

FDA Panel: Physician Opioid Training Should Be Mandatory

Pauline Anderson | May 06, 2016

Physician training on the risks of prescription opioids should be mandatory and include information on immediate-release (IR) as well as extended-release (ER) and long-acting (LA) formulations, a US Food and Drug Administration (FDA) advisory panel concludes.

At a 2-day joint meeting, the FDA's Drug Safety and Risk Management Advisory Committee and its Anesthetic and Analgesic Drug Products Advisory Committee unanimously voted to modify the ER/LA opioid analgesic Risk Evaluation and Mitigation Strategies (REMS).

In addition to most panel members recommending that the training be mandatory and include IR drugs, some suggested that it also focus on pain management rather than on opioids, be tied to the recently released Centers for Disease Control and Prevention (CDC) guidelines, and involve mental health and suicide screening.

At the meeting, the joint committee discussed results of assessments of ER/LA REMS. The FDA had received four assessments of the ER/LA opioid REMS from the "applicant holders" (manufacturers of opioid products).

Approved in July 2012, the ER/LA REMS is among multiple national and state efforts to reduce the risk for abuse, misuse, addiction overdose, and deaths due to prescription opioids, while continuing to provide access to these medications for patients in pain.

These opioids are indicated for the management of pain severe enough to require daily around-the-clock long-term opioid treatment and for which alternative treatment options are inadequate.

A central component of the ER/LA opioid analgesics REMS is an education program for prescribers, including physicians. It requires that opioid manufacturers make available education programs to prescribers.

FDA Blueprint

Applicant holders provide education grants to accredited continuing education (CE) providers who offer training to prescribers at no or nominal cost. One of the requirements of this training is that it include all elements of the FDA Blueprint for Prescriber Education for ER/LA opioids.

This blueprint includes information on proper patient selection for opioid use, guidance on safely initiating therapy, modifying dosing, discontinuing use, monitoring patients, and counseling patients and caregivers about safe use of these drugs. Prescribers also get information on how to recognize misuse, abuse, and addiction.

From background information provided by the FDA, deaths from prescription opioid overdoses have been increasing since 2001. In 2014, the number was in excess of 18,000.

But there's some evidence that opioid prescriptions have gone down. The estimated number of IR opioid prescriptions in the United States was 130.9 million in 2005 and peaked at about 184.1 million in 2011–2011 before dropping to 166.4 million in 2014. For ER/LA opioids, the number was 17.0 million in 2005, rising to 22.3 million in 2010 and slipping slightly to 21.2

million in 2014.

According to materials submitted by the pharmaceutical industry, factors that may be contributing to an apparent decrease in abuse and misuse — in addition to REMS — include the requirement in some areas for chronic pain patients to be seen by a pain specialist instead of primary care doctors or for prescriber training outside of REMS; changing societal patterns; increasing use of prescription drug monitoring programs; and approval of naloxone for opioid overdoses.

Such factors, according to the industry, were implemented within the same time frame as REMS, making assessment of the effect of the REMS "very complex."

Failed Goal

The goal of training 80,000 healthcare providers who prescribe opioids within 2 years (through the end of February 2015) was not met. Only 37,512 prescribers completed an accredited CE program by this time. However, according to information from the industry, another 28,707 completed the CE program by the end of February 2016, to bring the total to 66,219 completers.

During the meeting, committee members heard from the FDA, drug industry representatives and continuing medical education experts.

Graham McMahon, MD, president and CEO, Accreditation Council for Continuing Medical Education, stressed that continuing medical education must be engaging and "efficient and effective" as well as relevant. He also noted that learners and their needs "are incredibly diverse."

Committee members also heard about the model of opioid education initiated in New Mexico, the second largest state in terms of opioid-related overdose deaths.

Joanna Katzman, MD, University of New Mexico Health Sciences Center, spoke of the how the state mandated CE specific to pain and opioid substance abuse disorders. The model, she said, has had positive effects in terms of dispensing high-dose opioids and benzodiazepines and on overdose deaths.

In the end, all 30 voting members voted to make changes to the opioid-related REMS.

"All the data we reviewed at the meeting did not provide clear evidence either supporting or refuting the effectiveness of REMS training," commented Brian Bateman, MD, associate professor of anesthesia and pharmaco-economics, Department of Medicine, Brigham and Women's Hospital, and Department of Anesthesia, Critical Care and Pain Medicine, Massachusetts General Hospital, and Harvard Medical School, Boston.

"We know prescription opioids carry considerable risks and that inappropriate prescribing has contributed to the epidemic we are currently facing. It thus stands to reason that providers will benefit from training regarding their appropriate use."

