Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

25 May 2023 via Zoom

Present:

Name	Role
Dr Tony Calland	CAG Chair
Ms Clare Sanderson	CAG Alternative Vice Chair
Dr Joanne Bailey	CAG Member
Dr Rachel Knowles	CAG Member
Dr Harvey Marcovitch	CAG Member
Dr Stephen Mullin	CAG Member
Ms Diana Robbins	CAG Member
Mr Dan Roulstone	CAG Member
Mr Umar Sabat	CAG Member

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	HRA Confidentiality Advisor

Mr Will Lyse	HRA Approvals Administrator
Ms Emma Marshall	HRA Confidentiality Specialist
Mr Paul Mills	HRA Confidentiality Advice Service Manager
Mr Dayheem Sedighi	HRA Approvals Administrator
Ms Caroline Watchurst	HRA Confidentiality Advisor
Nabeelah Chothia	HRA Approvals Administrator (Observer)
Gail Holland	REC Member (Observer)
Susanna Keeling	HRA Information Governance and Complaints Manager (Observer)
Brian Eastwood	Head of Substance Misuse Demonstrator Pilot, OHID, DHSC (items 3a only)
Dan Lewer	Consultant in Public Health, Bradford Institute for Health Research (items 3a only)
Professor Sir Alex Stevens	Professor in Criminal Justice, University of Kent (items 3a only)

1. Introduction, apologies and declarations of interest

CAG members Mr Marc Taylor & Professor James Teo gave apologies.

There were no conflicts of interest declared.

2. Support decisions

Secretary of State for Health & Social Care Decisions

The Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care agreed with the advice provided by the CAG in relation to the **27 April 2023** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **27 April 2023** meeting applications.

Minutes:

The minutes of the following meetings have been ratified and published on the website:

- **April Sub-Committee minutes**

3. New Applications

a. 23/CAG/0052- The health effects of police diversion for drug-involved suspects

Context

Purpose of application

This application from The University of Kent set out the purpose of medical research that seeks to study the effect of 'police diversion' on people who have some involvement in use of controlled drugs. 'Police diversion' happens when someone is in contact with the police, for example because they have been found in possession of controlled drugs, and is offered an alternative solution instead of traditional punishments such as a caution or charge. The alternative solution might include educational programmes, one-to-one support, and referral to structured treatment for drug dependence. These schemes exist in some police forces and not others. Currently, the benefits of police diversion are not well understood.

Many police officers and government policy-makers recognise that people involved in drugs have poor health and social outcomes. Traditional punishments used by the police can worsen these outcomes by affecting employment prospects, social relationships, and mental health. 'Diversion' to educational or treatment programmes may have substantial benefits both for the individual involved in drugs and for society. However, there is very little robust research into these benefits, which means that diversion schemes do not attract long-term sustainable funding. The study aims to estimate the effect of police diversion schemes on reoffending rates and the health and wellbeing outcomes of people who use illicit drugs. This is a population with poor health outcomes and high health and social care costs. The frequent contact with the police means that police diversion is an opportunity to provide health interventions to a vulnerable and under-served group. This supports the NHS Long Term Plan and the Prevention Programme. The results are intended to inform policies that improve

health outcomes and reduce health and social care costs for this group. Local partnerships of police and healthcare organisations (such as drug and alcohol treatment services) will use the results to design pathways that reduce criminalisation, stigmatisation, and harm from controlled drugs. The descriptive data will also help the NHS understand the health needs of this population, which are not well-known because illicit drug use is not well-recorded in routine data.

Participating police forces will identify individuals who are suspected of offenses related to drugs, meeting the eligibility criteria. Data disclosed from police force to the Office for Health Improvement and Disparities (OHID) part of the Department for health and Social Care (DHSC) is not in scope for 's251' support. The police force will disclose identifying information such as PNC ID if available; name; sex; Date of Birth, and postcode, (which does not meet the criteria for confidential patient information as it is not in association with a health record), alongside ethnicity if available, and baseline police data. Name, sex, Date of birth and postcode will be disclosed to NHS England, for the purposes of linkage to the personal demographics service (PDS), in order to provide the applicants with NHS number. This linkage requires 's251' support, as this constitutes confidential patient information. Identifiers are linked by OHID (DHSC) to the NDTMS dataset, alongside the police information and MoJ (PNC) data, to create a pseudonymised dataset for analysis, none of which requires 's251' support as the ministry of Justice data is not confidential patient information, and the NDTMS cohort are consented. Linkage with PNC and NDTMS will be undertaken at 2 separate timepoints. NHS number is then used to link within DHSC to Hospital Episode Statistics and ONS mortality data, which also requires 's251' support as this constitutes confidential patient information. Applicants will create a pseudonymous dataset for analysis.

