

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

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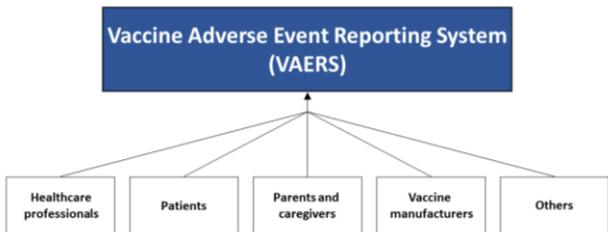
Background

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

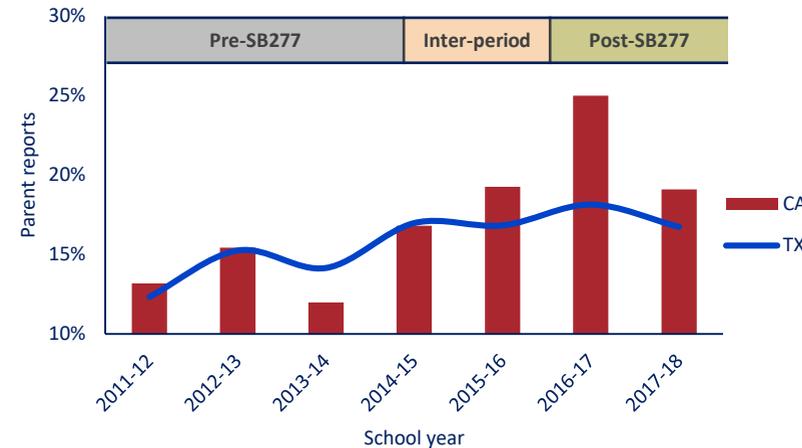


- VAERS is a national passive system for monitoring adverse events (AEs) following immunization
 - Co-managed by Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration
 - Accepts reports from any source
 - Outcome of AEs coded using Medical Dictionary for Regulatory Activities (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

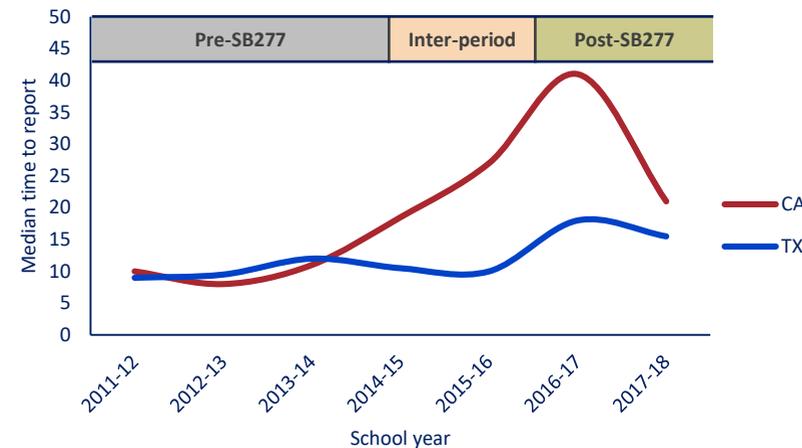


• **6,703 VAERS reports from California during the study period**
– 1,134 (17%) from parents

• **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

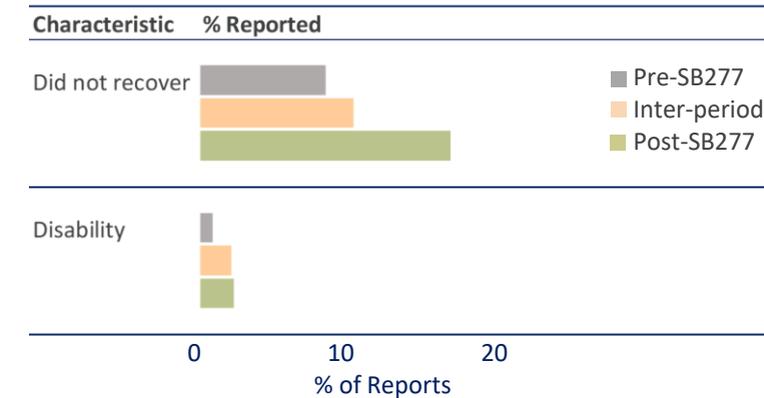
3 Behavioral and developmental PTs reported by parents >6 months after immunization

Pre-SB277 N=75	Inter-period N=88	Post-SB277 N=108
-	Abnormal behavior 16%	Abnormal behavior 11%
-	Anxiety 10%	Developmental delay 9%
-	Developmental delay 10%	Autism 8%
-	Sensory disturbance 8%	Speech disorder 8%
-	-	Aphasia 7%

Increase in behavioral and developmental PTs from parent reports

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

4 Outcome characteristics of VAERS reports, all sources



From pre-SB277 to post-SB277:

- Proportion of reports stating vaccinee had not recovered at time of follow-up doubled from 9 to 18%
- Proportion of reports reporting permanent disability doubled
– Other serious reports were similar by study period

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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