



Health Research Authority

2 Redman Place
Stratford
London
E20 1JQ

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Tel: 020 7104 8100
Email: cag@hra.nhs.uk

Helen Stacey
Epilepsy12 Project Manager
Royal College of Paediatrics and Child Health
5-11 Theobalds Road
London
WC1X 8SH

Dear Ms Stacey,

Application title: UK collaborative clinical audit of health care for children and young people with suspected epileptic seizures (Epilepsy12)
CAG reference: 17/CAG/0184

Thank you for submitting a deferral request to applying the National Data Opt-Out (NDO) in relation to the non-research activity reference 17/CAG/0184.

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 23 June 2022.

This outcome should be read in conjunction with the provisional support letter dated 15 July 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 17/CAG/0184 is conditionally supported, subject to satisfactory responses to the request for further information.

Please note that the National Data Opt-Out is now deferred from being applied to the confidential patient information used without consent under this application.

Scope of NDO deferral request

This is a request to defer the National Data Opt-Out for 17/CAG/0184, Epilepsy12 - the National Clinical Audit of Seizures and Epilepsies for Children and Young People.

Healthcare Quality Improvement Partnership (HQIP) commissions The Royal College of Paediatrics and Child Health (RCPCH) to undertake the Epilepsy audit of children and young people, within the wider National clinical audit and patient outcomes programme (NCAPOP).

Epilepsy12 has been supported since 2017 with consistent submission of annual reviews since that time. The Royal College of Paediatrics and Child Health delivered the audit between 2009 and 2014, however, the previous rounds of the audit had been delivered without the requirement for support under the Regulations.

Support is in place for clinical teams to provide the audit team with confidential patient information, which is linked with NHS Digital outcome data.

Confidentiality Advisory Group advice

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

- 1. Further information is required to evidence that application of the National Data Opt-Out would have an adverse effect on patient safety. This should include more detail on the examples provided in the meeting, and further examples.**

The applicant responded by confirming that Epilepsy12 supports patient safety in the NHS by monitoring the performance of paediatric epilepsy services against the national guidelines, and helping Trusts assure the safety and standards of their services. Excluding data from patients who have opted out via the NDO could compromise the mechanisms and safeguards that protect the safe care of these patients and that of non-NDO patients. As the only quality focused dataset collecting information on paediatric epilepsy services, Epilepsy12 provides a platform for knowledge sharing, promotes local and regional quality improvement and reports data to NHS England and the CQC. These functions are dependent on complete high-quality data collected by the audit on patient care and service provision. Excluding data from NDO patients reduces the quality and quantity of data available for services to monitor and improve the care they provide.

Examples provided include benchmarking performance against other services and national standards. By not being able to process the data of NDO patients, the ability of the audit to identify potential problems and prevent them occurring again in the future will be compromised. Epilepsy12 reports how many children and young people (CYP) are seen by the appropriate professionals, and whether services are employing enough paediatricians with expertise and epilepsy specialist nurses to provide quality care to patients. If NDO

patient data has to be excluded when calculating these results, applicants cannot accurately determine if Trusts have sufficient provision of epilepsy services and whether all patients with epilepsy are receiving equal levels of support and provision. There is therefore an increased risk of patients being treated by a service that doesn't have the necessary data to accurately ascertain whether it is maintaining the quality of paediatric epilepsy services that it provides, for example one where key professionals are not providing care in line with NICE guidance and quality standards, which would adversely impact patient safety.

Applicants reason that if the NDO was applied, Trusts would not be able to facilitate continuous improvement based on the learning from previous experiences. Epilepsy12 data collection aligns to NICE guidance and quality standards. Epilepsy12 Audit data highlights when patient care falls below these standards, for example when patients are not receiving crucial investigations such as an MRI when indicated. Clinical teams can use this information to put things right for the individual child, identify the oversight, investigate why it occurred and work to ensure the same does not occur for future patients. Adverse events and themes such as this may not be identified if the NDO were to be applied to Epilepsy12, particularly when considering the small numbers in certain groups such as those who require an MRI. This risks the safety of individual and collective patients, as services could miss opportunities to improve care for an individual child and also not have the appropriate information to identify areas for improvement and learn from previous experiences to assure safety and standards in future.

