Nonmedical Exemptions to School Immunization Requirements

Secular Trends and Association of State Policies With Pertussis Incidence

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Context School immunization requirements have played a major role in controlling vaccine-preventable diseases in the United States. Most states offer nonmedical exemptions to school requirements (religious or personal belief). Exemptors are at increased risk of acquiring and transmitting disease. The role of exemption policies may be especially important for pertussis, which is endemic in the United States.

Objective To determine if (1) the rates of nonmedical exemptions differ and have been increasing in states that offer only religious vs personal belief exemptions; (2) the rates of nonmedical exemptions differ and have been increasing in states that have easy vs medium and easy vs difficult processes for obtaining exemptions; and (3) pertussis incidence is associated with policies of granting personal belief exemptions, ease of obtaining exemptions, and acceptance of parental signature as sufficient proof of compliance with school immunization requirements.

Design, Setting, and Participants We analyzed 1991 through 2004 state-level rates of nonmedical exemptions at school entry and 1986 through 2004 pertussis incidence data for individuals aged 18 years or younger.

Main Outcome Measures State-level exemption rates and pertussis incidence.

Results From 2001 through 2004, states that permitted personal belief exemptions had higher nonmedical exemption rates than states that offered only religious exemptions, and states that easily granted exemptions had higher nonmedical exemption rates in 2002 through 2003 compared with states with medium and difficult exemption processes. The mean exemption rate increased an average of 6% per year, from 0.99% in 1991 to 2.54% in 2004, among states that offered personal belief exemptions. In states that easily granted exemptions, the rate increased 5% per year, from 1.26% in 1991 to 2.51% in 2004. No statistically significant change was seen in states that offered only religious exemptions or that had medium and difficult exemption processes. In multivariate analyses adjusting for demographics, easier granting of exemptions (incidence rate ratio=1.53; 95% confidence interval, 1.10-2.14) and availability of personal belief exemptions (incidence rate ratio=1.48; 95% confidence interval, 1.03-2.13) were associated with increased pertussis incidence.

Conclusions Permitting personal belief exemptions and easily granting exemptions are associated with higher and increasing nonmedical US exemption rates. State policies granting personal belief exemptions and states that easily grant exemptions are associated with increased pertussis incidence. States should examine their exemption policies to ensure control of pertussis and other vaccine-preventable diseases.

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STATE-MANDATED SCHOOL IMMUNIZATION requirements have played a major role in achieving and maintaining low rates of vaccine-preventable diseases in the United States.[1-5] All states and the District of Columbia require children entering school to provide documentation that they have met the state vaccine requirements. As of March 2006, all states permitted medical exemptions to school and daycare immunization requirements; 48 states allowed religious exemptions; and 19 states had a provision for personal belief exemptions.[6] Personal belief exemptions include religious, philosophical, and any other unspecified nonmedical exemption. Two states, Arkansas and Texas, added a personal belief exemption in the 2003-2004 school year.

Some states make exemptions widely available to parents either by offering a personal belief exemption rather than only a religious exemption or by easily permitting exemptions.[7] For example, California offers a personal belief exemption whereby the parent simply signs a prewritten statement on

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the school immunization form. This personal belief exemption is available to anyone regardless of the nature of their beliefs (religious or philosophical) and it is easier to claim this exemption than to complete the school immunization form that requires a health care clinician to obtain the child's medical record and transcribe the dates of vaccine administration. Other states, such as Maryland, call their exemption religious but also make it extremely easy for parents to take the exemption option. The Maryland school immunization form states, "Because of my bona fide religious beliefs and practices, I object to any immunizations being given to my child." As in California, parental signature to this Maryland statement provides for an exemption without any other administrative requirements and some Maryland parents are likely to use this exemption even though the reasons for not vaccinating are not religiously grounded. Some states that offer either religious or personal belief exemptions have administrative requirements, such as requiring a signature from a local health department official, annual renewal, notarization, or a personally written letter from the parents explaining the reasons for vaccine refusal.[7]

States that make exemptions widely available to parents, either by offering a personal belief exemption or making the exemption option easy to obtain, may have higher rates of exemptions or may experience substantial increases in exemption rates. Increasing exemption rates can increase individual and community risk to vaccine-preventable diseases.[8,9] The role of exemption policies may be especially important for pertussis, which remains endemic in the United States and has been increasing in incidence during the past decade.[10-13]

The primary objectives of this study were to determine if: (1) the rates of nonmedical exemptions differ and have been increasing in states that offer only religious vs personal belief exemptions; (2) the rates of nonmedical exemptions differ and have been increasing in states that have easy vs medium and easy vs difficult processes for obtaining exemptions; and (3) pertussis incidence is associated with policies of granting personal belief exemptions, ease of obtaining exemptions, and acceptance of parental signature as sufficient proof of compliance with school immunization requirements.

