

Title: Extended Release Oxycodone Abuse After Reformulation

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Abstract:

Background: In August 2010, Purdue Pharma introduced a reformulated extended release (ER) oxycodone product (ORF) that is intended to deter crushing and forms a gel when dissolved, with the goal of deterring abuse through routes that require tampering.

Objective: This study examines whether there was a decline in rates of abuse of ER oxycodone reported to poison centers participating in the RADARS® System after introduction of ORF. Poison centers participating in the program covered 90% of the US population in the first quarter of 2012. Methods: Mentions of ER oxycodone and other prescription products ("exposures") were obtained on a quarterly basis from participating poison centers. Intentional exposures were coded as abuse or nonabuse (misuse, self-harm, withdrawal, or unknown). Rates were calculated for abuse and for abuse intentional exposures per 100,000 population and per 1,000 unique recipients of dispensed drug (URDD) for each quarter. October 2008 through September 2010 was considered the period before and October 2010 to March 2012 was considered the period after introduction of ORF. The mean abuse rates for ER oxycodone as well as other prescription opioid drugs were compared before and after introduction of ORF using negative binomial regression.

<u>Results</u>: There was a 38% (95% CI: 31-45) decline in the average abuse rate of ER oxycodone per 100,000 population and 32% (95% CI: 24%-39%) decline in the rate per 1,000 URDD after the introduction of ORF. These declines were greater than changes observed for other opioids excluding ER oxycodone and declines observed in ER oxycodone non-abuse intentional exposure rates.

<u>Conclusions</u>: The introduction of the reformulation was followed by a decline in rates of abuse of ER oxycodone products manufactured by Purdue reported to poison centers participating in the RADARS® System. The observed decline for abuse was greater than that for other prescription opioids and that for non-abuse intentional exposures for ER oxycodone.