

# DEMONSTRATION PROJECT ON EPILEPSY IN BRAZIL

## Situation assessment

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**ABSTRACT - Purpose:** To provide a situation assessment of services for people with epilepsy in the context of primary health care, as part of the Demonstration Project on Epilepsy in Brazil, part of the WHO/ILAE/IBE Global Campaign 'Epilepsy out of the shadows'. **Methods:** We performed a door-to-door epidemiological survey in three areas to assess the prevalence of epilepsy and its treatment gap. We surveyed a sample of 598 primary health care workers from different regions of Brazil to assess their perceptions of the management of people with epilepsy in the primary care setting. **Results:** The lifetime prevalence of epilepsy was 9.2/1,000 people [95% CI 8.4-10.0] and the estimated prevalence of active epilepsy was 5.4/1,000 people. Thirty-eight percent of patients with active epilepsy were on inadequate treatment, including 19% who were taking no medication. The survey of health workers showed that they estimated that 60% of patients under their care were seizure-free. They estimated that 55% of patients were on monotherapy and that 59% had been referred to neurologists. The estimated mean percentage of patients who were working or studying was 56%. Most of the physicians (73%) did not feel confident in managing people with epilepsy. **Discussion:** The epidemiological survey in the areas of the Demonstration Project showed that the prevalence of epilepsy is similar to that in other resource-poor countries, and that the treatment gap is high. One factor contributing to the treatment gap is inadequacy of health care delivery. The situation could readily be improved in Brazil, as the primary health care system has the key elements required for epilepsy management. To make this effective and efficient requires: i) an established referral network, ii) continuous provision of AEDs, iii) close monitoring of epilepsy management via the notification system (*Sistema de Informação da Atenção Básica - SIAB*) and iv) continuous education of health professionals. The educational program should be broad spectrum and include not only medical management, but also psycho-social aspects of epilepsy.

**KEY WORDS:** epilepsy, anti-epileptic drug, primary care, seizure.

### **Projeto demonstrativo em epilepsia no Brasil: avaliação situacional**

**RESUMO - Objetivo:** Avaliar a situação da assistência à epilepsia no contexto da atenção primária sob o Projeto Demonstrativo em epilepsia no Brasil, parte da Campanha Global Epilepsia Fora das Sombras da WHO/ILAE/IBE. **Método:** Fizemos um levantamento epidemiológico para definir a prevalência e lacuna de tratamento em epilepsia. Avaliamos a percepção de 598 profissionais de saúde da atenção básica de diferentes regiões do Brasil sobre epilepsia e seu manejo na rede básica de saúde. **Resultados:** A prevalência acumulada de epilepsia foi de 9,2/1000 pessoas (95%IC= 8,4-10) e a prevalência estimada de epilepsia ativa foi de 5,4/1000 pessoas. Trinta e oito por cento dos pacientes com epilepsia ativa estavam sendo tratados inadequadamente, incluindo 19% que estavam sem medicação. A enquete com os profissionais de

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saúde mostrou que a média estimada de pacientes livre de crises sob os cuidados dos mesmos era de 60%. A média estimada de porcentagem em monoterapia era de 55%. A média estimada de porcentagem de referência para neurologistas era de 59%. A média estimada de porcentagem de pacientes que estavam trabalhando ou estudando era de 56%. A maioria dos médicos não se sente confiante em atender uma pessoa com epilepsia. *Discussão:* A análise situacional da Fase I - estudo epidemiológico nas áreas de interesse do PD mostrou que a prevalência da epilepsia é similar a outros países em desenvolvimento e a lacuna de tratamento é grande. Um dos fatores importantes para a lacuna de tratamento é a falta de adequação à assistência na atenção básica. Essa situação pode ser revertida no Brasil, pois os elementos-chaves existem na rede básica para o manejo de pessoas com epilepsia. Entretanto, para torna efetivo e eficiente é preciso i) estabelecimento de um sistema de referência e contra-referência, ii) fornecimento contínuo de medicação anti-epiléptica, iii) monitorização de manejo de pessoas com epilepsia através de sistema de notificação (SIAB – Sistema de Informação da Atenção Básica), e iv) educação continuada de profissionais de saúde. O programa educacional deve ser amplo incluindo não somente manejo médico, mas também aspectos psico-sociais.