METHODS

Secular Trends in Exemption Rates

We analyzed state-level exemption rates for the 1991-1992 through the 2004-2005 school years for the 48 states that permit nonmedical exemptions (all states but Mississippi and West Virginia) and the District of Columbia. Schools annually report to state health departments the number of students claiming an exemption to 1 or more vaccines (exemption rate numerator) and the number of students enrolled (exemption rate denominator) at school entrance. Since the 1991-1992 school year, states have summarized these data and reported them to the Centers for Disease Control and Prevention (CDC). State exemption rates were based on kindergarten data if no first grade data were available (59.5%; n=408), first grade data if no kindergarten data were available (3.2%; n=22), and combined kindergarten and first grade data if both were available (10.3%; n=71). Exemption rate data remained missing after initial reporting and follow-up for 27.0% (n=185) state-years. Some states (8 in the 2004-2005 school year)[14] included exemption information for home-schooled children and for these states, these data were part of our analysis.

Information on the type of nonmedical exemption permitted by states (ie, religious only vs personal belief) was obtained through a review of state laws available from state government Web sites and LexisNexis.[6] Data on the ease of obtaining an exemption were based on a previously published survey of state immunization program managers that assessed the formality of the procedures and the time and effort required to claim an exemption[7] in 1998. Exemption ease categories included consideration of: (1) whether a form was permissible vs a letter written by the parent; (2) where the parent obtained the form (ie, school vs the health department); (3) whether or not the form needed to be notarized; and (4) if a letter from the parent was required, whether or not the parent needed to expend extra effort to determine how the statements in the letter needed to be worded. States were categorized into 1 of 3 categories that represented the level of complexity of obtaining an exemption (easy, 15 states; medium, 14 states; difficult, 19 states) and 2 states that do not offer nonmedical exemption and District of Columbia were not categorized. Changes in state requirements for hepatitis B and varicella vaccines were determined from 2 organizations that track these laws.[15,16]

We used the *t* test to compare exemption rates in states with religious only vs personal belief exemptions and for comparison of states with easy vs medium and easy vs difficult processes for granting exemptions.

We used a population-average model (ie, a generalized estimating equation model) to estimate changes in nonmedical exemption rates over the study period in states that offer only religious vs personal belief exemptions and that have easy vs medium and easy vs difficult processes for obtaining exemptions.[17] We assumed that the number of exemptions for each year was distributed as a Poisson random variable with mean μ_i. The mean number of exemptions each year in each state had an offset term (denominator for exemption rate) defined as the number of new school entrants during that year. Since exemption rates for an individual state over time are correlated, we imposed an autoregressive correlation structure within states and considered exemption rates between states as independent. A negative binomial model was selected for regression analyses as it best fit the data and most adequately addressed issues of overdispersion. Year was treated as a continuous variable. The data are reported as incidence rate

ratios (IRRs) reflecting the annual change in exemption rates for states that permit only religious exemptions, states with personal belief exemptions, and states with easy, medium, and difficult exemption policies.

The model adjusted for new vaccine requirements for varicella and hepatitis B vaccines by treating these variables as time-dependent dichotomous variables indicating whether a law existed in a given year (ie, if hepatitis B requirements went into effect in 1999, the variable was set to 0 prior to 1999 and 1 afterward). These changes in state laws reflect the number of potential vaccines for which a parent could claim an exemption.

We performed a missing data analysis to examine patterns of missing data including whether missing data were related to exemption rates, year, and type of exemption (religious only vs personal belief and easy, medium, or difficult processes for obtaining exemptions). Analysis was conducted using SAS 9.1 (SAS Institute Inc, Cary, NC).

