Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group

August 2018

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1. APPLICATIONS

Group Members:

Name	*Present*	*Notes*
Ms Sophie Brannan	Yes	Lay Member
Dr Patrick Coyle	Yes	Vice Chair
Mr Andrew Melville	Yes	Lay Member
Mrs Diana Robbins	Yes	Lay Member
Mr Marc Taylor	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **HES and NICOR data linkage for cardiac failure population analysis**
CAG reference: **18/CAG/0102**
IRAS project ID: **232756**
REC reference: **18/LO/0614**

Context

Purpose of Application

This application from Kings College London set out the purpose of medical research which aims to understand population-based, patient-level analysis of heart failure in England over a five-year period using a data set created by linking HES and NICOR (National Institute for Cardiovascular Research Outcomes) databases. Analyses will look into the re-occurrence of hospitalisation after the initial diagnosis of heart failure, the influence of population factors on risk of re-hospitalisation and the resultant cost implications.

NHS Digital will be undertaking linkage between the NICOR (National Institute for Cardiovascular Outcomes Research) and HES databases and will provide a pseudonymised dataset to the applicant for analysis. The NICOR audit programme operates via support under the Regulations (application reference: 17/CAG/0071 (previously ECC1-06(d)/2011).

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

Confidential Patient Information Requested

Cohort

- All patients aged over 18 years old with heart failure in England between 2011 and 2016.
- Estimated sample size: 81,393.

The following items of confidential patient information are required for the purposes stated:

- NHS Number – Linkage,
- Sex – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

The Sub-Committee considered the applicant's written response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Further information is required to understand what items of confidential patient information will be released by NICOR to NHS Digital to facilitate the linkage. Evidence should be provided of agreement in principle from NHS Digital to this data linkage.**

The applicant confirmed that, in correspondence with NHS Digital and NICOR, it was clarified that at a minimum, only the NHS number is required to link HES data to the National Heart Failure Audit. Copies of the correspondence were provided for information purposes.

The Sub-Committee received the information and no further queries were raised in this area.

2. **Reconsider whether the fact of and date of death are required in order to achieve the study aims.**

The applicant clarified that information relating to patient death was not required as the project focussed on factors preceding rehospitalisation. Thus, patient death is not relevant as it will not precede a hospitalisation.

The Sub-Committee received the response and no further issues were raised.

3. **A revised application form should be provided which accurately reflects the study data flows which have been clarified above. Inaccurate references to the NICOR programme (audit and research) operating on a consented basis should be removed from the revised application form.**

A revised CAG application form was provided which removed in accurate references to the NICOR audit programme operating on a consented basis.

The Sub-Committee received the revised document and no issues were raised.

4. **Provide details of a revised plan of patient and public involvement and engagement activity which will be undertaken as the study progresses for consideration. Any activity in this area**

should provide an accurate description of the trial methodology and the use of confidential patient information in the production of the database which will be used for analysis.

The applicant confirmed that the post on the 'People in Research' website was amended and reposted. A further three new responses were received which all provided positive feedback on the ethics of the study – copies of the feedback were provided for information purposes. Respondents included one individual who had relatives that passed away due to heart failure, one individual with a family history of heart disease and one with a rare chronic illness (not specified).

It was also explained that contact was made with two respondents of the previous post and clarified the error in the original information provided. A revised study description was provided with amendments highlighted. From this, one reply was received from a previous respondent approving of the ethics for the study – a copy of the feedback was provided for information. The applicant explained that they would follow-up with the second respondent if they received a reply to the further correspondence.

The Sub-Committee received the response and whilst it was acknowledged that the individuals who responded to the website post were supportive of the project, the additional information provided was not a revised plan for further patient and public engagement and involvement as the project progressed. Members agreed that additional and wider activity would need to be undertaken in this area as the study progressed and it was recommended that this included patient representative groups. The CAG agreed to provide a recommendation of support to the project on the basis that feedback was given at the time of first annual review around the additional work which had been undertaken in this area, together with an overview of the findings.

5. **A copy of study-specific patient notification text, which will be displayed on the University website, should be provided for consideration. This should include a clear overview of the study, how confidential patient information would be used and link to the NICOR website.**

A study-specific patient notification text was provided for review. It was confirmed that this would be posted on the King's Technology Evaluation Centre (KiTEC) website and the University's departmental website. The text provided a clear overview of the study, defined the patient identifiers used for linkage, described the reporting plan and provided links to the HES and NICOR websites and how patients can opt out of the databases. Contact details were provided for the research centre and the PI with details of how to opt out of the study. It was confirmed that the information would be posted as soon as the project received full approval, in order to allow enough time for patients to opt out prior to NICOR providing the data to us.

