

The role of the hospital pharmacist to guarantee access and continuity of care for the management of epilepsy

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ABSTRACT

In this article the pivotal role of hospital pharmacists in the multidisciplinary management of epilepsy is discussed. Hospital pharmacists are members of national and local ethics committees, oversee clinical trials, and ensure adherence to regulations for patient access to novel therapeutic treatments. They actively contribute to regulatory processes and the definition of prescribing centers. In the post-launch phase, hospital pharmacists are a key member in the multidisciplinary team, they are involved in decisions relating to the local introduction of drugs, in the management of the drug within the hospital structure and with the direct distribution, and to ensure proper and timely treatment. The pharmacovigilance network, including hospital and community pharmacists, monitors and prevents adverse effects related to epilepsy medications and enhances a collaborative approach with specialists to promote prescription appropriateness, targeting therapy for better patient outcomes. Finally, the potential benefits of deprescribing are briefly discussed, underscoring the importance of a multidisciplinary approach involving doctors and clinical pharmacists to gather comprehensive data and enhance patient care in epilepsy management.

Keywords: Epilepsy, Deprescribing, Hospital Pharmacists, Management, Multidisciplinary, Novel Drug Distribution, Pharmacovigilance

Introduction

The optimal management of epilepsy requires not only a thorough diagnostic approach but also a concerted effort by all the healthcare professionals involved (general practitioners, general neurologists, epilepsy specialists, hospital pharmacists, nurses, psychologists) and caregivers likewise. This article briefly discusses how hospital pharmacists can contribute to facilitate a better outcome for persons with epilepsy. Indeed, the hospital pharmacist is involved in all phases that characterize the multidisciplinary management of epileptic disease.

The key role of hospital pharmacists in the pre-market phase at national and regional levels

The hospital pharmacist is routinely a member of national and local ethics committees and a key manager of new

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Marcello Pani email: marcello.pani@policlinicogemelli.it; marcello.pani@unicatt.it therapies in clinical trials. In this role, he/she guarantees compliance with national and European regulations, allowing patients eligible for clinical trials to have early and free access to promising new therapeutic treatments, before they are launched and progressively included in normal clinical practice.

Several hospital pharmacists work in the various organizational sectors of the Italian Medicines Agency (AIFA), some are members of the current CTS and CPR commissions of the regulatory agency, where requests for marketing authorization (AIC) of medicines are evaluated, defining the therapeutic value, place in therapy, classification, reimbursement, and innovativeness requirement and where the price and supply regime are negotiated with the company that holds the marketing authorization.

Italy has a national health system with a decentralized governance. Therefore, it is up to the regions, within their autonomy, to define the prescribing centers, include the new drugs into the Regional Formulary, wherever present, and initiate the purchasing procedures through the purchasing centers in compliance with current regulations.

In a scenario where regional pharmaceutical service has the task of guaranteeing the governance and sustainability of pharmaceutical care according to political-health indications, hospital pharmacists are deeply involved in all these activities.

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The key role of hospital pharmacists in the launch and post-launch phases

At the local level, hospital pharmacists are a key member in the multidisciplinary team responsible for the management of epileptic disease. In addition to the already described clinical trials, they are involved in decisions related to the local introduction of drugs, in the management of the drug within the hospital structure and with the direct distribution, and to ensure proper and timely treatment for patients followed by the reference center identified by the region (1).

Within the national pharmacovigilance network (RNF), hospital pharmacists detect, identify, evaluate, understand, and prevent adverse effects or any other problems related to the use of epilepsy medicines, to ensure a risk/benefit balance that is overall favorable for the population.

Whenever their activity is in direct contact with the patient/ caregiver, the national health system (NHS) pharmacists carry out an important counseling and therapy reconciliation activity for epileptic persons or patients with comorbidities.

Novel methods of distribution of drugs to ensure compliance

At the local or regional level, a method of distributing the drug to the patient's home is gradually being implemented.

