of the public who did not use mobile phones and of those who did, not all would expect to receive text reminders about the survey. There would be situations where this could cause problems for patients, for example where they did not want relatives to know about their attendance at hospital.

This was balanced by the assurance within the application that groups attending services considered most sensitive (for example mental health services and maternity services) would already have been excluded from the survey.

In line with these considerations, the CAG agreed that patients should be made aware that text messages would be sent, prior to the event. This could be easily achieved by adding this information to the first mailing.

It was noted that the pilot would also test the effectiveness of sending the first reminder letter out earlier than previously: - 5 days after the survey was sent. This appeared reasonable to members and no concerns were raised.

As a broader point, the CAG recommended explaining the survey to patients when they first attended hospital, so that patients would not later be surprised to receive it.

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.

- Feasibility of consent

Given the large scale of the surveys, it was agreed that it would be impracticable for clinical care teams at each Trust to seek consent from each individual patient.

- Use of anonymised/pseudonymised data

The methodology of the surveys was well-established. Although the CAG had originally recommended that the (identifiable) mailing file was separated from the sampling file by the Trust, prior to transfer of this data to the approved contractor, this had resulted in a breach at one Trust and therefore the CAG had agreed an amendment to enable the contractor to separate the two files. The contractor would anonymise the data before transferring it to the Patient Survey Coordination Centre. The CAG had been satisfied that this was the earliest practicable point at which the data could be anonymised.

The current application would adhere to this previously approved methodology.

Justification of identifiers

The CAG was satisfied that the disclosure of full contact details to the approved contractor was necessary for the purpose of mailing the surveys out to patients, and for sending text messages to patients included in the pilot.

Additional points

Public engagement

The CAG noted that the Inpatient Survey Advisory Group was involved with the development of the survey programme on an ongoing basis, and that changes suggested by the group in relation to the text message reminders would be incorporated into the patient notification posters for this survey (at the Trust sites where the pilot was running).

No concerns were raised in relation to the level of public engagement.

Patient notifications

Members commented that the posters were clear and unambiguous.

A Freephone number was given to patients in order to opt out of receiving text messages, rather than giving the option to text STOP – members agreed that this was necessary in order to establish whether patients objected to the text messaging or to receiving the survey as a whole.

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 Secretary of State, 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. The applicant was asked to provide the final wording of the text message reminders to be sent to patients.
2. The applicant was asked to update the first mailing letter to patients to inform them that text message reminders will be sent.

Specific conditions of support

1. The findings of the pilot should be reported back to the CAG, when available.
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **This is required for each individual contractor as specified in the application**

3. NEW APPLICATIONS – Non-research

a. 17/CAG/0080 – CHC Data Access

Purpose of application

This non-research application, submitted by Liaison Financial Services, asserted that several Clinical Commissioning Groups (CCGs) have voiced to the applicant their concerns about the rising spend on Continuing Healthcare (CHC) and the increasing pressure to manage and control this spend. These difficulties were specified to include duplicate payments, overcharging for revised care packages, recharges from Local Authorities and charges for deceased patients.

A recommendation for class 4 and 6 support was requested to enable the disclosure of data from NHS Digital to the applicant, on behalf of the CCGs.

Confidential patient information requested

This disclosure of information was indicated to cover the following items:

- NHS Number
- Date of Birth
- Date of death
- Hospital admission date
- Hospital discharge date
- GP details

Confidentiality Advisory Group advice

Public interest

It was stated that a key aim of the activity is to identify where CCGs have been overcharged and thus put in process a mechanism to recover the funds so these can be used for patient care and the benefit of the local public to the CCG. Responses to queries further clarified that internal processes for accurately validating and verifying payments/invoices can vary due to

transparency, CHC systems and databases, leading to potential financial 'leakage'. The application specified that currently CCGs are struggling to provide data with a unique reference number to allow any reconciliation to be completed and therefore NHS Number was required as a minimum to allow any identification of overcharges.

Noting this was primarily a financial management application, and in terms of a medical purpose could appropriately be considered to fall within the category of 'management of health and social care services' members noted this appeared to be a local variant of an 'invoice validation' application submitted by NHS England that covered all applicable CCGs and Commissioning Support Units (CSUs) at a national level.

In considering whether the public interest would be best served by the disclosure of information without consent, members were unclear on what value could be offered by this application that was not already being addressed by the national approved 'invoice validation' application from NHS England, where specified data items were permitted to flow to enable CCGs and supporting CSUs to reconcile and validate invoices. This question had been posed but members found the response did not fully address the consideration. It was therefore requested that in order to support the public interest that the applicant should clarify why this approach would provide better value than CSUs providing this service via the national application and why these issues were not being overcome through the national application already in place.

