Exemptions From Mandatory Immunization After Legally Mandated Parental Counseling

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BACKGROUND: The success of health care provider counseling–based interventions to address vaccine hesitancy is not clear. In 2011, Washington State implemented Senate Bill 5005 (SB5005), requiring counseling and a signed form from a licensed health care provider to obtain an exemption. Evaluating the impact of a counseling intervention can provide important insight into population-level interventions that focus on interpersonal communication by a health care provider.

METHODS: We used segmented regression and interaction and aggregation indices to assess the impact of SB5005 on immunization coverage and exemption rates in Washington State from school years 1997–1998 through 2013–2014.

RESULTS: After SB5005 was implemented, there was a significant relative decrease of 40.2% (95% confidence interval: −43.6% to −36.6%) in exemption rates. This translates to a significant absolute reduction of 2.9 percentage points (95% confidence interval: −4.2% to −1.7%) in exemption rates. There were increases in vaccine coverage for all vaccines required for school entrance, with the exception of the hepatitis B vaccine. The probability that kindergarteners without exemptions would encounter kindergarteners with exemptions (interaction index) decreased, and the probability that kindergarteners with exemptions would encounter other such kindergarteners (aggregation index) also decreased after SB5005. Moreover, SB5005 was associated with a decline in geographic clustering of vaccine exemptors.

CONCLUSIONS: States in the United States and jurisdictions in other countries should consider adding parental counseling by health care provider as a requirement for obtaining exemptions to vaccination requirements.

WHAT’S KNOWN ON THIS SUBJECT: Exemption rates for mandated immunizations are associated with ease of the administrative procedures to obtain exemptions. Several states, in recent years, have implemented the addition of health care provider counseling/signature as a requirement to obtain a nonmedical exemption.

WHAT THIS STUDY ADDS: The success of counseling-based interventions to address vaccine hesitancy is not clear. Evaluating the impact of a counseling intervention can provide important insight into population-level interventions that focus on interpersonal communication by an authority figure.

Dr Omer conceptualized and designed the study, drafted the initial manuscript, and reviewed and revised the manuscript; Ms Allen, Dr Chang, and Dr Bednarczyk conceptualized and designed the analysis, conducted analyses and reviewed and revised the manuscript; Ms Guterman interpreted data analysis, finalized analytical output, and critically reviewed and revised the manuscript; Drs Buttenheim and Jones provided input into the analyses and reviewed and revised the manuscript; Mr Jordan collected data and reviewed and revised the manuscript; Ms Hannan provided
Immunization mandates have helped the United States achieve and maintain high immunization coverage and low disease rates. However, local clustering of vaccine exemptions has been associated with outbreaks of measles and pertussis. In fact, elimination of endemic transmission of measles in the United States might be threatened by the accumulation of children with vaccine exemptions.

State laws in the United States mandate that the parent of every child entering kindergarten either provide proof of immunization or file for an exemption. All 50 states and Washington, DC, allow for medical exemptions from mandated vaccinations. Eighteen states allow religious, personal belief, and medical exemptions; 29 states and Washington, DC, permit religious and medical exemptions but not personal belief exemptions; and 3 states only allow medical exemptions. Immunization coverage and rates of nonmedical (ie, religious or personal belief) exemptions vary by state. After accounting for demographic differences, state-level and school-level nonmedical exemptions rates are associated with ease of the administrative procedures to obtain exemptions.

Given the association between procedures for obtaining exemptions and higher rates of nonmedical exemptions, several states have attempted to modify their administrative requirements for obtaining nonmedical exemptions. One strategy implemented by several states in recent years is the addition of health care provider counseling and/or signature as a requirement to obtain a nonmedical exemption. The ostensible rationale for adding such a requirement is to ensure that parents have sufficient information about the risks of nonvaccination and to correct misperceptions about vaccine safety. However, the success of such counseling-based interventions is not clear. There is evidence of a so-called “backfire” effect when attempting to correct misinformation. This backfire effect has been previously reported in the context of vaccines, although not consistently. Moreover, making procedures for granting nonmedical exemptions more difficult may have an “offset” effect, causing medical exemption rates to increase.