**PALAVRAS-CHAVE:** epilepsia, droga-antiepiléptica, atenção primária, crise epiléptica.

Brazil is a South American country of continental dimensions (8,511,965 km<sup>2</sup>). It is divided into 27 federal units, and in 2000 had a population of 170 million. The gross internal product (GIP) of the country (2000) averaged 6,560 Brazilian Reals (~ US\$ 2,630) per capita, with striking regional differences. The unemployment rate was estimated as around 6% in metropolitan areas in 2000. The illiteracy rate decreased from 25.5% in 1980 to 20% in 1991 and, in some regions in those less than 24 years old, is four percent. Thirty years ago, the population growth in Brazil was three percent per year, but presently is 1.9 percent mainly due to a falling birth rate. Eighty percent of the population has become urbanized in the last three decades, a fact which may have contributed to this marked decline in population growth.

Brazil has a well-structured federal constitution which states that health is the right of every citizen and that it is the duty of the State to provide this. This has been stated in law since 1990 when the Unified Health System (*Sistema Único de Saúde [SUS]*) was created. SUS comprises the combined health care delivery of local, state, and federal organisations and institutions. The same law allows for the coexistence of private medicine in its various forms. It is estimated that SUS provides health care coverage to 77% of the population.

Epilepsy is a common neurological disorder and affects approximately 50 million people worldwide, of whom five million live in Latin America and the Caribbean<sup>1</sup>. Few epidemiological studies have been carried out in Brazil. In 1986 the prevalence of the epilepsies in Greater São Paulo was 11.9/1,000 (SP)<sup>2</sup>, and in 1992 prevalences of 16.5 and 20.3/1,000 were found for active and inactive epilepsies respectively in Porto Alegre (RS)<sup>3</sup>. The prevalence in São José do Rio Preto was 18.6/1,000<sup>4</sup>. According to the Ministry

of Health, the epilepsies rank 30<sup>th</sup> among causes for hospitalization. Epilepsy was responsible for over 40 thousand hospital admissions per year in the early 1990s (approximately 0.54/1,000 inhabitants). It is unclear how many of these admissions are of patients in status epilepticus or with serial seizures.

Risk factors such as parasitic diseases may explain the high incidence of epilepsy in developing countries, including Brazil. Neurocysticercosis is the most prevalent brain disease caused by parasites, and is endemic in the southeastern, south, and central-western regions of Brazil. It is the most frequently diagnosed risk factor associated with epilepsy in adults in these areas. Perinatal brain damage is also said to contribute to the high incidence of epilepsy, particularly in regions with inadequate ante-natal care. High incidence of road traffic accidents leading to traumatic brain injury may also be an important risk factor for epilepsy. Thus the basic strategy for primary prevention of epilepsy in a country like Brazil should include improved ante- and peri-natal care, control of infectious and parasitic diseases, and reduction of brain injury due to trauma and stroke.

In addition to the increased risk of morbidity and mortality associated with epilepsy, patients face stigma placed on them by the community. Stigmatization prevents patients disclosing their condition, and may stop them seeking treatment. This clearly has an impact on employment, education, and ultimately on a patient's quality of life and societal inclusion. Knowledge about epilepsy by people in the general population is generally unsatisfactory and is surrounded by misperceptions. The lack of current information about epilepsy helps to perpetuate old prejudices against epilepsy.

