



Overview of accessibility and quality of antiepileptic drugs in Madagascar



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ABSTRACT

Purpose: To determine the accessibility of treatment and the quality of antiepileptic drugs (AEDs) in the Haute Matsiatra district of Madagascar.

Methods: Cross-sectional descriptive study and interviews. Samples of 10 units of each available AED were collected, and the active ingredient was quantified by reversed-phase high-performance liquid chromatography (RP-HPLC) with photodiode-array UV detection. The quality of an AED was considered satisfactory if the quantity of active ingredient in each tablet was in the range $\pm 15\%$ of the average value according to the *European Pharmacopoeia* (6th edition, 2008).

Results: The area was well served with health infrastructure but rescue facilities were poorly distributed. Available AEDs were all first-generation, and 73% were generic formulations. People with epilepsy (PWE) surveyed consulted traditional healers and most were treated with plants. PWE did not consider themselves sick but believed they were “possessed”; they consulted a doctor only immediately after a seizure, following the advice of traditional healers. The most prescribed AED was phenobarbital, costing between 0.03 and 0.12 US Dollar (US\$) per 100 mg. The purchase of full treatment was difficult for 77% of PWE and as a result, 39% took nothing. The quality of AEDs were considered unsatisfactory in 2.8% of cases.

Conclusion: The AEDs collected in Haute Matsiatra were globally of good quality. The main limiting elements were a lack of knowledge among PWE that epilepsy is a disease, and the cost of traditional treatments.

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1. Introduction

Epilepsy is a major public health problem in resource-limited settings. In addition to a high prevalence there are also shortages of specialists, of diagnostic equipment and of medicines [1]. As a

result, the majority of people with epilepsy (PWE) do not have access to adequate treatment.

In Madagascar, the prevalence of epilepsy is high, about 20.8 per 1000 persons [2,3] and the treatment gap is approximately 92% [4,5]. Knowledge and practices relating to the management of epilepsy have improved in recent years, resulting in a more medical interpretation and the use of modern healthcare methods. Behavior and attitudes toward PWE among the general population are inconsistent: the majority of people declare themselves to be tolerant of PWE and believe they should be able to work and get married, but not go out alone or attend school [6].

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The Haute Matsiatra region of Madagascar has no neurology services or brain-imaging centers, but religious camps (as distinct from traditional healers) are very numerous. These characteristics and the lack of studies of the therapeutic management of epilepsy in this region prompted us to conduct our research there.

Although first-generation antiepileptic drugs (AEDs) such as phenobarbital, carbamazepine, phenytoin and sodium valproate predominate, there are accessibility problems in several areas where patients and families must bear the costs, which can be considerable even when drugs are relatively inexpensive [3]. Several authors have reported on the quality of medications in developing countries, but few have studied AEDs [7–9].

Here, we describe the accessibility of AEDs and determine their quality in the Fianarantsoa I district with the main assumption that the financial cost of treatment limits its availability to PWE. Consideration will be given to three types of care: modern, traditional, and that delivered in religious camps.

2. Methods (study area, population, data collection, data analyses)

This cross-sectional observational study was conducted in Fianarantsoa I, one of seven districts in the Haute Matsiatra region of Madagascar. The region has 194 542 inhabitants with a population density of 1309/km². In 2010, there was one doctor there for every 5000 inhabitants [10].

Using a simple random sampling procedure, twenty-three of the fifty neighborhoods were selected for this descriptive study. Care and delivery sources were identified, and interviews conducted with health professionals, traditional healers and leaders of religious camps. PWE, identified by a door-to-door survey completed questionnaires. The study was made possible thanks to heads of neighborhoods who directed us and introduced us to families. The 100 PWE involved were selected regardless of age and drug-taking. PWE who had received prior medical treatment long time ago, had never seen a doctor, or were supported by other therapeutic options, were also considered.

