

'Section 251' Support – Annual Review

It is a standard condition of support that an annual review is supplied every 12 months, from date of the final support letter, for the duration of the support to process confidential patient information without consent. Applicants should submit this 4 weeks in advance of their annual review due date. The annual review due date is specified under the 'Next Review Date' field for each application entry in the [Register of Approved Applications](#). Please ensure all sections are fully completed to avoid invalidation.

Notification of changes through this Annual Review submission are not permitted and will not be processed nor receive support; changes are managed via a formal separate amendment process.

PIAG/ECC/CAG reference number:	17/CAG/0184
Full application title:	UK collaborative clinical audit of health care for children and young people with suspected epileptic seizures (Epilepsy12)
Application type: research or non-research	Non-research
Date annual review due: (If the annual review has been submitted after its due date, please include an explanation)	05/3/22

Information sharing:

Applicants should be aware that data controllers, such as NHS Digital, may wish to check whether an applicant has provided an annual review to the CAG, to ensure the applicant support to process information without consent remains active before the controller can process a request for data access. We will share confirmation with data controllers whether an annual review has been submitted or not, and whether it is valid, in order to facilitate local disclosure decisions.

1. Security arrangements

All applicants processing confidential patient information under the Regulations are required to provide evidence of suitable security arrangements via agreed routes. This must be in place before any support can come into effect, must be maintained for the duration of the support and is expected to be up to date and (in England) reviewed by NHS Digital at each annual review. Security assurance is required in relation to ALL organisations involved in processing confidential patient information. Please carefully assess where the processing is taking place, and provide security assurance based upon the jurisdiction and organisation where the information is being processed. Applicants may need to provide more than one security assurance depending on the jurisdiction information is processed, or if processing of identifiable information is taking place in more than one organisation.

Processing takes place in:	England	Wales	Scotland
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Security assurance provided by:	Data Security and Protection Toolkit (DSPT) – by organisation or specific function	Caldicott Principles into Practice (CPIP) report – by organisation	Review by the Public Benefit and Privacy Panel for Health & Social Care
Applicant should contact:	Exeter.Helpdesk@nhs.net	Darren.Lloyd@wales.nhs.uk	Public Benefit and Privacy Panel (PBPP) for Health & Social Care
How assurance is provided to CAG	<ol style="list-style-type: none"> 1. Organisational self-assessed completion of relevant DSPT. 2. Applicant contacts Exeter Helpdesk to request NHS Digital to review the relevant DSPT self-assessed submissions 3. NHS Digital review the DSPT submission and confirm to CAG when 'Standards Met' 	Relevant CPIP out-turn report provided directly by NWIS to CAG	An approval letter from PBPP, where processing is taking place in Scotland, is accepted as evidence of adequate security assurance.

For applicant completion:

Please list all organisations physically processing relevant information without consent for which security assurance is required. Security assurance is provided through NHS Digital reviewing the self-assessed submission. Please ensure you have contacted NHS Digital and asked them to review your submission. The annual review will not be valid until NHS Digital has reviewed the submission and confirmed its status as 'standards met'.

If confidential patient information is being processed by NHS Digital, please select this box:
 Security assurance has already been provided for NHS Digital so please do not complete any details below for NHS Digital.

Organisation (Full name)	ODS Code	Date self-assessment submitted to NHS Digital	Date NHS Digital confirmed assessment reached 'Standards Met'
Royal College of Paediatrics and Child Health	8HV48	Standards exceeded. Published 13/5/21	
Net Solving Ltd	8JA87	Standards met. Published 25/5/21	
Rackspace	8HL77	Standards exceeded. Published 22/6/21	
SysGroup PLC	8K915	Standards met. Published 29/6/21	

Is any processing of identifiable information taking place in Wales?
 Is there any processing of identifiable information taking place in Scotland?

If processing of confidential patient information is taking place in Wales or Scotland, please contact the Confidentiality Advice Team for advice on next steps.