Treatment with first line antiepileptic drugs (AEDs) medication can render up to 70-80% of patients seizure-

free<sup>5</sup>. In 1999, the most commonly prescribed AEDs in Brazil were carbamazepine (29%), clonazepam (22%), phenobarbital (17%), phenytoin (11%), and valproate (8%). These prescriptions came mainly from neurologists (45%), general practitioners (21%), psychiatrists (12%), and pediatricians (8%)<sup>6</sup>. It has been estimated, however, that 70% of patients in developing countries do not receive antiepileptic drug treatment<sup>7</sup>. The treatment gap has been estimated as being around 40% in Porto Alegre in Southern Brazil. A survey<sup>8</sup> in two cities (Campinas and São José do Rio Preto) estimated that the quantity of AEDs provided by the government in 2000 would treat 55% and 60% in each city respectively of the estimated pool of patients with epilepsy under SUS care.

Some patients with partial epilepsy refractory to current AEDs are potentially candidates for surgical treatment, which can be highly effective, achieving total seizure control in up to two thirds of people. Candidates for epilepsy surgery are referred mainly to centres affiliated to the Federal Epilepsy Program Services or to private services. Currently, despite the many emerging centres for surgical treatment, only eight are approved by the Ministry of Health for epilepsy surgery; these are in São Paulo (5); Goiás (1), Paraná (1) and Rio Grande do Sul (1).

Since 1997 a global effort to drive epilepsy out of the shadows has been promoted by the World Health Organization (WHO), the International League Against Epilepsy (ILAE) and the International Bureau of Epilepsy (IBE)<sup>9</sup>. In 2002 the Global Campaign entered the second phase of its activity, setting up demonstration projects (DPs)<sup>10</sup>. The main objective of

a DP is to demonstrate that a given set of procedures can provide a cost effective way to treat epilepsy<sup>11</sup>. The participating countries within the second phase of the Global Campaign were Brazil, China, Zimbabwe and Senegal<sup>12-14</sup>. ASPE (*Assistência à Saúde de Pacientes com Epilepsia*), a non-governmental organization, was created to execute the DP in Brazil<sup>15</sup>. The DP (duration four years) was launched in September 2002, and its framework is described in detail in the Appendix.

This paper brings the results based on previous publications<sup>16,17</sup> of the phase I of the Demonstration Project on Epilepsy part of the WHO/ILAE/IBE Global Campaign Against Epilepsy, in Brazil<sup>15</sup>. We aim to provide a concise overview of the situation regarding: i) the pharmacological treatment gap in the study area of the DP<sup>16</sup> and ii) the perceptions of primary health care workers on the management of people with epilepsy in the primary care setting<sup>17</sup>.

#### SITUATION ASSESSMENT

In Phase I of the DP, a door-to-door community survey to assess the prevalence and treatment gap of epilepsy was conducted in three areas of two municipalities (Campinas and São José do Rio Preto [SJRP]) in Southeast Brazil. The total population in these three areas was 96,300 people. A validated epidemiological questionnaire with sensitivity 95.8% and specificity 97.8% for epilepsy screening was used, and a neurologist further ascertained the positive cases. A validated questionnaire based on a household possessions inventory was used to produce a socio-economic classification that ranges from Class

Table 1. Treatment of active epilepsy according to social classes in Campinas and São José do Rio Preto<sup>16</sup>.

Social classes	Adequate treatment		Inadequate treatment			Active epilepsy (total number)	Treatment gap (% [95%CI])
	Mono-therapy	Poly-therapy	Inadequate dosage (% [95% CI])	Non treated (% [CI])	Unknown (% [95%CI])		
A	2	2	1 (14.3 [2.6 to 51.3])	1 (14.3 [2.6 to 51.3])	1 (14.3 [2.6 to 51.3])	7	3 (42.9 [6 to 79])
B	21	9	1 (2.4 [0.4 to 12.6])	5 (12.2 [5.3 to 25.5])	5 (12.2 [5.3 to 25.5])	41	11 (26.8 [13 to 40])
C	50	32	22 (15.4 [10.4 to 22.2])	31 (21.7 [15.7 to 29.1])	8 (5.6 [2.9 to 10.7])	143	61 (42.7 [35 to 51])
D+E	46	17	11 (11.3 [6.5 to 19.2])	18 (18.6 [12.1 to 27.4])	5 (5.2 [2.2 to 11.5])	97	34 (35.1 [26 to 45])
Not classified	2	-	-	-	2	-	-
Total	121	60	35 (12.1 [8.8 to 16.3])	55 (19.0 [14.9 to 23.9])	19 (6.6 [4.2 to 10])	290	109 (37.6 [32.2 to 43.3])