The Sub-Committee reviewed the document and it was agreed that it contained technical language which may not be accessible to an average reader with no technical training. It was agreed that the wording of the document should be considered as part of the wider patient engagement plan and revised accordingly. Feedback around this activity, together with copies of the revised document should be provided to the CAG at the time of first annual review.

6. **Contact should be made with NICOR to explore the possibility of a study-specific dissenting mechanism. The outcome of this discussion should be shared, and any relevant documentation revised to include details of the objection mechanism, where appropriate.**

It was confirmed that a discussion was held with Mr James Chal (Chief Operating Officer at NICOR) by teleconference on the 27/07/2018, in which an approach for a study-specific dissenting mechanism was agreed.

The patient notification text will be published on the KiTEC and the departmental King's College London websites. The text explicitly states how to opt out from the study and NICOR data collection with email addresses at NICOR and KiTEC provided. The text will be uploaded to the websites as soon as full

approval is in place for the study. This is to ensure there is enough time for patients to opt out prior to the data being released by NICOR.

NICOR confirmed that the notification text would also be published on their website and were in the process of developing a public page for patients to view ongoing studies and all data access requests on their website with information on how to opt out. Copies of correspondence were provided for information purposes.

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 (Final)

1. Further patient and public involvement and engagement activity should be undertaken as the project progresses. It is recommended that this include consultation with a patient representative group. Feedback around the actual activity undertaken together with an overview of the findings is required at the time of first annual review. If the responses given are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.
2. The patient notification text should be revised to make the language more accessible to lay reader. Feedback should be sought as part of the wider patient and public involvement and engagement activity. A copy of the revised text should be provided at the time of first annual review, together with an overview of the work which had been undertaken in its revision.
3. Favourable opinion from a Research Ethics Committee (**Confirmed – 19 April 2018**).
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – NHS Digital undertaking data processing**).

Group Members:

Name	*Present*	*Notes*
Dr Lorna Fraser	Yes	
Dr Harvey Marcovitch	Yes	
Ms Clare Sanderson	Yes	Alternate Vice Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **National Cancer Patient Experience Survey 2018 (CPES)**

CAG reference: **18/CAG/0107**

Context

Purpose of Application

This application from NHS England set out the purpose of administering patient surveys to evaluate services provided to cancer patients in 2018. This would enable comparisons between Trusts, for commissioners, providers and patients (all of whom could access the published results), would allow for monitoring of improvements in services, drive further improvements, and provide NHS England with an up to date overview of cancer patient experience across England.

The survey methodology and data transfer arrangements remain unchanged since 2011. Quality Health would request a list of eligible patients from participating Trusts, and would mail out surveys to patients after removing duplicates and checking to ensure no surveys were sent to the addresses of deceased patients. Quality Health would then anonymise the data.

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

Confidential Patient Information Requested

Cohort

- All adult patients (aged 16 and over), with a primary diagnosis of cancer, who have been admitted to hospital as inpatients for cancer related treatment, or who were seen as day case patients for cancer related treatment, and have been discharged between 1st April 2018 and 30th June 2018 will be invited to participate in the survey.

The following items of confidential patient information are required:

- Name – survey distribution,
- Address – survey distribution,

- Postcode – survey distribution and analysis (translated to index of multiple deprivation,
- Treating site – survey distribution,
- NHS number – sample validation,
- Date of birth – sample validation and analysis
- Sex – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Feedback from the Picker Institute Europe review of the Cancer Patient Experience Survey should be provided for review before a final recommendation for the application would be issued. If the delay pending the report of these outcomes would be detrimental to the facilitation of the survey, a strong rationale should be provided to explain how and why this would impact the programme for consideration by the Group.**

A copy of the Picker Institute National Cancer Patient Experience Survey (NCPES) review report was provided, together with a detailed covering report from the applicant explaining how the five key findings of the review had been addressed. An overview of the 2017 NCPES helpline activity was also provided for information purposes.

The Sub-Committee received the documentation with interest and were assured that no further action was required at this stage.

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 for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support (Final)

1. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Quality Health show a reviewed satisfactory grade on Version 14.1, 2017/18**).

