Unintentional Exposures to Buprenorphine/Naloxone Tablets and Oral Film Among Children Less Than Six Years Old
October 2010 Through June 2015
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Background
- Previous findings, over the period of 2010-2013, demonstrate that among children aged less than 6 years unintentional exposures to buprenorphine/naloxone oral film are less frequent than exposures to buprenorphine/naloxone tablets after adjustment for drug availability.
- However, since these studies were conducted significant changes in the buprenorphine/naloxone tablet market have occurred.
- We examined rates of unintentional exposures to buprenorphine/naloxone film and 2 comparators reported to poison centers in children aged less than 6 years, adjusting for drug availability.

Methods
- Pediatric (less than 6 years) unintentional general exposures to buprenorphine/naloxone oral film, buprenorphine/naloxone tablets, and single-entity buprenorphine tablets in the Researched Abuse, Diversion, and Addiction-Related Surveillance (RADARS®) System Poison Center Program from October 2010 to June 2015 were analyzed.
- The number of exposures in each drug group and quarter were adjusted for drug availability using number of unique recipients of dispensed drug (URDD), scaled per 10,000 URDD.
- Poisson regression analysis with drug specific dispersion parameters was used to compare differences in intercepts (expected rate in 2015Q2) and slopes (quarterly changes over time).

Results
- The expected buprenorphine/naloxone film rate in 2015Q2 (1.11/10,000 URDD, 95% CI: 0.94-1.30) was significantly less (p<0.001) than the expected rates in 2015Q2 for single-entity buprenorphine tablets (2.68/10,000 URDD, 95% CI: 2.28-3.14) and buprenorphine/naloxone tablets (3.77/10,000 URDD, 95% CI: 3.13-4.53) (Table 1).
- On average, the rate for buprenorphine/naloxone film increased by 2% (p=0.043) each quarter, the rate for single-entity buprenorphine tablet decreased 1% (p=0.199) per quarter, and the rate for buprenorphine/naloxone tablets decreased by 4% (p<0.001) each quarter.
- The change in the buprenorphine/naloxone film rate was significantly greater than the change in the single-entity buprenorphine tablet (p=0.018) and buprenorphine/naloxone tablet rates (p<0.001).

Conclusions
- Consistent with previous research, unintentional exposures to buprenorphine/naloxone oral film are less frequent than exposures to buprenorphine/naloxone tablets after adjustment for drug availability.

Table 1. Estimated Rates and Slopes for Unintentional Exposures for Children Less than Six Years per 10,000 URDD

<table>
<thead>
<tr>
<th>Drug Group</th>
<th>Expected Rate in 2015Q2 (95% CI)</th>
<th>Rate Ratio (95% CI), p-value</th>
<th>% Change in Slope (95% CI), p-value</th>
<th>Difference in Slopes, p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine/naloxone films</td>
<td>1.11 (0.94, 1.30)</td>
<td>1.02 (1.00, 1.04), 0.043</td>
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<tr>
<td>Single-entity buprenorphine tablets</td>
<td>2.68 (2.28, 3.14)</td>
<td>2.42 (1.92, 3.03), &lt;0.001</td>
<td>0.99 (0.97, 1.01), 0.199</td>
<td>0.018</td>
</tr>
<tr>
<td>Buprenorphine/naloxone tablets</td>
<td>3.77 (3.13, 4.53)</td>
<td>3.40 (2.66, 4.34), &lt;0.001</td>
<td>0.96 (0.95, 0.98), &lt;0.001</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Figure 1. Unintentional Exposures for Children Less than Six Years per 10,000 URDD

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