Vaccination status of children exempted from school-entry immunization mandates

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ABSTRACT

The child immunization schedule is one of the most successful public health interventions of the past century. Despite this success, parental vaccine hesitancy is widespread and increasing. One manifestation of vaccine hesitancy is rising rates of non-medical or "personal beliefs" exemptions (PBEs) from school-entry immunization mandates. Exemptions have been shown to be associated with increased risk of disease outbreak, but the strength of this association depends critically on the true vaccination status of children with exemptions, which has not been assessed. Additionally, little is known about school-level policies and practices that may promote exemptions independent of parental preferences. In this study, I use administrative data collected by the California Department of Public Health to estimate the true vaccination status of children with PBEs and to identify school factors associated with PBE rates. The study provides an important baseline prior to implementation of a new exemption policy in California in 2014.

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The routine child immunization schedule is widely claimed to be the most successful public health intervention of the past century, preventing an estimated 42,000 deaths and 20 million cases of disease, and saving $14 billion in direct medical costs, per US birth cohort.[1] Despite this success, parental vaccine hesitancy and refusal are widespread and increasing.[2-6] One manifestation of vaccine hesitancy is rising rates of non-medical (religious, philosophical or "personal beliefs") exemptions from school-entry immunization mandates—exemptions that parents can obtain in all but two states.[7] In California, the focus of this study, we recently reported that exemptions quadrupled from 0.5% of kindergarteners in 1996[8] to 2.3% in 2010.[9]

While higher rates of exemptions have been shown to be associated with increased risk of outbreak of vaccine-preventable childhood diseases (VPCDs), the strength of this association and its implications depend critically on the true vaccination status of children with exemptions. However, there is scant evidence on the vaccination status of exempted children, and prior studies that do find a significant relationship between exemption prevalence and disease risk assume that exempted children are unvaccinated. If these children are in reality partially or nearly fully protected, then the excess disease risk associated with vaccine refusal is *underestimated*.[10, 11] At the same time, little is known about school-level policies and practices that may promote exemptions independent of parental preferences. For example, data from the California Department of Public Health (CDPH) suggest that some schools may encourage parents to file an persona beliefs exemption (PBE) when a child is missing a vaccine dose or when the parent cannot produce evidence of vaccination. Such policies may inflate exemption rates and therefore *overstate* the disease outbreak risk associated with PBEs, as children who obtain exemptions for this reason may have received more vaccine doses than children whose parents file exemptions due to vaccine hesitancy.

The purpose of this study is to provide estimates of the true vaccination status of children with PBEs and to identify school-level policies and practices associated with higher PBE rates. Robust estimates of this relationship are needed in order for states and school districts to translate PBE rates into estimates of disease risk; and to target specific school policies that may be driving exemption rates independent of parental preferences. An additional goal of the study is to understand current exemption and vaccination dynamics prior to regulatory change in California that will make the exemption process more burdensome for parents as of 2014.

Using data routinely collected by the CDPH, I first describe the vaccination status of California kindergarteners with personal beliefs exemptions. I hypothesize, based on prior studies, that the majority of children with personal beliefs exemptions are at least partially vaccinated, but that exempted children at schools with more PBEs are less vaccinated than exempted children at schools with average PBEs. I then identify school-level policies and practices associated with higher vs. lower exemption rates. I hypothesize that schools that offer parents an exemption option for missed vaccine doses or unavailable records will have higher PBE rates compared to schools that do not offer parents this option. The results from these analyses will produce the first population-level estimates of the vaccination status of exempted kindergarteners in a large state, which can be used to model the actual disease outbreak risk associated with exemptions. The study will also identify school-level policies and practices that may be good candidates for interventions to reduce exemptions.

