NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

09 February 2017 at 10am at Novotel London Waterloo, SE1 7LS

Present:

Name	Capacity
Dr Kambiz Boomla	
Dr Patrick Coyle	Vice Chair
Mr Anthony Kane	Lay
Mr C Marc Taylor	
Ms Clare Sanderson (From Item 3 onwards)	Alternative Vice Chair
Ms Gillian Wells	Lay
Professor Jennifer Kurinczuk (From Item 3 to 7.a. only)	
Professor Barry Evans	
Mrs Hannah Chambers	Lay

Also in attendance:

Name	Position (or reason for attending)
Ms Kathryn Murray	Senior Confidentiality Advisor, HRA
Dr Janet Messer (Up to Item 3 only)	Director of Research Systems, Standards & HRA Approval Programme, HRA
Dr Beth Thompson (Up to Item 3 only)	Senior Policy Advisor, Wellcome Trust

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

There were no apologies for absence received ahead of the meeting.

Dr Janet Messer and Dr Beth Thompson were welcomed to the meeting.

The following interests were declared:

Professor Jennifer Kurinczuk declared the following issues in respect of the applications assigned for review:

Agenda Item 6.a. 17CAG0015 – Professor Kurinczuk declared ahead of the meeting that she was employed by the applying organisation. Professor Kurinczuk was not required to depart during discussions; however, she played no part in the deliberations or decision recommendation.

Agenda Item 7.a. 17CAG0019 - Professor Kurinczuk acknowledged a potential conflict with the application ahead of the meeting, due to the references within the proposal to an existing approval for which Professor Kurinczuk was the applicant. It was agreed that it was not appropriate for Professor Kurinczuk to take part in deliberations or decision recommendation; however, she remained during discussions to provide clarification and guidance around the subject matter concerned.

Agenda Item 7.b. 17CAG0017 - Professor Kurinczuk declared ahead of the meeting that she was a co-applicant for this application. Professor Kurinczuk left the meeting before the discussion of the application and decision recommendation took place.

2. APPROVAL DECISIONS

The following was shared with the CAG 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 12 January 2017 meeting applications.

HRA approval decisions

The HRA agreed with the advice provided by the CAG in relation to the 12 January 2017 meeting applications.

It was noted that in respect of application 17CAG0012, the HRA decision-maker requested further clarification around the recommendation which had been attached to the opinion in relation to the unencrypted transfer of data from WCISU. It was clarified that this point had been attached as a recommendation, rather than a formal condition, as it could not be mandated by the CAG and was also outside the remit of the REC. Following comments from the HRA decision-maker, the paragraph in question from the outcome letter was expanded to provide further clarification to rationale for the recommendation.

3. EDUCATION ITEM

The CAG welcomed Dr Beth Thompson, Senior Policy Advisor at the Wellcome Trust to the meeting. Dr Thompson provided Members with a verbal update around the upcoming General Data Protection Regulation and the potential implications of Brexit.

Members thanked Dr Thompson for her attendance and she left the Committee meeting.

4. ITEMS FOR CONSIDERATION

a. Patient and Public Involvement Event

A discussion took place around the planning and development of the Public and Patient Involvement event, which was scheduled to take place in February 2017. Members discussed the proposed agenda and it was agreed that any outstanding actions would be picked up by the Chair team.

5. AMENDMENTS TO APPROVED APPLICATIONS

a. ECC 5-05 (a)/2012 - Clinical Practice Research Datalink Service (CPRD) Annual Review – Support Extension

Context

This application was considered in 2012 with final approval issued in February 2013 during the time of the NIGB Ethics and Confidentiality Committee. This application is a unique research application that could be considered to provide an 'honest broker' or 'safe haven' processing environment. The CPRD is a discrete function within the MHRA. Due to its national nature, the annual review is considered at full CAG meetings. The application sets out the activity to process a broad range of research and national audit datasets, and specified datasets to enable de-identified disclosure to research recipients.

At a high level, support has been provided for the following aspects:

- GP practices and specified others (according to the master dataset list) to transfer identifiable patient information to NHS Digital.
- NHS Digital to receive identifiers, undertake linkages and provide the CPRD a pseudonymised linked dataset.
- The CPRD do not receive identifiable data from the HSCIC or others under the terms of this support. The CPRD process identifiable information but not under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 e.g. through another legal basis such as consent.
- NHS Digital was operating under the control of the MHRA (via CPRD) in a data processor relationship. The applicant for the purposes of this application is the CPRD who are responsible for the actions of NHS Digital (who in turn are operating under instruction of the CPRD).

Confidentiality Advisory Group Advice

Introduction

Members agreed that the public interest was clear and the annual review appropriate and acknowledged the key areas identified at the last annual review which the applicants were required to report back on.

Methodological Research

The CAG received and acknowledged the 2013 dated letter submitted together with the annual review, which confirmed that support was already in place for methodological research purposes.

Accessibility of Information around Disclosures

The applicants confirmed that CPRD now published a lay and technical summary of Independent Scientific Advisory Committee (ISAC) approved research protocols three months after the data was released to the researchers. Members received the information and no further queries were raised in this area.

Communication to General Practices

The CAG considered the information provided by the applicants in this area and it still appeared that the communications to GP's did not make the role of NHS Digital clear. It was acknowledged from the correspondence that the applicants were currently undertaking a comprehensive review of

all communications, including those to GP's which describe the data flows; however, it appeared that there had been little progress since the last annual review.

Members agreed that it was appropriate for the revised communication documents to be considered by CAG, following the completion of the internal review. It was recommended that the applicants sought representative patient involvement in the review of the documentation, as it was noted that the poster and leaflet provided with the annual review contained complex and technical language which was not appropriate for a broad audience. It was further advised that the documentation included clear details around the opt-out process.

The Committee considered the wider communications which had been referenced in the covering materials and it was acknowledged that some of the information included on the CPRD website was helpful; however, it was difficult to locate. Members commented that explanation provided here around opt-out was not complete as it did not cover NHS Digital, the two types of opt-out and it was also unclear how opt-outs were managed. Members also commented that there did not appear to be any information on NHS Digital's website around CPRD. The CAG agreed that there was a longer term requirement for the applicants to work together with NHS Digital to improve their overall communications around CPRD.

High-Risk Protocols

Members noted that there have been no further 'high-risk' studies, where there is a high-risk of re-identification, referred on for CAG consideration. The applicants had advised that an update on the policy and processes in place to manage the risk of re-identification could be provided; however, supporting documentation was not submitted together with the annual review. CAG agreed that sight of these documents was required. It was further stated that this should become a standing item at annual review to ensure ongoing consideration.

Free-Text

CAG acknowledged that whilst the retention of the free-text medical notes collected up to 2014 may be legal under the Data Protection Act, there was not a legal basis for the retention of the data under the COPI Regulations or the Common Law Duty of Confidentiality. As such, this information was out with the remit of the CAG's recommendation of support. Members noted that the applicants were undertaking a project to dispose of this information and it was recommended that this be taken forward as an urgent action and confirmation provided to the Committee when this was complete.

