Title:	Decline in rates of abuse of extended release (ER) oxycodone following the introduction of a reformulated ER oxycodone product using data from the RADARS® Poison Center Program
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Meeting:	International Association for the Study of Pain (IASP) Annual Meeting
Date:	August 2012
Location	Milan, Italy

Abstract:

Aim of Investigation: In August 2010, Purdue Pharma introduced a reformulated extended release (ER) oxycodone product that is intended to deter crushing and that forms a gel when dissolved. The goal of the new formulation is to deter abuse through routes that require tampering. This study examines whether there was a decline in rates of abuse of ER oxycodone manufactured by Purdue reported to poison centers participating in the RADARS® System, an established surveillance system for prescription drug abuse. Poison centers participating in the program covered 90% of the US population in the 3rd quarter of 2011.

Methods: Mentions of ER oxycodone and other prescription products ("exposures") were obtained on a quarterly basis from participating poison centers. The reason for the exposure is coded by poison centers; reasons include exposure due to abuse and due to other intentional exposures (e.g., misuse, self-harm, withdrawal, or unknown but suspected intentional exposures). Rates were calculated for abuse and for non-abuse intentional exposures. To adjust for changes in the program coverage, rates per 100,000 population were calculated for each year/quarter using the 2000 US Census data adjusted for population growth. To adjust for changes in drug availability, rates per 1,000 unique recipients of dispensed drug (URDD) were calculated for each year/quarter. Rates from October 1, 2008 through the September 30, 2010 were considered the period before introduction of the new formulation. Rates from October 1, 2010 to September 30, 2011 were considered the period after introduction of the new formulation. The mean abuse rate before introduction of the new formulation was compared to the mean abuse rate after introduction of the new formulation. This difference in ER oxycodone abuse rates was compared to the difference in ER oxycodone non-abuse intentional exposure rates and abuse rates for other prescription opioid drugs. Rates were compared using negative binomial regression.

Results: There was an estimated 34% (95% CI: 25-42%) decline in the average abuse rate per 100,000 population and an estimated 30% (95% CI: 20-38%) decline in the average abuse rate per 1,000 URDD after the introduction of the reformulation. These declines were greater than changes observed for other opioids excluding ER oxycodone. The estimated decline in the average ER

oxycodone non-abuse intentional exposure population rates was 8% (95% CI: 0-16%) and the estimated decline in the average URDD rate was 3% (95% CI: 11% decline – 5% increase) following introduction of the new formulation. Abuse URDD rates did decline for other opioids excluding ER oxycodone, but the decline in ER oxycodone abuse rates was significantly greater.
Conclusions: Our results suggest that the introduction of the new formulation was followed by a decline in rates of events associated with abuse of ER oxycodone products manufactured by Purdue reported to poison centers participating in the RADARS® System. The observed decline did not reflect a change in non-abuse intentional exposures or abuse of other prescription opioids.