Group Members:

Name	*Present*	*Notes*
Dr Malcolm Booth	Yes	
Dr Patrick Coyle	Yes	Vice Chair
Mr Anthony Kane	Yes	Lay Member
Professor Jennifer Kurinczuk	Yes	
Mr Marc Taylor	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Mechanisms of Change in Psychological Therapy**
CAG reference: **18/CAG/0014**
IRAS project ID: **225649**
REC reference: **17/SC/0204**

Context

Purpose of Application

This application from Royal Holloway University of London sets out the purpose of medical research to examine the relationship between cognitive change and symptom change during psychological therapy for people with symptoms of depressive and anxiety disorders. It is expected that the study will find that a change in a client's attitudes and beliefs will be associated with symptom change during psychological therapy, and that changes in cognition will occur before changes in symptoms. Data will be collected from clients receiving individual psychological therapy in City & Hackney Improving Access to Psychological Therapies (IAPT) service and the 'Let's Talk' IAPT service, Barnet, Enfield and Haringey Mental Health NHS Trust. Data from 200 participants will be required to examine the relationship between cognitive change and symptom change.

The project had originally been designed in such a manner that the IAPT therapists (direct care team) would identify potential participants; however, issues with recruitment were encountered which led to eligible patients not being invited to participate. The revised process proposes the main applicant review's patient medical records to identify potential participants and provide details to the team administrators, to enable participant information materials to be passed to the patients when they attend for their appointment or posted to them with their assessment letter.

A recommendation for class 1, 3 5 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

- Male/Female patients over 18 years of age,
- Clients who are receiving individual psychological therapy from City and Hackney IAPT service and the 'Let's Talk' IAPT service, Barnet, Enfield and Haringey Mental Health NHS Trust,
- There will be 120 patients recruited to the study (33 have already been successfully recruited, 87 further participants are required). It is estimated that access to 380-400 patient records will be required in order to achieve this recruitment target.

The applicant will need access to the full patient record in order to determine which patients are eligible for inclusion in the study. The following data items are required for the purposes as set out below:

- Patient Name – to allow invitation to participate to be provided,
- Therapist's Name – to allow invitation to participate to be provided,
- Date of Appointment – to allow invitation to participate to be provided,
- Gender – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group Advice

A Sub-Committee of the main CAG considered the written response to the request for further information detailed within the provisionally supported outcome in correspondence. This response was supported by an amendment request, which sought to change the main applicant (Chief Investigator) for the project – it was agreed that this amendment request would be considered together with the response to the provisionally supported outcome.

Amendment Request

The amendment sought to change the main applicant detailed on the project. Ms Iona Symington would become named Chief Investigator on the proposal and would be supported by Ms Justine Kinney. Dr Dorothy King, previously named main applicant, had completed her aspect of the overarching research project and provided a letter confirming she was relinquishing her duties in relation to the proposed application.

The Sub-Committee considered the amendment to the application. It was acknowledged that the reviewing Research Ethics Committee had undertaken an assessment of the suitability of the proposed replacing Chief Investigator to take forward the proposal. Confirmation of the REC Favourable Opinion in relation to the change of Chief Investigator was confirmed on 01 June 2018.

The Sub-Committee agreed that consideration the proposed amendment alongside the written response to the provisionally supported outcome was the most appropriate handling route and was content to provide a recommendation of support to the amendment and change to main applicant.

The below response was provided by the newly appointed main applicant to the request for further information detailed in the provisionally supported outcome.

1. Provide confirmation of which organisation is acting as controller for the project.

It was confirmed that Royal Holloway, University of London was the controller for the application activity. The Doctoral Thesis associated with the application activity was taking place at this institution.

The Sub-Committee received the clarification and no further issues were raised in this area.

2. **Patient and Public Involvement and Engagement – further information is required in this area to address the following points:**

a. **Provide details around the service group attendance to discuss the revised recruitment strategy, including an overview of how many people attended,**
b. **Provide details of the feedback provided by the attendees in relation to the proposed change to the project's recruitment strategy,**
c. **If the responses given were negative, the CAG would take this into account when considering whether support should continue, or whether further actions are necessary.**

It was explained that individuals associated with the proposal had attended three service user meetings at City and Hackney IAPT. Four service users attended the first meeting, with one service user being present at the following two attendances.

The general sense is that the service user feedback falls into two categories: (1) those who do not wish anyone but their therapist to have access to any identifying information and (2) those who accept limited use of identifying information insofar as it is necessary to facilitate data collection, once this has been explained.

Furthermore, in the final service user meeting, the relevance of GDPR regarding service-related research was discussed. The service user who attended explained that she did not see a problem with DClinPsych trainee staff having access to patient's name and problem descriptor in order to identify clients who may be interested in relevant research. It was explained that this is required due to clinician staff being very busy. It was also highlighted that this is all the data that the trainee staff would be able to access, and attendee agreed to this.

The Sub-Committee received the response and no further issues were raised in this area.

