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

31 March 2023 via correspondence

Present:

Name	Role	Items
Dr Patrick Coyle	Vice Chair	2a
Mr David Evans	CAG Member	2a
Dr Pauline Lyseight-Jones	CAG Member	2a

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/0041 - Management of Patients with Chronic Liver Disease Admitted to Hospital as an Emergency: MAP-CLD Social Science (CAG)

Context

Purpose of application

This application from Kings College Hospital NHS Foundation Trust set out the purpose of medical research that seeks to explore patients experience of chronic liver disease and how this is impacted by their local healthcare system and their life circumstances.

Recent studies have noted the increasing prevalence of liver disease in the UK, the resulting increase in morbidity and mortality, and regional variations in survival. Patients with chronic liver disease (CLD) living in the most deprived areas of England are likely to die nearly 10 years earlier and have a mortality rate nearly twice as high as those living in the most affluent areas. Several factors may cause these unequal mortality rates, including varying access across regions to specialist care, differences in ability to access high dependency or ICU units promptly, and continued engagement with liver specialists post-discharge.

The applicants will undertake ethnographic observations of different types of liver services to explore the day-to-day running of the services, who and what are present at different times and places, what is talked about, by whom, when and where. The observations will be conducted at four sites, Kings College Hospital NHS Foundation Trust, the Royal Blackburn Teaching Hospital at East Lancashire Hospitals NHS Trust, The William Harvey Hospital at East Kent Hospitals University NHS Foundation Trust and Derrisford Hospital at University Hospitals Plymouth NHS Trust. The researcher will observe team meetings and will shadow clinicians and patients. When patients or clinicians come into incidental contact with the researcher, the lead clinician will introduce the researchers to the patients and ask for verbal consent for the researcher to observe. The researcher will also attend clinical and multi-disciplinary team meetings, where patients are not in attendance, and patient care is discussed. Support is required for these observations.

A recommendation for class 5 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 have experienced an emergency admission or been seen by outpatient liver or medicine clinics for liver disease in one of the participating trusts.
Data sources	1. The researcher may be exposed to confidential patient information while undertaking observation of patient care and clinical meetings at the four participating trusts: a. Kings College Hospital NHS Foundation Trust b. The Royal Blackburn Teaching Hospital, East Lancashire Hospitals NHS Trust c. The William Harvey Hospital, East Kent Hospitals University NHS Foundation Trust d. Derrisford Hospital, University Hospitals Plymouth NHS Trust
Identifiers required for linkage purposes	No items of confidential patient information are needed for linkage purposes.
Identifiers required for analysis purposes	No items of confidential patient information are needed for analysis.

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.

The CAG noted that the application is clearly in the public interest, focussing as it does on situational features of treatment outcomes and the wellbeing of patients.

Scope

The CAG noted that the scope of the request is clear and in line with precedent set criterion 10.

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.

- **Minimising flows of identifiable information**

The CAG noted that great care has been given to minimise their exposure to confidential patient information. The applicants appear to have made every effort to introduce practical alternatives to the inadvertent exposure of such information. Where there has been observation of dissenting patients, the ethnographer will keep a note of this on an encrypted digital device and will delete any information related to the individuals when the site-specific ethnography is complete. This appears reasonable and appropriate. The overall research method itself does not include the retention of patient identifiable data where there has been accidental disclosure, or from ethnographic observation.

- **Feasibility of consent**

It is impracticable to identify and approach all the patients who are discussed in these meetings for consent for RL to hear their details. Tracing patients likely to be discussed at the meeting ahead of the meeting to contact them for consent will not be possible. The researcher's presence should not alter the nature of discussions in these clinical meetings, nor present an additional burden to clinicians' work, so it is not practicable or appropriate to modify the meeting such that patient identifiers will not be disclosed.

Members were content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

No confidential patient information is required. However, the researchers may be incidentally exposed to confidential patient information while undertaking observation of patient care and staff meetings. The CAG agreed that the application activity could not be conducted in any other way.

‘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.

Patients will be made aware that ethnographic research is taking place by display of poster in areas where the observations are taking place. The lead clinician will introduce the researcher to patients encountered in the observation area and will ask for patient consent to be observed. Patients are advised to let the researcher know they don’t want to be observed when the researcher approaches them for consent.

The REC had queried whether the poster could advise patients to notify a member of staff or one of the research team if they want to opt-out. A revised poster was provided, which advised patients that they could let their care team know if they did not want to be observed. The CAG noted that the poster had been revised to state that patients can let their care team know if they don't want to be observed, but the leaflet still refers to the researcher only. Members asked that the leaflet was revised in line with the poster.

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 had consulted with patients with CLD at an early stage. The applicants worked with the British Liver Trust to conduct an online survey of 57 patients with CLD, selected to be representative of the proposed study cohort.

Thirty-three of the respondents volunteered to join an online patient consultation group for the research project. A face-to face focus group was then conducted with 19 people who had liver transplantation for CLD, many of whom had experienced emergency admission at an early stage of their illness. This group also confirmed support for the proposed research and its methodology. They expressed enthusiasm for continued patient participation in the process of research.

The applicants plan to conduct ongoing PPIE involvement in the project by including a patient representative, who has lived experience of CLD, emergency admission and liver transplant, and a representative of a patient organisation the British Liver Trust, as grant co-applicants and members of the research team. They will be

involved in all stages of the research cycle, including determining the priority of research questions, advising on the opt-out process, and interpretation and dissemination of the results.

The project PPIE group will be convened at around 6 monthly intervals throughout the project. The group will consider and advise on research questions, conduct and the actions that should follow its findings, and feed back to the research team. The dissemination plan includes webinars, presentations and reports for patients and patient organisations.

The issue of incidental disclosures was discussed with the Patient and Public Involvement Group of 6 people. Those consulted thought it was reasonable for the researcher to sit in on meetings where they may be exposed to patient information.

The CAG noted that the application includes responses derived from a consultation with the PPI group (six people) about the acceptability of the risk of such accidental disclosures. All respondents were supportive of the researcher observing meetings without patient consent for several reasons: an expectation that the people in any such meeting would have a reason relevant to the care and wellbeing of the patient, that discussion in such meetings may refer to people as a case or by symptoms and that negative treatment outcomes might be affected in future through there being observation of doctors' discussion about patients when the patient is not present.

The CAG noted the patient and public involvement that had been conducted and raised no queries.

Exit strategy

No items of confidential patient information will be recorded by the researcher undertaking the observations.

Members were content with the exit strategy.

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. The patient notification leaflet needs to be revised to advise that patients can opt-out by informing their care team or the researcher, in line with the information given on the poster.

2. Favourable opinion from a Research Ethics Committee. **Confirmed:** 27 March 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 **King's College Hospital NHS Foundation Trust, East Lancashire Hospitals NHS Trust, East Kent Hospitals University NHS Foundation Trust and University Hospitals Plymouth NHS Trust** was confirmed as '**Standards Met**' on the NHS England DSPT Tracker (**12 April 2023**)

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

Minutes signed off as accurate by correspondence from		
Signed – Officers of CAG		Date
Dr Patrick Coyle, Vice Chair		*12 April 2023*
Signed – Confidentiality Advice Team		Date
Dayheem Sedighi, HRA Approvals Administrator		*12 April 2023*