

**MANDATORY SCHOOL IMMUNIZATION LAWS IN THE UNITED  
STATES: HISTORICAL ORIGINS, POLICY IMPLEMENTATION, AND  
ASSESSING THE IMPACT OF STRENGTHENING EXEMPTION  
REQUIREMENTS**

by

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## **Abstract**

**Problem Statement:** High immunization coverage among school-age children has been achieved in the United States through the collaborative efforts of federal agencies, state administrations, health care providers, and medical societies supporting a common objective.[1] However, recent parental vaccine hesitancy and refusal trends have been at least partially responsible for regional decreases in immunization coverage rates, increases in state exemption rates, and outbreaks of vaccine preventable diseases. State immunization mandates are an important strategy in protecting children from vaccine-preventable morbidity and mortality. Several states have responded to high exemption rates in their state by passing more restrictive exemption legislation.

**Methods:** This study assessed immunization and exemption mandates in the US in three ways: (1) a literature review and analysis of the evolution of state immunization mandates from 1902-2017; (2) a qualitative assessment of the implementation of restrictive exemption laws in Washington, California, Oregon, and Vermont between 2011-2016; and (3) an impact assessment of exemption rate changes in Vermont between 1989-2016.

**Results:** We found that while all US states and Washington DC have school immunization mandates requiring vaccines for childcare and school entry, there is considerable diversity across states in how states historically began mandating vaccines, the requirements for school entry, the populations to which mandates apply, the types and requirements of exemptions available, implementation and enforcement of mandates, and how states respond to new recommendations.

Through 81 in-depth interviews with stakeholders from state and local health departments, school nurses and health personnel, and immunization experts, we explored barriers and facilitators to effective implementation of new laws. We also found that exemption rates in Vermont were responsive to state vaccine law and policy changes. Changes in vaccine requirements in 2008, 2012, and 2015 impacted exemption rates in public and private schools in Vermont, but non-medical exemptions did not decrease until philosophical exemptions were removed in 2016.

**Discussion:** The results of this study will support legislative and administrative decision-making at state and local health departments, provide evidence to support mandatory immunization law changes at the state level, and support the implementation of requirements at the school level. The variability across state immunization law enactment and implementation has influenced the effectiveness of school mandates and the ease of the exemption requirements. Strengthening exemption requirements to include educational information and increasing the administrative complexity of non-medical exemption requirements is an effective strategy to lower non-medical exemption rates.

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## **Chapter 1 Introduction and Background**

### **1.1 Executive Summary**

The United States (US) immunization system has been responsible for wide-scale reduction in vaccine-preventable diseases (VPDs) among children.[1] High immunization coverage among school-age children has been achieved in the United States through the collaborative efforts of federal agencies, state administrations, health care providers, and medical societies supporting a common objective.[1] As outlined by the National Vaccine Plan 2010, there are efforts to remove barriers to childhood vaccination while supporting state level laws and policies that implement federally recommended immunization schedules. The magnitude of the effort can be seen in the number of children it reaches: half of children in the US are eligible for funding under the federal Vaccines for Children Program.[2] Success has also been measured through decades of high immunization coverage among US children and, consequently, reduced rates of vaccine preventable diseases and outbreaks. State and federal immunization programs create a safety net ensuring school children are up-to-date on specific immunizations against childhood vaccine preventable diseases.[1]

Combining mandatory immunization policies with mandatory school attendance policies has created a societal checkpoint manifesting the dual responsibilities of the federal and state governments to provide childhood education and to protect the health and safety of all children. However, there have been problems with increasing numbers of parents choosing to delay or refuse vaccines, leading to outbreaks of vaccine preventable diseases in the United States and world-wide. Some state health departments

and legislatures have explored changing state immunization and exemption laws and policies in an effort to reduce high exemption rates in schools.

This dissertation examines the phenomena of state-level changes to state immunization laws and the effective implementation of state mandates at multiple levels of school and health department administration, and describes the impact of changing mandates on state exemption rates. Between 2011 and 2016, four states passed state laws mandating changes to school exemption requirements: California, Oregon, Vermont and Washington. These four states were the first to pass laws increasing administrative difficulty of obtaining an exemption in an effort to reduce state exemption rates. Using both quantitative and qualitative research methods, this study examines the process of law change and implementation in each state and assesses the impact of law change on state exemption rates in Vermont. The results of this study will support legislative and administrative decision-making at state and local health departments, provide evidence to support mandatory immunization law changes at the state level, and support the implementation of requirements at the school level.

Chapter 1 provides the background context for understanding immunization laws and exemption types permitted in the US. We also include an explanation of how non-medical exemption rates can be used to understand parental vaccine trends, and a description of how this dissertation adds to the current school immunization and exemption law research landscape. We then provide an overview of the qualitative and quantitative methods used in this dissertation.

Chapter 2 is a review and analysis of mandatory immunization requirements for elementary school enrollment between 1902-2017. Using historical publications, we

compiled data for state-immunization law mandates by antigen, year, and age populations. Chapter 3 is a qualitative analysis of school law implementation Oregon, Washington, Vermont, and California between 2011-2016. Chapter 4 is a quantitative analysis of the impact of school law and policy changes in Vermont between 1989-2016. In chapter 5, we discuss the key findings, limitation, recommendations for future research, and policy implications.

## **1.2 Abbreviations**

ACIP	Advisory Committee on Immunization Practices
CA	California
CDC	Centers for Disease Control and Prevention
DC	District of Columbia
FDA	Food and Drug Administration
GLM	Generalized linear model
GEE	Generalized estimating equations
IRB	Institutional Review Board
ME	Medical Exemption
NME	Non-medical Exemption
OR	Oregon
RWJF	Robert Wood Johnson Foundation
US	United States
VPD	Vaccine-Preventable Disease
VT	Vermont
WA	Washington
WHO	World Health Organization

### **1.3 Background**

#### **1.3.1 School Immunization Laws**

Each state is responsible for the provision of health and educational services to state residents. States maintain a central or state health department that oversees health services throughout the state, and collaborates with district or regional offices. States vary in the amount of administrative and financial control retained by the state health department and in how independently the regional departments operate. However, the immunization responsibilities of the health department are largely consistent across states. State health departments are delegated by the legislature to coordinate and implement state health laws, including school immunization requirements. State health departments collaborate with state boards of education, regional education boards, and/or with local health departments to develop mandatory immunization and exemption policies. State health departments administer state immunization registries, conduct disease surveillance, outbreak investigation, and monitor state immunization rates.

National recommendations are one of the factors states use to establish state-level requirements for childhood immunizations prior to enrollment in day care programs and/or elementary school. Each state mandates the minimum number of doses of each vaccine that must be documented prior to the enrollment of children in school, with wide variability in the specificity and enforcement of the schedules across multiple school-age populations.

Most state vaccination laws include common language for which vaccines are included in the schedule, the department of health agencies responsible for implementing the immunization policy, and school agencies responsible for tracking and accepting

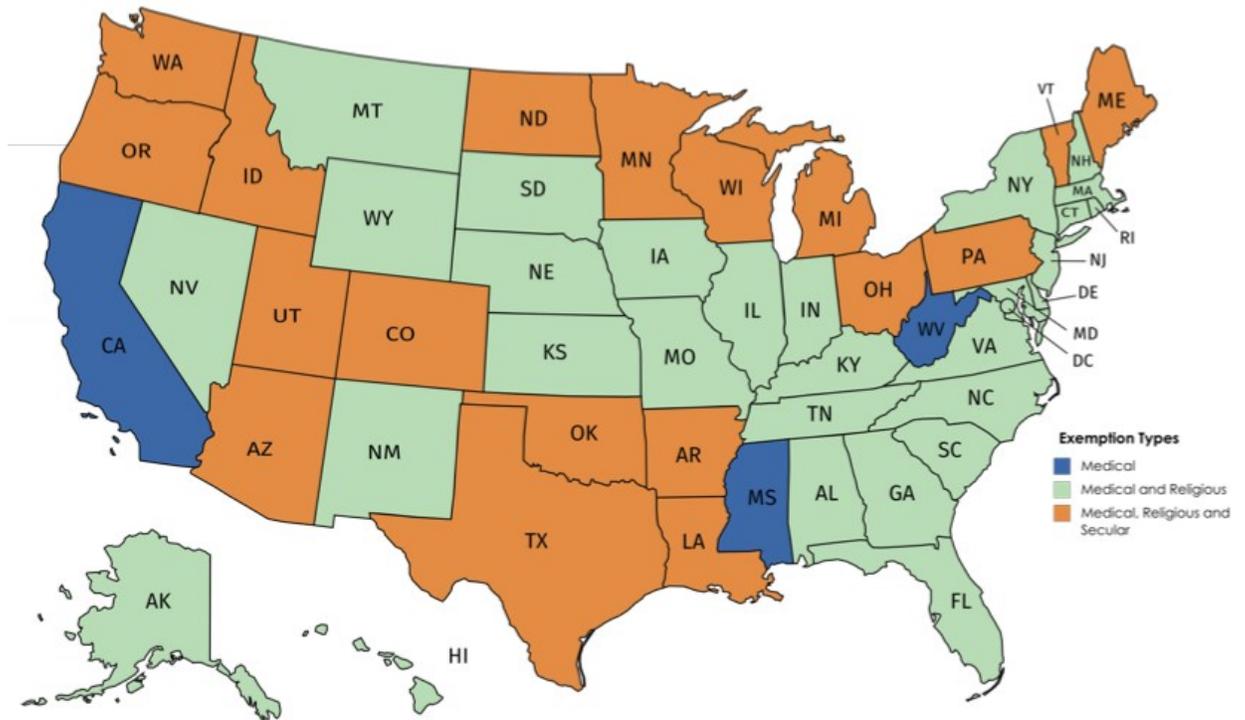
vaccination certifications. State laws and statutes also include language for the types of exemptions permitted, methods for updating the schedule, types of schools included, types of providers recognized by the requirements, issues of civil immunity, and enforcement mechanisms.

### **1.3.2 Exemptions to School Immunization Laws**

States allow medical and non-medical exemptions to school immunization mandates. Medical exemptions are offered in every state to exempt individuals contraindicated for vaccine administration. Rates of medical exemptions have nationally remained between 0.26%–0.41%; state medical exemptions rates do not vary significantly by year or by state, with minor exceptions.[3] Contraindications for children are provided for conditions resulting in decreased immunity, asplenia, previous allergic reactions, and acute or chronic illnesses.

Non-medical exemptions are permitted in states for reasons including religious beliefs, conscientious objections, personal beliefs, and philosophical reasons, depending on how the statute defines the non-medical exemption and the administrative procedures required. States offering non-medical exemptions can be roughly grouped by whether the state allows philosophical exemptions in addition to religious exemptions. In 2017, out of 47 states accepting religious reasons for not vaccinating, 18 also accepted philosophical reasons on the part of the parent; three states do not permit non-medical exemptions. Philosophical exemptions provide a mechanism similar to a conscientious objection for military service in the United States, allowing individuals holding very strong beliefs that preclude them, or their children, from receiving vaccinations to avoid required

vaccinations.[4] Figure 1-1 shows types of exemptions available in US states and Washington DC.



**Figure 1-1: US State Exemption Types, 2017**

### 1.3.3 State-Level Exemption Trends

State exemption requirements vary across states.[1,4,5] Non-medical exemption rates have risen over several decades, from 0.5% in 1991 up to a national high of 1.58% in 2011, with some states reaching more than 5%.[6,7] Over a 16-year period in California, the average statewide NME rate increased 9.2% per year, from 0.6% in 1994 to 2.3% in 2009.[8] Though this number is low overall compared to the national rate, it does not reveal the level of variability seen in schools and school districts. Atwell et al. found in California there were individual schools or districts with exemption rates as high as 80%.[9]

NME rates are higher and have increased more rapidly in states providing both religious and philosophical exemption options compared to states with religious NMEs only.[5] These states experienced larger increases when exemptions were easier to obtain administratively.[6,7] In recent years, several states have changed state immunization laws to allow fewer NME options or to make NMEs more difficult administratively to obtain. Omer et al. reviewed state vaccination policies from 2009-2012, including recent legislation proposed and whether the legislation passed.[10] They found that 18 states introduced at least one exemption-related bill, with a total of 36 introduced during the four years of review. Each bill proposed to expand the process for obtaining exemptions (i.e. making them easier to obtain) failed; the only bills passed were those to restrict exemptions further.[10]

When children are not immunized on the recommended schedule, there are increased risks of vaccine-preventable disease outbreaks, which result in increased rates of morbidity and mortality in children.[11,12] Exemptors have been shown to be at higher risk of both measles and pertussis, with exempt children in Colorado 22 times more likely to contract measles and six times more likely to contract pertussis.[13] In analyzing national rates of exemptions and measles, exempt children were 35 times more likely to contract measles than non-exempt children.[14] Increased community risk of both measles and pertussis is associated with high rates of non-medical exemption.[9,12,13] Using electronic health records, researchers have identified increased rates of missing or delayed doses of vaccines with increased risk of pertussis, varicella, and pneumococcal disease.[15–18]

### 1.3.4 Parental Vaccine Hesitancy

Research describing the complex factors and determinants associated with parental decisions about vaccines have attempted to define what it means for a parent to be “hesitant” or “confident”, and how what a parent thinks about vaccines influences what they do about vaccinating their children. While vaccine hesitancy has not been well defined by the research and academic communities, following a comprehensive review of the literature, the WHO SAGE Working Group on Vaccine Hesitancy proposed a standard definition to be used: *Vaccine hesitancy is a delay in acceptance, or refusal of vaccination despite availability of vaccination services.*[19]. Surveys and proxies have been used to measure vaccine hesitancy or refusal behavior, including assessing rates of and changes in immunization coverage, up-to-date status of children, parental trust in providers, exemption rates, and parental knowledge and attitudes towards immunization.