3. **Patient Notifications and Dissent – further information is required in this area to address the following points:**

a. **Provide a copy if the letter which will be included by the Trust in routine appointment letters to inform patients of potential access to medical records outside the direct care team to facilitate research activities for consideration,**
b. **Confirm why it is not possible to check patient records for evidence of historic dissent.**

It was explained that patient notification was not routinely provided within the participating sites at present. The applicant advised that they were working on the process of implementation of this procedure in co-ordination with the services involved. It was proposed that a slip of coloured paper within appointment letters which stated: "This service is actively involved in research to improve services provided. This can sometimes involve temporary and restricted access to personally identifying information. If you do not wish for your information to be accessed in this way, please tick this box and return this slip to the service". It was further explained that as historically the services involved with the proposal, did not have an established system to enable patient objections to be raised, this had not been previously recorded so there were no historic records to be checked.

The Sub-Committee received the response and agreed that the proposed system to enable patient dissenting was proportionate to the proposed activity and no further issues were raised in this area.

Confidentiality Advisory Group Advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support.

Specific Conditions of Support (Final)

1. Favourable opinion from a Research Ethics Committee **(Confirmed – initial approval issued 20/04/2017, Change in Methodology 22/11/2017 and Change of Chief Investigator 01/06/2018).**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed - Barnet, Enfield and Haringey Mental Health NHS Trust and Homerton University Hospital NHS Foundation Trust, V14.1, 2017/18 by email 16 August 2018).**

Group Members:

Name	*Present*	*Notes*
Ms Sophie Brannan	Yes	Lay Member
Dr Tony Calland MBE	Yes	Chair
Mrs Diana Robbins	Yes	Lay Member

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **The ACUTE (Ambulance CPAP: Use, Treatment Effect and Economics) feasibility study: A pilot randomised controlled trial of prehospital CPAP for acute respiratory failure**
CAG reference: **18/CAG/0094**
IRAS project ID: **201429**
REC reference: **16/YH/0406**

Context

Purpose of Application

This application from the University of Sheffield set out the purpose of medical research which aims to assess whether it is possible and worthwhile to undertake a full-scale study comparing continuous positive airways pressure (CPAP) delivered by paramedics to standard oxygen treatment for acute respiratory failure, and if so, how this trial should be carried out. The trial will also determine whether there are sufficient patients presenting with acute respiratory failure to make a large scale trial investigating the effectiveness of CPAP feasible. Evidence will also be collected to demonstrate that it is possible to randomise patients, collect data and follow up patients with acute respiratory failure in any future definitive trial.

The trial will be carried out within the West Midlands Ambulance Service. Paramedics will identify adults with acute respiratory failure when attending 999 emergency calls. The aim is to include 120 participants in the study – half will be randomly assigned to a group that will receive CPAP, while the other half will be treated with standard oxygen therapy. All the patients will then undergo normal hospital treatment and be followed up for a month to see if they survive. Patients will be recruited to the trial under emergency research procedures, whereby verbal consent will be sought from those patients with capacity to provide this. Patients who are assessed as without capacity to consent will be included within the trial without a verbal approach for consent. After arrival in hospital, research paramedics will approach patients, in order to seek informed consent for their continued involvement in the study. If the patient does not regain capacity, advice will be sought from a personal or nominated consultee around the patient's ongoing participation in the trial.

The trial has already begun recruitment; however, it was found that some patients were not well enough to be approached for consent about the study and subsequently died before this approach could be made. The rationale for the submission to the CAG is that the applicants are seeking support to access

confidential patient information for patients who were enrolled in the trial, but died in hospital prior to an approach being made around consent into the trial. The trial steering committee agreed that data in relation to this cohort of patients was important for the safety analysis of the study findings.

No confidential patient information will be recorded in relation to these patients; however, the research paramedics will require access patient's medical records in order to extract relevant clinical information for analysis.

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

Confidential Patient Information Requested

Cohort

The cohort to be included in the trial is as follows:

- Adults aged over 18 years with acute respiratory distress, identified by paramedics responding to 999 calls.
- The sub-cohort of patients of relevance to the CAG application is those who were enrolled in the trial, but died in hospital, prior to being approached for informed consent for their participation.

The research paramedic will have access to the full hospital record of the patient in order to extract the data relevant for analysis. The following items of confidential patient information are requested for the purposes of the identified:

- Name – to identify enrolled patients in hospital records systems,
- Date of death – recorded in days since admission – analysis
- Sex – analysis.

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's written response to the request for further information in correspondence.

