**1) Title**

Implementation and early evaluation of a quantitative electroencephalography programme for seizure detection in PICU

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**MeSH keywords**

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**Abstract**

**Objective:** To describe implementation and early evaluation of using quantitative electroencephalography (qEEG) for electrographic seizure (ES) detection by paediatric intensive care unit (PICU) clinician staff.

**Design:** Development of a qEEG training programme for PICU staff and a prospective observational study of ES detection in patients monitored with qEEG

**Setting:** PICU

**Patients:** Children <18 years of age admitted to PICU during the 14-month study period and deemed at risk of ES

**Interventions:** Continuous qEEG monitoring that consisted of two-channel amplitude-integrated EEG (aEEG), colour density spectral array (CDSA), and raw-EEG.

**Measurements and main results:** A training programme was established whereby PICU clinical staff were trained by neurophysiologists to set-up and interpret qEEG. ES detection by PICU team was analysed for diagnostic accuracy and promptness against ES identification by a trained neurophysiologist, retrospectively reading the same qEEG and blinded to patient details and clinician interpretation of qEEG. 101 (6.7%) of 1510 consecutive admissions during the study period underwent qEEG monitoring. Status epilepticus (35%) and suspected hypoxic-ischaemic injury (32%) were the most common indications for qEEG. ES was diagnosed by the neurophysiologist in 12% (n=12) of the cohort. ~~Onset of ES occurred within 4 hours of initiating monitoring in 83%~~ (~~n=10~~). PICU clinicians correctly diagnosed all 12 patients (100% sensitivity and negative predictive value) ~~In eight (8/12, 67%) patients, the first episode of ES occurred out-of-hours and may have remained undetected, or had a delayed diagnosis, without qEEG monitoring~~ ~~as there were no clinical correlates~~. An additional eleven patients had a false-positive diagnosis of ES [false-positive rate =52 (31-73)%]. ~~The overall specificity was 88% but improved from 80% in the first seven months to 95% during the following seven months~~Median time to detect seizures was 25 (5-218) minutes. Delayed recognition of ES (>1 hour from onset) occurred in five (5/12, 42%) patients.

**Conclusions:** Implementation of a qEEG monitoring programme to detect ES by PICU clinicians is feasible and early evaluation suggests ~~and~~ good sensitivity for ES detection, though ongoing refinement is needed to avoid delay in ES detection and reduce the false positive diagnosis of ES. A comprehensive training programme with regular refresher updates for clinical staff are key components of the programme. ~~Awareness of the limitations, and a continuing education programme may be needed to minimise the impact of lower positive predictive value of qEEG. However, continuing education appears to improve diagnostic accuracy.~~

**Introduction**

Seizures in critically ill children have been associated with adverse short term and longer term outcomes(1–3). However, seizure detection in paediatric intensive care units (PICU) may be challenging for various reasons, including the use of neuromuscular blocking agents, occurrence of non-convulsive seizures, and possible electro-mechanical uncoupling in critically ill states(4). Electrographic seizures (ES) have been reported to occur in 10-40% of critically ill children monitored with electroencephalography (EEG) in PICU(4). Continuous EEG monitoring (cEEG) of comatose patients with suspected or possible brain injury, has been recommended as part of multi-modal neuromonitoring(5). Continuous 16-channel EEG, utilizing 10-20 system, is the gold-standard technique for ES detection in ICU. However, it is not widely available, and even when available, fewer than 20% of institutions with cEEG have access to round-the-clock review, and half of the units that do only have expert neurophysiology review once or twice a day(6).

Given the limitations of cEEG, bedside seizure detection by intensivists using quantitative EEG (qEEG) techniques such as amplitude-integrated EEG (aEEG), and colour density spectral array (CDSA) have been suggested as an alternative monitoring method of choice(7). aEEG is a plot of processed, filtered, time-compressed and rectified EEG amplitude on a semi-logarithmic scale. CDSA is a time-compressed and color-coded display of power of EEG (amplitude2/Hz) at frequencies between 0-20 Hz after fast-fourier transformation of the raw EEG.

qEEG has been shown to have acceptable diagnostic accuracy in adult and neonatal ICU(7, 8). Reports of continuous qEEG in PICU are limited. Earlier studies in the PICU setting have only reported retrospective accuracy of qEEG interpretation by either EEG experts or paediatric intensivists using tutorials, questionnaires or surveys(9–12). While these reports suggest that aEEG and CDSA have acceptable degrees of accuracy, they recommend further evaluation at the bedside in the real-world setting. We describe our experience in implementation of an intensivist-led qEEG service in PICU with particular emphasis on the implementation training programme and an early evaluation of the diagnostic accuracy of qEEG for ES detection by paediatric intensive care clinicians.

