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20 December 2021

Jenny King
Buxton Court,
3 West Way,
Oxford
OX2 0JB

Dear Jenny King,

Application title: **Community Mental Health 2022 Survey**
CAG reference: **21/CAG/0181**

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 precedent set CAG meeting held on 03 December 2021. The application was considered via the precedent set process under category 11. Applications made by the Picker Institute Europe to administer surveys on behalf of CQC.

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:

1. The application, to allow the disclosure of confidential patient information from mental healthcare providers to an approved survey contractor, Picker Europe,

Quality Health and Patient Perspective, for the purpose of mailing out the 2022 Community Mental Health Survey, 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 application from the Care Quality Commission set out the purpose of administering the 2022 Community Mental Health Survey, to gauge patient experience and views of the service they received.

The Community Mental Health Survey is one of the more established surveys within the NHS Patient Survey Programme (NPSP). The NPSP was initiated in 2002 by the Department of Health and is now overseen by the Care Quality Commission (CQC), the independent regulator of health and social care in England. The CQC have commissioned Picker to manage and coordinate the survey programme under the title of the Survey Coordination Centre for Existing Methods (SSCEM).

The 2022 Community Mental Health Survey will be the nineteenth mental health survey carried out to date. All 53 eligible mental health provider trusts will be asked to conduct the survey, with preparations beginning in early December 2021 and fieldwork scheduled to start from February 2022. All trusts will draw a sample of service users according to set criteria and will follow standardised materials and procedures for all stages of the survey. A copy of the survey handbook and sampling instruction manual from 2021 was provided with the application. Due to changes in care and treatment as a result of the Covid-19 pandemic, the sampling criteria for the 2021 survey was expanded to include patients who received care remotely, such as via video-conference or telephone, as well patients who received face-to-face treatment. The 2022 survey will also use this amended sampling criteria, as NHS Community Mental Health Trusts have been consulted and confirmed that changes to service provisions made during the pandemic remain in place.

In administering the survey, NHS trusts will be advised to employ the service of one of the approved contractors to reduce the cost, burden and risk in the provision of survey data. In doing so, it is expected that the risks to data quality and delay to the timetable are reduced dramatically, as evidenced throughout this application. From previous studies, the applicants anticipate that most of the participating trusts will use an approved survey contractor, either Quality Health or Patent Perspective. Trusts will submit a single file to their Approved Contractor, which will contain both mailing data, such as patients' names and addresses, and sample information, such as the year of birth, ethnicity and gender of patients. The Approved Contractor will then send the surveys out and patients' participation would proceed on a consented basis.

Trusts may opt to undertake the survey themselves. In this event, the SCCEM (Picker) will provide trusts with the sampling materials and the process to be followed. This is outside the scope of support, as participating trusts will only process confidential patient information which they have an existing legal basis to process. At no point will the SCCEM receive mailing information for the service users in the sample file, apart from service user postcode.

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 at the time of drawing the sample who received specialist care or treatment for a mental health condition, including those who received care under the Care Programme Approach. Patients may have been seen face-to-face at the trust, via video-conference, or by telephone call between 1st September and 30th November 2021 (the sampling period), and will have had at least one other contact, either before, during or after the sampling period. 1250 patients in each trust will be included.
Data sources	1. Confidential patient information provided by 53 participating community mental health provider trusts.
Identifiers required to address questionnaires to the appropriate person. It contains:	1. Trustcode 2. A standardised unique identifier code, to be constructed as survey identifier, trust code followed by a whole number (consecutive across the sample of 1250 service users from each trust), e.g. MH22XXXnnnnn where XXX is the trusts 3 digit trust code and nnnnn is the 5 digit serial number relating to sampled service users 3. Title (Mr, Mrs, Ms, etc.) 4. First name 5. Surname 6. Address Fields 7. Postcode
Identifiers required to link demographic data to the survey responses, to aid analysis and to enable checks to be carried out for any errors in how the sample was drawn	1. Trustcode 2. The unique identifier code (as above) 3. Year of birth 4. Service users full 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. The CAG agreed that the application had a medica purpose and was in the public interest.

Practicable alternatives

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

- Feasibility of consent

The applicants noted a commitment to considering other ways in which surveys can be run. They have explored the feasibility of trusts seeking consent from patients, however there are three main arguments for not seeking consent. The first is that trusts would be required to arrange their own mailings to patients, which would remove the benefit of using a specialist contractor. Secondly, there was a risk of introducing bias should the survey moved from on opt-out system to an opt-in system. The third reason is to avoid placing additional burden on staff within the trusts. The CAG noted this information and raised no queries.

- Use of anonymised/pseudonymised data

The approved contractors require access to confidential patient information supplied by participating trusts in order to send the questionnaire to the sample. The CAG noted this information and raised no queries.

