RADARS® SYSTEM

Title:	Unintentional exposures to buprenorphine/naloxone tablets and film among children less than 6 years old: initial experience from the RADARS® System Poison Center Program
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Abstract:

Background: Unintentional exposures to potent opioid medications by young children can cause severe illness or death. An oral film formulation of buprenorphine/naloxone was introduced in September 2010. The RADARS® System Poison Center program collects and validates data about exposure to opioid medications, including patient age, reason for exposure, specific formulation, and medical outcome; in 2011Q4, 48/57 US poison centers provided data.

Objective: To determine total exposure rates and associated medical outcomes for unintentional exposures to buprenorphine/naloxone tablets and oral film among children less than 6 years old.

Methods: RADARS System Poison Center program case counts and associated medical outcomes for unintentional exposures to Suboxone® tablets and oral film among children aged 0 – 5 years from October 1, 2009 – December 31, 2011 were analyzed. To account for drug availability in the community, rates were standardized using unique recipients of a dispensed drug (URDD) per year-quarter. Negative binomial regression was used to estimate rates and confidence intervals.

Results: Exposures to buprenorphine/naloxone tablets (average 0.68 cases/1,000 URDD; 95% CI: 0.64 – 0.73) were more common than exposures to oral film (average 0.08 cases/1,000 URDD; 95% CI: 0.07 – 0.10; rate ratio 8.1; 95% CI: 6.5 – 10.0; $p < 0.0001$) during the 5 quarters during which oral film was marketed. Exposure rates for all time periods are shown in the figure. Major medical outcomes or death were reported in 0/92 (0%) oral film exposures and 19/869 (2.2%) tablet exposures ($p=0.24$).

Conclusions: Young child exposures to buprenorphine/naloxone oral film are less frequent than exposures to buprenorphine/naloxone tablets after adjustment for drug availability. Major medical outcomes and death were uncommon with either formulation.