Health Research Authority

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15 March 2019

Ms Jenny King
Chief Research Officer
Picker Institute Europe
Buxton Court
3 West Way
Oxford
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Dear Ms King

Application title: **Maternity Survey 2019**
CAG reference: **19/CAG/0021**

Thank you for your service evaluation application, submitted for approval under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process confidential patient information without consent. Approved applications enable the data controller to provide specified information to the applicant for the purposes of the relevant activity, without being in breach of the common law duty of confidentiality, although other relevant legislative provisions will still be applicable.

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 (SofS) for Health and Social Care on whether an application should be supported, and if so, any relevant conditions. This application was considered at the precedent set CAG meeting held on 22 February 2019. 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 the CQC.

Secretary of State for Health and Social Care Support decision

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

1. The application to allow the disclosure of specified confidential patient information from participating Trusts to the approved contractor in order to facilitate the distribution of the 2019 Maternity Survey is fully supported, subject to compliance with the standard and specific conditions of approval.

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 Picker Institute Europe, CQC and NHS England on behalf of all acute Trusts running eligible maternity services, set out the purpose of service evaluation which will be achieved through a patient survey in order to build up a national picture of women's experiences of maternity care. This will be the seventh maternity survey carried out to date and forms part of the NHS Patient Survey Programme. Preparations for the survey will begin in March 2019, with fieldwork expected to commence from the end of April 2019.

Support under the Regulations is sought for the transfer of confidential patient information from participating Trusts to the survey coordination centre to enable the facilitation of the survey invitation process. The survey methodology remains unchanged from that which was supported by the CAG for the 2018 survey; however, some additional variables will be included in the data extract disclosed by Trusts to the coordination centre, including complete patient postcode, to be used for deprivation scoring. 129 Trusts are expected to participate and will be asked to draw a patient sample according to set criteria and use standardised materials and procedures for all stages of the survey.

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

Confidential patient information requested

Cohort

Patients who had a live birth in January or February 2019 and were aged 16 years or over at the time of delivery. Trusts are instructed to sample all eligible service users in February 2019. If this is fewer than 300 records they are asked to sample back from the last date in January to the beginning of January until they reach 350 records (in order to achieve a sample of 300 post-DBS checks). Trusts that do not have 300 eligible service users across February and January combined have the choice whether to participate in the survey. Specific exclusion criteria have been established which will be applied by the Trust prior to drawing the patient sample.

Administration of the Maternity Survey requires NHS Trusts to share two distinct sets of information with their approved contractor:

1. A **mailing file** which is used to address questionnaires to the appropriate person. It contains:

- A unique identifier,
- Title,
- First name,
- Surname,
- Address Fields,
- Full postcode.

2. A **sample file** which 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. It will also be used to enable the identification of service users who received antenatal and postnatal care directly from the trust. This file contains:

- The unique identifier code (as above),
- Sex,
- Mother's year of birth,
- Mother's ethnic group,
- Delivery date (DD/MM/YY),
- Time of delivery (for multiple births, this will be the time that the last baby is born),
- Number of babies born at delivery,
- Place of birth: NHS site code,
- Actual delivery place,
- CCG code,
- Mother's full postcode.

3. An **attribution file** which includes the sample file fields above and additional information relating to the provision of antenatal care or postnatal community care as follows:

- Antenatal provider information,
- Postnatal provider information,
- Postcode sectors to which the Trust provides maternity services (ONLY if using the postcode method to complete the antenatal and postnatal provider information).

For clarity, please note that the Survey Coordination Centre does **not** receive any names or full addresses.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was the management of health and social care services. It was recognised that the ongoing evaluation of patient care via the NHS Patient Survey Programme was within the public interest.

Practicable alternatives

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

- Feasibility of consent

The applicant cited three central arguments to support why consent is not feasible for the survey process. Firstly, operation of a consent-based process would remove the benefits of the Trusts being able to employ a specialist contractor to facilitate the survey process as it would require them to arrange their own mailing to patients. Operation of a consent-based process would introduce a systematic bias in response rates by changing the nature of the survey from an opt-out system to an opt-in system. It was further noted that introducing a prior consent process for the survey would put an unrealistic burden on

busy clinical staff. The Sub-Committee recognised that this rationale had previously accepted for the survey programme and remained valid for the proposed application. No queries were raised in this area.

- Use of anonymised/pseudonymised data

Access to confidential patient information was required to facilitate the survey programme.

Justification of identifiers

The CAG was assured that the items of confidential patient information requested were appropriate and proportionate to achieving the proposed activity. Members noted that this application had requested the inclusion of complete postcode to facilitate deprivation analysis.

