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Dear Dr Moonesinghe

Application title:	**Epidemiology of Critical Care provision after Surgery (EpiCCS)**
CAG reference:	**16/CAG/0087**
IRAS project ID:	**154486**
REC reference:	**TBC**

Thank you for your research application, submitted for approval under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process patient identifiable information without consent. Approved applications enable the data controller to provide specified information to the applicant for the purposes of the relevant activity, without being in breach of the common law duty of confidentiality, although other relevant legislative provisions will still be applicable.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Health Research Authority on whether an application should be approved, and if so, any relevant conditions. This application was considered at the CAG meeting held on 13 July 2016. This letter should be read in conjunction with the letter dated 21 July 2016

Health Research Authority approval decision

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

1. The application is approved, subject to compliance with the standard and specific conditions of approval.

Context

Purpose of application

This pilot study is to explore how clinicians determine the risk of death in clinical practice and whether these risk estimates are accurate. Data will be collected on all patients undergoing surgery requiring overnight stay in hospital in participating UK hospitals for one week. The researchers will measure complications in these patients. In a sub-group of patients, the quality of recovery after surgery (e.g. ability to self-care, mobility etc) will also be recorded on day 3. The researchers will learn about if and when patients die after surgery through linkage to national databases held by the Department of Health.

This application from University College London set out the purpose of describing the rates and reasons for patients being admitted to critical care after inpatient surgery in the UK. A secondary aim is to estimate whether postoperative critical care admission is associated with patient benefit (a reduction in postoperative complications).

A recommendation for class 4 and 6 support was requested to support the processing of identifiable data for the purpose of data-linkage.

Confidential patient information requested

Access was requested to:

- Patient name
- Date of birth
- NHS number
- Sex
- Postcode

At the time of data-entry onto the EpiCCS webtool, confidential patient information will be retained and stored securely in their original format within the database, however different database access privileges (dependent on usernames and passwords) will apply to different users of the database:

- Local investigators within NHS Trusts will have access to their own full datasets, including patient identifiable information.
- The central EpiCCS study team will only have access to an anonymised dataset for analysis. Among the patient identifiers, only sex will be used for analysis. In this dataset the NHS number will be replaced by a unique study patient identifier; Date of Birth will be converted to Age on date of surgery, and trimmed to month and year of birth; Postcode will be converted to PCT, SHA of residence, and the Office for National Statistics Lower Super Output Area, which allows the allocation of the Index of Multiple Deprivation.
- The data custodian will extract the required patient identifiable data from the study database onto a password protected Excel spreadsheet, and email this securely to the HSCIC to perform data linkage.

Confidentiality Advisory Group advice

Public interest

Members agreed that studies of this type were potentially in the public interest.

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 group was content that seeking consent might introduce bias into the dataset and that would not be reasonably practicable to seek consent from the entire cohort.

- Use of anonymised/pseudonymised data

Members were satisfied that identifiable data was required to perform the linkage requested and for the analyses set out in the application.

Justification of identifiers

The members were unclear exactly which data items were required for linkage. The applicant should provide a justification for each data item required.

Exit strategy

The members noted that identifiable data would be retained within the database, with different levels of access granted; they were unclear how long it was proposed to retain this data and what, if any, exit strategy was proposed.

Patient and public involvement (PPI)

Members felt that much greater efforts could have been made to involve patients and members of the public. In particular, CAG would have liked to have heard the views of patients and the public in relation to whether patient notification and/or opt out was appropriate. The applicant will need to evidence that this has taken place and any suggestions with regards to the study design before CAG can recommend support.

Patient notification and objection

Members were concerned that notification and opt out on the day of the surgery might not be appropriate as patients would be more concerned with impending surgery than the details of the study. They also expressed a concern that this model could, potentially, be coercive, as patients might worry as to whether the decision to opt out would impact on the care they received. Members noted that many of them would attend a pre-op meeting, and questioned whether providing the notification at this point would be more appropriate – subject to the outcomes of the PPI, as above.

Subject to the same provisos with regards to patient notification, members recommended that, in drafting such materials, the applicant refer to the HRA style guide (http://www.hra-decisiontools.org.uk/consent/) & the ICO notifications guidance (https://ico.org.uk/media/for-organisations/documents/1610/privacy_notices_cop.pdf).

