Health Research Authority

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15 October 2018

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

Application title:	**Child Health Clinical Outcome Review Programme – Long-Term Ventilation**
CAG reference:	**18/CAG/0127**

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 16 August 2018.

Secretary of State for Health and Social Care approval 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 application is conditionally 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.

This letter should be read in conjunction with the outcome dated 10 September 2018.

Context

Purpose of application

This Healthcare Quality Improvement Partnership commissioned application from the National Confidential Enquiry into Patient Outcome and Death set out the purpose clinical audit which aims to review the quality of the delivery of care of patients receiving, or who have received, long-term ventilation and who range in age from 0-25. The organisation of care and clinical practice will be reviewed to identify potentially remediable factors in the care provided for children and young people. The audit is carried out across the UK, Guernsey, Jersey and the Isle of Man; however, the CAG remit extends only to data generated in England and Wales.

For the purposes of the audit, long-term ventilation is as 'ventilation provided every day for three months (including both invasive and non-invasive) where the intention is/was to discharge the patient home on the same level of continuing respiratory support (not home oxygen).

The audit will follow the standard NCEPOD retrospective questionnaire and case note review methodology on a sample of patients from hospitals, who match the inclusion criteria. Confidential patient information relating to eligible patients will be reported to NCEPOD from participating hospitals to enable a questionnaire to be sent to the clinician(s) involved in the patient's care, which will be returned with relevant copied extracts of the case notes to NCEPOD to undergo peer review.

Participating hospitals will be asked to identify all patients who meet the inclusion criteria over the two year period from 01 April 2016 to 31 March 2018. From the information, NCEPOD will sample cases which will include those patients who were newly commenced on long-term ventilation in the two year period, and those patients on the follow-up pathway. A limited number of cases will be randomly sampled for inclusion in the clinical questionnaire and peer review process to ensure hospitals are not overburdened. Sampling will include the following groups:

- A group of patients newly initiated on invasive long-term ventilation (initiations between 1st April 2016 – 31st March 2018) – clinical questionnaire only
- A group of patients who are not admitted to hospital during the study period – clinical questionnaire only
- A group of patients who have an acute admission to hospital during the study period – clinical questionnaire and case note review

Four questionnaires will be used to collect data for this study via a link to an online questionnaire housed on a dedicated NCEPOD server separate to the case identification data – the questionnaires will be linked by a unique NCEPOD case number only:

- Tracheostomy insertion questionnaire: A questionnaire will be sent to the named consultant responsible for undertaking the procedure (new insertions between 1 April 2016 –and 31 March 2018).
- Admission to hospital: A questionnaire will be sent to the named consultant responsible for the patient at the time of admission to hospital (where applicable).
- Ongoing long-term ventilation care: A questionnaire will be sent to the named consultant responsible for initiating and/or providing ongoing long term ventilation (all patients).

- (Main) Community nursing team: A questionnaire will be sent to the team responsible for providing the ongoing care to the patient in the community (all patients where applicable).

The case note review will focus on those patients who had an acute admission during the study inclusion dates. Where patients were transferred, notes will be requested from both the initial and subsequent admitting hospitals. NCEPOD will request photocopied/scanned copies of the relevant parts of the patient's notes to allow the peer review to take place and to identify other healthcare providers within the patient care pathway to enable additional questionnaires to be sent.

A recommendation for class 1, 4, 5 and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Cohort

Patients from 0 up to their 25th birthday who were receiving, or received, long-term ventilation over a two year period from the 1 April 2016 to 31 March 2018 will be included in the review. It is estimated that 3,000 patients would be identified of which 500 clinician questionnaires would be issued with an aim to receive 250 sets of corresponding notes.

The following items of confidential patient information are requested for the following purposes:

- NHS Number – sample validation and linkage,
- Hospital Number – sample validation and linkage,
- Date of birth – sample validation and linkage,
- Sex – sample validation and linkage,
- NCEPOD ID – linkage,
- Name – present in case notes; however, not required for the application,
- Postcode – present in case notes; however, not required for the application.

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed within the provisional outcome in correspondence.

1. **Provide further information around the data flows involved with receipt of data from General Practitioners.**

The applicant confirmed that GPs were not being approached for additional information – any information which was used in the programme would be extracted from case notes. An updated protocol was provided to reflect this.

The Sub-Committee received the response and no further issues were raised.

