Health Research Authority

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28 August 2020

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

Dear Ms King

Application title: **2020 Urgent and Emergency Care Survey**
CAG reference: **20/CAG/0093**

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 14 August 2020. 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 participating Trusts to the approved survey contractors, who will then send postal questionnaires to patients, is fully supported, subject to compliance with the standard and specific conditions of support.

Context

Purpose of application

This application from the Care Quality Commission set out the purpose of conducting a national survey of patients aged 16 years and over who attended a Type 1 emergency department in September 2020 or a Type 3 urgent care department in September 2020.

The NHS Patient Survey Programme (NPSP) was initiated in 2002 by the Department of Health and Social Care and is now overseen by the Care Quality Commission (CQC), the independent regulator of health and social care in England. The CQC have commissioned the Survey Coordination Centre for Existing Methods (SCCEM) at Picker to manage and coordinate the survey programme under the title of the SCCEM. The 2020 Urgent and Emergency Care Survey will be the eighth carried out to date. All eligible trusts will be asked to conduct the survey with preparations expected to begin in September 2020 and fieldwork expected to start from November 2020. All trusts will draw a sample of patients according to set criteria, and follow standardised materials and procedures for all stages of the survey. An overview of the survey methodology, and a copy of the Survey Handbook and Sampling Instructions from 2018, were provided with the application.

The methodology for the 2020 survey is unchanged from the 2018 survey. Two separate questionnaires will be created; one for patients attending a Type 1 department and another for patients attending Type 3. For trusts with only Type 1 departments, the sample size will remain at 1250. Trusts who have both departments will have a sample size of 950 for Type 1 and 420 for Type 3. 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. As in 2018, and across all surveys in the NPSP, NHS Trusts will submit a sampling checklist and declaration for trust Caldicott Guardians to sign, to minimise the likelihood of complete mailing details being sent to the SCCEM in error. The sampling checklist and declaration should be completed by the trust prior to sending the combined mailing and sample file to the approved contractor, and then by the approved contractor when sending the sample data only. The complete mailing data will be removed, except for the full postcode, which will be sent to the SCCEM as part of the sample file. Both the approved contractors and the SCCEM will not open a sample file until a satisfactory sample declaration form has been received. The end product from this survey will be a set of aggregate statistical data that does not contain patient identifiable information. The statistical data outputs will be provided at both national and at trust level. This statistical dataset is used for a wide variety of purposes, with the ultimate aim of supporting the improvement of patient experience in England.

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	People aged 16 and over who attended a Type 1 emergency department in September 2020 or a Type 3 urgent care department in September 2020. The applicants anticipate that

	127 trusts will be involved. Trusts will be instructed to contact the SCCEM if they are unable to draw the required sample size from their Type 3 department in which case they will be instructed to also sample back to August 2020. The Sampling Instructions will ask trusts to exclude: - deceased patients - children or young persons aged under 16 years at the date of their attendance at the emergency department - any patients who are known to be current inpatients - planned attendances at outpatient clinics which are run within the Emergency Department (such as fracture clinics) - patients without a UK postal address - patients attending primarily to obtain contraception (e.g. the morning after pill), patients who suffered a miscarriage or another form of abortive pregnancy outcome whilst at the hospital, and patients with a concealed pregnancy* - any patient known to have requested their details are not used for any purpose other than their clinical care - any patients who were admitted to hospital via Medical or Surgical Admissions Units and therefore have not visited the emergency department - Any attendances at Walk-in Centre's - Any attendances at Type 3 departments not wholly managed by the sampling trust.
Data sources	1. Electronic patient records held at the 127 participating trusts
Identifiers required for linkage purposes	Administration of the 2020 Urgent and Emergency Care Survey requires NHS trusts to share two distinct sets of information with their approved contractor: 1. The **mailing file** is used to address questionnaires to the appropriate person. It contains: ▪ A standardised unique identifier code, to be constructed as survey identifier, trust code followed by a whole number (consecutive across the sample of patients from each trust), e.g. UEC20XXXNNNN where XXX is the trusts 3 digit trust code and NNNN is the 4 digit serial number relating to sampled patients. ▪ Title (Mr, Mrs, Ms, etc.) ▪ First name ▪ Surname ▪ Address Fields ▪ Full Postcode

