Confidentiality Advisory Group

Minutes of the meeting of the Precedent Set Review Sub Committee of the Confidentiality Advisory Group held on *15 March 2024* via correspondence

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Present:

Name	Capacity	Items
Dr Tony Calland, MBE	CAG Chair	2a, 2b, 2c
Dr Rachel Knowles	CAG Expert Member	2c
Dr Pauline Lyseight-Jones	CAG Lay Member	2a
Professor Sara Randall	CAG Lay Member	2b, 2c
Mr Dan Roulstone	CAG Lay Member	2a, 2b

Also in attendance:

Name	Position (or reason for attending)
Ms Kathleen Cassidy	HRA Confidentiality Advisor
Mr Dayheem Sedighi	HRA Approvals Administrator
Ms Caroline Watchurst	HRA Confidentiality Advisor

1. DECLARATIONS OF INTEREST

There were no declarations of interest.

2. NEW PRECEDENT SET REVIEW APPLICATIONS FOR CAG CONSIDERATION

2.a	**24/CAG/0049**	**PROthrombin complex concentrate versus fresh**

		frozen Plasma for bleeding in adults undergoing Heart SurgerY (PROPHESY-2 trial): a phase III, randomised control trial
	Chief Investigator:	Dr Laura Green
	Sponsor:	Barts Health NHS Trust and Queen Mary University of London
	Application type:	Research

The Group reviewed the above application in line with the CAG considerations.

Summary of application

This application from Barts Health NHS Trust and Queen Mary University of London describes the purpose of medical research into whether prothrombin complex concentrate (PCC) is better at treating bleeding within 24 hours of cardiac surgery than the current standard care, fresh frozen plasma (FFP).

Every year in the UK, severe bleeding occurs in over 10,000 people having cardiac surgery. Severe bleeding increases the risks of complications like organ failure and infections, or death. Stopping bleeding quickly could reduce these risks and improve outcomes. Currently, severe bleeding is stopped by transfusion of fresh frozen plasma (FFP), part of donated blood that contains essential proteins for blood clotting. Over 30,000 (12%) of the 250,000 FFP doses sent to UK hospitals every year are used in heart surgery. As with all donated blood products, FFP is a precious resource, and from time-to-time there are national shortages. FFP also has potential side-effects including allergic reactions and transmission of infection. In heart surgery, patients have added risks because it is given in large volumes (1 litre or more depending on the patient's weight). In people with weak heart function (common after heart surgery), the large volume given can put too much stress on the heart, lungs and kidneys. FFP is also stored frozen and requires about 30 minutes thawing time prior to use, which results in delays to treatment in people with severe bleeding. The applicants seek to determine whether a blood product called prothrombin complex concentrate (PCC) is a superior treatment to FFP in adult patients who are actively bleeding within 24 hours of cardiac surgery.

Potentially eligible patients will be consented and screened prior to their cardiac surgery, and if they go on to develop bleeding during or within 24 hours of surgery, they will be randomised to receive either PCC or FFP. A total of 496 participants will be randomised (248 per group). Participants will be followed up for 90 days (+/- 7 days) post-surgery and will complete quality of life questionnaires. All eligible participants will be identified in the preoperative anaesthesia or cardiac surgery clinics up to 90 days before the index surgical event, or ward at each hospital in the case of urgent surgery. In some trusts, the research team undertaking screening is considered part of the clinical care team. In trusts where this is not the case, the applicants seek s251 support to allow the research team to access patient notes to identify eligible patients, and to approach them to discuss the trial.

Confidential information requested

Cohort	Patients aged 18 years and over undergoing elective or urgent cardiac surgery at participating trusts. 496 patients will be included.
Data sources	1. Electronic patient records at participating trusts
Identifiers required for linkage purposes	1. NHS Number 2. Hospital ID Number 3. GP Registration 4. Date of death
Identifiers required for analysis purposes	1. Date of death

Main issues considered, discussed and outcomes

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of section 251 of the NHS Act 2006.