Retention of Date of Death

It was identified through the consideration of the annual review that date of death was retained by CPRD together with gender and ethnicity. It was recognised that when the application was initially considered under the remit of the Ethics and Confidentiality Committee, it was agreed that the controls which were in place did not render this combination of data identifiable. However, Members were no longer clear why this was the case. CAG recommended that the applicants considered whether retention of date of death remained compliant with the ICO code of practice around anonymization.

Confidentiality Advisory Group Advice Conclusion

As a whole, it was recommended that the approval in place for the purposes set out in the application should continue for a further 12 months from the anniversary of the original final approval outcome letter, to 18 February 2018.

Further Information Required

The following points were identified as requiring further action and response within identified timescales:

1. Communication to General Practices:
   a. With four months – provide an outcome report on the internal review of communications which has been undertaken and provide updated copies of relevant information sheets, posters etc. for consideration. It was strongly recommended that patient engagement is undertaken here to assist with the revision of language used to make this more appropriate for a broader audience.
   b. Within six months – provide an overview of how communication improvements are planned more broadly, particularly in relation to providing a unified message between CPRD and NHS Digital.
2. Provide copies of documentation relating to the policies and processes which are in place to manage the identification of high-risk protocols. These should be provided within 20 working days of receipt of this letter.
3. The CAG do not believe the retention of free-text information from medical notes is lawful under the Common Law Duty of Confidentiality or the COPI Regulations. It was recommended that the identified project to dispose of the data is undertaken as an urgent action. Provide a status report on this within 20 working days of receipt of this letter.
4. Provide a statement to clarify how the retention of date of death is compliant with the ICO Code of Practice on Anonymization. This should be returned within 20 working days of receipt of this letter.

6. NEW APPLICATIONS – Research

a. 17CAG0015 – ARK Hospital

Context

Purpose of Application

This application from Oxford University Hospitals NHS Foundation Trust set out the purpose of a research project which will test whether a package of strategies can help doctors, nurses, pharmacists and patients stop antibiotics in hospital when they are no longer needed. The package includes internet-based training, standard systems to review patients, regular support from pharmacists/infection specialists, and materials for patients.

The applicants will test the package in one hospital to make sure that it is practical, which is classed as the feasibility study element. The implementation of the package will then extend to 1-3 more hospitals, testing how many people use it and improving the package as required during the internal pilot stage. Following these two stages, if specific criteria have been met, the package will then be implemented in 36 hospitals in total, which will be the main trial of the intervention.

The CAG were asked to consider a specific element of the proposal which was around the analysis of primary outcome measures, where the applicants will compare mortality and antibiotic use in patients admitted to general medicine before and after the introduction of the package, using data from electronic hospital records from admission to 90 days later. The project involved an additional qualitative element; however, this was fully consented and therefore outside the scope of the CAG considerations.

A recommendation for class 5 and 6 support was requested to cover activities as outlined within the application.

Confidential Patient Information Requested

Cohort

The applicant's estimated that the cohort will be in the region of 630,000 patients of whom approximately 30% would have been prescribed antibiotics. The cohort included all individuals being admitted to hospital as an adult within acute or general medical inpatients defined by specific admission codes (speciality code 300 for first consultant episode for an inpatient spell, or second consultant episode where the first consultant episode has speciality code 180, which relates to A&E admission). There will be 38 NHS Trusts included within the project.

Access was requested to the following items of confidential patient information for the purposes detailed:

- Date of death – essential to the analysis of the primary outcome of the application, which is evaluation of the intervention to ensure it is not associated with harm to patients,
- Age – in years at last birthday,
- Gender – for analysis,
- Ethnicity – for analysis.

Confidentiality Advisory Group Advice

Public Interest

The CAG acknowledged that antibiotic prescription and resistance was a key priority for the NHS at this time and the application presented a strong medical purpose. Members acknowledged the powerful public interest in this project as if successful; the novel intervention being tested in study could lead to better prescribing practice.

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 consent was not feasible in this instance due to the large cohort of patients who could potentially be involved in the project.

- Use of anonymised/pseudonymised data

It was acknowledged that the only item of confidential patient information required was date of death for those patients who died within 90 days of the hospital admission, to enable evaluation of the intervention tool. Members agreed that this outcome measure could not be achieved without the data item. The Committee discussed whether it was possible for the applicants to undertake the required evaluation on a calculation of the number of days death occurred following admission; however, it was acknowledged that data of death would still be apparent as there was access to the patient's admission date.

Justification of Identifiers

The CAG confirmed that access to date of death was justified and were satisfied with the rationale provided to support this data item by the applicants. Members acknowledged that date of death was a weak identifier when held only with gender and ethnicity.

Patient and Public Involvement

Members acknowledged the level of public and patient engagement which had been undertaken in relation to the wider research project and it was noted that substantial work had been undertaken to make the project comprehensible to a lay person.

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.

The Committee discussed the opportunities in relation to patient notifications for this project and it was noted that the applicant had suggested posters could be displayed about the project. In discussion it was agreed that study-specific posters would serve little purpose in this instance, as only data from people who subsequently die would be utilised without consent and it was recognised that there was potential for distress.

Members suggested that a more general poster could be displayed advising the focus of the project with signposting to where further information can be obtained. The Committee considered how a study specific opt-out mechanism could be managed, whilst accounting for the sensitivity of the matter and it was agreed that an opt-out mechanism would be required whereby patients could lodge the dissent to the use of the data, which could be fed back to the clinical teams who are undertaking the data extraction at the later time point, to ensure this is respected. It was also recommended that another communication channel was offered alongside email correspondence.

Additional Points

The application covered three phases of the project, including the feasibility, pilot and main trail. Whilst the historic precedent in these circumstances was only to approve the feasibility and pilot elements of the study to allow feedback to be given ahead of the main trial commencing, Members agreed that it was unlikely that the element of the trial which required support under the Regulations would change. The CAG agreed that approval would be recommended for the full project; however, the applicants would be required to submit an amendment or a new application, as deemed appropriate, should any revisions be made to the CAG aspects of the project following the pilot study.

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. Appropriate patient notifications and objection mechanism to be developed and reported back, together with an update on progress, at first annual review. The following points should be accounted for:
    a. A generic poster should be produced for display in the participating hospitals to provide high level information about the project. This should sign-post interested readers to where more detailed and specific information can be found, i.e. participating Trusts websites,
    b. A study-specific op-out mechanism should be devised which will allow patients to register dissent for the data to be used in the project, should they die.
    c. Provide alternative communications methods, together with a study specific email account.