*Table 2. Reasons given for being off treatment by people with active epilepsy<sup>16</sup>.*

Reasons for not using medicine	Campinas and São José do Rio Preto		
	n	%	95% CI
Side effects	2	3.6	1.0 to 12.3
Do not know about treatment	7	12.7	6.3 to 24.0
Do not want treatment	28	50.9	38.1 to 63.6
Medical orientation	11	20	11.6 to 32.4
Never sought treatment	7	12.7	6.3 to 24.0
Total	55	100	

A1 (highest) to E (lowest). We defined adequate epilepsy treatment as regular use of antiepileptic drugs (AEDs) at standard dosage. The lifetime prevalence of epilepsy was 9.2/1,000 people [95% CI 8.4-10.0] and the estimated prevalence of active epilepsy was 5.4/1,000 people. The prevalence of active epilepsy was higher in the more deprived social classes (7.5/1,000 in Class D+E compared with 1.6/1,000 in Class A). The prevalence of active epilepsy was also higher in elderly people (8.5/1,000 in those aged 60 years or older).

Sixty-two percent of people with active epilepsy were on adequate treatment, the remaining 38% were not; this included 19% who were not on any medication; the figures were similar in different socio-economic groups (Table 1).

The reasons for the treatment gap may be multifactorial<sup>16</sup>, ranging from logistic aspects of health care delivery to ignorance of the existence of medical treatment. In our study, the treatment gap was defined as no or inadequate treatment. The main reason given by people with active epilepsy who were not on treatment was that they were not keen on treatment (Table 2). It is important to point out that in this group of patients without medication around one quarter either never sought medical treatment or were not aware of the existence of medical treatment for the condition.

Campinas and São José do Rio Preto are located in one of the wealthier regions of Brazil, and there is a good public and private health care system available. Therefore, our findings are likely to represent the best scenario in the spectrum of epilepsy management in Brazil.

To assess the perception of primary health care workers on the management of people with epilepsy in the primary care setting we carried out a survey of 598 professionals allied to medicine and physicians from the Family Physician Program. The participants of this survey were interviewed using a structured questionnaire during a National Meeting of

Family Physicians. The information collected reflects an educated guess rather than "real data" on the primary health care system. Nevertheless we believe that the study is adequate for obtaining an overview of how primary health care professionals perceive epilepsy, and the current state of its management in Brazil. Overall both professionals allied to medicine and physicians had an appropriate perception of epilepsy.

The survey of physicians estimated that 0.78% (n=286, range 0% to 8%, median=0.37%) of the population had consulted them for epilepsy in the previous year. This estimate is relatively close to the estimated prevalence of epilepsy. Contrary to the negative impression of the primary health care system, the data seem to suggest that people with epilepsy seek help in the primary health care system. Nevertheless, a number of physicians, mostly paediatricians, stated that they saw a higher percentage (>3%) of the population for epilepsy; which may suggest that either there is a higher prevalence of epilepsy in the paediatric age group, or that epilepsy is over-diagnosed. Misdiagnosis is not uncommon in the paediatric age group. This is particularly so in cases of febrile seizures, which are often erroneously considered as epilepsy and often treated with long-term AED therapy.