RISING VACCINE HESITANCY AND EXEMPTIONS FROM SCHOOL MANDATES

Near-universal vaccination coverage among children has dramatically reduced vaccine-preventable childhood diseases (VPCDs) and associated costs in the US.[1] Despite this success, controversy over the safety and efficacy of childhood immunizations has produced widespread and increasing parental vaccine hesitancy and refusal.[2-6] One manifestation of vaccine hesitancy is exemptions from immunization mandates at the point of school entry—mandates that have historically been an important means of achieving high levels of immunization coverage.[12] School-entry immunization mandates have been upheld in courts as an appropriate exercise of state authority; however, all but two states provide for a non-medical exemption from those mandates to balance parental authority with the protection of the public's health. The exemption process is governed by state law, and varies widely across states.[7]

In California, the focus of this study, school-entry immunizations have been mandated since 1977.[12] To enroll a child in kindergarten, parents in California provide documentation of immunization[13] or file a "personal beliefs exemption" (PBE) from the immunization requirements.[14] Filing a personal beliefs exemption in California is currently very easy: a parent simply signs an affidavit stating that the immunization is contrary to the parent's personal beliefs.[14] A pre-printed affadavit appears on the back of the California School Immunization Record. Mirroring the rise of vaccine hesitancy and refusal nationally, PBE rates in California tripled from 0.5% of entering kindergarteners in 1996 to 1.5% in 2007.[8] In a published study, we showed that 2.3% of California kindergarteners in Fall 2010 had filed a personal beliefs exemption;[9] recent reports from the CDPH and our own analyses indicate that this rate climbed to 2.7% in 2012 (**see Figure 1**). Nationally, many other states have also seen increases in exemption rates, with 13 states reporting kindergarten non-medical exemption rates in excess of 3% in 2011-12. Due to concerns about rising PBE rates, the California legislature recently passed Assembly Bill 2109 (AB2109) to increase the burden on parents when applying for an exemption. Beginning in January 2014, the new law will require signed letters from both the parent and a health care provider stating that the parent and the provider have discussed the risks and responsibilities of refusing vaccination.

Because an exemption may be obtained for any or all of the required doses of mandated vaccines, a child with a PBE may be partially or even fully vaccinated. The one prior study that assessed the vaccination status of exempted children in four states found that, according to parent report, 22% were fully vaccinated, 7% had medical contraindication, 17% had received no vaccines, and 53% were partially vaccinated.[15] The CDC acknowledges the limitation of not being able to distinguish exempted children from up-to-date children in its annual reports of kindergarten vaccination coverage and recommends more routinized and standardized collection of these data by states.

Recent outbreaks of vaccine-preventable diseases in California and elsewhere suggest that school-level prevalence of PBEs is already playing a role in VPCD epidemiology in the US.[2, 16] For example, an outbreak of measles in San Diego, California in 2008 started with an intentionally unvaccinated child who contracted measles during travel in Europe.[17] The child attended a school with a high PBE rate—11% of enrolled children had a PBE on file for the measles-mumps-rubella (MMR) vaccine—and 2 additional children from the school contracted

measles.[2] While this case is a compelling example of the association between exemption prevalence and disease risk, estimates of the vaccination status of exempted children are needed to more accurately assess the outbreak risk associated with PBE rates on a wider scale.

Prior research highlights three important relationships between policies, exemptions, and outbreak risk: First, states with easier exemption regulations have more exemptions. Second, there is considerable heterogeneity in exemption rates within and across localities such as counties and school districts. Third, exemptions are associated with outbreaks of disease.[10, 11] Maintaining herd immunity requires high rates of vaccine coverage—up to 80-95% of the population, depending on the disease.[18, 19] Even when state- or county-level coverage is high, the aggregation of intentionally unvaccinated children within social and spatial units such as schools may lead to much lower local coverage rates[9], creating outbreak opportunities.[20]

Accurate assessment of the risk associated with exemptions depends critically on the immunization status of exempted children, which can range from completely unvaccinated to missing just one or two doses of a small number mandated of mandated vaccines. Only one prior study has attempted to assess the immunization status of exempted children.[15] However, this study relied on parental reports of child immunization status with no other verification. This evidence gap has important epidemiologic implications: Prior studies that find a significant relationship between exemption prevalence and disease risk assume that exempted children are unvaccinated. If these children are in reality partially or near full protected, then the excess disease risk associated with vaccine refusal has been underestimated.[10, 11] At the same time, prior research suggests that school-level policies and practices related to kindergarten registration may drive PBE rates independent of parental preferences. It is likely that the immunization status of children whose exemptions are driven by school policies may differ from that of children whose parents elected an exemption based on personal beliefs, but little is known about this relationship.