1. **Provide further information around the contact which is made with patients who are discharged from hospital prior to consent to participate in the trial being taken – under what legal basis is confidential patient information processed in order to facilitate this approach for consent. If support under the Regulations is required to extend to this activity, this would need to be appropriately described in the application.**

The applicant explained that when patients were discharged from hospital, before the Research Paramedic has conducted the consent visit, the Research Paramedic would only use ambulance service data (from West Midlands Ambulance Service/WMAS) to contact the patient in the community. As the Research Paramedics are part of WMAS and therefore a member of the direct care team, they would have access to this patient data as part of their clinical role. In these circumstances the Research Paramedics would not access any Hospital Trust data to contact the patient in the community.

The Sub-Committee received the clarification and no further issues were raised in this area.

2. **Provide copies of the patient notification posters which would be displayed in the Trust A&E and Ambulance Trusts for consideration.**

A copy of the ACUTE Trial notification posters to be displayed in Hospital A&E's and Ambulance Trusts was provided for consideration.

The document was received by the Sub-Committee, which raised no further issues in this area.

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 (Final)

1. Favourable opinion from a Research Ethics Committee (**Confirmed – Favourable Ethical Opinion for Substantial Amendment 4, 20 August 2018**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – V14.1, 2017/18 reviewed satisfactory grade by NHS Digital email on 09 August 2018 for the following organisations:**

- University Hospital of North Midlands NHS Trust – RJE,
- Burton Hospitals NHS Foundation Trust – RJF,
- The Royal Wolverhampton NHS Trust - RL4,
- Heart Of England NHS Foundation Trust - RR1,
- East Cheshire NHS Trust – RJN,
- University Hospital Birmingham NHS Foundation Trust – RRK,
- Sandwell and West Birmingham Hospitals NHS Trust – RXK,
- University Hospitals Coventry And Warwickshire NHS Trust – RKB,
- George Eliot Hospitals NHS Trust – RLT.
- Derby Teaching Hospitals NHS Foundation Trust – RTG (Confirmed at initial review).

Group Members:

Name	*Present*	*Notes*
Dr Tony Calland MBE	Yes	Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **2018 Urgent and Emergency Care Survey**

CAG reference: **18/CAG/0110**

Context

Purpose of application

This application from the Picker Institute Europe set out the purpose of carrying out the 2018 Urgent and Emergency Care Survey, sponsored by the Care Quality Commission. The findings of the survey are used by NHS Trusts and CCGs to facilitate local improvement, by the CQC as part of its regulatory activities and to support other relevant functions and will be shared in a non-identifiable format with NHS England, the Department for Health and Social Care and wider NHS Organisation to gain understanding of patients' experiences of NHS services and to drive improvements to them.

The 2018 survey will be the seventh carried out to date. The title of the survey has been revised for this year's proposed survey (from the previously titled 2016 Emergency Department Survey) to reflect changes in terminology and increased focus on urgent care as well as emergency care. All emergency department surveys prior to 2016 included patients attending Type 1 services only. The sampling approach was changed in 2016 to include Type 3 services. Broadly, these services are defined as:

- Type 1 - A major, consultant-led A&E department with full resuscitation facilities operating 24 hours a day, seven days a week.
- Type 3 - Other A&E / minor injuries unit / urgent care centre treating minor injuries and illnesses. Can be doctor or nurse-led and accessed without an appointment.

Participating Trusts will be asked to begin preparations for the patient sample to be drawn in September 2018. Confidential patient information will be shared with the approved contractors facilitating the survey to enable the standardised to be followed across the full programme of activities.

Some minor changes to the study methodology are proposed for the 2018 survey as follows:

- A separate survey questionnaire is under development for patients who attended a Type 3 Department (Urgent Care Department),
- The sample size for patients attending a Type 3 Department has been increased from 300 to 420 to enable benchmarking across Trusts. This is in addition to the 950 patient sample for Type 1 Department attendances (Emergency Department), as per the 2016 survey. For Trusts without a Type 3 Department, the sample size for Type 1 Department attendances will remain at 1250, as per the 2016 survey.

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

Confidential Patient Information Requested

Cohort

- People aged 16 and over who attended a Type 1 emergency department in September 2018 or a Type 3 urgent care department in September 2018. Trusts will be instructed to contact the Survey Coordination Centre if they are unable to draw the required sample size from their Type 3 department in which case they will be instructed to also sample back to August 2018.

The Sampling Instructions will ask Trusts to exclude:

- deceased patients,
- children or young persons aged under 16 years at the date of their attendance at the emergency department,
- any patients who are known to be current inpatients ,
- planned attendances at outpatient clinics which are run within the Emergency Department (such as fracture clinics),
- patients without a UK postal address,
- patients attending primarily to obtain contraception (e.g. the morning after pill), patients who suffered a miscarriage or another form of abortive pregnancy outcome whilst at the hospital, and patients with a concealed pregnancy*,
- any patient known to have requested their details are not used for any purpose other than their clinical care,
- any patients who were admitted to hospital via Medical or Surgical Admissions Units and therefore have not visited the emergency department,
- For the type 3 sample, any services which are mainly or entirely appointment-based.