Evaluating the impact of mass implementation of a counseling intervention can therefore provide important insight into population-level interventions that focus on interpersonal communication by an authority figure, in this case a health care provider. Moreover, it is important to identify the impact of any change in state-level rates of exemptions on local clustering of vaccine refusers, which can dramatically affect the risk of an outbreak.

Washington was the first state in recent years to make a significant change in its vaccine exemption requirements. The Senate Bill 5005 (SB5005) was implemented on July 22, 2011. The law requires parents seeking an exemption to submit a Certificate of Exemption (COE) signed by a Washington-licensed health care provider documenting that the parent(s) have discussed “the benefits and risks of immunizations” with the provider (Supplemental Fig 4 and 5). In this study, we evaluated the impact of adding a health care provider counseling and/or signature requirement to the Washington exemption process on subsequent vaccination and vaccine exemption rates, and on the local clustering of vaccine exemptions. This is the first study in which the impact of adding parental counseling to requirements for obtaining vaccine exemptions has been evaluated.

METHODS

Data

Kindergartener immunization coverage and exemption data were obtained from the Washington State Department of Health. The data included school- and state-level coverage (ie, the percentage of children who are vaccinated for each school) information for all mandated immunizations, exemptions (medical, personal, religious and/or religious membership), conditional entrants (students who were allowed to attend school on condition of parents to subsequently provide evidence of vaccination), and noncompliant entrants (entrants that did not provide subsequent evidence of vaccination or a signed exemption form) for each school year of interest. The data also included school enrollment data and disease-specific coverage for vaccines required by Washington (diphtheria-tetanus-pertussis, polio, pertussis, measles-mumps-rubella, hepatitis B, and varicella vaccines) for each school year of interest. The study period included school years 1997–1998 through 2013–2014. School addresses were obtained from the Washington State Office of Superintendent of Public Instruction and were geocoded by using the United States Census Bureau Census Geocoder.

Longitudinal Analysis

We fit 2 types of multivariable models to evaluate the impact of law on each coverage outcome of interest. Since Washington State did not report exemption type (ie, medical, nonmedical, and permanent medical exemption rates) before the 2012–2013 school year and changes in procedures can potentially have an “offset” effect on medical exemption rates, the dependent variable for both types of models was overall exemption rates. Using state-level data, we fit linear models corrected for first order autocorrelation between years to compute absolute changes in exemption/vaccination rates. For each linear model, we checked for autocorrelation before fitting the full model. We used negative binomial regression instead of ordinary
of Poisson regression because our outcomes of interest are statistically considered to be rare and there is overdispersion in the data as evaluated by Pearson and deviance statistics to test for overdispersion. By using school-level data, we fit a negative binomial model using robust SEs computed with generalized estimating equations considering school as the clustering variable, accounting for interaction between year and policy era (before/after SB5005), with first-order autoregressive covariance structures for residuals and random effects parameters to compute incidence rate ratios and relative change in rate. The number of students enrolled in each school was included as an offset term in the model to account for differences in rates by school size. Because schools are where children experience the majority of exposures to unvaccinated children, we chose to model school-level effects rather than effects at any additional levels of aggregation. We dropped models that provided a poor fit compared with observed values or that failed for mathematical issues such as nonconvergence, indefinite Hessian matrix, and infinite likelihood. For linear models, we used maximum likelihood, and for negative binomial models, we used generalized estimating equations to obtain parameter estimates.

Institutional review board approval for this study was obtained through Emory University. All analyses were performed by using SAS 9.4 (SAS Institute, Inc, Cary, NC).

