

# Models of care and relevance of territorial management in assisting persons with epilepsy

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## ABSTRACT

Epilepsy is a widespread social disease that affects people of all ages and often involves both diagnostic and therapeutic difficulties. Beyond seizure control, it is necessary to ensure people with epilepsy a good quality of life and respect for human rights, seeking to increase self-management capacity and break down stigma.

People with epilepsy should have privileged access to specialized epilepsy centers, where multidisciplinary care is possible. These centers, organized by different levels of complexity, should be uniformly distributed throughout the country and networked together.

The scientific community and health care organizations must therefore design all necessary strategies so that knowledge about epilepsy improves among the general population and the most effective pathways of care are effectively implemented.

**Keywords:** Antiseizure medications (ASMs), Epilepsy, Epilepsy management, Persons with epilepsy (PwEs)

## Introduction

Epilepsy is one of the most common chronic neurological diseases, affecting roughly 70 million people worldwide of all ages, races, social classes, and geographical locations. An estimated 600,000 persons with epilepsy (PwEs) currently live in Italy, more than one-third of whom are clinically classifiable as drug resistant (1-3). Epilepsy is a disease of the brain characterized by an enduring predisposition to generate seizures and by the neurobiologic, cognitive, psychological, and social consequences of seizure recurrences (4,5). Diagnosis and treatment are more challenging in epilepsy, and misdiagnosis rates are still alarming high (6,7). The burden of epilepsy is very relevant and often neglected in public health agendas; PwEs in addition to suffering from one of the many forms of epilepsy must also face numerous difficulties in various areas related to comorbidities, especially psychiatric (such as depression and anxiety), and all this reduces quality of life and also has significant economic implications (8-11). Epilepsy, like other chronic diseases, produces direct health and non-health economic costs but also equally important

indirect costs, that is, the costs represented by productivity losses (12-14). In addition, epilepsy is one of those chronic conditions that stigmatizes the person who has it. In Italy as well as in the rest of the world, epilepsy is little known among the population (15,16) and PwEs are subject to discrimination and prejudice, with violation of even human rights (17-19). For these and other reasons, in May 2022, the World Health Organization (WHO) General Assembly launched the IGAP (Intersectoral Global Action Plan) on Epilepsy and other Neurological Disorders, lasting 10 years (2022-2031), to bring to the attention of all Member States the global burden of epilepsy and the need for coordinated action at the country level to address its health, social, and public knowledge implications. One of the main strategic goals envisaged by IGAP is “provide effective, timely and responsive diagnosis, treatment and care,” ensuring PwEs the comprehensive multidisciplinary health care response, according to three levels of care diversified by complexity of services provided (primary, secondary, and tertiary health care levels), capable of providing everyone with the necessary diagnostic pathways and the most appropriate treatments for that specific form of epilepsy (20-22).

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## Models of care

### US model

A complete description of the full spectrum for epilepsy care in the United States is provided by the guidelines of the National Association of Epilepsy Centers (NAEC) (23). These



guidelines recognize that in clinical practice in the United States most PwEs who experience a first seizure – typically evaluated in an emergency room – are then managed by a primary care physician (*first level of epilepsy care*). If full seizure control has been achieved with the therapy prescribed by the primary care physician no further specialized epilepsy evaluation is performed. If, on the other hand, seizure control has not been achieved then consultation with a general neurologist in the local community is required (*second level of epilepsy care*). NAEC recommends that referral to a *level 3 and 4 specialized epilepsy center* should occur when: (1) the seizures are not fully controlled (pharmacoresistance); (2) the diagnosis needs to be reevaluated (nonepileptic events, pseudopharmacoresistance); (3) epileptological emergencies occurring (seizure clusters, status epilepticus); (4) the possibility of surgery should be considered. NAEC, however, also recommends that there be a well-developed cooperative strategy plan for the overall management of PwEs involving the primary care physician, the generalist neurologist, and the epileptologist working within a specialized epilepsy center. Level 3 and 4 epilepsy centers must ensure a multidisciplinary approach to PwEs (23). The treatment team must consist of neurologists and neurosurgeons, neuropsychologists, nurse specialists, electroencephalogram (EEG) technologists, and any other type of personnel who are able to meet the psychosocial needs of PwEs, with the goal of improving their safety and quality of life. In addition, the center must be able to rely on structured collaborations with other specialists (geneticists, neuroradiologists, gynecologists, etc.) in order to be able to intervene effectively in the resolution of all kinds of health problems.

