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Development of drug use indicators for epilepsy

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Abstract

Objective: To develop and use drug use indicators for epilepsy management.

Design: Descriptive prospective (outpatient) and retrospective (inpatient) drug use indicator survey.

Setting: Parirenyatwa Hospital epilepsy clinic and medical wards.

Subjects: Random sample of 35 cases of *status epilepticus* and a prospective series of 31 patients attending the epilepsy clinic.

Interventions: Indicators of drug use and patient care were developed and measured against national standard treatment guidelines (EDLIZ). Stock levels of all anti epileptic drugs (AEDs) were determined.

Main Outcome Measures: Adherence to EDLIZ; utility of indicator measures.

Results: For inpatients, average length of hospital stay was 8.7 days, with 60.0% adherence to EDLIZ. Less than half of the patients had an EEG performed and one third had an AED blood level measured. On discharge, patients were prescribed an average of 1.1 AEDs. Outpatient indicators showed good adherence to EDLIZ (89.2%) and an average of 1.2 AEDs drugs per prescription. Only 56.4% of prescribed drugs were actually dispensed. Most knew the dose and frequency of their medication but only 71.4% were aware of the expected duration of therapy.

Conclusions: The use of the indicators provided a snapshot of epilepsy management and indicated that problems may exist in the use of EEGs and in drug supply at Parirenyatwa Hospital. Sensitivity of the indicators to change and across levels of care still needs to be determined.

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Introduction

Rational drug use implies using the correct drug at the correct dose in the correct patient for the correct period of time.¹ Irrational use of drug leads to wasted resources and poor quality treatment with attendant increases in morbidity and mortality. Means to monitor drug use and factors which impact on drug use in an objective way are required

so as to make comparisons within an institution over time, to compare different institutions, to allow for assessment of the impact of interventions and to use as a supervisory tool so as to highlight problems in prescribing or drug use patterns. Indicators have been developed by the World Health Organisation (WHO) to assess drug use at clinic or out patient facilities² examining patient care e.g. average consultation time, prescribing e.g. average number of

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drugs per prescription, and facility indicators e.g. availability of key drugs. The measurement of indicators is intended to be a simple means of monitoring drug use behaviour using, as much as possible, routinely collected data. They are intended to be used as part of clinical audit to monitor the quality of care being provided to patients, and also to assist in identifying potential problems which may require more in-depth assessment. However, the existing drug use indicators are generic and do not deal with specific diseases. In addition, there are no indicators for hospital inpatients or hospital departments where the results could be used by the administration in policy development and drug management. There is need to develop drug use indicators for evaluation of hospital prescribing patterns in selected health problems.

Epilepsy is a relatively common neurological condition with a prevalence of between 0.4% and 0.75% in developed countries³ and perhaps up to 5% in some developing countries.⁴ The management of epilepsy has been intensively studied both in terms of diagnosis, acute and long term treatment. Almost three quarters of patients can have their seizures controlled on monotherapy⁵ and the titration of dosages to seizure control and side-effects is well recognised. Internationally, quality of care standards have been developed for the treatment of epilepsy and in Zimbabwe, there are standard treatment guidelines for the management of epilepsy including drug therapy (EDLIZ).⁶ Thus, epilepsy lends itself to audit through the measurement of indicators since there are standards for comparison. The main objective of this study was to develop and measure disease-specific drug use indicators for epilepsy management at in patient and out patient settings.

Materials and Methods

Possible indicators of the care of epilepsy patients were devised using a theoretical basis for both in patient and out patient scenarios. The WHO core and complementary prescribing indicators were used for some of the measures.² These indicators are shown in Table I, together with a brief explanation where necessary. The indicators were measured at Parirenyatwa Hospital, Harare, Zimbabwe, a large referral and teaching hospital.

The in patient indicators were measured retrospectively using a sample of 35 cases of status epilepticus selected from all such records for the period 1 January 1998 to 31 December 1999 (total 156 cases; 22.4% sample) using random systematic sampling. The labourious nature of record retrieval precluded validation of the hospital coding system (based on the International Classification of Diseases 9th Revision),⁷ but all records retrieved were of *status epilepticus* based on the clinical picture made up of both physician and nursing notes. No other exclusion or inclusion criteria were applied.

Out patient indicators were measured prospectively on 31 consecutive patients at the Epilepsy Clinic, Parirenyatwa Hospital during the period 3 January to 14 February 2000.

Table I: Proposed epilepsy inpatient and outpatient drug use indicators measured in the study.

