RETHINKING STUDY DESIGNS TO QUANTIFY REMS EFFECTIVENESS

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Disclosures

Dr. Alexander is past Chair and a current member of FDA's Peripheral and Central Nervous System Advisory Committee; Principal Investigator of an FDA-funded Center of Excellence in Regulatory Science and Innovation; has served as a paid advisor to IQVIA; is a co-founding Principal and equity holder in Monument Analytics, a health care consultancy whose clients include the life sciences industry as well as plaintiffs in opioid litigation; and is a member of OptumRx's National P&T Committee. This arrangement has been reviewed and approved by Johns Hopkins University in accordance with its conflict of interest policies.

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JAMA | Original Investigation

Assessment of the FDA Risk Evaluation and Mitigation Strategy for Transmucosal Immediate-Release Fentanyl Products

Jeffrey Eric Rollman, MPH, NRP; James Heyward, MPH; Lily Olson, BA; Peter Lurie, MD, MPH; Joshua Sharfstein, MD; G. Caleb Alexander, MD, MS

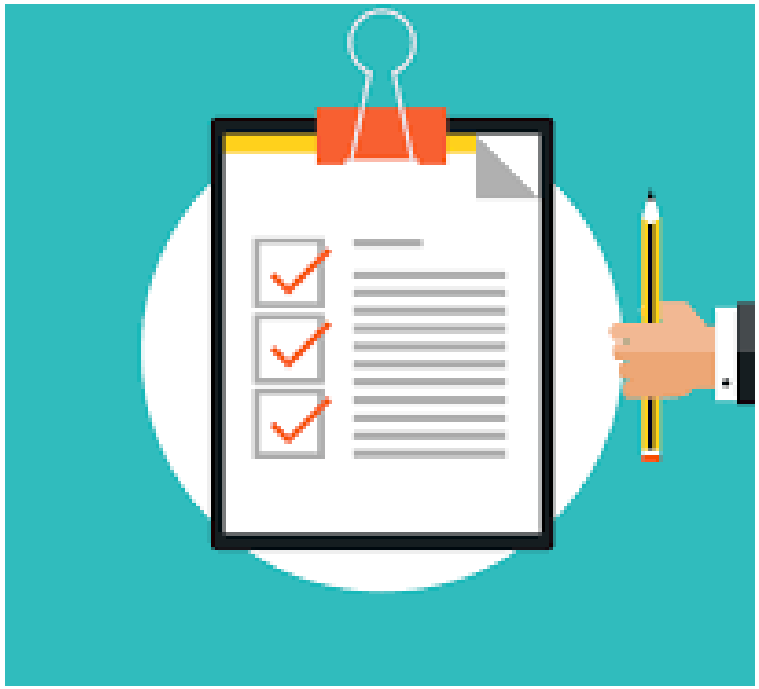
JAMA Internal Medicine | Review

Evaluation of the Extended-Release/Long-Acting Opioid Prescribing Risk Evaluation and Mitigation Strategy Program by the US Food and Drug Administration

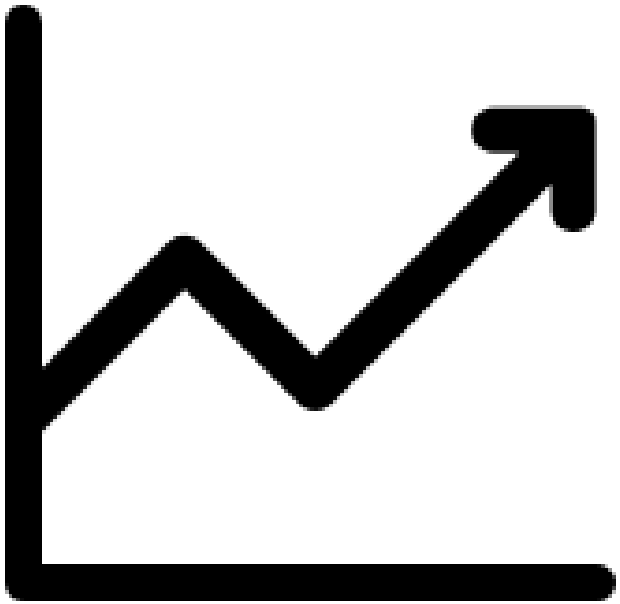
A Review

James Heyward, MPH; Lily Olson, BA; Joshua M. Sharfstein, MD; Elizabeth A. Stuart, PhD; Peter Lurie, MD, MPH; G. Caleb Alexander, MD, MS

Surveys



Surveillance



Evaluations of REMS

1. Totality of evidence approach should include…
2. Use of longitudinal, provider- and patient-level data
3. Linkage with receipt of educational interventions
4. Exploitation of variation in training over time and space
5. Analysis of impact within hospitals, physician groups and other systems of care

A few other points

1. Abandon distracting, low-value approaches
2. Consider focus on high-risk providers and patients
3. Revisit REMS content
4. Evaluations must be rapid and dynamic

How can you have risk evaluation and mitigation without measurement?

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