The main analysis will be based on comparing individuals in areas with diversion schemes to those in areas without these schemes. The two primary outcomes are; hospital episodes related to drugs, alcohol, or accidents, and reoffending, defined as any proven offense in the 12 months after the index police contact. Secondary outcomes will be entry into structured treatment for drug or alcohol use in a community setting; and among those who start drug or alcohol treatment, retention in treatment for at least 28 days.

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	Individuals will be eligible to participate if they were in contact with the police in relation to drugs between October 2021 and September 2022. Applicants estimate the cohort will be between 3,600 and 8,400 individuals.

	Participating police forces will identify individuals meeting the following criteria: (1) Had police contact between 1 October 2021 and 30 September 2022 (inclusive) (2) Contact was in relation to a qualifying offence committed in the police force area (listed in application) (3) Lived in the police force area at date of police contact (4) Was aged 18+ years at date of police contact
Data sources	1. NHS England – Patient Demographic Service 2. OHID (DHSC): a) Hospital Episode Statistics (HES) b) Office for National Statistics (ONS) mortality data Out of scope for 's251': • Police force data • MoJ – PNC data • OHID (DHSC) – NDTMS
Identifiers required for linkage purposes	Linkage to PDS: 1. Name 2. Sex/gender 3. Date of Birth 4. Postcode Linkage to HES/ONS: 1. NHS number
Identifiers required for analysis purposes	Pseudonymous for analysis; • Month and year of death (derived full date of death) • Ethnicity • Age • Multiple Deprivation score (derived from postcode)

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 this activity was of public benefit, if successful.

The CAG discussed the likelihood of success of being able to link to NHS numbers by linking police data with the PDS service, as the patient group might be mobile and hard to reach, and their medical records might therefore not be up to date, and they may not have an NHS number at all. The CAG asked the applicant to clarify the impact on the study if NHS number was not identified. The applicant responded that they had undertaken studies using this type of linkage before, and explained that it has been successful in the past. The applicant stated that it would not negatively affect the study, if even 20% of NHS numbers were not identified, as they explained they would be able to undertake the subsequent linkages using other additional identifiers. In addition, they will be able to complete validation of the completed linkage to test the degree of bias on their results. The CAG was satisfied with the response as the applicant provided good reasons around the likelihood of this not affecting the public benefit of the study.

Scope

The CAG requested that the applicant confirm the lawful basis for the sharing of police data with OHID. The applicant was unable to respond in the meeting, but will seek advice from their information governance team. The CAG agree that this would not constitute confidential patient information, so is out of scope for CAG, but the Committee need to confirm regarding a lawful basis for the initial stage.

The CAG noted that it appeared from the documentation provided that DHSC might be a joint data controller with University of Kent, for this application to CAG. The application to the Research Ethics Committee appears to be a single controller only – The University of Kent, and therefore the CAG would be grateful if the applicant could confirm that this is the same for the CAG application.

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 applicant's reason that it is not possible to ask participants for consent for three reasons:

a) this is a historical study of people in contact with the police;
b) participants are in contact with the police during 'usual police work', and there is often no easy time to discuss consent, especially for people who are not offered diversion;
c) some participating police forces are 'control' forces with no diversion scheme and there is no clear cohort to recruit.

Applicants had considered alternatives of using aggregated data (which was rejected due to insufficient controlling of confounding, in which participants in intervention and control areas have different characteristics) and recruiting prospectively and collecting consent (which would delay the project by a number of years and likely result in substantially higher costs and low power due to limited

resources to recruit participants). Applicants have developed the study design together with data protection specialists at the Department for Health and Social Care, police forces, and the National Police Chiefs Council. The CAG were content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for linkage between datasets. Anonymised data also would not allow individual-level linkage between the study cohort and healthcare datasets.