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.

- Feasibility of consent

Members were unable to reach a determination on this aspect. The initial clarification response had confirmed that the scope related to patients registered with the CCG who were deceased, patients who had undergone an inpatient stay and GP details for individual CCGs. This data would be for all patients registered with an individual CCG since 1 April 2013 to present.

It was noted that responses had clarified there were currently 24 CCGs signed up to this activity, with the potential for more. Members queried what the potential number of patients this would encompass and whether this was considered to be a pilot. It was considered helpful if any future new submission could provide copies of the details that the CCG had signed up to, and the list of the applicable CCGs.

- Use of anonymised/pseudonymised data

Members noted that they did not have sufficient information in the application to determine whether a reduced number of data items would be appropriate to achieve the purposes. This point is addressed further under 'justification of identifiers'.

Justification of identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less disclosive variants of each item would be sufficient e.g. month and year instead of full date of birth.

It was noted that the application listed a number of identifiers in order to achieve the aims of the activity. However, a response to queries appeared to explain only the necessity of NHS Number, and confirmed that the NHS Number is required as a minimum to allow any identification of overcharges. As such, members could not identify a clear justification for all of the items specified, and requested this should detailed and justified for each item should a new application be made. It was also noted that the responses to queries did not include date of birth as an item, so the application should also be reviewed for consistency.

Data Flows

Members reviewed the data flow diagram but found it unclear as to where data would flow from and how. It was advised that a more specific data flow diagram should be developed that follows the data requested at each stage and should fully explain who is involved in processing and how, the data items relevant to each stage and how information will be transferred. It should also explain each stage e.g. what is meant by data rejected; by whom and why. What is involved in the Caldicott Guardian review and what is checked; clarification of the precise security arrangements in relation to storage on a password protected folder and more detail as to specific storage arrangements.

Data Protection Act 1998 compliance

It is a requirement within the Regulations that any approved activity cannot be inconsistent with the Data Protection Act (DPA) 1998. Applicants must therefore demonstrate through the application that it is consistent with the DPA.

Members identified points that raised concern as to full understanding of this Act. For example, when asked whether Liaison would be acting as a data processor on behalf of the CCGs, the response indicated Liaison is both the data controller and processor. This raised a concern in relation to this application, as if Liaison is a data processor, this would only be the case if there is a contractual agreement with the CCGs, who would be the data controllers. Alternatively, if Liaison consider themselves to be the data controller for this activity, this would mean that Liaison would be determining the purpose and manner in which the data is processed, which could contradict the initial view that Liaison are the data processors acting upon instruction of the CCGs, and change the scope of this application. It was advised that this must be factually clarified so the data controller and processor relationships are clear to all concerned and are appropriate. It was also advised that it would not be appropriate for Liaison to act as the data controller for the purpose of this activity, but it would be for the applicant to address this aspect in accordance with the requirements of the DPA.

It was also advised that evidence of the contractual relationship to support the data processing arrangements and information sharing agreement should be provided. It was recommended that advice on compliance with all elements of this Act should be sought locally and guidance produced by the Information Commissioner's Office should be reviewed thoroughly and incorporated as part of any new application. Members also advised they remained unclear on the precise relationship of Liaison to the CCGs and requested greater clarity.

Please note that any application must be signed off by the applicable data controller as they are responsible for ensuring the application proceeds as detailed. In the event the CCGs are the data controllers, a mechanism to evidence and ensure all are fully signed up to this application must be submitted to ensure an application can be validated and proceed to CAG consideration. It was also advised that the responses to the DPA principles would require revision to reflect understanding of and compliance with the principles, and a specific time

period provided for retention of information e.g. how long do reviews take, which should help determine the retention period.

Patient Notifications and Dissent

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

It was noted that the application did not specify whether the applicant intended to take steps to notify and inform the relevant cohort of this proposed activity. Please note that this principle does not mean that consent should be sought, but rather patients informed and given opportunity to register any objection. Members advised that this principle should be considered and incorporated within any new submission, considering practical measures that could be taken, and highlighting any difficulties. Please note this is a general principle for all CAG considerations, so due emphasis should be given to this response.

Security assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory IG toolkit compliance. It was noted that a self-assessed score of 66% had been published, however this self-assessment had not yet been assessed by NHS Digital. In order to complete this element, the CAG must receive confirmation of satisfactory security arrangements directly from NHS Digital, or via population of the 'reviewed grade' field on the IGT website.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations did not appear to have been met, and therefore advised the Secretary of State for Health that the application should not be supported in its current form. It was advised that should a new submission be made, it would need to address the points raised above, as summarised below.

