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

19 May 2023 via correspondence

Present:

Name	Role	Items
Dr Tony Calland MBE	CAG Chair	2a, 2b
Mr Andrew Melville	CAG Committee Member	2a
Ms Rose Payne	CAG Committee Member	2a
Ms Diana Robbins	CAG Committee Member	2b
Mr Umar Sabat	CAG Committee Member	2b

Also in attendance:

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

1. Expressions of interest

There was no conflicts of interest declared.

2.New Precedent Set Review Applications

a. 23/CAG/0056 - How to improve communication from GPs to hospital specialists?

Context

Purpose of application

This application from the University of Cambridge set out the purpose of medical research that seeks to examine the impact of use of a primary-secondary care interface on communication and relationships between GPs and hospital specialists.

A recent study by the James Lind Alliance Priority-Setting Partnership in the UK identified communication issues between primary and secondary care systems as the third most important unanswered research question in improving patient safety. Most research exploring the communication processes across primary-secondary care interface has concentrated on discharge processes from hospital care to community care, rather than the reverse, i.e., the initial GP referrals from primary care to specialists.

The applicants will undertake a qualitative study to evaluate the Granta model of integrated care between GPs and hospital consultants. Interviews will be held with GPs from the Granta Primary Care Network (PCN), and a neurologist from Cambridge University Hospitals and a psychiatrist from Cambridge and Peterborough NHS Foundation Trust who frequently work with this GP group. Interviews will also be held with other stakeholders within the Trusts and PCN. Focus groups will also be held with Granta staff and teleconference meetings between the Consultant Neurologist or Psychiatrist and the Granta GPs will be observed.

The applicants sought support under the Regulations due to the possibility that confidential patient information may be disclosed during the observations of meetings. The researcher will take notes about the interactions occurring in the

teleconference, but will not record any patient identifiable information, and no audio or video recordings will take place.

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	The cohort included in the study are members of staff. However, incidental disclosures of confidential patient information may be made when observations of staff meetings take place.
Data sources	1. Incidental disclosures of confidential patient information may be made during observations of staff meetings at: a. The Granta Primary Care Network (PCN) b. Cambridge University Hospitals NHS Foundation Trust c. Cambridge and Peterborough NHS Foundation Trust
Identifiers required for linkage purposes	No items of confidential patient information are required for linkage purposes
Identifiers required for analysis purposes	No items of confidential patient information are required 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. The CAG noted 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**

Staff, rather than patients, are the focus of the research. However, incidental disclosures of confidential patient information may be made during observations of meetings. It is not possible to predict which patients may be discussed, so consent cannot be sought before the meetings. The researchers also will not record any items of confidential patient information so it will not be possible to seek consent after the observation.

The CAG was content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

The applicants do not require access to confidential patient information. Support is requested to allow for incidental disclosures of confidential patient information that may occur during observations of teleconference meetings between clinical staff.

The CAG 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 provided a poster. This will be placed in all branches of Granta Medical Practices. As the teleconference meetings are happening every 2 weeks, patients are advised to contact the applicant directly if they do not want the applicant to be present during the teleconference meeting.

A list of patients who will be discussed during the MDT teleconference will be provided to the applicant a couple of days in advance of the meeting, although the applicant notes that there may be last minute additions. The applicant will check the list of patients before the meeting takes place to make sure none of them have dissented. A list of dissenting patients will be retained by the applicant.

The CAG requested for revisions to be made to the patient notification poster, requesting for the purpose of the study to be explained, and for the role of CAG to be clarified. The CAG noted that the poster makes it seem as though CAG might be attending some meetings also. Therefore, reference should be made regarding the fact that although no confidential patient information is being recorded, ‘s251’ support from the Health Research Authority (HRA) has been provided, after advice from the Confidentiality Advisory group (CAG), as identifiable patient information may be discussed, and overheard by individuals who are not part of the direct care team, whilst observing meetings/clinical interactions.