2. Study progress

i. Conditions of support (if applicable)

Supported applications often have specific conditions of support, in addition to standard conditions of support. Applicants are expected to comply with all standard conditions of support by default to ensure the support remains active.

Please set out how you have met the conditions of support (expand box as required). This should include any difficulties experienced and mitigating action taken. Specific conditions of support are located in your conditional or final outcome letter

Please answer the following three questions and ensure you check the correct boxes for each question (double click on each box and select 'checked' where relevant).

1. **The application has no assigned specific conditions of support.**

Please note that if there are specific conditions of support (as per the outcome letters) that have not been reported against, this will invalidate the annual review and a new annual review will need to be submitted; this may jeopardise the status of support for those relying upon this lawful basis.

2. **The following provides an update against existing specific conditions of support.**

List each specific condition (expand as necessary) and explain how it has been met

1. Support extends to England and Wales only.

Epilepsy12 continues to currently extend to England and Wales only.

2. Support is in place for a non-research purpose only to support the audit programme and does not extend to any use of the data collected via this application for research purposes.

Epilepsy12 data is not used for research purposes, it is used for local, regional and national clinical audit and local provider service improvement.

3. Provide a report at the time of first annual review of actual patient and public involvement and engagement activity which has been undertaken. This should explain how children and young people were involved in the project. If the responses given are negative, the CAG will take these into account when considering whether support should continue, or whether further actions are required.

Between April - June 2018, members of the RCPCH CYP engagement team visited 10 epilepsy clinics across the country to undertake “clinic chats“. These were about “creating the best epilepsy service“. In total, more than 130 children, young people and families took part.

Visits to charity ‘Family Days’ also took place in 2 locations. The Children and Young People’s Engagement Team worked with children and young people through art-based activities, whilst parents shared their views and wishes in a forum meeting.

Children and young people told the team about their experiences of epilepsy care, how they want to get in touch with services, the kind of support they want to receive, their best experiences and their ideas for the future. Results from the clinic chats and family event days were then collated, and incorporated into a booklet style report which is [now available on the Epilepsy12 website](#).

The ‘clinic chats’ project was developed further by the children and young people working in support of the RCPCH Engagement Team and Epilepsy12 project team. They created a ‘Clinic Chat Checklist’ for services to review and assess the support they offer to young people for anxieties and worries. These Epilepsy12 Youth Advocates have been piloting the Clinic Chat Checklist since late 2019, with 8 paediatric epilepsy teams having completed self-assessments that have subsequently been reviewed by the Youth Advocates. The next stage is for in-person or virtual visits to the participating paediatric epilepsy services.

The Epilepsy12 CYP engagement activities have been driven by young people themselves supported by the College CYP Engagement Team. In addition, there were overwhelmingly positive responses from attendees to the CYP-led symposiums at the Epilepsy12/OPEN UK National Conferences in [2018](#), [2019](#) and [2020](#).

Their engagement work also received recognition via receipt of the inaugural Richard Driscoll Memorial award in October 2018, recognising their robust and sustained patient engagement in developing clinical audit and in reporting outcomes for patients. In 2020 the Epilepsy12 Youth Advocates were named National Volunteers of the Year in the HQIP Audit Heroes awards for their work with services to improve mental health support for children with long-term conditions.

The Epilepsy12 Youth Advocates will continue to develop their role in the Clinic Chat project, and providing input into the other planned audit activities.

4. Provide an overview of further engagement work which had been undertaken in relation to patient notification materials to support the audit programme, together with copies of the finalised documentation, at the time of first annual review.

The aim of Epilepsy12 is to help to improve the standard of care for children and young people with epilepsies and to be able to do this the audit collects and processes patient identifiable data. By collecting and processing such information the audit is able to highlight areas where hospitals and clinics are doing well, and also identify areas in which they need to improve.