Areas to be addressed (summary)

1. Clarification why this approach would provide better value than CSUs providing this service via the national application and why these issues were not being overcome through the national application already in place, in order to support the public interest in this activity proceeding.

2. Consideration of any issues regarding seeking consent; confirmation of CCGs signed up and provision of documentation confirming what the CCGs have signed up to.

3. Revised data flow diagram as per advice given above

4. Clear justification for all identifiable data items, identifying the necessity of each one to achieve the purpose, and considering less disclosive variants for each where appropriate. Revision of the application to ensure consistency.

5. Detailed revision of the application to accurately clarify and confirm compliance with all aspects of the Data Protection Act 1998, including appropriate data controller and processor

relationships and evidence to support these positions (including any written advice obtained from the ICO and local information governance specialists). A new application must be signed off by the relevant data controller as it appears that Liaison is not the data controller and therefore cannot sign off this application.

6. Provide consideration of opportunities to provide appropriate patient notification to the relevant cohort, provision of any relevant information to be provided to patients, and consideration of any difficulties to achieving this.

7. Ensure the CAG receive confirmation from NHS Digital that the IG Toolkit submission by Liaison is considered satisfactory

It was advised that if the applicant considers that the issues raised by the CAG can be addressed, a new application can be made. Such an application would be considered at a full CAG meeting.

4. NEW APPLICATIONS – Research

a. 17/CAG/0074 Effects of long term low dose Ketamine in chronic pain patients

Purpose of application

This research application from Wrightington Wigan and Leigh NHS Foundation Trust set out details of a retrospective cohort case control study. It was indicated that ketamine is an anaesthetic drug with analgaesic properties and is controversially used in patients with chronic pain as it has no licence. The applicant confirmed he has been treating a small group of patients with chronic pain with Ketamine for many years. Recently, concerns have been raised that ketamine can cause liver and urinary tract damage and critics point to a lack of long-term safety data.

The application set out the intention to compare the incidence of altered test results with two groups of age and sex matched control subjects. Execution of this study will add to the knowledge base and will help inform a wide group of clinicians as to the impact of long term use of this drug on these commonly performed biochemical tests. The primary aim is to identify the rates of blood test abnormalities in the control populations as this could help other clinicians prescribing ketamine to interpret the significance of any biochemical testing that they undertake in their patients.

Confidential patient information requested

A recommendation for class 5 and 6 support was requested to enable the disclosure of confidential patient information to the applying clinician to access the original cohort details (originally collected and used for the purpose of audit) for the purpose of this research, and to access the blood test results of age-sex matched control patients who have already had these blood tests carried out for other reasons

In particular, the application specified that first name and surname were required for correct age and sex matching. The cohort was specified to cover the following:

- 33 chronic pain patients identified by the original audit database as being on Ketamine.

- 33 age/sex matched control patients referred to the pain clinic who are not on ketamine who have blood test results.
- 33 age/sex matched participants who have blood test results on hospital computer systems.

Confidentiality Advisory Group advice

Public interest

Members raised a number of queries about the approach and whether the plan would yield the intended outcomes. Noting that scientific elements remained primarily within the REC purview, members expressed concerns about the science that they agreed were sufficiently strong to raise questions as to whether the public interest would be best served in processing patient information without consent in this instance.

It was advised that should the applicant wish to submit a new application to the CAG that statistical advice should be obtained and this provided to the CAG. Members also advised that they would wish to receive the REC favourable opinion and any correspondence with the REC that took into account their consideration of the science of the activity. The application stated that the REC application had not yet been submitted. Due to this fundamental issue, members were unable to proceed to a detailed review of this application as they expressed the view that they would need to be assured that the science was appropriate and would generate the intended results. Without this assurance it would not be possible for the CAG to consider and provide an advice recommendation.

Members also expressed concern with the application detail that specified this activity was not funded and it was being undertaken in the applicants' spare time, and there was a possibility it may not be carried out if excessive demands are made to time. While sympathetic to the issue, members advised this significantly impacted on the public interest consideration of this activity going ahead as seeking support to process patient information, without consent, is considered a measure of last resort and therefore any approved applications are expected to commit to proceeding with the activity. This was an issue of concern to the members as there should be confidence in completion, and it was advised that the applicant consider the feasibility of proceeding and to consider whether the activity can be delivered; this would be a critical factor linked to public interest considerations when seeking support via the CAG.

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.