Pertussis Incidence and Associations With State Policies

We analyzed pertussis incidence and state policies for the years 1986 through 2004 for the 48 states permitting nonmedical exemptions and the District of Columbia. Pertussis cases (numerator for pertussis incidence) among individuals aged 18 years or younger were acquired from the CDC's Nationally Notifiable Infectious Disease Surveillance System. These data are collected and compiled from reports sent by state health departments to the CDC in collaboration with the Council of State and Territorial Epidemiologists.[18] We used population estimates from the US Census Bureau's Population Estimates Program[19] of those aged 18 years or younger for pertussis incidence denominators. The population estimates program computes age-specific population estimates based on census enumerations, births and deaths in the United States, net international migration, and net movement of the armed forces since the previous census.[19]

Data on type of exemption and ease of exemption were obtained in the same way as in the secular trends analysis. Information on whether states accepted parental signatures as proof of immunization was obtained from state immunization program managers through a Web-based survey we conducted in 2002. We verified the information by reviewing the relevant laws for the states that reported accepting parental signatures as sufficient proof of compliance and a 1 in 5 random sample of all other states. We adjusted for demographic variables that have been associated with vaccine uptake or occurrence and reporting of pertussis,[10-13] including: the proportion of the population living in urbanized areas, the proportion of households in 11 various income categories, and the proportion of individuals aged 25 years and older in 7 education categories. We did not adjust for state-level immunization coverage because it could be in the causal pathway between state policies and pertussis incidence.

A negative binomial model was fit to estimate the rates of pertussis and associations with state policies. We assumed that the number of pertussis cases for each year (numerator for pertussis incidence) was distributed as a Poisson random variable with mean μ_i. The model used the number of individuals aged 18 years or younger in each state as the offset term (denominator for pertussis incidence). Annual state-level pertussis incidence was considered to be autocorrelated over time and independent between states. IRRs were derived directly from the models as the measure of association between pertussis incidence and the state policy. The IRR can be interpreted as the (multiplicative) difference in pertussis incidence associated with a particular state policy. Analysis was conducted using versions 7 and 8 of Stata (Stata Corp, College Station, Tex).

For all analyses, the variables for the models were selected a priori based on relevant literature, therefore, we did not adjust for multiple comparisons. No collinearity was found with the candidate models using a variance inflation factor. Since variance inflation factor is a less than perfect method, we did not include the variables for personal belief exemption and exemption ease in the same model.

We estimated power for Poisson regression by previously described methods.[20-22] Using a sample of 50 states and the District of Columbia, Poisson regression of the number of pertussis cases on a single normally distributed independent state policy variable (ie, $R^2=0$) with mean = 0 and standard deviation = 1 achieves 80% power at a significance level of $\alpha = .05$ to detect an IRR of at least 2.0 due to a 1-unit change in the independent variable. For the multivariate model, keeping all other assumptions the same, an R^2 of 0.25, 0.5, and 0.75 would detect an IRR of at least 2.2, 2.8, and 3.4 respectively. Associations were considered statistically significant with $P < .05$ or 95% confidence interval (CI) not containing 1.

The study was granted exempt status by Johns Hopkins Bloomberg School of Public Health's Committee on Human Research.

RESULTS

Secular Trends in Nonmedical Exemption Rates

Religious Exemptions vs Personal Belief Exemptions. When examining differences in states with only religious exemptions vs personal belief exemptions, there was no difference in the mean nonmedical exemption rates at baseline (1991-1992 school year; $P = .98$) using unadjusted t tests or in multivariate analysis. States that offered personal belief exemptions had higher rates of exemptions than states that only offered religious exemptions for each year from 2001 through 2004 ($P < .01$). FIGURE 1 demonstrates an increasing separation in exemption rates between states that only offered religious exemptions and states that offered personal belief exemptions.

In states offering personal belief exemptions, an increase in exemption rates from 0.99% in 1991 to 2.54% in 2004 was seen (IRR = 1.06; $P = .01$; 95% CI, 1.01-1.12), adjusting for whether

varicella or hepatitis B vaccine were required. Exemption rates did not change significantly in states that only offered religious exemptions over the study period (IRR=0.95; 95% CI, 0.90-1.01; *P*=.07).