According to the NAEC guidelines, level 3 centers must therefore guarantee: (1) electrodiagnostic EEG services including long-term monitoring; (2) epilepsy routine lesional surgery including vagal nerve stimulation; (3) neuroimaging; (4) psychological services; (5) pharmacological expertise; (6) nursing support; (7) rehabilitation; (8) consultative expertise in multiple fields. Epileptologists and epilepsy surgeons must demonstrate at least 2 years of experience in the field, and the center must annually perform long-term video-EEG monitoring in at least 50 patients.

Level 4 centers, on the other hand, represent the regional or national referral for patients with particularly complex drug-resistant epilepsy. These centers should provide a complete evaluation for epilepsy surgery including intracranial EEG recording (StereoEEG) and provide a broad range of surgical procedures. Epileptologists and epilepsy surgeons must demonstrate at least 5 years of experience, and the center must annually perform surgical evaluation in at least 100 cases (24).

### Models in Europe and Italy

In Europe, according with the prestigious NICE and SIGN guidelines (25,26), the diagnosis and treatment of epilepsy should be ensured by epilepsy centers organized in three levels of complexity in terms of their diagnostic and therapeutic possibilities. First- and second-level centers should take care of patients with forms of epilepsy that are responsive

to therapies and less severe in terms of prognosis, while an interdisciplinary care team approach should be ensured at third-level centers to ensure more accurate diagnosis and treatment, especially in the case of drug-resistant forms and those that are candidates for surgery.

In different European countries, the criteria identifying the different levels of care for epilepsy and also the network organization of the centers themselves are different. In some countries, a hub-and-spoke type model has been implemented, with territorial hospitals managing the simplest cases but then linking up with a referral hospital where more complex cases are sent regarding both diagnosis and treatment.

In 2022 the European Study of Burden and Care in Epilepsy (ESBACE) sponsored an Audit of Seizure Management in Hospitals (EuroNASH), in which 15 countries participated (Italy unfortunately did not participate), demonstrating the existence of a wide variability across the countries for most variables. Specifically, of the 2,204 patients who had been referred to an emergency department (ED) between August 1, 2016, and August 31, 2017, for a seizure, 41.2% were already diagnosed with epilepsy, but only 64.7% were followed by an epilepsy specialist. The position paper therefore recommends that guidelines on the management of those presenting to the ED with a seizure (either first seizure or relapse of an already diagnosed epilepsy) be agreed upon in Europe and that a pathway be implemented to ensure that patients are referred to a specialized center within a short period of time (27).

No national surveys have been conducted in Italy regarding the percentage of people with epilepsy who are regularly followed up at centers of various levels specializing in the diagnosis and treatment of epilepsy. It is common, however, to find admissions to EDs of patients with already diagnosed epilepsy for seizure recurrence who are not followed by an epileptology specialist but by their primary care physician or generalist neurologist.

The National Health System (SSN, Sistema Sanitario Nazionale) provides even excellent health care to all citizens but is unable to do so equally throughout the territory. For example, the level of health care provision is certainly better in northern regions than in southern ones, and this factor is mainly responsible for a very well-established phenomenon known as *health migration*. In addition, the territory of Italy is divided into 20 regions, each of which has regulated its own health system, with an organization and resources that are not homogeneous with those of other regions.

Having made this general premise regarding the organization of the SSN, it must be said that there are no national guidelines regulating the management of epilepsy and that only four regions have published and partially implemented Diagnostic-Therapeutic and Care Pathway for Epilepsy (in Italian PDTA, Percorso Diagnostico-Terapeutico-Assistenziale). At the current date, regions Emilia-Romagna, Lombardia, Toscana, and Veneto are the virtuous regions that have taken care to define a Standardized Care Pathway giving due consideration to both the patient's journey and the unmet needs of PwEs (28-31).

