Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

24 February 2022 – held via zoom

Present:

Name	
Dr Tony Calland, MBE	CAG Chair
Ms Clare Sanderson	CAG alternative vice-chair
Dr Martin Andrew	CAG vice-chair
Ms Sophie Brannan	CAG member
Mr Myer Glickman, OBE	CAG member
Mr Anthony Kane	CAG member
Dr Rachel Knowles	CAG member
Ms Rose Payne	CAG member
Ms Diana Robbins	CAG member

Also in attendance:

Name	**Position (or reason for attending)**
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

Apologies from Dr Murat Soncul, CAG Alternate Vice-Chair, and Mr Dan Roulstone, CAG member.

No conflicts of interest were declared.

2. Support decisions

Secretary of State for Health & Social Care Decisions

The Secretary of State for Health & Social Care has agreed with the advice provided by the CAG in relation to the **20 January 2022** meeting applications

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **20 January 2022** meeting applications.

3. New Applications

a. 22/CAG/0019 - CUREd+: Centre for Urgent and Emergency Care Research Database - refresh

Context

Purpose of application

This application from University of Sheffield (UoS) set out the purpose of medical research of updating and extending the CUREd Research Database (18/CAG/0126), to include more recent data and to extend the geographical area covered by the dataset. The CUREd Research Database refresh will expand the hospital data to cover all of England, update the linked ambulance service data, add death registration data, reduce variation within the hospital data, reduce the amount of confidential patient information processed and retained by UoS, and enable further research on a number of Urgent and Emergency Care (UEC) related topics.

The CUREd Research Database allows research from a UEC system perspective to examine patient flow through the whole system, from point of contact (e.g. call to 999/NHS 111) through different parts of the system, including the emergency department (ED) and into hospital. Understanding the system and how patients use it is key to developing appropriate patient-focused interventions that can lead to a sustainable, safe and cost-effective system of care. The CUREd database refresh will ensure that the data held reflects changing practices and continues to be useful for analyses.

Updated clinical data from NHS Digital and from Yorkshire Ambulance Service (YAS) will be combined with existing YAS data taken from the CUREd Research Database, which was originally created under 's251 support' by UoS using data from YAS and a number of NHS Hospital Trusts in Yorkshire and the Humber. The existing CUREd Research Database contains clinical and operational data, and the patient identifiers used during its creation are encrypted and stored separately. NHS Digital will act as the Trusted Third Party for linkage and provide an updated dataset back to the applicants.

Access to the environment containing the pseudonymised health data will be restricted to experienced data management personnel involved in the processing of the database. Research will focus on specific cohorts of patients, pathways through the UEC services, and trends over time of service use. Limited, de-identified extracts containing only the necessary data will be prepared as needed for analysis, and transferred to separate secure computing environments where analysis will take place. Analysis will be according to the research question of interest but will focus on how the UEC system is used. Researchers who are not part of the Applied Research Collaboration (ARC) will require approval from the UoS CUREd+ Data Release Committee to obtain data from the refreshed CUREd Research Database.

A recommendation for class 1, 2, 4, 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	Patient episodes of care between 1st April 2011 and 31st March 2023 Cohort A: Patients who 1) contacted or received care from the emergency ambulance service provided by Yorkshire Ambulance Service (YAS) NHS Trust, or 2) contacted the NHS 111 telephone triage service provided by YAS Cohort B: Patients who 1) received unscheduled care at a Walk-in Centre, Minor Injuries Unit, Urgent Care Centre or Emergency Department in England, or, 2) received inpatient or outpatient NHS hospital care in England, or 3) received care from Mental Health Services in England Cohort C: Patients who 1) are in cohort A, or 2) are in cohort B, and whose care was provided by a Trust in the Yorkshire and Humber region Approximate number of patients estimated as 80 million in Cohort B, plus additional minimal numbers in cohort A and C.