Figure 1. Mean Percentage and Interquartile Ranges of Nonmedical Exemptions for States That Only Permit Religious Exemptions and States That Permit Personal Belief Exemptions, 1991 Through 2004

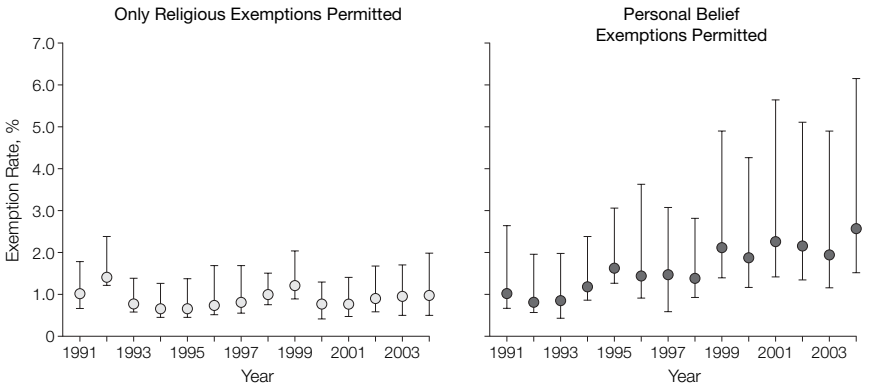


Table 1. Annual Change in State Nonmedical Exemption Rate Stratified by Ease of Obtaining an Exemption and Availability of Personal Belief Exemptions From 1991 Through 2004*

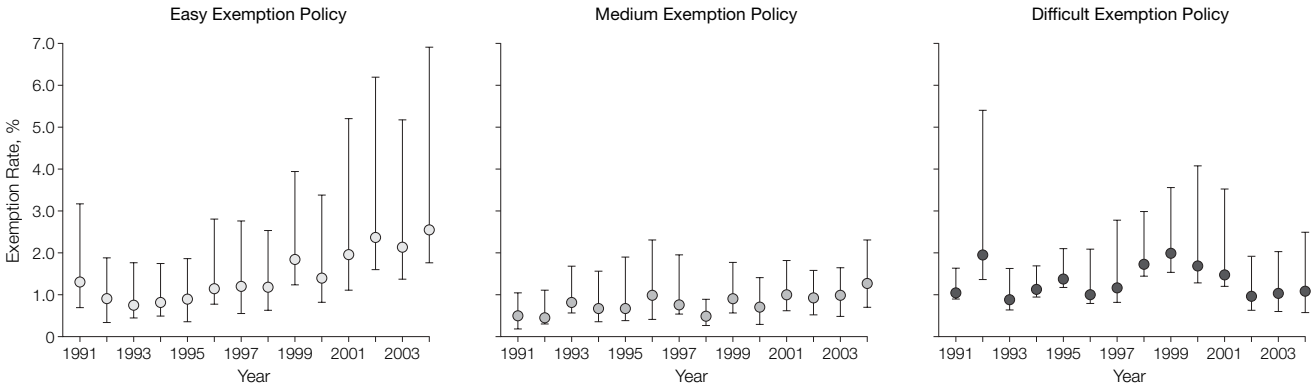
	No. of State-Years	Annual Change in Exemption Rate Incidence Rate Ratio† (95% Confidence Interval)	*P* Value
Type of exemption permitted by states for school and daycare			
Only religious exemption	328	0.95 (0.90-1.01)	.07
Personal belief exemption	175	1.06 (1.01-1.12)‡	.01
Exemption ease			
Difficult	185	0.96 (0.86-1.07)	.50
Medium	126	0.99 (0.96-1.03)	.66
Easy	158	1.05 (1.01-1.09)	.03

*All models adjusted for varicella and hepatitis B requirements.
†Annual change in exemption rates computed as an interaction with time (ie, personal belief exemption × year and exemption ease × year).
‡Interpretation of incidence rate ratio: states that permit personal belief exemptions experienced a 6% annual increase in exemption rates during the study period.

Easy, Medium, and Difficult Processes for Granting Exemptions. Using unadjusted *t* tests, we observed that states that easily permitted exemptions at baseline (1991-1992 school year) had higher mean nonmedical exemption rates compared with states that had a medium difficulty for granting exemptions (*P*=.01), but no significant difference with states that had difficult procedures for granting exemptions (*P*=.33). States that easily granted exemptions had significantly higher exemption rates compared with states with medium requirements for 2002 and 2003 (*P*=.01 and .03, respectively), and states with difficult requirements for 2002, 2003, and 2004 (*P*=.009, .02, and .01, respectively). In states that easily permitted exemptions, an increase from 1.3% in 1991 to 2.5% in 2004 was observed (IRR=1.05; 95% CI, 1.01-1.09; *P*=.03). No statistically significant change over the study period was seen in states that had medium or difficult processes for granting exemptions (TABLE 1). FIGURE 2 illustrates that the mean exemption rate increased in states that easily granted exemptions, and remained fairly constant in states that had medium and difficult processes for granting exemptions.