PDTAs regarding the organization of care refer to the criteria that LICE (Lega Italiana Contro l'Epilessia, Italian chapter of the International League Against Epilepsy, ILAE) has been publishing for several decades to certify centers that apply for them. LICE criteria for accreditation of centers are published at [www.lice.it](http://www.lice.it) (32) and are different for medically oriented centers than for surgical ones. Medical personnel with expertise in epileptology must work within the centers, identified as specialists in Neurology, Neurophysiopathology, Child Neuropsychiatry, Neurosurgery, and Pediatrics with documented experience in the field of epileptology. Specialists must have been LICE members for at least 5 years and regularly attend training events organized by the same scientific society. The three levels of medically oriented epilepsy centers (for adults or pediatric age) are diversified by the number of specialists working in it and the number of patients in charge/year, the complexity of neurophysiological and neuroimaging diagnostic evaluation, the possibility of multidisciplinary care, etc. For centers dedicated to epilepsy surgery, on the other hand, there are two levels, substantially differentiated on the basis of surgeons operating in them, operable patients/year and possibility of intracerebral recordings (Tabs 1 and 2).

**TABLE 1** - LICE criteria for certification of medically oriented epilepsy centers

Epilepsy Center	First Level	Second Level	Third Level
Epileptologists (number)	1	2	3
In-care PwEs (number)	300	500	700
Outpatient clinic days/week	2	3	4
EEG technician (number)	1 (available at the hospital)	2 (available at the hospital)	3 (present at the center)
EEG standard	Available at the hospital	Available at the hospital	Needed at the center
Ambulatory EEG	External collaborations also	External collaborations also	External collaborations also
Polysomnography	External collaborations also	Available at the hospital	Needed at the center
Video-EEG	External collaborations also	External collaborations also	Needed at the center
Pharmacological trials	Not needed	Not needed	Needed
Multidisciplinary collaborations	Needed	Needed	Needed and structured
Educational activity	Not needed	Not needed	Needed
Research activity	Not needed	Not needed	Needed

EEG = electroencephalogram; LICE = Italian League Against Epilepsy; PwE = person with epilepsy.

**TABLE 2** - LICE criteria for certification of surgically oriented epilepsy centers

Center for Epilepsy Surgery	First Level	Second Level
Epileptologists (number)	2	3
Epilepsy surgeons (number)	1	2
In-care patients (number)	300	500
Outpatient clinic days/week	2	3
EEG technicians (number)	2	3
Long-term video-EEG monitoring	yes	yes
Intracerebral recordings	Not needed	Needed
Surgical procedures	10-25/year	≥25
Multidisciplinary collaborations	Needed	Needed and structured
Educational activity	Not needed	Needed
Research activity	Not needed	Needed

EEG = electroencephalogram; LICE = Italian League Against Epilepsy.

Figure 1 shows the numerical extent of LICE-certified centers and their regional distribution. Obviously this is not a precise census of all the facilities that at various levels deal with epilepsy care in Italy, because some centers, even of excellence, do not consider it necessary to apply for LICE accreditation, but in any case the distribution of LICE centers along the peninsula is certainly emblematic of what was said earlier: numerically epilepsy centers are more present in the north than in the south of Italy.



**Fig. 1** - Territorial distribution of n. 64 LICE-certified epilepsy centers (to December 4, 2023)

### Educational curriculum in epileptology and new models of care organization

The international guidelines stipulate for the first level of patient pathway the involvement of the primary care physician and then the generalist neurologist. Since these physicians are actively involved in the setting of diagnosis and specific treatment with antiseizure medications, it is necessary that they be adequately trained regarding all the

peculiarities and complexity of epilepsies and epilepsy syndromes. This is such a relevant need that ILAE has already put in place a program to develop an evidence-based and consensus-driven educational curriculum for the management of epilepsy within the primary health care setting (32,33). This first-level educational program has since been joined by the ILAE Academy Level 2 Program, which will offer an evolving series of self-paced, interactive, case-based e-learning modules on diagnosis, treatment, and counseling of common as well as rare epilepsies at a higher level of care (34).