2. Support is extended to the three project phases (feasibility, pilot and main trial); however, it was noted that any amendments to the study design which impacted on the CAG recommendations would need to be submitted for consideration before progressing to the main trial.
3. Favourable opinion from a Research Ethics Committee. (**Confirmed – South Central – Oxford C REC issued on 07/02/2017).**
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed - Oxford University Hospitals NHS Foundation Trust has a published reviewed score of satisfactory at 97% at Version 13, 2015/16).**

b. 17CAG0020 – Clinical & biological factors associated with relapsed neuroblastoma

Context

Purpose of application

This application from Newcastle University set out the purpose of medical research into Neuroblastoma, which is an embryonal childhood tumour derived from cells which go on to form the sympathetic nervous system. It is one of the most difficult childhood cancers to cure with around 40% five-year survival in high risk cases (50% of all cases). Despite advances in neuroblastoma therapy relapse still occurs in 50% of high risk cases and in most high risk cases cure is no longer possible. Knowledge of factors which influence subsequent response and length of survival following relapse in neuroblastoma are important to determine which, if any, treatment at relapse is appropriate in individual cases, and may significantly affect the results obtained when evaluating new therapies for neuroblastoma in Phase I and II clinical trials.

Recent studies report an increased frequency of recurrent, genetic abnormalities at relapse including segmental chromosomal abnormalities (SCA) and gene mutations for which a targeted treatment exists. This study is a retrospective epidemiological and genetic study which aims to determine clinical and genetic factors associated with neuroblastoma relapse and length of survival following relapse.

The application contains three work packages; however, the CAG considerations only extend to two of these as the second relates to children whose parents have already consented for inclusion in this study. The applicants intend to contact all 21 Paediatric Oncology principal treatment centres (formerly known as Children's Cancer & Leukaemia Group (CCLG) centres) to identify relapsed/refractory cases in the UK and Ireland diagnosed in children and young people aged 0 – 40 years from the year 2000 onwards. Eligible cases will be those who relapsed from 1st January 2000 onwards. The applicants also wish to further analyse the DNA of three children for whom consent has not been obtained for additional genetic studies and these children have died; consent has been obtained for a further 27 who are therefore not included in CAG's consideration.

For work package one the CAG was asked to consider a recommendation of support to allow the relevant data extraction at the identified sites to be undertaken by clinical data co-ordinators, who are not be part of the direct care team. The extracted data will be added to an existing database, which includes cases diagnosed from four centres, from the pilot study, comprising information on all cases of recurrent neuroblastoma and will be enhanced with additional clinical, biological and treatment information from notes. Eligible cases will be those who relapsed from 01/01/2000 onwards. In the case of the four centres who have already contributed to the previous pilot study data from 2010 onwards will be collected as well as refractory cases from 2000.

A recommendation for class 1 and 6 support was requested to cover activities as set out in the application.

Confidential Patient Information Requested

Cohort

The cohort was defined as all cases of relapsed/refractory neuroblastoma in the UK and Ireland (CAG remit extending only to England and Wales) diagnosed in children and young people aged 0-40 years from the year 2000 onwards.

Relapse was defined for the project as recurrence or progression (any new lesion, soft tissue or bone) following an initial response (including partial) to any neuroblastoma therapy. Refractory disease will be defined as persistent disease after at least 2 different induction chemotherapy regimens (< partial response to induction) or patients who came off the high risk trial for refractory disease because they did not respond adequately to 2 lines of induction chemotherapy. The applicants expected to identify approximately 400 relapsed cases within the specified timeframe.

Access to the following items of identifiable patient information was requested for the purposes described:

- Name – identify records,
- NHS number – recorded on patient record and viewed by data extractors,
- Hospital ID – recorded on patient record and viewed by data extractors,
- Date of birth – required for analysis to calculate age at diagnosis,
- Date of death – required for survival analysis.

The end date for the sample had been identified as 31 December 2018.

Confidentiality Advisory Group Advice

Public Interest

CAG agreed that the application described a strong medical purpose and it was acknowledged that the outcomes from this study would increase knowledge of factors which influence subsequent response and length of survival following relapse in neuroblastoma that are important to determine which, if any, treatment at relapse is appropriate in individual cases, which was of clear public interest.

Scope of Support

The applicants had requested that support be considered to allow the relevant data extraction to be undertaken at the paediatric oncology sites by members of staff that were outside the direct care team. The data extraction would be undertaken by appropriately skilled workers. Members understood the rationale provided and were supportive of the request.

CAG discussed the information which the applicants intended to retain as part of project and it was noted that date of birth and date of death held together with gender and ethnicity were identifiable information. Members advised that a defined legal basis was required for the retention of these data items and it was agreed that the scope of support should be extended to cover the analysis database even though this had not been specifically sought by the applicants.

CAG also discussed the analysis of the DNA to be undertaken in work package 3. Consent had not been obtained for additional genetic studies to be conducted for three of the 30 children and these children had now died. It was agreed that clarification was required from the applicants around whether they would also be in receipt of a supporting identifiable data set for the three children, without consent, as this would need to be included within the scope of the support. It was clarified that the CAG could not recommend approval to undertake the additional DNA analysis as this was out with the remit of the Committee.

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

CAG acknowledged that consent was not feasible in this instance due to the number of patients involved, who may be deceased or difficult to trace and the potential distress associated with this process.

- Use of anonymised/pseudonymised data

Members commented that there appeared to be some misunderstanding within the application documentation around which data items are considered as identifiers. The applicants have stated that a de-identified data set will be used for the project; however, as detailed above, both date of birth and date of death are transferring into the database. Despite this not being specifically requested CAG was satisfied that the project could not be undertaken without access to the identifiers requested.

Justification of Identifiers

CAG were content with the justification provided for the identifiers requested by the applicants, to ensure that accurate survival analysis calculations could be undertaken.

Exit Strategy

Members observed that no plans had been identified by the applicants to reduce the identifiability of the dataset. It was agreed that the applicants would need to provide further information around plans to reduce identifiability or confirmation that data items that increase the risk of identification would be deleted as soon as they are no longer needed.

Patient Notifications

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 acknowledged the work which had been done around web-based patient notifications; however, it was agreed that these should be available in hard copy also. CAG agreed that further work should be undertaken to utilise the established charity links which had been described in the project documentation to further promote patient notifications about the project and extend this a wider audience.

It was acknowledged that an opt-out system was in place via clinicians; however, Members agreed that further work should be undertaken to extend and promote a wider opt-out system as it was acknowledged that some of the patients to be involved in the study may be deceased or no longer under the care of the clinician, which may make opt-out via this mechanism difficult.

Patient and Public Involvement

CAG noted that whilst formal patient and public involvement in the project had been limited, there were two parent collaborators involved with the project. The Committee agreed that undertaking

more broad patient and public engagement was recommended and would be helpful when reviewing literature in relation to patient notification.

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. Further information is required around the proposed exit strategy for the study – provide details around the steps which will be taken to reduce the identifiability of data items held in the analysis database (i.e. reducing dates to MM/YY or age at event format), or confirm that identifiable data items will be deleted once analysis has been undertaken.
2. Provide further information around work package 3 to confirm whether identifiable patient data would also be analysed further without consent, together with tissue samples, to clarify the scope of support required.