- Feasibility of consent

In light of the fact that members raised questions about the science, which may lead to changes, and subject to any changes requested by the ethical review, members were unable to assess in detail issues around whether consent may or may not be feasible.

- Use of anonymised/pseudonymised data

In light of the fact that members raised questions about the science, which may lead to changes, and subject to any changes requested by the ethical review, members were unable to assess in detail issues around whether there may be a less disclosive approach or not.

Patient Notifications and Dissent

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

Members expressed the view that they felt reasonable measures could be taken to provide information about this study, and asked for consideration of information being placed in clinics, along with a copy of this information in the event of a new submission.

Patient and public involvement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead. Members advised that an appropriate level of engagement could be undertaken, particularly with the 33 patients contained within the original audit database, and their views obtained on whether they would see this use of data as an appropriate one. Engagement should take place, or a detailed plan on how this will be undertaken with timescales, should be provided as part of any new submission.

Governance plans

Members noted that they had not received an adequate level of assurance regarding the ongoing governance of this potential database of results. Further assurance was sought on who would have access to this, what security and governance controls would be put in place regarding the data, how it would be managed, and how it would be managed within the trusts' overall governance structure. Clear information on the access and security controls, and how it will be managed over a long time period should be set out in any new submission.

Exit strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. Members could not locate a clear exit strategy and requested a clear update on how steps would be taken to move away from this support, if provided.

Security assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory Information Governance toolkit compliance. It was noted that a self-assessed score of had been published, however this self-assessment had not yet been assessed by NHS Digital. In order to complete this element, the CAG must receive confirmation of satisfactory security arrangements directly from NHS

Digital, or via population of the ‘reviewed grade’ field on the IGT website. This would need to be addressed by the applicant

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations did not appear to have been met, and therefore advised that the application to process confidential patient information without consent was not supported at present.

b. 17/CAG/0064 Testing a diagnostic aid for hip dysplasia in primary care

Purpose of application

This research application from Great Ormond Street Hospital for Children stated that developmental dysplasia of the hip (DDH) is a condition where the 'ball and socket' joint of the hip does not properly form in babies and young children. Dislocation occurs in 1-2/1000 infants per year but milder forms occur in 40-60/1000. As early recognition of disease is associated with better outcomes, it is national policy to examine all infants for the presence of DDH at birth and at 6 weeks in primary care (6-week hip check). Despite a compulsory hip check at the age of 6 weeks in primary care, missed diagnoses and infants incorrectly labelled with DDH remain an important problem, potentially leading to adverse consequences for infants, their families and the NHS.

The application set out details of a pilot study that seeks to improve the diagnosis of DDH in primary care through use of a diagnostic aid. The study is intended to test an existing previously developed diagnostic aid for DDH and will develop a training video that goes along with this checklist, tailored for use in primary care. The aim is to identify whether it may reduce the number of infants diagnosed late with DDH and that it may assist in infants being wrongly labelled with DDH.

A recommendation for class 1, 5 and 6 support was requested to cover access to confidential patient information as detailed in the application.

Confidential patient information requested

In this pilot, the aim is to look at the performance of a diagnostic aid when used by GPs who carry out the 6-week hip check. Data will be obtained based on the results of this hip check. In particular, this was specified to include: name (for patient identification purposes), NHS number and date of birth (to enable identification and following through to secondary care), gender, ethnicity (to analyse their influence in the primary and secondary outcomes) and follow up/ treatment details.

Three to six months following the 6-week hip check, the researcher will visit all practices again in order to discern if the infants had hospital contact for their hips. For this the research team would view any corresponding clinic letter, referral letters and any test results. Data to be extracted from each GP database includes; if a patient was admitted for treatment of a hip, if a patient obtained treatment of a hip in outpatients and if a patient had at least one hospital appointment for the hip. A researcher will collect any follow up data only from each GP practices’ database, using unique NHS patient numbers, and categorize the appropriateness of referrals by a practice.

Confidentiality Advisory Group advice

Public interest

Members noted that there was a potential public interest in the outcome of this activity.

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.

- Feasibility of consent

Members noted a negative response had been provided against the question, will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants). It appeared this was an error, however, members agreed that the application appeared to address the feasibility of consent as if the GPs were the data subjects, rather than acknowledging that the data to be used was that of the patient. For CAG purposes, the question should be addressed from the perspective as to whether it is feasible to obtain consent from the patients (data subjects). The response to q15-2 stressed that GPs are the participants, and this should obviate the need for individual consent. Members did not agree with this interpretation and therefore did not consider a sufficient justification was currently present to evidence that the seeking of consent from the patients (parents/carers) was not feasible.

