



Health Research Authority

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08 June 2023

Tamantha Webster
Care Quality Commission
2 Redman Place
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Dear Tamantha Webster

Application title: Community Mental Health 2023 Survey
CAG reference: 23/CAG/0059

Thank you for submitting a **non-research** application under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support') to process confidential patient information without consent.

Supported applications allow the controller(s) of the relevant data sources, if they wish, to provide specified information to the applicant for the purposes of the relevant activity without being in breach of the common law duty of confidence. Support provides a lawful basis to allow the information to be processed by the relevant parties for the specified purposes without incurring a breach of the common law duty of confidence only. Applicants must ensure the activity remains fully compliant with all other relevant legislation.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Secretary of State for Health and Social Care on whether application activity should be supported, and if so, any relevant conditions. This application was considered at the CAG meeting held on 25 May 2023.

Secretary of State for Health and Social Care decision

The Secretary of State for Health and Social Care, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

The application, to allow the disclosure of confidential patient information from participating mental health Trusts in England to the approved contractor Quality Health, for the purpose of sending out questionnaires for the 2023 Community Mental Health Survey, and to transfer the sample file (postcode) to the coordination centre for mapping to LSOA, is conditionally supported, subject to compliance with the standard and specific conditions of support.

Please note that the legal basis to allow access to the specified confidential patient information without consent is now in effect.

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	<p>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.</p> <p>1250 service users from each Trust, plus any 'boost' samples.</p> <p>Approximately 67,500 users of community mental health services in total.</p>
Data sources	Electronic patient records, Mental Health Trusts in England
Identifiers required for contact purposes	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 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 post 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 ensure 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.

Application maintenance

Annual review

Please note that this legal support is subject to submission of an annual review report, for the duration of support, to show that the minimal amount of patient information is being processed and support is still necessary, how you have met the conditions or report plans, any public benefits that have arisen and action towards meeting them. It is also your responsibility to submit this report every 12 months for the entire duration that confidential patient information is being processed without consent.

The next annual review should be provided no later than **08 June 2024** and preferably 4 weeks before this date. Reminders are not issued so please ensure this is provided annually to avoid jeopardising the status of the support. Submission of an annual review in line with this schedule remains necessary even where there has been a delay to the commencement of the supported activity, or a halt in data processing. Please ensure you review the HRA website to ensure you are completing the most up to date 'section 251' annual review form as these may change.

For an annual review to be valid, there must also be evidence that the relevant DSPT submission(s) for organisations processing confidential patient information without consent are in place and have been reviewed by NHS England. Please plan to contact NHS England in advance of the CAG annual review submission date to check they have reviewed the relevant DSPTs and have confirmed these are satisfactory.

Register of Approved Applications

All supported applications to process confidential patient information without consent are listed in the published 'Register of Approved Applications'. It is a statutory requirement for the Register to be published and it is available on the CAG section of the Health Research Authority website. It contains applicant contact details, a summary of the research and other pertinent points.

This Register is used by controllers to check whether support is in place.

Changes to the application

The application and relevant documents set out the scope of the support which is in place for the application activity and any relevant restrictions around this.

Any amendments which are made to the scope of this support, including but not limited to, purpose, data flows, data sources, items of confidential patient information and processors, require submission of a formal amendment to the application. Changes to processors will require evidence of satisfactory DSPT submission. The amendment form can be found in the Confidentiality Advisory Group pages on the Health Research Authority website.

Support for any submitted amendment would not come into effect until a positive outcome letter has been issued.

Changes to the controller

Amendments which involve a change to the named controller for the application activity require the submission of a new and signed CAG application form and supporting documentation to support the application amendment. This is necessary to ensure that

the application held on file appropriately reflects the organisation taking responsibility for the manner and purpose of data processing within the application, and that the legal support in place is related to the correct legal entity.

Applicants are advised to make contact with the Confidentiality Advice Team to discuss a change in controllership for an existing application in sufficient time ahead of the transfer of project responsibility to discuss the submission process timings.

Further information and relevant forms to amend the support is available on the HRA website.

Reviewed documents

The documents reviewed at the meeting are as follows.