Specific conditions of support

1. CAG recommendation of support extends to England and Wales only – alternative arrangements will need to be made for Scotland and Northern Ireland.
2. Support is extended to cover the data extraction at the Paediatric Oncology Centres by staff members who are outside of the direct care team.
3. Support is extended to cover the analysis database which holds items of confidential patient information. The terms of this condition of support may be revised in line with the response to the above request.
4. Further work is required to extend patient notification and objection for the project, accounting for the below points. An update on progress made should be provided at the time of first annual review:
5. Notifications should be available in both print and web-based,
6. Established charity links should be utilised to further extend the distribution of information about the project,
7. The opt-out mechanism requires further extension so this does not rely on previous treating clinicians and can be managed through communications with the applicants.
8. Patient and Public Involvement and Engagement with the project should be extended. It was recommended that collaboration be undertaken particularly in relation to patient notification literature. An update on progress made should be provided at the time of first annual review.
9. Favourable opinion from a Research Ethics Committee.
10. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. (Confirmed – Version 13, 2015-16, shows a published reviewed grade of satisfactory at 87%).

c. 17CAG0021 – Pregnancy after Kidney Donation

Context

<u>Purpose of application</u>

This application from Guy's & St Thomas' Hospitals Foundation NHS Trust set out the purpose of a medical research study which aimed to assess the risk of pregnancy complications after living donor nephrectomy using the database of living kidney donors held by NHS Blood and Transplant.

This database is unique, in that entry is mandatory if living donor nephrectomy is undertaken in the UK. By working in collaboration with NHS Blood and Transplant, the applicants will link the donor database to a separate national database of hospital records; Hospital Episode Statistics (HES), which will allow us to determine the outcomes after pregnancy in living donors. Linkage will be undertaken by NHS Digital. These outcomes will be compared with those of women of the same age (and with similar risk factors) who have not donated a kidney. The applicants will then be able to determine whether living donor nephrectomy confers increased risks in subsequent pregnancies and will be able to advise both clinicians and women considering donation accordingly. If there is an increased risk for example, women could be advised to complete their family before considering donation.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

The applicants have identified that the sample will include all female kidney donors who have had a subsequent pregnancy from 2001 to 2015. The estimated sample for the cases group (donors) based on available data is approximately 500 cases. The control group will be matched to that of the case group and is dependent on the actual number of cases; however, it is the applicant's intention to match controls to cases at a ratio of 10:1, with an estimated maximum number of patients at 10,000.

The items of confidential patient information required are identified as:

- NHS number – to identify cases and enable linkage,
- Date of birth – to validate linkage and for analysis,
- Postcode – at district level,
- Date of death – in relation to the mother,
- Gender – for the infant,
- Ethnicity.

Confidentiality Advisory Group Advice

Public Interest

CAG agreed that the application defined a clear medical purpose and commended the applicants as it was noted that they had articulated the potential public benefits to be achieved by the project outcomes very well.

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

The CAG was satisfied that consent was not possible for this project, which involved a large number of patients across a retrospective dataset.

- Use of anonymised/pseudonymised data

Members clarified that the analysis dataset was not anonymised as the applicants intended to retain postcode – further queries had been raised around this point when considering the justification provided for this identifier.

The CAG queried whether the applicants would be able to undertake the relevant analysis if mother's date of death was provided as an age at event and it was agreed that clarification was required.

Justification of Identifiers

The CAG considered the requirement for postcode at district level for both the patient and control cohorts and it was agreed that the applicants had not provided a strong enough rationale to support this requirement. Members queried whether it was possible for postcodes to be converted into Lower Super Output areas (LSOA) to enable deprivation scoring to be undertaken, or if it was possible that NHS Digital could provide the deprivation score when linking the datasets.

The CAG commented that this could have an impact on the requirement to undertake patient notifications in relation to the control cohort if the applicant's maintain that postcode must be retained. It was further noted that further rationale for the size of the control cohort would also be required; however, it was agreed that these implications would be considered when clarification had been received.

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.

It was noted that the applicants had not identified any plans for patient notification or objection and Members agreed that further consideration was required by the applicants before support could be recommended. The CAG recommended that consultation with appropriate renal charities should assist in the development of patient notification plans to ensure the relevant population is reached. Members further agreed that clarification was required around how the applicants would achieve a meaningful dissenting process and manage an opt-out mechanism.

Patient and Public Involvement

The Committee noted that a transplant recipient patient was a member of the study team and had provided input to the project; however, it was noted that this individual was representing the views of a transplant receiver, rather than a kidney donor, which was the focus of the project. Members agreed that further patient engagement was required for the project to ensure appropriate consultation had been undertaken. It was recommended that the applicants engaged with renal charities to access patient and public support groups.

Additional Points

Members noted contradiction within the application around who was undertaking the data linkage. It was understood that this would be undertaken by NHS Digital; however, it was noted that this had been cited as NHS Blood and Transplant at other points of the application and clarification was required.

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. Explore whether there is an alternative to receiving the district level postcode for patient and control cohorts, to enable deprivation scoring. Provide a clear response on the way forward, accounting for the following recommendations:
   a. Consider whether the required analysis and deprivation scoring could be calculated from the Lower Super Output Area (LSOA) code rather than district level postcode, to enable the reduction of identifiers held for both patient and control cohorts,
   b. Explore whether the deprivation scoring can be undertaken by NHS Digital when undertaking data linkage.
2. Confirm whether the relevant analysis could be undertaken if mother's date of death was provided in a truncated form, i.e. MM/YY or age at event.
3. Patient and Public Involvement – provide an outline of proposed activities which will be undertaken in order to engage with the relevant patient population around the project.
4. Patient Notification and Objection – provide an overview of proposed plan to improve patient notifications, identifying where information will be made available and any links with other external organisations/charities. Consider how an opt-out mechanism could be managed within the identified patient notifications and provide an outline of the system and how this would be maintained.

Specific Conditions of Support

1. Patient and Public Involvement – further work is to be undertaken to engage the relevant patient population about the study. An update on progress made against the outlined proposal and engagement undertaken should be provided at first annual review.
2. Patient Notifications and Objection – an update on progress made against the outlined plans, together with details of notification and opt-out mechanisms in place should be provided at first annual review.
3. Favourable opinion from a Research Ethics Committee.
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – Version 13, 2015-16, published reviewed grade at satisfactory rating of 74%)**.

7. NEW APPLICATIONS – Non-Research

a. 17CAG0019 – Northern Neonatal Network Perinatal Mortality Survey

Context

Purpose of Application

This application from the Northern Neonatal Network, which is part of City Hospitals Sunderland NHS Foundation Trust, set out the purpose of this audit which was to allow the pre-existing Perinatal Mortality Survey (PMS) to continue to perform surveillance of all deaths from 20 weeks' gestation to one year post delivery, to be operated by the Northern Neonatal Network and hosted by City Hospitals Sunderland NHS Foundation Trust and to retain the archived data from the establishment of the PMS in 1981.

