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

20 November 2020

Present:

Name	Capacity	Items
Dr Tony Calland MBE	CAG Chair	1a, 2a
Dr Lorna Fraser	CAG Member	1a
Mr Myer Glickman	CAG Member	1a, 2a
Mr Marc Taylor	CAG Member	2a

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

1. New Precedent Set Review Applications – Research

a. 20/CAG/0147 - Global Consortium Study of Neurological Dysfunction in COVID 19 - paediatric substudy (Short title: GCS NeuroCOVID paediatric substudy)

Context

Purpose of application

This application from Birmingham Women's and Children's NHS Foundation Trust sets out the purpose of medical research that aims to quantify neurological symptoms and diagnoses in paediatric patients with confirmed or presumed COVID-19 who are admitted to hospital. This study has three planned tiers, but this application is only for tier one, which aims to use routinely collected observational data.

As the COVID-19 pandemic evolves worldwide, reports of a spectrum of mild to severe neurological syndromes among patients infected with SARS-CoV-2 are emerging. Early reports indicate that adults experience a variety of neurological symptoms and diagnoses in approximately 36% of patients. In children, recent evidence highlights acute and long-term neurological manifestations due to other viral illnesses, however, COVID-19 reports in children lack detailed information on the frequency and outcomes of neurological findings. Identifying neurological manifestations of SARS-CoV-2 may identify an important fraction of COVID-19 patients who have non-classical presentation with neurological symptoms. Understanding neurophenotypes is particularly important in the paediatric population. Identifying post-infectious neurological events that can occur subsequent to the diagnosis and may impact long-term outcomes (e.g., cognitive, emotional, physical health) is equally critical.

This study aims to collect routinely collected data from children admitted to hospitals in England and Wales with confirmed or suspected COVID-19, from 01 January 2020 to 31 December 2021. Patient identifiers are only required to link to a pseudonymous study ID. The extraction of the data will be both retrospective and prospective. Consent is not planned to be taken due to the importance of studying the entire cohort, and also due to minimising infection risk between patients and researchers, and the importance of preserving personal protective equipment (PPE) for necessary clinical use. The extraction of data will in some cases be done by the clinical team which would not require support under Regulation 5, however in some cases this will be performed by researchers, due to the clinical team not having the resource to perform this extraction, and it is these cases where support under regulation 5 is requested.

The identifiers will be modified and removed to create a pseudonymous dataset. The key will be retained by individual trusts, however in some cases this will be retained by researchers who are not part of the direct care team, and in these cases support is required to retain the key linking the pseudonymous study ID to confidential patient identifiers until 31 December 2032. The pseudonymous clinical data will be securely sent to Birmingham Women's and Children's NHS Foundation Trust, quarterly, and to the central team at Birmingham. The data will not be able to be re-identified and so can be considered anonymous. The anonymous dataset will be securely sent to the UPMC Children's Hospital of Pittsburgh, USA, for central analysis, and this will be co-ordinated by the team at Birmingham.

A recommendation for class 1, 5 & 6 support was requested to cover 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	Any child aged 0-17, admitted to a hospital in England and Wales, with confirmed or presumed COVID-19 infection (including COVID-19 associated hyperinflammatory syndrome) From January 1, 2020 to December 31, 2021. Total UK sample size: 200 Total international sample size (including UK): 1000 This is a pragmatic estimate based on early data. It is likely that the numbers of patients could be significantly higher if there are further waves of COVID-19 infection

Data sources	Participating Trusts across England and Wales who treat paediatric Covid-19 cases (hospital electronic databases and medical records or physical medical records where appropriate) Confirmed: • Birmingham Women's and Children's NHS Foundation Trust • Guy's and St Thomas' NHS Foundation Trust (Evelina London Children's) • Barts Health NHS Trust (Royal London Hospital) • Alder Hey Children's NHS Foundation Trust • Nottingham University Hospitals NHS Trust (QMC) • King's College Hospital NHS Foundation Trust • University Hospitals of Leicester NHS Foundation Trust • Cardiff and Vale University Health Board (University Hospitals Wales) Discussions ongoing, support also requested for: • Great Ormond Street Hospital NHS Foundation trust • Imperial College Healthcare NHS Trust • Leeds teaching Hospitals NHS Trust • University Hospitals Birmingham NHS Foundation Trust • Manchester University NHS Foundation Trust • University Hospitals Southampton NHS foundation trust • University Hospitals Bristol NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Hospital ID 4. Date of birth 5. Date of Death (Required to link to psudonymous study ID)
Identifiers required for analysis purposes	1. Date of birth modified to age in months/years 2. Pseudonymous study ID 3. Date of admission 4. Date of discharge 5. Gender 6. Ethnicity 7. Covid-19 status

Additional information	Key linking pseudonymous study ID to identifiers held at each hospital Data will be submitted by trusts to Birmingham children hospital quarterly Dataset sent to USA for analysis; this dataset can be defined as anonymous.

