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

04 February 2022

Present:

Name	Capacity	Items
Dr Patrick Coyle	CAG Vice Chair	1a, 1b
Dr Sophie Brannan	CAG Member	1a, 1b
Dr Anthony Kane	CAG Member	1a
Ms Diana Robbins	CAG Member	1b

Also in attendance:

Name	Position (or reason for attending)
Mr Michael Pate	HRA Confidentiality Advisor

1. New Precedent Set Review Applications – Research

a. 22/CAG/0026 – Covid impact on RSV Emergency Presentations: BronchStart

Context

Purpose of application

This application by the University Hospitals of Leicester NHS Trust, for the purpose of medical research, seeks to understand the impact of the re-emergence of respiratory syncytial virus (RSV) on the rate of bronchiolitis in those under 2 years of age.

The emergence of COVID-19 has meant that RSV has disappeared. Now that the pandemic is waning, RSV is slowly returning. Some children are at a greater risk of hospitalisation, and even death, from RSV infection, so it is important to understand the spread and whether the population at risk is of a wider age range than normal.

In order to understand the spread of RSV and whether different genotypes of RSV are responsible for different severities of disease, anonymous routine data will be collected from the clinical record and linked to samples analysed by the UK Health Security Agency.
Support is requested to allow the incidental disclosure of confidential patient information from medical records to research nurses that are considered to be outside of the direct care team by some participating sites. There is no flow of identifiable data.

A recommendation for class 3 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	Children under two years of age presenting to participating emergency departments with clinical features of bronchiolitis, acute lower respiratory tract infection or first episode of wheeze Approximately 11,000 records to deliver 4,000 positive cases in total across the study. There will be 300-500 records screened across the 5 sites requiring support.
Data sources	1. Secondary care medical records
Identifiers required for linkage purposes	1. None – incidental access to identifiable data within medical records.
Identifiers required for analysis purposes	1. None
Additional information	

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.

Practicable alternatives

- **Feasibility of consent**

The applicant has stated that research from previous studies have identified parent and carer frustration with being asked to provide information which is routinely collected and won't change the participants pathway. No identifiable information is being recorded about the participant. It is purely a site decision as to whether research nurses are considered part of the direct care team and, at some sites, they are not.

The public are very used to concept of their clinical records being reviewed and in previous similar studies we have a clear steering from parents that being asked for consent in these situation is not perceived to be beneficial (https://adc.bmj.com/content/104/10/979.info and https://www.tandfonline.com/doi/abs/10.1080/24694193.2020.1812766?needAccess=true)

The CAG accepted that this was reasonable and should be supported.

- **Use of anonymised/pseudonymised data**

The data collected is pseudonymised with the key only identifiable to the direct care team. The breach of confidence is that research nurses, who are not considered part of the direct care team by some sites, will have incidental access to patient notes prior to inputting non-identifiable data.

The CAG accepted this explanation.

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 poster details the study and its aims but does not give details of the dissent mechanism and how any rights of dissent will be respected. The applicant, in correspondence with the CAT, has said that the poster will be amended and they will highlight to parents that they can let the nurse in charge know about the concern which will be forward onto the study team so that patient will not be included in the study.

The applicant has requested that the National Data Opt-Out should not apply to this study as no identifiable information is being collected.

The CAG requested a dissent mechanism be added to the poster, with details of how any rights of dissent would be respected. Should any sites in Wales consider there to be a breach of confidence by research nurses having incidental access to medical records, then the poster should also include the information in Welsh.

The CAG reviewed the request that the National Data Opt-Out should not apply to this study. It was felt that, although no identifiable data is being collected, as the common law duty of confidentiality is still being breached, the National Data Opt-Out should apply to the study, unless there is another justifiable reason for it not to apply.

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.

RESCeu has an online patient community (https://resc-eu.org/parents-patients/rsv/rsv-online-patient-community/) which is utilised in RESCeu funded studies to obtain information on patient views on the variety of RSV studies being undertaken. This group will be used for work around dissemination. The parent and carer group is relatively diverse but given bronchiolitis impacts on children 1-2 years of age this group is mainly focused on parents and carers with infants.