<i>Document</i>	<i>Version</i>	<i>Date</i>
CAG application from (signed/authorised) [23.CAG.0059_CMH23_cag section 251 form non research applications_]		
Other [CMH23_Data flow diagram - post codes__V1.0_PROTECT]	1.0	
Other [P101850_CMH23_DRAFT Third mailing letter_V1.0_PROTECT]	1.0	
Other [P101850_CMH23_DRAFT Sample construction spreadsheet_V1.0_PROTECT]	1.0	
Other [P101850_CMH23_DRAFT Sample Declaration Form for trusts using contractors_V1.0_PROTECT]	1.0	
Other [CMH23_Recontact question data flow_V1.0_PROTECT]	1.0	
Other [CMH23_Data flow diagram - post codes__V1.0_PROTECT]	1.0	
Patient Information Materials [CMH23_Sampling flow chart_V1.0_PROTECT]	1.0	24 April 2023
Patient Information Materials [P101850_CMH23 DRAFT Questionnaire_V1.0_PROTECT]	1 0	
Patient Information Materials [P101850_CMH23 DRAFT Questionnaire_V1.0_PROTECT]	1.0	
Patient Information Materials [P101850_CMH23 DRAFT Survey handbook_V1.0_PROTECT]	1.0	
Patient Information Materials [P101850_CMH23_DRAFT First mailing letter_V1.0_PROTECT]	1.0	
Patient Information Materials [P101850_CMH23_DRAFT Second mailing letter_V1.0_PROTECT]	1.0	
Patient Information Materials [P101850_CMH23_DRAFT Third mailing letter_V1.0_PROTECT]	1.0	
Patient Information Materials [SMS Guidance and Content]		
Patient Information Materials [CMH23_Multilanguage Sheet__V1.0_PROTECT]	1.0	
Patient Information Materials [16-17 year olds leaflet]		
Patient Information Materials [CMH23_Dissent poster_Background 1_V1_English_PROTECT]	1	
Patient Information Materials [CMH23_Dissent poster_Background 2_V1_English_PROTECT]	1	
Patient Information Materials [CMH23_Dissent poster_Background 3_V1_English_PROTECT]	1	
Patient Information Materials [CMH23_Dissent poster_Background 4_V1_English_PROTECT]	1	

Patient Information Materials [CMH23_Dissent poster_Background 4_V1_English_PROTECT]	1	
Patient Information Materials [CMH23_Dissent poster_Background 6_V1_English_PROTECT]	1	
Write recommendation from Caldicott Guardian (or equivalent) of applicant's organisation [CMH23 Survey - Caldicott Guardian recommendation letter]		19 May 2023

Membership of the Committee

The members of the Confidentiality Advisory Group who were present at the consideration of this item are listed below.

Please do not hesitate to contact me if you have any queries following this letter. I would be grateful if you could quote the above reference number in all future correspondence.

With the Group's best wishes for the success of this project.

Yours sincerely

Dayheem Sedighi
HRA Approvals Administrator

On behalf of the Health Research Authority

Email: cag@hra.nhs.uk

Included: List of members who considered application
Standard conditions of support

Confidentiality Advisory Group meeting 25 May 2023

Members present:

Group Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Joanne Bailey	CAG Member	Yes	
Dr Tony Calland MBE	CAG Chair	Yes	
Dr Rachel L Knowles	CAG Member	Yes	
Dr Harvey Marcovitch	CAG Member	Yes	
Dr Stephen Mullin	CAG Member	Yes	
Mrs Diana Robbins	CAG Member	Yes	
Mr Dan Roulstone	CAG Member	Yes	
Mr Umar Sabat	CAG Member	Yes	
Ms Clare Sanderson	CAG Alternative Vice Chair	Yes	

Also in attendance:

<i>Name</i>	<i>Role (position)</i>
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)

Standard conditions of support

Support to process the specified confidential patient information without consent, given by the Health Research Authority, is subject to compliance with the following standard conditions of support.

The applicant and those processing the information under the terms of the support will ensure that:

1. The specified confidential patient information is only used for the purpose(s) set out in the application.
2. Confidentiality is preserved and there are no disclosures of information in aggregate or patient level form that may inferentially identify a person, nor will any attempt be made to identify individuals, households or organisations in the data.
3. Requirements of the Statistics and Registration Services Act 2007 are adhered to regarding publication when relevant, in addition to other national guidance.
4. All staff with access to confidential patient information have contractual obligations of confidentiality, enforceable through disciplinary procedures.
5. All staff with access to confidential patient information have received appropriate ongoing training to ensure they are aware of their responsibilities and are acting in compliance with the application detail.
6. Activities must be compliant with the General Data Protection Regulation and relevant Data Protection Act 2018.
7. Audit of data processing by a designated agent is facilitated and supported.
8. The wishes of patients who have withheld or withdrawn their consent are respected.
9. Any significant changes (for example, people, purpose, data flows, data items, security arrangements) must be approved via formal amendment prior to changes coming into effect.
10. An annual review report is submitted to the CAG every 12 months from the date of the final support letter, for the duration of the support.
11. Any breaches of confidentiality around the supported flows of information should be reported to CAG within 10 working days of the incident, along with remedial actions taken/to be taken. This does not remove the need to follow national/legal requirements for reporting relevant security breaches.