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

23 June 2023 via correspondence

Present:

Name	Role	Items
Ms Clare Sanderson	Alternative Vice Chair	2a, 2b
Dr Martin Andrew	CAG Member	2a
Dr Malcolm Booth	CAG Member	2b
Mr Dan Roulstone	CAG Member	2a
C. Marc Taylor	CAG Member	2b

Also in attendance:

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

1. Expressions of interest

There were no conflicts of interest declared.

2.New Precedent Set Review Applications

a. 23/CAG/0081- Remote monitoring in virtual wards for acutely unwell patients being managed and treated on an ambulatory care pathway: feasibility study

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research that seeks to test the feasibility of continuous remote vital-sign monitoring in people receiving care in an NHS delivered home-based acute-virtual ward.

Virtual wards for admission avoidance are already being implemented across the NHS. They are being used to deliver health care to people who are otherwise reluctant to spend time in hospital and to help free up the limited number of hospital beds. When at home patients are regularly called and visited by doctors and nurses. To find out how their patients are feeling whilst at home, the NHS team might ask their patient to use devices to measure their blood oxygen levels using a pulse oximeter and then report this over the phone. Remote vital-sign monitoring has the potential to reduce the number of visits by nurses to carry out in-person vital-sign observations, but where vital-sign monitoring is carried out by patients and reported by phone, there is a possibility of inaccurate readings. Remote vital-sign monitoring has the potential to reduce the number of visits by nurses to carry out in-person vital-sign observations, but where vital-sign monitoring is carried out by patients and reported by phone, there is a possibility of inaccurate readings.

The applicants have developed a system using a vital-sign chest patch and a pulse oximeter finger probe to automatically collect health measurements. Patients will also be asked to use a blood pressure monitor and an in-ear thermometer, which will not be automated, regularly over the course of the monitoring period, to establish whether these devices can be consistently used by patients. 35 patients will be recruited from the Ambulatory Assessment Unit (AAU) at Oxford University Hospitals NHS Foundation Trust. Patient records will be screened for eligibility by members of the research team by accessing each patients' electronic notes for the current admission and their general contact details. A record with a unique study ID will be created in the secure screening log, which will include the patients age, gender, the date of screening and their eligibility based on initial checks. If a patient

is found to be eligible their name and NHS number will be used to immediately approach the patient about the study. Patients will be given a copy of the patient information sheet and study overview. Participants will either be consented by research staff during their hospital attendance or, if lacking capacity, will have a personal or professional consultee advise on their behalf.

A recommendation for class 2, 3 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Patients aged 18 years and over who the Ambulatory Assessment Unit at Oxford University Hospitals NHS Foundation Trust have determined are clinically appropriate to be managed at home via the Hospital at Home virtual ward.
Data sources	1. Patient records at Oxford University Hospitals NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Postcode – district level 4. Age
Identifiers required for analysis purposes	1. Gender 2. Age

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

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 the section 251 of the NHS Act 2006.

Following consideration of the risks to patient confidentiality versus the benefits of the study the CAG agreed that the application was in the public interest.

Scope

The CAG agreed that the screening log being sent to the university, which only includes Age and gender, does not require support as this is not confidential information.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- **Feasibility of consent**

The applicants explained that all recruitment will take place in the Oxford University Hospitals NHS Foundation Trust AAU, which sees more than 70 patients each day. Patients are on the ward for a relatively short amount of time before being transferred to other in-patient care pathways or discharged home. From the applicants experience of previous studies, approaching patients to seek consent to conduct the eligibility checks is inefficient and time-consuming, and places additional time burdens on unwell patients who potentially are not even applicable for this research.

Members were content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

The research team require access to confidential patient information to undertake screening for eligibility.

The Sub-Committee was content that using anonymous information was not a practicable alternative.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

Patient notification posters will be placed in patient facing areas of the AAU, explaining the aim of the research and that patient data will be accessed prior to consent being sought.

The patient notification posters will contain contact details for the research team for patients to register dissent. Patients will be required to provide two identifiers to ensure the research team can comply with their request (these will be held securely for the duration of study recruitment before being securely disposed of) and their data will not be used for the purposes of this research.

Oxford University Hospitals NHS Foundation Trust also operates a hospital wide data opt-out that allows patients to record their dissent to all research. Any patients who have made use of this system will not have their data accessed or used as part of this research.

The National Data Opt-Out will be applied.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The research groups hold regular patient and public events. At an event in March 2023, attended by 11 members of the public, opinions on use of confidential patient information to identify potential participants were sought. The group of representatives that attended included 5 men and 6 women, 10 were white (1 undisclosed ethnicity) and were of a range of ages (all 18+). Those consulted were positive about use of patient information for this purpose.

As this is a feasibility study, the applicants had only consulted patient and public involvement representatives on the patient identification procedures. Should this work be continued in a larger study, the applicants intend to undertake further patient and public involvement where the study is discussed in full to gain further feedback on all areas of the study and procedures. The applicants are working with University and departmental resources in order to ensure that when those discussions happen a more diverse group can be consulted.

The CAG noted that the research is planning further patient and public involvement prior to the main study and this should include a specific question regarding access to records prior to gaining consent.

The CAG also noted that there is an opportunity to get views from the participants in this study and this should not be wasted.