Specific views on the acceptability of BronchSTART have not been sought, mainly as identifiable patient information is not stored and that in a very similar study on collected data at presentation parent and carer feedback strongly supported not consenting for data collection. Please note in this study, identifiable information was recorded so that this study poses even less potential concern (https://adc.bmj.com/content/104/10/979.info).

As a data analysis project which is utilising already currently collected information and that the care of the patient is not being affected in any way, it was felt that specific service user involvement was not necessary. The research team will be looking at involving parents/parents' groups in dissemination and this work is being discussed with the RESCEU PPI network.

The study team are producing a virtual dashboard for this study demonstrating rates of bronchiolitis throughout the country. This dashboard contains aggregated data so that there is no possibility of patient identification (either by location or time). This came from feedback that parents and carers didn't want to be bothered at the time of data collection about data they expected to be shared but were keen that the outcomes of the study were made as public as possible as soon as possible.

The CAG accepted the above comments; however, it was noted that PPI for this specific study had not been sought. The CAG would like the views of one or two people from the RESCeu online community to be obtained, around the specific unconsented activity, and provided to the CAG for reassurance.

Exit Strategy

No identifiable information is entered into REDCap. Support is only needed for the very brief period a research nurse, if not considered part of the clinical team, has to access a clinical record and place the non-identifiable outcomes at 7 days into the REDCap database. We therefore we believe we have made every effort to minimise the support needed and we note that the issue is cause by a definition of a research nurse being a member of a clinical team not that any specific information is being accessed in some sites as opposed to others.

The study should end by May 2022; however, if there is a RSV surge, which is possible on current evidence, support would need to be extended to cover this. An approximation of end date cannot be made, as it depends on clinical need.

The CAG accepted this explanation.

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. A dissent mechanism be added to the poster, with details of how any rights of dissent would be respected. Should any sites in Wales consider there to be a breach of confidence by research nurses having incidental access to medical records, then the poster should also include the information in Welsh.

2. As the common law duty of confidence is being breached, it is felt that the National Data Opt-Out should apply to this study. Should the applicant still wish the National Data Opt-Out not to apply to the study, then a justification should be provided in response.

3. Support under Regulation 5 Health Service (Control of Patient Information) Regulations 2002 will come into effect automatically following expiry of the COPI notice.

4. Favourable opinion from REC **Received 18 January 2022.**

5. 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 applicant must ensure that NHS Digital confirmation of 'standards met' for University Hospitals Dorset and Sheffield Children's Hospital is in place once support under Regulation 5 is active.**

b. 21/CAG/0157 – CVD-COVID-UK/COVID-IMPACT: UK-wide linked routine healthcare data to address the impact of cardiovascular diseases and other health conditions and health-related risk factors on COVID-19 and the impact of COVID-19 on cardiovascular diseases and other health conditions.

Context

Purpose of application

This application from Health Data Research UK (with the controller for the activity confirmed to be the same) set out the purpose of medical research which aims to understand which patients with pre-existing conditions are most likely to be affected by Covid-19 infection.

Patients with pre-existing conditions are at a higher risk of becoming infected with Covid-19, which in turn, increases the likelihood of adverse outcomes and mortality. Understanding which patients may be affected will help to develop strategies to reduce this risk. In addition, Covid-19 affects existing health conditions such as stroke and increases the risk of developing various physical and mental conditions through increased inflammation, or risk of blood clotting.

To inform government and future NHS policy, a deeper understanding of these unintended consequences is needed, including the range of conditions affected, variation by age, sex, ethnicity, deprivation and geography, effects on different in- and out-patient services, and response to mitigating actions (e.g., regional and national government advice). Nationally

collated healthcare datasets from hospitals, primary care, community dispensed medicines, death registries, COVID-19 testing laboratories, COVID-19 vaccination data, and disease or service-specific audit databases, when linked together, provide a major resource for interrogating these crucial questions at scale across the four nations of the UK.