A systematic review of interventions to address parental vaccine refusal and vaccine hesitancy by Sadaf in 2013 defined ‘vaccine refusal behavior’ as either an act of refusing to vaccinate that was communicated by study participants or measured by nonmedical exemption rates.[20] A review by Phadke in 2016 likewise found at vaccine refusal, as measured by population-level non-medical exemption rates “was associated with an elevated risk for measles and pertussis, including among fully vaccinated individuals.”[20,21] Phadke also stated that “the most direct measure of vaccine refusal” is the rate of children with non-medical vaccine exemptions to school immunization requirements.[21] Some researchers have called for distinction between the terms ‘vaccine hesitancy’ and ‘vaccine refusal’, with refusal reserved for those parents who refuse all vaccines without hesitation, while vaccine hesitant parents should specifically

include only those parents “whose parents whose deliberations demonstrate something akin to indecision.”[22]

The difficulty with the existing definitions for vaccine hesitancy is the struggle between defining hesitancy primarily either as a belief system of parents who express concern about vaccines regardless of how completely they vaccinate their child, or defining hesitancy not by the concerns held by the parent but by their actions to vaccinate (or not) their child. A ‘belief’ definition can draw from Health Belief Models, while a definition focused on behaviors can draw inspiration from the Theory of Planned Behavior and includes a framework for vaccine hesitant parental attitudes, subjective norms, intentions, and ultimately, the parental behaviors measured by vaccine coverage and/or exemption rates.[23–25]

#### **1.4 Knowledge Gaps Addressed by Study**

A recent systematic review of interventions identified three major categories of interventions to reduce vaccine refusal and vaccine hesitancy: passage of state immunization laws, effective implementation of state laws, and parental education and information interventions.[20] This dissertation contributes to the understanding of the first two intervention categories through qualitative and quantitative analyses of the implementation and enforcement of state mandated school immunization laws over time in the United States.

The results of this dissertation may be used by policy-makers and stakeholders to understand the development of state immunization mandates, from the earliest requirements for smallpox inoculation at the turn of the 19th century to the most recently introduced vaccine mandates for childhood. This dissertation also examines the quality of

implementation of state laws changes in four states and describes the impact of legislative and policy changes on exemption rates in Vermont.

## **1.5 Dissertation Methods**

### **1.5.1 Study Aims**

Aim 1: To examine the historical context for public health laws in the US and assess the legislative change process for state mandated immunization laws, with a focus on school enrollment immunization requirements.

- To identify key federal and state laws relevant to mandatory immunizations, school enrollment, and immunization exemptions.
- To identify patterns in immunization law changes and the administrative mechanisms used for law change implementation in each state.

Aim 2: To qualitatively explore mandatory immunization law changes and the interpretation, implementation, and enforcement of immunization laws in four US states (California, Oregon, Vermont, and Washington).

- To document the experiences of state and local health department representatives, school health personnel, clinicians, and legislative representatives.
- To conduct semi-structured in-depth qualitative interviews with key informants responsible for interpreting legislative changes and developing policies and procedures for implementing and enforcing new laws.
- To identify key decision makers/roles and decisions made at each level of administration (state, local, school).
- To define and identify characteristics of effective law interpretation, implementation and enforcement.
- To identify barriers to or problems encountered during the process of law interpretation, implementation and enforcement.

- To describe the experience of each state’s effort to strengthen immunization laws with new legislation.

Aim 3: To quantitatively evaluate the impact of the changes to compulsory immunization laws on exemption rates in Vermont.

- To measure baseline exemption rates for at least 10 years prior to the changes.
- To measure changes in exemption rates following key law changes.
- To evaluate the types and quantities of exemptions available.
- To examine patterns in exemptions.

### **1.5.2 Study Design**

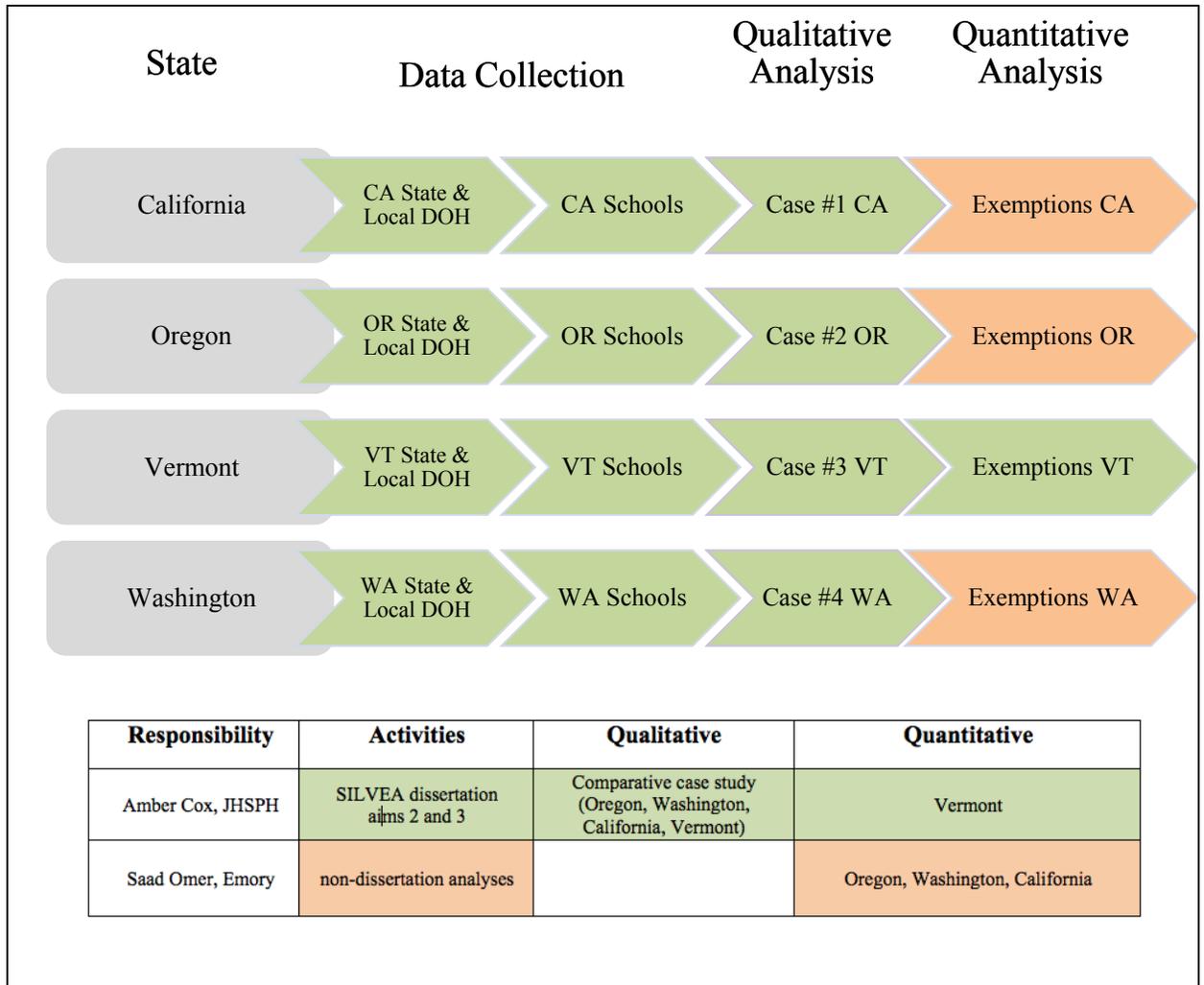
The study conducted for this dissertation was a sub-study of a Robert Wood Johnson Foundation (RWJF) project assessing public health law changes in California, Oregon, Vermont, and Washington, titled “Capitalizing on Recent Changes to School Immunization Requirements to Improve the Public’s Health”, led by principal investigator, Saad Omer, and co-investigator Daniel Salmon. The RWJF project aimed to conduct quantitative and qualitative analyses in each of the four states identified with exemption laws updated since 2011 (California, Oregon, Vermont, and Washington). The RWJF project used data collected and analyzed from this dissertation, along with additional analyses, to inform a Draft Model Exemption Law.

This dissertation research, identified hereafter as SILVEA (State Immunization Laws & Vaccine Exemption Assessments), included the qualitative assessment in each of the four states and a quantitative assessment for Vermont. Saad Omer oversaw the quantitative analyses for California, Washington, and Oregon. The qualitative and quantitative data collection and analysis progression for each state are included in Figure

1-2 along with responsibility for analysis for SILVEA (dissertation sub-study) and the overall RWJF study led by Drs. Omer and Salmon.

This dissertation used both qualitative and quantitative methods. A qualitative assessment utilized a multiple case study research design with historical and legislative analyses providing context for each state case study.[26] We used qualitative methods to document the experiences of individuals with responsibility for implementing and enforcing immunization laws in each state. For each case study, we first aimed to describe the context in which implementation occurred at the state-level, and then to understand how requirements were then implemented at the local level in regional health departments and schools. Through this process we attempted to identify the mechanisms and strategies used as well as key barriers and facilitators for implementing and enforcing state immunization laws in each state. Finally, through the interviews we sought to identify successful implementation strategies that may be applied in other states considering legislative changes to school immunization laws.

We complemented the qualitative analysis with a quantitative assessment of enrollment and exemption data for Vermont to longitudinally describe and analyze state-level exemption rates within the context of the historical and legislative timelines in order to evaluate the impact of changing state laws on exemption rates within Vermont.



**Figure 1-2: Dissertation Responsibilities, SILVEA 2014-2017**

### 1.5.3 Study Team

The study team consisted of faculty, advisors, state collaborators, and technical experts. In each state, health department collaborators provided guidance and experience to the project, identified key informants for qualitative interviews, and provided access to exemption data.

This study team met in March 2015 to assist in the refinement of the qualitative interview materials and identification of the key informants for in-depth interviews. State

collaborators assisted in the procurement of school enrolment and exemption data for each state. The study team met again in the spring of 2016 to review preliminary study results and provide feedback on the initial qualitative and quantitative analyses.

The Principal Investigators, Dr. Salmon and Dr. Omer, were responsible for overall ethical and research oversight for this study. The Student Investigator, Amber Bickford Cox, was responsible for both the quantitative and qualitative data collection.

The Student Investigator was responsible for:

- Planning and conducting the in-depth interviews with key informants of each of the four states included as case studies
- Transcription and coding of in-depth interviews
- Qualitative data analysis (4 states)
- Obtaining school-level enrolment and exemption data for each case study
- Quantitative data analysis (Vermont)
- Presentation of data at stakeholder and advisory meeting

Dr. Omer provided quantitative methods guidance and overall guidance for the study.

Dr. Salmon provided quantitative methods guidance and overall guidance for the study.

Dr. Teret provided technical guidance on legal issues.

Dr. Frattaroli provided technical guidance on qualitative research methods.

Dr. May provided technical guidance on ethical issues.

#### **1.5.4 Institutional Review Board Approval**

The study was submitted to Emory Institutional Review Board for ethical review; JHSPH IRB conceded review to Emory IRB for this study. No interviews were conducted prior to IRB approval. This study was approved by the Emory IRB July 24, 2015.

### **1.5.5 Qualitative Methodology**

In order to explore the process of implementation of compulsory immunization law changes in four US states through the experiences of state and local health department and school personnel, each state was treated as a case study and individually evaluated. Additionally, the four cases were compared to identify patterns in implementation and enforcement.

We conducted semi-structured in-depth interviews with several groups of individuals to gather knowledge about their experiences surrounding the legislation changes. The intention of the in-depth interviews was to document the experiences of personnel responsible for interpreting the changes and developing policies and procedures for implementing and enforcing the law. We interviewed representatives from each state with personal and institutional knowledge of the period surrounding the legislative changes in their state. The interviewees assisted in identifying the key decision makers in the implementation of the law, including those with interpretation, administrative, policymaking, and enforcement roles.