It has been estimated that 70% of people with epilepsy can achieve seizure control with one AED<sup>5</sup>; these are the people who might be expected to be under the care of primary care physicians. Nevertheless, only 55% (n=289, range 0% to 100%) of patients were estimated by physicians to be on monotherapy and 60% (n=287, range 0% to 100%, median=70%) of patients were estimated to be seizure free. The survey showed that 59% (n=303, range 0% to 100%) of patients are referred to neurologists and one-third for psychological support. Possible interpretations could be either that the physicians are dealing not only with low complexity cases, or that treatment is inadequate. The former interpretation

would reflect inefficient referral systems to secondary or tertiary health care level. The latter interpretation would therefore be more likely to be correct, as it is common to find inadequate AED therapy in the community (either no AEDs or AEDs used in sub-optimal dosage), and if the treatment were adequate one would expect a lower referral figure than that observed. Either interpretation, together with the fact that a majority (73%) of health professionals do not feel confident in managing people with epilepsy, reinforces the necessity of providing training in the management of people with epilepsy. This would be feasible, as 90% of physicians who did not feel confident in managing people with epilepsy said they would participate in a training course for improving the quality of health management.

Social inclusion appeared to be an important issue, as only half of the patients were thought to be socially engaged. This number probably reflects the rate of seizure-free patients, as patients who are not seizure-free have lower chances of getting a job or going to school.

The situation assessment derived from phase 1 in the catchment areas of the DP showed that the prevalence of epilepsy is similar to other resource-poor countries, and that the treatment gap is high. One of the important factors contributing to the treatment gap is inadequacy of health care delivery. The situation could readily be changed in Brazil as the primary health care system has the key elements required for epilepsy management. To make this effective and efficient requires: i) an established referral network, ii) continuous provision of AEDs, iii) close monitoring of epilepsy management via the notification system (*Sistema de Informação da Atenção Básica - SIAB*) and iv) continuous education of health professionals. The educational program should be broad spectrum and include not only medical management, but also psychological support for people with epilepsy and the management of social aspects of epilepsy.

#### **APPENDIX – DEMONSTRATION PROJECT PROTOCOL DESIGN**

This protocol is for a demonstration project testing the feasibility of diagnosing and treating epilepsy at primary care level with rational use of first line antiepileptic drugs (phenobarbital, phenytoin, carbamazepine and valproic acid). The long-term aim is to integrate epilepsy management into the existing primary health delivery system in a sustainable manner. If this project is shown to be effective it will be recommended for implementation nationwide.

#### **Overall aims**

- To generate procedures that will improve the identification and management of people with epilepsy in urban areas within the existing primary health care system and with community participation.
- To develop a model of epilepsy treatment at primary health level that can be applied nationwide

#### **Specific aims**

1. To assess current management practices (identification, treatment, and follow-up) of patients with epilepsy in urban areas of the country.
2. To estimate: a) the prevalence of active forms of epilepsy, b) the size of the treatment gap via an active case-finding methodology, and c) changes that this project may bring to these figures in the study area.
3. To ascertain the etiology and risk factors associated with epilepsy in the community.
4. To reduce and eradicate preventable causes of epilepsy in the community.
5. To ascertain the knowledge, attitudes and practice (KAP) of epilepsy amongst health practitioners at primary health level prior to the study and after they have undergone training for epilepsy.
6. To develop technical norms for identification, education, treatment and follow-up of patients with epilepsy at primary health care level
7. To carry out a feasibility study of the treatment of forms of epilepsy using first line antiepileptic drugs by primary health care physicians.
8. To develop strategies for the implementation of a cost-effective surgical program for the treatment of epilepsy.
9. To develop a program for continuous professional education on epilepsy for primary health workers.
10. To promote public awareness about epilepsy via an educational program aimed at the community.
11. To promote continuing education for primary and secondary school teachers and dissemination of information on epilepsy.
12. To develop a program to de-stigmatize epilepsy and improve its social acceptance.
13. To develop local advocacy and support groups for people with epilepsy.
14. To reduce the economic and social burden of epilepsy in the study areas.

#### **Methodology**

This demonstration project has three parts.

1. *Epidemiological estimation* – This will provide a realistic estimation of the prevalence of epilepsy and of untreated active epilepsy in the study area.