**Materials and methods**

We performed a single centre prospective observational study over a 14 month period from Feb 2013 to March 2014 in the cohort of PICU patients with qEEG monitoring. Birmingham Children’s Hospital has a mixed medical and surgical PICU with approximately 1400 admissions per year. Data from all patients identified by PICU clinicians to be at risk of ES and commenced on qEEG were included in the study. Unit guidance recommended application of qEEG in children with suspected or confirmed hypoxic, ischaemic, traumatic, infective or inflammatory brain injury, especially if they received neuromuscular blockade. All patients were deeply sedated with morphine and/or midazolam and 93% were muscle relaxed. Patients with decompressive craniectomy and allergy to collodion glue (used to secure EEG electrodes) were excluded. The study met the criteria for service evaluation as defined by the Governance Arrangements for Research Ethics Committees document and thus did not need Research Ethics Committee approval. This was registered as a service evaluation via our usual hospital procedure.

Standard qEEG montage consisted of an eight electrode montage using scalp surface electrodes (FP1, FP2, P3, P4, ECG 1, ECG 2, earth and reference). We used CareFusion, NeuroCare, NicVue 2.9 system, displaying two-channel (one for each hemisphere) aEEG, CDSA and raw-EEG in a split screen. aEEG and CDSA were displayed in a 4-hour timescale, whereas the raw EEG was displayed in a 12 second time scale (Figure 1). PICU clinicians (doctors and advanced nurse practitioners) and bedside nurses were provided training about theoretical and practical aspects of qEEG set-up including application of scalp electrodes and interpretation of qEEG. Formal training days, educational audit meetings and online teaching aids were all part of the continuous, competency based qEEG training programme throughout the study. A more comprehensive description of the education and training package is available in supplementary file 1. Bedside nurses reviewed the qEEG trace every hour and flagged up any significant changes to PICU clinicians. PICU clinicians were required to review qEEG recordings at least once every 4 hours (more frequently during any intervention).

Impedance of ≤5 kOhm was necessary for successful completion of qEEG electrode set-up. EEG leads were adjusted or re-applied until this impedance threshold was reached. Impedance was monitored continuously and was verified before any qEEG interpretation was made. Relevant clinical events (e.g., suction, physiotherapy, patient handling and position changes, diagnosis of ES, antiepileptic medication administration) were annotated on the qEEG system. Raw-EEG was reviewed to exclude artefacts (such as movement or ECG artefacts) before a diagnosis of ES was made and recorded. PICU clinicians recorded the time of occurrence and time of identification of ES whenever a diagnosis of ES occurred for the first occasion in any patient. Access to neurophysiology review was available at least twice a day but ad-hoc review during in-hours [09:00 to 16:00; Monday to Friday and 09:00-12:00 Sunday] was also possible. PICU clinicians recorded their interpretation prior to, and independent of, any neurophysiology review. Recording the interpretation of every subsequent ES was recommended. The total numbers of ES episodes per patient, or duration of ES, were not used for diagnostic utility assessment because of contemporaneous neurophysiology review in-hours and difficulty in categorizing patients with frequent ES as multiple discrete episodes of ES as opposed to status epilepticus.

One trained clinical neurophysiologist assessed each qEEG recording retrospectively for the diagnosis of and time of onset of ES, unaware of how the record had been assessed by the clinical team and unaware of any treatment given. The clinical neurophysiologist also reviewed the raw EEG trace from the same channels which were used for qEEG set up. This was considered the gold-standard against which the PICU clinicians’ interpretation was compared. An ES was defined as any repetitive, rhythmic activity lasting ≥10 seconds, with a distinct beginning, middle and end on either aEEG or CDSA or both. Electrical status epilepticus (ESE) was defined as ES for ≥ 30 minutes either continuously or within any one hour time period. Any episode of ES identified by a PICU clinician more than 1 hour from the onset of ES, as determined by a neurophysiologist, was categorised as ‘delayed seizure detection’.