Applicants also reasoned that the safety of NDO patients who are not entered onto the data capture platform is at risk, as the Epilepsy12 data platform acts as a clinical tool to ensure children and young people receive recommended care. The configuration of the data platform allows clinicians to monitor and focus on the core elements of epilepsy care and can check if patients are receiving these components compared to the national standards when entering audit data. For example, a clinician may realise that patient X meets the criteria for needing an MRI but has not had an MRI yet, when completing their Epilepsy12 record. Prospective data entry allows this error to be identified and then rectified within the first 12 months of care, enabling the clinical team to ensure that the patient receives the appropriate investigations and maintain their safety. This also holds clinical teams accountable for the care they provide as the tool highlights gaps in the provision of care for individual patients as well as the collective service. If an NDO patient is never entered onto the Epilepsy12 platform, it may not be identified that they are missing out on vital elements of care and their safety may therefore be affected. Therefore the applicant reasons that there is a strong patient safety element with regards to NDO patients, who would fail to benefit from the additional safeguarding checks the data platform provides, and risk not receiving safe and quality care for their epilepsy.

The CAG reviewed these responses, and requested further evidence that patient safety would be affected, using any different or more specific arguments/justifications in addition.

The applicant responded to further justify why application of the NDO would be damaging to patient safety. The applicant reasoned that the patient safety of individuals who are not included due to applying an NDO would be adversely affected. This is because, where an individual's clinical management is not reviewed using the Epilepsy12 tool, key elements of care provided would not be visible to the clinical team. Given Epilepsy12 is increasingly

capturing data and reporting performance prospectively, this additional check/safety net would not be applied to those children. This may be around any of the key elements of care planning for example;

- water safety
- Sudden unexpected Death in Epilepsy (SUDEP) and other risks
- involving key professionals for example paediatricians with expertise, an epilepsy specialist nurse or referral to paediatric neurology
- omission of key investigations, for example MRI and 12 lead ECG
- valproate teratogenic risks
- or securing a school individual health care plan

The audit already reveals how frequently these key elements of care are still missed, and is aiming to prompt earlier opportunities regarding those elements of care prospectively. For example, a child may be spotted through the audit who has not had basic water safety information highlighted. This prompt may then lead to this element of care being considered at subsequent follow up, as it has been omitted from the elements traditionally discussed early on in the diagnostic journey. The initial stage of the diagnostic journey can sometimes be irregular, for example where the first parts of the patient journey are an acute or an intensive care admission and epilepsy related aspects of care may be omitted given that other elements of care may be prioritised or non-specialist professionals initially involved. Therefore if the NDO was applied, this would directly adversely affect the safety of these children, as they may not be offered key elements of clinical treatment.

The applicants also reasoned that if the NDO was applied, patient safety would be adversely affected in marginalised groups, thereby extending health inequalities. This is because the audit is increasingly following a methodology and reporting that will investigate variation around characteristics of ethnicity, sex, socio-economic deprivation, learning disability and autism. These comparisons may be skewed or lose statistical significance by omission of individual children from the audit. This would be particularly true if certain groups of children were more likely to opt out of inclusion.

The applicants also reasoned that if the NDO was applied, patient safety would be adversely affected for Trust, ICB and regional level populations, as reporting will highlight Trusts, ICBs and regions where there is lower performance compared to others, and follow an outlier process for Trusts. Particularly at Trust level and particularly for the performance indicators where smaller numbers are involved they are likely to be impacted by the exclusion of individuals such that opportunities to highlight issues may be missed.

The CAG thanked the applicant for these further clarifications, and agreed that the application of the NDO to this audit would create a serious safety risk to patients. This is because the audit is multifactorial, and covers accurate data collection on patients with epilepsy, including demographic and ethnicity factors, a checklist of services and advice that should be offered to qualifying patients, and a series of indicators about individual professional performance and Trust performance which are there to support high standards of care based on best practice evidence. The CAG stated that parents or patients who might have registered an NDO may be unaware that they will be excluded from this audit, and therefore may miss out on the range of services and advice that is prompted by the audit which could have safety implications for individual patients, for example water safety advice. The audit monitors both individual clinician performance and Trust performance which could become inaccurate with serious consequences of error in either direction, for example failure to recognise good performance or poor performance if the NDO is applied due to missing data.

Therefore Members were supportive of exempting the NDO regarding the non-research elements of the audit, due to the strong patient safety impact.

2. Please provide a data flow diagram to show clearly where the NDO is currently being applied, in relation to which elements are pertinent to patient care.

The applicants have provided a data flow diagram, merely stating the NDO is applied by Trusts before being submitted to the platform. There is no indication of the interaction this has with the timepoints patients are seeking clinical care. However this is better explained in the response paper, which explains that patients are typically registered onto the audit by EEG teams when a patient undergoes their first EEG, or patients can also be registered onto the platform directly by paediatric clinical teams. The Epilepsy12 methodology and guidance for participating Trusts indicate that a patient's NHS numbers should be screened against the NDO list by EEG or clinical teams before any of their data is entered onto the Epilepsy12 data platform. When completing first year of care forms for patients, clinical teams can still indicate an opt out at this stage if one is identified after registration. Data is then deleted from the audit. The CAG were content with this response.

