



Title:	Unintentional exposures to buprenorphine/naloxone tablets and oral film among children less than 6 years old
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Abstract:

Objectives: 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 the United States (US) in September 2010. The RADARS® System Poison Center program collects 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. We sought to determine unintentional exposure rates and associated medical outcomes for buprenorphine/naloxone tablets and oral film among children less than 6 years old.

Methods: RADARS System Poison Center program case counts and medical outcomes for unintentional exposures to buprenorphine/naloxone tablets and oral film among children aged 0 – 5 years from October 1, 2010 – 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; $p < 0.0001$). 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: Among children aged 0 – 5 years, unintentional 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 and there were no deaths involving buprenorphine/naloxone oral film.