Data sources	1. University of Sheffield - School of Health and Related Research (ScHARR) a. the YAS clinical data (999 and NHS111) extracted from CUREd Research Database", between 2011 and 2017 b. patient identifiers for the existing YAS cohort of patients from the CUREd database 2. NHS Digital a. **For cohort B**: i. Hospital Episode Statistics (HES); 1. Emergency Care Data Set (ECDS) 2. Accident & Emergency (A&E) 3. Outpatient (OP) 4. Admitted Patient Care (APC) ii. Mental Health Services Data Set (MHSDS) iii. Demographic, and iv. Civil Registration – death data (ONS Mortality) b. **For cohort C:** i. Medicines Dispensed in Primary Care data, ii. and address information 3. Yorkshire Ambulance Service – (2017-2023) (cohort A) a. electronic Patient Records (ePR), b. Computer Aided Dispatch (CAD) and c. NHS111
Identifiers required for linkage purposes	1. Unique common pseudo-identifier 2. Name 3. NHS number 4. Date of birth 5. Postcode
Identifiers retained but separated from CUREd+ database	1. Address (cohort C) 2. Date of death

Identifiers required for analysis purposes	1. GP registration 2. Year of birth 3. Date of death – this is always modified for analysis 4. Output Area LSOA 5. Ambulance incident location postcode 6. Gender 7. Ethnicity 8. non-identifiable pseudonymised Unique Property Reference Number (UPRN) Effectively anonymous to researchers
Additional information	Dates of death will not be stored within the CUREd+ database, but stored separately (within University of Sheffield) and used to generate non-identifiable death-related variables such as 'death occurred within X days of Y event'. Address data for cohort C will also be stored in a separate computing environment, and only used for generation of pseudo-UPRN data and identification of institutional addresses (e.g. care homes).

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 agreed that this activity had a clear medical purpose, and was in the public interest, and noted that this method appeared more efficient and reduced the amount of confidential patient information processed when compared to the original CUREd research database design.

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**

'Section 251' support was obtained for the creation of the existing CUREd database (18/CAG/0126). Consenting the large numbers of patients involved in this processing and analysis of routine clinical data was impractical as there were approximately 23.5 million care records in total (including 7.4 million individuals) processed in a short time frame (approximately 12 months). Applicants are now seeking 'Section 251' support for this application, for the same reason: the large number of care records makes it impracticable to contact individuals and seek direct consent. In addition, a large number of these individuals will have died and therefore be unable to consent. The Members agreed with the justification provided, and considered consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for linkage between YAS, CUREd and NHS Digital data. It is not possible to link information together without using confidential patient information. The CAG agreed that using anonymised or pseudonymised information was not a practicable alternative.

Justification of identifiers

The applicant has minimised the confidential patient information required for analysis, and will only retain date of death and address data. The CAG were content that the applicant had justified the retention of date of death, as it would not be practicable for the applicants to calculate all possible required iterations of data relating to the full date of death, as these required outputs will be calculated at a later date, as and when researchers request this information from the database.

The applicant plans to delete the addresses of individuals within one year, however plans to retain the institution addresses indefinitely. The CAG felt that this information could potentially be used to identify an individual fairly easily, and therefore it was their preference that the institution addresses should be pseudonymised to UPRNs before being deleted at a certain timepoint, in a similar fashion to the individuals addresses. Or, the applicant should provide a strong justification for the requirement to retain these institution addresses.

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 poster and webpage text designed as part of the establishment of the CUREd database were displayed (where possible) in participating Yorkshire and Humber hospitals, to enable people to opt out of CUREd. Applicant has provided these, and CAG has already supported the design. These were to note rather than for review, as they are no longer relevant, as the CUREd database is now complete, and confidential patient information is retained only to create this CUREd+ database.

It is no longer possible to withdraw from CUREd, as the clinical data is stored separately from identifiers, and there is no pseudo ID linking the 2 together. However, if a patient wanted to withdraw from CUREd+, this would still be possible up until the point the CUREd team send the identifiers to NHS Digital. The applicant has therefore agreed to displaying a patient notification on the CUREd+ study website to state that if anyone wishes to opt-out of the CUREd+ research database, they should email the original CUREd team, stating that they wish to opt-out of the new CUREd+ research database. This will be possible until around 1st July 2022. The full website text for this notification regarding CUREd cohort has not yet been provided, however the applicant has agreed to implementing a study specific opt out option for existing CUREd cohort to opt out of CUREd+.