The CAG was content that using anonymous information was not a practicable alternative.

Data items

The CAG requested clarification as to whether sex or gender or both was required at all stages of the data flow.

'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 has been provided, that has a study specific opt-out option. The applicants have discussed adding the legal basis and information about CAG with User Voice, the Patient and public involvement (PPI) partner. Their advice is that people reading this notice will not understand 's251', CAG, or the possible legal bases of data processing. The applicant would therefore prefer not to add this information as it may be confusing for readers. The applicant has suggested they could add a link or QR code to a website that provides more detailed information about the data processing and legal bases, but this is currently not on the poster.

This notice will be published on the websites of participating police forces.

A study specific opt-out is available via the poster. The National Data Opt Out will be respected.

The CAG requested a layered approach to patient notification, for example by providing a QR code, as suggested by the applicant, or a website link which leads on to a longer privacy notice on a website if people want to have further information.

The CAG additionally requested revisions to the poster, requesting an explanation of the specific breaches of confidence requiring CAG review and 'section 251'

support. The CAG noted the reasons for not initially including this, but felt it was important that the legal basis for processing was stated.

The CAG also requested for the poster to include an explanation of what police diversion schemes were, as the control group may not know.

Furthermore, the CAG requested for the study specific opt-out, the poster should also include postal address and phone number as well as the email address. The CAG also requested a revision to the language of 'requesting' an opt-out as the terminology seems to be incorrect, as it suggests participants can ask and it might not be given.

The CAG discussed with the applicant regarding the timing of the opt-out, which should be operated via the police forces prior to the extraction of data. The applicant agreed that this should be possible, but will have to ask their police force contacts. The CAG recommended a time of 6 weeks or so should be given for participants to opt out once the notifications have been displayed.

The CAG noted that the PPI group recommended working with drug recovery organisations that are local to participating police forces, and particularly suggested Facebook groups run by these organisations. The applicants have confirmed they will use the same notification document for this purpose. Applicants will work with User Voice and participating police forces to identify drug recovery organisations who may be able to help publicise the research but have not yet done so. Therefore, the CAG requested that the applicant identify the drug recovery organisations who may be able to help publicise the research by displaying the posters, prior to 's251' support being in place.

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.

Applicants have undertaken various patient and public involvement (PPI) activities to prepare this application. The organisation User Voice is a partner in the research project. All staff at User Voice have lived experience of the criminal justice system. Five staff from User Voice were involved in the design of this research. They attend monthly steering group meetings and are closely involved in all aspects of the project.

The applicants attended a diversion workshop run by the charity DrugLink on 28 March 2023. This was a session including eight individuals who had been referred by the police to receive an educational intervention. Individuals in this group therefore represent the cohort. Applicants explained the research and asked for feedback about the non-consented data linkage. Two key themes from the discussion were:

- participants strongly supported the research and the use of personal data to investigate the health benefits of diversion;

- participants wanted clear and strong reassurance that their data would not be published, and particularly that their names would not be linked to the drug diversion schemes. Their concerns included potential employers learning that they attended the drugs education course.

The participants also gave advice about potential channels for publicising the research, highlighting Facebook groups run by local recovery organisations.

The applicant therefore appears to have some support for the processing of confidential patient information without consent, from a relevant set of individuals.

The CAG asked the applicant to clarify what 'staff' meant with regards to the charity user voice. The applicant confirmed that some staff within the charity user voice were employed and some were volunteers, but volunteers were also reimbursed. The applicant explained that all user voice PPI members have lived experience that were relevant to the cohort. The CAG was content with the response.

Some concerns were raised by the PPI groups, with regards to participants not wanting it to be known publicly that they were part of a drugs diversion workshop. The applicant commented that they have taken this on board, and will need to ensure strong ongoing communication about this, as the data of any participating individual will be kept confidential within the organisations stated, and this information would not be known publicly. The CAG recommend that the applicant ensure this point was also made clear on the poster to avoid more opt-outs than necessary, but this is not a condition of support.