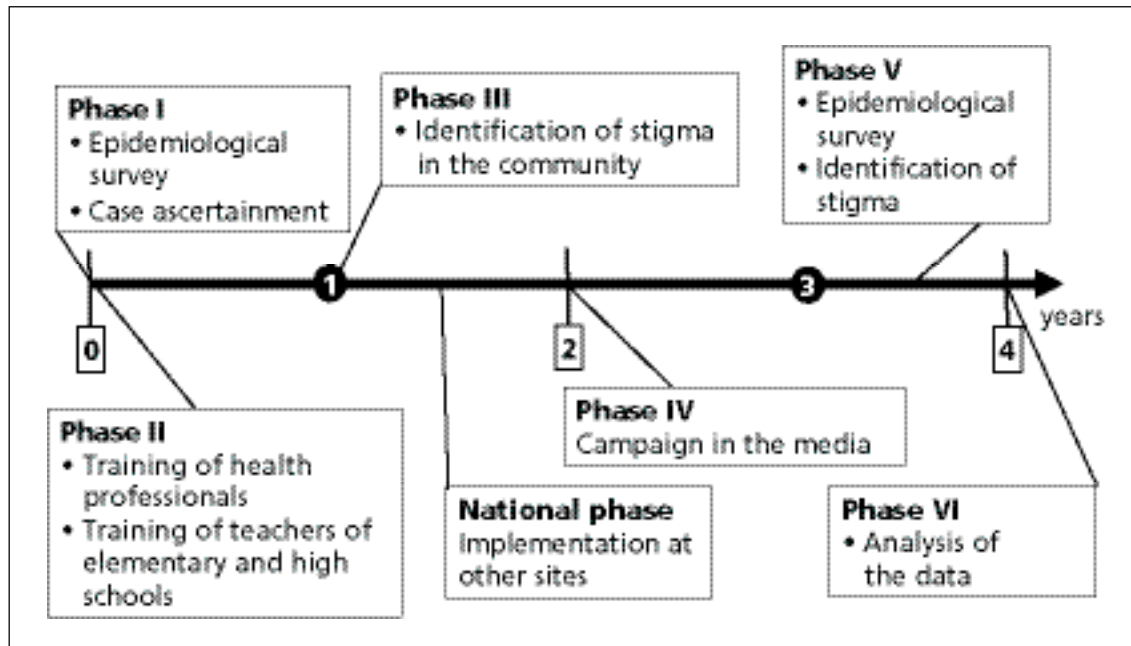


Fig 1. Timeline of demonstration project in Brazil.

2. *Service delivery (intervention study)* – This will cover the issues of diagnosis, AED treatment, follow-up and referral networks.

3. *Education, social and community intervention* – This will cover the educational and social aspects of the project

#### Timeline

This is a four year project subdivided into six phases as show in Figure 1.

#### Setting

The State of São Paulo is located in Southeast Brazil. It is one of the country's most populous and prosperous states. The region of Campinas, one of the five large regions in the State of São Paulo, comprises 95 urban communities and has a population of around 4.7 million. This region is responsible for nine percent of the national GIP. The city of Campinas has approximately one million inhabitants. The region of São José do Rio Preto comprises 96 municipalities and belongs to the eighth administrative region of the State of São Paulo. The city of São José do Rio Preto has approximately 340,000 inhabitants.

The health care systems of Campinas and São José do Rio Preto have primary, secondary, and tertiary care centers. Primary care consists of home care, health centers general support clinics, and diagnostic and therapeutic support services (Serviço de Atendimento Diagnóstico e Terapêutico - SADT). On a secondary level, as well as SADT, there are specialized outpatient

clinics and local and macro regional hospitals. On a tertiary level, there are specialized outpatient clinics (University Hospitals), regional hospitals, and SADT.

The district of Barão Geraldo is located in the north of Campinas. It has a structured health care system, with a primary health center that is undergoing expansion to serve 60% of the local population of around 40,000 inhabitants. The health center has four teams, each with a general physician, a pediatrician and a nurse, responsible for the sub-regions. A new program based on the concept of "family physician" is being implemented and should add to the existing setup in middle of 2002.