Demographic data, indication for qEEG monitoring, estimated probability of death on admission to PICU based on Paediatric Index of Mortality (PIM2r), relevant interventions, and PICU discharge status were collected and analysed. Continuous data were described by medians (IQR), and categorical data by counts (n) and percentages (%). Diagnostic utility of qEEG was described using sensitivity, specificity, positive, and negative predictive values. ~~Comparison of the diagnostic utility was performed between the first and second half of the study period.~~ EEG traces with false-positive, false-negative and delayed recognition of ES were analysed further for possible associated factors such as interventions performed and background pattern of the EEG. Chi-square tests were used to compare proportions and Mann-Whitney-U test for others. Statistical analyses were performed using Microsoft Excel [Redmond, WA, USA] and R version 3.5.1 [R Core Team, R Foundation for Statistical Computing, Vienna. <https://www.R-project.org/>]

**Results**

101 (6.7%) of the 1510 patients admitted to PICU during the study period were monitored using qEEG. Characteristics of qEEG monitored children are summarised in Table 1. An admission diagnosis of status epilepticus or other seizure disorder requiring PICU support (35%) and suspected hypoxic-ischaemic injury following resuscitation from cardiac arrest (32%) were the most common indications for qEEG monitoring (Table 1). 19 of the 32 children in the latter category had an underlying cardiac diagnosis, most commonly congenital heart disease. 36% of those monitored were infants <1 year of age. qEEG monitored cases had a significantly higher estimated median probability of death using PIM2r [6 (3-13)%], compared to PICU admissions in the same time period [3 (1-6)% (p<0.001)]. While 85% (86/101) were monitored for ≤48 hours, the range of duration of qEEG monitoring was variable (range: 1-171 hours). While most children were started on qEEG monitoring on the day of PICU admission, the range of time to initiate qEEG varied from 0-728 hours after PICU admission. Three patients (3%) had superficial skin abrasions or erythema related to application of the qEEG electrodes.

**Diagnostic utility:**

 PICU clinicians diagnosed ES in 23 of the 101 children. Expert neurophysiologist review concurred with a diagnosis of ES in 12 (true-positive) of the 23 children. Expert review did not detect any patients with ES missed by PICU clinicians (Table 2). Median time for onset of ES was 30 (9-100) minutes from start of qEEG monitoring. 10 of the 12 (83%) patients with ES had their first ES episode within the first 4 hours of initiation of qEEG monitoring. In the other two patients, the first ES episode occurred at 24 and 49 hours after initiation of qEEG monitoring. 87 (86%) patients had their qEEG monitoring commenced outside of normal working hours, when neurophysiology support was not available. Recognition of the first episode of ES occurred out-of-hours in 8 of the 12 (67%) patients.

 All ES occurred in children younger than 4 years of age, with 83% (10 of 12) occurring in infants <1 year of age. All 12 were on neuromuscular blockers, with no clinical correlate. Seven patients (7/12, 58% of true-positive patients) met the criteria for ESE at some point during their qEEG monitoring. ~~49 patients with qEEG monitoring, of whom 3 had true positive ES were admitted in the first half of the study period and 52 with qEEG, of whom 9 with true positive ES were admitted in the later half (Table 3). 9 of the 11 instances (82%) of false-positive ES diagnosis occurred in the first six months of the study period and only 2 (18%) in the subsequent six months.~~All 11 patients with a false-positive ES had abnormal background raw-EEG, including spontaneous burst suppression pattern or isoelectric/abnormally suppressed pattern in three patients each (Table 3).

**Time to seizure recognition:**

ES were recognised by PICU clinicians at a median (IQR) of 25 (5- 218) minutes from the onset of seizure activity on qEEG. Five of the 12 patients (42%) with true-positive ES had delayed seizure recognition (delay >1 hour). ~~Two of the five delayed seizure detection instances occurred in the first half of the study period and three in the later half.~~ We were unable to detect any significant differences in patient characteristics between the delayed and the prompt seizure recognition groups. The numbers of co-interventions performed during qEEG monitoring were similar in both groups.