The interview questions explored the legal and political environment prior to the change and the process of creating new legislation. Through the semi-structured interviews, we explored varied experiences over a multi-year time period. The interviews were designed to collect first-hand experience of the individuals involved in state immunization law requirements as well as their opinions about best practices and what may have been improved in their process. These experiential narratives are best captured through semi-structured in-depth interviews.

## **Participant Recruitment and Enrolment**

We targeted the following professional groups in the key informant interview sample:

- State health department leaders
- Regional health department personnel
- School health personnel
- Clinicians
- Legislative representatives

The initial state level interviewees were asked to provide contact information for other informants able to provide more specific or detailed experiences.[27] State and local health department personnel were queried to identify additional individuals to contact for qualitative interviews. Interviewees were queried for school health personnel contacts able to provide information about the experience of law change within the school system. This snowball sampling method was beneficial in the four state cases because of the administrative structure of the state and local health departments and the small number of individuals generally working in this field. School health personnel were queried for names of clinicians in the community with experience providing exemption information to parents.

We regularly assessed the qualitative data for saturation of each category of interviewee in each state before moving forward with additional interviews. This snowball sampling has been shown in qualitative research to be a useful way to identify and make positive contact with key informants especially in a multi-case analysis where the informants are all part of a single organization or administration, or several groups working together, as in the case of state and local health departments working with schools to document immunizations of enrolled children.[28]

The sampling of school personnel was based on the principle of maximum variation in order to capture heterogeneous experiences related to implementation of the exemption laws. There is a potential for bias in that interviewees may only recommend other likeminded individuals who are more likely to have similar experiences. This is a limitation of snowball sampling, though with a finite number of possible personnel in each state, triangulation of sampling methods may identify key informants multiple ways. When asking interviewees to recommend additional contacts, we emphasized the importance of diverse perspectives and requested individuals who may have had unique or unusual experiences. Confidential records were maintained of all names referred for key informant interviews and all methods used to contact the individuals, as well as reasons provided for interview declination.

In order to participate in the key informant interviews, the interviewees agreed to each of the following inclusion criteria:

- Individual has experience during the study period of interest in one of the key fields and/or with school immunization requirements
- Individual is willing and able to provide verbal consent to be interviewed, with notes and/or audio recording of the interview

If any of the following exclusion criteria applied, the interview was not conducted:

- Individual not willing to participate in an interview
- Individual not able to provide information about school immunization requirements

### **Interview Conduct**

Once an informant was identified, the student investigator contacted that individual by email or phone. After three unsuccessful attempts to contact an individual

referred through an email address or phone contact; if no contact was made, that name was removed from the contact list. If the potential interviewee declined to participate, their reason was recorded and they were no longer contacted.

Interviews were conducted by phone, considered standard practice in qualitative research methods when in-person interviews are not possible.[29] After discussing the study with the interviewee, the IRB approved informed consent and information sheets were shared and reviewed with the interviewee. Confidentiality of the interview and research process was explained and all interviewee questions were answered before beginning study related activities.

Following verbal consent, each interviewee was assigned a study identification number to be recorded on all source and data collection documents. Notes taken during interviews were assigned memo numbers and compiled by study identification number. Interview memos are a useful complement to the interview transcripts and provide a resource for the interviewer to record new information that arises during an interview, a summary of key findings, and observations about the interview. Each interview was audio recorded, with electronic MP3 files saved. Each interview lasted approximately one hour. Interviewees were not compensated for their time.

During each interview, the interview guide was used as a reference when asking questions of each interviewee. The in-depth interviews were intended to be semi-structured, meaning the interview guide was used to provide language and wording for questions covering the main subject areas in this study. However, the interview process requires enough flexibility to allow the interview to be conversational and to allow the interviewee time to answer questions completely. The interview guide was drafted by the

student investigator and reviewed by the study team prior to the beginning of data collection. The interview guide was amended to reflect prompts specific to each state and interviewee category. The interview guide was submitted to the IRB for initial approval and an updated interview guide was also submitted to the IRB.

### **Data Handling and Storage**

Qualitative data was collected in multiple paper and electronic formats. Each file was tracked using an Excel spreadsheet and identified by the unique study identification number assigned to interviewees. All paper and electronic copies of interview notes, audio files, contact summary forms, consent forms, and all other source documentation are securely kept. Paper documents were stored in a locked room. Electronic files were kept password protected, backed up regularly on password-protected cloud servers, and on an external hard drive in a locked room.

Audio recordings of the in-depth interviews were transcribed. Audio recording may contain confidential information provided by the interviewee and to protect confidentiality, transcripts of the interviews were edited to remove as much identifying personal information as possible, and names were replaced with study identification numbers in the transcript. Study faculty examined a subset of the interview recordings and transcripts for accuracy and oversight. Any changes or additions to the transcript file were been tracked and dated for quality control. The transcribed documents were imported into Atlas.ti (version 1.6.0) qualitative data management software for coding and analysis.

## **Qualitative Data Analysis**

In analyzing the data collected from semi-structured in-depth interviews, we attempted to identify patterns and differences that emerge from the data within a real life context.[30] We evaluated each state as a unit in a multi-case evaluation, with multiple embedded units of analysis.[26]

We imported memos, electronic and MP3 files, transcribed text, and other study documents into qualitative data management software for coding and analysis using Atlas.ti qualitative software. Data coding of transcripts and study memos was completed as soon as possible following the interview. A codebook was developed that included both *a priori* and emergent codes relevant to the in-depth interviews.

Following the first several interviews, initial codes and the draft codebook were shared with faculty investigators. The codebook was periodically updated to include emergent and process codes, and to explain when and how specific codes were to be used. The codebook was used to group codes identifying emergent ideas and keywords into major themes, as well as stratified across states and at each level of administrative influence in the state. Iterative review of the codebook and themes were important in order to organize and examine the data for patterns. Novel information or patterns found in early interviews were explored further in subsequent interviews. On-going data collection and analysis required periodically returning to original transcript text to update or add coding within the updated codebook and interview guide to ensure consistency of coding methods.

### **1.5.6 Quantitative Research Methodology**

To evaluate whether Vermont exemptions were impacted by law changes, we first modeled statewide exemption rates between 1989-1990 and 2016-2017 academic years. We compared the quantitative longitudinal exemptions data with the historical and legislative analysis of Vermont immunization and exemption laws and policies to identify key change-point years. Exemption rate changes were evaluated using an interrupted time series design and segmented regression analysis.

Segmented regression analysis of the exemption rates is an appropriate method for studying the effects of an intervention or an event, defined as the “change point” to be evaluated, with analysis of longitudinal data collected before and after the event “to draw formal conclusions about the impact of an event on the measure of interest”.[31]

This method is useful especially when the data are collected retrospectively from administrative or database records and there is not an appropriate control group available.[32] A benefit of the segmented regression is that it first establishes the baseline trend and level, and then allows these parameters to adjust in the post-event segments, which accounts for non-stationarity, autocorrelation, and periodicity/seasonality.[32] We used segmented regression analysis to measure and estimate the statistical significance of any changes to the exemption rates after the law changes.

We stratified state-level exemption data by exemption rate level, type of exemptions available, and type of school (public or private). Additionally, school-level data were stratified by school-level variables to explore local factors associated with exemption rate changes. Data analysis was conducted using Stata 12 (StataCorp, College

Station, Texas). Regression methods included generalized linear models (GLM) and generalized linear mixed models (GLMM).

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## **Chapter 2 School Law Review: Mandatory Immunization Requirements for Elementary School Enrollment: Historical Review, Trends in Implementation, and Changing Exemption Laws, 1902-2017**

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## **2.1 Abstract**

Originating in smallpox inoculations mandated during regional 19th century outbreaks, modern school enrollment requirements are a complex sequence of primary and booster doses throughout childhood and adolescence. State school immunization laws mandate childhood vaccines for school entry and establish limitations to parental autonomy based on the authority of a state to protect the health of all citizens. We reviewed historic, academic, and government resources to describe and analyze the introduction of school immunization laws in each state since 1902. During this time state mandates expanded to include new antigens, booster doses, and additional childcare and school populations. Implementation and enforcement of current school immunization laws vary by state, including how closely the state mandate matches the nationally recommended schedule, type and effectiveness of exemptions permitted, delegation of authority to health departments, school-level implementation, enforcement of exclusions during outbreaks, and tracking/exclusion of non-compliant children from schools. This analysis helps explain the differences in how state immunization laws are enacted, implemented, and enforced, and how these variations affect childhood vaccine coverage rates, exemption rates, and regional disease outbreaks.

## 2.2 Abbreviations

AAP	American Academy of Pediatrics
AB	Assembly Bill
ACIP	Advisory Committee on Immunization Practices
CA	California
CDC	Center for Disease Control and Prevention
DC	District of Columbia
DTaP	Diphtheria, Tetanus, and Acellular Pertussis Vaccine
FDA	Food and Drug Administration
HAV	Hepatitis A Virus
HB	House Bill
HBV	Hepatitis B Virus
Hib	Haemophilus Influenzae Type B
HPV	Human Papillomavirus
IRB	Institutional Review Board
ME	Medical Exemption
MMR	Measles, Mumps, and Rubella Vaccine
MMWR	Morbidity and Mortality Weekly Report
NME	Non-Medical Exemption
OR	Oregon
PCV	Pneumococcal Conjugate Vaccine
SB	Senate Bill
SCOTUS	Supreme Court of the United States
US	United States
VPD	Vaccine-Preventable Disease
VT	Vermont
WA	Washington
WHO	World Health Organization

### **2.3 Introduction**

State immunization laws were initially enacted and implemented to prevent contagious diseases by leveraging school system resources to improve routine childhood immunization coverage. All 50 states and Washington DC currently mandate certain vaccines for childcare (e.g preschool), elementary school, middle school, and college/university entry. School mandates are evidence-based and support the national immunization policy to achieve high vaccination coverage in childhood and adolescence. Outbreaks of measles, mumps, and pertussis are occurring with increasing frequency despite the success of school laws in establishing high immunization coverage.[1–3] Several outbreaks have been associated with low immunization coverage in regional clusters, as well as waning immunity, increased detection of cases, and a loss of confidence in vaccine safety and immunization recommendations. [4–11]

Herein we describe state laws mandating school immunization and exemption requirements to provide evidence-based approaches to balancing parental autonomy and public health needs in order to maintain high coverage and reduce outbreaks of disease. First, we discuss the history of school immunization laws and the legal authority for immunization mandates. Then we explore implementation of school immunization laws, including how state laws differ, providing examples of state law changes over time, and describe the impact of such changes. While this analysis acknowledges the multifaceted determinants that influence parent decision-making and behavior, we focus primarily on state laws and policies that mandate vaccines prior to school enrollment. This analysis of school immunization laws may be useful public health authorities, clinicians, professional

medical associations, lawmakers and policy makers to better understand and inform state-level immunization and exemption law changes.

## **2.4 Methods**

To examine the development of state immunization mandates and their context over time, we created a historical longitudinal database of state immunization and exemption law changes through a qualitative and quantitative review of historical, academic, and government publications. We identified the year state laws were implemented in each state for each antigen. With the exception of smallpox, once a state law mandated a specific vaccine we continued the mandate for subsequent years. For each vaccine, we started tracking state mandates counts from the date each vaccine was recommended for routine use by the ACIP.

Data were compiled from multiple sources. We began with keyword searches of several database resources (PubMed, JSTOR, Google Scholar, Embase, CDC MMWR Stacks) and supplemented our data with targeted searches in historical publications. We compared our findings with existing compilations of state immunization requirements and state health department websites. When differences between state requirements were found, we consulted and prioritized state legislative codes. Online resources include the National Conference of State Legislatures Immunization Action Coalition, the Association of Immunization Managers, and the History of Vaccines. We also included CDC School Immunization Law Surveys available between 1991 and 2007.

