

POLICY & PRACTICE

Investigating Autism Treatments

Officials at the National Institutes of Health are launching three new clinical studies aimed at defining the different subtypes of autism spectrum disorders and potential new treatments. In one study, researchers will compare two subtypes of autism—one with regression of normal development around age 3 years and another considered to be nonregressive autism that begins possibly before birth—with other developmental disorders and with child with normal development. Researchers will also investigate possible treatments for autism,

including minocycline in regressive autism and the use of chelation therapy, which is a popular treatment choice among families who believe that autism is linked to exposure to vaccines containing thimerosal. The NIH study will evaluate the efficacy and safety of chelation in children who have autism spectrum disorders. "Because chelation therapy is not specific for mercury alone, it is important to conduct a systematic, controlled trial to determine whether or not chelation therapy is beneficial or potentially harmful to children with autism," Dr. Susan Swedo of the National Institute

of Mental Health said in a statement. More information is available at www.clinicaltrials.gov.

DEA Reverses Pain Rx Restrictions

A new proposal from the U.S. Drug Enforcement Administration would allow physicians to issue up to a 90-day supply of schedule II controlled substances in a single visit. The notice of proposed rule making, which was issued in September, is open for public comment until Nov. 6. If finalized, the proposal would reverse the agency's previous position that physicians must write new prescriptions each month. Instead, physicians would be able to issue

three monthly prescriptions at once, specifying the fill date for each prescription. The agency also issued a policy statement aimed at answering physicians' questions about dispensing pain medications. "Today's policy statement reaffirms that DEA wants doctors to treat pain as is appropriate under accepted medical community standards," DEA Administrator Karen P. Tandy said in a statement. "Physicians acting in accordance with accepted medical practice should be confident that they will not be criminally charged for prescribing all appropriate pain medications." The American Academy of Pain Medicine praised the proposal, noting in a statement that it could help eliminate the burden on cancer patients and others with chronic pain who have been forced to visit their physician every month for a new prescription.

Views on Medicare Part D

Most physicians agree that the Medicare Part D drug benefit is saving money for patients, but they see the law as too complicated, according to a poll commissioned by the Kaiser Family Foundation. Seventy-one percent of physicians surveyed somewhat or strongly agreed that the program helps people on Medicare save money, while 92% somewhat or strongly agreed that it is too complicated. Physicians also reported that the program increased their day-to-day hassles. About 64% of physicians reported that the Medicare drug program put a lot or some burden on themselves or their staff, compared with 33% who reported not much or no burden associated with the Part D benefit. The survey was conducted between April and July and is based on a nationally representative sample of 834 office-based physicians involved in direct adult patient care. A separate survey of pharmacists showed similar views on the program. "The story is remarkably consistent: The benefit is providing help to millions as intended, but there are also problems, and the complexity of the law is an issue for many," Drew E. Altman, Ph.D., president of the Kaiser Family Foundation, said in a statement.

Pay-Cut Consequences

If Congress does not act to reverse a proposed 5.1% Medicare pay cut, nearly 40% of group practices may limit the number of Medicare patients they see, according to a survey commissioned by the Medical Group Management Association. The survey asked more than 1,600 group practices what they would do if the scheduled 5.1% pay cut went into effect. About 39% of practices said they would limit the number of Medicare patients in their practice, while 19% said they would refuse to accept new Medicare patients. In other money-saving efforts, about two-thirds of respondents said they would modify or eliminate staff health care benefits, 54% would cut administrative and support staff positions, and 80% said they would postpone investment in new technology. "These responses reflect the seriousness of the operating environment confronting physician practices," Dr. William F. Jesse, MGMA president and CEO, said in a statement. "If medical practices are to continue providing high-quality care, they may have to make some very painful decisions in order to stay financially viable."

