

Title:	Pediatric Serious Adverse Events after Exposure to Immediate and Extended Release Opioids
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Abstract:

Background: There is a constant safety concern surrounding children being exposed to prescription medications. While the imminent danger of pediatric exposures to medications is a well-known threat, it is also important for the public to be aware of potential outcomes and which prescription medications may be the most dangerous. This study examined the frequency of serious adverse events (SAE) in pediatric patients who were exposed to either immediate release (IR) or extended release (ER) prescription opioids.

Methods: Pediatric unintentional exposure cases from 1q2013 through 4q2013 were reviewed by the RADARS® System staff for either IR or ER oxycodone, hydromorphone tablets, morphine tablets, oxymorphone tablets, or tramadol tablets. A pediatric unintentional exposure was defined as a case involving a child less than 6 years of age who accessed a prescription opioid while outside of adult supervision. Cases involving both an IR and ER formulation of the same drug were excluded. SAE cases were defined as exposures resulting in a major medical outcome, death, or the child being admitted to a health care facility. The proportion of SAE cases for the IR and ER groups was calculated.

Results: There were 1,087 total IR cases, and 289 total ER cases observed in this study. The proportion of SAE cases reported to poison centers was greater for the ER formulations of oxycodone, hydromorphone tablets, morphine tablets, oxymorphone tablets, and tramadol tablets, compared to IR formulations of these drugs. One case involved both an ER and IR formulation product, and was excluded from this study. None of the cases within this study resulted in death.

Conclusion: A greater proportion of SAE cases involved ER formulation drugs compared to IR formulation drugs. Pediatric exposures to any formulation of prescription opioid are potentially dangerous. Our findings, however, suggest that children who are exposed to ER formulations are at a higher risk for major medical outcomes, hospitalization, and death, compared to those exposed to IR formulations.