Association Between Vaccine Exemption Policy Change in California and Increased Parental Adverse Event Reporting

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Background

- California Senate Bill 277 (SB277) eliminated non-medical immunization exemptions for school aged children July 1, 2016—Requires every child to be vaccinated or have a medical exemption (ME) on file before entering a new grade span
- Since its implementation, the proportion of kindergarteners who received all required vaccines has increased
- The rate of MEs has also increased
- The largest increases in MEs occurred in regions that previously had high levels of personal-belief exemptions

OBJECTIVE: to examine trends in VAERS reporting from California associated with implementation of SB277

Methods

- VAERS is a national passive system for monitoring adverse events (AEs) following immunization
  - Co-managed by Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration
  - Accepts reports from any source
  - Outcome of AEs coded using Medical Dictionary for Regulatory Activities (MedDRA) Preferred Terms (PTs)
  - Serious reports include: hospitalization, prolongation of hospitalization, life-threatening illness, permanent disability, or death

- Study population: children (<18 years of age at time of report) in California
- Texas was utilized as a reference state
- Reports (received June 1, 2011-July 31, 2018) were divided based on SB277 announcement and implementation

Results

1. Proportion of annual reports to VAERS by parents in California and Texas, 2011-2018

   - 6,703 VAERS reports from California during the study period
     - 1,134 (17%) from parents
   - The proportion of reports received from parents increased over time
     - pre-SB277: 494 (14%)
     - inter-period: 267 (19%)
     - post-SB277: 373 (23%)

2. Time from immunization to submission of VAERS report by parents

   - 2014-2015 school year
     - SB277 announced February 19, 2015
     - Reporting time begins to increase
   - 2015-2016 school year
     - Reporting time continues to rise
   - 2016-2017 school year
     - SB277 implemented July 1, 2016
     - Reporting time peaks

3. Behavioral and developmental PTs reported by parents >6 months after immunization

<table>
<thead>
<tr>
<th>Pre-SB277 N=75</th>
<th>Inter-period N=88</th>
<th>Post-SB277 N=108</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal behavior</td>
<td>16%</td>
<td>Abnormal behavior</td>
</tr>
<tr>
<td>Anxiety</td>
<td>10%</td>
<td>Developmental delay</td>
</tr>
<tr>
<td>Developmental delay</td>
<td>10%</td>
<td>Autism</td>
</tr>
<tr>
<td>Sensory disturbance</td>
<td>8%</td>
<td>Speech disorder</td>
</tr>
<tr>
<td>Aphasia</td>
<td>7%</td>
<td></td>
</tr>
</tbody>
</table>

Increase in behavioral and developmental PTs from parent reports

   - After SB277 publicly announced
   - Only reports submitted >6 months after child's immunization

Conclusions

- Increased proportion of parent reports following announcement of SB277 and increased reporting time suggests parents are often reporting AEs from the past
- A number of PTs reported by parents are not known to be causally associated with any vaccine
- May indicate that more parents are using VAERS to assist in applying for ME for their child
- VAERS report alone may not provide sufficient information to support ME
- Websites targeted to vaccine-hesitant parents include VAERS reports among sources of documentation for ME
- Follow-up by physicians, public health authorities, school district is important to ensure that children have a valid reason for ME

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