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

February 2021

1. New Applications

a. 21/CAG/0017 - Outcomes of Patients who survived Treatment on an Intensive Care unit for COVID-19 in England and Wales: a retrospective cohort study (OPTIC-19)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Simon Kolstoe	CAG Member
Mr Andrew Melville	CAG Member
Ms Clare Sanderson	CAG Alternative Vice-Chair

Context

Purpose of application

This application from University of Oxford set out the purpose of medical research which aims to characterise mortality and other adverse outcomes for patients treated on an Intensive Care Unit (ICU) with COVID-19 in England and Wales, one year after discharge from hospital. The study will use retrospective existing national audit data from The Intensive Care National Audit and Research Centre (ICNARC) linked to other healthcare datasets.

Across England and Wales, over 10,000 patients have been treated for severe COVID-19 on an intensive care unit. Around 60% survived to leave hospital. Research shows that patients who survive ICU treatment are at greater risk of death, and report lower health-related quality of life. Evidence also suggests that patients admitted with COVID-19 receive higher intensity organ support and suffer more complications than observed in other viral respiratory infections. The long-term consequences of severe COVID-19 on the health of survivors are unknown. Understanding the risks faced by patients treated in an ICU has the potential to help healthcare professionals mitigate those risks.

Participants will be identified from the existing Case Mix Programme (CMP) dataset held by ICNARC, by staff at ICNARC (the CMP data controller). The primary cohort will include patients admitted to ICU with confirmed COVID-19 between 1st January 2020 and 1st July 2020, who were discharged alive from hospital. ICNARC staff will then identify comparator groups of emergency ICU admissions between 1st January 2016 to 1st July 2020 as listed in the application, from the CMP dataset. Eligible participants identified from the ICNARC CMP audit will be assigned a pseudonymous Study ID. The Study ID will be sent alongside Date of Birth, NHS number, Postcode, and gender to;

- NHS Digital,
- NWIS,
- Barts health NHS Trust (on behalf of the National Institute for Cardiovascular Outcomes Research (NICOR),
- Kings College London (on behalf of the Sentinel Stroke National Audit Programme (SSNAP),
- The Renal Association (on behalf of the UKRR)

Linkage will be performed by these trusted third parties to clinical datasets as listed below, to obtain information on subsequent hospitalisations, and longer-term mortality, cardiovascular and renal outcomes. The linkages will be requested twice; in March 2021 and October 2021, to allow 6 month and 1 year follow up of the entire cohort, however identifiers are sent by ICNARC once only, and the third parties hold the pseudonymous study ID linked to confidential patient information for the 6 months in-between. Third parties performing the linkage will then remove identifiers from the datasets, including modifying postcode to deprivation score or LSOA, and transfer pseudonymised linked datasets to the University of Oxford. The University of oxford will receive the pseudonymous Study ID, and the datasets from NICOR, SSNAP and UKRR can be considered anonymous as the co-ordinating centre will not be able to re-identify any participant. The datasets received from NHS Digital and NWIS will contain full date of death, and as such this data flow will require support. The applicants will modify this date to 'time from hospital discharge to death' and delete the date of death prior to analysis.

The study will also link data from the UK Obstetric Surveillance System (UKOSS) to identify patients who were pregnant at the time of ICU admission using probabilistic matching. All data will be combined into a final study dataset containing no confidential patient information, by researchers at the University of Oxford for analysis. Analysis of the study dataset will be conducted by researchers at the University of Oxford and ICNARC. Pseudonymised data will also be securely transferred to ICNARC and accessed via secure servers managed by ICNARC. The ledger linking pseudonymous Study ID to direct identifiers will only be accessed by ICNARC for GDPR privacy enquiries and in the event of data quality concerns, and will be kept until the end of the study – 1st November 2021.

