



Title:	Changes in Oxymorphone Abuse Rates Following Introduction of a Crush-Resistant Formulation
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Abstract:

Background: Prescription opioid abuse remains a major public health issue in the US. Abuse-deterrent formulations have been advocated as one prevention strategy. In February, 2012, one manufacturer of extended release oxymorphone (Opana ER®, Endo) replaced the previous product with a crush-resistant formulation (CRF).

Hypothesis: This study evaluated whether the CRF was associated with fewer abuse exposures.

Methods: The Researched Abuse, Diversion, and Addiction-Related Surveillance (RADARS®) System Poison Center program collects data about prescription opioid and stimulant exposures from 50/57 US poison centers. Rates of “intentional-abuse” exposures to Opana ER were compared before (2010Q4 – 2011Q4, averaged) and after (2012Q2, 2012Q3) introduction of the CRF. Negative binomial regression was used to calculate rates based on population and on the number of patients filling prescriptions (Unique Recipients of a Dispensed Drug, URDD). Population rates estimate the overall public health burden from abuse of an opioid, while URDD rates estimate individual risk by controlling for drug availability in the community.

Results: Abuse rates decreased 64% (34-80%) after introduction of the CRF, from 0.022 (0.018-0.027) cases/100,000 population at baseline to 0.010 (0.006-0.018) cases/100,000 population in 2012Q2 and 0.008 (0.004-0.014) cases/100,000 population in 2012Q3 (p=0.001 for change from baseline to 2012Q3). Comparison based on the number of patients filling prescriptions showed a 50% (19-69%) decrease, from 0.552 (0.481-0.633) cases/1,000 URDD before reformulation to 0.302 (0.202-0.451) cases/1,000 URDD in 2012Q2 and 0.278 (0.177-0.437) cases/1,000 URDD in 2012Q3 (p=0.004).

Conclusions: Population and sales-adjusted rates of oxymorphone extended release abuse decreased significantly following introduction of a crush-resistant formulation.