The hospital complex of the State University of Campinas (UNICAMP) is the main referral tertiary center in the Campinas region. It has 597 beds and provides 450 thousand medical consultations a year, 22 thousand admissions, and 460 thousand non-medical appointments (social services, psychology, occupational therapy, audiology, pedagogy and physiotherapy) each year. The Neurology Department of UNICAMP has specialized clinics for adult and pediatric patients with epilepsy, and includes a surgical program for patients with medically refractory epilepsies. Patients with epilepsies are largely referred by health centers, emergency clinics and general clinics in the city and region of Campinas (55%), from other nearby regions (40%) and also from other states (5%).

The districts of Santo Antonio and Jaguaré are located in the northwest, Region IX of São José do Rio Preto. This has a structured primary health sys-

tem with a family physician program and is open 24 hours. Each center is designed to provide 100% health care cover for 55,000 inhabitants in the region (25,000 are covered by the health center in Santo Antonio and 30,000 in Jaguaré). In these two centers, there are 80 physicians and 16 nurses in total, plus social assistants, technicians and auxiliary nurses. There is no efficient referral system to the tertiary center for patients with epilepsy.

The hospital complex of Hospital de Base is a part of the Faculty of Medicine and is the main referral tertiary center in the São José do Rio Preto Region. It has 550 beds and provides 30,000 out-patient consultations and 3,320 admissions each month. The Neurology Department has specialized clinics for adult and pediatric patients with epilepsy. A new prolonged video-EEG monitoring unit has been recently established and a surgical program for treatment of epilepsy is being set up.

#### **Referral network for the study**

Patients with a diagnosis of epilepsy screened by the active search, self reported or referred by another health center will initially be interviewed and examined by a physician at the primary health center, who will complete the protocol and make a diagnosis. The patient will then be seen by a neurologist at a tertiary center who will confirm or refute the diagnosis and send the patient back to the referring physician for treatment and/or follow-up. This process of referral-and-contrareferral will take two to three weeks. It is expected with time that physicians at the primary health center will become more knowledgeable and confident in making the diagnosis, thus the need for referral for the purpose of diagnosis will decrease.

Patients who do not respond to medication (not attaining seizure-freedom) within three months after reaching the maximal tolerated dose of AED, or those in whom unpredicted problems arise, will be re-evaluated by a neurologist at a tertiary center. The process of referral will take one to two weeks. In cases of emergency, e.g. status epilepticus, patients will be referred to the emergency service of a tertiary center.

#### **Definitions**

For the purpose of this study the following definitions will be used:

*Active epilepsy* – Someone who has suffered two or more unprovoked seizures in the 12 months immediately preceding identification by study officials is defined as having active epilepsy.

*Unprovoked seizures* – These are defined as epileptic seizures not associated with a clear precipitant or triggering factor (such as drug, fever, acute head injury, acute cerebro-vascular accident, acute metabolic imbalance).

*Untreated epilepsy* – Any patient with active epilepsy who has not received regular antiepileptic drug treatment in the week preceding identification by study officials is defined as having untreated epilepsy.

*Appropriate treatment* – Appropriate treatment of active epilepsy includes the diagnosis and treatment of underlying causes, as well as treatment of recurrent seizures according to international standards, using anti-epileptic drugs and surgery whenever indicated.

*Treatment gap* – This is defined as the difference between the number of people with active epilepsy and the number whose seizures are being appropriately treated in a given population at a given point in time, expressed as a percentage.

#### **Treatment of patients**

Patients with a confirmed diagnosis of epilepsy who wish to participate in this study will be enrolled in the study protocol. Health assistants at the primary health center will be responsible for explaining the nature of this study, obtaining written consent and completing study entry forms (number 331/2002). Physicians at the primary health centers will be responsible for prescribing medication (following a guideline for AED prescription), and completing the medical report forms.

Demographic details, estimation of number of seizures, particularly convulsions, that the patient has experienced in the previous, week, month, and year will be recorded. A record of the current occupational status of the patient (work and school) will be made. If the patient is employed or attends school, an estimation of absenteeism from work or school due to epilepsy will be made and recorded.