## **2.5 State School Immunization Laws**

### **2.5.1 19th Century History and Origins**

State-level public health laws in the 19th century mandating proof of immunization evolved from regional and institutional smallpox requirements in schools, industrial mills, underground mines, and for patients and employees at state institutions and elsewhere.[12–14] The first mandate in the US requiring the general population to receive the smallpox inoculation was established in 1809 following smallpox outbreaks in Boston.[15] In the years that followed, additional communities and states passed mandatory smallpox immunization laws, including an 1827 school entry requirement in Boston.[16] State agencies developed policies for the protection of the public’s health; Massachusetts was the first state in 1855 to establish a state-wide immunization mandate for children entering and attending school.[17]

### **2.5.2 Legal Authority and Key Cases**

The US Supreme Court affirmed states’ right to enact and enforce immunization laws in 1905 following a legal challenge to a law requiring a smallpox vaccine after a 1902 outbreak in Massachusetts.[18] The US Supreme Court subsequently upheld the states’ right to mandate vaccine requirements for school entry in 1922.[19] More than 20 years later, the Court continued to uphold state mandates in the face of parental objections based on religious beliefs, specifying that the “right to practice religion freely does not include the liberty to expose the community or the child to communicable disease or the latter to ill health or death” (*Prince v. Commonwealth of Massachusetts, 1944*).[20] Though many states continue to offer religious exemptions to their immunization laws, the US Supreme Court has not deemed such exemptions constitutionally necessary and some state courts have invalidated state religious

exemption requirements that violate the establishment and equal protection clauses.[21–23]

### **2.5.3 20th Century Modernization**

State immunization mandates have improved vaccine coverage and reduced morbidity and mortality associated with childhood illnesses.[15,24–26] As novel vaccines were developed, licensed, and recommended for routine use in children, state laws and school requirements expanded adding one or more new vaccines in each decade: diphtheria in the 1920s, tetanus in the 1930s, pertussis in the 1940s, and polio in the 1950s. [27–29] In 1955, one hundred years after the first state school immunization mandates were created, nine states had compulsory immunization laws for children attending school. [27] An additional seven states mandated immunization when directed by a state health official, but only during smallpox or diphtheria outbreaks.[27]

Measles, mumps, and rubella vaccines were licensed in the 1960s and, after smallpox vaccinations were discontinued in 1971, the routine childhood schedule included seven antigens: measles, mumps, rubella, poliovirus, tetanus, diphtheria, and pertussis.[28,30–32] The structure and requirements of school immunization laws also evolved as newly licensed vaccines provided state legislatures with the opportunity to expand and modernize state law requirements.[33]

In spite of the availability of a vaccine, measles outbreaks in the 1960s and 1970s generated national attention and spurred state and federal efforts to strengthen and update state laws.[15,28,34] States with existing mandatory measles school immunization laws in 1973 had a 50% lower measles incidence than states without such laws.[15,35,36] The power of enforcement was demonstrated during large measles outbreaks in Fairbanks,

Alaska in 1976 and Los Angeles, California in 1977.[15,17,37,38] The state health departments struggled with the extent to which they would enforce their state's policies. Affected states and localities excluded children from schools during an outbreak, an action they were legally allowed to take but that some feared would be impractical to enforce.[35,37] Both states enforced the exclusion of unvaccinated children and were able to reduce measles transmission and control their outbreaks; exclusion from school affected only a small percentage of children and lasted less than a month for most children, demonstrating the power of enforcement to curb transmission.

Following these and other measles outbreaks, the CDC encouraged states to implement laws requiring immunizations prior to school entry regardless of whether or not there was an outbreak.[15,35,39,40] Supplemental Vaccines for Children 317 federal funding for immunization programs became available with the requirement that state immunization personnel develop plans to work with legislators encouraging school immunization mandates.[15,41] By 1981, all 50 states and DC had modernized their school immunization requirements.[15] State legislative updates removed smallpox requirements, expanded requirements from school entry to comprehensive requirements mandating vaccines at all grades, expanded age populations, changing the mechanisms and authority to set state mandates, and updating state health department policies and requirements.[15,35,42]

Requirements for school immunizations evolved from outbreak-only periods to year round requirements at school entry, then to requirements at all grades between kindergarten and high school graduation. State mandates became increasingly comprehensive along with updates for newly licensed or recommended vaccines. In the

1980s, mandates expanded from elementary school to preschool and childcare facilities, adolescents in middle school, and college students. [13,35]

#### **2.5.4 Novel Vaccines Licensed**

In the 1990s and 2000s, eight additional vaccines were licensed and recommended for the routine childhood immunization schedule: Hepatitis A (HAV), Hepatitis B (HBV), *Haemophilus influenzae* type b (Hib), pneumococcal, rotavirus, varicella, Human Papillomavirus (HPV), and meningococcal vaccines.[15,43]

The CDC General Recommendations on Immunization published in 1989 advised state health agencies to “take necessary steps, including developing and enforcing school immunization requirements, to assure that students at all grade levels, including college students, and those in child-care centers are protected against vaccine-preventable diseases”[44–47] In 1999, the independent and nonfederal Task Force on Community Preventive Services reported that school entry requirements increased community demand for immunization and should be used as an intervention to increase vaccine coverage.[48]

Subsequently, school immunization laws were used to implement HBV and varicella vaccine recommendations and school entry requirements were adopted across states and expanded to additional populations, including for preschool and childcare, middle schools, and colleges and universities. [15,49–52]

#### **2.6 Immunization Mandates Vary By State**

All 50 states and the District of Columbia require immunizations for school enrollment, with state-variation in antigen-specific requirements.[53] State-level differences in immunization and exemption requirements may reflect regional influences,

including the structure of state lawmaking institutions, recent vaccine-preventable disease outbreaks, differences across state and local health departments, and regional differences in vaccine hesitancy. [54–57]

Geographically, East Coast states have more comprehensive school laws reflecting a longer history of school laws and historically, more densely populated urban areas.[28,58] Variability in state laws exist with regard to antigens and the number of doses are required, how states implement immunization mandates at the local and school level, and how difficult it is for parents to obtain exemptions or not comply with state mandates. **Table 2-1** summarizes state mandates by antigen and age population.

### **Elementary School:**

The number of states with smallpox vaccine mandates peaked in 1969 and declined thereafter following withdrawal of the recommendation for routine administration in 1971 (Figure 2-1). In 2017, elementary school mandates show consistency across the states for the earliest vaccines introduced, with more than 96% of states mandating requirements for vaccines against poliovirus, diphtheria, tetanus, pertussis (DTaP), and measles, mumps, rubella (MMR) (Table 2-1). HAV, HBV, and varicella vaccines were added to the recommended routine schedules in some states in 1995 and 1996, but requirements have not been implemented uniformly across states. Varicella is required in 51 (100%) states and HBV is required in 46 (90%), while HAV vaccine is only required in 14 (27%).

### **Preschool:**

Kindergarten and school entry mandates expanded to include younger children enrolled in preschool or daycare facilities in the 1990s (Figure 2-2). Childcare mandates were implemented in most states for the historic vaccines (poliovirus, DTaP, and MMR) but also included vaccines for childhood diseases (rotavirus, pneumococcal, and Hib) not mandated for school entry in older children. Hib conjugate vaccine, introduced in 1991, was implemented in most states following the trends of DTaP and MMR. Varicella, HBV, and pneumococcal vaccines were required in the majority of states, while HAV and rotavirus vaccine, the most recently introduced vaccine for childcare, was only required in three states in 2017.[59]

### **Middle School:**

Middle school immunization mandates consist of catch-up doses, booster doses, and adolescent-specific recommendations (Figure 2-2). The first middle school immunization mandates were implemented to provide a checkpoint for catching-up adolescents on HBV, varicella, and measles vaccines recommended at an earlier age.[60–63] Adolescent varicella and measles vaccine mandates were introduced following measles outbreaks in school-age children associated with low immunization coverage.[51,64] Since measles vaccine is only available in the US as a combination vaccine (MMR), there is less pressure to introduce specific mandates for mumps and rubella vaccines.[15]

Pertussis outbreaks associated with low coverage, incomplete protection, and waning immunity were addressed by adding recommendations for a booster dose of

acellular pertussis vaccine (Tdap) for children 11-12 years old, which began appearing in state mandates in 2006. The first state laws mandating meningococcal and HPV vaccines were passed in 2005 and 2008, respectively. While meningococcal vaccine is mandated in the majority of states, a second dose is only mandated in 14 states and HPV is mandated in only three states.

### **College and Universities:**

Mandates for students entering college have been adopted more slowly than the other age populations and college mandates have remained static for the last decade (Figure 2-2). Meningococcal vaccines are mandated in 37 states (73%) for college entry. Measles, rubella, and mumps vaccines are mandated in more than half of the states. Poliovirus, varicella, HAV, and pertussis vaccines are mandated for college entry in less than ten states each.

#### **2.6.2 Process for Adding Requirements**

State governments enact legislation to mandate requirements for school enrollment, including vaccines, health screenings, and hearing and vision tests. Several states have given authority to health departments to introduce new vaccine mandates through administrative (rather than statutory) changes, and other states have both legislative and administrative options for adding vaccines to the mandated schedules.[27,42,58,65] For example, a 2001 Maine immunization law permitted changes through rulemaking managed by the health department rather than statute changes through the legislature (Maine HB1163).[58]

Similarly, a few states have included language within statutes delegating authority to state health departments that they will update vaccine requirements “in accordance

with recommendations of the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices (ACIP)” (Missouri State Law 210.003).[15] However, some states require that updates to mandatory immunization schedules are enacted through legislative change.[62,66] Most recently, meningococcal, varicella, and hepatitis B vaccine requirements were added by legislature in Iowa, Indiana, North Dakota, and Oklahoma.[58] The additional administrative effort to update requirements via legislation contributes to the variability in adding requirements for these vaccines

### **2.6.3 Local Implementation and Enforcement**

During the early 20th century before state-level mandates were widespread, it was not uncommon for state legislatures to delegate exclusion authority to local health departments and school boards.[12,65] While the existing state laws empowered schools to exclude unimmunized children or those without a physician-documented history of disease during outbreaks, the majority of states did not enforce penalties for non-compliance unless a regional outbreak occurred.[13,14,65,67]

The implementations of school entry requirements differ by state, both in method and by groups tasked with enforcement. Responsibility for implementation falls on state health department in some states, and the local health department or school board in others. Implementation responsibilities include annual assessments and tracking of each child’s immunization record at kindergarten and middle school entry, and for some states with comprehensive requirements, annually until high school graduation.

Authority for enforcement, excluding non-compliant children, is most often left to school principals and in some states, such as Oregon, the local health department. A survey of the knowledge, attitudes, and beliefs of school health personnel in four US

states found variability in implementation of these laws and the knowledge, attitudes and beliefs of the school health personnel was associated with rates of non-medical exemptions.[53] Negative opinions about vaccination held by parents or school health personnel were associated with higher exemption rates, and many individuals implementing state laws had misconceptions about vaccines. As a result implementation of laws at the local level may have been inadequate in some locations.[53]

## **2.7 Exemption Requirements Vary by State**

All states and Washington DC permit medical exemptions (ME) to school immunization requirements, 47 states permit non-medical exemptions (NMEs) for religious beliefs, and 17 states permit NMEs for philosophical beliefs (Figure 2-3). Washington DC allows both medical and religious exemptions.

### **2.7.1 Medical Exemptions**

Severe immune deficiency, asplenia, or history of severe allergic reactions to prior vaccine doses, and certain acute or chronic medical conditions can be contraindications for some vaccines. Medical exemptions may require documentation of a health condition contraindicating the vaccine and typically a signature of the medical provider. Some states have added expiration dates or specified conditions acceptable for medical exemption status, though few states have an approval process to assess the validity of medical exemptions.[68,69] Medical exemptions are rare; the proportion of kindergarteners with medical exemptions consistently remains between 0.26%–0.41% nationally; annual medical exemption rates have not varied significantly by year or by state, with minor exceptions.[69]

Medical exemptions may change when state laws affecting non-medical exemptions change. Following a 2003 Arkansas law change allowing philosophical exemptions, rates of medical exemptions decreased initially (see 2.8.1 below)[39,70,71] indicating that perhaps there had been ‘medical’ exemptions granted that were more appropriately classified as non-medical. After parents had the option of a non-medical philosophical exemption, they changed their request. Nationally, easier processes for obtaining medical exemptions are associated with higher rates of medical exemptions, as is the availability of permanent rather than temporary exemptions.[69]

### **2.7.2 Non-Medical Exemptions**

Non-medical exemptions are permitted in most states for parents with beliefs against vaccinating their children. Religious beliefs as reasons for not vaccinating are accepted in all 47 states granting religious exemptions. However, many religious leaders have concluded that these beliefs do not preclude immunizations.[72][73] State religious exemption procedures vary in complexity from requiring documentation from local religious leaders to parental statements documenting their religious objection, with several states offering simple exemption forms with checkboxes for type of exemption.[68]

Similarly, philosophical exemptions tend to be permissive and allow exemptions across states for secular reasons, personal beliefs, and conscientious objections. The easiest state laws permit a single non-medical exemption form without requiring information from the parent about their reason, as long as the parent completes the administrative process for obtaining the exemption. Ambiguous legal definitions of non-medical exemptions have resulted in inconsistent school-level implementation. In

Maryland, the parent certifies on the back of the immunization record that they are choosing not to follow the age appropriate immunization requirements due to “bona fide religious beliefs and practices” that do not permit vaccination. Maryland schools accept religious exemptions without a review process ensuring the parent has religious rather than philosophical beliefs. In several states, the religious exemption functionally allows exemptions for any reason.

