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epilepsy RESOURCE CONNECTION

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hotline

No Generic Substitution of AEDs Without Physician and Patient Consent, Says AAN

Generic substitution of antiepilepsy drugs (AEDs) should not occur without the full knowledge and consent of both the treating physician and the patient, according to a position statement released by the American Academy of Neurology (AAN).

Published in the April 17 issue of *Neurology*, the paper addresses the long-standing issue of whether generic substitution of AEDs places patients with epilepsy at undue risk for breakthrough seizures in the name of reducing health costs.

According to the AAN position statement, the FDA allows for significant differences between name-brand and generic drugs. However, for some patients with epilepsy, even minor differences in the composition of anticonvulsant drugs can make a big difference.

"Epilepsy is unlike other disorders. The marker for success is whether or not you're having seizures and whether or not you're having side effects. So unlike a condition such as hypertension, where, if you make a change in dose you can monitor blood pressure to determine whether it's working or not, with epilepsy you have an all-or-nothing phenomenon—you're either seizure free or you're not," says Gregory Barkley, MD, of Wayne State University, one of the AAN position statement authors.

"As an organization whose goal is to improve the lives of people with neurologic problems—the lives of people with epilepsy in particular, the AAN feels it is important we speak out on behalf of patients who we know have had problems because they have been switched [to generic AEDs], frequently without their knowledge," he added.

The consequences of switching to a generic anticonvulsant that results in subsequent breakthrough seizures or adverse events can be devastating. Having a breakthrough seizure could mean a person could lose their driver's license or their job or injure themselves or someone else. This has to be weighed against the potential cost savings of switching to a generic anticonvulsant.

In an accompanying editorial, Michel Berg, MD, from the University of Rochester (NY) School of Medicine and Dentistry, suggests one of the reasons the FDA remains unconvinced there is an equivalency issue between generic and brand-name AEDs is because physicians are not reporting such events through MedWatch, the FDA's voluntary drug-reporting system.

According to Dr. Berg, several surveys have shown that the majority of physicians and patients perceive that generic AEDs are not always equivalent to the brand-name drug. But this is not reflected in case reports to MedWatch. He suggests this may, in part, be due to a lack of physician awareness of the MedWatch system.

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Dr. Barkley added that underreporting of such events might also be due to the fact that in many cases, physicians are simply not aware that their patients have been switched to a generic agent.

Unless a patient specifically says to a doctor that their pills look different or they know for a fact that they've been switched to a generic drug, physicians may attribute a breakthrough seizure or increased side effects to the brand-name drug.

In addition to opposing generic substitution without physician and patient consent, the AAN statement also supports the use of newer-generation anticonvulsant drugs, which generally have a much more favorable adverse-event profile but tend to be more expensive.

"The AAN believes that physicians should make every effort to identify when patients may be effectively treated with less expensive alternatives. However, the discretion for this decision should remain with the prescribing physician and should not be determined by coverage limitations," the authors write.

According to Dr. Barkley, because of the higher cost of these agents, some insurers are putting up "roadblocks" to prevent physicians from prescribing them by imposing a painstaking and protracted approval process.

As a result, the AAN's position statement also opposes prior authorization requirements by public and private formularies.

↳ MEDSCAPE

First National Walk For Epilepsy Raises \$1 Million for Awareness & Research

"To see thousands of us marching in Washington DC, in front of the Nation's Capitol—that's exciting, that's really exciting! I never thought I'd see anything like this in my lifetime."

—Tony Coehlo, Chair, Epilepsy Foundation

The first-ever 'National Walk for Epilepsy' brought more than 5,000 people to the National Mall in D.C. and raised one million dollars to help build awareness of epilepsy, eliminate stigma attached to this condition, and raise much needed funds for research toward finding a cure. The event was sponsored by the Epilepsy Foundation and Ortho-McNeil Neurologics. ↳ EPILEPSY FOUNDATION

New Medication Shows Promise

German researchers say a new drug shows promise for treating epileptic seizures and may prove beneficial for bi-polar disorder and neuropathic pain.

The study, which appears in the journal *Epilepsia*, shows that Eslicarbazepine (ESL) may be useful as a treatment for patients whose epilepsy symptoms aren't controlled by existing medications.

A drug trial conducted in five European countries found that ESL fully eliminated seizures in 24% of test patients.

"We believe that ESL may have the potential to become an important new central nervous system drug not only for the treatment of epilepsy, but also for patients suffering from bipolar disorder and neuropathic pain," said co-author of the study Patrício Soares-da-Silva. ↳ EPILEPSY ACTION



Adult Epilepsy Support Group

Meets Second Tuesday of Month,
6:30 PM @ 2919 W. 2nd Street, Wichita

May 8th: "Discussing Epilepsy With Others"
June 12th: "Group's Choice"

Researchers Work to Predict Epilepsy

Researcher is underway to find ways to predict who is most at risk of developing epilepsy from brain injury and to find methods of protecting their brains. The research includes studies to see if the newer anti-epileptic drugs Topamax and Keppra might actually prevent epilepsy if they're taken immediately after a serious brain injury.