Members also noted that the information provided was unclear at points. The data processors should be set out, and the reference being unable to link an individual to their data would be clearer were it rephrased to say that none of the data would be identifiable.

The group did not consider it reasonable to provide opt out via e-mail for patients who would be confined to a hospital bed. Alternatives, such as being able to express dissent to their clinicians, should be explored. If no other alternatives are reasonably practicable, a full justification should be provided.

Finally, and also subject to the outcomes of the PPI, members agreed that opt out should be arranged so that the data did not leave the trust in which care was provided. Justification should be provided if this is not reasonably practicable.

Additional points

Members queried whether, as described in the application, the patients would, in every instance, be seen by the anaesthetist on discharge, or whether in some cases this would be performed by another individual.

The group wished to stress that any recommendation of support would extend only to the pilot study and that a new full application would need to be submitted for any subsequent studies. The applicant should note that CAG's remit extends only as far as England and Wales and that an alternative legal basis would need to be found for any processing conducted outside these regions.

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. Justification of each data item required for linkage.

The following response was received by email:

'*We propose to link the prospective patient-level dataset to:*

i. Mortality database from the Health and Social Care Information Centre (HSCIC) and the Office for National Statistics (ONS)
ii. Hospital Episode Statistics (HES)

The HSCIC/ONS mortality data provides a validated date of death for patients. HES will provide information on patient co-morbidity and inpatient hospital treatments, and will be used to validate some aspects of the prospective data (eg, dates of admission, discharge) as well as in the analysis of treatment patterns and outcomes (eg, a HES-derived comorbidity index will be used to risk-adjust postoperative complication rates).

The following patient identifiers are required in order to identify individual patients and to subsequently request mortality data from the HSCIC/ONS and HES, and co-morbidity data, inpatient hospital treatments and operative procedure codes from HES.

- *Date of birth*
- *NHS number*
- *Postcode*

- *Sex*

Using these identifiers, a match rank value obtained from the HSCIC/ONS and HES linkage process is an indication of the level of confidence that an EpiCCS record has been correctly matched to a HSCIC/ONS death record and patient data in HES. Matching is performed by comparing patient identifiable fields, such as date of birth, sex, NHS number and/or postcode, which are present in both HES and HSCIC/ONS. The lowest rank (1) is considered the best quality match and the higher rank (8) the lowest quality match. This process is similar to that outlined in the HSCIC's 'Guide to Linked Mortality Data from Hospital Episode Statistics and the Office for National Statistics'(http://www.hscic.gov.uk/media/11668/HES-ONS-Mortality-Data-Guide/pdf/mortality_guide.pdf).

The match ranks used will take the following schema:

- *Match rank 1: Exact match of Date of birth, Sex, NHS number and Postcode; if no match is found then*
- *Match rank 2: Exact match of Date of birth, Sex, NHS number; if no match is found then*
- *Match rank 3: Partial match of Date of birth and exact match of Sex, NHS number and Postcode; if no match found then*
- *Match rank 4: Partial match of Date of birth, and exact match of Sex, NHS number; if no match found then*
- *Match rank 5: Exact match of Postcode and NHS number; if no match found then*
- *Match rank 6: Exact match of Date of birth, Sex and Postcode where NHS number does not contradict the match and Date of birth is not 1 January and the Postcode is not in the 'ignore' list (communal establishments such as hospitals, prisons, army barracks, etc).*
- *Match rank 7: Exact match of Date of birth, Sex and Postcode where NHS number does not contradict the match and Date of birth is not 1 January.*
- *Match rank 8: Exact match of Date of birth, Sex and Postcode where Date of birth is not 1 January.*

Patient name will be used in the IT system to support its relational data-structure, as well as for local hospital sites to identify patients at a trust level to ensure all patients have had their data captured. Patient name would also further be required in order for trusts to identify data corresponding to patients who choose to opt out of the study prior to entering the data onto the secure EpiCCS database webtool'

Members queried the phrase 'patient name will be used in the IT system to support its relational data-structure'. Members assumed that this meant that the name of the patient was needed alongside the NHS number in order to identify patients at local hospital level, and were happy to give support on this basis.

No other queries or concerns were raised.

