Minutes of the meeting of the Confidentiality Advisory Group

30 September 2021 – held via Zoom

Present:

Name	Position
Dr Tony Calland MBE	CAG Chair
Dr Patrick Coyle	CAG vice-chair
Mr David Evans	CAG member
Dr Harvey Marcovitch	CAG member
Ms Diana Robbins	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Ms Rose Payne	CAG member
Mr Dan Roulstone	CAG member
Dr Pauline Lyseight-Jones	CAG member

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	Confidentiality Advisor
Ms Caroline Watchurst	Confidentiality Advisor
Mr Paul Mills	Senior Confidentiality Advisor/Service Manager
Ms Natasha Dunkley	Head of Confidentiality Advice Service

1. Introduction, apologies and declarations of interest

2. Support decisions

Secretary of State for Health & Social Care Decisions

No non-research applications were reviewed at the **02 September 2021** meeting.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **02 September 2021** meeting applications.

3. For information

a. **a. Digital Health and Care Wales - withdrawal from Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002**

4. COPI Transition Application

a. **21/CAG/0119 – PEACH Procalcitonin: Evaluation of Antibiotics in COVID-19 Hospitalised patients**

Context

Purpose of application

This application from the University of Leeds sets out the purpose of medical research which aims to determine whether the use of procalcitonin (PCT) testing reduced antibiotic use amongst patients who were hospitalised with Covid-19.

A mixed-methods research project will be undertaken, with three work packages. The CAG application relates to work package 1.2, a retrospective observational analysis of routinely collected, patient-level, clinical data. Data from approximately 7000 patients hospitalised with COVID-19 will analyse antibiotic prescriptions in the context of prior procalcitonin testing, or not. WP 1.2 is split into two parts. The first part relates to collection of hospital data which is undertaken by members of the direct care team and is outside the scope of support.

In the second part, a list of unique PEACH study numbers, NHS numbers and registered GPs of eligible patients will be generated. This will be shared with local Clinical Commissioning Groups research departments to allow linkage with primary care records for collection of specific variables. These will be shared back to local participating centres for addition to the study database.

A recommendation for class 1,4 and 5 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	Workstream 1.2 part 2. Approximately 7000 patients with confirmed Covid-19, admitted to one of 11 participating Trusts between 1 February 2020 and 30 June 2020, and

	within 24 hrs of a positive test, who did, or did not, have PCT testing at baseline. 5000 patients will require support i.e. those who were admitted to Trusts that do not hold a full care record.
Data sources	1. Leeds Teaching Hospitals NHS Trust 2. Liverpool University Hospitals Foundation Trust 3. Salford Royal NHS Foundation Trust 4. Brighton and Sussex University Hospitals NHS Trust 5. Royal Cornwall Hospitals NHS Trust 6. Aneurin Bevan University Health Board 7. Sheffield Teaching Hospitals NHS Trust 8. North Bristol NHS Trust 9. North Yorkshire Hospitals NHS Trust 10. Nottingham University Hospital NHS Trust 11. NHS Kernow CCG 12. NHS Wakefield CCG 13. NHS Kirklees CCGs 14. NHS Bradford district and Craven 15. NHS Leeds CCG 16. NHS Brighton and Hove CCG 17. NHS East Sussex CCG 18. NHS West Sussex CCG 19. NHS Rotherham CCG 20. NHS Barnsley CCG 21. NHS Sheffield CCG 22. NHS Derby and Derbyshire CCG 23. NHS Bristol, North Somerset and South Gloucestershire CCG 24. NHS Bath and North East Somerset, Swindon and Wiltshire CCG 25. NHS Summerset CCG 26. NHS Liverpool CCG 27. NHS Southport and Formby CCG 28. NHS Knowsley CCG 29. NHS South Sefton CCG 30. NHS Nottingham and Nottinghamshire CCG 31. NHS Salford CCG

Identifiers required for linkage purposes	1. Name 2. DOB 3. Registered GP 4. NHS number
Identifiers required for analysis purposes	1. Postcode – to find a patient index of multiple deprivation 2. Gender 3. Ethnicity
Additional information	The applicant confirmed that linkages of hospital data to primary care data via local CCGs and data teams had been successfully carried out in Leeds for a previous study.

