The Impact of Epilepsy Review Service on Seizure Control in Primary Care

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Abstract

Introduction: Epilepsy is a debilitating disease affecting more than 200,000 people in Malaysia. Only 9.6 per cent (%) of epilepsy patients had their seizure well-controlled in our facilities. Epilepsy Review Service (ERS) was initiated to improve health outcomes among epilepsy patients.

Objective: The primary objective of the study was to evaluate the impact of ERS on seizure control in patients with epilepsy after implementing ERS.

Methods: A comparative, non-controlled study on epilepsy patients attending government health clinics in Klang district was conducted over a period of 12 months. All eligible and consented patients were enrolled into ERS at the point where baseline data was collected. Patients were reviewed at 0, 6 and 12 months where interventions were undertaken by the healthcare team. Data was retrieved using a review form, Therapeutic Drug Monitoring (TDM) records, and patient self-reported seizure frequency before and after the interventions.

Results: Data from a total of 156 patients was analysed. Before implementation of ERS, there was delayed completion of TDM cases (40.6%), lack of counselling related to epilepsy issues (21.8%), lack of review on medication side effects (5.1%) and drug interactions (20.5%). Post-intervention showed increments in the completion of TDM cases within 72 hours (84.1%), counselling done (89.3%), as well as review of medication side effects (77.9%) and drug interactions (82.1%). Seizure improvement among epilepsy patients increased from a baseline of 9.6% to 37.8% at 6 months and 52.6% at 12 months. The mean monthly seizure frequency of patients was significantly reduced from 1.91 (SD 2.02, range 0-7, median 1.0) at the end of 6-month post intervention to 0.94 (SD 1.30, range 0-7, median 1.0) at the end of 12-month post intervention (p <0.001).

Conclusion: Pharmacist-initiated implementation of ERS has great potential in improving seizure control.

Keywords: pharmacist medication review, seizure control, primary care

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Introduction

Epilepsy is one of the common neurological disorders seen in primary care. The World Health Organization (WHO)[1] reported that patients with epilepsy (PwE) have up to 3 times higher risk of premature death and there are significant economic implications due to health care expenses and loss of productivity. In Malaysia, it was estimated that more than 200,000 people suffer from epilepsy in which anti-epileptic drugs (AEDs) remain the cornerstone of epilepsy treatment[2,3]. With effective management, up to 70% of people with active epilepsy have the potential to become seizure-free[4,5,6].

Primary healthcare services should focus on continuity of care for stable PwE who have been discharged from tertiary care[7.] A study conducted in the United Kingdom (UK) showed that a structured review process for epilepsy in primary care has been advocated as the best practice in providing quality care[8.] Majority of the patients felt that pharmacists' review was good, helped improving the understanding of their condition, and was informative and reassuring.

In our current setting of Ministry of Health (MOH) health clinics in Klang district, state of Selangor, Malaysia, pharmacists have established review services for patients with common chronic conditions (e.g., diabetes, asthma) but not epilepsy. We found a lack of structured framework in managing PwE with several shortfalls such as poor documentation, lack of efficiency of therapeutic drug monitoring (TDM) service and epilepsy-related counselling. Prior to any interventions, it was found from our initial survey that only 9.6% of PwE had their seizure well controlled in all outpatient clinics in the district.

Therefore, we established the Epilepsy Review Service (ERS) to improve the quality of care to PwE. ERS is a pharmacist-led service which consists of three components: clinical assessment and documentation, improvement in TDM service, and individualised epilepsy counselling. Through ERS, we review PwE at least once a year, improve the standard of TDM service, and provide individualised epilepsy counselling during their follow-up appointments. Our project aimed to assess the outcome of ERS and its potential in improving seizure control and the overall management of epilepsy patients in primary care.

Methods

Design and setting

This was an experimental, comparative, non-controlled study conducted over a period of 12 months in three phases. This study comprised of an intervention period and two observational periods. Baseline data collection was conducted from January 2014 till March 2014. This was then followed by a 3-month intervention period from April 2014 to June 2014. The first assessment was conducted from July 2014 to September 2014. The second assessment was then performed from October 2014 till December 2014 using the same data collection tool. All pharmacists and other healthcare providers were given education sessions on Epilepsy, AED, TDM and ERS implementation. Standardised workflow of care, TDM guide and epilepsy counselling guide were distributed among the team members. The ERS team met once a month within the course of intervention for discussion and ensuring the progress of ERS implementation.

