

Will the FDA's REMS for opioids become an Emerging Solution in Pain (ESP)?

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Purpose

A recent report highlighted the many chronic pain patients whose treatment remains inadequate. Reasons for this include clinician beliefs and knowledge regarding ways to optimize pain management and concerns regarding minimizing the risks of misuse. The FDA announced a new risk reduction program, REMS for all extended-release and long-acting opioid medications in April 2011. The purpose of this survey was to investigate clinician beliefs and knowledge of the new FDA Opioid REMS.

Method

ESP sent an email invite in June 2011 to approximately 30,000 loyal pain clinician members to participate in a survey to assess beliefs and knowledge towards the FDA's REMS key elements. Clinicians were asked to respond to questions regarding demographics, current opioid prescribing, and knowledge and attitudes regarding the Opioid REMS. All surveys were completed online and the results were collected and analyzed in aggregate.

Results

A total of 634 surveys were completed. Most respondents were either hospital (28%), office (24%), or community-based (16%). When asked about their current prescribing practices, 34% said that they prescribed opioids for acute, 26% for cancer, and 41% for chronic noncancer pain. Of those who prescribe opioids, 71% prescribe long-acting (LA), extended-release (ER), and methadone. The most routinely utilized risk assessment tool was opioid treatment agreements (26%) followed by urine drug testing (18%). Interestingly, almost 13% reported that they do not routinely use any risk assessment tools. Most clinicians indicated that they were confident (81%) in fulfilling their regulatory responsibilities to demonstrate compliance with federal and state requirements for prescribing opioids; however, less than 70% correctly responded to knowledge questions related to REMS and opioid abuse. Only 34% admitted that they had not yet heard or read about the FDA REMS elements, while 72% said that there is currently not enough information available to healthcare professionals about REMS. Interestingly, 43% thought that the REMS currently required prescribers to take the training or be certified to prescribe LA and ER opioids.

Most responders felt that the REMS will have the most impact on prescribers (44%) or patients (24.6%).

The key elements of REMS felt MOST necessary included the need for a nationwide prescription monitoring program with real-time data available to physicians and pharmacists at point of care (45%), and education initiatives for physicians and other care team members (26%). The latter response for more education was also reflected in the number of responders who would complete a pain education certification process to retain their DEA registration if it became a mandatory requirement to prescribe LA and ER opioids (87%).

Conclusions

Two of the 4 Obama's National Action Plan goals are to:

- Increase prescriber and public education on opioid risks, and
- Expand authorized prescription drug monitoring programs (PDMP)

The survey responses showed that 87% would complete an education certification process and 45% felt the most necessary REMS component would be a nationwide PDMP.

So although there are many unanswered questions including:

- Will the Opioid REMS become an Emerging Solution in Pain?
- Will it strike a balance between minimizing abuse and the need for legitimate access?

This survey provides optimism that a REMS program may have a positive impact on pain medicine.