There is also a study specific opt out option for the new YAS data - YAS will display information on their website about the study, indicating that any individual wishing to remove themselves and their data from the study should contact YAS and ask to be removed from any future data submissions. If YAS receive a request for removal of an individual's data from the data they will submit to CUREd+, before the data has been submitted, they will remove the individual's data before submission. This YAS website information has been provided, which provides a study specific opt out. However this text doesn’t mention that the legal basis for processing is ‘s251’, and mentions a CUREd+ study privacy notice to see for more information, but this privacy notice has not been provided to CAG.

Both YAS and NHS Digital respect the national data opt-out. If an individual later decides to request removal of their data, (after the CUREd+ refresh is complete and the YAS and NHS Digital data has been received and added to the database), it will not be possible to identify the individual within the database in order to remove their data, as the database will have been de-identified.

The CAG considered that the new CUREd+ patient notification should be provided for review before the application is supported. This should be presented in a similar design to the old CUREd website text, and poster– which can be accessed via the CUREd website. The applicant is reminded to ensure that at least an email address and phone number are provided in order for individuals to be able to opt out. The applicant should provide both CUREd+ website text and a poster for review.

It is noted that in the old CUREd website text, which is not relevant for this application, the applicant has included a sentence stating '*The project has approval (Confidential Advisory Group)'.* As the CAG is an advisory group, and does not provide approval, the applicant is requested to ensure the role of CAG is accurately stated on the newly provided CUREd+ notifications. For example, using a similar statement to the following; *'The Health Research Authority, on advice from the Confidentiality Advisory Group, has supported the processing of confidential patient information without consent under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support').'*

The YAS website text provided does not provide much detail about the research database, and does not mention the role of CAG or that 's251' is the legal basis for processing. The privacy notice has not been provided. The CAG considered that the YAS notification should be consistent with the newly developed CUREd+ notifications, and therefore these should be updated and provided back to CAG, to ensure that all patients across the cohort are provided with the same information. This includes the YAS website text, and possibly a newly developed YAS notification poster, modelled on the CUREd+ newly developed poster, and the YAS privacy notice.

The CAG request that the newly developed CUREd+ and YAS notifications are shown to a patient and public involvement group for feedback.

In addition, and given the expansion of the research database, the Committee were interested if the applicant had considered any media communications strategies to try to inform the relevant cohort. For example, using local newspapers to try to publicise the database within the Yorkshire area, or if there were any options for publicising nationally, outside of Yorkshire.

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 Sheffield Emergency Care Forum (SECF) offers formal Patient and Public Involvement (PPI) support to researchers in order to help them ensure their research is relevant to their target audience. Their special interest is in emergency care, and the group have long-standing collaborations with The University Of Sheffield (UoS) offering independent and impartial general public and patient perspectives on research proposals, patient information sheets and lay person summaries.

The SECF were sent a project overview of CUREd+ as well as the protocol. Members of the CUREd+ Study team then attended a SECF meeting and presented the project in December 2021, outlining the background, aims, methodology, processes and expected outcomes. A period of discussion followed (similar to a focus group) allowing members to voice their opinions and ask questions.

A supporting letter and comments from the meeting have been attached to the application. These state that the SECF are happy to support the proposal, the refresh has significant benefit to patients and researchers, and that the safeguarding in place is satisfactory to protect patient confidentiality. There appears to be support from patients for the use of confidential patient information without consent.

The SECF was established in 2009 and has 16 members including 2 Yorkshire Ambulance Service representatives and 4 medical students. The SECF meets on a quarterly basis and often has visiting observers.

The CAG commented that the Patient and Public Involvement undertaken, although thorough, appeared to only involve discussions with a maximum of 10 lay members, as the 16 members of the SECF include 2 YAS staff and 4 students. This seemed a small group, considering the number of people whose data would be collected to form the database. Members also noted that the comments provided only numbered 3 in total, and only one of those comments mentioned the use of confidential patient information without consent. Acknowledging the size of this application, and given the expansion of

the previous CUREd database, the CAG consider that the current level of patient and public involvement is not sufficient.

The applicant is required to undertake further patient and public involvement with a bigger group/more lay individuals. The discussions and feedback should provide clear support for this use of confidential patient information without consent, as it is noted there is currently only one comment regarding this. The discussions should also be broadened, as Members noted that this database seemed to include mental health data and information about children and young people, which could be considered particularly sensitive. Further patient and public involvement should therefore also discuss this use of sensitive data. The patient and public involvement undertaken should also provide feedback on the notification materials (some of which are yet to be developed), as per the section of this letter entitled 'Patient Notification' and mechanism for managing dissent.