Inpatient indicators

- Average number of AEDs prescribed on discharge
- Percent of AEDs prescribed by generic name
- Percent of prescribed AEDs present in essential drug list (EDLIZ)
- Percent of patients with blood level taken for any reason during hospital stay
- Percent of patients with antiepileptic drug assay performed during hospital stay
- Percent of patients with an EEG done during hospital stay
- Percent adherence to standard treatment guidelines
- Average length of hospital stay

Outpatient indicators

- Average number of drugs per prescription
- Percent AEDs prescribed by generic name
- Percent prescribed AEDs present in essential drugs list (EDLIZ)
- Average consultation time (time between patient entering and leaving consultation room)
- Average dispensing time (total from receipt of prescription to patient leaving)
- Average dispensing counselling time (time taken when handing over prescription)
- Percent of patients satisfied with care
- Percent of patients who have returned for review
- Percent of patients with uncontrolled seizures
- Percent of patients with an EEG performed in the past year
- Percent of patients with AED blood level taken in past year
- Percent patients members of epilepsy patient support group
- Percent adherence to standard treatment guidelines
- Percent prescribed drugs actually dispensed
- Percent adequate labelling of dispensed medication
- Percent patient knowledge of drug dose, frequency and duration of therapy

This clinic handles referred new patients for full diagnostic workup, patients with problematic or resistant epilepsy as well as some well-controlled patients for review. A member of the Epilepsy Support Foundation of Zimbabwe, a patient support group, is usually present at the clinic for consultation.

For generic prescribing, any abbreviations or incomplete drug names were not considered to be the generic name, whilst for valproic acid, the names valproate, and sodium valproate were also considered acceptable generic names.

The Zimbabwe standard treatment guidelines set out in EDLIZ 1994⁶ were used for comparison. Drug management of epilepsy is based on monotherapy starting with phenobarbitone as drug of first choice, followed by phenytoin and carbamazepine respectively i.e. phenobarbitone first, if ineffective change to phenytoin and then to carbamazepine. Sodium valproate may be prescribed by specialists. Ethosuximide was indicated for absence seizures. For *status epilepticus*, oxygen plus *i.v.* dextrose 50% plus *i.v.* diazepam or *i.v.* phenobarbitone or *i.m.* paraldehyde or *i.v.* phenytoin is the prescribed treatment. In terms of adherence to the standard treatment guidelines (STGs), the use of any of the alternatives as a single drug was considered acceptable since it was not possible to accurately determine if the drugs had been commenced in the order specified in the STGs. The drug had to be used at the dose recommended in the STGs to meet the criteria of adherence.

The stock levels of all AEDs were assessed at the main pharmacy in the hospital since availability can impact on prescribing patterns. Both dispensary shelves as well as the main store were examined for the drugs which were reported as either in or out of stock. This check was performed only at the start of the study period. Permission to conduct the study was received from the Hospital Medical Superintendent.

Sample Size.

According to WHO drug use indicator methodology, a sample of 30 drug use encounters at an institution provides adequate power to provide a cross sectional overview of drug use at that facility.²

Results

Of the six oral AEDs which are recommended in EDLIZ 1994 for the management of epilepsy, only three phenobarbitone, carbamazepine and sodium valproate were in stock at the hospital's main pharmacy, with phenytoin, clonazepam and ethosuximide out of stock. Of the drugs recommended for *status epilepticus*, only diazepam injection and dextrose 50% *i.v.* fluid were available with parenteral phenobarbitone, phenytoin and paraldehyde not in stock. The indicator values measured are shown in Tables II and III

Table II: Inpatient indicators for epilepsy care at Parirenyatwa Hospital (n = 33).

Indicator	Value
Ave number of AEDs prescribed at discharge	1.1
% AEDs prescribed by generic name	100.0
% AEDs prescribed in EDLIZ	97.2
Ave length hospital stay (days)	8.7
% adherence to STGs	60.0
% patients with EEG	43.3
% patients with blood sample (any reason)	66.7
% patients with serum AED assay	36.7

AED — Antiepileptic drug.

EEG — Electroencephalogram.

EDLIZ — Essential Drugs List for Zimbabwe.

STGs — Standard treatment guidelines.

Inpatient Indicators.

Of the 35 cases, two patients died before discharge and were not incorporated into the prescribing indicators or the length of hospital stay (Table II). The average length of hospital stay was 8.7 days, with 60.0% adherence to standard treatment guidelines for drug management. Less than half of the patients had an EEG performed during their hospitalisation and just over one third had a blood sample drawn for serum assay of antiepileptic drugs. On discharge, patients were prescribed an average of 1.1 AEDs drugs.

Outpatient Indicators.

In general, there was good adherence to standard treatment guidelines (89.2%) with complete generic prescribing and an average of 1.2 AEDS drugs per prescription (Table III). However, only 56.4% of prescribed drugs were actually dispensed but 77.4% of patients were satisfied with the care they received. Over 85% of patients were returning for

Table III: Out patient indicators of epileptic drug use at Parirenyatwa Hospital (n = 31)

Indicator	Value
Ave number of AEDs per prescription	1.2
% AEDs prescribed by generic name	100.0
% AEDs prescribed in EDLIZ	97.1
% adherence to STGs	89.2
Ave consultation time (min)	6.6
Ave dispensing time (s)	111
Ave dispensing counselling time (s)	11.5
% patients satisfied with care	77.4
% review patients	87.1
% patients with uncontrolled seizures	12.9
% patients members of support group	80.7
% patients with AED assay in past year	22.6
% patients with EEG in past year	80.7
% prescribed drugs actually dispensed	56.4
% drugs correctly labelled:	
• drug name	100.0
• strength	100.0
• quantity	95.5
• date	81.8
• patient's name	50.0
• dose	100.0
• facility name	36.4
% patients with knowledge of:	
• drug dose	93.6
• dose frequency	87.1
• duration of treatment	71.0

review with 12.9% having uncontrolled seizures. Most (80.7%) had had an EEG performed over the past year. About 90% of patients knew the dose and frequency of their medication but only 71.4% were aware as to how long they would have to take the drugs for. Labelling of medication containers was acceptable apart from the name of the patient (50% of labels) and the facility name (36.4%). Most patients were members of a patient support group.

