Health Research Authority

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

**16 September 2022**

## Present:

| Name | Role | Items |
|---|---|---|
| Professor William Bernal | CAG Alternate-Vice Chair | 2a, 2b |
| Mr David Evans | CAG Member | 2a |
| Dr Rachel Knowles | CAG Member | 2b |
| Ms Rose Payne | CAG Member | 2a |
| Mr Dan Roulstone | CAG Member | 2b |

## Also in attendance:

| Name | Position (or reason for attending) |
|---|---|
| Mr Michael Pate | HRA Confidentiality Advisor |
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

# 1. Expressions of interest

No expressions of interest were declared.

# 2.New Precedent Set Review Applications – Research

## a. 22/CAG/0123 - A single-centre, retrospective cohort study of CT head pathologies in infants and toddlers presenting to ED due to head injury from an accidental fall

**Context**

### Purpose of application

This application from Oxford University Hospital NHS Foundation Trust set out the purpose of medical research which aims to identify the range of cranial and intracranial injury, and the effect of fall height and surface on levels of head injury, in CT heads of infants and toddlers after accidental head injury due to falls. Applicants will undertake a retrospective, data-analysis only, cohort study of infants and toddlers (≤2 years) who presented to the Emergency department (ED) with head injuries due to a fall within a 10 year period at the John Radcliffe hospital, and who underwent a CT scan to examine the consequences of those injuries. Applicants will be looking at CT scans of the heads of those children who suffered falls and identifying patterns of intracranial and cranial injury. 's251' support is required, as confidential patient information will be processed in order to link scans to clinical history using local medical records, to extract an anonymised dataset for analysis, and this will be undertaken by a medical student who is not considered part of the direct care team.

Paediatric head trauma is an important cause of hospital attendance in young children. While these injuries are mainly minor, some result in intracranial and cranial injury which is observable on CT head. A significant proportion of these head injuries is due to falls. Although there is reasonable data regarding the indications for CT in such injuries, very little is understood about the effect of the characteristics of falls on the possible intracranial and cranial injuries sustained. Results from this study will aim to help clinicians to better understand the expected spectrum of particular patterns of injury on CT head caused by a fall from a given height. Applicants also aim to identify the existence of 'outlier findings' on CT head of children who have suffered accidental

injuries. There is a danger that these very uncommon injuries are more likely to be labelled as the result of abuse due to their rarity. This should improve healthcare for patients as it will clarify the CT findings which may be found as a result of accidental head injury, and reciprocally will clarify the injuries which are not seen (or are extremely unlikely) due to accidental injury. The study aims to better understand the relationship between intracranial injury and nature of fall to improve patient care in the future.

Data will be collected from the CRIS imaging database and cross-referenced with patient notes (via ORBIT and EPR, electronic patient records at the Trust) to link to clinical information regarding patients admission to ED, using MRN number (hospital ID). After this linkage has been undertaken, the patient's MRN number will be removed from the dataset for analysis. A pseudo ID will be applied. A link between the MRN number and the pseudo ID will be maintained in a separate, password protected database on hospital servers, and this will be deleted at the end of the study.

A recommendation for class 1, 4 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.

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| **Cohort** | Infants and toddlers (≤2 years) who presented to the ED with head injuries due to a fall within a 10 year period (1 January 2012-1 January 2022) at the John Radcliffe hospital, and who underwent a CT scan to examine the consequences of those injuries<br><br>Applicant has estimated 100 patients will meet the inclusion criteria.<br><br>However ‘s251’ required for all those viewed by the researcher who is not considered direct care team (ie. all infants who presented to ED with head injury and had a |

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| | CT head), and the applicant estimates this to be about 300 |
| **Data sources** | 1. Medical records at John Radcliffe Hospital (part of Oxford University Hospital NHS Foundation Trust) including CRIS, ORBIT and EPR reporting systems, and CT scans |
| **Identifiers required for linkage purposes** | 1. MRN number (hospital ID)<br>2. Date of birth<br>3. Online medical records will be viewed in order to extract a dataset for analysis |
| **Identifiers required for analysis purposes** | 1. Date of birth modified to age at scan.<br>2. Gender |

**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 Members were agreed that this activity 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 reason that as the study is retrospective, and covering a 10 year period, it will not be possible to approach parents/carers of eligible children, as this patient group is unlikely to have regular healthcare contact. The CAG agreed with the justification provided that consent would not be practicable.

