Title: RADARS® System Poison Center Intentional Exposures to OxyContin®: A look at the differences in rates of abuse via unintended routes before and after reformulation intervention

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Abstract:

**Background:** OxyContin was reformulated in August of 2010. The new formulation is intended to deter abuse through inhibiting use via unintended routes, such as chewing, injecting, and inhalation. The purpose of this analysis is to compare routes of administration before and after reformulation within the RADARS® System Poison Center (PC) Program.

**Methods:** The RADARS System PC data for route of administration in OxyContin abuse cases from October 2009 – December 2011 were analyzed. Swallowed whole was considered "intended route of administration"; all other routes were considered "unintended". To adjust for changes in study coverage, rates per 100,000 population were calculated for each year/quarter using the 2000 US Census data. To adjust for changes in drug availability, rates per 1,000 unique recipients of dispensed drug (URDD) were calculated for each year/quarter. Abuse rates were calculated by intended and unintended routes of administration. Abuse rates from before the reformulation (October 2009 – September 2010) were compared with those after reformulation (October 2010 – December 2011) using negative binomial regression.

**Results:** For unintended routes of administration, there was a 43% (95% CI: 24 to 57%, p<0.001) decline in the average abuse rate per 100,000 population and a 36% (95% CI: 14 to 52%, p<0.002) decline in the average abuse rate per 1,000 URDD after the introduction of the new formulation. For intended routes of administration, there was a 29% (95% CI: 8 to 45%, p=0.004) decline in the average abuse rate per 100,000 population and a 19% (95% CI: 0 to 37%, p=0.091) decline in the average abuse rate per 1,000 URDD after the introduction of the new formulation. All decreases were statistically significant with the exception of the decrease in URDD rates for intended routes of administration. The declines in unintended routes of administration rates were not significantly different from the declines in intended routes of administration.

**Conclusion:** Results suggest that overall abuse rates for OxyContin have declined since the introduction of the reformulated product. However, the rate of change is not different between the routes of administration.