Exit strategy

Support is required until the linkage is completed, and the key is deleted. The pseudonymisation key will be held by the Department for Health and Social Care. A table of personal identifiers and the pseudonymisation key will be held separately and only accessible by team members who are conducting data linkage. Tables for research use will be stored separately. These research tables will include the pseudonymous identifier and clinical data, but not personal identifiers such as names and addresses. Once the final research tables have been created, the individual identifiers will be deleted. The applicant has confirmed the key will be deleted by approximately 31 November 2024. 's251' support is required until then.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1) Please confirm whether the application has a lawful basis for the sharing of police data with OHID.

2) Please confirm whether the DHSC would be joint data controllers with the University of Kent for this CAG application.

3) Please confirm at all points of the data flow whether it is sex, gender or both required for the linkage.

4) Please update the patient notification materials as follows, and provide to CAG for review.

    a. The poster doesn't explain what police diversion schemes are – this should be included, as the control group may not know.
    b. The legal basis for processing of 's251' and that the application has been supported by the Health Research Authority (HRA), following advice from the Confidentiality Advisory Group (CAG), should be included on the poster.
    c. There is an email only for opt-out, a postal address and phone number should also be included.
    d. The language regarding 'requesting' an opt-out is not correct terminology, as it suggests patients can ask and it might not be given. Please re-word this.
    e. CAG feel a layered approach should be undertaken, for example a QR code on the poster that links on to a longer privacy notice on a website if people want to have further information.

5) Please confirm if it is possible for the police force to operate the study specific opt-out, and provide a period of 6 weeks for participants to opt-out once the notifications have been displayed.

6) Please identify the drug recovery organisations who may be able to help publicise the research by displaying the posters.

Specific conditions of support (provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

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

2. Confirmation provided from the DSPT Team at NHS England 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 England 21/22 DSPT reviews for **OHID (DHSC)** and **NHS England were** confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 17 April 2023).

b. 23/CAG/0053 - National Audit of Cardiac Rehabilitation (NACR)

Context

Purpose of application

This Non-research application from NHS England set out the purpose of continuing the National Audit of Cardiac Rehabilitation.

The National Audit of Cardiac Rehabilitation (NACR) collects comprehensive audit data to quality assure programmes, to support improvement and monitoring of cardiac rehabilitation services in terms of their uptake, quality, and clinical outcomes. The remit of the audit is to support clinical cardiac rehabilitation teams in auditing their service. NACR use the data to produce annual reports and ad hoc reports by request for individual programmes. Data is also provided to NHS England, Cardiac Networks, and ICBs. NACR runs a joint National Certification Programme for cardiac rehabilitation with the British Association of Cardiovascular Prevention and Rehabilitation where programmes are assessed on seven standards. It also informs research papers submitted to journals.

Participating hospital trusts and health boards input confidential patient information into the Clinical Audit Platform (CAP), a secure online data entry platform provided by the Clinical Audit service in NHS England. A monthly extract of data is taken from CAP. The data is pseudonymised by replacing the NHS number with an audit ID, converting date of birth to age at initiating event, and converting postcodes to Lower Super Output Area. The pseudonymised dataset is then disclosed to the University of York for analysis, to be used to create annual reports.

A recommendation for class 1, 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	Patients referred to Cardiac Rehabilitation Programmes in England and Wales.

	The audit includes all patients referred to cardiac related to the following conditions / events: • Myocardial Infarction (MI) • MI plus Percutaneous Coronary Intervention (PCI) • PCI • Coronary Artery Bypass Graft (CABG) • Unstable Angina • Heart failure
Data sources	1. Data supplied by participating NHS trusts and health boards in England and Wales
Identifiers required for linkage purposes	1. Name 2. Address & Postcode 3. Date of Birth 4. NHS number
Identifiers required for analysis purposes	1. Sex 2. Gender
Additional information	Patients' postcodes and dates of birth are used for linkage. The postcodes are then used to derive Lower Super Output Area and dates of birth to derive Age at Initiating Event. The derived fields are supplied to the University of York for analysis. The dataset held at the University of York is effectively anonymised but referred to as pseudonymised in the data flow diagram, in line with ISO guidance.