2. **Additional information and revised patient-facing documentation is required in relation to the communications strategy to support the proposed activity to address the following points:**
   a. **Copies of all final patient-facing documents should be provided for review,**
   b. **Documentation should be specific to this activity, providing a clear overview of the two elements of the audit (clinician questionnaire and case note**

review) and providing clear information in relation to the patient's right to object to the use of their data,

c. **Is it recommended that guidance is sought from patient and public involvement representatives to ensure that the content and language used within the documents is accessible to a wider public audience,**
d. **Established links with patient organisations, i.e. National Children's Bureau and WellChild, should be approached to widen the communications strategy for the project,**
e. **Confirmation should be provided that the patient information leaflet will be distributed within the community settings, as well as being made available in hospitals, to ensure wide distribution of information in relation to the audit.**

The applicant submitted a revised document for consideration by the CAG. It was confirmed that the National Children's Bureau, a parent on the study advisory group and WellChild had been involved in the review of patient-facing materials. It was confirmed that the output of this activity was that one document should serve both as a leaflet and a poster. The applicant confirmed that the established networks with patient organisations would be used throughout the programme and had a close working relationship with the NCEPOD team. A copy of the overarching communications strategy was provided for information purposes.

The Sub-Committee received the response and supporting supplementary documentation. It was recognised that the final document had been reviewed and supported by the referenced patient groups. Members raised some points around the wording in the documentation and it was agreed that these revisions would be fed back as for information purposes to the applicant.

The following supplementary point was raised as a recommendation only within the provisional outcome – the applicant addressed this in correspondence.

1. **It is recommended that the protocol for raising concerns be revised to ensure this accounts for any concerns identified by care provided outside of the hospital to be appropriately raised.**

The applicant acknowledged the point queried by CAG and noted that the process had been established by HQIP. The applicant confirmed that the process had been revised for the programme use and feedback had been provided to HQIP around this.

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. Support extends to data generated in England and Wales only.
2. Provide feedback at the time of first annual review around the involvement and engagement activities which have been undertaken with patients and their families in relation to the audit. If the responses given are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.

3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – National Confidential Enquiry into Patient Outcome and Death shows a satisfactory reviewed grade on Version 14.1, 2017/18**).

As the above conditions have been accepted 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.

Recommendation:

The following points were raised by Members in relation to the patient-facing information document as guidance only and compliance is not mandatory in order to comply with conditions of support.

1. The paragraph in relation destruction of programme records may be interpreted as hospital records would be destroyed by November 2019 – consider revision of the text here.
2. The opt-out information is unclear as it suggests that patients can only partially opt-out from the programme ('…opt out of identifiable information being used in this study'). This could be revised to 'you can opt-out of involvement in the study', to make the objection mechanism clearer.

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 October 2019** and preferably 4 weeks before this date.

Reviewed documents

The documents reviewed at the meeting were:

Document	*Version*	*Date*
CAG application from (signed/authorised) [Application Form Updated]		31 July 2018
Data Protection Registration [NCEPOD Data Protection Registration Certificate]		02 July 2001
Other [CAT Advice Form_NCEPOD Repsonse]		31 July 2018
Other [NCEPOD_CORP cause for concern guidance]		
Other [NCEPOD_Privacy Notice]	4	13 June 2018
Other [NCEPOD PPI policy]		
Other [C_Sponsor support_HQIP contract commissioning the project]		09 November 2017
Other [18CAG0127_LTV Communication Strategy]		
Other [NCEPOD Response_18CAG0127_20th September 2018]		20 September 2018
Patient Information Materials [NCEPOD data collection poster]		
Patient Information Materials [LTV Leaflet]		
Patient Information Materials [NCEPOD_Each and Every Need_patient question sheet]		

Patient Information Materials [NCEPOD_Inspiring Change_ patient question sheet]		
Patient Information Materials [NCEPOD_Inspiring Change_ infographic summary]		
Patient Information Materials [NCEPOD_Treat as One_patient question sheet]		
Patient Information Materials [NCEPOD_Treat as One_patient question sheet]		
Patient Information Materials [Attachment L_18CAG0127_NCEPOD_NCEPOD data collection poster - LTV v.2]	2	
Research protocol or project proposal [NCEPOD_Data flow]		
Research protocol or project proposal [NCEPOD_Identifier spreadsheet]		
Research protocol or project proposal [NCEPOD_Study Protocol]		
Research protocol or project proposal [Attachment A_18CAG0127_NCEPOD_Study Protocol2]	2	

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 relation to 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/

HRA Training

We are pleased to welcome researchers and R & D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

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.

With the Group's best wishes for the success of this project.

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*

cc. Health Quality Improvement Partnership (HQIP) – jill.stoddart@hqip.org.uk

Confidentiality Advisory Group Sub-Committee Meeting in Correspondence

Group Members:

Name	*Present*	*Notes*
Dr Tony Calland MBE	Yes	Chair
Mr. Myer Glickman	Yes	
Mr Andrew Melville	Yes	Lay Member
Mrs Diana Robbins	Yes	Lay Member

Also in attendance:

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

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 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.