Identifiers required for analysis purposes	1. The **sample file** is used 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. This file contains: ▪ The unique identifier code (as above) ▪ NHS Trust code ▪ Date and time of attendance ▪ NHS Site code ▪ Department type (Type 1 or Type 3) ▪ Ethnicity ▪ Gender ▪ Year of birth ▪ CCG code ▪ Patients full postcode ▪ Mobile phone indicator

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 proposed activity had a medical purpose and was within 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 applicant explained that there are three central arguments why seeking consent for this survey would not be practicable. Firstly, it would remove the benefits of the trust employing a specialist contractor as it would first require them to arrange their own mailing to patients. Second, there was a risk of introducing a systematic and damaging bias in response rates by changing the nature of the survey from an opt-out system to an opt-in system. Trusts, CQC, the Department of Health and Social Care and NHS England and Improvement, need accurate measurements in order to assess the quality and impact of their services and policies, and act upon the results to improve the experience of patients. Changing the nature of the survey would invalidate the main published statistical series arising from these surveys and impact on the reliability of the baseline used to monitor the NHS Outcomes Framework indicator for the survey. Whilst analysing the survey, unreliable data would lead people to conclude that they could not say whether a policy or initiative was working; or worse, to stop those which were working because the data were inaccurate and did not demonstrate the improvement. Thirdly, given the often extremely busy nature of hospitals and the volume of patients it

could be viewed as an unrealistic burden on staff to seek prior consent for this survey. The CAG noted the information given and raised no queries.

- Use of anonymised/pseudonymised data

The applicants advised that the approved survey contractors required confidential patient information in order to send questionnaires to selected patients. The CAG noted the information given 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 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.

Trusts will be required to display dissent posters in their site locations to inform service users that they may be sent a questionnaire. Contact details for the trust will be included on the posters so service users can indicate dissent. The trust is required to keep a record of this so these service users can be removed from the eligible population of patients attending A&E or Urgent Treatment Centre in September 2020 (including August for some trusts). The dissent posters are to be displayed for the full sample period (August and September 2020) and have been made available in English and 9 other languages (most commonly spoken in England). Trusts will be informed in July 2020 to display these posters and will be made publicly available on the NHS Surveys website.

Trusts will be required to keep a record of objections and dissent. However, the method in which they do this is at the discretion of the trust. The applicants noted 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 Urgent and Emergency Care Survey and this process has previously been successfully managed by trusts. The CAG accepted the information given.

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 explained that the methodology used in the 2020 survey is broadly similar to that used since the NHS Patient Survey Programme was established in 2002. The first Emergency Department survey was developed in 2003. Consultations with relevant policy stakeholders and patient involvement was undertaken when designing the questionnaire. Where possible, questions are kept the same to facilitate year-on-year comparisons. However, the questionnaire content is reviewed before each survey to consider if any questions are not working and if new questions are needed to ensure the questionnaire is up to date and in line with current policy and practice. Questionnaire

development work began in March 2020 to determine what changes were needed to questionnaire content, across both Type 1 and Type 3 questionnaires. The finalised questionnaire was expected to be ready in August 2020. The CAG accepted the information given.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Secretary of State, 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: Patient Perspective Ltd (by check of the NHS Digital DSPT tracker on 25 August 2020), Picker Institute Europe (by NHS Digital email dated 17 July 2019) and Quality Health Ltd (by NHS Digital email dated 23 July 2019) have confirmed 'Standards Met' grade on DSPT 2018/19).**

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

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 **28 August 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 are as follows.

Document	*Version*	*Date*
CAG application from (signed/authorised) [20.CAG.0093_P101362_UEC20 Section 251 form non research applications V3]	3	
Other [ED18_Survey handbook_V1.0_PROTECT]	1.0	
Other [ED18_Survey instructions_V1.0_PROTECT]	1.0	
Other [UEC20_Data flow diagram - post codes_V1_PROTECT]	1.0	
Other [UEC20_GDPR Model service contract_V1_PROTECT]	1.0	
Other [16.CAG.0041]		
Other [UEC20 Sampling flowchart V1 PROTECT]	1.0	
Patient Information Materials [UEC20_Type 1 dissent	1.0	

poster_V1.0_PROTECT]		
Patient Information Materials [UEC20_Type 3 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.

User Feedback

The Health Research Authority is continually striving to provide a high-quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R & D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

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: HRA.CAG@nhs.net

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

Confidentiality Advisory Group precedent-set meeting attendance
14 August 2020

Members present:

Name	
Ms Sophie Brannan	CAG member
Dr Patrick Coyle	CAG vice-chair
Professor Barry Evans	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 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.