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 to transition the study to support under Regulation 5.

Scope

The CAG noted that the application is currently relying on an alternative legal basis to process confidential patient information without consent, under the 'COPI notice' and that this will continue for its duration. The group therefore considered the elements of the project that are expected to be continuing following expiry of the 'COPI notice', and which require support under regulation 5.

Much of the work within this project remains outside the scope of support. Support is requested to link hospital data with CCG held primary care data within work package 1.2. This support relates only to those hospitals that do not have full care records, and therefore require the sharing of identifiable patient data with the CCGs to enable linkage,

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 felt that this medical research had a high level of 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

Many of the patient population will have died and it is not practical or possible to seek consent retrospectively in every case.

The CAG accepted this explanation for why consent would not be taken.

- Use of anonymised/pseudonymised data

The application seeks to link records in primary and secondary care together, where those secondary care sites do not hold a complete care record, thus anonymised/pseudonymised data cannot be used.

However, no organisation will hold the full identifiable clinical dataset. The trust will pass identifiers to the CCG, but no clinical information. The trust and the CCG will each pass clinical information to the PEACH research team at Cardiff University, but no identifiers. The applicant is taking steps to minimise the risk of disclosure.

The CAG accepted this approach.

‘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.

Patient notification will be displayed on the study website, which includes a local mechanism to opt-out of the study. Whilst the CAG was content with the method of local opt-out, the CAG felt that participants can be notified through other routes (for example, through participating Trusts). As such, the applicant is asked to consider increasing the routes by which participants are notified, and provide a summary of notification routes by March 2022.

Whilst acting under the COPI notice, the national data opt-out does not apply. However, upon transitioning to regulation 5 support the national data opt-out will ordinarily apply. As part of the application, the research team requested for the national data opt-out to be exempted from this application under Regulation 5 support because doing so could create bias in the outcomes of this study which is already ongoing. This reasoning was considered by CAG who, given the circumstances of this application, agreed that the national data opt-out should not be applied under Regulation 5 support.

Patient and Public Involvement

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 advised that they had held several meetings with their two PPI study team members explaining the study, and seeking their input into the design and conduct of the data extraction. Both have provided feedback that the design of the study meets the best standards to protect patient confidentiality.

Whilst the CAG noted the feedback from the PPI study team members the CAG felt that the PPI conducted to date did not demonstrate sufficient public views on the use of identifiable information without consent for the purpose of this research. As such, the CAG requested that further PPI is conducted as the study progresses, specifically involving people who had experienced Covid-19 infection. This should be completed before March 2022 and evidence provided for review.

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. Further PPI is conducted as the study progresses, specifically involving people who had experienced Covid-19 infection. This should be completed before March 2022 and evidence provided for review. The evidence should detail what patient and public involvement and engagement activities have been undertaken to discuss the use of confidential patient information without consent and provide evidence of the outcomes of these events, for example - how many patients were approached?, what exactly they were they asked?, and what comments were received?

3. Provide by March 2022, details of further notification routes that are in place to ensure as many patients as possible have access to the materials.

4. Whilst the national data opt-out will not apply to the processing of Confidential Patient Information under Regulation 5, the local opt-out will continue to apply.

5. Favourable opinion from REC **Received 3 March 2021**

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 applicant must ensure that NHS Digital confirmation of 'standards met' for organisations processing confidential patient information is in place once support under Regulation 5 is active.** See below for further details.

   Due to the number of participating care providers involved it is the responsibility of the applicant, as controller, to ensure that all organisations processing confidential patient information meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a care provider. These will not be individually checked by the CAT team due to the number of organisations involved.

5. Response to provisional

a. 21/CAG/0064 - The Use of Child Neglect Assessment Tools

Context

Purpose of application

This application from Newcastle University set out the purpose of medical research that seeks to establish which reconfiguration of services, practices and strategies for disabled children made during the coronavirus pandemic worked well.