Participant recruitment

Prior to the enrolment, we established an epilepsy registry by screening all PwE attending outpatient pharmacy. Patients who fulfilled the criteria of having a clinical diagnosis of epilepsy, taking at least one type of AED, and attended regular follow-up appointments at our clinics were registered. Patients below 18 years of age, on temporary referral to the clinic, or having follow-up appointments at a tertiary care setting were excluded. We introduced ERS to PwE by explaining to them the expected objectives of this newly implemented service. Verbal informed consent was obtained from patients or their caregivers. This research was conducted according to the World Medical Association (WMA) Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects.

Data collection

Consented patients were interviewed and their baseline seizure frequencies were documented in a self-constructed ERS record form within a period of three months. Baseline AED level monitoring, medication understanding and compliance were assessed and issues on medication side effects and other medication safety issues were identified and recorded. Subsequently, remedial actions were taken and patient monitoring was continued for another three months with appointment intervals scheduled according to individual patient need.

All patients were given education on how to identify the frequency, type, duration and possible triggers of their seizure, and how to record them. Specially designed seizure diaries were distributed to the patients and standard instructions on diary recording were given. Patients were interviewed in the next encounter and their follow-up seizure frequencies were recorded in the ERS record form.

In order to evaluate ERS as a new service, quality indicators as shown in Table 1 were adapted from Quality Indicators in Epilepsy Treatment Tool (QUIET) tools (Chronic Epilepsy Care Section)[9] published by the Agency for Healthcare Research and Quality (AHRQ), USA and standards for each indicator were set. Only tools numbered 11 to 16 as shown in Appendix 1 that suit the primary care setting practice and resources were selected. We also adapted three other indicators that were deemed important in measuring quality of TDM service.

Table 1: ERS quality indicators

Indicators	Descriptions
Review for epilepsy	All epilepsy patients are interviewed and data documented at each visit regarding: • Number of seizures • Types of each seizure episode • Drug side effects experienced
Improve TDM service	– Request baseline TDM level for all PwE – All TDM ordering should achieve: • TDM request completed within 72 hours • Acceptance of TDM Case Interpretation & Recommendation by Medical Officers (MO)
Provide individualised epilepsy counselling	All epilepsy patients are given individualised epilepsy counselling at least once a year: • Seizure Diary • Safety advice • Lifestyle advice • Medication interactions and side effects review

Data analysis

In this study, we evaluated the impact of ERS in improving seizure control and measured the percentage of patients who had improvement in seizure control through seizure frequency reduction. The difference in seizure frequencies pre- and post-intervention was computed and accounted as reduction or increment in seizure frequency. The standard end point in clinical trials and clinical practice worldwide outlined a 50% reduction in seizure frequency from the baseline to indicate improvement in seizure control[10,11,12]. This indicator was selected as our primary outcome.

The number and demographic characteristics of patients attending ERS appointments at baseline, at 6-months and at 12-months period respectively were expressed as frequencies and percentages. Differences in the indicator achievement were analysed and described accordingly. As for the seizure frequency, the data were expressed as the mean and standard deviation (SD).

Wilcoxon signed rank test was used to compare the mean seizure frequency at baseline, at 6-months and 12-months, comparing before and after interventions at 6-monthly interval respectively. Data were analysed using the Statistical Package for Social Sciences (SPSS) 22.0. The significance level was fixed at 95% confidence interval.

Pharmacist-based interventions

The intervention period was divided into two parts. The first part was intended to improve the process of epilepsy care through workflow restructuring and the empowerment of both pharmacists and prescribers. The epilepsy patient registry was established and ERS record form was designed and used by all pharmacists with the aim to produce systematic and accessible information on patient disease progress during their follow-up appointments. In our centre, TDM for epilepsy patients were done on patients on AEDs therapy such as Sodium Valproate, Carbamazepine, Phenobarbitone and Phenytoin. TDM is well accepted as an objective measure of patient adherence towards medication prescribed, monitoring of drug toxicity and adverse drug reaction[13].

In this phase, prescribers were encouraged to use existing TDM services managed by the pharmacists. Prior to the interventions, prescribers were not well aware of the availability and accessibility of TDM service. A standardized ERS TDM Guide which consists of a compact-sized quick reference on TDM sampling times for TDM and the therapeutic range were distributed for prescribers. A checklist of patients' situation in which TDM need to be ordered was also included in the guide.