- **Use of anonymised/pseudonymised data**

MRN number is required to cross-reference across different clinical systems at the Trust, and date of birth is required to check eligibility. It is not possible to link between the clinical systems at the Trust without some minimal identifiable information. The Sub-Committee agreed with this justification.

## '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 have developed patient notification in discussion with patients. A poster will be displayed in John Radcliffe emergency department, as well as a notification from the Trust twitter account. These will offer an option to opt out by emailing the study team. The National Data Opt Out will be also applied. The CAG were content with the patient notification 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.

As a response to Confidentiality Advice Team (CAT) queries, the applicant has sought the views of a patient and public involvement group affiliated with Oxford university Hospital Emergency Department. Comments have been provided, from 4 patients, and it appears that there is largely support for this use of confidential patient information without consent. The CAG noted that despite the low numbers of patients involved in

the discussions, this appeared proportionate to the number of individuals who would be included in this small study. The Sub-Committee were content that some patient and public involvement had been undertaken which discussed the use of confidential patient information without consent, and were therefore satisfied to recommend support for the application.

## Exit strategy

Identifiable data will be destroyed at the completion of the study, approximately 6 months after the start. The applicant estimates 's251' support will be required until 1 May 2023. After this linkage has been undertaken, the patient's MRN number will be removed from the dataset for analysis. A pseudo ID will be applied. A link between the MRN number and the pseudo ID will be maintained in a separate, password protected database on hospital servers, and this will be deleted at the end of the study. The Members were content with this exit strategy.

### 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 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 the actions required to meet the specific conditions of support where indicated, within one month.

## Request for further information

1. Please provide the Favourable Opinion of the Research Ethics Committee when available.

Once received, the information will be reviewed by the Confidentiality Advice Team (CAT) in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the

next available CAG meeting. If the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

### 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 Digital 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:**

   The NHS Digital **21/22** DSPT review for **Oxford University Hospital NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 03 October 2022)

## b. 22/CAG/0130 - Enhancing The Utilisation Of COVID-19 Testing In Schools Studies: The Joint Analysis Of The COVID-19 Schools Infection Survey (SIS) And The COVID-19 Mapping And Mitigation In Schools (CoMMinS) Study

### Context

### Purpose of application

This application from the University of Bristol and the London School of Hygiene and Tropical Medicine (as joint data controllers) sets out the purpose of medical research which aims to investigate the health consequences of SARS-CoV-2 infection in children and young people (CYP) using two school surveys: the Schools Infection Survey (SIS) in England, and the Bristol-based COVID-19 Mapping and Mitigation in Schools (CoMMinS) study.

Data will be linked from the surveys to electronic health records held by NHS Digital and the Bristol, North Somerset and South Gloucestershire System-Wide Dataset.

This research will help quantify the burden of short- and long-term adverse health outcomes of SARS-CoV-2 infection in CYP and the link between them. It will help determine the risk factors for developing disease, such as age, gender, ethnicity and the nature of the SARS-CoV-2 infection itself.

ONS will send NHS Digital NHS number, date of birth and a unique study identifier from *one dataset* for SIS held at ONS (the personal data dataset). NHS Digital will remove NHS number and date of birth from the data it sends back to ONS. ONS will make available in their Secure Research Service (SRS) a *second, separate dataset* for SIS held at ONS (which is actually composed of a number of data tables, all de-identified) containing only the attributes data, along with the data from NHS Digital. We understand that, in practice, what will happen is that ONS will put their attributes datasets, and the data from NHS Digital, in the SRS, with each dataset containing the unique study identifier, so that UoB and LSHTM researchers can link the files together in the SRS.

ONS split their project areas and access permissions so that the data linkage team have access to the files with the unique IDs and personal data and then the analysts have access to the pseudo IDs (a random number that is a 1-1 match with the NHS number but is not actually the NHS number) plus the attributes data needed for analysis but all personal identifiers are removed from these files.