In general, data for all inpatient indicators were easily extracted from the medical records and the time required would be markedly reduced if only a few priority indicators were to be measured. Out patient indicators required a bit more time due to the need for observations and interviews. However, the time would also be shortened if only a few core indicators were to be measured.

Discussion

Indicator studies were initially developed as a tool for rapid assessment of drug use² where it is assumed that the diagnosis made is correct. As such they should be relatively quick and easy to measure using routinely gathered data where available. Indicators for measurement of drug use in general have been previously developed² but they are in the main unsuitable for the assessment of prescribing within a particular disease state. The aim of this study was to develop a more specific set of indicators, based on the WHO core and complementary indicators, to be used for investigation of drug use within the management of epilepsy. No differentiation was made between adult and

paediatric patients in this study. Whilst this may add a degree of variability into the results, it does not detract from the potential usefulness of the indicators, which could be limited to study particular age groups in practice.

Inpatient Indicators.

Whilst not possible to validate that all of the 156 cases identified were *status epilepticus* there is no reason to believe that this introduces bias into the results since all the selected cases did represent *status* according to the clinical picture.

All of the proposed indicators for epilepsy in patients were able to be measured with relative ease retrospectively from the patient case notes. A number of interesting issues arise from the indicators which were measured in this study. Less than half of the patients had received an EEG and only two thirds had had a blood sample drawn for any reason e.g. to measure blood glucose or AED drug levels. One would normally expect higher levels of use of the EEG and blood sampling to exclude non-epileptic causes of seizures⁸ although the resource limitations of a developing country must be taken into account.⁹ It is possible that in some cases the physicians were aware of the past history of epilepsy in these patients and assumed a diagnosis of *status epilepticus*. The low level of blood sampling may also reflect poor laboratory backup where results are slow to come back to the wards so they are of little consequence on the clinical intervention.

The average number of drugs on discharge is low suggesting that attempts are made to maintain patients on monotherapy even after an episode of *status*. Generic prescribing is high but adherence to standard treatment guidelines was relatively low, something which should be investigated further to determine the reasons for this.

Outpatient Indicators.

A recent survey of drug use in a variety of public health institutions in Zimbabwe (Zimbabwe Public Sector Survey)¹⁰ found the average number of drugs to be 1.8 with 90% prescribing by generic name. One would normally expect the average number of drugs in a referral hospital to be higher than this figure, which also includes primary care centres. However, compared to this data, the average number of drugs per prescription in this study was low suggesting that monotherapy is being adhered to in the main whilst generic prescribing was somewhat higher. This view is supported by the adherence to standard treatment guidelines which was around 90% of cases, but it is also possible that the low average number of drugs was due to many being out of stock.

In terms of patient care indicators, The Zimbabwe Public Sector Survey found patient knowledge of the dosing of their drugs to be around 90% and of the duration of therapy 79%, both of which are similar to the findings of this study. However, one would wish people with epilepsy to have a better understanding of how long they will be expected to take their medication due to the chronic nature of the disease and the serious consequences if they do not adhere to prescribed therapy.

The average consultation time (6.6min) was slightly higher than that reported in the Zimbabwe Public Sector Survey (5.1 min) and is rather short when allowing for adequate history taking and examination. However, the caseload and the fact that the majority of patients were simply attending for review should be taken into account. The dispensing/counselling time was very short (11.5s) and barely enough time to give instructions on how to take the medicines. In spite of this, about 90% of patients knew the dose and dosing frequency. This could be attributed to the fact that many patients were attending for review and had taken the drugs before. The level of adequate labelling may also have overcome adverse consequences of the short dispensing/counselling time.

It is of concern that just over 50% of the prescribed drugs had been dispensed due to poor stock levels. In spite of this, only 12% of patients had uncontrolled seizures but this may relate more to the availability of drugs in the previous month. Some patients will be able to afford purchasing their drugs from private pharmacies but the majority would rely on the pharmacy within the hospital. Over three quarters of patients reported that they were satisfied with the care they were receiving.

Conclusion

This study has described the development of drug use indicators for epilepsy for use in both in and out patient settings which will allow for the audit and supervision of epilepsy care services. Not all indicators need to be measured as this will depend on the purpose of the monitoring of care. As shown above, they are able to provide an insight into the management of epilepsy patients and to indicate areas where problems may exist and which require more detailed study. For their full interpretation there needs to be data collection on a serial basis with prior studies for comparison, both nationally and internationally. The next step will be assessing these indicators at other hospitals and levels of care to determine their sensitivity to change.

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