**Spatial Analysis**

With school data for each school year from 1997–1998 through 2013–2014, we used kriging tools in ArcMap 10.2.2 (Esri, Redlands, CA) to create predicted local exemption rates for the whole state. We dropped schools in the 99th percentile for exemption rates before generating the predicted surface because kriging is influenced by extreme values. Each data year was standardized by using quantiles of the average predicted exemption rate for all years.

**Interaction and Aggregations Indices**

We used 2 measures of exposure, interaction and aggregation indices, to estimate the likelihood that kindergarteners would be exposed to other children with exemptions at their school. These measures have been used to estimate the exposure of a racial minority population to a majority population but have also been used in a similar analysis assessing exemptions in California. To calculate the interaction and aggregation index, we used methods as described by Buttenheim et al.

The interaction index is a measure of the probability that kindergarteners without exemptions will have contact with kindergarteners with exemptions at school. The index is calculated as the sum, across all schools, of the school-specific exemption rate weighted by the proportion of all nonexempted kindergarteners who attend that school:

\[
\text{Interaction Index} = \left( \sum_{i=1}^{N} \left( \frac{a_i}{A} \right) \left( \frac{X_i}{K_i} \right) \right) \times 100
\]

wherein \(a_i\) is the number of adherent kindergartners in school \(i\), \(A\) is the total number of adherent kindergartners for all schools, \(x_i\) is the number of exempted kindergartners in school \(i\), \(K_i\) is the total kindergarten enrollment in school \(i\), and \(N\) is the number of schools in the area for which the index is being calculated.

The aggregation index is a measure of the probability that kindergartners with exemptions will have contact with other exempted kindergartners at school. The index is calculated as the sum, across all schools, of the school-specific exemption rate weighted by proportion of all exempted kindergarteners who attend that school:

\[
\text{Aggregation Index} = \sum_{i=1}^{N} \left\{ \left( \frac{x_i}{X_i} \right) \left( \frac{X_i}{K_i} \right) \right\} \times 100
\]

RESULTS

After SB5005 was implemented, there was a significant relative decrease of 40.2% (95% confidence interval [CI]: −43.6% to −36.6%) in exemption rates in Washington. Moreover, there was a significant absolute reduction of 2.9 percentage points (95% CI: −4.2% to −1.7%) in the rates of immunization exemptions at the state level (Table 1, Fig 1, Supplemental Table 2). Vaccine coverage for all vaccines required for school entrance either increased or remained the same (Table 1). There was also an increase in conditional entrants after the implementation of SB5005; however, this increase was small and insignificant (0.6%, 95% CI −0.9% to 2.1%) (Fig 1C, Table 1, Supplemental Table 2). Additionally, there was an absolute decrease in entrants who were out of compliance (Fig 1D, Supplemental Table 2).

The probability that kindergarteners without exemptions would encounter kindergarteners with exemptions (interaction index) generally decreased after SB5005 became effective. Similarly, the probability that kindergarteners with exemptions would encounter other such kindergarteners (aggregation index) also decreased after SB5005 (Fig 2). Based on spatial analysis, high exemption rates appeared to be clustered in the northern areas.
of the state until 2010. In most cases, predicted exemption rates were found to decrease, specifically in geographic areas with high exemption rates, after SB5005 became effective (Fig 3).

**DISCUSSION**

The implementation of SB5005, which added a health care provider counseling and/or signature requirement for parents requesting immunization exemptions for their children, was associated with decreases in exemption rates. This highlights the importance of more stringent policies for obtaining immunization exemptions. There did appear to be variation in the trend line between 2008 and 2009 in the rates for any exemptions and overall vaccination coverage. This variation can potentially be explained by the updates made to the Certificate of Immunization Status (CIS) and COE, which were implemented in the 2009–2010 school year. Before 2008, the CIS and COE were on 1 form, front and back (Supplemental Fig 6 and 7). In 2008, the COE was separated from the CIS, becoming a stand-alone form (Supplemental Fig 4 and 5). This additional form may have increased the difficulty of obtaining an exemption, therefore decreasing exemption rates. Another possible explanation for this variation is the change in varicella vaccination requirement that took place in 2008; all children attending kindergarten after July 1, 2008, are required to have 2 doses of varicella vaccine or provider verification of varicella disease. This new requirement may have caused an increase in overall immunization coverage after 2008. However, despite this variation, the trend line was generally stable. Furthermore, the data indicate that exemption rates are approaching a steady state.