Since 1981, the surveillance of perinatal and infant mortality in the North east and North Cumbria was undertaken by the Regional Maternity Survey Office (RMSO). In recent years, this has formed a key part of the audit of outcomes for the Northern Neonatal Network. Except for Congenital Anomaly Surveillance, which was taken over by Public Health England, the RMSO ceased to exist in early 2016. The Northern Neonatal Network, an operational delivery network covering the same

geographical area as the RMSO needs to retain a high quality audit of its outcomes, which includes mortality.

The purpose of the proposed data collection is:

- To provide continuous data collection to monitor the frequency, nature and causes of late pregnancy loss from 20 weeks' gestation (including terminations of pregnancy for fetal anomalies), stillbirths and postnatal infant deaths.
- To maintain surveillance for clusters of infant death or stillbirth, to alert providers of such findings and to support further investigation of underlying causes for clustering.
- To audit mortality outcomes in relation to evolving patterns of maternity and neonatal care.

A recommendation for class 1, 4, 5 and 6 support was requested to cover activities as detailed in the application.

Confidential Patient Information Requested

Cohort

The cohort includes all pregnancy loss and stillbirths from 20 weeks' gestation and all infant deaths up to one year postnatally. This is a request for ongoing prospective data collection together with the retaining of all historic archived data previously collected by the Regional Maternity Survey Office.

Below is a detailed list of the confidential patient identifiable information requested and the rationale each item is required:

1. As an identifier,
2. To ensure no duplication,
3. To enable surveillance, audit and routine analysis,
4. To investigate clusters (DOB, region, postcode etc.),
5. To investigate potential risk factors,
6. To determine the long-term survival of babies, this is essential information for patients, their families and healthcare providers, by matching with outcome datasets, i.e. ONS mortality files.

- Local ID (1)
- Baby's forename (2)
- Baby's surname (2)
- Baby's delivery hospital number (2)
- Baby's transfer hospital number (2)
- Baby's NHS Number (2,6)
- Baby's address and postcode if different from mother (2,4)
- Date of booking – first check up in pregnancy (5)
- Date of birth of baby (2,3,4,5,6)
- Date of death of baby (5,6)
- Place of booking (3,4,5)
- Place of delivery (3,4,5)
- Hospital of baby transfer (3,4,5)
- Hospital where baby died (3,4,5)
- Mother's forename (2)
- Mother's surname (2)
- Mother's delivery hospital number (2)
- Mother's transfer hospital number (2)
- Reason for maternal transfer (3,5)
- Mother's NHS number (2)

- Mother's address and postcode at conception, booking and birth (2,4)
- Mother's date of birth and age at delivery (2,5)
- Father's name (2)
- Sex (2,5)
- Number of babies delivered (5)
- Birth order if multiple pregnancy (5)
- Birth weight (3,2,5)
- Estimated date of delivery (5)
- Gestation at delivery (3,5)
- Number of previous pregnancies (5)
- Previous spontaneous abortions (5)
- Previous induced abortions (5)
- Previous stillbirths (5)
- Previous neonatal deaths (5)previous post-natal deaths (5)surviving children (5)
- Assisted conception (5)
- Mother's ethnicity (5)
- Mother's smoking in pregnancy (5)
- Mother's body mass index (5)
- Mother's occupation (5)
- Father's occupation (5)
- Father's age (5)
- Mother's drug use (5)
- Mother's alcohol use (5)
- Mother's medical history (3,5)
- Method of labour (3,5)
- Fetal presentation (3,5)
- Mode of delivery (3,5)
- Type of birth 3,6)
- Post mortem performed (3)
- Date post mortem performed (3)
- Diagnoses, including syndromes and malformations with ICD-10 codes (3)
- Syndromes and malformations prenatally diagnosed (6)
- Outcome of pregnancy including miscarriage/stillbirth/termination (3,4,5,6)
- Clinical-pathological code (3,5)
- Aberdeen (maternal factors) code (3,5)

Confidentiality Advisory Group Advice

Public Interest

Members agreed that the application was in the public interest; however, it was noted that a clear medical purpose needed to be articulated to determine why this audit was required in addition to the nationally directed MBRRACE-UK audit.

It was acknowledged that this proposed audit was likely to be capable of more sophisticated and timely analysis than the nationally directed audit and it covered a wider scope, including early loss from 20 weeks gestation (MBRRACE-UK covered from 22 weeks gestation) and post-natal mortality up to one year post-natal (MBRRACE-UK captures deaths up to 28 days post-natal). The CAG was satisfied that this defined the merits of the proposed audit and was supportive in principle of the audit supplementing the existing national audit.

Historic Processing under the Regional Maternity Survey Office

The CAG were still unclear of the historic basis for processing data for the perinatal mortality survey under the Regional Maternity Survey Office. It was noted from the applicant's response to queries that the legal basis for this from April 2008 through to March 2015 was part of the statutory child death review process through explicit reciprocal arrangements with the Child Death Review panels. However, Members noted that stillbirths and late foetal losses were not covered under this legislation so further clarification was required around the legal basis for processing of information in relation to these specific cohorts of deaths, and prior to this legislation coming into effect in 2015. It was also noted that it remained unclear why the previous survey had ceased and further clarification was required.

The applicants had advised that the current data controller for the historically gathered data was Public Health England. The CAG detailed that support could not be recommended to provide a legal basis for the retention of a historic dataset, as it was unable to recommended retrospective support. It was stressed that the applicants would need to provide confirmation of the historic processing arrangements to allow support to be recommended for the dataset to form part of the database under review here. It was recommended that Public Health England may be able to provide historical context as the current data controllers.

Purpose of the Project

Members acknowledged that the value of the audit dataset when complete and noted that purposes in addition to the perinatal death survey had been identified, including safeguarding issues, which were outside the remit of the CAG. It was recognised that historically, data of this kind had been utilised as a research resource, and Members recommended that the applicants consider whether this maybe a future purpose, stressing the importance of transparency in relation to purpose from the outset of the establishment.

Data Sources

The CAG acknowledged that the applicants intended to link data from ONS, hospitals, MBRRACE-UK and Child Death Overview panels in order to populate the database; however, it was noted that there are references within the documentation to other datasets and Members agreed that confirmation of the exact data sources was required to ensure that specific support can be recommended. It was further queried how the applicants would be able to provide information in a more timely fashion than the existing national audit, if they were relying on this audit as one of the data sources.

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 acknowledged the difficulties and sensitives surrounding consent in relation to this project and agreed that it was not appropriate in this instance.

- Use of anonymised/pseudonymised data

The CAG acknowledged that the initial data linkage could not be undertaken without the requested identifiers.

Justification of Identifiers

The Committee discussed the identifiers which were requested and whilst it was satisfied that the identifiers requested were required to undertake the necessary data linkages, Members were unsure about the requirement to retain the identifiers, which is explored below.