Missing data did not affect our findings. Exemption rates over time for all states were nearly identical to rates in states that provided at least 10 state-

Figure 2. Mean Percentage and Interquartile Ranges of Nonmedical Exemptions by Ease of Obtaining an Exemption, 1991 Through 2004



Policy descriptions by Rota et al,[7] 2001.

years of data, and incidence of missing data does not appear to be strongly correlated with exemption rates (data available by request).

Pertussis Incidence and Associations With State Policies

The mean annual incidence of pertussis in the 50 states and the District of Columbia is presented in FIGURE 3. Vermont had the highest incidence at 12.8 per 100 000. In unadjusted analysis, pertussis incidence in states allowing personal belief exemptions was more than twice as high as in states that only offered religious exemptions (IRR = 2.06; 95% CI, 1.77-2.4). States with easy procedures for granting exemptions were associated with a 90% higher incidence of pertussis (IRR = 1.90; 95% CI, 1.06-2.28) and states with a medium difficulty for granting exemptions were associated with a 27% higher incidence of pertussis (IRR = 1.27; 95% CI, 1.06-1.51) compared with states with difficult procedures to obtain exemptions. Pertussis incidence was 41% higher for states that considered parental signature as sufficient proof of immunization compared with states that did not (IRR = 1.41; 95% CI, 1.12-1.77) (TABLE 2).

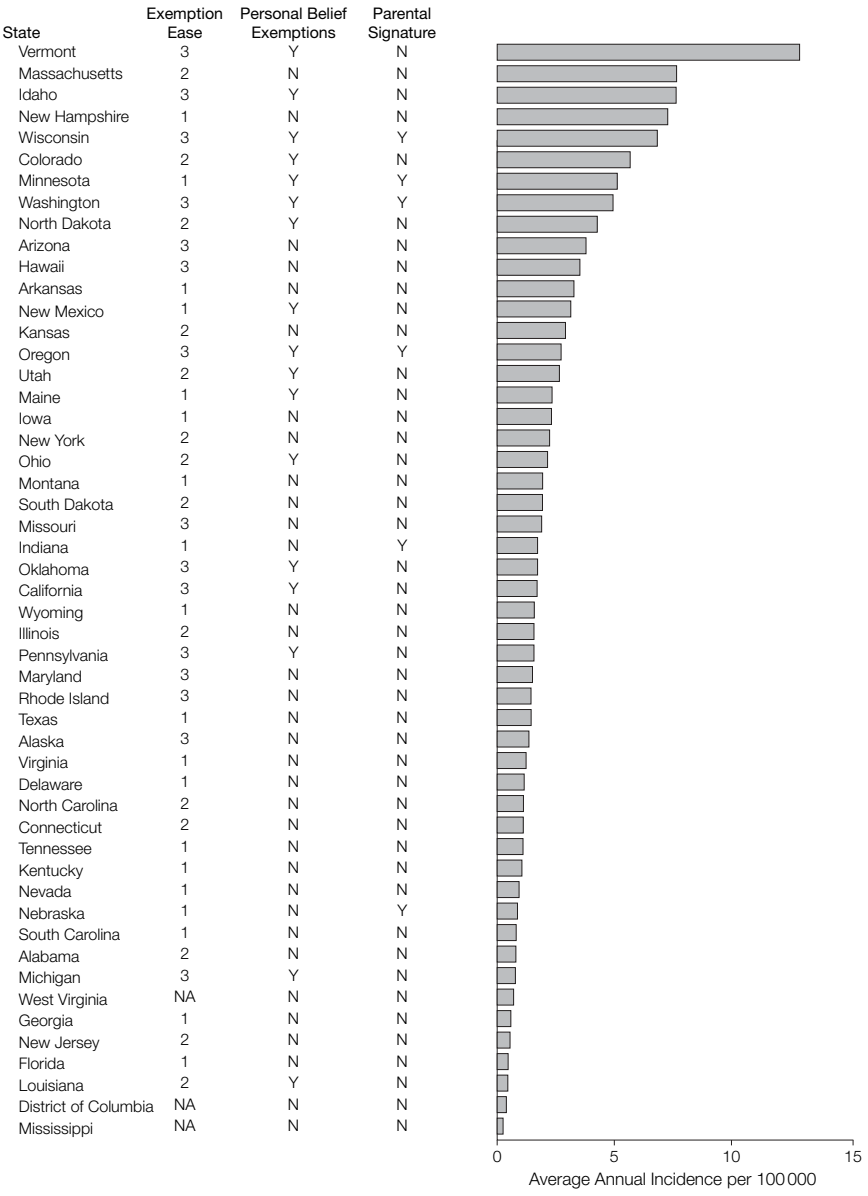
Easily granting exemptions (IRR = 1.53; 95% CI, 1.10-2.14) and availability of personal belief exemptions (IRR = 1.48; 95% CI, 1.03-2.13) remained associated with higher pertussis incidence in the multivariate analysis (Table 2). The IRRs for medium exemption ease and parental signature as sufficient proof of immunization were somewhat, but not statistically significantly elevated in the multivariate model (Table 2).