Empowerment of pharmacists was also emphasised in this phase where training and workshops were conducted to standardised TDM results calculation and interpretation. To this end, a Microsoft Excel worksheet with pre-set calculations was constructed to ease counterchecking of pharmacokinetic calculations and interpretations.

In the second part, the focus was to establish patients' awareness and knowledge about their disease. There was no standardized counselling or education materials regarding epilepsy self-management and medication given to patients in our setting prior to the intervention. The seizure diary that was distributed to each patient or caregiver contains diagrammatical explanation on AEDs, adverse reactions and interactions, and how to handle a patient experiencing a seizure. Using the seizure diary as counselling aid, pharmacists gave counselling on these aspects to the patients when distributing the diary.

Medication counselling was given to patients based on the ERS Epilepsy Medication Counselling Guide by trained pharmacists. The pharmacists provide individualised medication counselling based on patients' level of understanding, compliance and other drug related problems. They also gave an overview about safety and injury advice, lifestyle advice, family planning and contraception as well as other epilepsy-related issues.

The content of all documents and guides used in ERS were developed by the team member based on current references and guidelines and validated by 3 expert panels within the district that are not the group member of the study.

Results

Patient characteristics

A total of 254 patients with epilepsy registered in the clinic were screened and 203 of them were enrolled based on our inclusion and exclusion criteria. The final number of patients enrolled in ERS stands at 156 patients after 47 more patients were excluded due to the following reasons; transferred to other care setting (n=16), unable to be contacted (n=10), refused to join ERS (n=12), and other reasons (n=9). In terms of racial composition, Indians made up 40.3% (n=63), followed by 33.9% Malays (n=53), and 25.8% Chinese (n=40). The demographic characteristics of the study population were shown in Table 2.0.

ERS quality indicators

Measurement of improvement based on Epilepsy Review Service (ERS) components adopted from Quality Epilepsy Indicator Tool (QUIET)[9] was shown in Table 3.

Seizure control

The seizure control improvement among PwE was presented in Figure 1. We found that the percentage of PwE achieving at least 50% reduction in seizure frequency increased from a baseline of 9.6% to 37.2% at the end of 6-month, and 52.6% at the end 12-month period. The mean monthly seizure frequency dropped from 1.95 (SD 2.04, range 0-10, median 1.0) at the baseline to 1.91 (SD 2.02, range 0-7, median 1.0) at 6 months and the reduction was not significant (p=0.635). However, the mean monthly seizure frequency of patients was significantly reduced from 1.91 (SD 2.02, range 0-7, median 1.0) at the end of 6-month post intervention to 0.94 (SD 1.30, range 0-7, median 1.0) at the end of 12-month post intervention (p <0.001).

Table 2: Demographic characteristics of the study population

Characteristics	n (%)
Age, mean (SD)	52.21 (15.75)
range	20 - 75
Gender, n (%)	
Male	84 (53.9)
Female	72 (46.1)
Ethnicity, n (%)	
Malay	53 (33.9)
Chinese	40 (25.8)
Indian	63 (40.3)

Table 3: Measurement of improvement based on components of ERS

ERS component	Indicators	Percentage of patient, %		
		Before ERS	After ERS	
		0-month	6-month	12-month
Review for epilepsy	Number & type of seizure	8.3	65.40	97.9
	Drug side effects	5.1	55.70	77.9
Improve TDM service	Request baseline TDM level for all PwE	43.6	55.40	80.7
	TDM results informed within 72 hours	40.4	62.50	67.9
	Acknowledgement of TDM interpretations and recommendations by MO	41.7	67.80	70.7
Provide individualised epilepsy counselling	Provide seizure diary	0	65.40	96.4
	Provide safety advice	2.6	55.70	83.6
	Provide lifestyle advice	21.8	55.40	89.3
	Review medication interactions and side effects	20.5	62.50	82.1