Other states have more complicated procedures; parents may be required to document vaccine education from a physician or health department, complete personal statements or other tests of sincerity, have documents notarized, and/or to renew exemptions annually.[68] Exemptions are reviewed by a regulatory authority or school administrator in only a few states.[74] Rates of non-medical exemptions have consistently increased in states with the least administratively difficult exemption laws and in schools with inconsistent implementation and enforcement.[6,22,75–77] Exemption rates have increased more rapidly in states accepting religious and philosophical exemptions compared to religious exemptions only, and experienced larger increases when exemptions were easier to obtain administratively.[6,77] Additionally, exemption type and ease of obtaining an exemption have been associated with pertussis and measles incidence.[70,71,75,78]

## **2.8 Challenges and Changes to School Exemption Laws**

Comparing exemption rates across states longitudinally provides opportunity for epidemiological research into the effectiveness of school and childcare requirements in the prevention of disease. State and regional increases in exemption rates and outbreaks

of vaccine preventable diseases have focused attention on state legislative strategies as a means of reducing exemption rates and controlling VPD transmission.

A recent legal analysis of immunization-related state legislative activity since 1998 described laws enacted to reduce immunization requirements by removing immunization mandates, establishing more permissive exemption requirements, enacting laws banning the use of mercury in vaccines, and establishing parent informational policies.[58] The authors suggested that the five-year period between 1998-2003 was when the most vaccine-critical laws were proposed and enacted. Below we describe two distinct legislative trends, (1) a period of easing exemption requirements between 1998-2003, and (2) a period of more restrictive exemption requirements since 2011.[58,77,79]

### **2.8.1 Legislative Trends to Ease Exemption Requirements**

Religious tests of sincerity and membership declarations are vulnerable to challenge, as occurred in Arkansas in 2003 when the existing religious exemption was declared unconstitutional for violating the constitution prohibition of the government holding one religious belief above another. The state health department requested that stakeholders draft a model law proposal for the new exemption provision. A model law<sup>1</sup> suggested key elements to include in a school immunization mandate.[22] The legislature adopted some model law suggestions into the final law, which required that exemption forms to be notarized, parents to complete an educational component, and acknowledge exclusion policies for unvaccinated children during outbreaks.[22] The Arkansas

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<sup>1</sup> Model law was drafted in a collaborative project by the Arkansas Academy of Pediatrics, The Johns Hopkins Institute for Vaccine Safety and the Johns Hopkins Center for Law and the Public's Health, in consultation with the Arkansas Medical Society

exemption process became more administratively complex for parents; however, the exemption definition was broadened to allow religious and philosophical exemptions. Exemption rates increased each year after the exemption law changed and clustering of nonmedical exemptions was detected at the community-level.[71] There was a 23% increase in all exemptions annually for the seven years following the law change.[70]

### **2.8.2 Legislative Trends to Restrict Exemption Requirements**

Beginning in 2011, states with high exemption rates and vaccine preventable disease outbreaks began strengthening their immunization laws. These legislative changes were designed to reduce exemption rates by increasing the administrative complexity of the exemption processes. Law changes adding educational requirements in Washington, Vermont, and California have had some success in reducing exemption rates, as have removing exemption options in Vermont and California in 2015.[80,81]

## **2.9 Discussion**

The earliest legislative mandates requiring smallpox vaccine emerged alongside school attendance mandates and have expanded since the late 19<sup>th</sup> century to require an increasing number of doses and vaccines. State laws in the mid-20<sup>th</sup> century broadened to include vaccines against childhood illnesses with high-mortality and high-morbidity and as part of the measles elimination campaign in the US. More recently introduced vaccines prevent less common diseases (e.g. meningococcal) and diseases children may be exposed to later in life (HPV and HBV).

The strength of this analysis comes from our comprehensive review of professional, academic, and government reports and utilizing multiple sources of data to visually examine patterns in the implementation of immunization laws over time.

However, there are limitations associated with using historical data collected for purposes other than our study, including the possibility for error in categorizing state laws. Additionally, because this was a directed review focused on keyword and database searches for original sources of state law and immunization data rather than a systematic review, we may have missed sources.

State-level school immunization laws have provided an effective strategy for supporting high immunization coverage among children of all ages. However, variability in state and local implementation and enforcement of laws has limited their effectiveness. State requirements vary by how closely states follow the ACIP recommended schedule, the types of exemptions available, school policies and procedures, strategies for tracking immunizations and exemption, and how non-compliant children are excluded from schools.

## 2.10 References

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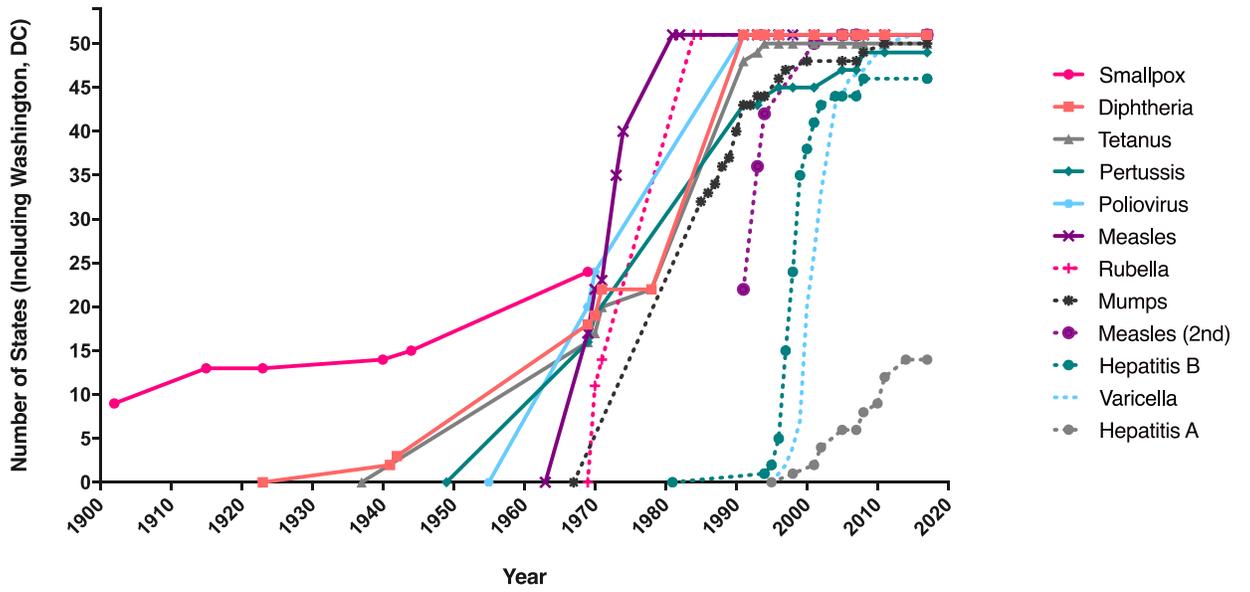
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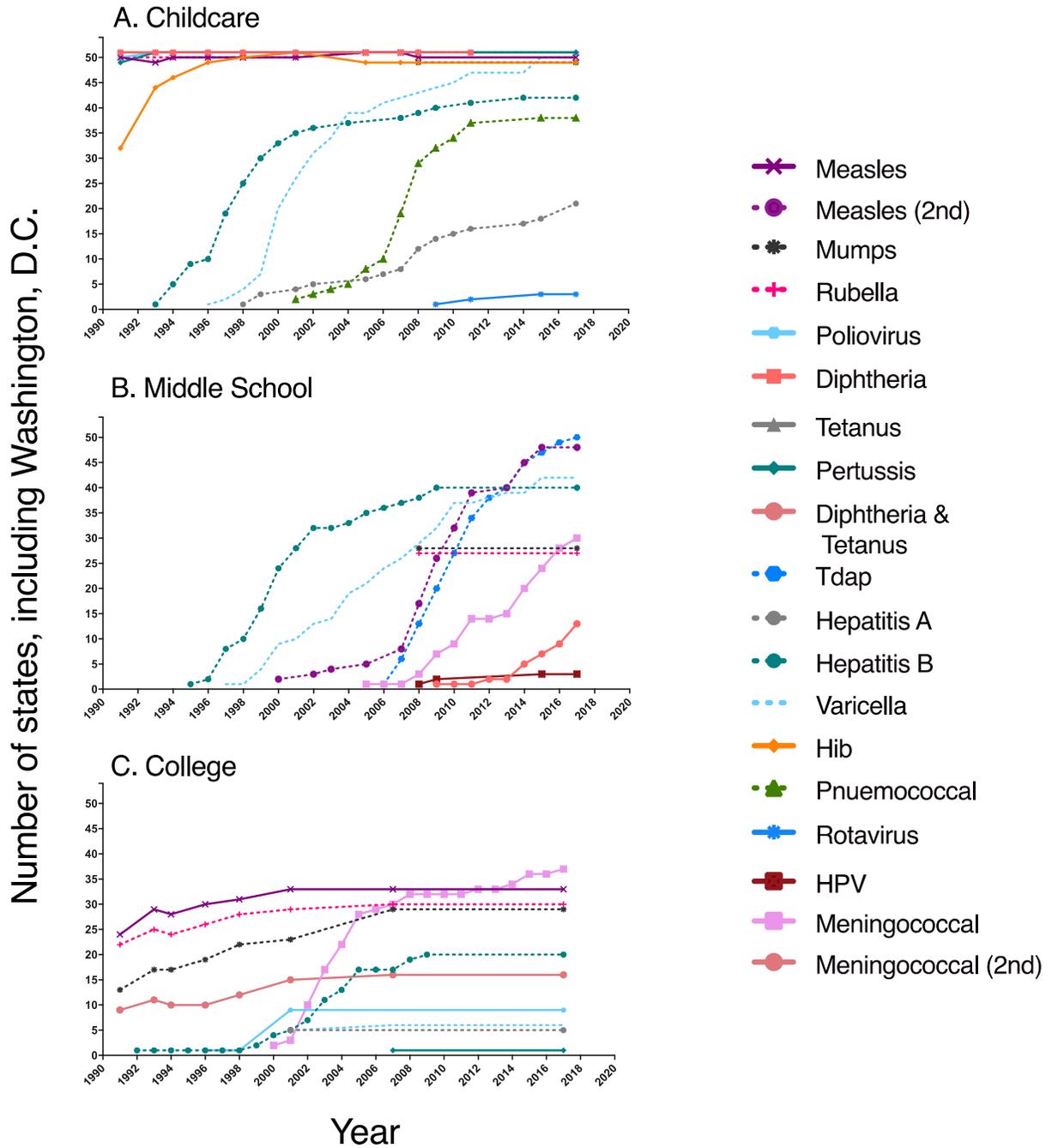
**Table 2-1: United States Vaccine Requirements by Antigen and Targeted Population, 2017**

Vaccine	Childcare & Pre-School		Elementary School		Middle School		College & University	
	N*	(%)	N*	(%)	N*	(%)	N*	(%)
Diphtheria	51	100%	51	100%	24	47%	16	31%
Tetanus	51	100%	50	98%	24	47%	16	31%
Pertussis	51	100%	49	96%			1	2%
Measles	50	98%	51	100%			33	65%
Measles**			51	100%	48	94%		
Mumps	49	96%	50	98%	28	55%	29	57%
Rubella	51	100%	51	100%	27	53%	30	59%
Poliovirus	51	100%	51	100%			9	18%
Varicella	47	92%	51	100%	40	78%	6	12%
HBV	42	82%	46	90%	40	78%	20	39%
HAV	18	35%	14	27%			5	10%
Hib	49	96%						
HPV					3	6%		
Meningococcal					29	57%	37	73%
Meningococcal**					12	24%		
Pneumococcal	38	75%						
Rotavirus	3	6%						
*Out of 51, including 50 US states and Washington DC								
**Second Dose								