Support is requested to allow the disclosure of confidential patient information from the legal entities of the unlinked datasets listed on the Trusted Research Environment (TRE) dataset provisioning dashboard to NHS Digital (for English data) or the Trusted Third Party of the SAIL databank (for Welsh data). These datasets will be the ones that are unlinked post-COPI Notice expiry.

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.

Cohort	The entire populations of England and Wales
Data sources	ICNARC a. ICNARC COVID dataset Bart's Health NHS Trust (NICOR) b. Adult Percutaneous Coronary Intervention (England) c. Myocardial Infarction National Audit Program (England) d. National Heart Failure Audit (England) e. National Congenital Heart Disease Audit (England) f. National Adult Cardiac Surgery Audit (England) g. National Audit of Cardiac Rhythm Management (England) h. Transcatheter Aortic Valve Implementation (England) i. NICOR audits and registers (Wales) NHS England and Improvement j. Pillar 3 antibody data (positive and negative) (England)

	King's College London k. Sentinel Stroke National Audit Programme Royal College of Surgeons of England l. National Vascular Registry (England and Wales) NHS Digital (Office for National Statistics) • ONS Census 2011 (Wales)
Identifiers required for linkage purposes	2. NHS number 3. Name 4. Date of Birth 5. Postcode
Identifiers required for analysis purposes	2. Date of Death 3. Postcode (LSOA level)
Additional information	

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.

Practicable alternatives

- **Feasibility of consent**

To address the research questions with high levels of statistical power, without selection bias and to ensure that the results are relevant to all groups across the population, irrespective of age, ethnicity, geography, deprivation level or any other personal

characteristic, we need to be able to access and study data from the entire population (67 million people) of the UK. Hence it is not practical to seek consent from all research participants.

The CAG accepted this explanation.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to create a unique pseudo ID in order to link national datasets together in either a TRE hosted by NHS Digital for English data, or the SAIL databank for Welsh data. Without any identifiers, the different datasets could not be linked together.

The CAG accepted this explanation.

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.

A privacy notice on how personal data is used in this project is on the study website.

The study team will also make information available via a data use register on HDR UK's Innovation Gateway. Information on which datasets are being used for which sub-project and links to any outputs are made available.

The HDR UK website details the purpose of the project and the different analyses, the datasets used and any outputs (results, publications etc) from this work.

Providing information on websites will reach a large number of the population. This is whole population research and so is not practical or cost-effective to create posters or leaflets for all GP practices and hospitals for this study specifically. However, both SAIL Databank and NHS Digital have their own communications strategies to ensure that the public are aware of how their health data may be used to support a wide range of healthcare planning and research activities (of which our research programme is one component).

This research is on the whole population and uses de-identified data which has been collected as part of routine care. This data is held by national data custodians (e.g. NHS Digital) and provided to researchers in a pseudonymised format in a TRE once

they have the relevant approvals in place. Therefore, the research team do not have the ability to process opt-out requests.

Any individual who wishes to dissent from the use of their routinely collected health data being used in research and planning purposes would contact the relevant body in England and Wales. Data custodians that hold health data have their own notification processes. The research team believe that it is not appropriate for them to provide this notification, as it may cause confusion for patients.

NHS Digital: https://digital.nhs.uk/services/national-data-opt-out provides a link and guidance for patients to set their opt-out choice.

SAIL Databank holds only anonymised data and is not able to identify individuals, so does not have the ability to process opt-out requests. Anyone wishing to opt out of anonymised data related to them being sent to SAIL or used for other secondary purposes, should make an enquiry to the relevant data provider(s) about what options they may provide for allowing individuals to opt out. For primary care records, individuals can opt out by making a request to their GP.

For primary care data, records will not be extracted from patient records with a recorded dissent from secondary use of GP patient identifiable data, therefore respecting the current national Type 1 data opt-out.

As data controllers of data in their GP systems, GP practices are required to opt-in to this extraction via the standard GPES mechanism by accepting an offer of participation in the CQRS (Calculating Quality Reporting Service) system. Data is not extracted for any practices that have not opted-in via CQRS.