**Treatment:**

All patients with true-positive ES had at least one anti-epileptic medication administered (Table 4). Two of the seven patients who met the criteria for ESE at some point during their qEEG monitoring were managed with thiopentone infusion, titrated to achievement and maintenance of burst-suppression as end-point of therapy, with the other five managed with a combination of anti-epileptic medications and a high dose midazolam infusion.

Seven of the eleven patients (7/11, 64%) with a false-positive ES diagnosis also received at least one anti-epileptic medication (Table 4). Four patients (4/11, 36%) with a false-positive ES were continued on anti-epileptic medication after neurophysiology review confirmed the absence of seizure activity, as per unit protocol relevant to their underlying condition (e.g., seizure prophylaxis following traumatic brain injury).

**Outcomes:**

Median PICU length of stay for qEEG monitored children (7 [3-14] days) and children with ES (13 [7-21] days) were both significantly longer than overall PICU length of stay during the study period (2 [1-6] days)[p<0.001]. In-PICU mortality for qEEG monitored children (19.8 [95% CI: 13-29] %) was significantly higher than overall PICU mortality in the same time period (5.7 [95% CI: 4.6-7]%; p<0.001). Mortality rate for children who had ES (16.7 [95% CI: 2-48] %) was not significantly different to overall PICU mortality (p=0.1) or qEEG monitored children (p=0.8)

**Discussion**

 This study is the first of its kind to describe the implementation of a PICU-led qEEG service and to evaluate the real-world utility of qEEG for seizure detection by PICU clinicians. The study demonstrates that following a robust training and education strategy, and using a qEEG set up that included aEEG, CDSA and raw-EEG, PICU clinicians can effectively detect ES with a high degree of sensitivity [100 (74-100)%], and acceptable specificity [88 (79-94)%].

 A systematic review of aEEG monitoring in neonates showed a lower median sensitivity of 76% (71-85) and specificity of 85% (39-96) for seizure detection by neonatologists(8). The reported neonatal studies only utilized aEEG and most used a single channel EEG. Diagnostic accuracy was noted to be higher in the studies that included raw EEG trace along with aEEG, compared to those that didn’t. In an adult ICU study, seizures were accurately diagnosed in 80% of patients by neuro-intensivists using a combination of aEEG, CDSA, burst-suppression rate and raw-EEG(7).

Previous PICU studies have compared neurophysiologists’ interpretation based on a full-montage of cEEG as the gold-standard with a retrospective review of qEEG, with or without CDSA, by clinicians using a tutorial/questionnaire format, rather than prospectively at the bedside. One study reported a sensitivity of 77% and specificity of 68% for seizure detection by paediatric intensivists using aEEG and CDSA(11). Although addition of CDSA to aEEG did not improve the diagnostic accuracy, critical care providers felt that the combination improved their ability and confidence to detect ES. CDSA alone has been reported to have a sensitivity of 70% and specificity of 68% for seizure detection in PICU patients(10). Another study using eight-channel aEEG and CDSA, reported that PICU providers had a high degree of sensitivity (94%) to identify at least one seizure in patients with ≥1 seizure(12).

 Two thirds of true-positive ES occurred out-of-hours in this study at a time when neurophysiology review and interpretation would generally not be available in many hospitals. This is consistent with other reports which highlight the need for cEEG initiation and interpretation out-of-hours(13) underlining the need for continuous round-the-clock access to a neuromonitoring set-up in PICU.

