

RADARS[®]

S Y S T E M

Title:	Reformulation of Extended Release Oxymorphone: Changes in Intentional Abuse Exposures Before and After Introduction of Tamper Resistant Formulation
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Abstract:

Background: Studies have indicated that abuse of extended release (ER) oxymorphone tablets increased following the reformulation of an ER oxycodone product (OxyContin®) in August 2010. In February 2012, Endo pharmaceuticals reformulated ER oxymorphone (Opana® ER) to be resistant to tampering.

Aim(s): This analysis examines changes in Opana ER abuse rates following the introduction of these formulations using intentional abuse exposure case mentions from the RADARS® System Poison Center Program.

Methods: Rates per number of prescriptions filled were compared across three time periods: before the reformulation of ER oxycodone and ER oxymorphone (2009Q3 to 2010Q2), after reformulation of ER oxycodone and before the reformulation of ER oxymorphone (2011Q1 through 2011Q4), and after the reformulation of both ER oxycodone and ER oxymorphone (2012Q3 to 2013Q2). Transition quarters are excluded from this analysis. Changes in ER oxymorphone rates were compared to select Schedule II opioids indicated for the treatment of pain (oxycodone, fentanyl, morphine, hydromorphone, and IR oxymorphone). Poisson regression was used to compare differences in rates.

Results: The ER oxymorphone rate increased from 1.02 to 2.57 per 10,000 prescriptions dispensed after reformulation of ER oxycodone and before reformulation of ER oxymorphone; a 150% increase (95% CI: 100%-210%, $p < 0.001$). The abuse rate fell to 1.17 per 10,000 prescriptions dispensed after the reformulation of ER oxymorphone; a 54% (95% CI: 46%-62%, $p < 0.001$) decline from the period after reformulation of ER oxycodone but before reformulation of ER oxymorphone. The changes in ER oxymorphone rates were significantly different from those observed for other Schedule II opioids.

Conclusion: Findings suggest that the reformulation of ER oxycodone was associated with significant increases in intentional abuse exposures mentioning ER oxymorphone. In turn, the reformulation of ER oxymorphone corresponded with decreases in intentional abuse exposures to levels similar to rates prior to reformulation of ER oxycodone. These changes were unique to ER oxymorphone.