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15 June 2016

Hannah Knight
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Dear Ms Knight

Application title: **National Maternity and Perinatal Audit**
CAG reference: **16/CAG/0058**

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 CAG meeting held on 26 May 2016.

Secretary of State for Health 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 is approved, subject to compliance with the standard and specific conditions of approval.

Context

Purpose of application

This application from the Royal College of Obstetricians and Gynaecologists set out the purpose of delivering a new Healthcare Quality Improvement Partnership (HQIP)-commissioned national, prospective, clinical audit of maternity services in England,

Scotland and Wales, in order to improve the quality of services and the outcomes achieved for mothers and newborns.

The commissioned audit programme consists of three phases of work:

1. An 'organisational survey' to collect provider-level information on service delivery and the organisation of maternity care, which will contribute to a better understanding of the care provided to pregnant women.
2. A continuous prospective clinical audit that produces information for maternity units to monitor patterns of care and maternal and perinatal outcomes.
3. A series of in-depth topic-specific, time-limited audits ('sprint audits'), predominantly focusing on specific types of maternal and neonatal outcomes.

Most maternity units in the UK already use electronic maternity information systems (MIS) to capture demographic and clinical information related to each pregnancy and delivery under their care. These databases cover antenatal booking through to postnatal care. Although each MIS collects slightly different information, there is sufficient similarity between MISs to allow a minimum dataset to be developed.

In order to collect data covering a four-year period, for the first extract the applicants will request delivery data for the two previous financial years. Data on deliveries occurring between April 2014 and March 2016 will be requested in 2016, with refreshed data extract for the 2016-17 and 2017-18 periods requested in 2017 and 2018 respectively.

The data collected from English MIS systems will be linked to Hospital Episode Statistics (HES) maternity data from 2017, pending approval from the Health and Social Care Information Centre (HSCIC) Data Linkage and Extract Service. The HES data will in turn be linked to the Office for National Statistics (ONS) birth and death register. These linkages will be repeated annually and will enable the applicants to calculate case ascertainment for English births, and to examine additional processes and outcomes of maternity and perinatal care, including maternal and neonatal hospital readmission. A similar linkage exercise is planned for the data collected from Welsh MIS systems using the Patient Episode Database for Wales (PEDW), pending approval from the Welsh Information Services Division.

Additional data linkages are planned as part of a series of topic specific 'sprint audits'. The linked MIS-HES/PEDW-ONS data will be further linked with data from the Intensive Care National Audit and Research Centre (ICNARC), the RCPCH's National Neonatal Audit Programme (NNAP) and Public Health England's surveillance systems (SCSS and LabBase2) to investigate maternal and neonatal intensive care admissions and blood-stream infections, respectively. This information will be released in a link anonymised format.

A recommendation for class 1, 4, 5, and 6 support was requested to cover disclosure of confidential patient information from English & Welsh NHS trusts to the Royal College of Obstetricians and Gynaecologists, in order to link this data with data contained in other national databases.

<u>Confidential patient information requested</u>

Access was requested to the following identifiers:

- Baby's date of birth
- Baby's time of birth
- Mother's postcode
- Mother's date of birth
- Mother's NHS number

- Baby's NHS number

Identifiers used for risk adjustment during data analysis:
- Mother's Ethnicity
- Mother's socioeconomic status (Index of multiple deprivation (IMD) category)

Confidentiality Advisory Group advice

Public interest

Members agreed that studies of this type were potentially in 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 group was content that it would be unfeasible to seek consent from such a large group, especially for the retrospective component of this cohort.

- Use of anonymised/pseudonymised data

Members were content that identifiable data was required to perform the linkages for this study.

Justification of identifiers

The members concluded that the access to the identifiers requested was necessary and appropriate to achieve the purposes.

Exit strategy

The group noted that the contract period of the audit will be 1 June 2016 to 31 May 2019 with the possibility of a further 2 year extension.

Patient notification and objection

The members agreed that the opt-out mechanism should be reviewed in the first annual review to the committee. They recommended that the applicant seek patient and public views on how easily information on opt-out can be accessed and as to whether other mechanisms for opting-out (e-mail or telephone, for example) should be included.

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. Provision, in first annual review, of an update on the mechanisms for opting-out of the study which have been adopted as a result of patient and public engagement, as above.
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Confirmed (version 13) 01 June 16**

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 15 June 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		15/04/16
16CAG0058 assessment form		
16CAG0058 advice form FINAL		06/05/16
NMPA Data Flow Diagram FINAL		
Appendix 1 MIS Data Items		
NMPA - HQIP supporting letter		14/04/16
Patient Information Materials	V1	12/04/16

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.

Professor Kurinczuk and Dr Harron expressed conflicts of interest and did not participate in the discussion. Dr Marcovitch knew the Caldicott Guardian; this was agreed not to be a conflict.

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

On behalf of the Secretary of State for Health

Christopher Ward
Senior Confidentiality Advisor
Email: HRA.CAG@nhs.net

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

Copy to David McKinlay david.mckinlay@hqip.org.uk

Confidentiality Advisory Group meeting 26 May 2016

Group Members:

Name	*Present*
Dr Mark Taylor	Yes
Dr Tony Calland	Yes
Dr Kambiz Boomla	Yes
Professor Jennifer Kurinczuk	Yes
Dr William Bernal	Yes
Mr Andrew Melville	Yes
Mr David Smallacombe	Yes
Dr Harvey Marcovitch	Yes
Ms Ellen Lim	Yes
Dr Katie Harron	Yes

NHS
Health Research Authority

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.