False-positive seizure identification has been reported consistently in other neonatal and PICU studies(8, 9, 11, 12). In one study PICU providers falsely identified at least one seizure in 85-96% of patients (12). Others have highlighted the ‘steep learning curve’ in the real-world use of qEEG to detect seizures(12). ~~In this study the majority of false-positive ES identification episodes happened in the first half of the study period.~~ It is note-worthy that many of the false-positive seizure diagnoses happened in patients with abnormal background EEG, such as those with burst-suppression or superimposed fast-activity perhaps due to underlying brain injury and/or medications. Artefacts related to movements have been reported as a common reason for false-positive seizure identification,(14) but this was not felt to be a significant factor in this study as qEEG monitoring was initiated only in deeply sedated children who were often on neuromuscular blockade medications. False-positive seizures were all treated with anti-epileptic medications which were often stopped after subsequent neurophysiology review, unless otherwise indicated. None had any adverse incidents related to the medications during the study period. However this may be a concern and a key limitation of intensivists led qEEG programme. In addition to awareness of the issue, suitable education and training may help minimize false-positives. Remote/networked qEEG review service by a small expert user-group of intensivists and/or neurophysiologists may also be helpful in reducing the false-positive ES detection rate.

 The qEEG monitoring service provided access to prompt intervention, with seizure detection within 1 hour of onset in 58% of instances. Though there was a delay in seizure detection of more than 1 hour on 42% of occasions, the clinical significance of this is delay is uncertain. Prior to implementation of the qEEG service, identification of sub-clinical seizures was only possible during weekday and in-work hours. The complexity of EEG interpretation has to date prevented development of a reliable automated ‘alarm’ system within qEEG systems, which could prompt clinician review and earlier diagnosis and treatment. Early seizure detection is not the only potential benefit of a qEEG monitoring programme. Useful prognostic information can be obtained from the presence of favourable (e.g., sleep spindles, sleep-wake cycling, continuous activity) or unfavourable features (discontinuous, burst suppression, isoelectric) in background EEG(15–17). In addition, qEEG monitoring may guide titration of anticonvulsant infusions to achieve therapeutic burst-suppression as was the case in two patients in this study.

 The incidence of ES in this study was 12% (95% confidence interval: 7-20%) using qEEG, which is lower than many other reports(4). A number of explanations are possible. First, the threshold for and indications for EEG monitoring are likely to be substantially different amongst the various studies. We did not mandate the indications for initiating qEEG. Rather, we provided pragmatic guidance around clinical situations, leaving the final decision about qEEG monitoring to the relevant clinicians. This undoubtedly, leads to selection bias, which is an important limitation of this study. Some studies used EEG monitoring only in children who had acute brain injury [with 34-57% incidence of ES], and others used it in critically ill children with any concern about encephalopathy [7-39% incidence of ES]. In addition we utilized raw EEG recordings from only 2-channels making it possible that a full montage of cEEG may have picked up more seizures. It is also possible that some patients may have had ES before initiation of qEEG monitoring. Another limitation of the study is that we are unable to separate out the relative contributions of qEEG and CDSA to clinician decision making in this study. We also did not recommend either a minimum or maximum duration of qEEG monitoring and this was left to clinicians’ discretion, though in keeping with our findings other studies have reported that about 50% and 90% of patients with ES are identified with 1 hour and 24–48 hours of EEG monitoring(4).

 ES is common in a high risk PIC population. Implementation of a qEEG monitoring programme for ES detection by PICU clinicians has a high degree of sensitivity and acceptable specificity. Further work is needed to reduce delays in ES detection and to reduce false positive rates. A comprehensive initial training programme run collaboratively between PICU and neurophysiology, together with continuing education and regular audit/review meetings are emphasized as key components of the programme. ~~Children who met the criteria for qEEG monitoring appeared to have longer PICU length of stay and worse mortality than the overall PICU population, regardless of the presence or absence of seizures.~~

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**Figure 1 legend**

Image showing typical qEEG set-up that includes amplitude-integrated EEG, Colour Density Spectral array (spectrogram), raw EEG waveforms from each cerebral hemisphere and the ECG waveform in a 4-hour time window.

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**Supplement 1:**

**Educational & Training Programme for CFAM in Paediatric Intensive Care Unit, Birmingham Children’s Hospital**

Cerebral function analysing monitor (CFAM) programme via two channel quantitative electroencephalography (qEEG) at Birmingham Children’s Hospital provides continuous qEEG monitoring capability (24/7 & 365 days/year) to patients within paediatric intensive care unit (PICU). A core CFAM management team, comprised of collaborative members from PICU and neurophysiology departments, oversee the CFAM service. Since its inception there has been a programme of training, education, audit and governance for all clinical staff members involved in the delivery of the CFAM service. This document outlines the key components of the CFAM service which include: CFAM team structure, educational programme content and schedule of training.