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 agreed that the application was in the public interest and has a clear medical purpose.

Scope of support

Members considered if the COPI notice provided an alternative legal basis under which the applicant could process confidential patient information without consent. However it was agreed at the time of this review, and also at the time of informal advice given after a CAG discussion on 19 June 2020, that despite the application involving patients with a Covid-19 diagnosis, the study is not of sufficient urgency to fulfil the criteria of the COPI notice, and it was agreed that support under Regulation 5 is an appropriate route.

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 reason that consent is not practicable or appropriate for a number of reasons. This is due to the need to ascertain all possible cases, and reduce bias in a small population. The applicant has designed the study to not take consent in order to reduce infection risk, reduce burden on clinical and research teams, to ensure PPE is protected for important clinical uses, and to allow for batch collection of retrospective data when possible.

The CAG agreed with the rationale given for not seeking consent, understanding the risks inherent in non-essential contacts for this study population.

- **Use of anonymised/pseudonymised data**

Confidential patient data is required for identification of the correct cohort, and to link to a pseudonymous study ID. Identifiers are modified, and data is pseudonymised for sending to the central NHS Trust and to USA, and the key linking pseudonymous study ID to identifiers will be held locally. The CAG were content that this could not be performed in any other way that would reduce the use of identifiers, and were content that the datasets flowing to Birmingham Women's and Children's NHS Foundation Trust and the academic institution in the USA could be considered anonymous, as these organisations would not be able to re-identify the cohort.

- **Direct care team**

The applicant is requesting support as in some cases the data extraction will be performed by researchers who are not members of the direct care team. In the cases where this is possible, cohort identification and data extraction will be performed by the direct care team to avoid a breach in patient confidentiality. However, the applicant has set out the reasons why this sometimes may not be possible and is difficult to predict. The applicant explained that always using the clinical team would not be a practicable alternative, because some of the children's hospitals involved have many wards, and a paediatric Covid-19 patient could be on any of them; therefore despite each participating Trust having interested clinicians working on the study, it is very unlikely that the clinician would be part of the direct care team in each eligible case, so the applicant is applying for support on this basis. The CAG accepted this justification, and have provided a condition of support for clarity.

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 objection 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 which will be displayed at various locations in participating sites to provide information for families, with individual NHS Trust details to be inserted at the bottom. These details on the poster will provide a local dissent mechanism if any parent wishes to opt their child out of the research.

The poster has a QR code, which will take you to the website of Birmingham Women's and Children's NHS Foundation Trust containing further information about the study. This website hasn't been uploaded yet.

Applicants do not mention if the National Data Opt Out will apply to this study.

The CAG were content with the poster, and the opt out mechanism, however would like to see the website text, and would like the applicant to explore if the National Data Opt Out could be applied to the cohort.

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 is in discussion with the Birmingham Women's and Children's Young person's advisory group (YPAG), both to feedback on the notification posters, and to discuss the study model. Confirmation of meeting dates is awaited.

The CAG were content to recommend support on the condition that the applicant provides feedback of the planned patient and public involvement undertaken, surrounding the use of confidential patient information without consent.

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. Support is provided for occasions where confidential patient information is processed by a researcher who is not a member of the direct care team. Support under Regulation 5 is not required if this is performed by a member of the direct care team. This condition will remain for the duration of the study.

2. Please provide the patient notification text that will be used on the website, which is linked to the QR code on the study poster provided, within 3 months of the date of this letter.

3. Please clarify if the National Data Opt Out will be applied to the cohort and provide this information to the CAG within 3 months from the date of this letter.

4. Please provide feedback on the outcomes of the planned patient and public involvement, surrounding the use of confidential patient information without consent, and report back within 3 months from the date of this letter.

5. Favourable opinion from REC
   Favourable Opinion Received 12th November 2020

6. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review.

   The Trusts where patients are identified will be required to have security assurances in place. However, as there are more than five organisations, the CAT team will not check each one individually; it is the responsibility of the applicant to ensure these are in place.

Declarations of Interest

There were no declarations of interest.

2. New Precedent Set Review Applications – Non-Research

a. 20/CAG/0155 - Community Mental Health Survey 2021

Context

Purpose of application

This non-research application from Picker, on behalf of the Care Quality Commission, set out the purpose of administering the 2021 Community Mental Health Survey.

The community mental health Survey falls within the NHS Patient Survey Programme (NPSP). The NPSP was initiated in 2002 by the then Department of Health, and is now overseen by the Care Quality Commission (CQC), the independent regulator of health and social care in England.

The 2021 community mental health Survey will be the eighteenth carried out to date. All 55 eligible mental health provider trusts will be asked to conduct the survey, drawing a sample of service users according to set criteria, and following standardised materials and procedures for all stages of the survey.