COMMENT

States that permitted personal belief exemptions had higher nonmedical exemption rates than states that only offered religious exemptions, and states that easily granted exemptions had higher exemption rates compared with states with medium and difficult processes for granting exemptions. The mean nonmedical exemption rates increased in states that permitted personal belief exemptions and in states that easily granted exemptions. In contrast, the mean exemption rates did not increase in states that only offered religious exemptions and states that had medium and difficult processes for obtaining an exemption.

Availability of personal belief exemptions and easily obtained exemptions were associated with increased pertussis incidence. The small number of states with acceptance of parental signature may have limited the power of this comparison. These study findings indicate that state exemption policies affect vaccine exemption rates as well

Figure 3. Annual Reported Pertussis Incidence per 100 000



Mean annual reported pertussis incidence by state (1986-2004) among individuals aged 18 years or younger. Exemption ease descriptions: 1, difficult; 2, moderate; 3, easy. NA indicates not applicable: West Virginia and Mississippi do not offer nonmedical exemptions and the District of Columbia was not surveyed.

Table 2. Association of Ease of Obtaining Exemptions, Availability of the Personal Belief Exemption Option, and Acceptance of Parental Signature as Sufficient Proof of Having Met School Immunization Requirements With the Incidence of Pertussis From 1986 Through 2004

	No. of States	Unadjusted Incidence Rate Ratio (95% Confidence Interval)	Adjusted Incidence Rate Ratio (95% Confidence Interval)
Type of exemption permitted by states for school and daycare			
Only religious exemption	32*	Reference	Reference
Personal belief exemption	17†	2.06 (1.77-2.40)‡	1.48 (1.03-2.13)§
Exemption ease			
Difficult	19	Reference	Reference
Medium	14	1.27 (1.06-1.51)	1.35 (0.96-1.91)‖
Easy	15	1.90 (1.60-2.28)	1.53 (1.10-2.14)‖
Parental signature accepted as sufficient proof of compliance with school immunization requirements			
No	45	Reference	Reference
Yes	6	1.41 (1.12-1.77)	1.10 (0.73-1.68)‖

*A total of 48 states and the District of Columbia offer nonmedical (ie, religious only and personal belief) exemptions.
†Arkansas and Texas added a personal belief exemption in the 2003-2004 school year, and Arizona offers a personal belief exemption for school but not daycare.
‡Incidence rate ratio: states that permit personal belief exemptions had more than twice (2.06 times) the pertussis incidence compared with states that only permit religious exemptions.
§Model terms: personal belief exemptions available, proportion inside urbanized area, income (11 categories), and education (7 categories). Interpretation of incidence rate ratio: states that permit personal belief exemptions had a 48% higher pertussis incidence compared with states that only permit religious exemptions, adjusting for proportion inside urbanized area, income, and education.
‖Model terms: exemption ease (3 categories), parental signature, proportion inside urbanized area, income (11 categories), and education (7 categories).

as pertussis incidence. States should examine their exemption policies to ensure control of pertussis and other vaccine-preventable diseases.