The RCPCH and Epilepsy12 project team members take their responsibilities for maintaining the security of patient identifiable data extremely seriously. The project team created a detailed [Epilepsy12 Privacy Notice](#) in conjunction with the patient organisations represented on its methodology group and project board. The Privacy Notice is available to download via the Epilepsy12 web pages and it addresses the following questions:

- What is Epilepsy12?
- Why are hospitals and clinics taking part in Epilepsy12?
- What information does Epilepsy12 collect?
- What private information about you does Epilepsy12 collect?
- What happens to the private information?
- How long do you keep my personal information for?
- Why didn't anyone ask me if they could collect my personal information for Epilepsy12?
- What if I do not want Epilepsy12 to collect my personal information?
- Can I get a copy of any personal information that Epilepsy12 has collected about me?
- What other rights do I have?
- Who should I contact if I need more information?

Epilepsy12 has also provided each participating Health Board and Trust with posters and postcards in English and Welsh which can be displayed in clinic areas and shared with patients, parents and carers. These materials introduce the audit and signpost the full privacy notice.

4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission.

Royal College of Paediatrics and Child Health shows a 'standards exceeded' on the 2020/21 submission.

Net Solving Ltd shows a 'standards met' for 2020/21 submission.

Rackspace who provide the servers for the Net Solving data platform show a 'standards exceeded' on the 2020/21 submission.

The Royal College of Paediatrics and Child Health back up provider SysPro (SYSGROUP PLC) show a 'standards met' submission on the 2020/21 submission.

Epilepsy12's Information Governance Checklist was updated and submitted to the audit's commissioning body, HQIP, January 2022.

Net Solving Ltd. develop and administer the Epilepsy12 data platform. They use a server provided by Rackspace to host the platform. In order to do this, Rackspace have administrator rights to the server and can access the data (other than user passwords which are encrypted). Rackspace have ISO 27001 certification. Rackspace would only access the data when necessary and only at the direction of NetSolving if they have written authorization from RCPCH. There are also contracts in place.

The Epilepsy12 project team in RCPCH download Epilepsy12 data from the Epilepsy12 data platform for analysis, this data is stored on the College's own servers. Those are backed up by RCPCH's data processor Syspro (part of SYSGROUP PLC: <https://www.dsptoolkit.nhs.uk/OrganisationSearch/8K915>. They also have ISO 27001 certification).

The back-up hardware for these servers is provided by LDex. LDex provide the physical storage space for the back-up hardware on behalf of Syspro, but they do not process identifiable data as they do not have any access or any means to access any identifiable data. Syspro hold all admin rights and utilise their own connectivity and software. RCPCH data (including Epilepsy12 data) is encrypted before it even leaves RCPCH and the key is held by RCPCH and Syspro only.

3. I can confirm the application adheres to all the standard conditions of support.

ii. Steps taken to anonymise the information or obtain consent from individuals

What steps have been taken to reduce the identifiability of the information or seek consent from the patients? If this has not been done yet, please confirm at what stage you intend to or the reasons why you are not going to.

Identifiable data is fully encrypted on the data platform server. On the data platform itself approved users from participating Trusts can view identifiable data for the purpose of clinical care and service improvement, but only for patients within the care of their own Trust. Approved users can also generate and view summary reports of patient data within the platform, for patients within the care of their own Trust.

Whilst the current CAG approval permits the RCPCH to process patient identifiable information without consent for the purpose of Epilepsy12, patients or their parents can indicate to their care team that they wish to opt out of the audit. The data platform provides a function for Trusts to indicate opt out status at which point the Epilepsy12 audit team cannot process their data from the system. The project team have included information on our website and in our communications to patients and parents about the audit, how the data will be used, and how to opt out by informing the epilepsy service.

We have been communicating with users, and providing guidance where possible to support the implementation of the NHS National Opt-out requirements when the requirements for audit data come into force (due later in 2022).

iii. Projected end date

What is the expected end date for your study; **this is the date by which all confidential patient information is no longer identifiable and support is no longer required.**

The RCPCH has been commissioned by HQIP to deliver the Epilepsy12 audit up until 31 March 2022.

