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PROFESSION

Opioid safety is focus of \$1 million-a-year educational initiative

Industry-supported PainSAFE targets how physicians and patients can avoid abuses and misuses of pain treatments.

By KEVIN B. O'REILLY, *amednews* staff. Posted Oct. 25, 2010.

A group that represents patients living with pain has launched an initiative aimed at educating physicians and patients on how to prescribe and use opioids and other pain treatments safely.

The \$1 million-a-year project is called Pain Safety & Access for Everyone, or PainSAFE. It comes in response to a striking rise in deaths and overdoses related to opioid abuse and controversy over how the drugs are marketed.

Fatal opioid overdoses tripled to nearly 14,000 deaths from 1999 to 2006, according to Centers for Disease Control and Prevention data reported in September 2009. In June, the CDC estimated that 305,885 emergency department visits in 2008 were related to opioids, more than double the 2004 estimate of 144,644.

The effort is supported by contributions from Endo Pharmaceuticals Holdings, King Pharmaceuticals and Medtronic, makers of pain medications and implantable therapies.

The firms exert no control over PainSAFE educational content, said Will Rowe, executive director of the American Pain Foundation, the Baltimore-based, physician-founded group behind the project. The foundation has long-standing ethics policy designed to prevent industry support from influencing content, he added.

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The PainSAFE website features separate educational tracks for patients as well as physicians and other prescribers, with webinars, posters and frequently-asked-questions pages. The group plans to offer physicians continuing medical education credits for its content. Educational modules now focus on opioid therapy and implantable pain therapies. Content to come next year will address the safety of complementary and alternative therapies and over-the-counter medications such as acetaminophen.

"We are aware that there are safety concerns about the abuse of pain medications, and those concerns tend to lead to less use of available treatments," Rowe said. "Our notion is that if people have a better idea how to use these treatments safely, they will be more inclined to use them, and therefore people will benefit more. If you know how to fly a plane, you're more likely to get in the cockpit and do it."

The initiative comes as the Food and Drug Administration continues to consider a Risk Evaluation and Mitigation Strategy for long-acting and extended-release opioids such as fentanyl and oxycodone.

An FDA advisory panel in July rejected as too lenient an agency proposal to require manufacturers of these medications to boost their efforts to educate physicians and patients about the abuse potential of the drugs through medication guides, patient education sheets and CME. Many panel members said the FDA safety plan also should target immediate-release opioids and argued that physicians should be required to take CME courses to prescribe opioids.

The FDA is analyzing how to proceed, an agency representative said.

Building on guidelines

The two leading professional organizations devoted to pain medicine, the American Academy of Pain Medicine and the American Pain Society, jointly released clinical guidelines last year for physicians using opioids to treat patients with chronic noncancer pain. But that advice falls short in helping physicians prescribe opioids safely, said Lynn Webster, MD, who helped develop the PainSAFE educational materials.

"With those guidelines, they attempted to make their recommendations evidence-based," said Dr. Webster, medical director of Lifetree Clinical Research and Pain Clinic in Salt Lake City. "There's a paucity of evidence out there, but there's a lot of clinical know-how. ... We've come up with some recommendations for physicians to target specifically how to avoid overdose deaths."

PainSAFE is closely modeled on Dr. Webster's Zero Unintentional Deaths educational campaign in Utah. Among the things that can put patients at risk for death when taking opioids: asthma, undiagnosed sleep apnea and rapid titration of methadone.

Scott M. Fishman, MD, a past president of the American Academy of Pain Medicine and now chair and president of the American Pain Foundation's board of directors, said PainSAFE is one of many ways to spread the word to physicians on how to treat pain safely. Neither the academy nor the American Pain Society has officially endorsed PainSAFE.

A principal focus of the project is clarifying the patient's role in avoiding misuse, said Samantha Libby-Cap, director of the initiative.

"The responsibility for the patient is: 'You need to follow this as prescribed,' " she said. "If the pain isn't going away, you need to go back to your health care professional, and they may need to change something. ... But instead of going back to the doctor, they think, 'I'll take another pill, and that will make me feel better.' That's where your unintentional overdoses are coming from."

This content was published online only.

ADDITIONAL INFORMATION:

Opioid safety suggestions

Opioid therapy can be effective in treating patients with chronic pain, but it is sometimes associated with fatal abuse, misuse and accidental overdose. A new initiative from the American Pain Foundation aims to educate doctors and patients about how to use these and other pain treatments safely. Here are the foundation's eight tips for physicians prescribing opioids:

- Assess patients for risk of abuse before opioid therapy and manage appropriately.
- Watch for and treat comorbid mental health disorders when they occur.
- Use conventional conversion tables cautiously when switching from one opioid to another.
- Avoid combining benzodiazepines with opioids, especially during sleep hours.
- Start methadone at a very low dose and titrate slowly regardless of whether patients are opioid-tolerant or not.
- Assess for sleep apnea in patients on high daily doses of methadone and other opioids and in those with a predisposition.
- Tell patients on long-term opioid therapy to reduce opioid dose during upper respiratory infections and asthmatic episodes.
- Avoid using long-acting opioid formulations for acute postoperative and trauma-related pain.

Source: American Pain Foundation (www.painfoundation.org/painsafe/safety-tools-resources/six-opioid-safety-steps.pdf)

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The American Pain Foundation's PainSAFE initiative (www.painfoundation.org/painsafe)

"Opioid Drugs and Risk and Evaluation and Mitigation Strategies," Food and Drug Administration, Sept. 23 (www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm163647.htm)

"Emergency Department Visits Involving Nonmedical Use of Selected Prescription Drugs, United States, 2004-2008," *Morbidity and Mortality Weekly Report*, June 18 (www.cdc.gov/mmwr/preview/mmwrhtml/mm5923a1.htm)

"Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain," *The Journal of Pain*, February 2009 (www.ncbi.nlm.nih.gov/pubmed/19187889)

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