Children with nonmedical exemptions are at increased risk of disease and they increase community risk of disease transmission. From 1985 through 1992, exemptors in all states were 35 times more likely to contract measles than nonexempt children.[8] In Colorado, exemptors were 22 times more likely to have had measles and 5.9 times more likely to have had pertussis than vaccinated children.[9] Moreover, the incidence of measles and pertussis in nonexempt children in a county was associated with the frequency of exemptors in that county.[9]

Nonmedical exemptions tend to be geographically clustered, providing the critical mass of susceptibles and increasing individual and community risks. State-level data may obscure refusal rates that are much higher in individual communities. For example, exemption rates of 15% to 18% are found in Ashland, Oregon and Vashon, Washington.[23,24] Social clustering of exemptions increases the risk of disease outbreaks, as was recently exemplified in an Indiana measles outbreak.[25]

The understanding of how demographic factors influence exemption-seeking behavior is limited. Parents of exempt children had higher levels of education than parents of fully vaccinated children from the same school in a recent study.[26] In our multivariate models, the association between pertussis incidence was associated with state policies after adjusting for education, as well as urbanization and income.

The success of immunizations has paradoxically shifted many parents' concerns from the risks of vaccine-preventable diseases to the risks of vaccine-adverse events.[27] Safety concerns in the United States and many developed countries have increased since the 1970s. A recent case-control study revealed that vaccine safety concerns were the primary reason parents were claiming nonmedical exemptions.[26] Vaccine safety concerns were also identified as the primary reason for vaccine refusal in the recent Indiana measles outbreak.[25] Increased vaccine safety concerns among parents may explain increases in exemption rates in states that make exemptions widely available to parents by offering personal belief exemptions or easily permitted exemptions.

School and state reporting of exemptions are based on the frequency of children who have an exemption for 1 or more vaccines. A recent study in 4 states found that about 25% of children with nonmedical exemptions received no vaccines; the remaining children with exemptions were antigen-specific.[26] An increase in the frequency of children with exemptions for 1 or more vaccines would be expected as new vaccines such as varicella and hepatitis B have been required by state laws. However, the rates of nonmedical exemptions are increasing in states that permit personal belief exemptions and in states that easily grant exemptions, even adjusting for the effect of new vaccine requirements.

Our study findings should be interpreted with several caveats. Exemption rate data were self-reported by schools, there were missing data, and the methodologies for collecting and reporting exemption data vary by state. These sources of bias could have an effect on the study findings if bias was differential by type of exemption permitted or study year. Our analyses suggest that missing data did not have a qualitative effect on our findings. Standardization of the manner in which states collect and report exemption data would reduce the theoretical possibility that some of the differences we observed were due to variability in surveillance for exemptions by type. Variability in ensuring compliance with school immunization requirements may not be completely reflected in the categories of exemption ease and availability of personal belief exemptions. Thus, the effect of policies may vary among states with the same policy. Underreporting of pertussis is widely recognized and could have affected our results.[28] Complexity of procedures for obtaining exemptions was measured in 1998 and changes could have oc-

curred over time. We are aware of only 3 states making changes from 1993 to 1998.[7] The state-level data could be subject to ecological fallacy, however, conclusions from individual-level studies enhance the validity of the findings.

Most states do not collect or report exemption rates among home-schooled children. Assessment of vaccine refusal rates among home-schooled children is an area that deserves further research. Incomplete reporting of exemption rates among home-schooled children likely had no impact on our study findings as reporting of these data was not differential by exemption type, ease, or rates.

CONCLUSIONS

States must balance parental autonomy with the tremendous public health benefit of vaccines when considering the types of exemptions allowed and how policies are implemented. An approach similar to the model applied to conscientious objectors to conscription, which focuses on the sincerity of the applicants' beliefs and includes administrative controls, may provide a reasonable middle ground.[29] Our findings support the need for effective administrative controls over granting nonmedical exemptions. Moreover, state-level policies on nonmedical exemptions and documentation of immunization status should be viewed as part of the efforts to control or eliminate vaccine-preventable diseases.

Author Contributions: Dr Omer had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Omer, Pan, Halsey, Stokley, Moulton, Navar, Pierce, Salmon.
Acquisition of data: Omer, Pan, Halsey, Stokley, Moulton, Navar, Pierce, Salmon.
Analysis and interpretation of data: Omer, Pan, Halsey, Stokley, Moulton, Navar, Pierce, Salmon.
Drafting of the manuscript: Omer, Pan, Halsey, Moulton, Navar, Pierce, Salmon.
Critical revision of the manuscript for important intellectual content: Omer, Pan, Halsey, Stokley, Moulton, Navar, Salmon.
Statistical analysis: Omer, Pan, Moulton.
Obtained funding: Salmon.
Administrative, technical, or material support: Halsey, Stokley, Navar, Salmon.
Study supervision: Salmon.

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