Health Research Authority

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30 November 2020

Tamatha Webster
CQC Survey Manager
151 Buckingham Palace Road
London
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Dear Ms Webster,

Application title: **Community Mental Health Survey 2021**
CAG reference: **20/CAG/0155**

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 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 precedent set CAG meeting held on 20 November 2020. The application was considered via the precedent set process under category 11: CQC annual surveys.

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 one of three approved contractors for the purpose of sending out questionnaires for the 2021 community mental health survey, and to transfer the sample file (containing postcode) to the coordination centre for linkage of demographic data to survey responses, and validation of data, is fully supported, subject to compliance with the standard 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, on behalf of the Care Quality Commission, set out the purpose of administering the 2021 Community Mental Health Survey.

The community mental health Survey 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 Care Quality Commission (CQC), the independent regulator of health and social care in England.

The 2021 community mental health Survey will be the eighteenth carried out to date. All 55 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 2021 methodology is broadly unchanged from the 2020 survey. However, due to the impact of Covid-19, the eligibility criteria for drawing the sample has been amended to include not only face to face contact but also contact via video conferencing or telephone. Applicants are also seeking support to disclose additional variables to the Survey Coordination Centre for Existing Methods' (SSCEM); postcode (to map LSOA) – this is in line with other supported surveys. The reason for this addition is to allow the SCCEM 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. This information will enable researchers, governmental bodies, service users and providers of services to better understand the quality of service in their local area. Applicants are also additionally collecting email address indicator (similar to the mobile phone indicator supported in 2020), and mode of contact, in line with the changes to eligibility criteria. There are no other changes to the survey, specifically Covid-19 status is not being collected in this instance.

Trusts will collect information of all eligible patients and, following suitability checks, will share confidential patient information with the coordination centre (Picker Institute Europe under the title 'Survey Coordination Centre for Existing Methods' (SSCEM)) and once of three approved contractors (Patient Perspective, Quality Health or Picker Institute Europe).

A recommendation for class 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

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

Cohort	Patients aged 18 and over who had been in contact with NHS mental health services in the three-month period from 1 September 2020 to 30 November 2020, and who were receiving specialist care or treatment for a mental health condition, including those who receive care under the Care Programme Approach (CPA)

	'Contact' in the 2021 survey is defined as face-to-face, via video-conference (e.g. using Attend Anywhere, MS Teams, Zoom, etc.) or telephone call **However:** Service users who only had telephone appointments during the sampling period are eligible to be included in the sample if they would otherwise have had at least one face-to-face appointment if it were not for the COVID-19 pandemic. Do not include service users who would have only ever had telephone appointments regardless of the COVID-19 pandemic**.** 1250 service users from each Trust.
Data sources	1. 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
Identifiers required for analysis purposes	1. Trust code 2. The unique identifier code (as above) 3. Year of birth 4. Postcode 5. Gender 6. Ethnic category 7. Day of last contact 8. Month of last contact 9. Year of last contact 10. CPA status 11. CCG code 12. Mental Health Care Cluster Codes 13. Mobile phone indicator 14. Email address indicator 15. 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 the management of health and social care services and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

Members agreed that the activity has a medical purpose and the public interest in capturing the experience of community mental health patients is especially strong due to service changes caused by the Covid-19 pandemic.

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 group agreed that consent is not feasible, given the potential to introduce bias, and the lack of capacity of Trust staff.

- Use of anonymised/pseudonymised data

Members were content that the use of anonymised or pseudonymised information was not practicable, given the need to distribute information to patients. The Sub-Committee also were content with the postcode being used for analysis; postcode is deleted after mapping to LSOA and local authority, as per previous CQC surveys. The CAG were content with the widening of the inclusion criteria surrounding virtual contacts.

'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 objection and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicants provided an overview of the patient notification and awareness raising mechanisms offered to Trusts. 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 9 other languages to improve accessibility. Trusts will be asked to consider the impact of Covid-19 on the visibility of posters, and to think carefully about where to place them appropriately. Trusts have also been advised to display a copy of this poster on their website for those service users who do not frequently attend the trust premises.

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 through press releases and local social media.

The CAG agreed that the patient notification materials were clear and direct, and accepted the materials provided.

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 an overview of the patient and public involvement activities which were undertaken in advance of the 2021 survey within the application. This included consultation with a survey specific Advisory Group; 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.

In addition to this,18 service users are interviewed (recruited from the general public over three rounds) to seek views and inform the survey design and process.

This is the same level of PPI as the CAG accepted for the 2020 community mental health survey, and this was once again accepted for the 2021 survey.

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. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review.
   Confirmed: The NHS Digital **2018/19** DSPT submission for **Patient Perspective, Quality Health and Picker Institute Europe** were confirmed as '**Standards Met'** by NHS Digital by check of DSPT tracker (24 November 2020). The **2019/20** DSPT submissions have not yet been reviewed by NHS Digital, but the applicant has requested that these be reviewed.

As the above conditions have been accepted and 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 **30 November 2021** 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 Digital. Please plan to contact NHS Digital 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 were:

Document	*Version*	*Date*
16/CAG/0041 Outcome letter		August 2016
17/CAG/0185 Outcome letter		23 November 2017
18/CAG/0098 Outcome letter		31 July 2018
18/CAG/0110 Outcome letter		28 August 2018
19/CAG/0206 s251 non-research fully supported outcome v2.0		25 November 2019
20/CAG/0155_P101550_CMH21 cag section 251 form non research applications_20201112		12 November 2020
CMH20_Sample Declaration Form for trusts using a contractor_V1_PROTECT		
CMH20_Sampling instructions_V1_PROTECT	V1	December 2019
CMH20_Survey Handbook_V1_PROTECT	V1	December 2019
CMH21_Data flow diagram - post codes_V2_PROTECT	V2	
CMH21_Dissent poster_V1_PROTECT	V1	
CMH21_Dissent_V3_PROTECT	V3	
CMH21_Draft Questionnaire_V1_PROTECT	V1	
CMH21_Multilanguage_sheet_V1.0_PROTECT	V1	
CMH21_Sampling flow chart_V2.0_PROTECT	V2	

Membership of the Committee

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

There were no declarations of interest in relation to this item.

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

Caroline Watchurst
Confidentiality Advisor
On behalf of Health Research Authority

Email: cag@hra.nhs.uk

Enclosures: *List of members who considered application*
Standard conditions of approval

Confidentiality Advisory Group precedent-set meeting attendance
20 November 2020

Members present:

Name	
Dr Tony Calland MBE	CAG Chair
Mr. Myer Glickman	CAG member
Mr Marc Taylor	CAG member

Also in attendance:

Name	*Position (or reason for attending)*
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

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Standard conditions of support

Support to process the specified confidential patient information without consent, given by the Secretary of State for Health and Social Care, 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 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.