2. Provision of a clarification and justification of the exit strategy proposed.

ONS will provide quarterly updates on patients within the database who have died. Thus, patient identifiable data will be retained within the database for 10 years and 3 months after the final patient has been recruited. This will enable the ONS mortality data at 10 years post-recruitment to be linked to the patient records contained within the database. Following linkage of these data, all patient identifiers will be destroyed.

Members were satisfied with this response and raised no further queries or concerns.

3. Clarification as to whether the patients would, in every instance, be seen by the anaesthetist on discharge.

'Due to the observational nature of the study, large number of patients planned for enrolment (sample size calculation of 8,177 patients), and the fact that the study is not introducing any additional interventions, the study protocol does not require that patients would be seen in every instance by the anaesthetist on discharge. To further clarify, patients would not be seen by the anaesthetist unless it was required as part of their routine medical/surgical care'.

Members were satisfied with this response and raised no further queries or concerns.

4. Provision of the outcomes of PPI, as set out above.

Representatives from patient and user organisations have been involved from the very early stages of the study; this included a patient representative being one of only three applicants on the grant which was awarded to support this study. The study Steering Group includes patient representatives and representatives from a variety of organisations including clinicians, nurses and professional representatives who have personal experience of surgery and anaesthesia. The study project team have also engaged the Royal College of Anaesthetists' (RCoA) Lay Committee for their opinions of the study protocol and patient information material. The Lay Committee is well established and engaged in many aspects of the RCoA's work.

After reviewing the study protocol, and supporting appendices, the patient representatives on both the Steering Group and the RCoA's Lay Committee have been supportive of our approach. They have also specifically reviewed the wording used in our Participant Information Sheets, and agree with the amount of information provided and manner in which the study is handling notification and opt out.

We enclose correspondence from Richard Shawyer, a patient representative sitting on the Steering Group, responding directly to the issues raised by the CAG. We also attach correspondence from Elspeth Evans, a lay member of the Lay Committee.

Subject to the outcomes of the PPI and taking due note of the CAG deliberations, as set out above, provision of suitable patient notification materials together with a description of how these will be disseminated. Please find enclosed copies of our revised Participant Information Sheet. The information sheet has been designed according to the HRA style guide. It has undergone revision since our CAG application and following review by the Research Ethics Committee (REC), as outlined further below. In our revisions, we have made the following amendments:

i. made it more explicit that study data will be retained for 10 years,
ii. rephrased sections to say that none of the patients' data would be identifiable under the section "Why haven't I been asked for permission to use my information?",
iii. highlighted that exemption under Section 251 of the Health and Social Care Act 2001 has been sought with regards to not seeking consent for patient identifiable information to be recorded,
iv. emphasised that patients can opt out of the study by expressing dissent to their clinicians as the first option, with email opt out changed to being the alternative option.

We plan to distribute the information sheets in pre-operatively on the day of surgery. This approach has been discussed with our patient representatives within the study Steering Group and the RCoA Lay Committee, and it was felt by all patients consulted to be an acceptable approach. All patient notification material will also be available on our study website (http://www.niaa-hsrc.org.uk/SNAP-2-EpiCCS-Project-Outline). We will also be asking participating hospitals to prominently display posters (see enclosed appendix 7) alerting patients to the fact that the study is taking place around pre-operative areas in the hospital.

Members noted that changes had been requested to the information sheets by the Research Ethics Committee. Although members were not entirely convinced that the patient and public involvement issue was resolved by the involvement of just one or two lay members, it was agreed that the information sheets were fit for purpose.

5. Favourable opinion from a Research Ethics Committee. **Confirmed 22 August 2016**

6. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Confirmed 27 April 2016.**

Scope of support

The applicant sent the following query by email:

'In addition to the conditions laid out above. We note on page 4 of the letter from CAG that the group wished to stress that "any recommendation of support would extend only to the pilot study and that a new full application would need to be submitted for any subsequent studies."

We would like to understand why the CAG felt that support could only be extended to our pilot. Our application for HRA approval was not for the pilot on its own, instead our application described the EpiCCS main study and indicated that the pilot was going to be conducted to address logistical issues before the main study was rolled-out nationally. We would like to stress that this pilot has only been included in our study design to ensure that the main EpiCCS study is feasible, and that the dataset is manageable.

We would also like to stress that we will not be linking any data collected in the pilot to HSCIC/ONS or HES, and therefore would not require Class IV or Class VI support under Section 251 for the pilot study itself. Class IV and VI support is only being sought for the main EpiCCS study.