Exit strategy

The proposed exit strategy is anonymisation. YAS identifiers currently retained will be deleted once linkage with NHS Digital is completed (however these are retained under 18/CAG/0126 support), alongside address details for cohort c.

Addresses for patients in institutional settings (e.g. care homes) will be retained for the duration of the research database. These will be kept in a separate computing environment to the health data. Combined health and identifiable address data will never be released to researchers.

All other (non-institutional) address data will be deleted once the Unique Property Reference Number has been created, pseudonymised and this process validated. This processing will be done in a separate computing environment to the health data. Applicants estimate this will be accomplished within a year of receipt of data.

Date of death is modified to be less identifiable for analysis, however the full date of death is retained separately in order to do the calculations required for data extracts for researchers. Support required until full date of death deleted, and is required for the duration of the project.

Applicants expect the project to be ongoing, with no specified end date, however REC Favourable opinion has been provided for 5 years, so ‘s251’ support will also be provided for 5 years in the first instance.

The Members were content with the proposed exit strategy, with the exception of the retention of institutional address data, which is queried in the section above entitled ‘Justification of Identifiers’.

Data Access Committee

The applicant provided query responses regarding terms of reference and information about the make up of the Data release committee. In these responses, the applicant has described the recruitment process for this committee which is not yet formed, which will include lay representation, and provided a terms of reference document relating to the original CUREd database. Applicants will form a new CUREd+ data release committee on the basis of those terms of reference, and including lay people (who are yet to be recruited). The CAG strongly felt that there should be more than one lay individual recruited to this data release committee, when it is created. The Members also noted that although data released to researchers will not be confidential patient information, it will have been collected under ‘s251’. The Members therefore felt that the data release committee should assess the medical purpose of specific projects prior to the release of data.

Cohort Size

It is noted that the approximate number of patients is estimated as 80 million in Cohort B, plus additional minimal numbers in cohort A and C. However the Committee queried this, as the population of the entire UK is less than 70 million individuals. It is noted that this could mean 80 million care records rather than 80 million individuals, but this is not clear. If this is 80 million care records, it is not clear approximately how many individual patients this might relate to.

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 would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

Request for further information

1. Please provide a justification for the retention of institutional addresses indefinitely, or commit to pseudonymising before deleting at a defined timepoint.

2. Please provide updated patient notification to CAG;
   a) Provide CAG with CUREd website text, and a CUREd poster regarding opting out of CUREd+,
   b) Update YAS website text to provide more description, and more information around legal basis/CAG, and provide YAS privacy notice.
   c) The CUREd and YAS notifications should be consistent with each other (consider creating YAS poster which matches the CUREd poster, and can be accessed via YAS website)
   d) At least a phone number and email address should be included for people to opt out
   e) Ensure clarity surrounding role of CAG
   f) Ask patient and public involvement group to review the updated CUREd+ and YAS notifications

3. Please consider implementing a communications strategy across local or national media, and provide feedback on any plans to publicise the database.

4. Please undertake further patient and public involvement as described in this letter;
   a) with a bigger group/more lay individuals,
   b) discuss the use of confidential patient information without consent,
   c) discuss the inclusion of mental health data and information about children and young people,
   d) and ask for feedback on the patient notification materials

5. Please confirm there will be more than one lay individual recruited to the data release committee.

6. Please confirm that the data release committee will assess the medical purpose of specific projects prior to the release of data.

7. Please clarify how many individuals in the cohort, and confirm if the reference to 80 million relates to care records rather than individuals.

Specific conditions of support (provisional)

The following sets out the specific conditions of support.

1. Support provided for 5 years initially. A duration amendment will be required at this time to extend support.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 2 February 2022**

3. 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 **20/21** DSPT reviews for **University of Sheffield - School of Health and Related Research (8D715 – SHRR), Yorkshire Ambulance Service (RX8), and NHS Digital** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 14 March 2022)

b. 22/CAG/0029 - Mapping Neurodevelopmental Trajectories for Adult Psychiatric Disorder: ALSPAC-MRI-II

Context

Purpose of application

This application from the University of Bristol set out the purpose of medical research which aims to examine neurodevelopmental trajectories associated with psychotic experiences (PE), psychosis, and autism, to enhance understanding of the aetiology of psychosis. Applicants plan to do this by identifying if brain scans taken at age 20 can predict the onset of mental health disorders at age 26.