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The CAG agreed that the poster needs to state that potential participants would be identified by looking at health records and, if people specifically did not want to be considered (i.e. date to be accessed), then they could contact the trust to opt-out. **(Action 2)**

The CAG noted that all patients screened for the trial would be recorded on the trial screening log, which would record their initials and Medical Record Number (MRN). The members agreed, whilst they acknowledge there would be a case number relating to the patient, it is not sufficient pseudonymisation to use the initials of the patient, even if the log was paper based. The CAG requested a justification to explain why an electronic version with more effective pseudonymisation was not possible. **(Action 3)**

The CAG noted that the application stated that all records (paper and electronic) would be destroyed following the archiving period of 25 years. The CAG requested that the applicant retain/archive records for 10 years then review to consider whether longer retention was necessary, in line with their organisational retention policy. **(Action 4)**

The CAG also requested that the applicant delete the data related to patients who have dissented or left the trial within 7 days. **(Action 5)**

Confidentiality Advisory Group advice: Provisionally supported

The CAG was unable to recommend support to the Health Research Authority for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

Number	Action required	Response from the applicant
1.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	
2.	Add a statement to the poster to explain that potential participants will be identified by looking at health records and if people specifically do not want to be considered (i.e. data to be accessed) then they can contact the trust to locally opt-out.	
3.	Provide justification as to why an electronic version with more effective pseudonymisation is not possible and why the project requires use of patient's initials.	
4.	The CAG requested that instead of retaining the records for 25 years, the records need to be retained for 10 years then reviewed to consider whether longer retention is necessary, in line with your organisational retention policy.	
5.	The CAG requested that the data related to patients who have dissented or left the trial to be deleted within 7 days and not retained until the end of the trial.	

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

2.b	24/CAG/0050	Recording Antimicrobial Resistance during Death Certification in England
	Chief Investigator:	Dr Louis Grandjean
	Sponsor:	University College London
	Application type:	Research

The Group reviewed the above application in line with the CAG considerations.

Summary of application

This application from University College London set out the purpose of medical research that aims to estimate the total number of deaths associated with antimicrobial resistance in England in the years 2021 - 2023.

Antimicrobial resistance (AMR) has been declared a public health emergency by the World Health Organisation (WHO), as previously effective treatments for infections will soon no longer work. The number of antibiotic-resistant infections are rising every year, but understanding as to how many people die because of antibiotic resistant infections is limited, as well as which resistant infections have the highest mortality burden. This is important to know, in order to raise public and political awareness about the problem, as well as prioritise diagnostics and treatments for the infections with the highest burden.

Patients will be identified via the NHS England Civil Registration of Death Database. NHS England will then link the dataset to the HES dataset. The combined dataset will then be disclosed to UK HSA for linkage to the SGSS database. The dataset will be anonymised by removal of the date of death and NHS number before disclosure to the research team at University College London.

Confidential information requested

Cohort	All patients who had their death registered in England between 01/01/2021 and 31/12/2023 will be eligible for inclusion in this study.
Data sources	1. The Civil registrations of death database and the Hospital Episode Statistics database, held by NHS England 2. The Second Generation Surveillance System (SGSS), held by UK Health Security Agency (UKHSA)
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Date of death 4. Postcode – unit level
Identifiers required for analysis purposes	1. Ethnicity

Main issues considered, discussed and outcomes

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of section 251 of the NHS Act 2006.

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The CAG noted that the applicants had advised that, having discussed the application with Antibiotic Research UK, the charity had advised that consulting patient representative of the patient group was not indicated as it might be psychologically harmful for them. Therefore, no other public involvement had been undertaken or was planned. The members agreed that the applicant's explanation for not engaging with the patient group was not acceptable. The CAG explained that this was a matter of general concern to all people, not just patients with reduced immunological response so consulting a general patient group (10-20) was essential. The CAG asked further patient and public involvement was undertaken, particularly around the specific issue of use of confidential patient information without consent. Members suggested that the applicant engage with at least 10-20 representatives. **(Action 1)**

The CAG noted that the applicants did not plan to undertake any patient notification as all patients would be deceased. The members noted that patients would be deceased, however agreed there needed to be some notification on the UCL website explaining that the research was being done. **(Action 2)**

<u>Confidentiality Advisory Group advice:</u> Provisionally supported

The CAG was unable to recommend support to the Health Research Authority for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

Number	Action required	Response from the applicant
1.	Specific patient and public involvement needs to be undertaken with a representative group, to discuss the use of confidential patient information, without consent, for the purpose of this application. Members suggested that the applicant engage with at least 10-20 representatives.	
2.	Produce a patient notification for display on the UCL website, which clearly describes the purpose and content of this project for public information.	

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

2.c	**24/CAG/0055**	**Adult gonococcal eye infection: a study of the incidence, clinical features, management, complications and antimicrobial resistance in the United Kingdom**
	Chief Investigator:	Ms Alice Milligan
	Sponsor:	Moorfields Eye Hospital NHS Foundation Trust
	Application type:	Research

The Group reviewed the above application in line with the CAG considerations.