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

Confidential patient information requested

Cohort	319,600 Patients over 16 admitted to an intensive care unit in England or Wales and discharged alive from hospital. Admitted between 1st January 2016 to 1st July 2020
Data sources	1. The Case Mix Programme (CMP), (The Intensive Care National Audit and Research Centre (ICNARC)) 2. NHS Digital; a) Hospital Episode Statistics (HES), b) ONS Civil Registration data, c) GPES Data for Pandemic Planning and Research COVID-19 (GPES)

	3. Patient Episode Database for Wales (PEDW), (NHS Wales Informatics Service (NWIS) 4. National Institute for Cardiovascular Outcomes Research (NICOR), (Barts Health NHS Trust, HQIP) 5. Sentinel Stroke National Audit Programme (SSNAP), (Kings College London, HQIP) 6. UK Renal Registry (UKRR), (The Renal Association) 7. UK Obstetric Surveillance System (UKOSS) (University of Oxford) All datasets have a legal basis to process confidential patient information.
Identifiers required for linkage purposes	1. Date of Birth, 2. NHS number 3. Postcode 4. Gender 5. Pseudonymous Study ID
Identifiers required for analysis purposes	1. Postcode (modified to deprivation score or LSOA by third parties) 2. Date of death (modified to time from hospital discharge to death by applicants) 3. Pseudonymous 'study ID' (This can be considered anonymous)
Additional information	Follow up period: 1 year after discharge from an intensive care unit. 2 linkages will be performed, one at 180 days (March 2021) and one at 365 days (October 2021).

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. **Please provide a favourable opinion from a Research Ethics Committee, when available**

The applicant provided a favourable opinion from the REC on 22 February 2021.

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 as set out below.

Specific conditions of support

The following sets out the specific conditions of support.

1. Applicants should conduct a small survey with patients from an appropriate patient forum. Applicants should outline their approach, explore the use of confidential patient information without consent in this specific context, and provide a report back to the CAG within three months from the date of this letter.

2. Favourable opinion from a Research Ethics Committee **Confirmed 22 February 2021**

3. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed: As there are more than 5 organisations processing confidential patient data these will not be individually checked by the CAT team, and it is the responsibility of the applicant to ensure the DSPTs for the following organisations have been assessed as 'standards met' by NHS Digital;**

    - **University of Oxford**
    - **ICNARC 8HN44**
    - **NHS Digital**
    - **NICOR (Barts Health NHS Trust)**
    - **SSNAP King's College London - Sentinel Stroke National Audit Programme EE133874-SSNAP**
    - **UKRR (The Renal association) 8HQ50**

    - **A CPiP assessment is in place for NWIS.**

2. New Amendments

a. 19/CAG/0137- National Cancer Patient Experience Survey 2019

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from NHS England set out the purpose of administering patient surveys to evaluate services provided to cancer patients in 2019. Support is currently in place to allow the disclosure of confidential patient information from participating NHS Trusts to Picker Institute Europe, to enable the 2019 patient survey to be distributed.

The National Cancer Patient Experience Survey is run on an annual basis and each year a separate application for support under Regulation 5 is submitted. However, the current pandemic placed unprecedented pressures on cancer services in 2020, which resulted in NHS England and NHS Improvement making the decision not to mandate the National Cancer Patient Experience Survey in 2020. However, it is recognised that there is value in learning from patients' experience of care during 2020.

This amendment is requesting support in the form of a duration amendment, to enable trusts to participate in the 2020 survey on a voluntary basis. Identifiers will be retained until 31 August 2022, at which point they will be deleted and support will no longer be required. The applicant has confirmed that data sources, data processes, and data flows remain the same as 2019 survey. A new application will be submitted for the 2021 National Cancer Experience Survey.

The applicants notified the CAG of minor amendments to the questionnaire to ensure that it remains appropriate to the way care delivery has changed during the pandemic. This includes the collection of the most recent version of the International Classification of Diseases, ICD-11 in addition to ICD-10, which was supported in the application. This is

because Trusts are in the process of switching from ICD-10 to ICD-11. This is no more disclosive than original support.