*As per 2016, Trusts will be advised to check ICD-10 codes, or obstetric or gynaecology codes. If the use of these codes will not enable identification of women who should be excluded, the Trust would then be required to check notes on their records to ascertain reason for attendance.

Administration of the 2018 Urgent and Emergency Care Survey requires NHS trusts to share two distinct sets of information with their approved contractor:

The **mailing file** is used to address questionnaires to the appropriate person. It contains:

- A standardised unique identifier code,
- Title (Mr, Mrs, Ms, etc.),
- First name,
- Surname,
- Address Fields,
- Postcode.

The **sample file** is 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. This file contains:

- The unique identifier code (as above),
- Date and time of attendance,
- NHS Site code,

- Department type (Type 1 or Type 3),
- Ethnicity,
- Gender,
- Year of birth,
- CCG code.

The two sets of information listed above will be submitted by participating Trusts to approved contractors as one file. Approved contractors will split the data out and only the sample data will be provided to the Survey Coordination Centre to enable centralised checks on the appropriateness of samples drawn. The Survey Coordination Centre does **not** receive any names or full addresses.

Confidentiality Advisory Group advice

The Chair considered the below response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Provide copies of the finalised poster and flyer, together with any wider patient-facing documentation which has been revised, which will be used within the 2018 survey programme for consideration.**

The applicants provided finalised dissent posters, one for Type 1 departments and one for Type 3 departments. It was also explained that, since the initial submission of the application, it had been confirmed that both posters will be developed in the nine other most commonly spoken languages in England, which were currently under development. Trusts would be required to display the posters in English in all the relevant areas. Those in other relevant languages would be displayed alongside the English-text version.

The applicant also explained that it had been decided to remove the CQC flyer from the first and third mailing packets following the Community Mental Health 2018 pilot where the CQC flyer was found to add no benefit on the overall response rate and potentially impacts response rate negatively for patients age 18 to 35. It was clarified that all of the information on the CQC flyer was already included on the covering letters meaning patients would still receive all relevant information. The removal of the CQC flyer would also reduce paper waste and cost; therefore it was felt that removing it from the mailing was the best direction moving forward considering it had no statistical benefit to the survey. Due to the removal of the CQC flyer, it had not been included as an attachment with the response.

In addition to the above clarifications, the applicant explained that additional patient-facing documents had been updated and developed since the initial application and had been included as part of the response to the provisional outcome letter. This included the following documents that had since finished three rounds of cognitive testing and were in the process of sign off:

- UEC18_Type 1 First Covering Letter_V1,
- UEC18_Type 1 Second Covering Letter_V1,
- UEC18_Type 1 Third Covering Letter_V1,
- UEC18_Type 3 Frist Covering Letter_V1,
- UEC18_Type 3 Second Covering Letter_V1,
- UEC18_Type 3 Third Covering Letter_V1,
- UEC18_Type 1 Questionnaire_V1,
- UEC18_Type 3_Questionnaire_V1,
- UEC18_Sampling Instructions_V1,
- UEC18_Survey Handbook_V1.

The Chair received the response and supporting documentation. The rationale for the removal of the CQC leaflet was noted. No further issues were raised in this area.

2. **Trusts should be advised to include a postal address to facilitate patient objection where possible – confirm that this guidance has been disseminated to participating Trusts.**

The applicants clarified that the dissent posters had been developed to include space and specific guidance on including a postal address where available (see both Type 1 and Type 3 dissent posters attached). Once these are published on the NHS Surveys website, an email would be sent to survey leads at all participating Trusts announcing the availability of the posters and providing instructions on where, when and how to display them. This will be the first opportunity to directly inform Trusts to include a postal address if available. The applicant also planned to include this information in the UEC Survey Trust webinar where all participating Trusts would be invited to attend an hour long presentation on changes made to the survey and specific Section 251 requirements.

The Chair received the response and noted that participating Trusts should be strongly advised to include a postal address as a means of raising objection to inclusion in the survey.