Eight percent of children living in the UK are disabled. Half of these children have neuro disability conditions, affecting their brain and central nervous system. Many have complex physical and mental health needs, which are generally met through multiple services. In response to the coronavirus pandemic, disabled children who are at

increased risk due to poor respiratory function were advised to shield. The duty to deliver care as specified in children's individual Education, Health and Care Plans (EHCPs) was relaxed and most community services for children were de-prioritised as efforts centred on those most at risk from the virus. Services were stopped and re-organised, with some resuming via video link and others face-to-face, but the practice varied and has continued to flex and change in response to policy changes. Many parents reported their children's mental health as deteriorating, and parents' own isolation and distress. Impacts on physical health are currently unclear, however virtual consultations may not suit physical examination, diagnosis or interventions requiring touch or instrumentation. There is emerging evidence of delays to diagnosis and treatment of children, increases in abuse, and in regional and socio-economic inequity in the impacts of coronavirus. The applicants seek to conduct research into changes to service provision and their consequences for children's physical mental health, as well as the impact on their families' wellbeing. The research will be used to inform practical policy solutions for integrated service recovery.

This study is comprised of six work packages. The applicants are seeking support under Regulation 5 for Work Package 2, as this involves analysis of routinely collected data and consent will not be sought for access to this confidential patient information. Children aged 0-19 years with a confirmed or suspected diagnosis of a neuro disability condition, and living in one of five local authority areas in England, will be included in the study. Areas have been selected so that findings will be generalisable and representative UK-wide and internationally relevant. The NHS Trusts in the five areas will provide the pseudonymised NHS number of each child who meets the inclusion criteria to the North of England Commissioning Support Unit (NECS). NHS medical, community and learning disability services, as well as non-medical services, in participating areas will transfer data on contacts with services to NECS. This data will be individual level data and individuals will be identified by their pseudonymised NHS number and diagnostic category. NHS Digital will also disclose pseudonymised HES and MHSDS data relating to identified children's use of services to NECS. NECS will create unique identifiers for all participating children and will apply a second pseudonymisation code to the datasets. NECS will then send datasets in which children are identified by second pseudonymisation code to the research team. Each process will involve data being shared once, e.g. one list of identified children will be shared once with NECS by a lead NHS Trust；NECS will provide NHS Digital pseudonymised data on children from an area once to the research team.

The applicants are seeking support as, while the data disclosed between individual NHS organisations, NECs and NHS Digital will be pseudonymised, NHS Digital will retain the pseudonymisation key and will be required to identify patients before sharing the relevant datasets.

A recommendation for class 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.

Cohort	Children aged between 0 and 19 years of age, diagnosed with a neuro disability (disability arising from maldevelopment or damage to the brain in early development)
Data sources	1. HES and MHSDS datasets at NHS Digital
Identifiers required for linkage purposes	1. Pseudonymised NHS Number NHS Digital will hold the re-identification key and will be able to re-identify patients to conduct the linkage. NHS Digital will link datasets using; 1. NHS Number 2. Date of birth 3. Postcode
Identifiers required for analysis purposes	1. Date of birth (this is modified to month and year of birth for analysis) 2. Gender 3. Ethnicity

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 had a medical purpose and was in the public interest.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- Minimising flows of identifiable information

The CAG noted that no identifiers had been selected in answer to Q37 on the CAG form and that only the pseudonymised NHS number will be required for linkage across datasets. When the Confidentiality Advice Team queried this prior to the meeting, the applicants explained that participating sites only provide patients NHS number to NHS Digital, but that NHS Digital require date of birth and postcode in addition to NHS number to ensure the correct patient data is selected from the HES and MHSDS data. The CAG asked the applicant to clarify where NHS Digital would obtain the dates of birth and postcodes from, i.e. would this be obtained from records already held by NHS Digital. Clarification on why NHS Digital needed these identifiers also needed to be provided.

- Feasibility of consent

The applicants advised that participants in Patient and Public Involvement carried out determined that use of routine data without consent was appropriate, as researchers would be able to access data without burdening families.

The applicants also noted that families with complex needs and disabilities would been adversely affected by COVID because of the intensive, daily demands of looking after young people with reduced state support. Requiring families to complete an additional task may lead to those families not consenting, potentially biasing the results. The CAG agreed that consent was not feasible.