Confidentiality Advisory Group advice

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

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The CAG agreed that the application was in the public interest.

Practicable alternatives

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

- **Feasibility of consent**

When beginning a cardiac rehabilitation programme, patients are given a questionnaire. The first page of the questionnaire contains information about the audit and how patients can dissent to the use of their data. The applicants noted that, although this meets the spirit of informed consent, going through the full consent process was not feasible due to burden on the clinical staff.

The CAG was content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

The applicants noted that confidential patient information is not required for analyses to take place. However, the clinical teams inputting the data require access to confidential patient information to ensure that the data entered is accurate and under the correct patient record. Local staff must have access to NHS numbers and patient name, the latter being used routinely by local services to access address, General Practice, Date of birth, etc.

The CAG was content that using anonymous information 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.

When beginning a cardiac rehabilitation programme, patients are given a questionnaire. The first page of the questionnaire contains information about the audit and how patients can dissent to the use of their data. Information is also available on the NACR website.

The CAG requested clarification on specific examples and the types of questions used within the participant questionnaires.

The applicants also provided the Opt-Out Form and Patient Information Sheet. The website information, Opt-Out Form and Patient Information Sheet all inform patients that the National Data Opt-Out does not apply and they will need to register complete the Opt-Out Form to dissent to inclusion in the NACR. Furthermore, patients can dissent to the inclusion of their data by informing the Clinical Audit Team via an Opt-Out Form or by telephone.

The Patient Information Sheet and Opt-Out Form were reviewed when the application for deferral of the National Data Opt-Out was made in December 2022.

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 conducted patient involvement with the Coronary Care Partnership UK (CCP-UK), which is a national cardiovascular registered charity hosted by the British Cardiovascular Society (BCS). CCP-UK Patient involvement occurs through membership of the NACR Steering Group and also on the National Certification Programme Steering Group.

The NACR team supports CCP UK activity, including patient conference events, and supports the public through specific webpages on use of patient data and patient privacy. Patient Privacy Notice Patient representatives are actively involved in NACR Steering Group and NCP_CR Committee including recent involvement in discussions regarding the impact of the National Data Optout.

A statement of support from a patient representative was provided. This had previously been provided in support of the application for deferral of the National Data Opt-Out.

The Steering Group members will continue to work with the audit to provide the patient and service user perspective on the work.

The CAG noted disappointment that the applicant did not fulfil the original condition which requested that further patient and public involvement was conducted, particularly around the non-application of the National Data Opt-Out' and that feedback was provided to the CAG in the refreshed application. The CAG requested for this condition to be met.

The CAG noted the importance of including underrepresented groups in the patient and public involvement. Members asked the applicants to ensure that these groups were included in the further patient and public carried out. Members also noted that, as this is a national audit, then representatives from different areas of the country also needed to be consulted.

Exit strategy

The data is kept for the duration of the audit; if the audit closes the data will be retained for 8 years, in line with the NHS England records management policy; after that time the data will be destroyed, following processes in accordance with the data destruction policy.

The CAG was content with the exit strategy.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

The following sets out the specific conditions of support.

1. Support under 23/CAG/0053 will supersede the existing application ECC 3-04 (a)/2012.

2. Provide specific examples and types of questions used within the participant questionnaires. Please feedback to CAG within six months.

3. Further patient and public involvement needs to be carried out, and feedback provided to CAG within six months:
    a. The specific issue of non-application of the National Data Opt-Out needs to be discussed,
    b. Underrepresented groups need to be included,
    c. Patients from different areas of the country need to be included.

4. Confirmation provided from the IG Delivery Team at NHS England 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 England **21/22** DSPT review for **NHS England** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 25 May 2023).

c. 23/CAG/0059- Community Mental Health 2023 Survey

Context

Purpose of application

This non-research application from Picker Institute Europe, on behalf of the Care Quality Commission (CQC), set out the purpose of administering the 2023 Community Mental Health Survey (CMH23).

CMH23 falls within the NHS Patient Survey Programme (NPSP). The NPSP was initiated in 2002 by the then Department of Health, and is now overseen by the CQC, the independent regulator of health and social care in England. CMH23 will be the twentieth carried out to date. All 53 eligible mental health provider trusts will be asked to conduct the survey, drawing a sample of service users according to set criteria, and following standardised materials and procedures for all stages of the survey.