This information is available on NHS Digital's website https://digital.nhs.uk/coronavirus/gpes-data-for-pandemic-planning-and-research/guide-for-analysts-and-users-of-the-data

With the exception of type 1 opt outs for data from general practices, the national opt out has not been applied on COVID-19 related research due to direction from the Secretary of State for Health, Chief Medical Officer and Chief Scientific Adviser that health information on the whole population is required for policy and healthcare decisions during the pandemic. This is also the case because the data are pseudonymised (and effectively anonymised from the point of view of the research uses in the trusted research environments).

The CAG accepted the research team's explanation re the opt-out mechanisms employed by the study, including the fact that the National Data Opt-Out could not be applied.

With respect to the privacy notice, the CAG would like to recommend that the notice is placed on the British Heart Foundation's website, given that the logo for that organisation is present on the notice itself. The CAG suggest that it would be useful to have a shorter version of the notice on the relevant websites, with an additional link to the full version, should people wish to read it. These are, however, suggestions only, and do not form any specific conditions of support.

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.

Discussions with patients and public have taken place over a long period of time and are ongoing.

When the CVD-COVID-UK/COVID-IMPACT project was initially conceived, it was reviewed both scientifically and from a public perspective, convened and coordinated by the NIHR-BHF Cardiovascular Partnership (https://www.nihr.ac.uk/explore-nihr/support/cardiovascular-partnership.htm).

The review by public contributors was by an independent patient panel with good understanding of health data use in research – which allowed in depth questioning by the panel on the project proposal and use of unconsented patient data, ethical issues and how patient data would be used. The CVD-COVID-UK/COVID-IMPACT programme was approved and given flagship status.

Oversight from this panel is ongoing with the Chief Investigator (Professor Sudlow) presenting to this panel on a regular basis (approx. quarterly) to provide an update and take on board advice and comments.

In addition, an Approvals and Oversight Board which includes lay members (currently 4 lay members – 3 patients and 1 carer from different regions of the UK, with representation across gender, age and ethnicity) has also been established. These lay members are able to provide far greater oversight of each project/analyses, with dedicated time to discuss and input into project proposals with each research team. This includes: raising any concerns, questions on the data being used and analyses being proposed, assessing the patient involvement plans and offering suggestions. Analysis and results from projects are also discussed with these lay members – especially to identify those aspects of most importance to patients and the public

The CAG felt that the PPI conducted was impressive. There is reference to an independent patient panel that considered the use of confidential patient information without consent. The CAG would like to be provided with further details about what questions were asked of the independent patient panel, what their feedback was, specifically around the use of confidential patient information without consent, and how many patients were involved.

Exit Strategy

No identifiable information is entered into REDCap. Support is only needed for the very brief period a research nurse, if not considered part of the clinical team, has to access a clinical record and place the non-identifiable outcomes at 7 days into the REDCap database. We therefore we believe we have made every effort to minimise the support needed and we note that the issue is cause by a definition of a research nurse being a member of a clinical team not that any specific information is being accessed in some sites as opposed to others.

The study should end by May 2022; however, if there is a RSV surge, which is possible on current evidence, support would need to be extended to cover this. An approximation of end date cannot be made, as it depends on clinical need.

The CAG accepted this explanation.

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 under Regulation 5 Health Service (Control of Patient Information) Regulations 2002 will come into effect automatically following expiry of the COPI notice.

2. To provide with further details about what questions were asked of the independent patient panel, what their feedback was, specifically around the use of confidential patient information without consent, and how many patients were involved.

3. The National Data Opt Out will **not** apply to processing of Confidential Patient Information under Regulation 5.

4. Favourable opinion from REC **Received 27 May 2020**

5. 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 applicant must ensure that NHS Digital confirmation of 'standards met' for ICNARC, Bart's Health NHS Trust, NHS England and Improvement, King's College London, Royal College of the Surgeons of England, NHS Digital and Digital Health and Care Wales is in place once support under Regulation 5 is active.**

Signed – Officers of CAG	Date 17 February 2022
	
Mr Michael Pate	17 February 2022
Signed – Confidentiality Advice Team	Date