Figure 1: Percentage of PwE achieving at least 50% reduction in seizure frequency and mean monthly seizure frequency at 0, 6 and 12 months (n=156)
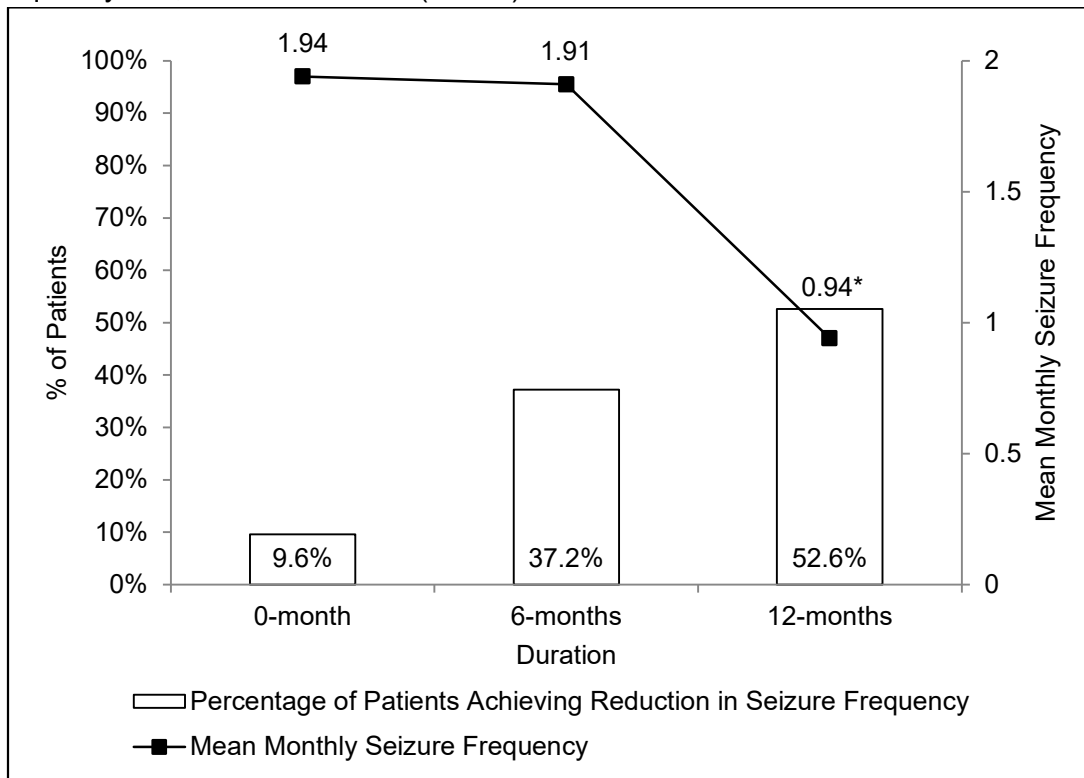
* statistically significant reduction of mean seizure frequency from month 6 to month 12 (p < 0.001)

Discussion

Pharmacists-led ERS interventions resulted in reductions in seizure frequencies, signifying improvement in seizure control. Through the implementation of ERS, we found that the longer the follow-up duration with ERS, better improvement can be attained in patients' seizure control. Positive observations as such were also the findings from previous studies abroad on structured care of PwE[8,14]. There was a need to address issues in epilepsy patient management, improvement in TDM service and provision of individualised patients' counselling at the primary care level. From the pre-remedial findings, poor documentation was identified and there was a lack of medication review for epilepsy patients. Pharmacists can play a major role in implementing structured epilepsy patient review and work together with other healthcare providers in a multi-disciplinary approach to ensure sustainability of the service.

Pharmacists in our setting were occupied with the role of dispensing most of the times. There was no standard epilepsy counselling guide or specific encounter scheduled for epilepsy patients for pharmacist's review. Through ERS, the competency of pharmacists in managing epilepsy patients has greater potential for improvement. ERS pharmacists can now provide individualised epilepsy counselling and manage TDM cases better using the guides provided. In addition, patients should be regularly reviewed (at least once a year) by pharmacists so that issues related to disease management such as lifestyle and safety issues can be resolved in a timely manner. With continuous review, patients and caregivers are better empowered and motivated to self-manage their condition[8,15].

The current practice for TDM service varies from one clinic to another and it affects the efficiency of service provided. Before implementing ERS, we discovered that the availability of baseline TDM level was recorded in only less than half of the patients. Additionally, only half of TDM

results were informed and acknowledged to prescribers within 72 hours. This was due to the current practice of informing prescribers of the TDM results during the patient's next appointment; and only upon request. To ensure that patients receive the optimum dose for their AEDs, TDM results should be communicated to prescribers within 72 hours. ERS has improved the efficiency of TDM service, whereby the time to inform, interpret and intervene TDM cases to prescribers had been shortened from 3 months to a standard of 72 hours. This is important as to ensure that the decision of dosage adjustment related to AEDs could be carried out promptly especially in toxic cases[16].