"It is among the most frustrating things in medicine to know that someone's at risk ... and be unable to do anything about it," says Dr. Marc Dichter of the University of Pennsylvania, who is leading the Topamax study.

After the initial injury and treatment there is a 'silent period' during which the brain works to recover. It can be months or even years before epilepsy appears.

"This silent period is not really silent," said Dr. Shlomo Shinnar of the Albert Einstein College of Medicine at a meeting of epilepsy specialists at the National Institutes of Health.

Misfiring connections can form in the brain as it tries to rewire itself during a crucial process called plasticity. Damaged neurons can make new connections in the wrong places, or make overly excitable connections. Even the brain's genes change the way they work after head injury.

"You need the plasticity for recovery. You don't want to stop it. You just want to structure it in a way that it aids recovery without causing seizures," Temkin explains.

It's not clear yet how to guide plasticity, so scientists are testing seizure-controlling drugs as possible preventers of epilepsy. Three existing medications have failed and Topamax and Keppra are currently being tested. ↵ EPILEPSY ACTION

New Drug Helps Reduce Seizure Frequency

An epilepsy drug with a new method of action is safe and effective, according to a new study.

Retigabine works by opening potassium channels and is being developed to treat people with partial-onset seizures whose seizures are not fully controlled by other drugs.

The finding, published in the April 10 issue of the journal *Neurology*, may be good news for people with epilepsy who don't respond well to current available medications, said study author Dr. Roger J. Porter, of the University of Pennsylvania in Philadelphia. When the study was conducted, Porter worked for Wyeth Pharmaceuticals, which developed retigabine. The study was sponsored and conducted by Wyeth.

Of the study's 399 patients: 3 groups received different doses of retigabine for 16 weeks, and one group received a placebo. At the start of the study, all of the patients were having an average of 8-10 seizures a month. Patients who took the highest dose of retigabine had an average of 35% fewer seizures during the study, compared with 13% for patients who took the placebo. The study also found that 33% of the patients who took the highest dose of the drug had a 50% or greater reduction in seizure frequency.

Drowsiness, dizziness, confusion, tremor, amnesia, and speech disorders were among the side effects experienced by patients who took retigabine. ↵ MEDLINE PLUS



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Hospitals vs. Epilepsy Centers

Hospitals are outfitted to treat most illnesses, respond to emergency situations and carry out practically all surgical procedures, but not all are equipped for full treatment and counseling of people with epilepsy. What separates the nearly 60 nationwide epilepsy centers from hospitals is specialization. An epilepsy center's organization and staff is set up solely to treat and counsel those who have epilepsy or seizure disorders. Many epilepsy centers are partnered with hospitals or medical centers, but to receive epilepsy surgery, patients must go to a hospital teamed with an epilepsy center.



Epilepsy centers are also more likely to have epileptologists - neurologists who specialize in epilepsy - on staff, as they are considered these organizations' principal doctors. Epileptologists can also be found in some hospitals, but almost all epilepsy centers have epileptologists on staff. An epileptologist's training includes exposure to a host of epilepsy-related problems and input from various health care workers. Epileptologists are taught to interpret electroencephalograms (EEGs) and video EEG results, as well as when to prescribe certain medications and often how to perform epilepsy surgery.

Other substantial differences between hospitals and epilepsy centers are the counseling and educational programs. Epilepsy centers are not only medical treatment facilities. They are also educational institutions and "safe havens" for people with epilepsy, or people who think they might have epilepsy. In most cases, patients are even referred to epilepsy centers by their neurologists or doctors because the nature of their seizures are uncertain or the treatments they have been provided are not working or are resulting in adverse side effects. Questions like: "Is it epilepsy or something else?" and "What type of seizures are they, partial or generalized?" can sometimes be better answered by experts at epilepsy centers. They are better suited to provide advice on how to improve the use of antiepileptic drugs and changing lifestyles, such as more sleep. ↵ EPILEPSY FOUNDATION

Editor's Note: There are two comprehensive epilepsy centers in Kansas, both are staffed by an epileptologist:

Via Christi Comprehensive Epilepsy Center in Wichita is the state's only Level 4 Epilepsy Center. (316) 268-8500

The KU Comprehensive Epilepsy Center is located in Kansas City, KS. (913) 588-4580

Considering VNS Therapy®?

Cyberonics and Via Christi Comprehensive Epilepsy Center host a monthly luncheon presentation on VNS THERAPY® for patients and their families. The session includes time for questions & answers. For more information or to make a reservation to attend, call: (316) 268-8562



You must RSVP to attend.
11:30 a.m. - 12:30 p.m.
Third Wednesday of the month
(May. 16th; June 20th)



Via Christi
Comprehensive Epilepsy Center