There is also scant prior research on school-level characteristics that are associated with exemption prevalence. Not surprisingly, exemptions are more common at schools with higher proportions of non-Hispanic white and high socioeconomic status students, mirroring the sociodemographic profile of vaccine hesitant parents more generally.[21] One prior study examined characteristics of the school personnel tasked with monitoring immunizations. Exemptions were more common among children attending a school at which the staff member responsible for

monitoring immunizations had the following characteristics: not a nurse; low perceived disease susceptibility and severity; low perceived vaccine efficacy and safety; and low confidence in local and state health departments.[22] Another study in Washington State evaluated school-based immunization clinics, and found them capable of increasing significantly the number of fully-immunized children; this suggests that exemptions may have been a matter of convenience rather than of conviction in this population.[23] No prior research, however, has investigated role of school policies and practices in promoting or preventing exemptions.

Similar to students in other states, students in California are assigned an immunization status at kindergarten enrollment: up-to-date, permanent medical exemption, personal beliefs exemption, or conditional admission. Conditional admission is granted to students who have been partially immunized but are not yet due for remaining required doses. Conditional admission requires a records review every 30 days until required immunizations are up-to-date, and students must be excluded from school if required immunizations are not received within 10 days of eligibility. Because conditional admission places a significant burden on schools, some school officials may offer PBEs to parents in lieu of a conditional admission. PBEs may also be offered if parents cannot provide evidence of required immunizations due to lost or incomplete records. Schools where PBEs are routinely offered to parents to avoid conditional admission or to circumvent missing records are therefore likely to have higher PBE rates that may be independent of parental vaccine hesitancy.[24, 25]

The goals of the present study are to provide needed estimates of the immunization status of exempted children and to illuminate the associations between school policies, exemption rates, and immunization status. These results will allow school and public health officials to more accurately assess the risk associated with PBE prevalence and clustering and to refine exemption policies and procedures to minimize that risk. These results are also policy-relevant given upcoming changes in exemption regulations in California, and will provide baseline estimates prior to implementation of the new exemption law in 2014.

METHODS

Data

I use two surveys conducted by the California Department of Public Health Immunization Branch. The Kindergarten Retrospective Survey (KRS) is conducted every 3-5 years, provides

estimates of immunization coverage among kindergarten students from a sample of 2-3% of schools that enroll kindergarteners. Local health departments visit approximately 250-300 schools (of 8,000 total schools with kindergartens in California) and collect copies of every sixth student's permanent California School Immunization Record (CSIR). Given the observed rising rates of PBEs in California, the CDPH added two additional samples of kindergarteners to the 2009 KRS (KRS09): (1) All children with PBEs from a stratified random sample of 256 schools; and (2) All children with PBEs from the 50 schools with the highest number of PBEs in the state. The KRS captures demographic data and immunization history from each CSIR (**see Table 1**). Dates are recorded for each dose of each immunization required for kindergarten entry. For the purposes of this study, the CDPH will provide de-identified data, with immunizations recorded for each child in age in completed months. The KRS09 random sample includes 262 kindergarteners with PBEs from the 103 of 256 schools in the sample with at least one PBE. The KRS09 high PBE sample includes 1,107 kindergarteners with PBEs from 50 schools.

The second survey, collected in parallel with the KRS, is the Selective Review (SR). The SR is intended to validate the data on immunization coverage and exemptions collected from all kindergartens each fall, and to assess school procedures for tracking exemptions and conditional entrants over the course of the school year. The SR records the number of kindergarteners, up-to-date kindergarteners, medical exemptions, personal beliefs exemptions, and conditional entrants. Schools are also asked several questions about the procedures for recording PBEs, following up on conditional entrants, and tracking exempted children in the case of an infectious disease outbreak. The 2009 SR (SR09) school sample comprised the same stratified random sample of 256 schools plus the 50 schools with highest number of PBEs as in the KRS09.