Persistent PE increase the likelihood of the development of psychotic disorders and poor psychosocial outcomes such as unemployment. It is not known how changes in the brain underlie or affect PE. If changes in brain structure and function occurring prior to any mental illness are understood, it may be possible to develop preventative or early treatment interventions.

Permission to access medical records without consent (ECC 1-05(b)/2012) has already been obtained for ALSPAC participants who did not respond to the consent campaign.

One condition of this approval was that mental health data would be excluded from any data extracts unless subsequently approved by the committee on a study specific basis.

The applicants seek support to process confidential patient information regarding mental health from GP records, NHS Digital and Avon and Wiltshire Mental Health Partnership, in line with ALSPAC's existing approval.

ALSPAC wish to:

- Repurpose sensitive data already collected though a previous project specific s251 support within ALSPAC, for this specific project, in order to reduce flow of confidential information,
- And for data not already collected though a previous project specific s251 support, request data from GP providers, NHS Digital and Avon and Wiltshire Mental Health Partnership using existing processes.

The data will then be combined/anonymised by the ALSPAC team within UKSeRP (managed by the University of Swansea but the work will be undertaken by ALSPAC staff). ALSPAC staff will then make the anonymised combined data available to University College London and the Cardiff University Brain Research Imaging Centre research team, within UKSeRP.

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.

Cohort	Cohort are 447 individuals enrolled in ALSPAC (excluding those who have explicitly withdrawn from ALSPAC, declined consent to linkage to their health record, have not received ALSPAC fair processing information or have consented to data linkage); These 447 individuals have already had consented MRIs at baseline;

	248 individuals who had MRI at age 20 (David cohort) - plus, 197 individuals who had MRI at age 22 (Linden cohort) total=**447** And all have previously consented to and mostly completed a follow up MRI at age 26.
Data sources	4. ALSPAC administrative database (University of Bristol) 5. NHS Digital a. Hospital Episode Statistics (HES), b. Mental Health Minimum Dataset (MHMD) c. Mental Health and Learning Disabilities Data Set (MHLDDS) d. Mental Health Services Data Set (MHSDS) 6. GP data software providers 7. Avon and Wiltshire Mental Health Partnership NHS Trust
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Date of death 4. Postcode sector level (not direct identifier) For those in the ALSPAC database where linkage has already been undertaken: 1. NHS Number 2. Date of birth 3. Gender
Identifiers required for analysis purposes	9. Gender 10. Age at event Effectively anonymous for analysis.

Additional information	Of the 15,000 ALSPAC participants around 5500 consented (or dissented) to data linkage and are not part of this request for support.

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 application was an appropriate medical research purpose which was in the public interest.

Scope

The reason for the deferral of this application is because the scope of support is not clear. The Members understood that ALSPAC (ECC 1-05 (b) /2012) has 's251' support to undertake extensive linkages, with a cohort that had previously consented into the study, but at the time of the original consent, the linkages were not explained or undertaken. The data compiled is used as a research database, which external applicants can apply to access, with the condition that; *'Projects collecting particularly sensitive data (e.g. (mental health, sexual health, termination of pregnancy, abuse) would be excluded from data extracts, unless project specific s251 support is provided.'* This application seeks project specific support on this basis.

This application appears to be regarding the use of mental health data from ALSPAC, regarding 447 individuals who have consented to having an MRI. This is a small proportion of the entire ALSPAC cohort. On querying at the time of submission, the applicant confirmed that these 447 individuals who had consented to an MRI scan required 's251' support, because they did not consent to the linkages undertaken by ALSPAC at the time of the MRI scan, as the applicant did not realise that ALSPAC mental health data would be required. This is because initially the predictive power of the scans was going to be measured by the self-report responses within ALSPAC

questionnaires, but it transpired there were bias issues around engagement and there is better diagnostic data in the NHS records.