The linkage of electronic health records to CoMMinS data has been done entirely separately, through the BNSSG Integrated Care Board (ICB). NHS Governance for the CoMMinS linkage has gone through the BNSSG ICB's governance structure. This application is not to request ethical approval for linkage for the CoMMinS study, only for SIS. The researchers mentioned CoMMinS because similar analyses will also be done on the linked CoMMinS data (independently, and in a separate environment), and the results compared to those obtained from SIS through meta-analysis of aggregate estimates. At no point will the individual-level data from CoMMinS be brought together with the individual-level data from SIS.

A recommendation for class 4 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.

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|---|---|
| **Cohort** | Children aged between 4 and 18 years who participated in the Schools Infection Survey (SIS) |
| **Data sources** | Office of National Statistics<br>• Schools Infection Survey<br><br>NHS Digital<br>• General Practice Extraction Service (GPES) Data for Pandemic Planning and Research (GDPPR) data<br>• Emergency Care Dataset<br>• Hospital Episode Statistics<br>• Covid-19 Second Generation Surveillance Systems<br>• Medicines Dispensed in Primary Care (NHSBSA) data<br>• Covid-19 Second Generation Surveillance Systems (held by NHS Digital but a subset of the UKHSA second generation surveillance system) |
| **Identifiers required for linkage purposes** | 1. NHS number<br>2. Date of birth |
| **Identifiers required for analysis purposes** | 1. Postcode for deprivation scoring prior to deidentification. This will be MSOA, local authority district, integrated care system and deprivation score from ONS in their Secure Research Service (SRS). |

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| **Additional information** | Data will be split into two tranches from April 2019 to March 2022 and from April 2022 to March 2023. |

## 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 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.

## 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 initial SIS study was a large-scale project involving participants from 150 schools. Any attempt to re-consent participants for this additional linkage work would be a significant administrative undertaking requiring staff to access the (identifiable) consent forms and contact details for all participants - this degree of interaction with participant data would be far in excess of the interaction required by the study: a largely automated linkage process during which identifiable data will only be accessible by ONS staff, who will largely not need to access it directly. There is also no funding available to re-consent participants as SIS has now ended and ONS do not have existing infrastructure available to do this (all the participant contact for SIS1 went through IQVIA who are no longer under contract).

The CAG considered the explanation to be acceptable.

- **Use of anonymised/pseudonymised data**

A unique study identifier will be sent alongside date of birth and NHS number to NHS Digital, and NHS Digital will send back only the EHR data and the unique study identifier. To clarify, the SIS dataset to which the EHR data will be linked contains only the unique study identifier.

The CAG considered this explanation and made the following comments.

**Given ONS send the unique study identifier, DOB and NHS number to NHS Digital to obtain anonymised/pseudonymised data, the CAG would like to know how long the ONS will keep that original table (containing NHS number and DOB) and how will it be stored?**

### '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 privacy notice has not yet been developed, but ONS are aware that a privacy notice specific to this study will need to be added to the SIS study information on ONS's website. The researchers planned to draft the notice after ethical approvals were obtained. They will word the privacy notice using the existing privacy notice for the main SIS study as a basis https://www.ons.gov.uk/surveys/informationforhouseholdsandindividuals/householdandindividualsurveys/Covid19schoolsinfectionsurveysis/legalinformation which lists the email address, telephone number, and postal address for which to contact the Data Protection Officer with any queries or concerns or to be removed from the study.

The researchers will work with ONS to devise a suitable patient notification strategy.

If an individual contacts ONS and requests that their data collected as part of the study is deleted, then this will be deleted from all ONS datasets (both on ONS's system and in the SRS).

As well as the SIS opt-out option, the National Data Opt-Out will also apply. Individuals who have opted out using the latter process will not be included in the data sent to ONS by NHS Digital.

**The CAG noted that the SIS website made mention of the original study. The CAG would like to see information about the proposed linkages involved in this study added to the SIS website, with details about how to withdraw or object from data linkage, including who to contact.**

**The CAG would like to see a copy of the privacy notice and details of how this information would be communicated.**

## 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.

As part of the HDR UK-funded project to undertake this linkage, in 2021, the researchers undertook public involvement by gathering views about long-COVID in children and young people, discussing possible research questions, and seeking views around methods, by:

- Attending a Young Persons Advisory Group with seven young people
- Running an online discussion group with five families (parents/caregivers and/or young people) recruited through the Long Covid Kids online support group
- Circulating a survey completed by four GPs and one paediatrician, and holding an online meeting with two paediatricians.