Beyond that point no identifiable data would be retained for analysis purposes unless the contract is extended with all related governance approvals in place via the HRA. As of January 2022, RCPCH is working with HQIP on re-tender activity to extend this for the next period of the Epilepsy12 audit.

iv. Project changes

Please provide a summary of any formal amendments made to the CAG that have been supported.

It is important to note that only those details specified in the original application (and any formal amendments) have been supported. For applications supported over 5 years ago, or where the application detail no longer reflects current activity, a new application may be required.

One change has been addressed in an amendment request which was approved by the HRA in March 2019. A copy of the amendment approval letter has been attached with this annual review documentation.

3. Justification for ongoing support

i. Practicable alternatives/exit strategy

It is a requirement of the Regulations that applicants review the requirement to continue processing confidential patient information without consent on an annual basis. Please provide an overview of alternatives being considered or taken to remove the need for ongoing support, such as the receipt of anonymised data only or the movement towards a pseudonymised approach.

Online submission to the Netsolving-developed Epilepsy12 data capture system has improved the experience of those submitting data to the audit. It has also enabled us to offer prospective data entry throughout the audit year. This enables clinics to track performance throughout the audit year, which feeds into quality improvement initiatives including PDSA cycles. The Netsolving data capture platform and associated server will be active for as long as RCPCH require it to deliver the audit..

It would be possible to amend the Epilepsy12 data platform so that only anonymised data could be captured through the system however, as per the original application the project board and methodology group believes that doing so would detract from the ability of participating Health Boards and Trusts to use the many data platform functions which help them to monitor and improve services and patient care.

4. Patient and public feedback

Please provide details of any complaints, queries or objections that you have received from patients (which specifically relate to this application to process confidential patient information without consent) and the steps you have taken to resolve them. Have any patients requested that their data is not processed and how has it been ensured that this has been respected?

To date (January 2022) the details of over 32 thousand children and young people have been registered onto the Epilepsy12 data platform and a small number (<100) have “patient opted out” status as indicated by their Trust. Trusts have also contacted Epilepsy12 about a small number of patients they wish to remove due to the national opt out (although prior to the guidance applying to national audit). The RCPCH cannot therefore process any data for those patients.

In August 2018 Epilepsy12 received one direct request via its mailbox from someone who asked that their baby’s data be deleted from our database. The RCPCH Information Governance Manager wrote to the person in question and to verify their guardianship for the baby; RCPCH did not receive a response. The request has been recorded on the Rights Request log held by the Information Governance Manager. As an additional note, no-one with the name used in the request email had been registered onto the data platform by any of the participating Trusts.

We are continuing to review our website and communications to ensure the process for handling rights requests in relation to our audits is clear, that parents and participants are aware to ask their service directly where they wish to be opted out of the Epilepsy12 audit, and that the information for the NHS National Opt-Out is shared with services, individuals inputting data and patients.

5. Public benefits

To support the need for continued support, applicants should set out what public benefits have arisen since support has been in place, and from time of last annual review. Support to process confidential patient information without consent is based upon there being a public interest in the activity proceeding so applicants should consider this section carefully. Applicants should set out what public benefit has been achieved, or whether a public benefit is still anticipated.

Epilepsy12 was designed to stimulate national improvements in the diagnosis of seizures, and on-going treatment and support for children and young people with epilepsy. Epilepsy12 has aimed to improve the consistency of care, by strengthening regional knowledge, skill and resource sharing in the OPEN UK regional paediatric epilepsy networks. Epilepsy12 hosts the national meetings of OPEN UK (bringing all the regional leads together), jointly hosts the annual conference with OPEN UK, and provides regional analysis and comparison data via a dashboard on the data platform and in our annual reporting.