Summary of application

This application from Moorfields Eye Hospital NHS Foundation Trust set out the purpose of medical research which aims to establish incidence, clinical features, risk factors, current management, complications and antimicrobial resistance of adult gonococcal conjunctivitis (GC) or gonococcal keratoconjunctivitis (GKC) patients in the UK, over a one year surveillance programme operating via the British Opthalmological Surveillance Unit (BOSU) methodology, using the monthly reporting card amongst UK ophthalmologists.

Gonorrhoea is a sexually transmitted infection, which is increasing in England by 50.3% between 2021 and 2022. GC/GKC are caused when gonorrhoea infects the eye. Gonorrhoea is a potentially blinding infection that requires early diagnosis and treatment to avoid long-term visual complications. There is limited national epidemiology available on GC/GKC, including on antimicrobial susceptibility. Antimicrobial resistant gonorrhoea is a major public health concern; N. gonorrhoeae is evolving high levels of antimicrobial resistance, including to ceftriaxone, the last available option for empirical therapy. This study will not just ascertain the incidence of GC/GKC but also of antimicrobial resistance in GC/GKC, to monitor the changing epidemiology, inform treatment guidelines, aid investigation into cases of treatment failure and guide appropriate public health response.

The BOSU methodology is established and has received support in principle from the CAG. Ophthalmologists will anonymously indicate that they have seen a new patient who has suffered sight loss as a result of delay in their ophthalmic care, through the BOSU reporting system via University of Dundee. The University of Dundee system will generate the initial questionnaire for the reporting ophthalmologist to fill in via the University of Dundee data safe haven online platform. The completion of this questionnaire will contain confidential patient information, and therefore requires ‘s251’ support. Each case will be given a unique study number by the BOSU study centre. Hospital number, month and year of birth, gender, and first half of postcode will be recorded alongside clinical data on the questionnaires. A follow up questionnaire will be undertaken at 3 months. All identifies will be deleted once the follow-up is completed, and duplicates identified.

Confidential information requested

Cohort	Approximately 80-120 (but actual incidence as yet unclear) patients aged 16 or over, suffering gonococcal conjunctivitis (GC) or gonococcal keratoconjunctivitis (GKC) who report to a treating ophthalmologist across the 12 month reporting period, expected to be between June 2024 – May 2025.
Data sources	1. Clinical records at the Trusts of BOSU reporting ophthalmologists
Identifiers required for linkage purposes	1. Unique BOSU study number 2. Hospital number (to identify duplicate reports) 3. Gender 4. Month and Year of birth 5. Diagnosis 6. Postcode (first half)
Identifiers required for analysis purposes	1. Month and Year of birth 2. Gender 3. Postcode (first half) This will be an effectively anonymised dataset for analysis as the applicant will not have the means to re-identify.
Additional information	1 year of baseline collection - Expected start date June 2024 – May 2025. There is a follow up at 3 months.

Main issues considered, discussed and outcomes

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of section 251 of the NHS Act 2006.

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The CAG noted that the exit strategy for s251 support was the deletion of identifiers and anonymisation of the dataset at the end of the study. Surveillance will be 12 months, then follow-up 3 months after this (so a total of 15 months). However, chasing of the follow-up data may take longer. The applicants have not specified either a time-frame or date for when deletion of identifiers is expected to happen. Members commented that the final data collection is expected to be completed 18 months after the study start, however noted that sometimes this can be delayed if clinicians are slow to respond. CAG therefore recommend seeking s251 support for up to 24 months. However the applicant should confirm the end date either as a date (potentially May 2026) or duration (potentially 24 months). **[Action 3].**

The Precedent Set Review Sub Committee requested that further information as set out below (actions 1-3) should be provided.

<u>Confidentiality Advisory Group advice:</u> Provisionally supported

The CAG was unable to recommend support to the Health Research Authority for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

Number	Action required	Response from the applicant
1.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	
2.	Security assurances for the Health Information Centre - University of Dundee – Data Safe Haven in the form of PBPP approval is outstanding.	
3.	Please confirm the date or timeframe that you expect to require 's251' support until, as per advice in the minutes. The CAG suggest May 2026, or 24 months might be suitable.	

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

Dr Tony Calland, MBE, CAG Chair — 03 April 2024
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Signed – CAG Chair *Date*

Dayheem Sedighi & Caroline Watchurst — 27 March 2024
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Signed – Confidentiality Advisory Team *Date*