Epilepsy patients were seen by different prescribers each time they came for their follow-up appointments. We observed inconsistencies in the recording of patients' medical progress especially in terms of number and types of seizures, side effects of AED, and other related information. This led to difficulty to trace and understand patient's condition as a whole. Importance of documentation should be emphasized for better continuity of care for these patients[17], and this was established in ERS implementation.

The newly-designed Seizure Diary served as a useful tool for patients, pharmacists and prescribers. Patients and their caregivers were able to record the seizure frequency systematically and thus have better understanding to self-manage their conditions. In our view, pharmacists can monitor patients' condition and further assist prescribers to better manage patients' seizure episodes, disease control and optimisation of AEDs dosages and this was also supported by the findings of Halls *et al.*[18]. Furthermore, the diary also served as a medium for information transfer between primary, secondary and tertiary care or between public and private healthcare services especially in emergency, walk-in visits or unplanned admission to the wards. Hence, ERS has strengthened the communication between prescribers and pharmacists in handling epilepsy patient care and bringing benefits to the patients.

The ERS was implemented in order to provide better service for our epilepsy patients. We also believed that there will be different or possibly even better management of epilepsy patients in other primary care settings. It requires support from tertiary care settings in the form of advice and timely referral to ensure complicated epilepsy cases are managed appropriately.

The current study measured seizure control based on patient self-reported seizure frequency. Data was presumed to be accurately reported by the patient as a trustworthy source of data. Although actual seizure frequency may be poorly reported by patients, their ability to estimate and document their seizure frequency should not be ignored[19,20,21]. The number of hospital admissions, emergency visits or electroencephalogram would serve as a more objective clinical outcomes measurement. There were patients whom did not attain seizure control from our optimised care due to the nature of the disease[22]. The seizure frequency in these patients had been increased, unchanged or had less than 50% reduction throughout the study period. This preliminary finding proposed a repeated study with a control group to prove the effectiveness of the intervention. As ERS was implemented to all our patients as a service improvement, there was no group of patients without ERS intervention that can be assigned as control. Other issues that could be important concerns to address in future studies would be interventions on patient's compliance and cost-economic aspects of ERS implementation. As the ERS is still novel in our health care setting, there are still room for improvement to achieve better patient care and quality of life. Since the study was only conducted in a single setting, the findings may not represent the whole Malaysian population of PwE.

Conclusion

The project team has identified gaps in PwE management in primary care. This problem was addressed through the implementation of ERS as an intervention, and has thus far led to the improvement of seizure control in most of our patients. Our study suggested implementation of ERS can lead to improvement in seizure control through seizure frequency reduction over time. Continuous education sessions need to be arranged to ensure competency of the healthcare personnel involved.

An audit team shall be established in the future to ensure continual compliance to the improved standard of care. The project team will also carry out proactive approaches to address any issues regarding the service in a timely manner as well as enhancing the awareness of the epilepsy services provided within the primary care setting.

Acknowledgement

Conflict of Interest Statement

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Appendix 1

QUIET | QUALITY INDICATORS IN EPILEPSY TREATMENT

Adapted from AHRQ, 2014

CHRONIC EPILEPSY CARE

11. When a patient with epilepsy receives follow-up care, then an estimate of the number and types of seizures since the last visit and an assessment of drug side-effects should be documented.

12. When a patient with epilepsy receives follow-up care, then drug side-effects should be assessed and documented.

13. If the patient continues to have seizures after initiating treatment, then interventions should be performed. Options include:

- Compliance assessment/enhancement
- Monitor SM blood levels
- Increased SM dose
- Change SM dose
- Patient education regarding lifestyle modification
- Referral to higher level of epilepsy care

14. If a patient with epilepsy continues to have seizures after three months of care by a primary care provider, then further assessment by a neurologist should be conducted.

15. If a patient continues to have seizures after 12 months of appropriate care by a general neurologist, then the patient should receive a referral to an epilepsy specialist.

16. Patients with epilepsy should receive an annual review of information including topics such as:

- Chronic effects of epilepsy and its treatment including
- Drug side-effects, drug-drug interactions, and their effect on bone health,
- Contraception, family planning, and how pregnancy or menopause may affect seizures,
- Screening for mood disorders,
- Triggers and lifestyle issues that may affect seizures,
- Impact of epilepsy on other chronic and acute diseases,
- Safety issues (injury prevention, burns, driving restrictions, etc.)
- Other patient self-management issues