The findings were published as an online report (https://commins.org.uk/documents/Long-COVID-in-children-report-21_07_21.pdf) which was tweeted and shared with the participants. Press reports, news stories, blogs,

and a case report (e.g., https://www.hdruk.ac.uk/case-studies/long-covid-in-schools) were also published. The report was featured on BBC Points West and South Today.

The PPI input was a major factor in the decision to look at healthcare use as a way of measuring the long-term effects of SARS-CoV-2 infection, and broad categories of diagnoses/related prescriptions.

Subsequent to the initial meeting, on 17/05/2022, another online discussion group was held with four of the previous participants (three parents/caregivers and one young person with long-COVID) to discuss subsequent funding proposals. All members who attended the meeting were interested in further involvement, although the diversity of the group needed to be expanded.

Key points to come out of this meeting were:

- The proposed research questions were considered to be appropriate and sufficiently comprehensive
- There should be some 'nod' to the full range of possible symptoms, even if a simplified/limited range is investigated
- 'Post-COVID' syndrome may be a more appropriate term than 'long-COVID'; 'fatigue syndrome' should be avoided
- Minimising language should not be used: 'brain fog' is potentially offensive
- Information offered to families should avoid overwhelming families
- Videos could be more accessible than a lot of written information.

All of these suggestions will be implemented going forwards.

Views were not sought around the acceptability of using confidential patient information without consent, as it was not known at the time of carrying out the PPI activities that this would be the route the researchers would take.

Regular PPI activities will continue throughout the duration of the analyses to gather opinions and input at all stages, with PPI involvement crucial to shaping the study outputs. PPI involvement has been fully costed in all funding applications.

**Whilst the CAG were mindful of having to get the study off the ground during the Covid-19 pandemic, it was noted that PPI relating to the acceptability of using confidential patient information without consent had not been undertaken. The CAG wished for PPI to be undertaken to this effect, with details of what has been undertaken to be provided in response.**

## Exit strategy

The researchers have requested two data cuts from NHS Digital: the first covering April 2019-March 2022, and the second an update additionally covering April 2022-March 2023. Again, to clarify, the full process described above, by which ONS will send NHS Digital NHS number, date of birth and a unique study identifier from one dataset for SIS held at ONS, and NHS Digital will then remove NHS number and date of birth from the data it sends back to ONS, applies to the first cut. After the first cut, NHS Digital will retain the set of NHS numbers, dates of birth and study identifiers, so that ONS do not need to re-send these for the second data cut. Thus, there will be no transfer of personal information after the first data cut. Instead, NHS Digital will send across the second set of Electronic Health Record (EHR) data with the study identifiers for ONS to use to link the EHR with their (de-identified) attributes dataset. The exit strategy is therefore de-identification.

**The CAG were content with the exit strategy to anonymise the SIS linked dataset. The retention and storage of identifiers by the ONS, in line with the query raised on page 4, would clarify the exit strategy for linkage to EHR data.**

## 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 applicant should provide details on how the NHS number and date of birth will be handled throughout the study, and whether these will be retained, and if so, for how long**

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory a final support outcome will be issued.

## 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. The CAG would like to see information about the proposed linkages involved in this study added to the SIS website, with details about how to withdraw or object from data linkage, including who to contact.

2. The CAG would like to see a copy of the privacy notice and details of how this information would be communicated.

3. PPI relating to the acceptability of using confidential patient information without consent had not been undertaken. The CAG wished for PPI to be undertaken to this effect, with details of what has been undertaken to be provided in response.

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

5. Confirmation provided from the IG Delivery Team at NHS Digital 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**

The NHS Digital **21/22** DSPT review for the Office of National Statistics was confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 4 October 2022)

The NHS Digital **21/22** DSPT review for NHS Digital was confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 4 October 2022)

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| *Minutes signed off as accurate by correspondence from* | | |
| Signed – Officers of CAG | | Date |
| *Professor William Bernal, CAG Alternate Vice-Chair* | | *03 November 2022* |
| | | |
| Signed – Confidentiality Advice Team | | Date |
| *Caroline Watchurst, HRA Confidentiality Advisor* | | *28 October 2022* |