Whilst it was recognised that applicants were ordinarily asked to reduce the identifiability of datasets, the applicants had requested access to complete postcode for analysis purposes. The Sub-Committee was assured by the applicant's rationale in this area around small pockets of deprivation which would be overlooked with this level of granularity and were content to provide support to the additional item of confidential patient information.

The applicant had also requested access to gender as part of the sample information, to ensure that the sampling approach was not systematically excluding individuals, such as those who self-identify as transgender. The Group was assured by the rationale provided to support this additional patient identifier, and was content to provide a recommendation of support on this basis.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. Confidential patient information is required for a time-limited basis only to facilitate the survey distribution and analysis processes. This would be retained for a maximum of 12 months following which this would be destroyed. The CAG was assured by the exit strategy described and raised no concerns in this area.

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 an unconsented activity should go ahead. The applicant explained that, in the development phase for the 2019 iteration of the survey, they had undertaken a consultation where interviews were held with Expert stakeholders (such as organisational bodies, policy makers, Public Health England and women's interest groups such as Maternity Action) and with recent mothers (babies who have been born in the last 12 months). This development work enabled the feedback of data end users and maternity service users themselves to contribute to the overall content of the questionnaire to ensure that it was fit for best and best matched the experience of women who have recently used the services. Members were assured that the activity undertaken in this area was appropriate and proportionate. No further follow-up was requested.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending 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 the Data Protection Act 2018. The applicant provided standardised information leaflets and posters which participating Trusts would be required to display. It was clarified that these documents would also be translated into the ten most commonly spoken languages to be displayed alongside the English text. Members agreed that the documentation provided clear information around the survey and offered a means of patient objection. No issues were raised in this area.

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 for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support (Final)

1. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed - Picker Institute Europe, Quality Health and Patient Perspective – all have a published satisfactory reviewed grade on V14.1, 2017/18**).

As the above conditions have been 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 your approval is subject to submission of an annual review report to show how you have met the conditions or report plans, and action towards meeting them. It is also your responsibility to submit this report on the anniversary of your final approval and to report any changes such as to the purpose or design of the proposed activity, or to security and confidentiality arrangements. An annual review should be provided no later than **15 March 2020** and preferably 4 weeks before this date. If at any stage you no longer require support under the Regulations as you will cease processing confidential patient information without consent you should inform the Confidentiality Advice Team of this in writing as soon as possible.

Reviewed documents

The documents reviewed at the meeting were:

Document	*Version*	*Date*
CAG application from (signed/authorised)		20 December 2018
Other [Sampling Instructions]	1.0	23 March 2018
Other [Sampling Flowchart]	1.0	
Other [Briefing for trusts on informing 16 and 17 year olds]	1.0	

Other [Survey Handbook]	1.0	26 February 2018
Other [Supplementary GDPR information]	1.0	19 February 2019
Other [Questionnaire]	1.0	
Patient Information Materials [Poster]	1.0	20 December 2018
Patient Information Materials [Leaflet]	1.0	20 December 2018

Membership of the Committee

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

There were no declarations of interest in this item.

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/

Yours sincerely

Miss Kathryn Murray
Senior Confidentiality Advisor

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

Email: HRA.CAG@nhs.net

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

Confidentiality Advisory Group Sub-Committee Meeting 22 February 2019

Group Members:

Name	*Present*	*Notes*
Dr Martin Andrew	Yes	
Dr Tony Calland MBE	Yes	Chair
Dr Liliane Field	Yes	
Mr. Anthony Kane	Yes	Lay Member

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Standard conditions of support

Support to process confidential patient information without consent, given by the Secretary of State for Health and Social Care, is subject to the following standard conditions of support.

The applicant and those processing the information 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.

6. Activities remain consistent 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.

Standard conditions of approval

The approval provided by the Secretary of State for Health is subject to the following standard conditions.

The applicant will ensure that:

1. The specified patient identifiable 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.

4. All staff with access to patient identifiable information have contractual obligations of confidentiality, enforceable through disciplinary procedures.

5. All staff with access to patient identifiable information have received appropriate ongoing training to ensure they are aware of their responsibilities.

6. Activities are consistent with the Data Protection Act 1998.

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. The Confidentiality Advice Team is notified of any significant changes (purpose, data flows, data items, security arrangements) prior to the change occurring.

10. An annual report is provided no later than 12 months from the date of your final confirmation letter.

11. Any breaches of confidentiality / security around this particular flow of data should be reported to CAG within 10 working days, along with remedial actions taken / to be taken.