Training in EEG is also very important for the physician who intends to deal with epilepsy. EEG is a very important neurophysiological examination for the classification and management of epilepsies and has a critical role in the differential diagnosis between epileptic seizures and paroxysmal attacks of other nature. Despite the crucial role of this neurophysiologic investigation, there is currently a well-known lack of education worldwide regarding the correct execution and interpretation of EEG among both generalist neurologists and adult and child neurology residents, so much so that the scientific societies (particularly ILAE and IFCN) continue to point out the need for continuing education in EEG, with appropriate assessments of the skills achieved as well (35-38).

The LICE criteria for certification of centers specializing in epilepsy care contrast somewhat with international guidelines. In Italy in fact, according to LICE recommendations, it is required that always the PwEs be followed by an epileptologist working at a specialized center, albeit of a different level. According to the indications of PDTAs, the person who has a first seizure – for which they are admitted to an ED – must be quickly referred (preferably within 7 days) to a level 1 or level 2 epilepsy center for a thorough diagnostic level. This is not to say that all PwEs in Italy are followed by an epilepsy center. In fact, many PwEs are unfortunately referred to the general practitioner or a generalist neurologist, even though the recommendations of the scientific society and specific regional PDTAs give quite different indications, and this frequently happens because the exact location of the centers themselves is not adequately publicized.

Therefore, it is very important to make sure that the population knows exactly the treatment options and the location of the centers at which to seek treatment. It is also necessary for epilepsy centers to be evenly distributed throughout the country, so that PwEs do not have to travel from their place of residence to be cared for at a specialist center sometimes far away. In order to prevent PwEs from having to move from the south to the north central part of the country (where, moreover, the second- and third-level centers are most concentrated), it would be necessary to take full advantage of the possibilities made available by new digital technologies. Telemedicine emerged as a necessity during the recent COVID-19 pandemic, but we need to accept now the challenge of making it an opportunity, to be exploited especially for follow-up visits and teleconsultations. A randomized open controlled non-inferiority clinical trial is currently underway in Italy precisely to demonstrate that telemedicine for epilepsy care can be a viable

alternative to conventional care, avoiding PwEs and their caregivers to face long journeys to reach qualified health providers (39). Telemedicine also makes it possible with ease to connect level 1-2 with level 3 epilepsy centers, thus creating an efficient network, which is very useful for discussing especially complex cases, exchanging neurophysiological and neuroimaging investigations, asking for opinions regarding new treatment strategies, etc. Even neurophysiological examinations can be performed by organizing a teleneurophysiology system that can be used by several centers with a hub-and-spoke system. Especially in the case of epileptological emergencies, rapid access to EEG is necessary, and this can be easily achieved through the implementation of a tele-EEG system that allows urgent performance of the examination at a community hospital with remote expert interpretation, without the need to transfer the patient to a more qualified center (40-42). Finally, the use of new digital tools (electronic seizure diaries, wearable devices, digital platforms for implementing narrative medicine, etc.) is very useful for PwEs to increase self-management and empowerment, enabling them to better manifest their needs, fight for them to be met, and counteract both perceived and enacted stigma (43).

## Conclusions

Epilepsy represents a chronic neurological disorder with a significant burden on both sufferers and society. The many forms of epilepsy are very diverse and complex in both diagnosis and treatment. For these reasons, it is necessary for people with epilepsy to be cared for at specialized centers for the treatment of this condition, at which multidisciplinary care is possible, taking into account both the underlying pathology and comorbidities. Centers for the diagnosis and treatment of epilepsy should be organized by different levels of services provided and personnel working in them, so that the person can access all kinds of diagnostic investigations and the most innovative therapeutic strategies, both medical and surgical. On the national territory these centers must have a homogeneous distribution in order to avoid health migration from less organized regions to those with health levels of excellence. In order to improve care possibilities, it is also necessary to take advantage of modern digital technologies that allow for easy follow-up visits and networking of centers of various levels, realizing the teleconsultation and health tele-cooperation, necessary for particularly complex cases. In addition to everything related to the health management of epilepsy, it is finally important that public institutions organize campaigns to promote awareness of this disease among the general population, in order to break down both the enacted and perceived stigma that has always accompanied it.

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