The response to question 31-2 indicated that the Chief Investigator or researcher will make sure there is a sufficient supply of study information sheets at each participating practice. The practice receptionist(s) will need to hand these to the carers of infants attending the 6-week hip check upon their arrival. Whilst the carers are waiting to be seen, they can read through the information and inform the GP if they have any objections. For those carers that do not wish for their child to be involved in the study, their data will remain at the practice.

Members expressed the view that this would appear to be an opportunity to seek explicit consent, and requested consideration as to whether this would be a feasible approach. If not considered to be, members requested detail on this aspect to provide evidence that consent would not reasonably be feasible. Members also noted the cohort size had been specified as eight practices, however, requested to receive an understanding of the anticipated numbers of patients that may be covered by this activity to aid in assisting conclusions as to whether consent may or may not be feasible.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

It was noted an information sheet would be provided in addition to a mechanism to allow opt-out. Members were unclear as to whether patients were able to opt out of the whole study, or able to opt out only from the access to information without consent by the researcher, as the understanding was the diagnostic tool would be completed by the GP as a matter of course. The view was that the opt-out mechanism should relate only to the unconsented access to information by the researcher and the information leaflet was not explicit on this aspect and would benefit from amendment.

Data flows

The application confirmed that patient details will be entered directly from the primary care system to UCL Data Safe Haven; this identifiable data is transferred via a secure gateway technology and is then retained via policy and systems that prevent data leakage.

Members were unclear on the process of data transfer to University College London and requested clarification on this element. Members also raised a query as to why patient data was removed from the practice, and requested justification for this aspect as they did not consider they had a clear understanding to justify this element. Additionally, members sought further justification for the retention of the identifiable information for the time period specified.

Patient and Public involvement

Members requested detail of the PPI involvement referred to; when this took place and details of the changes that were indicated to be incorporated into the design of the research. Any feedback provided on comments made in relation to access to confidential patient information from this involvement was also requested.

Additional points

Members sought clarity on the upper age limit for the cohort and requested confirmation that any call made by the GP practice at the 6 month follow-up to check if the child had been referred, would be made by the GP practice and not the research team.

Members also noted that it may be helpful to consider using control GP practices to enable a comparison in the results of practices pre- and post-intervention.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that 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. It is advised that a detailed letter, and supporting information, should be submitted once points 1-6 have been fully considered. These should be submitted no later than 20 days from date of the outcome being provided.

1. Further justification to demonstrate why the seeking of explicit consent from patients, to allow researcher access to confidential patient information, would not be feasible. This should include an indication as to patient cohort size.
2. Revision of the information provided to patients to ensure the mechanism of opt-out applies only to the researcher unconsented access to information.
3. Lay person explanation of the process of transfer of information to UCL, and the key measures in place to appropriately protect the confidentiality, integrity and availability of the information.
4. Explanation and justification for transfer of patient information to UCL, from the context of seeking to minimise the flows of identifiable information.
5. Further justification for the retention period of identifiable information
6. Further detail on impact of the PPI involvement undertaken
7. Clarification of the upper age of the cohort.
8. Confirmation that calls made to the parent/carer would be by a member of the GP practice and not the researcher.

Once all of the above is received the information will be reviewed by the original reviewers, and a recommendation provided as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting.

c. 17/CAG/0072 IRIS+ feasibility study

Purpose of application

This research application from the University of Bristol set out, for the purpose of CAG consideration, a feasibility study. The IRIS+ (Enhanced Identification and Referral to Improve Safety) feasibility study is part of the REPROVIDE (Reaching Everyone Programme of Research on Violence in diverse Domestic Environments) Programme. IRIS+ aims to increase the safety and wellbeing of victims of domestic violence and abuse (DVA) by improving how general practice professionals respond to adult patients who experience or perpetrate DVA and to their children.

IRIS+ is enlarging the original IRIS model beyond women survivors of DVA. IRIS+ aims to enhance, integrate and streamline DVA training and support intervention for general practice professionals. The intervention will assist general practice professionals in identifying, documenting, and referring female and male patients who may have experienced DVA as victims, perpetrators, or both and their children who may have been exposed to DVA to specialist services and offering them appropriate support. The intervention will include a training intervention to clinicians and access to IRIS+ service/hub support workers who specialise in female and male victims and perpetrators and their children.

The current mixed method study will test the feasibility and acceptability of IRIS+ DVA training and support intervention. The training and advocate roles will be tried out initially in four practices (current study) and then in a large experimental study (definitive trial) investigating whether the programme works and is value for money.
Building on the success of IRIS, the IRIS+ project will thus develop, assess the feasibility of (current study) and conduct a definitive trial of a new integrated training and support intervention. The feasibility study is part of the development phase.