Additional Point – Faster Distribution of Reminder Letter

The applicant also advised of a change to the methodological approach for the sending of the three mailings to patients as part of the provisional response. It was proposed to reduce the timeframe between the first, initial mailing and the second mailing (first reminder letter) from 10 days to 5 working days. This follows a methodological pilot which was undertaken alongside the 2017 Adult Inpatient Survey. For this pilot, the impact of reducing the time gap between the first and second mailing on overall response rates was investigated. This pilot found that there was a significant increase in response rate of 3 percentage points when the time gap was reduced to 5 days between these mailings, compared to the advised 10 days (current methodological approach). This modification to the timing of the mailings has been confirmed with both NHS Trusts who participate in the survey, and the approved contractors who implement the survey on behalf of some of the trusts. It was clarified that this modification did not constitute a change to the information being provided by the Trust for the purpose of mailing nor did it introduce a change to the data flow of information or increase the number of contacts made with patients. This change will only result in a change to the timings of mailings. As per usual, Trusts will be required to conduct local checks for deceased patients prior to the second mailing (as is standard on the programme).

The Chair received the additional information and recognised that this change was also proposed and supported in relation to the 2018 Adult Inpatient Survey (18/CAG/0098) and content to provide a recommendation of support to this revised methodology here also.

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 for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support (Final)

1. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Version 14.1, 2017/18 satisfactory reviewed grade for the following organisations: Picker Institute Europe, Quality Health, Patient Perspective, Capita Business Services Ltd. and Member Engagement Services**).

2. NEW AMENDMENTS

Group Members:

Name	*Present*	*Notes*
Ms Clare Sanderson	Yes	Alternate Vice Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Use of administrative data for the evaluation of gynaecological cancer care services in England**

CAG reference: **16/CAG/0028**

Context

This application from Clinical Effectiveness Unit set out the purpose of this service evaluation to develop valid, clinically relevant, methodologically rigorous and technically robust performance indicators to access the quality of gynaecological cancer care in England.

The applicant wished to examine the potential of using linked Cancer Registry (CR), Hospital Episode Statistics (HES) and Office for National Statistics (ONS) data to describe the pattern of care on women diagnosed with gynaecological cancer in England, including the treatments they receive and their outcomes in terms of complications, readmissions and mortality. With this linked dataset the applicant will be able to determine how successfully these performance indicators could be used to compare quality between different levels of care including;

- Regional level/Cancer networks
- Hospital provider
- Individual consultant (e.g. surgeon level)

A recommendation for class 4, 5 and 6 support was requested to cover access to an extract of linked patient level cancer data from the Public Health England (PHE) Office of Data Release (ODR).

<u>Confidential patient information requested</u>

The applicant was requesting an extract of linked patient level cancer data from the Public Health England (PHE) Office of Data Release (ODR) which will include the date of death.

Amendment request

This amendment was submitted to seek an extension to the duration of support under the Regulations through to 31 December 2020. Due to delays experienced during data extraction and processing, the data sets required for analysis were not received until January 2018.

Confidentiality Advisory Group Advice

The amendment was considered by the Alternate Vice-Chair, who recognised the delays which had been experienced in the early part of the project. The extension to support would enable the applicants to complete analysis in line with the originally supported application. The Alternate Vice-Chair was content to provide a recommendation of support to the amendment.

Confidentiality Advisory Group conclusion

In line with the considerations above, the Alternate Vice-Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission (**Confirmed – The Royal College of Surgeons of England – satisfactory reviewed grade on V14.1, 2017/18**).

Group Members:

Name	*Present*	*Notes*
Ms Clare Sanderson	Yes	Alternate Vice Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **National Chronic Kidney Disease Audit**
CAG reference: **17/CAG/0058**
IRAS project ID: **219521**
REC reference: **17/LO/0049**

Context

Purpose of Application

The National Chronic Kidney Disease Audit (NCKDA) collected between 2014-2016 data from 1057 general practices in England and Wales on testing of patients at risk of chronic kidney disease, as well as the identification and management of patients with chronic kidney disease. This non-research application is covered under reference CAG 6-07(c)/2013.

This current application requested support to allow the data to be used in future research of long term outcomes of audit participants after the audit ends, as otherwise the data would need to be deleted. The application requested support to transfer existing stored data which is currently held by Informatica. Anonymised clinical data will be stored at the London School of Hygiene & Tropical Medicine. Identifiable data (e.g. NHS numbers) will be stored separately in the secure data haven at the University College London. Future data on the outcomes (e.g. hospitalisations, deaths, heart disease, acute kidney problems in the context of other illness, complete kidney failure with need of dialysis) of patients who provided data for the audit will be collected by linking the NHS numbers to clinical records held in other databases in the coming years, thus forming a large cohort study on outcomes and health needs of patients at risk of or with chronic kidney disease in primary care.

