



Health Research Authority

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21 March 2024 – REISSUED 08 May 2024 to correct documents reviewed

Dr Marisa Mason
National Confidential Enquiry into Patient Outcome and Deaths (NCEPOD)
Ground Floor, Abbey House
74-76 St John Street
London
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Dear Dr Mason,

Study title: National Confidential Enquiry into Patient Outcome and Death
CAG reference: PIAG 4-08(b)/2003

Thank you for your amendment request to the above non-research application, submitted for support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process confidential patient information without consent. Supported 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 for Health and Social Care on whether an application should be supported, and if so, any relevant conditions.

Secretary of State for Health and Social Care support 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 amendment, to include the second retrospective case note review for 2023, investigating blood sodium, is supported, subject to compliance with the standard conditions of support.

Amendment request

In line with the original application, the applicant had been commissioned by HQIP to undertake two confidential reviews of case notes every year. This amendment covered the second of the reviews due to take place for 2023, which will identify and explore the avoidable and modifiable factors in the care of adults with extreme levels of sodium in hospital.

Sodium levels in the body are usually carefully controlled. A number of conditions can lead to extremes of sodium levels that the body cannot adjust for which requires corrective action. If high levels of sodium levels fall too quickly the brain can swell (cerebral oedema) and this can lead to loss of consciousness, seizures and ultimately death. Conversely if very low sodium levels rise too

quickly the brain can shrink, which can lead to an intracranial catastrophe. Moreover, correcting sodium levels too quickly can lead to a devastating irreversible locked-in syndrome called Osmotic Demyelination Syndrome (ODS) which is preventable if managed in the right clinical setting with the appropriate expertise. Therefore, managing alterations in sodium concentrations can be complex and challenging.

The applicants aim to publish the results of the review in late 2025.

Confidentiality Advisory Group advice

The amendment request was considered by Chair's Action. The Alternate Vice-Chair agreed that the amendment request was a straightforward amendment for NCEPOD to use its well-established methods to audit blood sodium as part of its regular programme, noting it was not an amendment of the methodology, but of the clinical work being audited. The Alternate Vice-Chair commented that NCEPOD is very well-established as one of the most effective audits undertaken in the UK, and was content to recommend support.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

Specific conditions of support

1. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed – The NHS England 22/23 DSPT review for National Confidential Enquiry into Patient Outcome and Death (NCEPOD) was confirmed as 'Standards Met' on the NHS England DSPT Tracker (by check of the NHS England DSPT Tracker on 13 March 2024)**

Reviewed documents

<i>Document</i>	<i>Version</i>	<i>Date</i>
PIAG 4-08(b) 2003_Blood_Sodium_amendment-request		27 February 2024
NCEPOD Blood Sodium Study Protocol		February 2024
Blood sodium_Patient Information Leaflet		
Blood sodium Poster		
NCEPOD blood sodium Poster_Easy read		

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.

Yours sincerely

Caroline Watchurst
Confidentiality Advisor

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

Email: cag@hra.nhs.uk

Enclosures: Standard conditions of support



Health Research Authority

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 supported 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.