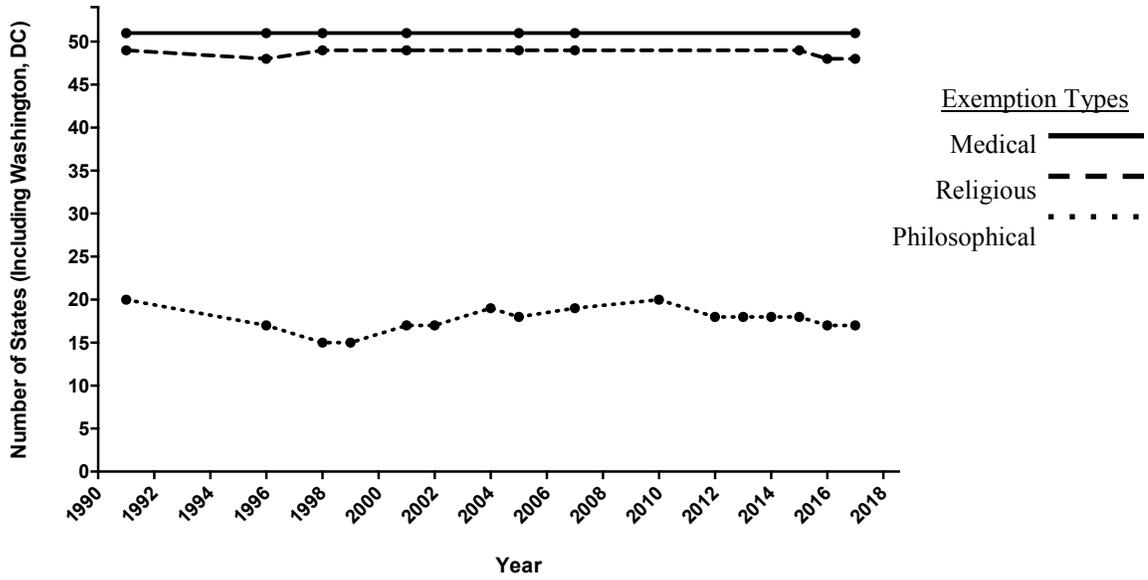
**Figure 2-1: Number of States with Elementary School Immunization Mandates by Antigen and Year (1902-2017)**



**Figure 2-2: Number of States with Childcare, Middle School, and College Immunization Mandates by Antigen and Year (1991-2017)**



**Figure 2-3: Number of States with Exemptions for Immunization Mandates by Exemption Type and Year (1991-2017)**



### **Chapter 3 A Qualitative Assessment of Stakeholder Experiences with Implementation of Restrictive School Exemption Laws: Recommendations for Effective Law Change**

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### 3.1 Abstract

**Background:** School immunization requirements have been an effective tool in controlling vaccine preventable diseases. Non-medical exemptions (NMEs) to these requirements are permitted in 47 states. Amid increasing rates of NMEs and consequent resurgence of diseases, four states recently tightened their exemption laws.

**Objective:** To investigate how restrictive NMEs to school requirements are implemented and enforced at state, local, and school levels and to identify key factors positively influencing implementation of exemption laws.

**Methods:** We interviewed state and local health department personnel and school health personnel with experience with new laws passed between 2011 and 2015 in California, Oregon, Vermont, and Washington. We used qualitative case study methods for in-depth analysis of multiple laws and implementation processes, and to permit comparisons across states and stakeholder roles.

**Results:** We conducted 81 in-depth stakeholder interviews between August 2015 and January 2016; five people invited declined participation. Stakeholders comprised 22 state health department employees, 21 local health department employees, 24 school health personnel, and 4 immunization experts from California, Oregon, Vermont, and Washington. We describe school law implementation across states, including administrative and educational components of each new law, and identify six factors influencing effective implementation of new exemption laws: (1) how NMEs were defined by the law, (2) stakeholder support for law changes, (3) collaborations among professional stakeholders, (4) the role of school nursing, (5) rulemaking processes, and (6) the accessibility of new requirements. Finally, we synthesize recommendations for

other state implementers and policymakers engaged in or contemplating similar implementation efforts for their school exemption laws.

**Conclusion:** School and health department stakeholders with experience in immunization and school health issues attributed effective implementation of restrictive exemption laws to strong multi-level collaborative support for, and understanding of, the amended laws.

### **3.2 Abbreviations**

AB	Assembly Bill
CCD	Common Core of Data
CDC	Center for Disease Control and Prevention
DC	District of Columbia
DoH	Department of Health
ME	Medical Exemption
NME	Non-Medical Exemption
NASN	National Association of School Nurses
SB	Senate Bill
US	United States
VPD	Vaccine-Preventable Disease

### **3.3 Introduction**

State laws requiring students to be vaccinated to attend school contribute to the success and sustainability of childhood immunization programs in the United States (US)[1]. All 50 states and Washington, D.C. have laws mandating childhood immunizations for kindergarten enrollment. Forty-seven states include non-medical exemptions (NMEs) for parents whose beliefs conflict with one or more of the vaccines mandated for school entry.[2–5] NMEs are characterized as religious or philosophical. The type of NME available and the ease by which exemptions are granted are associated with rising exemption rates and disease outbreaks.[6–11] NME rate increases in recent decades and reductions in childhood immunization coverage have been associated with outbreaks of measles and pertussis.[12–17] Analyses of such outbreaks suggest geographic, temporal and social clustering of parents opting for exemption is creating vulnerable groups of children at the school/community level.[7,12–14,16,18–22]

Four US states (California, Oregon, Vermont, and Washington) experiencing vaccine-preventable disease (VPD) outbreaks and high exemption rates passed legislation between 2011-13 mandating additional restrictive requirements for parents seeking exemptions. In 2015, lawmakers in California, Oregon and Vermont again enacted laws to further restrict, and in some cases remove, exemptions. With these updates, California and Vermont became the first states to remove exemption options previously offered.

To investigate how restrictive laws are being implemented and enforced at state, local, and school levels, we interviewed the professionals responsible for implementation in all four states. The objectives of this study were to: 1) describe the implementation of exemption laws in the four states; 2) identify key factors across the four states that

influenced implementation; and 3) synthesize recommendations for other state implementers and policymakers engaged in similar implementation efforts or contemplating changes to their school exemption laws.

### **3.4 Methods**

We used the case study method to allow for in-depth analysis of multiple laws and implementation processes within each state, and to permit comparisons across states and stakeholder roles. The Emory University Institutional Review Boards approved this research.

#### **3.4.1 Data Collection**

We collected data through in-depth interviews with key informants and used the text of the states' immunization laws and reported exemption data as additional sources to inform the study aims. Our sample of key informants included representatives from state and local health departments, school systems, and technical experts. We identified the initial round of key informants based on their positions within key organizations (purposive sampling[23,24]) and consistent with the principle of maximum variation sampling.[25] We identified additional interviewees by asking those initially interviewed through the purposive approach to identify additional informants to include in our sample (snowball sampling).[23,24] We continued this strategy until reaching data saturation, or the point at which the sampling process was unlikely to yield additional, substantive information related to the study aims.[23,24] We invited key informants to participate by email, and then followed-up with phone calls to schedule interviews.

Using a semi-structured interview guide developed with study investigators and state collaborators, the lead author conducted phone interviews. The guide provided a

general structure for the interviews and included questions about the following domains: professional experiences, typical day and responsibilities, involvement in policy development or implementation, success and challenges encountered, and recommendations. All interviewees provided verbal informed consent prior to the start of each interview and permission to digitally record and transcribe the interview.

### **3.4.2 Data Analysis**

We analyzed interview data concurrently with data collection and revised the interview guide based on preliminary analyses.[24] Following initial thematic and inductive coding, we stratified coded data by stakeholder role (e.g. state or local health department, school representatives, technical experts) to identify experiences common to each. After identifying common themes independently, we grouped themes and experiences into a case study for each state. Document analysis provided additional background and context for each case study. Within case studies, we stratified stakeholder experiences and examined the resulting data for within-state variability. We summarized themes related to the effective implementation of state laws and identified stakeholder recommendations from the thematic analysis.

### **3.5 Results**

We invited 86 key informants to participate; five declined because of insufficient time (n=3) or not having permission (n=2). We conducted 81 interviews with 13 to 31 interviewees per state from August 2015 through January 2016, yielding 79 hours of recordings. State (n=19) and local (n=24) health department interviewees (Table 3-1) included epidemiologists, policy analysts, immunization managers, school health liaisons, public health and medical officers, departmental directors, and a state health

commissioner. School health personnel (n=31) were primarily nurses responsible for immunization activities. We also interviewed seven experts providing academic, medical, and advocacy perspectives.

### **3.5.1 Factors Affecting Implementation**

We identified five themes reflecting the factors interviewees identified as influencing implementation of new exemption laws: (1) exemption definitions, (2) stakeholder support, (3) stakeholders collaborations, (4) school nursing, (5) administrative rulemaking process, and (6) convenience of exemption requirements. Table 3-2 provides details of state implementation processes.

#### **Exemption Definitions**

Each state permitted exemptions for both religious and philosophical reasons (Table 3-2). Our analysis indicated that the clarity with which requirements were defined in the law and during implementation affected how well the requirements were enforced at the local school, health department, and clinical levels. However, interviewees across states expressed concern about their understanding of constitutional protections afforded to an individual based on religious beliefs. School interviewees described a desire to be more sensitive to parents with strongly held beliefs, whether secular or religious, when implementing state laws. A Vermont school nurse recounted her questions to her health department liaison, as an example of this concern: *I asked, “What do you do to evaluate whether something is a religion or whether someone is just marking the box, or do you have to have proof?” I’m thinking I don’t ever want to be in the position where I have to decide whether somebody’s religion is real or not.* Interviewees suggested these types of decisions make implementation more difficult for nurses and school health personnel.

## **Stakeholder Support**

We found support for changes to exemption laws across states and professionals working in child health. A state health department interviewee who participated in the rulemaking process described the objective underlying the law's implementation: *A lot of what we had to do was to make sure that what was written in there complied with the law. So we had the attorneys take a look at it and make sure that the language was really clear and it met the law and it included everything that would meet the law... We were trying to make it easy for the schools, because for California and some of the other states that have physicians sign off on the form, the schools do a lot of checking. So it's a lot of work for them.*

All four states added an educational requirement to their exemption policies (Table 3-2). Interviewees described the benefit of these educational requirements in providing parents with evidence-based information about the risks and benefits of vaccines, and of policies excluding exempted children from schools during outbreaks. Interviewees were also pragmatic about the impact: they described how the 2011-2013 law changes adding educational requirements primarily reduced convenience exemptions and had less impact on parents with strongly held beliefs. Interviewees in all states supported the more restrictive law changes in 2015 adopted by California and Vermont that removed exemption options.

## **Stakeholders Collaborations**

Interviewees described efforts to improve collaboration between stakeholders associated with successful implementation of the new laws. Collaborative efforts

included creating advisory boards, institutionalizing communications between implementing agencies through liaisons and reporting requirements, and sharing authority between stakeholder groups. Several interviewees attributed problems identified with enforcing mandates at the school-level to lack of shared authority for excluding students from school.

Interviewees reported more effective enforcement when the exclusion authority was shared between stakeholders. Oregon interviewees described the shared authority process as including consecutive review of immunization records by the school system and health department to identify non-compliant students. A local health department representative described how sharing responsibility and authority for school requirements benefits the school and supports efficient implementation: *Technically the school still has to enforce the exclusion, but with the authority coming from public health the school can say, "Look, the health department says you have to have these immunizations and we are required to enforce this by law." So it sort of makes the health department the bad guy, and schools are helping families stay in school.*

Conversely, the lack of collaborative exemption enforcement was cited as a barrier to effective implementation in states where school administrators held primary authority for exclusions. Excluding children may anger parents and create a possible financial conflict of interest among principals responsible for enforcing school vaccine laws when school funding is based on a per-student attendance calculation. One Washington interviewee described this situation: *We are really having difficulty with principals. If kids aren't immunized they still let them in because they don't want to lose dollars; that's part of their state budget.*

## **School Nursing**

Interviewees emphasized the importance of school nursing and expressed concern about low nurse to student ratios contributing to low immunization rates. Health department interviewees described variability in the role of school nurses and school health personnel in immunization-related tasks (Table 3-2), such as obtaining, reviewing, and tracking student immunization records. Many school interviewees expressed concern about the negative impact underfunding school nursing has on immunization rates.

The relationship between support for school nursing and implementation of vaccine laws is evident in Vermont, where state law requires one nurse for every 500 students (the lowest ratio in the country) and mandates immunization data reporting to the state by school nurses.[26] Vermont school nurses described workload increases when new laws were implemented, but also expressed their commitment to continued immunization monitoring in their schools. Interviewees in multiple states described more confidence in implementing requirements when school nurses were involved in assessing medical records, tracking exemptions, and interacting with parents. Conversely, without experienced nursing staff responsible for immunization health, the infrastructure is less effective, as described by one interviewee from Washington: *One of the problems we've had is that the resources in the schools have been dwindling to the extent that the schools, and the school nurses in particular, don't have the time to really chase all the people who don't turn in their forms. ... So nobody knows if they're really immunized or not.*

Local interviewees in Oregon, Washington, and California were concerned about the diminishing role of school nursing due to state and school budget cuts, reporting that

administrative employees were increasingly responsible for reviewing student vaccination records while school nurses focused on clinical practice in their limited time.

### **Administrative Rulemaking Process**

There were several administrative components included in the bills that affected their implementation. Each successful bill included effective dates and implementation periods, ranging from 6 weeks in Vermont to 15 months in California (Table 3-2).