Committee members had a number of suggested changes for the REMS. Some felt that it should be altered to reflect best available guidelines, with a starting point being the recently released CDC guidelines.

Others, including Erica Lee Hoffman, MD, assistant professor of medicine, University of Pittsburgh School of Medicine, Pennsylvania, called for more focus on patient education. "If we

do a better job of educating the patient on alternative means of pain control along with risk/benefit ratio, the number needed to treat, number needed to harm, there are people that we will end up not treating with opiates."

There was a suggestion that the pharmaceutical industry be at arm's length in the training process. Echoing the sentiments of some others, Linda Tyler PharmD, chief pharmacy officer, University of Utah Hospitals & Clinics, and professor (clinical) and associate dean for pharmacy practice, University of Utah College of Pharmacy, Salt Lake City, said the role of the pharmaceutical industry "needs to be separated from the development of the education" of physicians.

Some panel members, including Dr Bateman, suggested a broader focus that includes alternative pain management modalities, such as nonopioid medications and nondrug approaches (eg, acupuncture and exercise).

Several panel members suggested the possibility of tying training with Drug Enforcement Administration licensure. Some felt that the target of education should be those who need it the most, such as problem prescribers.

Two members toyed with the idea of eliminating the REMS (voters had three choices: continue the REMS without modification, eliminate the REMS, or modify the REMS). One was Mary Ellen McCann, MD, associate professor of anesthesia, Harvard Medical School, and senior associate in anesthesia, Boston Children's Hospital.

"There has been very little evidence shown in the last 2 days that the present REMS has altered behavior by much at all," said Dr McCann. "It's basically a manual on how to prescribe opioids when it should be a manual or blueprint on how to treat pain."

The training process, said Dr McCann, needs to be "streamlined" and there should be "shortcuts" for people already educated in pain management, such as pain specialists, to make it "as least burdensome as possible."

Elaine Morrato, DrPH, associate professor, Department of Health Systems Management and Policy, dean for public health practice, Colorado School of Public Health, University of Colorado, Aurora, cautioned about introducing "unwanted burden or unintended consequences" in terms of limiting access to needy patients, but stressed that misuse of prescription opioids "remains a public health crisis" that should be treated "like a medical emergency."

Dr Morrato also recommended that training not only be mandatory but routinely renewed "so it becomes institutionalized."

David Craig, PharmD, clinical pharmacy specialist, Department of Pharmacy, H. Lee Moffitt Cancer Center & Research Institute, Tampa, Florida, said "stratification for suicidality and mental health makes sense" to be included in the training.

Charles W. Emala Sr, MD, professor and vice-chair for research, Department of Anesthesiology, Columbia University College of Physicians & Surgeons, New York, New York, said it's "critical" to develop a better objective measure of the effectiveness of the REMS program. Along with others, Dr Emala said he wanted the training extended to "the whole healthcare team."

Committee chairperson, Almut Winterstein, PhD, professor and interim chair, pharmaceutical outcomes and policy, College of Pharmacy, University of Florida, Jacksonville, suggested the

training involve pharmacists as well as prescribers as these experts "can play a role in patient education."

For Raeford E. Brown Jr, MD, professor of anesthesiology and pediatrics, College of Medicine, University of Kentucky, Lexington, a "very important" element of the Blueprint for REMS should be "assessment of success vs failure of the program" that would include things like the number of people who complete the REMS and whether it "changes the way they manage patients."

Niteesh Choudhry, MD, PhD, associate professor, Harvard Medical School, and associate physician, Brigham and Women's Hospital, Boston, stressed that "we clearly need a better evaluation strategy to figure out whether this is worth the money."

Jeffrey Galinkin, MD, professor of anesthesiology and pediatrics, University of Colorado, and director of pain research, CPC Clinical Research, University of Colorado, favored expanding the educational process to include those who manage pediatric patients.

For Anita Gupta, DO, PharmD, vice-chair, pain medicine, and associate professor, Department of Pain Medicine and Regional Anesthesiology, Drexel University College of Medicine, Hahnemann University Hospital, Philadelphia, Pennsylvania, the delivery of information "should be engaging and digestible" and potentially use "innovative technological solutions" to ensure "a firm, definitive broad public health impact."

Finally, many members called for a unified message. "It should also be collaborative with all federal agencies and stakeholders to ensure a clear and concise message," said Dr Gupta.

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Cite this article: FDA Panel: Physician Opioid Training Should Be Mandatory. *Medscape*. May 06, 2016.

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