The applicant also notified the CAG of a new way for Trusts to submit patient sample lists to a secure online platform. This is using the same data processor, and does not constitute a change in confidential patient arrangements,

The applicant has described the changes to patient notification materials as appropriate, which have already been displayed in Trusts.

An updated flow diagram and questionnaire have been provided, and the only changes to these are the changes described in this amendment.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs action. The CAG chair confirmed that in these exceptional circumstances he was happy for an amendment to be submitted instead of a new application, and raised no queries.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG 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

The following sets out the specific conditions of support.

1. Confirmation of suitable security arrangements via IG Toolkit submission.
   Confirmed – Picker Institute Europe (by check of DSPT tracker 22 January 2021**) and Greens Limited (**by check of DSPT tracker 22 January 2021) **have confirmed 'Standards Met' grade on DSPT 2019/20).**

b. 20/CAG/0148 - Evaluating alternative protocols for identifying and managing patients with familial hypercholesterolaemia: cost-effectiveness analysis with qualitative study

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from the University of Nottingham is a multi-centre mixed methods study with a focus on Familial Hypercholesterolaemia, which is the most common autosomal dominant disorder with at least 1 in 500 individuals (0.2%) affected by the more common heterozygote form. Support is currently in place to allow confidential patient information to be released from the Simon-Broome Registry, held by University College London, to NHS Digital to facilitate linkage with HES data.

This amendment sought to extend the duration of support until 30 June 2021. This is due to delays experienced due to the Covid-19 pandemic.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The team understood the rationale for the amendment and raised no queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold :

   Confirmed:
   The NHS Digital **2019/20** DSPT review for **UCL School of Life and Medical Sciences (**EE133902-SLMS) and **NHS Digital** DSPT equivalent for 2019/20 were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 05 February 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial 03 February 2021

c. 19/CAG/0194 - Identifying models of care to improve outcomes for older people with emergency and urgent care needs

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from the University of Leicester seeks to determine what aspects of interventions, context and approaches to implementation both facilitate and hinder delivery of emergency and urgent care interventions for older people in emergency departments. Support is currently in place to allow the incidental disclosure of confidential patient information during observations of clinical care undertaken on emergency departments and while observing staff meetings about service delivery.

This amendment sought support for the addition of a further site; Harrogate and District NHS Foundation Trust. The extra site has been added due to problems in obtaining research governance permissions to pursue the research in one of the originally specified sites (Airedale NHS Trust). Harrogate and District NHS Foundation Trust has been selected as an alternative site, since it has similar characteristics to Airedale in relation to the sampling criteria used.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The rationale for this amendment was understood and no queries were raised.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold :

   Confirmed: The NHS Digital **19/20** DSPT review for **Harrogate and District NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 16 February 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed as part of original REC application; Confirmed 24 September 2019**

d. 19/CAG/0018 - Understanding the health needs of mothers involved in family court case: A research study exploring linkage between family court and health data

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from the University College London Great Ormond Street Institute of Child Health aims to generate evidence about the extent to which the healthcare needs of mothers are being addressed before, during and after court involvement among mothers subject to care proceedings. Support is currently in place for the processing of specified confidential patient information by NHS Digital in order to create linkage files using the Personal Demographics Service, which will be retained for a 12 month duration, between information disclosed by the Children and Family Court Advisory and Support Service (Cafcass) and the Hospital Episode Statistics (HES) database. The cohort is women aged between 15 and 50 years, with at least one live birth recorded in the HES database between 01 April 1997 and 31 March 2017, and women involved in care proceedings between 01 April 2007 and 31 March 2018.

This amendment sought support to extend the study cohort to include women with a live birth recorded in the HES Database up to 31st March 2019 (total cohort 01 April 1997 until 31st March 2019). This will ensure that study findings are more up-to-date, and therefore more useful to inform present-day policy and practice decision-making.

This amendment also sought support to extend the study cohort to include women involved in care proceedings up to 31st March 2019 (total cohort 01 April 2007 until 31st March 2019). This will ensure that study findings are more up-to-date, and therefore more useful to inform present-day policy and practice decision-making.