Exit Strategy

Members considered the applicants request to retain the audit information indefinitely, with the exception of name, which it was anticipated would be redacted within three years and it was agreed that there did not appear to be a strong enough rationale articulated to support this. Members commented that date of birth and death were easily translatable into a less identifiable format.

The CAG was unclear why information would need to be retained for longer than one year, as it was acknowledged that once linked, the information would not change and the audit focus only extended to include mortality data up to one year post-natal. It was agreed that the applicants needed to provide further consideration in this area to further support the retention of information or provide details of how the identifiability of the data will be reduced.

Patient and Public Involvement

The Committee stated that the response provided to queries around patient and public engagement in the project was not sufficient and further information was required. Members requested specific information on engagement activities which had been undertaken and how these had shaped the project together with information on involvement plans for the duration of the project.

Patient Notification and Objection

Members stated that confirmation of what patient notification plans were in place specifically in relation to this application were required, together with a detailed overview of how patient objection would be managed in relation to this project. The Committee commented that it was not appropriate to rely on the existing mechanisms for the national audit or historic practices in relation to the Regional Maternity Survey Office.

It was acknowledged that the applicants were undertaking work as part of the palliative care pathways, which it was anticipated that this audit would be integrated; however, the CAG agreed that an outline was required of the planned undertakings here before support could be recommended. The Committee suggested that utilising established links with relevant charities may assist with the design of patient notification plans and increase engagement with the project.

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. A revised application form should be supplied, together with a covering letter addressing each of the points detailed below and any further additional documentation.

1. Provide confirmation of the historic legal basis for processing of information under the Regional Maternity Survey Office. It was recommended that guidance be sought from Public Health England as the current Data Controller for the historic information.

2. Provide further consideration to the purpose of the dataset, particularly in relation to whether this may be utilised for research purposes. It was advised that research purposes needed to be accounted for from the outset, so consideration and decision was required at this stage.
3. Provide confirmation of all data sources which will be providing information to the survey and confirm who will be undertaking any required linkage.
4. It was queried how the proposed survey was expected to provide data in a more timely manner than the existing national audit, MBRRACE-UK, when this was cited as one of the data sources.
5. Further consideration is required around the retention of confidential patient information – it is requested that plans are outlined around how the identifiability of the retained dataset will be reduced, or a stronger rationale is articulated to support the indefinite retention of identifiable data.
6. Public and Patient Involvement – clear and detailed information is required around what public and patient engagement has been undertaken to date and how this has impacted on the project design, together with an overview of future ongoing involvement plans.
7. Patient Notification and Objection – clear and detailed information is required around how patient notifications specific to this proposal will be distributed together with detailed overview of how a system of objection will be established and managed. An outline of ongoing plans in relation to notifications and raising the profile of the audit is required for the future.

b. 17CAG0017 – Confidential enquiry of intrapartum-related perinatal deaths in births planned in midwifery-led settings in Great Britain (ESMi)

Context

Purpose of application

This application from National Perinatal Epidemiology Unit, University of Oxford set out the purpose of a confidential enquiry of intrapartum stillbirths and intrapartum-related neonatal deaths occurring in births planned in midwifery–led settings (AMUs, FMUs and home) in England, Wales and Scotland between 2013 and 2016. This application concerns an 'add-on' confidential enquiry which is designed to complement the current MBRRACE-UK 2016 confidential enquiry into term intrapartum stillbirths and intrapartum related neonatal deaths.

A UK-wide confidential enquiry into term intrapartum related stillbirths and neonatal deaths (collectively referred to as perinatal deaths) is currently being conducted as part of the MBRRACE-UK run UK-wide Maternal, Newborn and Infant Clinical Outcome Review Programme (MNI-CORP). The majority of births and thus perinatal deaths in England (87% of births in 2013) occur in consultant-led obstetric units. The findings of the MBRRACE-UK enquiry will therefore predominantly relate to care provided in obstetric units, and only a small proportion of the cases investigated are likely to have occurred in planned home births or in planned births in freestanding (FMU) and alongside midwifery units (AMU). Deaths in births planned in these midwifery-led settings are an equally important group to investigate because the proportion of births in these settings is increasing and the nature of suboptimal care may be different, particularly in out-of-hospital settings (FMUs and home).

The primary purpose of the ESMiE confidential enquiry is to review the quality of care during pregnancy and birth received by women and babies in births planned in midwifery units, freestanding maternity units and at home which end in intrapartum-related perinatal death. The overall aim of the enquiry is to increase understanding of the potentially avoidable or remediable factors involved in intrapartum stillbirths and intrapartum-related neonatal deaths in births planned in midwifery-led settings and to identify areas where care might be improved to avoid future similar deaths. Reports of the findings and recommendations of this work will be disseminated to policy makers, commissioners, service providers, practitioners and patient groups with the aim of supporting changes that improve the quality and safety of maternal and newborn health care.

Support was requested to enable the following activities:

- To use identifiable patient data held in the MBRRACE-UK perinatal death surveillance system (held in the MBRRACE-UK data hub at the University of Oxford) to identify a sample of intrapartum stillbirths and intrapartum-related neonatal deaths that occurred in births planned to occur in AMUs, FMUs and at home between 1 January 2013 and 31 December 2016.
- To collect and process patient identifiable information from case notes for the purposes of conducting a confidential enquiry of intrapartum stillbirths and intrapartum-related neonatal deaths.

A recommendation for class 1, 5 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

The cohort will include intrapartum stillbirths and intrapartum-related neonatal deaths occurring in births planned in alongside midwifery units (AMU), freestanding midwifery units (FMU) and at home. There will be 50 cases identified per planned place of birth setting. The list of sampled cases will be identified using the MBRRACE-UK perinatal surveillance database.

The items of confidential patient information requested for the service evaluation are:

Maternal details
- Full name,
- Date of birth,
- Hospital/NHS number,
- Ethnicity
- Country of birth
- Home address including postcode,
- Full clinical information relevant to the pregnancy, baby death and postnatal and bereavement care of the woman.

Baby details
- Full name,
- Date of birth,
- Hospital/NHS number,
- MBRRACE-UK ID,
- Ethnicity,
- Planned and actual place of birth (Trust/Health Board),
- Birthweight,
- Gestation at delivery,
- Sex,
- Home address including postcode,
- Place and cause of death,
- Full clinical information relating to events surrounding the death.

Confidentiality Advisory Group Advice

Public Interest

The CAG agreed that the proposal defined a clear medical purpose in the study of perinatal deaths focussed outside of consultant-led obstetric units. It was agreed that the project was in the public interest as it may identify areas of improvement which may lead to prevention of similar deaths in the future.

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 discussed the rationale provided by the applicants around the feasibility of consent and it was agreed that the evidence supplied in respect of Northern Ireland, where there was no equivalent to COPI Regulations support to waive the common law duty of confidentiality, demonstrated that consent was not feasible for this project.