Measures

I will use the KRS to develop dose-specific and summary measures of the immunization status for exempted children. For each of the 15 doses of the 5 vaccines mandated by California law for kindergarten entry (e.g., the first dose of MMR, the third dose of DTaP), I will calculate the proportion of exempted children who have received that dose. Summary measures will include (1) the proportion of mandated vaccine doses received (0-100%), and (2) a binary measure of immunization status (unvaccinated vs. vaccinated). For the purposes of this analysis, I define "unvaccinated" as having received 10 or fewer of the 15 mandated vaccine doses, and

"vaccinated" as having received 11 or more of the mandated doses. I consider this cutoff as a proxy for missing one dose each of the mandated immunizations, and will explore the sensitivity of our results to this cutoff. The policy and practice questions on the SR will be used to create a set of indicator variables for the presence/absence of specific policies and practices (**see Table 2** for examples of questions asked in the SR). The school-level outcome variable for this analysis is being in the high-PBE vs. the random sample of schools.

Analytic approach

Immunization status of exempted children. I will first describe the immunization status of exempted kindergartners in 2009 using the summary and dose-specific measures described above, separately for the exempted children in the stratified random sample of schools ("random sample") and those in the 50 schools with the highest number of PBEs ("high PBE sample"). I will then compare exempted children's immunization status in the two samples to determine if there are significant differences in the immunization status of exempted children in random vs. high-PBE schools. Assuming that 50% of exempted children are vaccinated, a two-sided 95% confidence interval with a width equal to .118 can be estimated. Assuming that 50% of these exempted children are vaccinated, a two-sided 95% confidence interval with a width equal to 0.057 can be estimate. The sample sizes of 262 students clustered in 256 random schools and 1107 students clustered in 50 high-PBE schools achieves 80% power to detect a difference between the group proportions of unvaccinated of 0.105 when the proportion of unvaccinated children in the high-PBE sample is 0.50, using a two-sided unpooled Z test with a significance level of 0.05.

I anticipate that some exempted children will have no vaccine doses reported on the CSIR. California law does not currently require parents to supply immunization records for children when they obtain a PBE. A preliminary analysis of KRS09 conducted by CDPH[26] indicates that 45% of exempted children in the random sample and 54% of exempted children in the high-PBE sample have no immunization records on file. I recognize the limitation this places on the analysis, and plan to address it in two ways: First, I will bound the estimates of immunization status by assuming that all exempted children with no immunization records have received the same vaccine doses as the *most vaccinated* exempted child at their school (upper bound) and then that all exempted children with no immunization records have received *no*

immunizations (lower bound). To complement the bounded estimates, I will also use Latin Hypercube Sampling (LHS). LHS is a common and efficient technique to sample across the uncertainty inherent in parameters that can only be partially observed or otherwise estimated with some degree of error. LHS ensures that the uncertainty in each parameter is equally and comprehensively considered in the calculation of the outcome variable, in our case the child vaccination status. Briefly, the outcome range (0 to 1) of each individual dose will be divided into 1,000 equal-probability units; these will then resampled at random and independently, and the resampled estimates used to calculate the probability of having received each mandated vaccine dose. The LHS will yield not a single estimate, but a range of estimates that incorporate the uncertainty surrounding vaccination status of exempted children.

School factors associated with PBE rates. To accommodate the sampling strategy of the SR, I will adopt a case-control approach to calculate the odds of reporting specific policies and practices in high-PBE (case) vs. randomly-selected (control) schools. I will also use logistic regression models to estimate the same association, adjusting for school-level variables and county fixed-effects. The policy of most interest to the study is offering a PBE as an option to parents whose children are not up-to-date for immunizations. I will analyze other policies to identify those with a significantly higher odds of being reported at high-PBE schools compared to randomly-selected schools. The SR09 sample includes 50 schools in the high-PBE sample and 256 schools in random sample. This sample offers 87% power to detect a ratio of 4.0 in the odds of offering PBEs to parents of children who are not up-to-date, assuming a prevalence of 8% in the random sample (consistent with preliminary analysis from the CDPH). The test statistic used is the two-sided Fisher's Exact test with a significance level of 0.05.

Exploratory analyses. I will also conduct exploratory analyses of the relationship between vaccination status and school policies to inform future work. Specifically, I will compare the vaccination status of exempted children in schools that do and do not offer parents PBEs. I hypothesize that the exempted children in schools with this policy will be more vaccinated than exempted children in schools without it. I consider this to be exploratory analysis because the sampling strategy of the SR makes this comparison challenging.