Furthermore, if possible, the CAG asked that the poster was displayed on all Patient Care practices’ websites, and on the Patient Care Network’s website.

The CAG requested that a contact telephone number and address was added to the poster, as a means of opt-out.

Lastly, the CAG requested clarification on when the list of dissenters retained by the applicant would be deleted.

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 undertaken patient and public involvement when designing the research proposal. The Granta PCN has an active Patient Participation Group (PPG) with a patient-focused voice. The applicants aim to run 3 sessions with the Granta PPG, one prior to the start of the research, one in the middle of the research and one towards the end of the research for the dissemination of research findings.

The application held a PPG (Patient Participation Group) discussion on 2nd May 2023 to inform committee members of the Granta Medical Practice of the research, it's aims and objections and methods and welcomed feedback from the committee members. 6 members attended. The group was supportive of the project.

The CAG requested clarification as to whether the incidental disclosure of confidential patient information was discussed, as it was not clear from the information provided. If this was not the case, this was requested to be discussed within the next meeting.

Exit strategy

No items of confidential patient information will be collected during the study. However ‘s251’ support will be required until the end of the incidental observations.

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. The poster needs to be updated to clearly describe the purpose of the study and the role of CAG.

2. If possible, please display the poster on the practice's website.

3. A telephone contact number and address need to be included within the poster, as a means of opt-out.

4. Clarify when the applicant will delete the list of dissenters regarding the opt-out process.

5. Clarify whether the incidental disclosure of confidential patient information was specifically discussed within the patient and public involvement group. If not, please raise this within the next meeting, and provide feedback to CAG.

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. **Pending**

2. Confirmation provided from the IG Delivery 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. **Pending:**

   The NHS England **21/22** DSPT reviews for **Cambridge University Hospitals NHS Foundation Trust** & **Cambridge and Peterborough NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 31 May 2023)

   The NHS England **21/22** DSPT review for **Granta Medical Practices** is pending.

b. 23/CAG/0064 - Stroke Audit Machine Learning

Context

Purpose of application

This application from the University of Exeter College of Medicine and Health set out the purpose of medical research that seeks to investigate what a machine-learning model based on SSNAP data should look like and how it should be delivered.

Stroke is a leading cause of death and disability, with over 85,000 people hospitalised in the UK each year. One way of treating stroke and preventing disability is to treat with thrombolysis, where medication that breaks down blood clots is given. Thrombolysis is not suitable for all patients and can involve risk for some patients. For thrombolysis to be useful it needs to be given as soon after the stroke as possible. The use of thrombolysis varies hugely, even for patients with similar treatment pathways and with similar characteristics. Some hospitals rarely use it, some use it in a quarter of stroke patients. The speed of giving thrombolysis also varies. Some hospitals take an average of 90 minutes, others less than 40 minutes, to administer the drug. In a previous study, SAMUeL-1, reasons for variations in use of thrombolysis were investigated. One reason was clinical decision-making. The applicants are now seeking to collect further information on the clinical decision-making process.

The applicants will trace how physicians currently make decisions around stroke/thrombolysis in real time, and the resources and decision-making tools they have available. As part of this process of observation, the researcher will observe Multi-Disciplinary Team meetings during the sections where stroke care and thrombolysis are discussed. Observations of patient care will also take place. The researcher will overhear confidential patient information, but will not document, gather or process the information as it not relevant to the study. No confidential patient information will be used for research purposes.

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	194 members of NHS staff will be included. Observations will be conducted in 3 hospital sites. It is not possible to give a precise figure for those included in the observations.
Data sources	1. Incidental disclosures of confidential patient information may be made during observations of staff meetings at: a. University Hospitals Sussex Foundation Trust b. The Royal Cornwall hospital Foundation Trust c. Northern Lincolnshire and Goole Foundation Trust
Identifiers required for linkage purposes	No items of confidential patient information will be used for linkage.
Identifiers required for analysis purposes	No items of confidential patient information will be used 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. The CAG noted the application was in the public's 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**

Staff, rather than patients, are the focus of the research. However, incidental disclosures of confidential patient information may be made during observations of meetings. It is not possible to predict which patients may be discussed, so consent cannot be sought before the meetings. The researchers also will not record any items of confidential patient information so it will not be possible to seek consent after the observation.