'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.

Trusts will be advised to display Dissent postersin their site locations to inform possible service users that they may be sent a questionnaire. As not all service users are receiving face-to-face appointments, due to the Covid-19 pandemic, the posters will also be hosted on websites of participating trusts.

Trusts will be asked to include email, telephone and postal contact details for patients to dissent. Trusts are required to keep a record of this so these service users can be removed from the eligible population from which the sample of 1250 service users would be drawn. The dissent posters are to be displayed for the full sample period and have been made available in English and the 9 other languages most commonly spoken in England. Trusts have already been informed to display these posters and they are publicly available on the NHS Surveys website.

Trusts will be required to keep a record of objections and dissent. The method in which they do this is at the discretion of the trust.

The applicants advised that the majority of trusts use a flag on the electronic records systems and have a data field specifically about whether the service user is happy for their contact details to be used for any other purpose than clinical care.

Other trusts will keep a separate record which is cross referenced against the eligible population before the final sample file is drawn. This method is a long-standing approach adopted for the Community Mental Health Survey and the applicants are not aware of any incidences where this process has not been managed successfully by trusts. The CAG noted this information and raised no queries.

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 methodology for the survey is broadly similar to that which has been used since the national NHS patient survey programme was established by the Department of Health in 2002, and is based on best research practice and evidence accrued during the course of the programme to date. The questionnaire was substantially redeveloped for 2014 in order to reflect changes in policy, best practice and patterns of service use.

Trusts were consulted in 2021 via an online survey for their feedback on how the COVID-19 pandemic had affected their service provision and what changes had been implemented locally in response to the pandemic (including an estimation of how long those service provision changes were likely to be in place for).

The questionnaire is currently being designed. While it is not anticipated that significant changes will be made to the questionnaire, to allow for historical comparability, but it is likely that some of the current items will be modified to better reflect current policy and service provision. Some items may be removed and new items added following review of feedback from stakeholders. Possible changes will include new items on whether an agreement was made with a service user regarding changes to the delivery method of their care, the nature of the agreement (the mode by which care and treatment was to be delivered) and whether care and treatment was delivered in line with that agreement. This is in response to national changes of service delivery provision. A new item is also being considered regarding crisis care and the time taken for a service user to make contact with a crisis care service. This question has been included due to increased pressure on crisis care services in light of the pandemic and gaining an understanding of how accessible crisis care currently is for service users. Additionally, some question items may be reworded slightly to improve comprehension and data quality.

The applicants will also interview 18 service users, recruited from the general public over three rounds, who will review the questionnaires to assess whether the aims of the study will be met and to check that it is sensible and applicable to service users. Three rounds of interviews are done and at the end of each round the feedback is reviewed with the CQC, changes made and another round of interviews carried out. The CAG noted this information and raised no queries.

Exit strategy

The participation of those who respond to the survey will proceed on a consented basis. The CAG noted this information and raised no queries.

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. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   The NHS Digital **2020/21** DSPT reviews for **Patient Perspective, Quality Health (IQVIA Group) and Picker Europe** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 December 2021).

As the above conditions have been 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 **20 December 2022** 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 are as follows.

Document	*Version*	*Date*
CAG application from (signed/authorised) [20211116 CMH22 cag section 251 form non research applications_v5]		
Other [CMH21_Sampling instructions_V1.0_PROTECT]	1.0	
Other [CMH21 Survey handbook_V1.0_PROTECT]	1.0	
Other [CMH22_Multilanguage sheet_V1.0_PROTECT]	1.0	
Other [18.CAG.0098]		
Other [17.CAG.0185]		
Other [16.CAG.0041]		
Other [18.CAG.0110]		
Other [CMH21_Main Questionnaire_V1.0_PROTECT]	1.0	
Other [CMH22_Sampling flow chart_V1_PROTECT]	1	
Other [CMH22_Dissent_V1.0_PROTECT]	1.0	
Other [CMH21_Sample Declaration Form for trusts using a contractor_V1.0_PROTECT]	1.0	
Other [CMH22_Data flow diagram - post codes_V1.0_PROTECT]	1.0	
Patient Information Materials [CMH22_Dissent poster_v1.0_PROTECT]	1.0	

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

Kathleen Cassidy
Confidentiality Advisor

On behalf of the Secretary of State for Health and Social Care

Email: cag@hra.nhs.uk

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

Confidentiality Advisory Group precedent-set meeting attendance
03 December 2021

Members present:

Name	
Dr Patrick Coyle	CAG vice-chair
Mr David Evans	CAG member
Mr Tony Kane	CAG member
Dr Harvey Marcovitch	CAG member
Ms Diana Robbins	CAG member

Also in attendance:

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

Health Research Authority

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 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.