**CFAM Team Structure**

**Core management team**

The CFAM service is led by a core CFAM management team that meets regularly and collaborates on all key decisions regarding service delivery, governance and education. All education & training is solely delivered by the core team to guarantee consistency and level of expertise. The core team comprises of one PICU Advanced Nurse Practitioner (ANP), two PICU Consultants and two senior neurophysiology clinical scientists.

**Clinical service delivery team:**

All PICU clinicians (consultants, ANPs, clinical fellows) who care for patients within PICU are required to be able to interpret CFAM to guide their clinical decisions around seizure detection and treatment using CFAM. PICU Nurses, as part of the Paediatric Intensive Care Specialist course, are trained as the key group to apply, maintain, troubleshoot and remove electrodes and CFAM equipment. Newly qualified PICU nurses (with less than two years’ experience) receive basic level training for troubleshooting problems, escalating CFAM changes and annotating clinical records.

Overall, the CFAM service remains the responsibility of the PICU , with its delivery supported by the Neurophysiology department

**Education/ Training Programme**

Table 1 provides an overview of the education and training programme. All clinicians are expected to have initial training, followed by annual maintenance of competence.

In addition to the scheduled programme and on-line educational course, there is regular bed-side teaching and electronically distributed learning materials. These include:

1. Twice daily bedside teaching by the reviewing neurophysiologist or core PICU CFAM team when a patient is receiving CFAM
2. Troubleshooting alerts & updates to all PICU staff via regular email communication

The CFAM service has produced CFAM guidelines & training documents, which include: CFAM application and removal, CFAM interpretation examples, review and troubleshooting guides. These are updated every 2 years

**CFAM Education & Training Schedule**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Professional Group** | **Group Description** | **Initial Training** | **Ongoing Training** | **Certification** |
| **Components** | **Training Schedule & Delivery** | **Components** | **Training Schedule & Delivery** |
| **PICU Clinicians** | Consultants,Advanced Nurse Practitioners,Clinical Fellows | 1. How CFAM works
2. Indications
3. Set-up CFAM machine
4. Application & Removal of EEG leads (Practical session)
5. Troubleshooting
6. Escalation & review for CFAM concerns
7. Importance of artefact recognition & reduction
8. CFAM Interpretation
 | 2-3 face to face sessions/year timed with induction of new clinical fellows.+Online Course | 1. General updates
2. CFAM interpretation & troubleshooting
 | 3 face to face sessions per year as part of a set medical/ANP educational programmeQuarterly CFAM AuditMeetings (for whole PICU department)Annual online courseTri-annual CFAM Quiz | Online course certificateMedical devices competencyTeaching programme attendance |
| **PICU CFAM Nurse Team** | All PIC Nurses who have completed the specialist PIC course (>2 yrs experience) | Twice yearly face to face course, set as part of the PICU Specialist nursing course that guarantees at least 1 CFAM trained PICU nurse per 12 hour clinical shift+Online Course | Quarterly CFAM Audit MeetingsAnnual online courseTri-annual CFAM Quiz | Trust validated CompetencyMedical Devices Competency |
| **Newly Qualified PICU nurses**  | PICU Nurses who are <2 years in post & pre-specialist course | 1. Basic Interpretation
2. Impedance checks
3. How to annotate
4. Escalation and review
 | Face to face bedside teaching by the CFAM nurse for that shift | 1. Basic Interpretation2. Impedance checks3. How to annotate4. Escalation & review  | Face to face bedside teaching by the CFAM nurse for that shiftQuarterly CFAM Audit MeetingsTri-annual CFAM Quizzes | Medical Devices Competency |
| **Allied health professionals** | Respiratory & neuro-physiotherapists in PICU | 1. How and what to annotate
 | Face to face bedside teaching by the CFAM nurse or CFAM lead ANP | 1. How and what to annotate | Face to face bedside teaching by the CFAM nurse or CFAM lead ANP | Medical Devices Competency |