The Members reviewed the patient information sheet (PIS) which is dated 8th September 2020, which implies this was sent to the 447 participants regarding having a 2nd MRI scan. The applicant has confirmed that most of these 2nd scans have now been undertaken. The CAG noted that on page 2 of the PIS, it is clearly stated that NHS mental health records will only be accessed with consent, and that if a participant hasn't consented to the ALSPAC linkages, then this would be facilitated at the time of the 2nd MRI. The CAG therefore noted that the proposed 's251' application for linkage directly contradicts the promise given to participants in the 2020 information sheet that linkage would only proceed with consent.

The Committee were therefore of the opinion that 's251' support could not be provided for this application. This is because the cohort of 447 participants who have had 2 consented MRI scans will be in 1 of 3 groups; Either they will have previously consented to the ALSPAC linkages, and will be out of scope for 's251' support, or they will have consented to the ALSPAC linkages at the time of the 2nd MRI scan, facilitated by the applicant, and therefore any confidential patient information accessed for individuals in either of these groups will have been undertaken with patient consent. Alternatively, and for an unknown reason, a participant may have consented to only the MRI scan, but not the ALPSAC linkages, which is what the applicant appears to have applied for 's251' support for. However, the Members were of the opinion that 's251' support cannot be provided for this 3rd group of individuals, because it appears the applicant has requested the participants consent for these linkages, and if no response has been received, the participant is defined as a 'non-responder', and 's251' support cannot include non-responders if consent has been specifically asked for. These non-responders must be taken as dissenters, as per ICO guidance. managing-non-response-guidance-v1-2_Aplc9nj.pdf

Therefore, no individuals in the cohort of 447 can be in scope for 's251' support, as it appears that linkages are either undertaken with consent as the legal basis under common law, or for non-responding individuals, this must be taken as dissent to linkage, and are therefore also out of scope of 's251' support. This is assuming that all individuals who have had the 2 consented MRI scans have been provided with the PIS which explains that linkages facilitated by ALSPAC to NHS Mental health records will be undertaken with consent. It is also noted that although there are 3 separate groups of individuals, (previously consented into ALSPAC linkage element, consented into ALSPAC linkage element at 2nd MRI scan, not consented into ALSPAC linkage element), no information has been provided about how many individuals of the 447 are in each group.

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 ALSPAC team are undertaking an ongoing project to seek consent from participants to no longer need s251 support. However with regards to this specific project, participants with schizophrenia and related disorders are more likely to be lost to follow-up in the ALSPAC study, and it is important to include those people in addition to those who have consented.

It has been accepted as part of reviews of the previous ALSPAC studies that consent is not a practicable alternative for this additional processing.

However, this particular application is to link ALSPAC clinical data to data retained on MRIs that have already been undertaken as part of this research project. The applicant stated that participants consented to the MRIs, however at the time, it was not realised that linkage to the ALPAC clinical data may be undertaken, and therefore consent was not obtained for the linked health data at the time. It is not practicable to go back and reconsent all individuals involved. The CAG would have been content with this justification, had consent not been requested, however they noted from the information sheet provided that consent for the ALSPAC linkages was requested in 2020. Therefore, it is understood that consent is a practicable alternative, as either participants are already consented to ALSPAC linkage, or the suggestion is that consent to ALSPAC linkages would be facilitated at the time of consenting to the 2nd MRI scan.

- **Use of anonymised/pseudonymised data**

In order to link the data from different datasets confidential patient information is needed. The CAG agreed that using anonymised or pseudonymised data was not a practicable alternative.

Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient

information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

ALSPAC has provided the cohort with ongoing materials informing them about the study's intention to link to health and social care data (including primary and secondary care) routine records for the enrolled cohort, and only the records of those who have been provided with the materials will be used. Their website provides full information about the ALSPAC study and how to opt out.

In addition, materials specific to this proposal will be made available via the study website. It is stated in the application that materials are also available in large print, and in audio versions. The provided website notification states the study will start May 2019. The applicant states this will be updated once CAG support is in place.

In addition, a participant information sheet (PIS) has also been provided, which is from 2020. At this time, consent was taken for a follow up MRI at age 26. Participants have already been provided with these, and the MRIs have already been undertaken.

There is a study specific opt out option for linkage on the website notification, and option to opt out of ALSPAC linkages, or ALSPAC entirely, through the ALSPAC website. The study cohort would also have had an opportunity not to consent into the MRI study at the time of consenting to the MRI. The national data opt out is applied.