Lastly, we have received REC approval for both the pilot and the main study as a combined study, and the REC did not make a distinction between the pilot and the main study in its considerations.'

This was discussed by the CAG. It was agreed that the rationale for seeing the results of the pilot before approving the main study was so that the level of public acceptance for the study could be gauged. However, on further discussion it was agreed that confusion had arisen over the use of the word 'pilot'. The first, or pilot, stage of the study did not require support from CAG as it involved no access to data outside the patient's surgical team. This aspect had been referred to as a pilot as it would determine the feasibility or logistics of the study. The linkage of the data via NHS Digital, which was the aspect requiring CAG support, would occur during the second stage, or 'main study'.

In the light of this clarification, and in consideration of the patient information materials which enabled participants to opt out at Stage 1, members agreed that support should be recommended for the entire study.

As the above conditions have been accepted and/or met, this letter provides confirmation of final approval. I will arrange for the register of approved applications on the HRA website to be updated with this information.

Annual review

Please note that your approval is subject to submission of an annual review report to show how you have met the conditions or report plans, and action towards meeting them. It is also your responsibility to submit this report on the anniversary of your final approval and to report any changes such as to the purpose or design of the proposed activity, or to security and confidentiality arrangements. An annual review should be provided no later than **16 September 2017** and preferably 4 weeks before this date. If at any stage you no longer require support under the Regulations as you will cease processing confidential patient information without consent you should inform the Confidentiality Advice Team of this in writing as soon as possible.

Reviewed documents

The documents reviewed at the meeting were:

Document	*Version*	*Date*
CAG application from		29 June 2016
Covering letter on headed paper		
Data Protection Registration		
CAG Checklist		
Information Governance		
Registration details		
Sponsorship confirmation		
Therapeutic Assessment FU protocol		
Information sheet, parent/guardian	4	06/02/15
Information sheet, child	6	17/12/07
Consent, child		
Assent, parent/guardian		
Response to CAG		15/08/2016
Correspondence PPI Elspeth Evans		12/08/2016
Correspondence PPI Richard Shawyer		25/07/2016
Appendix 5 Study PIS	0.6	25/07/2016
Appendix 7 Patient Poster		

Membership of the Committee

The members of the Confidentiality Advisory Group who were present at the consideration of this item or submitted written comments are listed below.

Yours sincerely

On behalf of the Health Research Authority

Rachel Heron
Confidentiality Advisor
Email: HRA.CAG@nhs.net

Enclosures: *List of members who considered application*
Standard conditions of approval

Confidentiality Advisory Group meeting

Name	*Present*
Dr Mark Taylor	Yes
Dr Patrick Coyle	Yes
Ms Claire Sanderson	Yes
Mr Anthony Kane	Yes
Dr Miranda Wolpert	Yes
Ms Hanna Chambers	Yes
Dr Martin Andrew	Yes
Mr Andrew Melville	Yes
Ms Diana Robbins	Yes
Ms Sophie Brennan	Yes

Standard conditions of approval

The approval provided by the Health Research Authority is subject to the following standard conditions.

The applicant will ensure that:

1. The specified patient identifiable information is only used for the purpose(s) set out in the application.

2. Confidentiality is preserved and there are no disclosures of information in aggregate or patient level form that may inferentially identify a person, nor will any attempt be made to identify individuals, households or organisations in the data.

3. Requirements of the Statistics and Registration Services Act 2007 are adhered to regarding publication when relevant.

4. All staff with access to patient identifiable information have contractual obligations of confidentiality, enforceable through disciplinary procedures.

5. All staff with access to patient identifiable information have received appropriate ongoing training to ensure they are aware of their responsibilities.

6. Activities are consistent with the Data Protection Act 1998.

7. Audit of data processing by a designated agent is facilitated and supported.

8. The wishes of patients who have withheld or withdrawn their consent are respected.

9. The Confidentiality Advice Team is notified of any significant changes (purpose, data flows, data items, security arrangements) prior to the change occurring.

10. An annual report is provided every 12 months from the date of your final confirmation letter.

11. Any breaches of confidentiality / security around this particular flow of data should be reported to CAG within 10 working days, along with remedial actions taken / to be taken.