PRELIMINARY AND EXPECTED RESULTS

Preliminary analyses of the KRS09 indicate some important differences in the overall immunization status of children from the high-PBE vs. randomly selected sample. While 44% of exempted children from the random selected sample report no vaccine doses, 54% of exempted children from the high-PBE sample report no vaccine doses. 26% of exempted children in the random sample and 16% in the high-PBE sample are partially vaccinated (1-10 doses), while the proportion of exempted children with more than 10 mandated doses is 30% in both samples. Further analyses planned in this study will suggest whether this is due to stronger vaccine hesitancy among parents or more lenient implementation of exemption policies at the school level. Preliminary analyses of the SR09 data suggest that the odds of offering a PBE to parents who cannot provide documentation of immunization or whose child is otherwise not up to data is more than 5 times higher for high-PBE schools compared to the odds in the random sample (**see Table 3**).

This study will produce the first population-level estimates of the immunization status of exempted kindergarteners in a large US state with rising exemption rates. Summary and dose-specific measures will be used describe immunization status in high-PBE schools compared to a random sample of schools. Estimates will be bounded to account for missing immunization records. These estimates will contribute to a better understanding of the disease risk associated with exemptions, and will provide baseline analysis of vaccination status of exempted children prior to California's exemption policy change. The analysis of school-level data will identify policies and practices that may be good candidates for interventions to reduce exemptions. These results will be useful in refining the estimates of disease risk associated with PBEs calculated in from child-level data, and with assisting public health and school officials and policy makers in designing exemption laws that minimize convenience exemptions

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FIGURES AND TABLES

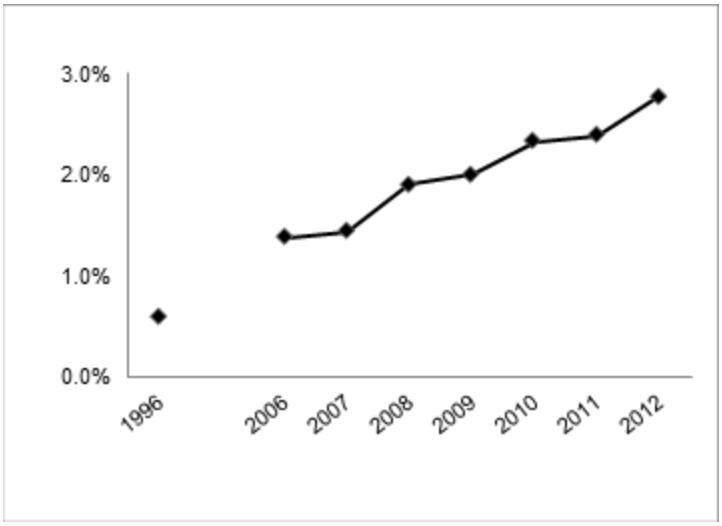

Figure 1—Personal beliefs exemption rate (PBEs per 100 kindergartners), California, 1996-2012.

Table 1—Child-level variables in CDPH Kindergarten Retrospective Survey.

Race
Ethnicity
Place of birth
Type of vaccine record
Exemption status
Age (in months) at each required dose of:
Polio
Diphtheria, Tetanus, Acellular Pertussis
Measles, Mumps, Rubella
Hemophilus influenza B
Hepatitis B
Varicella
History of varicella disease

Table 2—Example school policies and practices related to PBEs collected in the CDPH Selective Review.

- At kindergarten entry, are parents whose children are not up-to-date for immunizations given the option of signing a PBE statement as a short-term alternative while they seek out current records or complete the student's required immunizations?

- For parents who may choose a PBE for their child, did you inform them that their unvaccinated child may be excluded from school if there is an outbreak if disease that the child has not been vaccinated against?

- When a student enters your school and you find that he or she is currently due for a required dose, what does the school do?

Table 3—Prevalence of school-level policy to offer parents the option of signing a PBE statement while seeking documentation or completing immunization by school type, CDPH Selective Review, 2009. (OR=5.1)

	Random sample	High PBE sample	Total
Offered PBE	20 (8%)	15 (30%)	35
Not offered PBE	236 (92%)	35 (70%)	271
Total	256	50	306