A recommendation for class 5 and 6 support was requested to cover details of the feasibility study set out in the application. References to a full trial were confirmed not to be the subject of the application to the CAG.

Confidential patient information requested

The application sought support to in order for the research team to have access to confidential patient information while on-site at practice and agency sites. The application confirmed it will be necessary to search the patient record database by read and study specific codes to measure identification and referral.

In order to measure the prevalence rates of the identification of domestic violence and abuse in patients in 8 months following the first IRIS+ training intervention, it will be necessary to access individual patient records in GP practices without consent to measure identification of domestic violence and relevant referral; the fact of identification and referral, gender and age of the patient would be extracted.

Agency referral and contact data: In order to determine the source of referrals (count the number of referrals from pilot general practices) and the number of agency contacts with the client referred to the agency, it will be necessary to access individual client records without consent to measure referral and contact. The following would be extracted from the record: the referral source, number of contacts, gender and age of the client.

Confidentiality Advisory Group advice

Public interest

Members agreed that this was an important and valuable area and there was a public interest in the research commencing. It was also agreed it fulfilled an appropriate medical purpose in terms of potentially improving support offered to GPs and to improve the health and wellbeing of the cohort.

Scope of proposed support

Members identified that they were unclear as to which elements may require support; noting it is the applicant's responsibility to make clear why they are submitting to the CAG.

The application stated that: *it will be necessary to search the patient record database by Read and study specific codes to measure identification and referral. Moreover we will need to examine individual patient records to resolve use of ambiguous coded terms, such as "domestic dispute", which may or may not signify DVA. It will be necessary to access individual patient records without consent to measure identification of domestic violence and relevant referral*.

It appeared to members that the applicant was seeking support for the research team to physically access patient records in the event of ambiguously coded terms. However, a later statement indicated that:

The practice/agency data extraction procedure will be carried out by a member of the practice/agency team in the presence of a researcher (the researcher will not see any

identifiable personal information) in order to adhere to ethical concerns about accessing personal information without the consent of individual patients/clients.

In light of this, members sought clarity on whether a member of the research team will have any access – physical or viewable – to confidential patient information where coding is ambiguous. In the event that access is considered necessary, members sought clarity on how many anticipated instances there could be where a record is ambiguously coded. Members requested the applicant make explicit why they are applying to the CAG and for which elements.

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.

- Feasibility of consent

Members agreed that due to the specific characteristics of the proposed cohort that consent was not likely to be feasible in this instance.

- Use of anonymised/pseudonymised data

It was noted that the applicant would be accessing information on-site and would therefore be subject to each sites' governance policies and procedures.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

Members asked for consideration as to whether it would be feasible to provide information to notify the potential cohort about this activity, along with a mechanism for respecting objection. Any difficulties or issues should be provided within this consideration.

Patient and public involvement

Members noted that they thought the patient and public involvement that had been undertaken was entirely appropriate and a good example of effective involvement in research.

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.

In order to complete the processing of this application, please respond back to the following request for further information within 20 working days:

Request for further information

1. Clarification as to whether the research team will have any access to identifiable information on-site, and clarification as to whether access by the research team is requested where there is ambiguous coding. Clear understanding provided of the reason for applying to the CAG with these elements made clear.

2. Estimation as to how many ambiguously coded entries there could be.

3. Justification as to why members of the practice/agency team, with pre-existing legitimate access to the information, cannot review medical records where ambiguous, so that the research team does not need to receive viewable/physical access to identifiable information.

4. Consideration to providing information and right of objection about the activity, or to set out the issues that may mean this would not be feasible.

Once received the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and evidence to support the conditions of support are met, the HRA will confirm approval to process confidential patient information is in place.

d. 17/CAG/0077 Can pre-operative troponin and CRP predict post-operative mortality

Purpose of application

This application from South Tee NHS Foundation Trust asserted that studies have shown that small levels of troponin (a blood test used to detect heart muscle damage) detected before patients undergo planned or urgent major surgery on parts of the body other than the heart can predict death following the operation. However, only patients undergoing high risk operations or patients with a high risk of heart problems have been studied and the reasons for this association between troponin detected before an operation and death after the operation are not clear. The study will include a consecutive sample of all patients attending for major non-cardiac elective surgery at our centre in a cohort observational study.