Although there was an increase in conditional entrants (ie, students who were allowed to attend school on condition of parents subsequently providing evidence of vaccination), there was, reassuringly, a decrease in entrants who were out of compliance. However, the proportion of enrolled students that are conditional entrants and out of compliance was \(-10\%\) after the implementation of the law. This indicates that efforts should also focus on enforcing compliance of these conditional entrants. Moreover, there was a sustained decrease in the interaction index, indicating that the risk of a vaccinated child interacting with a child with an exemption declined after the implementation of SB5005. Although this is the first study in which the impact of adding a health care provider counseling and/or signature requirement has been evaluated, previous data reveal the utility of state and school policies that increase the overall administrative requirements to obtain exemptions. In an analysis of state-level exemptions data from 2005 through 2011, states that had easy procedures for granting nonmedical exemptions had almost double the rates of nonmedical exemptions compared with states with difficult procedures for exemptions. A similar association was observed in a study evaluating the interaction between ease of obtaining exemptions and change in exemption rates from 1991 through 2004. One concern associated with interventions that increase overall administrative difficulty for obtaining nonmedical exemptions is a potential increase in vaccine-hesitant parents seeking medical exemptions from sympathetic providers. However, in a study of medical exemptions and procedures for granting such exemptions, states with difficult procedures for granting nonmedical exemptions had only slightly higher rates of medical exemptions, indicating a minimal offset in exemption rates. Given the concerns of a potential backfire effect for information-based

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**TABLE 1 Absolute and Relative Increase or Decrease in Immunization Status After SB5005**

<table>
<thead>
<tr>
<th>Vaccine specific, %</th>
<th>Absolute Change (Linear Regression)</th>
<th>Relative Change (Negative Binomial Regression)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>( \beta ) Law (95% CI)</td>
<td>Incidence Rate Ratio (95% CI)</td>
</tr>
<tr>
<td><strong>Population level, %</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any exemption ( ^a )</td>
<td>(-2.9 (-4.2 to -1.7))</td>
<td>(-40.2 (-43.6 to -36.6))</td>
</tr>
<tr>
<td>Complete for all immunizations ( ^b )</td>
<td>(4.0 (1.2 to 6.8))</td>
<td>(3.4 (2.4 to 4.4))</td>
</tr>
<tr>
<td>Conditional entrant ( ^c )</td>
<td>(0.6 (-0.9 to 2.1))</td>
<td>(26.0 (12.0 to 42.0))</td>
</tr>
<tr>
<td>Out of compliance conditional entrants ( ^d )</td>
<td>(-1.8 (-3.2 to 0.1))</td>
<td>(-26.5 (-32.0 to -20.0))</td>
</tr>
<tr>
<td><strong>Vaccine specific, %</strong></td>
<td>(0.9 (-0.2 to 2))</td>
<td>(0.9 (0.2 to 1.6))</td>
</tr>
<tr>
<td>Diphtheria, tetanus, and pertussis ( ^e )</td>
<td>(0.4 (-3.3 to 4.0))</td>
<td>(1.0 (-0.5 to 0.8))</td>
</tr>
<tr>
<td>Mumps ( ^f )</td>
<td>(0.6% (-1.7 to 3.0))</td>
<td>(0.3 (-0.3 to 0.9))</td>
</tr>
<tr>
<td>Rubella ( ^g )</td>
<td>(0.6 (-1.8 to 3.1))</td>
<td>(0.3 (-0.3 to 0.9))</td>
</tr>
<tr>
<td>Polio</td>
<td>(0.0 (-1.1 to 1.2))</td>
<td>(-0.6 (-1.3 to 0.1))</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>(-0.2 (-2.5 to 2.1))</td>
<td>(-0.4 (-0.9 to 0.1))</td>
</tr>
<tr>
<td>Varicella ( ^h )</td>
<td>(4.3 (-5.7 to 14.3))</td>
<td>(2.1 (1.1 to 3.1))</td>
</tr>
</tbody>
</table>