Exit strategy

Consent is the exit strategy for patients who agree to participate.

No confidential patient information will be retained for patients who are either not approached or are approached and do not consent.

Members were content with the exit strategy provided.

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

1. Further patient and public involvement need to include discussion re the specific question regarding access to records prior to gaining consent.

2. Favourable opinion from a Research Ethics Committee. **Confirmed: 10 July 2023**

3. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. **Confirmed:**

   The NHS England **21/22** DSPT review for **University of Oxford and Oxford University Hospitals NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (04 July 2023)

b. 23/CAG/0083 - Embotrap eXtraction & Clot EvaLuation & Lesion Evaluation for NeuroThrombectomy

Context

Purpose of application

This application from Imperial College Healthcare NHS Trust set out the purpose of medical research that seeks to assess the efficacy of the EmboTrap Revascularisation Device in a real-world setting.

15 million people worldwide suffer from a stroke each year. Approximately 90% of all strokes are Acute Ischemic Strokes (AIS), the majority of which are due to Large Vessel Occlusions (LVO) Numerous studies have shown that removing the blood clot or occlusion can limit disability and drastically improve the patient's chances of having a good functional outcome. Intravenoustissues plasminogen activator (IV t-PA) is routinely used to treat patients experiencing AIS in the United States, Europe and other regions. However, many patients do not meet the therapy's eligibility criteria and IV t-PA has been shown to be less effective in recanalizing proximal LVOs. Previous trials have shown that mechanical thrombectomy can be a safe and effective alternative to IV t-PA alone. Previous trials have used stent retrievers, however successful revascularisation is not achieved in all patients. The applicants seek to test the effectiveness and safety of the EmboTrap Revascularisation Device in treatment of AIS.

Eligible patients will be identified by the direct care team who will inform the research team and provide them with the patients contact details. The research team will also access patient records to check eligibility. Patients will then be contacted by the research team and their consent sought to take part in the study.

A recommendation for class 3 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Patients with Acute Ischemic Stroke treated with the EmboTrap or Embovac Revascularization Devices. 150 patients will be recruited within the UK.
Data sources	1. Patient records at Imperial College Healthcare NHS Trust
Identifiers required for linkage purposes	5. Name 6. Hospital ID
Identifiers required for analysis purposes	3. Date of death 4. Gender 5. Ethnicity

Confidentiality Advisory Group advice
The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest
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 the section 251 of the NHS Act 2006.

Following consideration of the risks to patient confidentiality versus the benefits of the study the CAG agreed that the application was in the public interest.

Practicable alternatives
Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- **Feasibility of consent**

The applicants advised that it was not practicable for the direct care team to undertake the consent process due to clinical time commitments. The interventional radiology team also do not typically follow up patients on the wards. Patients may also be transferred to other hospitals before eligible patients can be identified and approached.

The study has been running since 2019. Initially, the direct care team were undertaking consent. In the first phase of the trial, 35 patients were noted as eligible on the screening log but only 2 patients were recruited. In the second phase, 51 patients were eligible and 1 recruited. 7 patients were not approached as their next of kin was not available to discuss the project with the direct care team.

The Members were content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

The research team require access to confidential patient information in order to check patient records to assess eligibility and to make contact with patients.

The Sub-Committee was content that using anonymous information was not a practicable alternative.

‘Patient Notification’ and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient

information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicants noted that they had not devised a patient notification or dissent mechanism, as support is needed for the research team to contact patients over the telephone to seek consent.

The National Data Opt-Out will be applied.

The Sub-Committee requested that the applicant should develop a simple poster to display in clinical areas which would inform people about the study. The patient notification needs to explain how patients can dissent to inclusion and provide appropriate contact details.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicants have not undertaken any patient and public involvement. The applicants have suggested that the clinical team ask their general patient population whether they would be in support of a research team member making contact to seek their consent to take part in research without prior permission.

The CAG requested that patient and public involvement was undertaken with a small group of people. including stroke patients. This should describe the purpose of the research and specifically seek their views on whether they would be in support of a research team member making contact to seek their consent to take part in research without prior permission.

Exit strategy

Consent is the exit strategy for patients who agree to take part.

If a patient declines to take part the site will update the screening log with a screening number and date, but no confidential patient information will be recorded. A note will also be added to the patient's medical record, advising that the patient was contacted about the study and declined to participate, and the details held by the research team will be deleted immediately.

Members are content with the exit strategy provided.

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

1. Further methods of patient notification need to be developed, making information available in brief, accessible posters in clinical areas. The patient notification needs to explain how patients can dissent to inclusion and provide appropriate contact details.

2. Patient and public involvement needs to be undertaken with a small group including stroke patients.

3. Favourable opinion from a Research Ethics Committee. **Confirmed: 04 November 2023**

4. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. **Confirmed:**

   The NHS England **21/22** DSPT review for **Imperial College Healthcare NHS Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (05 July 2023)

Minutes signed off as accurate by correspondence from		
Signed – Officers of CAG		Date
Ms Clare Sanderson, Alternative Vice Chair		*07 July 2023*
Signed – Confidentiality Advice Team		Date

Dayheem Sedighi, HRA Approvals Administrator		*05 July 2023*