A recommendation for class 1, 4 and 6 support was requested to cover access to the patient information specified within the application. Study participants will be identified from pre-operative assessment clinic lists at James Cook University Hospital. Those attending for pre-operative assessment requiring blood tests are identified on this system by the direct care clinic teams to allow investigations to be followed-up and this will identify the patient cohort. When a patient attends and has bloods taken, they will be highlighted on the electronic patient information system clinic lists. The research team would then use these clinic lists to identify the patients for study, and subsequently extract the relevant information.

Public interest

Members agreed that there appeared to be a public interest in this activity.

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.

- Feasibility of consent

It was noted that a conversation had taken place with the REC where it appeared that a consent based approach could be a potential option. The applicant confirmed separately via email that:

- The general hospital procedure consent form has a section entitled 'Laboratory Testing' which asks the patient 'Do you agree to the retention and subsequent use of samples in research, education and quality assurance?' and is answered Yes/No by the patient at the time of consenting for their procedure.
- At the time of the patient consenting for their operation, they are asked to fill out this section; this gives consent for tissue and samples that would be routinely collected during the operation to be used as detailed.
- This form would be reviewed by the research team prior to collecting any data.
- If the patient did not want their samples to be used and indicated 'No' on this form, no further data would be collected and their samples would not be analysed.
- If the patient indicated 'Yes', the research team would proceed with the study as per the protocol.

Members expressed the view that the consent had to be sufficiently detailed so that it could be considered to be providing genuine informed consent. The view of the CAG was that the line to be relied upon within the form indicating consent to the retention and subsequent use of samples in research, did not appear to be sufficiently detailed to constitute genuine informed consent for the scope of this activity. The view was taken that the REC would have the remit to review the adequacy of the consent detail to ensure it was sufficient, and to meet relevant Human Tissue Act requirements. The CAG also expressed the view that if ONS mortality data would be required then the current detail of consent may not be sufficient to cover this aspect based on the current phrasing.

In principle however, members agreed that this appeared to provide a genuine opportunity to seek consent, although the adequacy of the current information was in question. While the specifics of consent are not generally within the CAG remit, their view was that the current text was not likely to be considered sufficient to achieve the purpose of specific informed consent to cover the activities and information specified in the application. Members agreed that providing the consent information was amended to ensure clarity then this appeared to be an opportunity to provide a practicable alternative from seeking support under this Regulation.

Data Protection Act 1998 section 33

Any application to the CAG should contain sufficient information to evidence that the activity is not inconsistent with the Data Protection Act 1998. The extract from an email from the Trust IG specialist stated that" the use of previously collected data for research within the trust is covered under section 33 of the Data Protection Act 1998 and further patient consent is not required". This appeared to reflect a misunderstanding of the applicability and relevance of section 33 of the Data Protection Act in the context of this application.

In summary, section 33 of the DPA, where applicable, proves an exemption against some of the data protection principles (the Second, Fifth and Sixth) being applied to the activity. The First principle still applies (which requires personal data to be processed fairly and lawfully, and still requires at least one of the conditions set out in Schedule 2 DPA to be met, and in the case of sensitive personal data, at least one of the conditions in Schedule 3). Where s33 DPA applies it does not provide justification that, in and of itself, consent is not required. It was noted that this misunderstanding had led to some confusion within the application and considerations.

It was noted that the potential revised approach no longer reflected the detail in the application form considered by the CAG and therefore any information regarding not seeking consent would need to be amended/removed.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that there appeared to be a practicable alternative to seeking support using a consent based approach. However, it was agreed to defer the application to enable the applicant to follow-up with the REC to ensure the consent information was genuinely specific and informed and in compliance with HTA requirements, noting that CAG commented it did not currently appear adequate to cover all information requested within the application. Members noted that depending on the steps to be taken to amend the consent detail, there may be a possibility that support may be needed for ONS mortality data, but the applicant should seek to ensure this was adequately captured within the consent form detail.

e. 17/CAG/0076 - (The Invasive Dentistry – Endocarditis Association (IDEA) Study

Purpose of application

This research application from the University of Sheffield set out that there is a concern that bacteria entering the circulation during invasive dental procedures (IDP) could lead to critical medical conditions including infective endocarditis (IE), myocardial infarction (MI), stroke, pulmonary embolus (PE) and spontaneous pre-term-birth (SPTB). Most concern has centred on IE, a heart infection with 30% first-year mortality where oral bacteria are the causal organism in 35-45% of cases. Before 2008 it was standard care for people at risk of IE to receive antibiotics before IDP. The effectiveness of doing this has never been proven, and in 2008 NICE recommended this should stop. However, the UK is the only country where antibiotics are not recommended for those at high-risk of IE and a recent study found that UK IE incidence has risen since 2008. The purpose of this study is to determine if there is a link between IDP and IE.