\( ^{a} \) Adjusted for year (centered), law, and law*year (centered).  
\( ^{b} \) Adjusted for year (centered), law, and law*year (centered), and school-level effects.  
\( ^{c} \) The student has a signed COE on file at the school excusing the student from 1 or more vaccinations because of medical, personal, or religious beliefs.  
\( ^{d} \) The student meets all the school-entry requirements for his or her age and grade and is in compliance.  
\( ^{e} \) The student lacks appropriate documentation or is missing 1 or more of the required immunizations.  
\( ^{f} \) Conditional status has ended, but the student has not been fully immunized, does not have an exemption on file, or lacks appropriate documentation.  
\( ^{g} \) Beginning in the 2006–2007 school year, pertussis is reported separately from diphtheria and tetanus.  
\( ^{h} \) Beginning in the 2012–2013 school year, measles, mumps, and rubella are reported as the measles-mumps-rubella combination.
intervention, it is reassuring to see that parental counseling was not associated with a net increase in exemption rates or net decrease in vaccination rates. This could be caused by many factors. First, the so-called backfire effect has not been consistently replicated. Second, the clinical interaction between a health care provider and a parent revolves around not only correcting misinformation but also, among other things, increasing disease salience, which may be more relevant to parents. Moreover, physicians are the most trusted source of vaccine information. Third, the effect of this policy change might be caused by an increase in administrative difficulty of obtaining an exemption, rather than by persuasive interpersonal communications.

FIGURE 1
Observed and forecasted rates in Washington State before and after implementation of SB5005 plotted against negative binomial regression lines for (A) any exemption, (B) students complete for all immunizations, (C) conditional entrants, and (D) entrants out of compliance.

FIGURE 2
The probability that kindergarteners without exemptions would encounter kindergarteners with exemptions (interaction index) and the probability that kindergarteners with exemptions would encounter other such kindergarteners (aggregation index) by year in Washington State.
Several states have attempted to eliminate nonmedical exemptions altogether, and in 2015, California state legislators were successful in doing so. California is only the third state to implement a policy that does not allow any nonmedical exemptions and is the first state in over 3 decades to eliminate a nonmedical exemption provision. Given that the new California law only went into effect in the 2016–2017 school year, it will be a few years before its impact can be appropriately evaluated; currently only 1 year’s postimplementation data are available. Meanwhile, evidence that adding a parental counseling requirement may be effective in reducing vaccine exemptions and is likely to inform vaccine policy in many states. Notably, legislative efforts to restrict exemptions have been more successful than attempts to eliminate them entirely.6

There are several limitations of our study. First, we did not have a control population; therefore, unrelated secular changes may have impacted our findings. However, given the demographic heterogeneity among states, using another state as a comparison may have introduced additional problems. Moreover, our findings should be generalized to other states and jurisdictions with some caution. The impact of adding parental counseling may depend on state-specific variation in immunization laws, health infrastructure, and other context-specific factors. Therefore, this type of analysis will have to be repeated for other states with recent changes in vaccine laws as their postchange data become available.

CONCLUSIONS

Our findings highlight the importance of evidence-informed legislation to reduce the risk of vaccine preventable diseases. States in the United States and jurisdictions in other countries should consider adding parental counseling as a requirement for obtaining exemptions to vaccination requirements.

ABBREVIATIONS

CI: confidence interval
CIS: Certificate of Immunization Status
COE: Certificate of Exemption
SB5005: Senate Bill 5005
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