Impact of Unit Dose Packaging on Unintentional Pediatric Buprenorphine Exposures

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Introduction

• The prescription opioid epidemic has impacted millions in the United States.
• In pediatrics, accidental, small dose exposures in young children have the potential to result in death.
• Unit dose packaging (UDP) is a method intended to prevent unintentional pediatric exposures where each unit dose is individually packaged.
• We evaluated the impact of UDP on unintentional general buprenorphine pediatric exposures.

Methods

• Data involving children under 6 years from the Researched Abuse, Diversion, and Addiction Related Surveillance (RADARS®) System Poison Center Program between July 2014 and September 2015 were analyzed.
• Buprenorphine products with UDP included Suboxone®/Sublingual Film, Zubsov®/Sublingual Tablet, and Bunavail® Buccal Film (launched in 2010Q3, 2013Q3, and 2014Q4, respectively).
• Using Poisson regression, average unintentional general pediatric buprenorphine exposure rates of the following drug groups were compared:
  - Buprenorphine products with UDP
  - Combination buprenorphine tablets without UDP
  - Single entity buprenorphine tablets without UDP
• Two denominators were considered:
  - Number of prescriptions dispensed
  - Number of dosing units dispensed

Results

• The average rate of buprenorphine products with UDP was 0.26 (95% CI: 0.24 - 0.29) per 10,000 prescriptions dispensed. (Table 1)
• This was significantly less (p<0.0001) than the average rate of combination buprenorphine tablets without UDP (1.11, 95% CI: 0.96 - 1.29) and the average rate of single entity buprenorphine tablets without UDP (0.84, 95% CI: 0.69 - 1.03). (Table 1)
• Similar results were found for rates per dosing units dispensed. (Table 2)

Table 1. Rate per 10,000 Prescriptions Dispensed

<table>
<thead>
<tr>
<th>Drug group</th>
<th>Average Rate (95% CI)</th>
<th>Rate Ratio (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine products with UDP</td>
<td>0.26 (0.24, 0.29)</td>
<td>Reference</td>
<td>Reference</td>
</tr>
<tr>
<td>Combination buprenorphine tablets without UDP</td>
<td>1.11 (0.96, 1.29)</td>
<td>4.23 (3.54, 5.05)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Single entity buprenorphine tablets without UDP</td>
<td>0.84 (0.69, 1.03)</td>
<td>3.20 (2.57, 3.99)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Table 2. Rate per 100,000 Dosing Units Dispensed

<table>
<thead>
<tr>
<th>Drug group</th>
<th>Average Rate (95% CI)</th>
<th>Rate Ratio (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine products with UDP</td>
<td>0.10 (0.09, 0.11)</td>
<td>Reference</td>
<td>Reference</td>
</tr>
<tr>
<td>Combination buprenorphine tablets without UDP</td>
<td>0.38 (0.33, 0.43)</td>
<td>3.70 (3.12, 4.39)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Single entity buprenorphine tablets without UDP</td>
<td>0.30 (0.25, 0.36)</td>
<td>2.96 (2.41, 3.63)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Figure 1. Prescription and Dosing Units Dispensed Rates

- The average unintentional general pediatric exposure drug utilization rates were significantly lower for buprenorphine products with UDP than for combination buprenorphine tablets without UDP rates and single entity buprenorphine tablets without UDP rates per prescription dispensed and dosing units dispensed.
- Unit dose packaging may decrease morbidity and mortality from pediatric buprenorphine exposures.

Conclusions

- The average unintentional general pediatric exposure drug utilization rates were significantly lower for buprenorphine products with UDP than for combination buprenorphine tablets without UDP rates and single entity buprenorphine tablets without UDP rates per prescription dispensed and dosing units dispensed.
- Unit dose packaging may decrease morbidity and mortality from pediatric buprenorphine exposures.

Limitations

- These data rely on spontaneous calls made to participating poison centers, which may not be representative of the US population.

RADARS System Poison Centers


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