The key performance measures used by Epilepsy12 are mapped to quality and care standards from NICE, SIGN and the BPNA. Through the organisational audit Epilepsy12 is able to provide key insights into how the current workforce reflects the expectations of those standards. The clinical aspect of the audit examines how care and outcomes compare to the national guidelines. Improvement goals set in recommendations based on the audit findings are therefore year on year increases in the percentage of children and young people with epilepsy receiving care in line with national expectations and best practices.

The results of Round 3 of Epilepsy12 have been published in [2019](#), [2020](#) and [2021](#).

These analyses have highlighted a number of areas of improvement in care:

- More children with epilepsy now had specialist input into their care from both Epilepsy Specialist Nurses (78%) and Consultants with Expertise in Epilepsy (87%)
- 91% of children and young people with epilepsy now had a recognised seizure formulation assigned (based on ILAE seizure categorisations)
- There were fewer withdrawals of an epilepsy diagnosis (which is used as a proxy for misdiagnosis); 98% of children initially diagnosed with epilepsy maintained the diagnosis after 1 year of care.
- 90% of children and young people diagnosed with epilepsy and on rescue medication, had a parental prolonged seizure care plan
- 98% of children and young people with epilepsy received an EEG investigation
- Between 2018-2020 there has been an increase in the care functions supported by Epilepsy Specialist Nurses. This includes providing rescue medication training for parents (in 87% of Health Boards and Trusts in 2020, from 75% in 2018), and facilitating meetings with schools (86% in 2020 from 72% in 2018).

There was still need for considerable improvement in some areas in order to meet national standards, and reduce variation between services at regional and local levels. National recommendations were made in 2021 that targeted both improved access to key services and an increased specialist workforce to support children and young people with epilepsy (or suspected epilepsy). These will be monitored and reviewed in light of future findings; and the Epilepsy12 audit is also supporting the work of the NHS England Epilepsy Oversight Group.

In 2019 Epilepsy12 initiated a pilot quality improvement collaboration of 10 paediatric epilepsy services; the [Epilepsy Quality Improvement Programme](#). Drawing on the audit intelligence, local data, and quality improvement training teams are working together to implement a quality improvement project to improve care and services. Teams meet virtually each month to share their progress and learning. The results of the pilot were shared at the annual Epilepsy12/OPEN UK conference in September 2020, and posters detailing each of the quality improvement projects achieved in the programme are available online, to support other teams looking to use similar ideas. Two new quality improvement collaboratives were launched by EQIP in 2021, with teams supported to work on local improvement projects through to March 2022.

The public benefits of the audit include better quality of life of children and families with epilepsy as a result of improved care, transparency around the performance of different hospitals and Trusts, and empowering families to demand better care and appropriate access to support or services. It is also expected that improvements in care will result in healthcare savings associated with later avoidance of complications associated with poor seizure control, inappropriate medications or treatments.

5. Confirmation of contact details

Please confirm contact details for the publicly available register of approved applications.

The contact details below are the same as those currently published in the Register of Approved Applications.

The contact details below are NOT the same as those in the Register of Approved Applications. In order for this change to be processed the reason for this change must be specified here.

Name of controller for application: Royal College of Paediatrics and Child Health

Contact Name and role: Helen Stacey, Epilepsy12 Manager

Full address:

Royal College of Paediatrics and Child Health

5-11 Theobalds Road

London

WC1X 8SH

Telephone: 020 7092 6056

Email: helen.stacey@rcpch.ac.uk

Named applicant Name: Helen Stacey

Signed: H Stacey

Date: 24/01/22

Please return this completed form to cag@hra.nhs.uk. Questions over completion should be directed to cag@hra.nhs.uk or contact the CAG general advice line on 0207 104 8100 between 9-5.

Please note this document will be assessed by the Confidentiality Advice Team in the first instance. Depending upon the content, the team might request further information, arrange a subsequent meeting to discuss the content of the annual review, or escalate to the Chair or to CAG.