The amendment also sought to extend the duration of support required until 31st May 2022, which is partly due to delays caused by the Covid-19 pandemic.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Chair noted that the application which was given support in 2018 has suffered a number of delays before the relevant data has been made available. Because of the delay, the applicant is seeking to extend the duration of the study and to extend the scope of the cohort to include more women. The Chair commented that since the delays are through no fault of the applicant, this amendment seems reasonable and appropriate and therefore was content to support this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG 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

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold:

   Confirmed: The NHS Digital **19/20** DSPT reviews for **University College London, School of Life and Medical Sciences and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 16 February 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 22 February 2021**

e. 19/CAG/0226 - The SAFER Trial: Screening for Atrial Fibrillation with ECG to Reduce stroke - a randomised controlled trial

Name	Capacity
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

The applicants have existing support under Precedent Set category 10 to legitimise any incidental disclosures of confidential patient information during the ethnographic observations held in GP practice sites.

In this amendment, the applicants are seeking support to include the option of remote observations of practice meetings and training sessions and of staff interactions with patients instead of the researcher being present in the practice in person. The observations will take place via phone or video call. This would apply as an option for ethnographic observations in both the internal pilot and the main trial.

The amendment form also cited an increase in the number of GP practices involved in the ethnographic observations from three to five in the internal pilot phase of the SAFER trial. The fully supported outcome letter issued on 17 January 2020 gave support for the inclusion of 11 practices, therefore support is already in place.

Observations will either be undertaken in person, in line with the original support, or remotely by phone or video call. If remotely, the researcher will dial into the telephone conference call or join the video call. All other aspects of the observations will remain the same as in the 'in person' option. To avoid interfering with the clinical consultation, the individual GPs will determine the sequencing of the call. In all cases patients will only be observed with their permission and agreement and the permission of clinical staff. All patients will be advised that they can decline observations.

The applicant explained that support was needed as the researchers may be party to confidential patient information before the patient joined the call and consented to the observations. The applicants did not think it acceptable to ask the GP to put the patient on hold while the GP dials the observer, as patients may be anxious about the consultation. The applicants also sought to avoid placing a burden on GPs. The applicants had discussed this issue with GP colleagues and with Patient and Public Involvement representatives, who were in agreement with the proposed methodology.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The CAG agreed that support should be recommended.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG 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

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 23 October 2019**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the

‘Standards Met’ threshold. See section below titled ‘security assurance requirements’ for further information. **Not checked due to the number of sites involved. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations.**

3. Annual Review Approvals

CAG Reference	Application Title
18/CAG/0013	Evaluating the real-world implementation of the Family Nurse Partnership in England: a data linkage study
PIAG 4-08(d)/2003	National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH)
19/CAG/0135	Derby Monitoring Study of Self-harm
18/CAG/0177	Evaluation of the medium to long term impact of commercial open-group behavioural weight loss programmes on body weight and diabetes risk in adults with overweight and obesity
17/CAG/0071	Barts Health (NICOR) National Cardiac Audit Programme (NCAP)
CR12/2014	Oxford Vegetarian Study/Study of Cancer in Vegetarians
17/CAG/0015	Antibiotic Reduction and Conservation in Hospitals (ARK-Hospital)
16/CAG/0064	The Renal Association: UK Renal Registry a research database
ECC 2-06(n)/2009	National Cardiac Arrest Audit (NCAA)
19/CAG/0018	Understanding the health needs of mothers involved in family court case: A research study exploring linkage between family court and health data
ECC 5-05(e)/2012	National Drug Treatment Monitoring System
18/CAG/0205	International Surgical Outcomes study: Long-term survival
19/CAG/0220	Linked de-identified research database for congenital anomaly outcomes
18/CAG/0071	Avoiding Cardiac Toxicity in Lung Cancer Patients
CAG 9-08(b)/2014	Linkage of readmissions to birth data

Signed – Chair	Date

Signed – Confidentiality Advice Team	Date