- Use of anonymised/pseudonymised data

NECS and the researchers at Newcastle University will only have access to pseudonymised information. The CAG raised no queries in this area.

'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.

Notices will be displayed as posters in waiting rooms and in newsletters for parents and families of children with neuro disability. These notices will include information on how to opt-out of Work Package 2. The notices included contact details for the Data Protection Office (DPO) at each participating trust, should participants wish to opt-out. If participants contact the DPO to dissent, the DPO will contact NECS to request the removal of the patient from the data. NECS will forward the pseudonymised code of the dissenting participant to the research team, if the data have been forwarded to the researchers. The research team will inform the Sponsor DPO if the data have been analysed and can no longer be removed. The applicants advised that NHS Digital would apply the National Data Opt-Out.

The CAG noted the information provided and asked that the notices to be displayed in waiting rooms and newsletters were revised to include further details on how data would be processed.

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 consulted with chairs of local Parent Carer Networks in the National Network of Parent Carer Forums, which is a voluntary organisation of parent carers who have come together to support the development of statutory services for children with special educational needs and disabilities. One of the co-investigators is a parent of a disabled young adult and is also a Special Educational Needs and Disabilities (SEND) officer for a local authority. This co-investigator will lead the involvement of parent carers in the Parent Carer Advisory Group. This group will advise on the methods and procedures of the research, the analysis of the findings and their dissemination. Also, young people will be recruited to the projects Young People's Advisory Group. This Group will advise on how best to engage with disabled young people.

When designing the project, the applicants consulted with the Steering Group of the Eastern Region Parent Carer Forum, whose members comprise chairs of eight local forums, who each work with a local steering group across one local authority. The chair of the Eastern Region tabled the research for discussion and provided a verbal summary of the study design. Members of the Eastern Region Forum then cascaded information to their local steering group. In total, up 80 parent-carers across eight local authorities considered the study design. These parent-carers are of both sexes, are diverse in age (30's - 60's), are both working and not working, and are from ethnic backgrounds reflecting the population they serve. Some of the group have additional needs/disabilities. The children of the parent carers consulted range in age from preschool to early twenties and have a wide range of needs. They are educated in a range of settings: mainstream, day and residential special schools, and at home.

The use of routine data without consent was judged by the parent-carers consulted to be appropriate because it would give the study access to data without burdening

families. It was also felt that requesting consent would lead to a biased sample. Families of children with complex needs and disabilities have been adversely affected by COVID because of the intensive, daily demands of looking after young people with reduced state support. Requiring families to complete an additional task when they had already given consent to the use of their medical information at source by not opting out was felt to be unnecessarily burdensome.

The CAG commended the applicants for the patient and public work conducted, noting that relevant groups had been involved early on and meaningful engagement conducted.

Exit strategy

The dataset provided to the researchers for analysis will be pseudonymised. The pseudonymisation key will be held by NHS Digital, so the dataset accessed by the researchers is effectively anonymised.

NECS and NHS Digital will delete the confidential patient information provided to facilitate linkage 36 months after the project completion.

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 response to the two first two conditions below need to be provided within one month of the issuing of this letter.

2. Please clarify where NHS Digital will obtain patients dates of birth and postcodes from. Clarification also needs to be provided on why NHS Digital require these identifiers.

3. Please revise the notices to be displayed in waiting rooms and newsletters to include further details on how data would be processed.

4. Favourable opinion from a Research Ethics Committee. **Confirmed 23 November 2021.**

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 2020/21 DSPT review for North of England Commissioning Support Unit (NECS) was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 23 November 2021).

6. Resubmitted new applications

a. 21/CAG/0142 - Bystander availability and AED acceptability during OHCA

Context

Purpose of application

This application from the University Hospital Southampton NHS Foundation Trust set out the purpose of medical research that seeks to understand how frequently bystanders are available at out of hospital cardiac arrest (OHCA) events to perform chest compressions and collect a defibrillator, and the demographics of bystanders.