With the approval of the Regional Director of Health, data were collected by four investigators (three doctors and one pharmacist) using standardized questionnaires for PWE and physicians, guides for interviewing traditional healer and/or pre-printed forms for information about drugs. The questionnaires were ad hoc questionnaires based on existing stigma scales, or KAP tools in particular EMIC tool [11]. They were translated in local languages and the translation was verified after back-translation and pre-test. The investigators visited the offices of the different health professionals and the homes of PWE. Before each interview, oral consent was obtained. Further information was also used as follow-up in the health register.

All results were coded to maintain the anonymity of each participant, and data were analysed using EpiInfo software. For the descriptive analysis, qualitative variables were expressed as numbers and percentages, and quantitative variables as means. A sample of 10 units of each available AED was collected without any prescription. If the stock was sufficient for more than one month of treatment with the standard dose, the investigator bought 20 units of each AED.

The quality of AEDs was evaluated using standardized pharmaceutical tests (mass uniformity and uniformity of content of active ingredients) according to the recommendations of the *European Pharmacopoeia* (6th edition, 2008) [12]. The uniformity of mass analysis was used to determine the difference between the mass of each unit and the average mass of the sample. This test was performed on 20 tablets, or 10 if there were no more, which were weighed and the average mass was calculated. When weighed singly, the limits for deviation of individual masses from the

average mass were $\pm 10\%$ for tablets with an average mass less than 80 mg, $\pm 7.5\%$ for tablets between 80 and 250 mg and $\pm 5\%$ for tablets more than 250 mg. The test was considered satisfactory if no more than two of the individual masses deviated from the average mass by more than the limits and none deviated by more than twice that percentage limit.

The assay of active ingredient (AI) was determined using high-performance liquid chromatography (HPLC) with an ultraviolet (UV) diode-array detector (DAD) to evaluate uniformity of content. This test was considered to be satisfactory if the AI content of each tablet fell within $\pm 15\%$ of the average amount of AI, according to the criteria recommended by the *European Pharmacopoeia*. Content uniformity was determined using 10 tablets selected randomly. The lot succeeded the test if the individual content of each unit was between 85% and 115% of the mean. It was not valid if the individual content of more than one unit was not within these limits, or if the content of a single unit was outside the limits of 75–125% of the mean. These requirements are the pharmaceutical technical procedures.

Accessibility was evaluated according to the following criteria: number of different systems and sources of care and support; number of physicians supporting a standard population of PWE; presence of delivery systems; variety and quantity of AEDs available and delivered; percentage of PWE able to travel to a consultation and purchase an AED within a day; and the total monthly cost of treatment.

3. Results

3.1. Mapping facilities and areas of intervention

District Fianarantsoa I consists of 50 districts with 28 health facilities and 10 delivery sources.

The seven boroughs considered were served by one:

- One University Hospital (UH).
- 10 Basic Health Centres (BHC) in Public Management: where patients receive treatment and pay for all medical expenses.
- One preventive medicine services within the University under semi-private management that support students and administrative staff, all expenses paid.
- 16 private facilities included both private medical offices belonging to private doctors or health centers managed by religious centers or private facilities to support company personnel. In these centers, patients pay medical expenses.
- Three traditional healers including two members of the Malagasy Traditional Healers Association, recognized by the Department of Traditional Medicine and Pharmacopoeia of the Ministry of Public Health.
- Three religious camps supported by Protestant churches help patients with neuropsychiatric disorders, whom they describe as "possessed by evil spirits", which must be expelled using prayer and exorcism rituals. The camps have fields where patients can work. Religious camps hold an emergency kit containing drugs and when a patient has a seizure decisions are made about the nature and amount of medication to be administered. The three religious camps surveyed were on the outskirts of their districts; two of them run by religious, and a pastor administers the third.
- 10 outlets for AEDs were delivered by the following: pharmacies, pharmaceutical organizations owned and managed by qualified pharmacists, the pharmacy at the University Hospital run by a religious organization, dispensaries, private bodies controlled by people holding at least the national patent holder of the general education and an illicit market in the city center selling drugs of unknown origins at prices agreed with buyers by haggling.

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