The Members considered that date on the website notification should be amended from May 2019 to correctly reflect when the process will be undertaken, and allow people to opt out if they wish. The CAG noted that although it was the same format as previously submitted ALSPAC website notifications for additional studies, that the information provided did not seem very accurate. The Members felt that a phone number should be provided as well as an email address in order for people to opt out. The website notification also did not make clear that the legal basis for linkage was planned to be 's251'. It was also not clear on the website notification that this concerned only the cohort of 447 individuals who had consented for the MRI study. Members also commented that it should be stated on the website notification that the national data opt out would be respected.

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 patient and public involvement work undertake for main ALSPAC linkage in 2016, an investigation into participants' understanding of and feelings towards the acceptability of accessing sensitive data without consent was carried out. This information was obtained from a focus group discussion with ALSPAC's participant advisory committee OCAP (Original Cohort Advisory Panel). This is an advisory group of around 25 young participants.

Applicants have also conducted focus group discussions with OCAP to inform them about the data linkage process and determine their understanding and feelings towards accessing sensitive information mental health and other data without consent. A paper has been provided from 2016 looking in detail at attitudes to linking health data without consent. There appears to be support for this use of CPI without consent.

in addition, the independent ALSPAC Ethics and Law Committee includes two study parents and young study participants (approx. 50% participant/ 50% professional mix). The committee meets monthly to consider the ethical and legal aspects of the ALSPAC study itself as well as any studies requesting ALSPAC data. The ALSPAC Ethics and Law Committee therefore would have formally reviewed and approved this study, however CAG has not seen an correspondence regarding this specifically.

The patient and public involvement information provided is from 2016, and identical to that provided in the 2020 supported CAG applications. The applicant confirmed they did not have any further patient and public involvement update or specific feedback about this particular application.

The CAG were of the opinion that although the patient and public involvement undertaken in 2016 was very through and good quality, and the 25 members of OCAP were very supportive of linkage, they were more cautious about mental health data. Additionally, the patient and public involvement work undertaken is now 6 years old. Since 2016, attitudes towards linkage in general, and this study specifically, may have

changed. The CAG noted that this application seemed to be potentially linking criminal records and health records, whilst also comparing to brain scans, and that this element is important to discuss with a patient and public involvement group. The Committee noted that the information provided states that each substudy is required to be considered by 2 parents and 2 children as part of the ALSPAC Ethics and Law Committee, however the committee has not seen evidence of any recent consultation with the ALSPAC Ethics and Law Committee about this application. If a resubmission is required, additional and recent patient and public involvement should be undertaken, which is specific to this application, and discusses the particularly sensitive linkages involved, including to criminal records if this is relevant. Evidence of review by the ALSPAC Ethics and Law Committee should be provided as part of a re-submission.

Exit strategy

The exit strategy for this specific application regarding 447 patients is not clear, because it appears 's251' support is not required for the cohort requested. Consent for ALPSAC linkages is the exit strategy for the main ALSPAC study.

Main ALSPAC application ECC 1-05 (b) /2012

The CAG wish to state they continue to be supportive of the ALSPAC project in its entirety. However this application has highlighted some points that require clarity regarding the main ALSPAC application. A separate letter will be provided regarding these points.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, on the basis of the information provided, they did not have sufficient information to provide a recommendation under the Regulations.

Further information required

To support a future application(s), the below points should be taken into consideration. A detailed covering letter should be provided to support the revised application submission, which addresses the below points and sets out where revisions have been made to the revised CAG application.

1. It is the opinion of the CAG that none of the 447 individuals are in scope for 's251' support. If this application is to be re-submitted, clarity around scope must be provided.

2. If a resubmission is planned, the website notification should be amended, as per advice in this letter.

3. If a resubmission is planned, further patient and public involvement is required, as per advice in this letter.

4. Any other business

No other business was raised.

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

Signed – Chair		Date
Dr Tony Calland, MBE, CAG Chair		*31 March 2022*
Ms Clare Sanderson, CAG Alternate Vice-Chair		*30 March 2022*
Signed – Confidentiality Advice Team		Date
Ms Caroline Watchurst, Confidentiality Advisor		*29 March 2022*