Confidential patient information requested

Support was requested to enable national data on courses of dental treatment and hospital admissions for infective endocarditis (IE), myocardial infarction (MI), stroke, pulmonary embolus (PE) or spontaneous pre-term-birth (SPTB) to be linked by NHS Digital, prior to returning a pseudonymised dataset to the applicant to investigate if there is a temporal link or association between invasive dental procedures and any of these events.

Hospital Episode Statistics data will be used to identify patients who develop IE, MI, stroke, PE or SPTB and, using identifiable information, link this to routinely collected dental data to identify those who had an IDP in the period preceding their medical event. Dental data would be obtained via the NHS Business Service Authority Dental Database. The research team will not receive confidential patient information.

Confidentiality Advisory Group advice

Public interest

Members noted and agreed with the view that the study is important as if IE is linked to IDP there is potential to reduce the number of IE cases by using antibiotics. This could improve patient safety and reduce costs to the NHS. Identifying if IDP precipitates these other medical conditions is also important for patient safety and could allow preventative action to be taken. Members agreed that this appeared to be a well-designed 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.

- Feasibility of consent

Members noted and agreed with the view that due to the large numbers involved, and the fact that some were likely to be deceased, that consent was not likely to be feasible in this instance.

- Use of anonymised/pseudonymised data

It was noted that identifiable information would be necessary to enable NHS Digital to undertake the linkages, prior to returning a pseudonymised dataset to the applicant.

Justification of identifiers

Members noted the dataflow set out in the application, the datasets and the detail provided on how the datasets would be managed and linked. It was agreed that the arrangements appeared appropriate.

Patient and public involvement.

Members noted that this appeared to be appropriate and a good example of involvement.

Patient Notification and Objection

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

Members discussed this aspect and were of the view that reasonable attempts could be made to make information about this study publicly available, in addition to providing a right of objection for those who may choose to exercise this. Members advised that relevant information should be placed in the public domain on this study, via the University website, that includes this right of objection, and the steps that would be taken to achieve this should be provided back to the CAG.

Research Ethics Committee favourable opinion.

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. The letter was noted by the University however, as the application involves the processing of NHS data this is not an ethical opinion as defined under the Regulations. An application should be submitted to the HRA Research Ethics Service in order for final approval to be reached, noting this is a standard requirement for all research applications seeking to process confidential patient information without consent. The advice provided by the CAG should be submitted as part of that application, and once this favourable opinion letter is available this should be provided to the HRA.

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 provisional support to the Health Research Authority, subject to satisfactory responses to the requests for clarification, and compliance with the specific and standard conditions of support as set out below.

Request for clarification:

1. Members noted a possible typographical error as the time period listed for the dental dataset was specified as April 09 – March 2016, but later in the form (q26) the dataset time period was listed as April 09 – March 2015. Members sought clarity on the precise time period.

2. Members requested clarification on whether month and year, instead of full date of death would be sufficient and requested further detail if full date of death would be required.

3. Members agreed that a proportionate attempt should be made to inform the relevant cohort of the activity, and advised that some information should be placed in the public domain on

this study, via the University website. Feedback on practical steps that would be implemented prior to commencement was requested.

It was agreed these clarifications could be resolved at the office level.

Specific conditions of support (provisional)

1. Provision of a favourable ethical opinion from a HRA Research Ethics Committee. **Pending**.

2. Confirmation of a satisfactory (as reviewed by NHS Digital) Information Governance Toolkit submission for entities processing identifiable information under this support (NHS Digital – confirmed; **NHS Business Services Authority – pending)**.

Once the clarifications and outstanding documents are received, these would be considered and if satisfactory, final approval would be issued.

5. MINUTES OF THE MEETING HELD ON 06 April 2017

The minutes were agreed as an accurate record, with no changes.

An update was requested on the status of the NHS Digital outcome. It was confirmed this had not yet been sent and the Chair would be copied in once sent. Members were notified that work was taking place to work with Comms in preparation for the new website and structure. The plan was for a specific section on NHS Digital advice so that it would be clearly accessible as current CAG minutes appropriately provided details of considerations under the COPI Regulations, and inclusion within this of NHS Digital specific information would be opaque to readers; a preference was expressed by the Chair for information on NHS Digital to be published in the current location in the interim period whilst the new website is being prepared.

6. OFFICE REPORT

Members were advised that in accordance with the distribution cycle, this would be circulated to all members outside of the meeting.

7. ANY OTHER BUSINESS

The Chair thanked members for their time and consideration and the meeting was concluded.