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

Confidential Patient Information Requested

The data set will include the following items of confidential patient information:

- NHS Number – to be stored at UCL separately from the clinical dataset, which will be held at LSHTM – to be used for data linkage,
- GP Practice Codes/CCG codes – to be stored at UCL and utilised to calculate deprivation scoring and undertake geographical analysis,
- Gender – retained to validate data linkage at LSHTM,
- Ethnicity – for analysis – to be stored at LSHTM.

The cohort is already established from the existing audit programme and contains data from 1,057 GP practices in England and Wales.

Amendment request

This amendment was submitted to seek support to reduce the flow of confidential patient information from the UK Renal Registry (UKRR) to the National Institute for Cardiovascular Outcomes Research (NICOR), hosted by Barts Health NHS Trust. The existing data flow supported the transfer of the complete UKRR dataset to NICOR. The amendment proposed reducing the dataset disclosed to NHS Number and UKRR pseudo-identifier.

Confidentiality Advisory Group advice

The amendment requested was considered by the Alternate Vice-Chair who recognised that the proposed data flow reduced the flow of confidential patient information to facilitate linkage. No issues were identified with the proposed amendment and support was recommended.

Confidentiality Advisory Group conclusion

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

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission (**Confirmed – University College London, School of Life and Medical Sciences and Barts Health NHS Trust – satisfactory review grade on V14.1, 2017/18**).
2. Confirmation of a favourable opinion from a Research Ethics Committee (**Confirmed – 17 July 2018**).

Group Members:

Name	*Present*	*Notes*
Dr Tony Calland MBE	Yes	Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Study title: **National Prostate Cancer Audit**

CAG reference: **CAG 8-03(PR9)/2013**

Context

Purpose of application

This application refers to a collaborative prostate cancer audit which is part of the Healthcare Quality Improvement Partnership programme looking at treatment and outcomes for all patients. The application detailed the linkage of the HES dataset already held by the Royal College of Surgeons (PIAG 2-07(i)/2004 Audit of outcomes after surgical procedures using linked HES data and ONS mortality data) to cancer registry data held by Public Health England using the Health and Social Care Information Centre's date linkage service.

Amendment Request

The amendment sought support for an extension to the duration of support which was in place for the Prostate Cancer Audit. The audit will collect data on a continual basis from 01/07/2018. The audit is delivered under contract to Healthcare Quality Improvement Partnership (HQIP). Support is requested on an ongoing basis and the data will be retained for the duration of time that a contract remains in place and where there is no change in data controller or data processors. The Royal College of Surgeons was successful in recent retendering process to continue to provide the audit as commissioned by HQIP.

Confidentiality Advisory Group advice

The amendment request was forwarded to the Chair, who recognised that the audit remained in the public interest. The Chair was content to provide a recommendation of support on an ongoing basis under the current contractual arrangements. The applicants were reminded that any change to the controller or processor arrangements for the delivery of audit in future would need to be submitted for consideration by the CAG.

Confidentiality Advisory Group conclusion

In line with the considerations above, the Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission (**Confirmed – Royal College of Surgeons, V14.1, 2017/18 reviewed grade of satisfactory**).

Group Members:

Name	*Present*	*Notes*
Dr Tony Calland MBE	Yes	Chair
Ms Clare Sanderson	Yes	Alternate Vice Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Non-Hodgkin's Lymphoma in Young Adults**

CAG reference: **ECC 7-05(c)/2011**

Context

Purpose of application

This application refers to a collaborative prostate cancer audit which is part of the Healthcare Quality Improvement Partnership programme looking at treatment and outcomes for all patients. The application detailed the linkage of the HES dataset already held by the Royal College of Surgeons (PIAG 2-07(i)/2004 Audit of outcomes after surgical procedures using linked HES data and ONS mortality data) to cancer registry data held by Public Health England using the Health and Social Care Information Centre's date linkage service.

Amendment Request

The amendment sought support for an extension to the duration of support which was in place for the Prostate Cancer Audit. The audit will collect data on a continual basis from 01/07/2018. The audit is delivered under contract to Healthcare Quality Improvement Partnership (HQIP). Support is requested on an ongoing basis and the data will be retained for the duration of time that a contract remains in place and where there is no change in data controller or data processors. The Royal College of Surgeons was successful in recent retendering process to continue to provide the audit as commissioned by HQIP.

Confidentiality Advisory Group advice

The amendment request was forwarded to the Chair, who recognised that the audit remained in the public interest. The Chair was content to provide a recommendation of support on an ongoing basis under the current contractual arrangements. The applicants were reminded that any change to the controller or processor arrangements for the delivery of audit in future would need to be submitted for consideration by the CAG.

Confidentiality Advisory Group conclusion

In line with the considerations above, the Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission (**Confirmed – Royal College of Surgeons, V14.1, 2017/18 reviewed grade of satisfactory**).