3. Please consider if it is possible for a consent option to be built in to the audit, which would override the NDO.

The initial response to this query was misunderstood by the applicant, as their response focused on why it would not be appropriate to seek consent from every individual in Epilepsy12. The CAG accept that consent would not be feasible for the entirety of Epilepsy12, but were seeking clarification on whether consent could be used for the small subset of individuals who applied an NDO, in order to ensure they gained the correct clinical care. The CAG therefore sought further clarification on this response.

The Epilepsy12 team agreed that it would be possible to build targeted consent into the audit process, where consent for patient level data into Epilepsy12 could be sought specifically for those children and young people who have opted out via the NDO. However, given that consent may be declined or not achieved for other reasons, then the safety issues, although reduced would continue. The applicant reasoned that it would be difficult to ensure that consent is sought/achieved for all NDO patients. This pathway would also introduce bias and variation between services, as it creates confusion as to where the consenting responsibility lies. Additionally, this consent process would increase the burden experienced by clinical teams, and may lead to services withdrawing from the audit completely.

The CAG were content with this response, and agreed that this would add layers of burden to the NHS, and would add a considerable risk of system error. The CAG considered it is easier and safer to allow the NDO exemption, without the complication of a consent mechanism. CAG is a strong supporter of using appropriate data flows to improve patient care, not to inhibit it, and therefore agree that a consent mechanism is not practicable in this case.

4. Please provide further detail on planned communication strategy.

CAG was originally provided with a communication strategy detailing how Epilepsy12 would inform Trusts/Health Boards, commissioners, patients and their families, and the public. This has now been updated to provide further information and was provided for review. The privacy notices will be updated, and the main communication routes of the NDO exemption are described in this document. The CAG were content with this response.

5. Please provide evidence of discussions with patients and the public, surrounding the non-application of the National Data Opt-Out. Feedback from this activity needs to be provided to the CAG.

The applicant confirmed that the Audits Team within the RCPCH has undertaken a number of engagement activities with children, young people, parents and carers. The Epilepsy12 project team has worked closely for a number of years with the Epilepsy12 Youth Advocates. These are a group of epilepsy experienced or interested children, young people and families who volunteer together to help shape Epilepsy12 and to lead their own aligned improvement activities with families and epilepsy services. At their most recent regular catch-up session in early November, the Epilepsy12 Youth Advocates were asked for their views on the National Data Opt Out (NDO) process. There was a consensus that Epilepsy12 data is a powerful tool used to improve services and quality of care, and should continue doing so as long as published data is anonymised and information around the audit, the NDO and how to withdraw from Epilepsy12 specifically is clearly communicated to patients and families. The CAG accepted this response.

Confidentiality Advisory Group advice conclusion

The CAG would like to note that the decision to overrule patient's wishes expressed through their enrolment in the NDO, is not taken lightly, and that the Group is only minded to do so in exceptional circumstances. The CAG recommendation is based on the documentation provided.

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, 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

1. This outcome confirms a change to the original conditions of support. The National Data Opt-Out is not to be applied to patients included in the activities specified in 17/CAG/0184
2. A local patient objection mechanism must continue to be used in relation to 17/CAG/0184

Reviewed documents

The documents reviewed at the meeting are as follows.

<i>Document</i>	<i>Version</i>	<i>Date</i>
Application for NDO exemption (Epilepsy12)_Final 090622		09 June 2022
Epilepsy12 2022 NDO engagement plan		
20220620 Epilepsy 12 Privacy Notice for NDO exemption DRAFT v0.4	0.4	20 June 2022

Epilepsy12 NDO deferral request response		15 November 2022
Epilepsy12 2022 NDO engagement plan_V2	2	
Epilepsy12 external data flow diagram_NDO		

Membership of the Committee

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

CAG member Dr Harvey Marcovitch declared a potential conflict of interest, noting he was on the Council of RCPCH for many years, is an Honorary Fellow, as well as one by qualification. Although he remained in the meeting for the discussion, he did not comment or participate in the development of the recommendation provided by CAG.

Yours sincerely

Caroline Watchurst
Confidentiality Advisor

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

Email: cag@hra.nhs.uk

**Confidentiality Advisory Group meeting attendance
23 June 2022**

Members present:

<i>Name</i>	
Dr Tony Calland MBE	CAG Chair
Mr David Evans	CAG member
Dr Harvey Marcovitch	CAG member
Professor Sara Randall	CAG member
Ms Diana Robbins	CAG member
Ms Clare Sanderson	CAG alternative vice-chair

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor