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

05 May 2023 via correspondence

Present:

Name	Role	Items
Dr Patrick Coyle	CAG Vice Chair	2a
Mr David Evans	CAG Member	2a
Mr Anthony Kane	CAG Member	2a

Also in attendance:

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

1. Expressions of interest

There were no conflicts of interest declared.

2.New Precedent Set Review Applications

a. 23/CAG/0055- Understanding patient uptake and experience of interpreter services in primary care (Interpret-X)

Context

Purpose of application

This application from Queen Mary University of London set out the purpose of medical research that seeks to investigate how interpreting services are currently implemented in primary care.

In the UK there is a growing and ageing population of people for whom English is not their first language. Interpreter services are provided to ensure patients, carers and clinicians understand each other, and to try to avoid worsening inequalities in healthcare access and outcomes. This is particularly important in primary care because it is the main source of NHS healthcare. Over 98% of people in the UK are registered with a GP, so provision of good interpreter services in primary care is key to the reduction of health inequalities. Research suggests that providing interpreters improves quality of care, and when patients with limited language proficiency have access to trained professional interpreters, they report higher patient satisfaction, higher comprehension and there are fewer errors of potential clinical consequence and equalisation of healthcare access. Findings will help understanding of the potential impacts of interpreting services on reducing health inequalities in primary healthcare access.

A researcher is undertaking a number of different methodologies at 4 participating General Practitioner (GP) surgeries, including consented staff interviews and consented interviews with commissioners and policy-makers at local and national levels, documentation reviews, and verbally consented observations of patient consultations. These elements do not require ‘s251’ support.

However the researcher, who is not considered direct care team, is also undertaking ethnographic observations, of clinical meetings of different types e.g. primary care staff meetings, commissioning meetings. Support under Regulation 5 is required for this aspect of the study as the applicants may be exposed to confidential patient information when undertaking the observations. Observations will be recorded via handwritten field notes. Identifiable patient information will not be recorded.

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 who were discussed during clinical observations at participating GP practices
Data sources	1. Clinical meetings/observations in participating GP practices, recorded via written field notes, at the following sites; 1. Page Hall Medical Centre, 101 Owler Lane, Sheffield, S4 8G 2. Evergreen Surgery, 1 Smythe Close, Edmonton, N9 0TW 3. Mathukia Surgery, 281 Ilford Ln, Ilford, IG1 2SF 4. Jubilee Street Practice, 368-374 Commercial Road, Tower Hamlets, E1 0LS 5. St Andrews Health Centre, 2 Hannaford Walk, Bow, E3 3FF 6. Bromley by Bow Health Centre, St Leonards Street, London, E3 3BT
Identifiers required for linkage purposes	No items of confidential patient information will be recorded for linkage purposes
Identifiers required for analysis purposes	No items of confidential patient information will be recorded for analysis purposes

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 and 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 researcher will be observing clinical meetings in GPs surgeries. It will not be possible to seek informed consent from every person who may be discussed in these interactions, as the discussions are often spontaneous, the patient will not be present, and the researcher will therefore not know in advance who will be discussed. Therefore, seeking consent in advance of observations taking place is not possible.

Consent will be sought wherever it is practicable, for example patient consultations, and consented interviews.

Members were content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

The researchers may be exposed to confidential patient information when observing meetings. No items of confidential patient information will be recorded.

Patient data is not the focus of the research activity and no patient data will be recorded or used for research purposes in the study

During observations of clinical meetings, the research may be incidentally exposed to identifiable patient information, however this data is not being collected and no identifiable information will be recorded by the researcher. The researcher will not write down any personal information about the patient.

Sub-Committee were 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 applicant has provided a poster for the waiting room that states there are researchers observing clinical interactions surrounding interpreter services, and indicates that if the patients wish for the researcher not to observe, then they should tell the practice staff, who will then be able to organise for the researcher to step out of any meetings for specific patients where possible.

It is not possible for the applicant to apply the National Data Opt Out (NDOO), and it has previously been accepted by CAG that it is not possible to apply the NDOO to incidental disclosures.

The Members were broadly content with this method of patient notification, but suggested a few changes to the content of the poster. The Members commented that although the poster does mention that '*A researcher is observing interactions surrounding interpreter services. This include attending meetings where information about your care may be discussed*', it does not make clear that the researcher is not part of the direct care team, and it does not make clear that the information overheard would be identifiable information. As the breach is not clearly stated, the fact that the applicant has a legal basis to do this under 'Section 251' has also not been stated. A layered approach could address this more detailed information, either via a newly developed leaflet which could be mentioned on the poster, or via a website address or QR code. The CAG feel that developing additional optional notifications would be preferable to filling the poster with too much information, and thereby reducing its impact.

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 applicant consulted with a lead patient and public involvement member who has worked as an interpreter and health advocate in the South Asian community in East London. She stressed that patients would not want researchers to record personal details about their gender, medical conditions or personal situations without consent. She made suggestions about how to conduct the research in a manner acceptable to patients, based on her experience, mainly in relation to notes taken during periods of observation.

The Members noted that the patient and public involvement was inadequate as the research only consulted the views of one person, who although an interpreter, was not a patient requiring access to interpreter services, and as such, did not represent the cohort.

The Members agreed that further patient and public involvement needed to be carried out directly with a small group of patients requiring interpreter services, to include discussion of the use of confidential patient information as proposed in the application, and feedback provided.

Exit strategy

No items of confidential patient information will be recorded. Therefore the exit strategy will be the time point that the applicant stops the observations. Observations of meetings are estimated to be completed by 31st August 2024. 's251' support required until this point.

The Sub-Committee were content with the exit strategy provided.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Please alter the poster to make it clear that the researcher is not part of the direct care team, that the information overheard would be identifiable information, and the fact that the applicant has a legal basis to do this under 'Section 251'. Alternatively, please alter the poster to lead on to either a leaflet or a website, which contains this additional information, and provide to CAG for review.

2. Further patient and public involvement needs to be carried out directly with a small group of patients requiring interpreter services, to include discussion of the use of confidential patient information as proposed in the application, and feedback provided.

Specific conditions of support (provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 29 March 2023**

2. 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. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   Due to the number of participating organisations involved it is the responsibility of **Queen Mary University of London** as controller, to ensure that participating organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised.

Minutes signed off as accurate by correspondence from		
Signed – Officers of CAG		Date
Dr Patrick Coyle		*17 May 2023*
Signed – Confidentiality Advice Team		Date
Dayheem Sedighi, HRA Approvals Administrator		*16 May 2023*