The CMH mainstage survey has previously been conducted using a postal approach. However, A stand-alone pilot study (21/CAG/0074) tested the effectiveness of a mixed methods approach, offering the questionnaire online (in addition to a postal survey), and sending SMS reminders (in addition to postal reminders). The 2023 mainstage methodology is changing as compared to CMH22, to include offering the questionnaire online (in addition to a postal survey), sending SMS reminders (in addition to postal reminders), including 16-17 year olds, excluding service users who have been accessing Memory Clinics, the including of 'boost' samples as relevant to 's251' support, changes to timings, and other changes as listed in the application.

Trusts will collect information of all eligible patients and, following suitability checks, will share confidential patient information with the approved contractor, Quality Health, and the coordination centre - Picker Institute Europe under the title 'Survey Coordination Centre' (SCC). Full postcode will be disclosed to the SCC (to map LSOA) – this is in line with other supported surveys.

Questionnaires will be distributed to patients using the approach detailed below;

- **Contact 1**: Letter with URL link for online questionnaire
- **Contact 2:** 5 working days after contact 1, SMS despatched with URL link for online questionnaire
- **Contact 3**: 10 working days after contact 1, letter with URL link for online questionnaire, and paper questionnaire
- **Contact 4**:15 working days after contact 1, SMS despatched with URL link for online questionnaire
- **Contact 5**: 20 working days after contact 1, letter with paper questionnaire (no URL)

Ahead of each reminder, it will be necessary to remove all respondents who have completed the survey already, and to conduct a DBS or local check on the full sample to ensure any deceased individual is removed from the sample. If anyone has requested to be opted out of further reminders, they should also be removed at these timepoints.

A recommendation for class 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application, which can be got from the CAT assessment form, class support requested section.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Patients aged 16 and over who had been in contact with NHS mental health services in the two-month period from 1 April to 31 May 2023, and who were receiving specialist care or treatment for a mental health condition, and fulfil the inclusion criteria as detailed in the application. 1250 service users from each Trust, plus any 'boost' samples. Approximately 67,500 users of community mental health services in total.
Data sources	Electronic patient records, Mental Health Trusts in England
Identifiers required for contact purposes	1. Trust code 2. A standardised unique identifier code, 3. Title (Mr, Mrs, Ms, etc.) 4. First name 5. Surname 6. Address Fields 7. Postcode 8. Mobile phone number
Identifiers required for analysis purposes	1. Trust code 2. The unique identifier code (as above) 3. Year of birth 4. Postcode 5. Sex 6. Ethnic category 7. Day of last contact 8. Month of last contact 9. Year of last contact 10. Sub-ICB codes 11. Mental Health Inpatient indicator 12. Service level information variable 13. Mental Health Care Cluster Codes 14. Mode of contact

Confidentiality Advisory Group advice

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

Public interest

The CAG noted that this activity fell within the definition of 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 and the application was in the public interest.

Practicable alternatives

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

- **Feasibility of consent**

There are three central arguments as to why consent is not practicable, and which have been accepted across the National Survey Programme:

- Trusts will not benefit from the expertise of a specialist survey contractor,
- Potential to introduce bias into the survey findings,
- Potential burden on clinical staff through the requirement to take consent.

The CAG was content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to facilitate the invitation process which could not be otherwise achieved.

Full post code is disclosed for analysis to allow the SCC and the CQC to conduct sub-group analysis to understand the link between deprivation and quality of community mental health services at the local level. Full postcode is deleted after mapping to LSOA and local authority, as per other surveys. This information will enable researchers, governmental bodies, service users and providers of services to better understand the quality of service in their local area.

The CAG were content that full postcode needed to be disclosed to the SCC from Trusts, as it would not be practicable for Trusts to map to LSOA and disclose that instead.

The CAG was content that using effectively anonymous information was not a practicable alternative.