—Mary Ellen Schneider

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Juvenile Myoclonic Epilepsy (JME): Often underdiagnosed or misdiagnosed

More prevalent than one might think

JME affects approximately 7% of all people with epilepsy worldwide.¹ The true prevalence remains unclear since many cases are underdiagnosed or misdiagnosed.^{2,3} Typically, JME presents between the ages of 12 and 18 years and is characterized by myoclonic jerks that usually occur upon awakening. The jerks rarely cause the patient to fall; however, the patient is likely to drop an object that he/she may be holding.¹ The syndrome, which patients have throughout their lives,¹ is inherited, although the mechanism for inheritance is still unclear.⁴

An idiopathic generalized epilepsy syndrome that is often treated as a focal epilepsy

JME is classified as a seizure syndrome within the group of idiopathic generalized epilepsies (IGEs). Some of the other syndromes included in the IGE group are: epilepsy with myoclonic absences, epilepsy with myoclonic astatic seizures, childhood absence epilepsy, juvenile absence epilepsy, and epilepsy with generalized tonic-clonic seizures.¹

Oftentimes, IGE seizure syndromes, such as JME, can be difficult to identify because features from one syndrome overlap with another.¹ For instance, generalized tonic-clonic seizures (GTCS) occur in over 90% of patients with JME; up to one third of these patients also experience absence seizures.^{1,4} And not all seizure types associated with the JME syndrome manifest at the same time.¹

myoclonic jerks, that a diagnosis of JME is made.³ It is for these reasons that the patient's medical history plays such an important role in the accurate diagnosis of JME.⁷

Correct diagnosis and appropriate treatment are key

The goal of AED therapy is to provide seizure freedom while minimizing side effects of the medication.⁷ Patients with JME require life-long treatment.¹ Establishing the correct diagnosis and prescribing appropriate AED therapy right from the start are critical to reducing patient morbidity.⁷

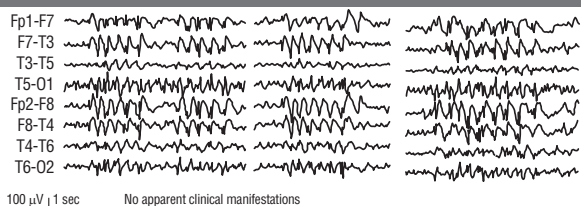
Recognize the characteristics of JME¹⁻³

- Symptoms begin during adolescence and require lifelong treatment
- Myoclonic jerks are the primary symptom
- Seizures usually occur upon awakening
- No loss of consciousness with myoclonic seizures
- Photosensitivity (about 30% of patients)
- Precipitating factors
 - Sleep deprivation
 - Fatigue
 - Stress
 - Alcohol
 - Menstruation
- Patients are of normal intelligence

Current treatment in JME

The selection of appropriate therapy for JME is difficult due to the scarcity of class I clinical trial evidence.⁶ Phenytoin, carbamazepine, and oxcarbazepine are sodium channel blockers and gabapentin enhances GABA-mediated transmission. These drugs have a narrow spectrum and are not considered optimal therapeutic choices for IGE syndromes such as JME.^{6,8-11} Lamotrigine, a sodium channel blocker, has been reported to worsen myoclonic seizures.^{6,9,12} Valproic acid, while shown to be effective in the treatment of JME, is associated with side effects such as hepatotoxicity, polycystic ovarian syndrome, and weight gain.¹⁰ It has been reported that it may bear a risk associated with developmental delays in children whose mothers were taking this drug while pregnant.^{10,13}

At UCB, Inc. we are keenly aware of the diagnostic and therapeutic challenges of JME and are dedicated to finding new ways to help clinicians manage their patients with this condition.

Video-EEG of JME patient during hyperventilation⁵

Adapted with permission from Panayiotopoulos, 2005.

This can lead to a misdiagnosis and the selection of antiepileptic drug (AED) therapy that does not cover the spectrum of seizure types that the patient with JME may experience.^{2,6}

JME can present a diagnostic challenge for the clinician

JME is frequently underdiagnosed because myoclonic jerks can be missed for years. Often, it is not until after the patient has had the first generalized tonic-clonic seizure and the clinician then reviews the patient's history of earlier

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