- Use of anonymised/pseudonymised data

The CAG acknowledged that the applicants had drawn on their experience within the main MBRRACE-UK audit to evidence why use of pseudonymised data was not possible for this enquiry. Members also agreed that with the issues that had been identified around the redaction of patient records being undertaken within the hospital sites. The Committee was satisfied with the rationale provided and accepted that the enquiry required access to confidential patient information.

Justification of Identifiers

Members were satisfied that the items of confidential patient information requested by the applicants were appropriate to enable sample identification, linkage and verification of data.

Patient and Public Involvement

The Committee commended the patient engagement which had been undertaken within the project as it was acknowledged that this was very comprehensive.

Patient Notification and Objection

The CAG acknowledged the draft material provided for the website around the enquiry; however, it was recommended that some revisions were made to ensure the language utilised in the notifications was in layman terms which was accessible to all readers.

Additional Points

The applicants had clarified ahead of the meeting that they intended to sample up to 50 sets of notes for each birth setting to ensure that approximately 35 eligible cases can be found for full panel review. Members considered this and it was noted that there was potential for the applicants to access a considerable number of additional records once the sample size had been achieved. The CAG acknowledged the applicant's explanation that there was evidence from the current audit that place of birth may have been inaccurately recorded, rendering some of the cases sampled ineligible as well as some case notes being incomplete; however, it was agreed that the applicants should cease the case notes review within each birth setting once the required sample has been reached, to complete the 100 overall case notes required for the enquiry.

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

Specific Conditions of Support

1. Support is extended to cover England and Wales only.
2. Support is extended to cover up to 100 samples across the three specified birth settings – once the sample size has been achieved within each cohort, up to the total cohort of 100 patients, no further records can be screened for eligibility.
3. Patient Notification Materials – review draft information for the website and revise language used to make this more accessible for a broader audience. Provide an update at the time of first annual review around the revisions which have been made.
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed in place as follows:**
   University of Leicester – The Infant Morbidity and Mortality Studies (TIMMS): EE133832/ECC0013 (hosted second use team/project), Version 13 (2015-16) reviewed satisfactory grade at 79% (with an improvement plan in place).
   University of Oxford – National Perinatal Epidemiology Unit: EE133863-8J017-NPEU (hosted secondary use team/project), Version 13 (2015-16) reviewed satisfactory grade at 100%.)

8. MINUTES OF THE MEETING HELD ON 12 JANUARY 2017

The minutes were agreed as an accurate record were received and signed as an accurate record of proceedings.

9. CAG CHAIR REPORT

Members received and noted the Chair's report.

10. CAG OFFICE REPORT

Operational update

Precedent set review

1. Update on progress and work

The purpose of the review is to clarify and update the Precedent Set Review Process in line with recent trends and developments, reflecting member feedback and responding to common themes and issues which have manifested in the applications recently submitted via the Precedent Set Process. The full review will be complete by March and will be presented at full CAG meeting or Away day for member feedback. Any CAG comments will be added and the documents taken to the Confidentiality advice Management Board for final approval before being published.

The review will comprise the following 3 documents:

1. Precedent Set Review Process for Members (internal document)
2. Precedent Set Review Process for Staff (internal document)
3. Precedent Set Review Process (external document).

The first document has been completed and circulated amongst the Chair team for comment. The document incorporated feedback given by members at the latest CAG Away Day, including the following:

1. The assessment form to be completed by the Confidentiality Advisor and sent to members with Precedent Set applications (***already actioned and being sent for all reviews****)*

2. Letters to be sent to members for a quality check of the recommendation given to applicants, prior to sign off by the approver **(*already actioned and being sent for all reviews)***
3. Clearer direction regarding the email discussion, particularly who should respond and when (***detailed within the document***)

2. BOSU and BPSU meeting with Dr Rachel Knowles.

A meeting was arranged by Dr Rachel Knowles between Dr Knowles, Dr Barny Foot and Rachel Heron, to discuss patient notification and public involvement.
The CAG had noted that applicants were assuming that patient notification could be done through BOSU, and that there was public involvement during review by the BOSU Committee.

Public involvement: It was confirmed that the BOSU Committee does not include lay members, although the scientific Committee which completes a review on behalf of BOSU does have one lay member. Mr Foot advised that BOSU studies are often funded by patient groups, however, and agreed that applicants could be advised to make this explicit in their applications.

Dr Knowles gave advice on processes followed by BPSU: the Committee includes 2 lay members who advise on further public involvement. As a minimum they require a patient group to be consulted, who would comment on the Protocol and patient notifications. BPSU also provide guidance to applicants on how to carry out public involvement work.

It was agreed that BOSU public involvement could be improved and some of these processes adopted.

3. Patient notification

There was some discussion about whether posters or leaflets would be appropriate for BOSU. Dr Foot thought that clinicians would become confused if sent the leaflet and would treat it as a patient information sheet and try to gain consent. This had happened previously, and interfered with complete ascertainment. Posters to be placed in surgery waiting rooms would be less open to misinterpretation. They would be seen by patients, as all patients with eye conditions would attend surgeries. Although clinics were dispersed and small, it was likely that patients would visit a large clinic at some point.

However, due to the number of studies, this would result in clinicians being sent a large number of posters to be placed in waiting rooms. A generic poster with a link to the website was considered; this could list the conditions currently under surveillance, avoiding the need for a study specific poster for each condition. Conditions under surveillance did change approx. every 3 months so it would need to be updated regularly.

It was agreed that guidance from CAG with regards to the acceptability of posters or leaflets would be useful.

Dr Foot advised that he would update the BOSU newsletter with details of patient notification to increase awareness amongst clinicians. It was also agreed that the possibility of sending posters or leaflets to secretarial staff rather than to clinicians could be explored.

4. Bespoke Process – surveys commissioned by CQC

The bespoke process is currently being developed with Dr Sophie Brannan, Ms Clare Sanderson and Dr Patrick Coyle. The intention is to establish a process which can be incorporated into normal Precedent Set review, in which all members participate. This process has been described up to now as the CQC survey process, however this is not correct given that the surveys are now run by Picker Institute Europe, which acts as data controller. This category will be appropriately named

during the Precedent Set Process Review, which should be complete towards the end of March 2017.

Two applications have been through this process so far, the most recent in December. The applications concern the provision of information from Mental Health Trusts to established contractors, for the purpose of mailing out questionnaires which ask patients about their experience of mental health services. No concerns were identified by the Sub-Committee.

A meeting was held by teleconference between Rachel Heron and the team at Picker Institute. The current process for review of the applications was explained and discussed. No issues were raised by Picker Institute. Applicants were asked to focus on making the applications concise and lay friendly.