The 2021 methodology is broadly unchanged from the 2020 survey. However, due to the impact of Covid-19, the eligibility criteria for drawing the sample has been amended to include not only face to face contact but also contact via video conferencing or telephone. Applicants are also seeking support to disclose additional variables to the Survey Coordination Centre for Existing Methods' (SSCEM); postcode (to map LSOA) – this is in line with other supported surveys. The reason for this addition is to allow the SCCEM and the CQC to conduct sub-group analysis to understand the link between deprivation and quality of community mental health services at the local level. This information will enable researchers, governmental bodies, service users and providers of services to better understand the quality of service in their local area. Applicants are also additionally collecting email address indicator (similar to

the mobile phone indicator supported in 2020), and mode of contact, in line with the changes to eligibility criteria. There are no other changes to the survey, specifically Covid-19 status is not being collected in this instance.

Trusts will collect information of all eligible patients and, following suitability checks, will share confidential patient information with the coordination centre (Picker Institute Europe under the title 'Survey Coordination Centre for Existing Methods' (SSCEM)) and once of three approved contractors (Patient Perspective, Quality Health or Picker Institute Europe).

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 and over who had been in contact with NHS mental health services in the three-month period from 1 September 2020 to 30 November 2020, and who were receiving specialist care or treatment for a mental health condition, including those who receive care under the Care Programme Approach (CPA) 'Contact' in the 2021 survey is defined as face-to-face, via video-conference (e.g. using Attend Anywhere, MS Teams, Zoom, etc.) or telephone call **However:** Service users who only had telephone appointments during the sampling period are eligible to be included in the sample if they would otherwise have had at least one face-to-face appointment if it were not for the COVID-19 pandemic. Do not include service users who would have only ever had telephone appointments regardless of the COVID-19 pandemic**.**

	1250 service users from each Trust.
Data sources	1. Electronic patient records, Mental Health Trusts in England
Identifiers required for contact purposes	1. Trust code 2. A standardised unique identifier code, 3. Title (Mr, Mrs, Ms, etc.) 4. First name 5. Surname 6. Address Fields 7. Postcode
Identifiers required for analysis purposes	1. Trust code 2. The unique identifier code (as above) 3. Year of birth 4. Postcode 5. Gender 6. Ethnic category 7. Day of last contact 8. Month of last contact 9. Year of last contact 10. CPA status 11. CCG code 12. Mental Health Care Cluster Codes 13. Mobile phone indicator 14. Email address indicator 15. Mode of contact

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

Public interest

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

Members agreed that the activity has a medical purpose and the public interest in capturing the experience of community mental health patients is especially strong due to service changes caused by the Covid-19 pandemic.

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 group agreed that consent is not feasible, given the potential to introduce bias, and the lack of capacity of Trust staff.

- **Use of anonymised/pseudonymised data**

Members were content that the use of anonymised or pseudonymised information was not practicable, given the need to distribute information to patients. The Sub-Committee also were content with the postcode being used for analysis; postcode is deleted after mapping to LSOA and local authority, as per previous CQC surveys. The CAG were content with the widening of the inclusion criteria surrounding virtual contacts.

'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 objection 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 an overview of the patient notification and awareness raising mechanisms offered to Trusts. Posters will be displayed in participating Trusts throughout the sampling period to inform patients that they may be approached to participate in the survey and provide a means for prior dissent to be raised. These have been produced in English and translated into 9 other languages to improve accessibility. Trusts will be asked to consider the impact of Covid-19 on the visibility of posters, and to think carefully about where to place them

appropriately. Trusts have also been advised to display a copy of this poster on their website for those service users who do not frequently attend the trust premises.

Although the provision of posters is the primary method of informing the study population of the survey, trusts will also be informed that they can undertake their own additional promotional activities, where considered appropriate, for example through press releases and local social media.

The CAG agreed that the patient notification materials were clear and direct, and accepted the materials provided.

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 has provided an overview of the patient and public involvement activities which were undertaken in advance of the 2021 survey within the application. This included consultation with a survey specific Advisory Group; The service users involved in the Advisory Group are current mental health service users. They feed into the development of the survey including feedback about the methods used.

In addition to this,18 service users are interviewed (recruited from the general public over three rounds) to seek views and inform the survey design and process.

This is the same level of PPI as the CAG accepted for the 2020 community mental health survey, and this was once again accepted for the 2021 survey.

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 Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review.

   Confirmed: The NHS Digital **2018/19** DSPT submission for **Patient Perspective, Quality Health and Picker Institute Europe** were confirmed as '**Standards Met'** by NHS Digital by check of DSPT tracker (24 November 2020). The **2019/20** DSPT submissions have not yet been reviewed by NHS Digital, but the applicant has requested that these be reviewed.

Declarations of Interest

There were no declarations of interest.

Signed – Officers of CAG	Date
Signed – Confidentiality Advice Team	Date