Many interviewees reported that staging the implementation of new requirements over time allowed schools to mitigate one-time and recurring increases in workloads, and provided time to educate families and clinicians about the changes. School health personnel reported that slowing the implementation process at the school-level resulted in increased time for community members and stakeholders to adjust to the changes. When describing the long implementation periods in California, a state-level interviewee suggested, *“some of that time was to appease the public, and some of that could also be implementation because it would be very hard to all of a sudden at every grade level to start requiring the vaccines as if they were entering kindergarten. If they did that, it would be really hard for schools to enforce that.* School-level interviewees also described “grandfathering” students, where schools accept previously approved exemptions while applying new requirements to newly enrolled students and to all students in specified grades.

New educational requirements staged in California and Oregon applied to kindergarteners and 7<sup>th</sup> graders, while students in other grades were able to maintain pre-existing exemptions. In Oregon, a local health department representative responsible for

monitoring school exemptions described how staging affected the implementation process: *I thought we'd get a lot of pushback from parents, but we really didn't. And I think part of that reason is because all of those religious exemptions were grandfathered in, so we were really only talking about new kindergartners and new enrollers in daycare, which aren't really that many kids when you look at the whole big picture.* Oregon's new requirements were initially staged, but the subsequent legislative session repealed the staged implementation in 2015 and applied the educational requirement to all students with NMEs. Several interviewees at the local and state levels described the more restrictive second law change as a positive indicator that implementation of the initial law was successful, and could now expand to all students.

Convenience of Exemption Requirements: Annual educational requirements and clinician signatures on exemption forms increased the administrative complexity in obtaining exemptions, maintaining a process that parents who oppose vaccination are able to meet without being disproportionately burdened. Lawmakers in California and Washington added a clinician signature requirement to document that the parent received vaccine education (Table 3-2). According to one local health department interviewee, *"We were trying to take additional steps to educate parents about vaccines and requirements and exemptions and also make this have some parity with the process for getting an exemption and getting vaccinated. Functionally it was simpler to get an exemption than it was to get vaccinated and that makes it hard to know how many parents had fundamental beliefs against immunization and how many parents were exercising the exemption because of running out of time and convenience."* In 2012,

Vermont also added an annual form documenting vaccine risk and benefit information, but did not require the parent to meet with a clinician.

Oregon offered two pathways for parents to meet their educational requirement to obtain an NME. Parents could obtain a clinician signature on the exemption form or complete an online vaccine module created by the health department. Interviewees at all levels favored this approach, explaining that having two pathways increased access and flexibility for parents. State health department interviewees reported that clinicians unwilling to sign exemption forms were able to refer parents to the online module. Parents obtained more exemption certificates through the on-line vaccine module relative to clinician signatures. Importantly, the increased flexibility of the process did not necessarily make the process more “convenient” for a parent, something that has been associated with higher exemption rates.[8,27,28]

### **3.6 Discussion**

Implementation studies of other school health laws, such as nutritional or physical activity mandates, found similar facilitators associated with local and state level implementation. Effective implementation is supported by partnerships between stakeholders and policy makers, and reinforced by the clear delineation of implementation and enforcement roles.[29–32] Assessments of sports concussion laws identified associations between implementation effectiveness and school-level stakeholder knowledge and understanding of key requirements.[33–36] Similarly, school health personnel’s knowledge of state immunization and exemption requirements were associated with higher exemption rates.[8,27,28]

Our data suggest that the quality of collaboration among implementers across agencies improved implementers' experiences with realizing the law, particularly when operationalized through shared authority for oversight. School and health department employees responsible for implementing laws attributed effective implementation to support for the new laws among implementers. Though the restrictive laws were controversial in the media and with parents, school and health department staff overwhelmingly supported activities limiting NMEs.

Some interviewees also expressed support for further restricting, and even eliminating, NMEs. The findings from our study may assist stakeholders and legislators drafting more restrictive exemption laws, as we provide insight into implementation strategies informing such laws. Stakeholder support at the local community level for restrictive law changes was seen in advocacy groups in both California and Vermont, and interviewees reported more effective law change when health departments acted in a supportive role to other stakeholders rather than taking the lead on proposing legislation.

Our state selection included the universe of states that enacted restrictive exemption laws between 2011-2015, though these states are not representative of the diversity of states that may be considering such legislation. We collaborated with state health departments to identify diverse key stakeholders to interview and relied on interviewees to expand our sample to identify other relevant informants. In spite of these efforts to obtain many perspectives, it is possible that selection bias occurred, resulting in data that may be more likely to describe successful implementation rather than failures. This analysis also has the potential for bias in how we collected and analyzed the interview data, as the lead author conducted all of the interviews and led data analysis. To

mitigate this potential source of bias, we used an interview guide to provide consistency in the types of questions asked across interviewees. In addition, senior investigators reviewed ongoing data analysis procedures, and assisted in interpreting themes.

Strengths of this study are the inclusion of the first states passing more restrictive exemption laws in response to outbreaks and our ability to conduct this study in real time. This natural experiment allowed us to systematically analyze qualitative data from a large number and broad range of implementers. This analysis complements existing studies demonstrating associations between the ease of obtaining exemptions, exemption rates, and disease rates with prospective data from implementers.[8,14,27]

As with most public health laws, the ability to affect immunization child health outcomes depends on implementation quality and effectiveness.[37] Until exemption laws were enacted, few opportunities existed to assess implementation or the effectiveness of increasingly restrictive exemption law changes in states with high exemption rates and VPD outbreaks. The findings from this case study provide insight and recommendations useful to legislators, agencies and schools in states considering or implementing restrictive exemption laws.

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**Table 3-1: Number of In-depth Interviews Conducted, by State and Stakeholder Type**

	<b>California</b>	<b>Oregon</b>	<b>Vermont</b>	<b>Washington</b>	<i>Type of Stakeholder Total</i>
<b>State Health Departments</b>	5	3	7	4	19
<b>Local Health Department</b>	6	6	6	6	24
<b>School Health Personnel</b>	3	4	17	7	31
<b>Immunization Experts</b>	1	0	1	5	7
<i>State Totals</i>	15	13	31	22	81

**Table 3-2: State Immunization and Exemption Requirements Implemented Following Law Changes; 2011-2016**

Law Characteristic		CALIFORNIA	OREGON	VERMONT	WASHINGTON
2011-2013 Law Changes	<b>Law Name, Approval and Effective Dates</b>	<b>AB 2109</b> Approved 9/30/2012 Effective 1/1/2014	<b>SB 132</b> Approved 6/19/2013 Effective 3/1/2014	<b>Act 157</b> Approved 5/16/2012 Effective 7/1/2012	<b>SB 5005</b> Approved 5/10/2011 Effective 7/22/2011
	<b>Implementation Time Window</b>	15 months	9 months	2 months	2 months
	<b>Staged Implementation</b>	At kindergarten, 7th grade	Accepted existing NME, applied to new students	none	none
	<b>New Components Added</b>	Required clinician signature documenting vaccine risk and benefit education; Annual renewal	Required vaccine risk and benefit education, available from (1) clinician, or (2) web-based vaccine module developed by health department; NME language changed from religious to optional reason.	Required vaccine risk and benefit education signed by parent; Annual renewal; Increased reporting and transparency of exemption data; Reduced provision catch-up to 6 months; Expiration date; Mandated report to General Assembly	Required clinician signature documenting vaccine risk and benefit education.
	<b>Types of NME available</b>	Single secular NME with additional religious exemption	Optional selection of religious or philosophical reasons	Required selection of religious or philosophical reasons.	Required selection of religious or philosophical reasons.
	<b>Provisional window?*</b>	Admitted pending next catch-up appointment	Admitted for catch-up until February exclusion date	Admitted for catch-up for 6 months	Admitted for catch-up for 30 days
	<b>Who tracks and reviews student records?</b>	School nurse/ administrative staff	School administrative staff/ reviewed by local health department	School nurse	School nurse/ administrative staff
	<b>Delegated authority to exclude students</b>	School governing authority (principal or headmaster)	Local Health Department	School principal or headmaster	School principal or headmaster
	<b>Timing of excluding students?</b>	Rolling exclusions	Annually	Rolling after 6 month provisional	Rolling
2015 Law Changes	<b>Law Name, Approval and Effective Dates</b>	<b>SB 277</b> Approved 6/30/2015 Effective 7/1/2016	<b>SB 895</b> Approved 7/27/2015 Effective 7/27/2015	<b>Act 37</b> Approved 6/30/2015 Effective 7/1/2016	n/a
	<b>Implementation Time Window</b>	12 months	Effective for 2015-2016 school year	12 months	n/a
	<b>Exemption Changes</b>	Removed NME to existing specified immunization requirements	Removed grandfathering of exemptions for SB132 law; Increased reporting and transparency of school-level immunization and exemption data to community	Removed NME for philosophical reasons, religious exemption permitted	n/a
	<b>Staged Implementation</b>	Staged at kindergarten, 7th grade	none	none	n/a
*Provisional window is a catch-up period to obtain scheduled vaccines n/a= not applicable; NME= non-medical exemption; AB= Assembly Bill; SB= Senate Bill					

**Table 3-3: Stakeholder Recommendations for Effective Implementation of Exemption Laws**

<p>We identified four primary recommendations through the analysis of the stakeholder interview data. These recommendations reflect interviewees’ most salient recommendations.</p>
<p><b>1. Consider length of the implementation timeframe:</b> Effective dates for state laws should take into consideration academic calendars, state and CDC-mandated immunization reporting dates, and should include adequate time for effective implementation of the new law. Interviewees agreed that at least 6-12 months is needed to create the systems and documents, and to educate parents, clinicians, and communities before the law becomes effective.</p>
<p><b>2. Stage implementation of new requirements.</b> New requirements are best implemented through a staged approach, or structured to include grandfathering. Staged implementation benefits implementers by spreading workloads and financial investments across several years, which allows more time for training and systems development.</p>
<p><b>3. Streamline NMEs.</b> States with high NME rates or outbreaks should consider implementing a single NME with appropriately complex administrative procedures. A single NME option could decrease confusion about subjective religious and secular definitions while providing parent education and administrative controls. Administrative procedures may include a clinic visit, parent education, DoH review, and annual NME renewal.</p>
<p><b>4. Develop alternative pathways for obtaining NMEs.</b> Interviewees recommended flexibility in implementing the mechanisms and processes for obtaining exemptions, without making exemptions more convenient. Alternate pathways for meeting administrative requirements to obtain an exemption should demonstrate an understanding of general parent and community concerns, parent access to health care, and technological resources.</p>

## **Chapter 4 The Impact of School Exemption Requirement Changes: Kindergarten Medical and Non-Medical Exemptions Rates in Vermont Over 28 Years 1989-2016**

Short title: Impact of Recent Vermont School Exemption Changes

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## **Table of Contents Summary**

This study examined how Vermont kindergarten immunization exemption rates changed over 28 years and measured the impact of legislative and non-legislative changes to school requirements.

## **What's Known on This Subject**

Previous studies have shown that easier state exemption laws are associated with higher exemption rates and vaccine-preventable disease outbreaks. Vermont kindergarten exemptions suddenly doubled in 2008 and have remained some of the highest nationally in spite of recent law changes.

## **What This Study Adds**

This study suggests that state-level changes increasing the administrative complexity of exemption requirements or removing non-medical exemption options may have an impact on reducing school exemptions, though short-term increases may occur after adding requirements.

## **Contributors' Statement Page**

Dr. Cox contributed to study design, conducted a literature review, collected and cleaned the data, conducted the data analysis and interpretation of the analysis, created the tables and figures, and drafted, reviewed and revised the manuscript.

Dr. Atwell contributed to the interpretation of the data, reviewed, and revised the manuscript.

Ms. Finley contributed to study conception and design, acquisition of data, interpretation of results, reviewed and revised the manuscript

Ms. Hannan contributed to study conception and design, and reviewed the manuscript

Dr. Omer contributed to the design and analysis of the study, and has reviewed the manuscript.

Dr. Salmon contributed to the design and analysis of the study, and has reviewed the manuscript.

All authors reviewed and approved the final manuscript as submitted.

## 4.1 Abstract

**Background:** U.S. states allow exemptions to school immunization requirements for medical, religious, and/or philosophical/personal belief reasons. Vermont requirement changes in 2008, 2012, and 2015 created an opportunity to examine the impact of changing laws and requirements on exemption rates.

**Methods:** We conducted an observational longitudinal study to evaluate annual kindergarten exemption rates in Vermont over 28 years, focused on exemption trend changes in 2008, 2012, and 2015. Segmented regression models were used to estimate state and school-level exemption rates.