During a cardiac arrest, the heart stops pumping blood to the brain. Brain cells can only survive a few minutes without oxygen, there it is vital to restore blood flow straight away. Chest compressions go some way to moving blood temporarily around the body, but the best way of saving the patient is to restart the heart as soon as possible. Defibrillators are used to deliver an electrical shock to the heart via sticky pads on the skin. Members of the public can help to save the person by using an AED until the ambulance arrives. Modern defibrillators (AEDs) are easy for any person to use and automatically provide instructions by speaking to the user when the packaging is opened. AEDs should be used within a few minutes to provide the best chance of survival. Thousands of AEDs across the UK are available, however a second person needs to be available to fetch one while the first person does chest compressions. The

applicants are seeking to determine how often a second person is available and whether they can follow the instructions of the 999 call-handler to successfully fetch an AED.

This observations study will use retrospectively collected data from previously recorded telephone calls to emergency services. Calls answered by South Central Ambulance Service (SCAS) within the study period for patients experiencing an out-of-hospital cardiac arrest (OHCA) will be reviewed in order to identify outcome data. A list of calls meeting the inclusion criteria will be compiled by SCAS data analysts and recordings will be sequentially selected from the database until the sample size is reached. The student researchers will access the call recordings via a virtual private network (VPN) connection to the SCAS computer system, so that no call recordings will be stored or transferred outside of SCAS. Outcome data of interest will be coded directly into an Excel file. This file will not contain any items of confidential patient information and will therefore be fully anonymised before quantitative analysis takes place.

A recommendation for class 1 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	Calls made to 999 and recorded by South Central Ambulance Service, where cardiac arrest was identified, between 01 August 2019 and 31 December 2019. 500 calls will be included. Most calls will not have been made by those suffering a cardiac arrest, therefore the number of patients whose details may be disclosed cannot be estimated.

Data sources	2. Telephone recordings held by South Central Ambulance Service.
Identifiers required for linkage purposes	2. Gender
Identifiers required for analysis purposes	4. 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.

Scope

During the review of the previous application, the CAG noted that the applicants were seeking support for the processing of confidential patient information for both patients and “service users” (in this application, the 999 callers and other bystanders, who are not themselves patients). Members noted that the CAG remit is limited to the processing of confidential patient information, as defined in s251 of the NHS Act 2006 and the processing of information related to the service users is outside the CAG remit. The applicants had noted and accepted this.

The CAG had also suggested that the applicants consider using more recent calls than those made during 2019, as bystander readiness to intervene may have changed following the Covid-19 pandemic. The applicants had decided not to undertake screening of more recent calls, anticipating that there would be no change in bystander behaviour post-pandemic. The CAG noted this, and advised that the applicants may wish to consider conducting a follow-up study of post pandemic data to validate that their findings from calls made in 2019 are still relevant.

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 explained that consent would not be feasible as it may not be possible to trace those who made the call, or the patients involved.

- Use of anonymised/pseudonymised data

An anonymised dataset will be extracted.

The applicants advised that the SCAS Business Analytics team, who will ensure that all calls meet the inclusion criteria, cannot undertake the listening in and extraction of data as this would be overly burdensome to the Team.

During the previous review, the CAG had noted that the business analysts are required to verify that a number of items of information are included in the call record in order to determine that the inclusion criteria is met. The applicants were asked to specify the additional information that would be collected by researchers when listening to the calls.

The applicants provided this list and the CAG accepted that the further information required could only be obtained by the researchers listening to calls.

‘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 transparency notice (21_CAG_0142_20210815_transparency-noticev1.2). This notice explained the timeframe of the study and the activity that would be undertaken. The applicants explained that this will be displayed on the SCAS patient-facing websites with a fair lead-in time for members of the public to dissent. Telephone, postal and email contacts were given for dissent.

The applicants also created a dissent mechanism for SCAS call handlers, although this is outside the scope of the CAG application. The CAG noted that clearer information on how to opt-out was included on the information for staff. The information aimed at patients, the ‘Transparency Notice’ advised that patients could ‘object’ and the CAG asked that this was revised to make it clear that patients could request that their information was not included.

The lead-in time during which the patient facing information will be displayed before the data extraction begins needs to be specified. The CAG usually requests that the lead-in time scale is 4-6 weeks.

