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21 December 2022

Rachel Winch, National Neonatal Audit Programme Manager
Royal College of Paediatrics and Child Health
5-11 Theobalds Road
London
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Dear Ms Winch,

Application title: **National Neonatal Audit Programme (NNAP) data flow**
CAG reference: **21/CAG/0007**

Thank you for submitting a deferral request to applying the National Data Opt-Out (NDO) in relation to the non-research activity reference 21/CAG/0007.

The National Data Opt-Out (NDO) enables patients to opt-out from the use of their confidential patient information for research and planning purposes where the data flows rely upon Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002.

It is a standard condition of support under Regulation 5 of the COPI Regulations 2002 that patient wishes are respected. In line with the National Data Opt-Out Operational Policy Guidance document (v4.0), the Confidentiality Advisory Group (CAG) may exceptionally advise the decision-maker that the NDO should not apply to a specific data flow supported under Regulation 5 of the COPI Regulations 2002. This item was considered on 08 December 2022.

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 request to defer applying the National Data Opt-Out in relation to 21/CAG/0007 is conditionally supported, subject to compliance with the specific conditions of support.

Please note that the National Data Opt-Out should now not be applied to the confidential patient information used without consent under this application reference.

Scope of NDO deferral request

The National Neonatal Audit Programme (NNAP) was established in 2006. IT was originally commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP) and operated under CAG reference ECC 8-05(f)/2010. In 2021, NNAP was given support under 21/CAG/0007.

The Audit Programme assesses whether babies admitted to neonatal units in England and Wales receive consistent high-quality care and to identify areas for service and quality improvement in relation to the delivery and outcomes of neonatal care. Participating neonatal units input confidential patient information for all babies admitted to NHS neonatal units in England and Wales associated with a delivery unit into the BadgerNet system. Data extracted for the audit is held in the dedicated NNAP SQL Server Dataset within the Clevermed Microsoft Azure environment. A pseudonymised version of the NNAP is held within the Royal College of Paediatrics and Child Health (RCPCH) Azure environment and it is this pseudonymised version of the data that the NNAP project team use.

Confidentiality Advisory Group advice

1. <u>Deferral rationale: patient safety</u>

The applicants had advised that the data loss from even a small number of patients would negatively impact on the ability of the audit to monitor the quality of care and patient safety. The reporting of uncommon, serious complications or prematurity or important interventions given to a small number of babies at each unit would also be negatively affected.

Women of child-bearing age are more likely to register with the National Data Opt-Out. Take up of the National Data Opt-Out also varied widely across ethic groups and geographical areas. The variations in application of the National Data Opt-Out would impact on the usefulness of the NNAP in identifying poorly performing units and in assessing the quality of the care provided. The CAG recognised the potential impact on patient safety.

2. <u>Deferral rationale: Introduction of bias</u>

The applicants noted that applying the National Data Opt-Out may introduce bias. Application of the National Data Opt-Out is not random, shown by the variation in opt-out rates within the NNAP dataset by neonatal unit, neonatal network and by mother’s ethnicity. Introduction of bias may adversely impact the ability of assess care equity and undermine the integrity of the risk adjustment procedures relating to issues such as ethnicity and deprivation.

3. <u>Local Opt-Out, Notification Strategy and Materials</u>

Should the deferral be granted, patients would still be able to opt-out via the existing NNAP opt-out mechanism. A project-specific opt-out mechanism exists within BadgerNet. Parents can approach neonatal unit staff and request that their child’s data is opted-out of NNAP data collection.

The applicants provided the draft Privacy Notice, which will be used should the National Data Opt-Out be deferred. A Dissemination and Engagement Plan was also provided. As well as the updated Privacy Notice, a short description of the National Data Opt-Out deferral will be highlighted on the landing page of the NNAP website. More detailed information would be available on the further webpage. A patient and parent guide to the audit is also available on the RCPCH website.