The applicants also note that it is not practical to consent patients in acute stroke care as there must be no time burden placed on them, and they may be very unwell.

As soon as possible following a patient's arrival, the treating physician will inform the patient of the research, and of the presence of the researcher, in order to ensure that they are happy for the researcher to be present. At this point, they will also be offered a patient information guide sheet and given the opportunity to ask the researcher questions.

The CAG was content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

The applicants do not require access to confidential patient information. Support is requested to allow for incidental disclosures of confidential patient information that may occur during observations of teleconference meetings between clinical staff.

The CAG 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.

As soon as possible following a patient's arrival, the treating physician will inform the patient of the research, and of the presence of the researcher, in order to ensure that they are happy for the researcher to be present. At this point, they will also be offered a patient information guide sheet and given the opportunity to ask the researcher questions. If the patient says that they would prefer that the researcher not be present, the researcher will immediately discontinue any observational work around that patient’s treatment and all records made around decisions about that patient's treatment will be destroyed.

If a patient 'opts out' of physicians discussing their treatment in the study, the researcher will not observe any further activities related to that patient, and any information regarding their treatment will be destroyed.

The CAG requested that the applicant review the patient notification, specifically relating to sections on data protection, to ensure that the wording flows appropriately and was not too complex, as members noted that parts of it were in a different text.

The CAG was otherwise content with the patient notification materials and opt out options.

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.

A SAMueL-2 Patient and Carer's Involvement group consists of 6 members (5 stroke survivors and one carer) who are consulted 4-6 times a year. The lead Patient and Carer's Involvement group facilitator has worked across multiple stroke projects (including SAMueL-1) and is supported by PenPEG administrative staff.

The Patient and Carer's Involvement group reviewed the main qualitative research documents. Their role is to contribute their patient and carer perspectives on decisions made on the study as well as to make suggestions and changes regarding the protocol, design, analysis and dissemination. They will be consulted with throughout analysis stage, and to discuss findings and their implications for practice.

The Patient and Carer's Involvement group were consulted about the acceptability of the researcher potentially overhearing confidential patient information during the research project, and their answers were favourable. They fully support the research project. They believe the research is timely and important. The applicant provided further details on the feedback provided in their answer to CAT validation queries.

The CAG noted that the patient and public involvement undertaken was proportionate. The CAG however requested that continued engagement with the Patient and Carer's Involvement group was undertaken, and for the applicant to try to increase the number of volunteers, by adding in new voices to undertake ongoing patient and public involvement specifically related to this study.

Exit strategy

No items of confidential patient information will be collected during the study. 'S251' support will be required until the observations are completed.

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. The patient notification, specifically relating to the sections on data protection, to ensure that the wording flows appropriately and is not too complex, and the formatting is correct, and provide an updated document to CAG.

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. Engagement with the Patient and Carer's Involvement Group is to be continued, including engagement with new volunteers, and ongoing patient and public involvement specifically related to this study. Feedback is to be provided at the first annual review.

2. Favourable opinion from a Research Ethics Committee. **Pending**

3. Confirmation provided from the IG Delivery 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. **Pending:**

   The NHS England **21/22** DSPT reviews for **University Hospitals Sussex Foundation Trust** & **The Royal Cornwall Hospitals NHS Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 31 May 2023)

   The NHS England **21/22** DSPT review for **Northern Lincolnshire and Goole NHS Foundation Trust** is pending

Minutes signed off as accurate by correspondence from		
Signed – Officers of CAG		Date
Dr Tony Calland MBE – CAG Chair		*31/05/2023*
Signed – Confidentiality Advice Team		Date
William Lyse – Approvals Administrator		*31/05/2023*