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 explained that they had tested the acceptability of use of confidential patient information without consent by seeking formal peer review of the draft protocol from two doctors. The project has also been discussed with nurses and other research staff from the SCAS research and development office.

A patient and public involvement (PPI) group meeting was held on 09 August 2021. Participants were asked to discuss the utility of the research, the design of the study including the time period to investigate, the processing of confidential information without consent, and mechanisms of dissent. A summary of the PPI meeting was provided with the application.

The CAG noted that the activity carried out was small in scale, however it was proportionate to the aims of the study. Members asked that the applicants consider conducting further patient and public involvement as the study continues, particularly around the possibility of re-running the study post-pandemic.

Exit strategy

An anonymised dataset will be extracted for analysis. The CAG raised no further queries in this area.

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.

Request for further information

1. Clarification to be given on whether continuing patient and public involvement will be undertaken as the study progresses.

2. The wording of the Transparency Notice is to be revised to explain that patients can ask for their information to be removed.

3. The lead-in time during which the patient facing information will be displayed before the data extraction begins needs to be specified.

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 13 July 2021.**

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. **Pending:**

   The NHS Digital **2020/21** DSPT review for **South Central Ambulance Service** is pending.

7. New applications

a. 21/CAG/0147 - 2021 NHS Adult inpatient mainstage survey

Context

Purpose of application

This non-research application submitted by Ipsos MORI on behalf of the Care Quality Commission, sets out the purpose of conducting the 2021 NHS Adult Inpatient Survey.

The Adult Inpatient Survey is the most established survey 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 Adult Inpatient survey will be the nineteenth carried out to date, and the second mainstage to be completed using a mixed method approach, following a pilot of the approach during 2019 and the first mainstage during 2021. The NHS Patient Survey programme is used to help the CQC understand what patients think of the NHS healthcare services they use. The results from the Adult Inpatient Survey will help to assess NHS performance and the CQC will use the findings for regulatory activities such as monitoring ongoing compliance and reviews. Trusts will also use the findings to monitor performance, and to drive improvements and initiatives at a local level.

All eligible trusts (137) will be asked to conduct the survey, with preparations expected to begin in the autumn of 2021 and fieldwork expected to start from January 2022. All trusts will draw a sample of patients according to set criteria, and follow standardised materials and procedures for all stages of the survey.

The 2021 Adult Inpatient Survey will be managed and coordinated by Ipsos MORI in their role as the Coordination Centre for Mixed Methods. The survey will follow the same mixed method approach as the 2020 Adult Inpatient Survey, which was developed and tested during the 2019 Adult Inpatient Pilot Study, and completed in 2021 with a response rate of 45.9%, which is consistent with other surveys in the NPSP. The applicants anticipate that the vast majority of trusts involved will opt to use an approved survey contractor, either Picker, Quality Health, Patient Perspective, to facilitate the sending of surveys.

	Mode of contact
Contact 1	Postal letter inviting the patient to take part online
Contact 1.1	Three days later an SMS reminder will be sent, including a direct link to the online survey
Contact 2	In week 2, a reminder letter will be sent to non-responders

Contact 2.2	Three days later an SMS reminder will be sent, including a direct link to the online survey
Contact 3	Final, postal reminder sent, along with a paper questionnaire

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	Inpatients aged 16 years old or over who were discharged from acute and specialist NHS hospitals in November (and earlier for smaller trusts), having had at least one overnight stay in hospital. A list of reasons for exclusion, such as deceased patients and those under 16 years of age at the time of sampling, was included in the application.
Data sources	3. Electronic patient records with acute and specialist trusts in England.
Identifiers required for contact purposes	3. Title 4. Initials or first name 5. Surname 6. Address fields including postcode 7. Mobile phone number 8. Patient unique identifier

Identifiers required for analysis purposes	1. Unique identifier (a three-digit Trust code and 4 digital serial number related to sampled patient) 2. Postcode 3. Trust code 4. Year of birth 5. Gender 6. Ethnic category 7. Date of admission 8. Date of discharge 9. Length of Stay 10. Treatment Function Code 11. ICD-10 Chapter Code 12. Treated as a suspected or confirmed covid-19 case 13. CCG code 14. Treatment Centre Admission 15. Admission method 16. NHS Site code-Admitted 17. NHS Site code-Discharged 18. Discharge Pathway

Confidentiality Advisory Group advice

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. The CAG agreed that the application has a medical purpose and is 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.