The applicants will also work with relevant clinical teams to ensure that they understand by the deferral has been given and discuss how best to communicate this with parents and carers. The BadgerNet provider, Clevermed ltd, will also be included in discussions about how to disseminate information about the National Data Opt-Out deferral. The NNAP project team will also work with colleagues within the RCPCH Media and Public Affairs team to brief charity partners and other stakeholders.

The CAG noted the plans for notifying the public that the National Data Opt-Out would not be applied. Members agreed that the patient notification materials required revision as the information given was very detailed and complex. The CAG suggested that a layered approach was implemented, where simplified, easy-read versions of the material were available, with more detailed information to be provided on request.

Patients wishing to opt-out were advised to speak to the nursing staff at the unit. Dr Sam Oddie, the NNAP Clinical Lead, advised that this had been decided on as the local opt-out needed to be applied at trust level and it was thought that nursing staff would be less intimidating to approach than the doctors.

The CAG noted this explanation. Members asked that telephone and email contact details were provided, should parents wish to register an opt-out after their child had left the unit.

4. Patient and public involvement and engagement

The NNAP Methodology and Dataset Group and Project Boards, which include parent representatives and the parent representative charity, Bliss, have requested that the NNAP project team submit an application to the CAG seeking an exemption from the National Data Opt-Out.

The NNAP and Bliss held a joint online focus group in early November to discuss the National Data Opt-Out deferral. 14 people took part, including current and immediate past NNAP parent representatives, members of the Bliss Insight and Involvement Group, members of parent advisory groups (PAGs) within neonatal networks in England and representatives of the Sands and Best Beginnings charities. The majority of attendees were parents of babies who had required neonatal care, but also adults who themselves had received neonatal care as babies. The applicants provided examples of the feedback received in their paper.

Confidentiality Advisory Group advice conclusion

The CAG agreed that they were supportive, in this specific instance, of the request for the application of the National Data Opt-Out to be disapplied in relation to the non-research activities contained within 21/CAG/0007. The CAG therefore recommended to the Secretary of State for Health and Social Care that the National Data Opt-Out deferral request be conditionally approved.

Specific conditions of support

1. The patient notification materials need to be revised as follows:

    a. A layered approach is to be adopted, making simple, easy-read versions available, with more detailed information to be provided on request.

    b. Telephone and email contacts need to be provided.

2. The National Data Opt-Out is not to be applied to patients included in the activities specified in 21/CAG/0007.

3. A local patient objection mechanism must continue to be used in relation to 21/CAG/0007.

Reviewed documents

The documents reviewed at the meeting are as follows.

Document	*Version*	*Date*
Letter for CAG from UKHSA - NNAP NDO		
NDO exemption application NNAP 171122		17 November 2022
NNAP NDO engagement plan 171122		17 November 2022
NNAP Privacy Notice NDO exemption draft 171122		17 November 2022

Membership of the Committee

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

Yours sincerely

Kathleen Cassidy
Confidentiality Advisor

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

Email: cag@hra.nhs.uk

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Confidentiality Advisory Group meeting attendance
08 December 2022

Members present:

Name	
Dr Malcolm Booth	CAG member
Dr Patrick Coyle	CAG vice-chair
Dr Sandra Duggan	CAG member
Dr Rachel Knowles	CAG member
Dr Harvey Marcovitch	CAG member
Mr Andrew Melville	CAG member
Ms Rose Payne	CAG member
Mr Umar Sabat	CAG member
Dr Murat Soncul	CAG alternative vice-chair

Also in attendance:

Name	*Position (or reason for attending)*
Ms Kathleen Cassidy	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Mr Will Lyse	CAG Approvals Administrator
Mr Dayheem Sedighi	CAG Approvals Administrator
Rachel Winch	NNAP Project Manager
Calvin Down	Head of Audits, Royal College of Paediatrics and Child Health
Dr Sam Oddie	NNAP Clinical Lead, Consultant Neonatologist