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| Title: | An analysis of the abuse and associated deaths of immediate release opioid analgesics as compared to extended release formulations in the United States. |
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| Meeting: | NACCT |
| Date: | October 2014 |
| Location | New Orleans, LA |

Abstract:

Background: The US market share of the opioid analgesics is 10% extended release (ER) products (including abuse deterrent formulations [ADF]) and 90% immediate release (IR) products. Recently the FDA has proposed limitations and Risk Mitigation and Evaluation Strategies (REMS) for ER formulations. However, there is no requirement for REMS for most IR formulations and there are no published data supporting REMS for IR formulations. Our objective was to compare rates of abuse of ER opioid analgesic formulations to IR formulations in the US in 2013 and to compare deaths from IR and ER opioid analgesics.

Methods: We compared rates of diversion and abuse of ER to IR opioid formulations using data from the Research, Abuse, Diversion and Addiction Related Surveillance (RADARS®) system. The RADARS System is a real-time surveillance system that measures prescription drug-related misuse, abuse and diversion for specific products across the US. We evaluated data from 2013 and included mentions of opioid misuse from each of the programs and total opioid abuse related deaths in 2013. Average quarterly population and prescription rates are presented with 95% CIs.

Results: Mean population and prescription rates are presented in the table below. The mean population rate for IR formulation per 100,000 persons for the RADARS programs were significantly greater for the IR as compared to ER in all 4 RADARS System programs. Conversely, mean rates per 1000 prescriptions were significantly greater for ER as compared to IR. In 2013 there were 177 deaths where IR products were mentioned compared to 27 deaths where ER products were mentioned as reported to poison centers participating in the RADARS System.

Conclusion: While ER formulation opioids are associated with higher rates of abuse per prescription dispensed in 2013, IR formulation opioids have higher abuse rates per 100,000 persons and are associated with more deaths than ER formulations.