5. Delivering education items via alternative methods

Members are aware that for education items, members are offered the opportunity, if they cannot attend in person, to join by teleconferencing facilities if the meeting is taking place via HRA offices. Early feedback mid 2016 indicated that at times, the connection can be intermittent and it can be difficult to hear all conversations. As the HRA is dependent upon the technical infrastructure provided, this was fed back and issues around the Lync system are regularly reported to aid resolution. A piece of initial work was undertaken by the HRA training team and systems administrative support to seek to trial alternative technical mechanisms for recipients to participate when these education items are being held e.g. recorded sessions. This activity was halted upon the Training team request as there were issues with contractual delivery and technical aspects. When the Training Team advise this can commence again this will be picked up accordingly.

6. Assessment training

As part of sharing information and seeking to maintain consistency, the advice team and Dr Mark Taylor delivered a short training session to the Assessment team, as part of their broader training event. We have generally found that research ethics committees have a strong understanding as to when an applicant should be directed to CAG, or are clear when to refer to CAG if unsure, but as Assessment is a new and evolving function it is important there is a consistent understanding. Various members of the assessment team have attended the CAG as part of the HRA Technical Talent Management programme however this was an ideal opportunity to provide a clear understanding of the CAG role and when it is and is not appropriate to refer applicants to CAG. It is a positive that members of the CAT team are dispersed in different locations as these enables HRA staff to seek advice, when necessary, in a timely manner. The training session was positively received and feedback indicated that the Assessment staff had requested further training and more time to be spent on the topic of CAG.

CAT Resources

An update was provided around staffing issues with the CAT team to make Members aware of pressures in relation to the management of current workload.

Social Care Applications – Terminology

Following the recent review and approval of a social care application, it was pointed out by the decision-maker that the terminology which was used within the standard conditions of approval, together with other set text within outcome letters was NHS patient-centric and did not account for social care service users. Revisions were made to the outcome letter in question to make the text appropriate to the social care environment of the project – for example, references to be patient identifiable information within the standard conditions and other template text was revised to read service user identifiable information. However, it was acknowledged that this issue would need to be addressed more formally moving forwards.

Meetings

The Research Data Board, which is attended by representatives from PHE, NHS Digital, CPRD and NIHR HIC. This Board was set up as a result of the Health Data Programme, which aims to bring data custodians together and streamline / improve the ways for requests for access to and dissemination of health data. Mr Bill Davidson and Ms Dunkley attended a meeting that arose as a sub-group to identify any constraints against undertaking data linkages and obtaining information from data custodians. The primary concern appeared to be accessing data from NHS Digital so discussions focused upon considerations NHS Digital take into account. There was some clarification required regarding the remit of the CAG however no issues were identified in relation to the process for seeking support via the CAG.

Clinical Practice Research datalink service

Due to changes in staffing, a meeting took place between the new Information Governance Manager and Ms Dunkley. The purpose of the meeting was to provide an update on current CPRD activities and following some queries from other CPRD staff where it appeared there had been a loss of knowledge as to what had been agreed with the CAG and CPRD processes where ISAC take the initial assessment of risks of identifiability.

HRA – advice and guidance

A meeting has taken place with internal HRA staff who manage the initial portal into the HRA, the general queries line. As this is a common entry point for applicants, work has been undertaken to ensure that those in charge of the advice line have a greater understanding of the issues CAG can consider and alternatives provided e.g. who is part of the care team. This has reduced the number of direct queries sent to the CAG mailbox, and work is taking place in parallel to work with the queries line to support the official correspondence provided.

Information Governance Alliance (IGA) conference.

Ms Dunkley attended the conference in order to support networking and to provide a physical presence on the stand in the event of queries regarding CAG. The conference was primarily designed for Caldicott Guardians and supporting staff. The HRA presented on a session relating to research and the development of information governance questions, undertaken by Dr Mark Taylor, that are intended to be integrated into IRAS. Dr Taylor's role in developing the IG questions was emphasised and hard copies provided to attendees. The majority of queries regarding the CAG were related to access to social care information and there was a notable presence from local councils.

Update on previous applications

1. 16/CAG/0129 – Metal on metal

There has been significant activity since this application was considered; namely caused by various parties becoming involved with limited current understanding of what had been requested in the application. The advice team engaged in a number of discussions with individuals and advisory groups as they had indicated they had been unable to obtain clarity from the applicant directly. There was some discussion following the initial CAG recommendation prior to the outcome being issued to the decision-maker. The primary issue was a misunderstanding that support cannot be applied to information already collected, and it appeared this is what the applicant sought. Further correspondence clarified that there was no intention to undertake further processing of the information already held, and no intention to link to additional data sources. As the applicant confirmed there would be no further disclosures and therefore no further breaches of confidentiality without consent, the applicant agreed to withdraw their application.

2. 16/CAG/0140 BAUS audits

Further to the review of the application 16CAG0140 – BAUS Audits, as agreed at the meeting on 31/10/16, a report was made directly to the ICO around the potentially unlawful processing by Dendrite on behalf of BAUS in connection with the audits, following an introduction of a new way of processing the audit information.

The report was submitted on 11/11/16 and acknowledged by the ICO on 16/11/2016. No further correspondence has been received from the ICO around the report; however, the applicants have shared correspondence to confirm they also reported the breach. The applicants provided an update in late January to explain that the ICO currently has a substantial backlog and as such, this case has not yet been allocated. The applicants confirmed they would provide updates as received.

Security Assurances Regarding Wales

Members should be aware that where entities are processing information within Wales, suitable security assurances are required. In England, this is demonstrated through satisfactory completion of the Information Governance Toolkit (this will be known as 'CareCERT Assurance' as its working name through the development and piloting phases). Welsh organisations complete the Caldicott Principles into Practice (CPiP). For various reasons, there has been a significant delay of approximately two years to move to the position where the CPiP assessment is accepted as an adequate security assurance mechanism. The CAG has not been responsible for progressing aspects of this development, but has been highly supportive of a resolution being reached. It has now been agreed between the relevant Welsh bodies and the Department of Health that a relevant CPiP assessment must be obtained to a standard of 91% - this is the standard that is indicated to be the equivalent of the current English Level 2 'satisfactory' standard. Bodies that are directly impacted are Public Health Wales. The NHS Wales Information Service (NWIS) is hosted by Velindre NHS Trust and has agreed to take responsibility for providing an external assurance review (similar to the role of NHS Digital in England). Some actions are resting with NWIS regarding provision of the actual process however, in light of this a letter confirming this approach was sent to the non-research approver and they have confirmed they are satisfied with this arrangement. This has enabled some national clinical audits to proceed in terms of the welsh flow of data a previously NHS Digital had refused to approve this dataflow without receiving confirmation of appropriate security assurance.

Confidentiality Advice Management Board

An internal management board has been established within the HRA that has remit for the Confidentiality Advice Service, which includes the CAG. The meeting is attended by representatives from functions including learning and guidance, assessment, policy and corporate services. This will be the forum to provide updates on KPI, business planning, risks and approval of relevant documentation and policies/procedures associated with the Service. Meetings take place on a monthly basis.

10. ANY OTHER BUSINESS

No other formal business was noted.

The meeting was closed.