Health Research Authority

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6 February 2017

Mr Chris Graham
Picker Institute Europe
Buxton Court
3 West Way
Oxford
OX2 0JB

Dear Mr Graham

Application title: **CQC Maternity Survey**
CAG reference: **17/CAG/0027**

Thank you for your audit application, submitted for approval under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process patient identifiable 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 on whether an application should be approved, and if so, any relevant conditions. This application was considered at the Sub-Committee of the CAG meeting held on 20 January 2017.

Secretary of State approval decision

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

1. The application is approved, subject to compliance with the standard and specific conditions of approval outlined below.

   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, submitted by the Picker Institute Europe, CQC and NHS England on behalf of all acute trusts running eligible maternity services, set out the purpose of carrying out surveys in order to build up a national picture of women's experiences of maternity care.

The information would be shared with individual trusts to use for local improvement planning and share with commissioners, used by the CQC to enable them to assess trusts in England, published on the CQC website so that trusts could compare themselves, and findings for England would be incorporated into the 2017 State of Care report.

Trusts would provide names and full addresses of women who gave birth at the Trust in January or February 2017 to the contractor to enable them to mail out questionnaires. The questionnaires would be returned voluntarily to the contractor for collation, checking and review before being transferred to the Coordination Centre.

This methodology was the same as for previous CQC surveys and had been supported by CAG.

In addition, there was a new aspect for this specific survey due to variations in the location where women received antenatal, birth and postnatal care – these three stages of care were not always provided at the same Trust. Information from trusts concerned women who had given birth at the Trust. The Co-ordination Centre would receive additional information from trusts to enable them to flag women who had received antenatal and/or postnatal care at the same Trust.

A recommendation for class 5 and 6 support was requested for auditing, monitoring and analysing patient care and treatment and to allow access to an authorised user for one or more of the above purposes.

Confidential patient information requested

Access was requested to name and postcode for the mailing of questionnaires.

The sample file containing: unique identifier code, mother's year of birth, mother's ethnic group, day of delivery, month of delivery, year of delivery, actual delivery place, place of birth, NHS site code, CCG code, Postcode sector (optional), and Trust-held provider information (optional).

This information would be 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.

Confidentiality Advisory Group advice

Public interest

The CAG was convinced that there was a public interest in this evaluation of the care pathway and agreed with the more detailed arguments presented later, that it was also in the public interest for additional information to be provided to the Coordination centre to identify where ante-natal and post-natal care were received. This would allow for the entire care pathway to be evaluated.

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 CAG accepted the arguments that seeking consent could also introduce bias and result in the survey producing inaccurate data.

It was also accepted that it would be unrealistic and unfeasible to ask staff to seek consent for each patient during labour and birth. Seeking consent would also remove the benefit to the Trust of employing a specialist contractor, as it would first require them to arrange their own mailing to patients.

- Use of anonymised/pseudonymised data

Members were satisfied that the datasets included a minimum of identifiers. The use of MES services was accepted, as was the analysis of free text comments.

Justification of identifiers

Members noted that the survey methodology was the same as that previously approved by the CAG, with one additional proposal which was to add information to the sample file in order to establish if a woman also received antenatal and postnatal care from the same trust at which she gave birth. It was clarified that the co-ordination centre would receive either two trinary variables (0/1/2) indicating none/some/all of a patient's ante/post-natal care was received at the same trust, or would receive postcode sector. (The latter was less likely but needed to be included in case of delay in updating electronic records).

Members agreed that this was necessary in order to analyse the entire care pathway, and was in the public interest.

Additional points

The CAG discussed patient notification and opt outs. It was agreed that the general explanation of the use of data in the patient notifications was adequate for the purpose, and that opt outs were explained. The cover letter also gave a clear process for patients to follow if they did not wish to take part in the survey.

There was a distinction between sharing the patient's name and address for a mail-out and including the patient's postcode in the sample file so that the coordination centre could flag whether a patient had received ante/post-natal care at the Trust. While it was agreed that this could not be explained in the limited space of patient notification, Members felt that it would be helpful to provide a more detailed explanation on the CQC website for patients interested to know more.

Following on from this, it was agreed that a public involvement exercise should also provide the opportunity to explain this process to patients and gauge their opinions. The CAG therefore recommended that this was explored in the future. It was agreed that this would be given as a recommendation for future applications, rather than a condition of support for the current survey.

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.

Recommendations

1. The CAG recommends that a fuller explanation of the distinction between sharing the patient's name and address for a mail-out, and including the patient's postcode in the sample file so that the coordination centre could flag whether a patient had received ante/post-natal care at the Trust, is provided on the CQC website. This is a recommendation only and support is not conditional on this point.
2. The above explanation can also be given to patients during public involvement work, to enable public and patient opinion on the matter to be gauged. This is a recommendation only; the CAG requests that you take this into consideration for future applications. Support is not conditional on this point.

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 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 February 2018 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) [CAG Form]		13 January 2017
GP/consultant information sheets or letters [First Reminder Letter]	1	
GP/consultant information sheets or letters [Second Reminder Letter]	1	
GP/consultant information sheets or letters [First Mailing Letter]	1	
Patient Information Materials [leaflet]	1	
Patient Information Materials [poster]	1	

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.

Yours sincerely

Rachel Heron
Confidentiality Advisor

Email: HRA.CAG@nhs.net

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

Confidentiality Advisory Group sub-committee meeting 20 January 2017

Group Members:

Name	*Profession*	*Present*	*Notes*
Ms Sophie Brannan		Yes	
Dr Patrick Coyle		Yes	
Ms Clare Sanderson		Yes	

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.