- **Minimisation of data flows**

Although CAG accepted that postcode was necessary for the purposes of mapping to LSOA for analysis, and accepted that it is not a practicable alternative for Trusts to disclose LSOA to Picker instead of full postcode, the Committee noted that as part of initial previous applications (19/CAG/0102) regarding the disclosure of postcode, that this was planned to be deleted within 4 weeks, although more recent applications state 6 months, (same as 23/CAG/0059). The applicant is to justify why the full postcode needs to be retained for 6 months, rather than 4 weeks, given that it is only required to map to LSOA.

‘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.

- Prior to breach

Posters will be displayed in participating Trusts throughout the sampling period to inform patients that they may be approached to participate in the survey and provide a means for prior dissent to be raised. These have been produced in English and translated into 10 other languages to improve accessibility. The posters have been designed with 6 different backgrounds this year, allowing Trusts to select the posters that best fits with their branding.

Although the provision of posters is the primary method of informing the study population of the survey, Trusts will also be informed that they can undertake their own additional promotional activities, where considered appropriate, for example, the survey instruction manual recommends that Trusts issue a local press release prior to mailing questionnaires, and suggests local social media. Trusts have also been advised to display a copy of the poster on their website given that some service users do not frequently attend the trust premises.

Although we are currently in the sampling period (1 April to 31 May 2023) the Trusts have already been asked to display these posters.

To support the inclusion of 16 and 17 year olds in the survey, applicants have designed a specific poster for this cohort that provides details about the survey (purpose), how their personal data (contact details) will be used for administering the survey, anonymity and confidentiality and how to indicate dissent. Trusts have the option to print and display on site, hand out to 16 and 17 year old service users, and display on their website and social media.

Newly for CMH23, the applicants have designed an Impact Strategy, comprising of a number of publicity and engagement tools to advertise the survey and communicate with the wider service user population. Social media cards, publicity posters, website banners, letter and newsletter banners will be shared with Trusts and third sector organisations prior to and during the fieldwork. These tools will provide information about the purpose, value, survey timeframe and information about how service users can participate and/or find more information about the survey. All materials are currently being designed by SCC, in collaboration with CQC, and will be shared with Trusts and third sector organisations in June 2023. This is after the sampling frame, however this is still in advance of fieldwork and during fieldwork to help promote the survey and increase response. While they won’t be shared during the sampling period, there is potential that service users may still attend the trusts during June

2023, as service users must have had contact during the sampling period AND before or after this period. If this is the case, they can still record their dissent before samples are due to be drawn in July.

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.

The surveys have exemption from the National Data Opt Out – see here.

The CAG was impressed by the format of the 16–17-year-old poster and queried whether this content and format could be used for the other posters also. The Committee requested that the applicant develop a separate patient notification leaflet in addition to poster, to be given to all 16–17-year-old patients by staff to inform patients that they may be approached by posy and text message to participate in the survey and provide a means for prior dissent to be raised. This is as per previously supported surveys (20/CAG/0139) and (19/CAG/0181).

The Committee noted that as requested in previous surveys, the applicant has begun to look at more ways of informing the population that the survey is being undertaken, which is being done via the development of an Impact Strategy. The CAG requested that the applicant provide these additional patient notification materials that are being developed as part of the impact strategy.

In general, it was noted that the application specific opt-out process is clear, and is appropriately displayed prior to the breach of confidentiality.

- Post breach

The CAG noted that the SMS messages sent to participants did not contain an opt-out mechanism. This was discussed in the meeting, however the applicant has previously justified this decision, as this was initially queried as part of previous application (19/CAG/0180), and answered as part of previous application (20/CAG/0085). The Members were content that the applicants had previously adequately explored the use of an SMS opt-out mechanism and agreed with the decision and reasoning not to use an SMS opt-out mechanism as part of the actual SMS message.

The CAG noted that the number of contacts by letter and SMS that a patient would receive is quite high, however the same methodology has been previously supported by CAG for all the mixed methods surveys, (for example 19/CAG/0102 and 20/CAG/0085). The Members were content to accept the amount and types of contact, as this is laid out clearly in the communications that the patients receive, and work done by the application with patients and the public on this topic appears to be supportive.