- Practicable alternatives

The CAG recognised that the applicants were still investigating and considering practicable alternatives to support under s251, even though the survey programme had

been running for a number of years with the current design and commended the applicants for doing so.

- Feasibility of consent

The applicants cited three central arguments as to why consent is not practicable, and which have been accepted across the National Survey Programme. These arguments included the potential burden on clinical staff and the potential of introducing bias. Also that the trusts would not benefit from the expertise of a specialist survey contractor if they facilitate the survey. The CAG agreed that consent was not feasible.

- Use of anonymised/pseudonymised data

Confidential patient information is required to facilitate the invitation process which could not be otherwise achieved. The CAG agreed that this could not be undertaken in any other way.

'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 National Patient Survey Programmes are exempt from the National Data Opt-Out, however a dissent mechanism is in place. The poster provides information about how a patient can opt out of the survey. Trusts are also asked to remove any records where existing dissent has been recorded. Contractors and those trusts that administer the survey themselves, will provide a freephone telephone line, email address and postal address on survey materials and posters (which must be displayed in trusts throughout

the sampling period) for people to call for advice, assistance or to opt-out of future mailings.

During fieldwork, patients can opt-out at any point through a variety of means. Firstly, contractors and those trusts that administer the survey themselves, will provide a freephone telephone line, email address and postal address on survey materials and posters (which must be displayed in trusts throughout the sampling period) for people to call for advice, assistance or to opt-out of future mailings. Additionally, if a survey (paper or online) is returned/submitted blank then the individual's unique identifier can be used to remove them from the mailing list. Respondents can also withdraw consent any point and ask for their response to be removed from the dataset.

The CAG noted the difficulty in publicising the survey via posters, since patients are discouraged from spending time unnecessarily in all NHS settings during the pandemic. The CAG also noted that the applicants would not be responsible for undertaking patient notification via other means, such as social media, local radio, etc, as this would be done by participating trusts at a local level. Members advised that the applicants work directly with the participating Trusts to promote the use of all available, innovative ways of notifying the public.

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 application form provides a detailed overview of the patient and public involvement in the development of this survey, including the activity undertaken in advance of the 2019 and 2020 surveys.

Section (s) of the application form stated that "Ahead of the 2021 Adult Inpatient Survey, three rounds of cognitive testing will be undertaken with patients to ensure that any revisions to the questionnaire continue to reflect their experiences and are also easy to read and understand. The questionnaire will be updated based on the feedback between each round of testing." The applicants explained that the cognitive testing is still in progress, and that an update will be provided to the CAG once completed.

The CAG noted the quality of the patient and public involvement undertaken by the applicants. Members noted that little recent activity has been taken regarding the use of confidential patient information without consent and recommended that this was re-run before future applications.

Exit strategy

Identifiable information will be destroyed within 12 months from the receipt of the sample files. The CAG raised no queries in this area.

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 Secretary of State for Health and Social Care 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.

Request for further information

1. The DSPT for Patient Perspective, as noted below, needs to be provided.

Once received, the information will be reviewed by the Confidentiality Advice Team 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 and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

Specific conditions of support

The following sets out the specific conditions of support.

6. Patient and public involvement around the specific issue of processing of confidential patient information without consent needs to be conducted and fed-back to the CAG at the first annual review.

7. More work should be done with participating Trusts to encourage effective notification, and an account of this should be fed back at Annual Review.

8. 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 **2020/21** DSPT review for **Ipsos Mori, Quality Health Ltd and the Picker Institute Europe** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 30 September 2021).

   Pending:

   The NHS Digital **2020/21** DSPT review for Patient Perspective is pending.

8. Minutes of the meeting held on 02 September 2021

The minutes of the meeting held on 02 September 2021 were not reviewed as an outcome is pending.

9. Any other business

No other business was raised.

The Chair thanked Members for their attendance and the meeting was closed.

Signed – Chair Date

Signed – Confidentiality Advice Team Date