RADARS® SYSTEM

Title:	Difference in Rates of Abuse Following Reformulation of Extended Release (ER) Oxycodone using Data from the RADARS® System Poison Center Program
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Abstract:

Study Objectives: In August 2010, a reformulated version of OxyContin (oxycodone HCl controlled-release) tablets was introduced, which is intended to deter crushing and forms a gel when dissolved, with the goal of deterring abuse through routes that require tampering. This study examines whether there was a decline in rates of abuse and therapeutic errors of OxyContin reported to poison centers participating in the RADARS® System after introduction of reformulated OxyContin (ORF). Poison centers participating in the program covered 90% of the US population in the 3rd quarter of 2011.

Methods: Mentions of OxyContin and other prescription products ("exposures") were obtained on a quarterly basis from participating poison centers. Exposures were coded by reason, including intentional abuse and unintentional therapeutic errors. Therapeutic errors are defined as a deviation from a proper therapeutic regimen that results in the wrong dose, incorrect route of administration, administration to the wrong person, or administration of the wrong substance. Rates were calculated for abuse and for unintentional therapeutic error exposures per 100,000 population and per 1,000 unique recipients of dispensed drug (URDD) for each year/quarter. October 1, 2008 through September 30, 2010 was considered the period before and October 1, 2010 to December 31, 2011 was considered the period after introduction of ORF. These poison center data do not differentiate between exposures to original OxyContin versus ORF in the after period. The mean abuse rates for OxyContin as well as other prescription opioid drugs were compared before and after introduction of ORF using negative binomial regression.

Results: There was a 34% (95% CI: 26-42%) decline in the average abuse rate of OxyContin per 100,000 population and 29% (95% CI: 20-36%) decline in the rate per 1,000 URDD after the introduction of ORF. The declines in the abuse rate for OxyContin were greater than changes observed for all other opioids (P<0.0001). There was a 22% (95% CI: 12-32%) decline in the rate of unintentional therapeutic error exposures of OxyContin per 100,000 population and a 16% (95% CI: 10-22%) decline per 1,000 URDD after introduction of ORF. The declines in the therapeutic error rate for OxyContin were greater than changes observed for all other opioids when measured per 100,000 population (p=0.0003), but not when measured per 1,000 URDD (p=0.098).

Conclusion: In the 15 months after the introduction of the reformulation there was a decline in rates of abuse and unintentional therapeutic errors of OxyContin reported to poison centers participating in the RADARS® System. The observed decline for abuse was greater than that for other prescription opioids.

Intentional abuse exposure rates per 100,000 population and 1,000 individuals dispensed drug for OxyContin® from 4th quarter of 2008 through 4th quarter of 2011