The CAG raised concerns regarding the receipt of SMS messages for the 16-17 year old patient group, noting that it is possible that this number may belong to a parent, and that the 16-17 year may not have disclosed to their parents regarding mental health treatment. The CAG requested clarification on whether the applicant had considered if this text message may end up going to the parent rather than the patient, to ensurie that no 16-17 year old, who may not have disclosed to their parents regarding mental health treatment, would be identified in this manner.

The CAG requested confirmation that the mobile number used will be the mobile number taken from the Trust as provided by the patient, and not linked with PDS. As such, this would therefore be the number provided by the patient to the Trust, and whether it is the parent or the patients number, it would have been provided as the number to use for clinical correspondence.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicant has provided a detailed overview of the patient and public involvement activities which were undertaken in advance of the 2023 survey within the application. This included interviews with service users. As part of the interviews, the applicants tested the concept of using contact details (without prior consent) to administer the survey. Comments included that as long as the value of giving feedback was made clear to recipients (i.e: service improvement), interviewees were comfortable with contact details being used without prior consent.

Applicants also consulted with a survey specific Advisory Group, including national bodies, charities specialising in Mental Health such as Young Minds, front line mental health practitioners and current service users. The service users involved in the Advisory Group are current mental health service users. They feed into the development of the survey including feedback about the methods used.

Patient and public involvement has also been undertaken with regards to lowering the eligible age range to 16, and it was felt that that gathering feedback from service users who will be transitioning from Child and Adolescent Mental Health Services (CAMHS) into Adult services was key, as there is currently a gap in this area and limited information gathered at a national level to understand how transitions within mental health services are performing from a patient perspective.

Applicants have developed an Engagement and Impact Plan for CMH23. The engagement plan includes identified third party organisations that applicants have begun reaching out to in support of publicising the survey. These organisations are focussed on groups that are traditionally classed as ‘hard to reach’ populations. For CMH23 in particular, it is known that ethnic minority groups tend to be under represented in the survey data and so applicants have begun to reach out to representative organisations (e.g: Black Minds Matter UK, Taraki, Sharing Voices).

The CAG requested clarification on how many service users were involved in the described Patient and Public Involvement regarding the use of confidential patient information without consent.

Exit strategy

The mailing file, containing names and addresses, will be destroyed when the survey is complete, and no later than six months after the close of fieldwork.

Service user postcodes will be deleted after the analysis has been completed and no later than six months after the close of fieldwork.

Fieldwork is due to close on 1st December 2023. Reporting and analysis to be conducted, with publication due February 2024. 'Section 251' support is expected to be required until 6 months after end of fieldwork – approximately June 2024.

The CAG was content with the exit strategy proposed.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. The applicant is to justify why the full postcode needs to be retained for 6 months, rather than 4 weeks, given that it is only required to map to LSOA, and feedback to CAG within one month.

2. Please confirm whether the content and format of the 16–17-year-old poster could be used for other posters, and feedback to CAG within one month.

3. Please provide a separate leaflet to be given to all 16–17-year-old patients by staff to inform patients that they may be approached to participate in the survey and provide a means for prior dissent to be raised, and feedback to CAG within one month.

4. Please provide the additional patient notification materials that are being developed as part of the impact strategy, as soon as they are developed.

5. Please clarify whether it was considered that the text message may end up going to the parent, and any plans to ensure that no 16-17 year old who maybe had not disclosed to parents regarding mental health treatment would be identified in this manner, and feedback to CAG within one month.

6. The CAG requested confirmation that the mobile number used will be the mobile number taken from the Trust as provided by the patient, and not linked with PDS, and feedback to CAG within one month.

7. The CAG requested clarification on how many service users were involved in the described Patient and Public Involvement regarding the use of confidential patient information without consent, within one month.

8. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. **Confirmed:**

   The NHS England **21/22** DSPT review for **Quality Health and Picker Institute Europe** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (30 May 2023)

As the above conditions have been accepted or met, this letter provides confirmation of final support. I will arrange for the register of approved applications on the HRA website to be updated with this information.

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 & Ms Clare Sanderson, CAG Alternate Vice-Chair		*31 May 2023 & 02 June 2023*
Signed – Confidentiality Advice Team		Date
Dayheem Sedighi, HRA Approvals Administrator		*31 May 2023*