The clinician or pediatrician will explain to the patient and relatives the importance of adherence to the medication regime, and how the medication should be used. They will also explain to the patients about potential side-effects, and advise the patient to report any experienced to the physician who started the treatment. Patients will receive a health card with follow-up appointment dates. During the first two months, each patient will return every two weeks to adjust medication. Patients will also be evaluated by a neurologist; after the initial assessment, each

patient will return to primary care physicians every three months in the first year to check for compliance, side-effects, and level of seizure-control. In case of doubt, severe or persistent side-effects or recurrent seizures, patients will be re-evaluated by neurologists.

Each patient and/or parent will record seizures, medication taken, any effects of treatment and other problems. Those patients working or at school will be questioned about their attendance since the previous visit, and any changes of occupational status will be recorded.

Patients may be withdrawal from the study if any of the following situations arise:

- Patient or guardian decides against continuing treatment.
- Patient is found to have a progressive neurological disorder.
- Patient has refractory epilepsy (patient will be followed-up at a tertiary center).

### **Treatment outcomes**

At the end of the study, one objective and two subjective assessments will be carried out to determine the effectiveness of treatment.

*Objective assessment* – This is defined by the number of seizures since the introduction of the AED.

- Excellent: Seizure-free.
- Effective: > than 50% reduction in seizure frequency.
- No effect: < than 50% reduction in seizure frequency.

We arbitrarily chose 50% reduction in seizure frequency as a cut-off for effectiveness; we will, however, record the actual frequency of seizures for each patient for later analysis.

*Physician's assessment* – The physicians will rate whether, in their opinion, treatment has improved each patient's overall well-being significantly, a little, or not at all.

*Patient's or guardian's assessment* – Patients or guardians will also be asked whether in their opinion the overall well-being of the patient has improved significantly, a little or not at all since the institution of treatment.

### **Outcome measures**

A series of evaluations will be carried out to measure the effectiveness of this project. We will follow the guidelines for measurements of results based on the report from the Epilepsy Impact Meeting.

The outcomes to measure the project's effectiveness have been taken from the Global Campaign Report on the Burden of Epilepsy.

1. The overall effectiveness of the project in reducing the treatment gap will be determined by the two epidemiological estimations that will be carried out at the onset of the study and four years later, measuring changes in the number of untreated patients between the two estimation points.

2. The effectiveness of the management of people with epilepsy at primary health care level will be determined by:

2.1. The clinical efficacy of the intervention (number of patients seizure-free and number with significant improvement in seizures).

2.2. Safety and tolerability of treatment (number of people who drop-out due to side effects).

2.3. Social changes observed in patients and community.

3. The effectiveness of the training module to induce changes in knowledge, attitudes and practice among health professional will be measured by:

3.1. Changes in the information recorded in KAP questionnaires prior to training and six months later.

3.2. Changes in the number of patients identified and treated by the trainees.

4. The effectiveness of the program to reduce the social and economic burden will be measured by:

4.1. The numbers of patients who return to school or gainful work; or start to work or to go to school for the first time.

4.2. Changes in the attendance record of those at work and school.

### **Social and community intervention**

*Community education/school* – The issue of stigma in epilepsy and the lay perception and prejudice against patients with epilepsy will be explored in different segments of society.

An educational program aimed at decreasing the amount of social stigma in areas of social relations, employment, leisure activities, schooling etc, will be developed. This will be aimed at local primary and secondary school teachers because they exercise an important role in their communities. The aim of this program will be to address attitudes regarding etiology, shame and the lack of infectiousness of epilepsy. A questionnaire on the public perception of epilepsy will be completed by the teachers before and



after the educational program as well by students to assess changes.

The following activities will also be carried out in the community:

- Information dissemination about epilepsy through the media.
- Distribution of material on epilepsy.
- Display of posters.
- Creation of a website.

*Developing local advocacy/support group – We will help create an advocacy/support group consisting of local laymen and health professionals.*

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