This is an innovative distribution method, which, if accompanied by the use of a software application (commonly defined app) in which the patient enters information relating to the administration of the drug and possible adverse reaction, allows periodic checks by the clinician who follows the patient and by the reference pharmacist. This translates into clinical benefits in terms of adherence and therapeutic persistence, which may be very important in the day-to-day clinical practice.

The whole process is under the control, monitoring, and responsibility of the NHS pharmacist.

The role of the hospital pharmacist is selecting the appropriate drug

The hospital pharmacists and/or clinical pharmacists collaborate with the specialists to promote the appropriateness of the prescription. Epilepsy offers an excellent, albeit challenging, opportunity for a personalized treatment, given the complexity of the disease from a genetic perspective and its multifactorial etiology (2).

Pharmacists may evaluate medication use, identify problems with specific drugs, and propose changes in prescription to a panel of healthcare professionals when pharmacotherapy is not successful and proves inappropriate; they are involved in pharmaceutical consultancy and pharmacotherapeutic follow-up, as well as in the systematic measurement and evaluation of results.

During pharmaceutical consultancy sessions for patients and healthcare professionals, the pharmacists summarize the characteristics of the drugs, discuss the rationale of pharmacotherapy, and educate patients on taking antiepileptic drugs (AEDs). These scenarios testify the positive impact of the pharmacist's intervention and demonstrate that his/her inclusion in a multidisciplinary group of healthcare professionals improves the patient's quality of life and their adherence to drug therapy.

All these activities should be structured in proper diagnostic and therapeutic pathways (PDTA). While several hospitals and regions have implemented or are in the process of implementing and defining them, this process is far to be finalized for epilepsy.

The synergy with the community pharmacists

A function of counseling, similar to the one described earlier for hospital pharmacists, is also performed by community pharmacists, in the event that for some AEDs the regions activate specific direct delivery method (DPC). In this case the patient can decide to collect their therapy in the local pharmacy and the community pharmacist is involved in the process.

In this case, also the role of the community pharmacist becomes important within the national pharmacovigilance network (RNF).

The role of hospital pharmacists in deprescribing

Several definitions of the process of deprescription have been proposed (3). According to a systematic review published some years ago, deprescribing "is the process of withdrawal of an inappropriate medication, supervised by a health care professional with the goal of managing polypharmacy and improving outcomes." It is clear that epilepsy represents a therapeutic area where the potential role of deprescribing needs to be carefully evaluated.

What are the key points that doctors and clinical pharmacists must consider to promote deprescribing in epileptic patients?

- 1. Risk prediction: One of the most delicate points of deprescribing is the epileptic patient's reaction to the proposal to interrupt AED therapy. Although patients with epilepsy may have improved cognitive performance and quality of life after discontinuing therapy, there is always an increased risk of relapse that should be carefully monitored.
- 2. Compliance and patient preferences: It is known that, even if the doctor and clinical pharmacist have reached optimal risk prediction in the multidisciplinary assessment, the decision-making process must still take into account the patient's compliance and preferences. The existing guidelines report that the decision to interrupt antiepileptic treatment should consider implications for the patient from a personal and social point of view, considering seizure relapse or the continuation of chronic AED-based therapy could have.
- 3. Implementation of clinical research: The available literature does not currently report how widespread deprescribing is in epilepsy or how much it is possibly being abused due to underestimation of the risk. In this sense, a large-scale project collaboration between clinical pharmacists and other healthcare professionals would be desirable to collect significant data.

Conclusions

Epilepsy represents a chronic neurological disorder with a significant burden on both sufferers and society. The availability of novel treatments opens the door for new opportunities to improve the quality of life and outcome in epilepsy. Besides his/her role in the pre-launch phase of new drugs, hospital pharmacists play an increasing role in supporting physicians in the selection of the proper treatment, in making sure that the drug is delivered in a timely manner, and that all possibilities, including deprescribing, are thoroughly evaluated for an optimal overall management of the disease.

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