**Results:** Prior to 2008, medical exemptions averaged 0.2%, religious exemptions averaged <0.1%, and philosophical exemptions increased to 2.7% in 2007. Exemption rates doubled to 6.5% (95% CI: 5.6%, 6.7%) in 2008 primarily due to public school philosophical exemption increases. One in five Vermont kindergarteners in 2008 (16.7% public schools, 40.6% private schools) had an exemption or provisional admission. Post-2008 medical and religious exemption trends remained <1% while philosophical exemptions varied across public (4.5%-5.3%) and private (8.3%-14.1%) schools. Vermont's legislature responded with Act 157 in 2012 changing the process for obtaining exemptions and intended to decrease overall exemptions, yet public school philosophical exemptions rose until Act 37 in 2015 removed the philosophical exemption.

**Conclusion:** Exemption rate increases in 2008 were likely responses to additional vaccines on the required schedule. Legislative activity in 2012 had limited impact until the philosophical exemption was removed in 2015. State health department can impact

exemption rates through legislative and non-legislative means, however short-term increases in non-medical exemptions may occur.

## **4.2 Abbreviations**

U.S. United States of America

CI Confidence Interval

GLM Generalized linear model

GEE Generalized estimating equations

AR1 Autoregressive 1

### 4.3 Introduction

State governments in the US are responsible for creating, implementing, and enforcing immunization requirements for school enrollment. State laws vary in terms of which vaccines are mandated, the complexity of the processes for obtaining exemptions, and the types of exemptions allowed.[1] As of January 2018, all 50 U.S. states and the District of Columbia allow medical exemptions. Though non-medical exemptions are not required under federal constitutional and statutory law[2], they are permitted in 47 states, with 30 states and Washington DC permitting only religious exemptions and 17 states permitting both religious exemptions and philosophical exemptions.[3] Three states, (California, Mississippi and West Virginia), do not permit non-medical exemptions.

In the summer of 2012, following multiple vaccine-preventable disease outbreaks across the U.S. and steadily increasing statewide and national non-medical exemption rates, the Governor of Vermont signed Act 157 mandating changes to the process for obtaining school immunization exemptions. [4] The new law increased the complexity of the administrative process for parents seeking non-medical exemptions by requiring them to sign an updated health department form each year with educational information about risks and benefits of vaccines. Three years later in 2015, Act 37 restricted the non-medical exemption by removing the philosophical exemption, leaving only religious and medical exemptions available effective 2016.

We examined kindergarten exemption rates longitudinally from school years beginning in 1989 to 2016 to describe trends in exemption rates over time, and to evaluate whether the introduction of new immunization mandates or restrictions to the

exemption processes were associated with changes in exemption rates for kindergarten students in Vermont.

#### **4.4 Methods**

State law and Department of Health changes impacting school immunization and exemption requirements were identified through the Vermont Department of Health website and the Vermont Legislative Bill Tracking Database over 14 legislative sessions (1989-2016) accessed through the Vermont General Assembly website.

Vermont public and private (called independent in Vermont) schools report student enrollment, exemptions to one or more required vaccines, and verified coverage data for required vaccines to the Department of Health annually. State-level summary data were available between academic years 1989-2016 (missing 1994) and school-level data were available between 2007-2016 for the approximately 300 kindergartens in Vermont.

Annual exemption rates were calculated by dividing the number of each type of exemption in the kindergarten by total kindergarten enrollment in each school, providing a single rate for the kindergarten cohort in each school. Descriptive statistics were generated to examine mean annual exemption rates by exemption type and school type using Stata, version 12.0 (StataCorp, College Station, TX).

##### **4.4.1 Statistical Analysis**

We conducted an observational longitudinal quasi-experimental study to describe annual kindergarten exemption rates in Vermont between 1989-2016 and to assess exemption rate changes subsequent to policy changes in 2008, 2012, and 2015. Using 27

years of state-level data, we compared exemption rate level and trend estimates with proposed legislation and policy changes. We then created an interrupted generalized linear segmented regression model (GLM) to estimate discontinuous trends for the periods 1989-2007, 2008-2011, and 2012-2014, and exemption rates changes following policy changes.[5]

School-level data available for 2007-2016 were used to create separate statistical models for public and private schools using the school as the unit of analysis. Generalized estimating equations (GEE) using negative binomial distribution and autoregressive (AR1) correlation estimated population-averaged trend and level parameters for each exemption type following 2008, 2012, and 2015 policy changes.[6,7] A kindergarten enrollment variable for each school and year was included to transform the counts for differently sized schools into binomial data.

#### **4.4.2 Ethical Approvals**

The Institutional Review Board (IRB) of Emory University approved this research.

### **4.5 Results**

#### **4.5.1 Legislative and Policy Changes; 1989-2016**

The analysis of Vermont immunization-related policy and legislation from 1989-2016 identified several significant changes in immunization and exemption requirements. Below we define and describe changes in (1) the non-medical exemption form, (2) provisional admissions, (3) new vaccines required in 2008, and (4) exemption rates following two law changes (Act 157 in 2012 and Act 37 in 2015).

The Vermont Department of Health permitted non-medical exemptions for religious beliefs or philosophical convictions between 1979 and 2015. In 2000, the non-medical exemption form that parents submitted to school nurses began requiring parents to select the reason for their non-medical exemptions; either that the immunization requirement conflicts with “free exercise of religious rights” or “free exercise of moral (philosophical) rights”.[8] In 2008, religious and philosophical exemptions were documented on separate forms. (Appendix for Vermont Exemption Form Examples)

Schools began reporting the number of students admitted provisionally in 1999. The Vermont immunization policy allows schools to provisionally enroll students while they are in the process of catching-up on immunization doses. Students attending school without adequate immunization records or exemptions are also provisionally admitted until the school enforces an exclusion date.

The state health department implemented a rule change in 2008, requiring varicella and hepatitis B (HBV) vaccines for kindergarten enrollment; a tetanus, diphtheria and acellular pertussis (Tdap) booster and the varicella series for 7<sup>th</sup>-graders; and meningitis vaccine for residential and college students.

In 2012, Act 157 was passed in an effort to reduce rising exemption rates, with early versions of the bill proposing the elimination of philosophical exemptions completely. The final law did not remove philosophical exemptions; instead adding administrative steps to the process for parents seeking non-medical exemptions. Exemptors were required to submit a signed form each year after review of educational information written by the Vermont Department of Health on the risks and benefits of

vaccination. The law increased the transparency of school-level immunization rates reports to the public and limited the time allowed for provisional catch-up of students to 6-months (Table 4-1).

Three years later, Vermont Act 37 passed in July 2015 removed the philosophical exemption that had been available in Vermont since 1979, effective the following academic year. Sequential modifications to immunization requirements and procedures for exemptions are summarized in Table 4-1, and Table 4-2 identifies key immunization policy changes in Vermont.

#### **4.5.2 Descriptive Analysis by School and Exemption Type; 1989-2016**

In 2014, public schools enrolled 87.2% and private schools enrolled 10.1% of Vermont school-age children. Home study children (2.6%) are not included in state immunization requirements.

The total number of individual kindergarten exemptions to one or more required vaccines in Vermont increased from 43 exemptions in 1989 to 205 exemptions in 2007, reflecting a steady linear annual increase from 0.5% of kindergarteners to 3.0% over 19 years. In 2008, state exemption rates doubled from 3.0% to 6.5% and remained at a higher plateau through 2014, fluctuating between 5.7% and 6.3%. During the 7-year period between 2008-2014, the mean private school exemption rate was 10.9% (95% CI 8.8%, 13.2%) and the public school rate of 5.9% (95% CI 5.5%, 6.4%)(Tables 4-1 and 4-2).

Provisional admittance counts are not included in statewide exemption rates. The mean statewide provisional admittance rate between 1999 and 2007 was 5.3% (CI 4.2,

6.4%). In 2008, the statewide provisional admittance rate doubled to 12.5% (CI 11.7%, 13.3%), with the mean private school provisional admittance rate increasing to 25.7% (CI 22.0%, 29.4%).

Between 1989-2007, the medical exemption trend increased by 0.01% annually (CI 0.01, 0.02%). Following a 0.49% (CI 0.41%, 0.57%) increase in 2008, both public and private school medical exemption rates decreased over the subsequent years to pre-2008 rates, with a mean medical exemption rate of 0.23% (CI 0.16%, 0.30%) over the 28-year study period.

The mean statewide religious exemption rate remained steady between 2000-2007 at 0.07% (95% CI 0.04, 0.09%). Between 2008-2014, mean rate of religious exemptions in private schools was 3.6 times (95% CI: 1.9, 6.8; p-value<0.01) higher compared to public schools, but both remained under 1.0% average trend.

The philosophical exemption patterns differed from other exemptions by school type and period. Prior to 2008, philosophical exemptions increased statewide from 0.5% in 1989 to 2.7% (95% CI 2.3, 3.1%) in 2007. When public school philosophical exemption rates doubled in 2008, private schools remained constant from 2007 with a philosophical exemption rate already three times higher (13.3%) than public schools (p-value <0.01). In subsequent years, the mean rate of philosophical exemptions in private schools was 2.1 times (95% CI: 1.1, 3.9; p-value<0.01) higher than public schools. Private school philosophical exemption rates dropped slightly in 2010 and 2012, and the 2008-2014 private school mean philosophical exemption rate was 12.3% (CI: 10.6, 14.1). In contrast, public school philosophical exemption rates increased stepwise in 2008 and

2012, and the 2008-2014 public school mean philosophical exemption rate was 5.0% (CI: 4.7, 5.3). Table 4-4 includes trend estimates for each time period and Table 4-5 identifies policy level exemption changes measured in 2008, 2012, and 2015 following law changes.

In 2015, the last year philosophical exemptions were available, religious exemptions increased in both public and private schools to record high rates (0.6% in public schools; 5.1% in private schools) and philosophical exemption rates decreased statewide. In 2016 religious exemptions increased to 3.7% statewide (3.1% in public schools; 11.4% in private schools and provisional admission increased to 6.4% (6.1% in public schools; 11.4% in private).

#### **4.6 Discussion**

Public health law research has characterized the years after 1998 as the “vaccine scare” years as there followed a decade of vaccine-critical laws in U.S. states, increasing vaccine hesitancy among parents, and rising exemption rates.[9] In 2010, a growing organized response to strengthen exemption laws began, first on the West Coast (Oregon, California, Washington) and then in Vermont. In 2014, California became the first state to respond to disease outbreaks by removing all non-medical exemptions, indicating that state legislators were willing to take drastic action to reduce exemptions.

Tracking exemption rates longitudinally reveals important trends.[10–12] Easier state exemption processes and the availability of multiple exemption type (i.e. philosophical and religious) have been associated with higher exemption rates and increased vaccine-preventable disease incidence.[10,12–20]

However, studies that examine associations between state laws and exemption rates are limited in their ability to determine causality. The direction of the relationship between exemption laws, policies, and rates cannot be established given that it is not possible to know if high parental demand for exemptions results in permissive exemption laws or if permissive laws lead to higher prevalence of exemptions. When states make changes to their exemption requirements through laws or policy changes, a natural experiment allows for an assessment not possible with association studies.

This policy analysis provides context to assess the exemption rate patterns seen in Vermont and the impact of administrative and legislative changes. The longitudinal analysis of 28-year period identified several trends in exemption types. Philosophical exemption rates were much higher than other exemption types, were higher in public schools than private, and remained the most frequent exemption until 2015. The observed increases in philosophical exemptions among public schools and high provisional admittances rate in 2008 may be a response to new vaccine requirements implemented through health department policy changes, with increasing numbers of parents following delayed and alternate dosing schedules. Vermont was among the last 10% of states to mandate HBV and varicella for school enrollment in 2008.

Provisional admittances effectively provided parents with one-year grace period to delay receipt of required doses without obtaining an exemption. If so, this may explain why provisional admittance rates increased in 2008 following the addition of new immunization requirements, such that 40.6% of students in private schools and 16.7% of students in public schools had some type of exemption or provisional admission.

Following the increase in 2008, provisional admission rates dropped, increasing again in 2016 following the implementation of new legislation removing the philosophical exemptions. Parents who previously utilized philosophical exemptions may have transitioned to religious exemptions or received provisional admissions (if the parents were non-compliant or if their children were in the process of catching-up on required immunizations).

The 2012 law change adding an annual educational requirement for parents appeared to have minimal impact on the statewide public and private religious exemption rates in Vermont. Removing philosophical exemptions in the 2016 school year decreased the non-medical exemption rate, but with provisional admission rate increases statewide, the rate of children with either an exemption or provisional admission remained constant at 10.3% between 2015 and 2016. This may indicate parental non-compliance or vaccine hesitancy as well as the ongoing implementation of the law change at the school level, where school nurses are tracking exemptions and provisional admission students. Where available, provisional admission rates should be evaluated alongside state exemption rates as indicators of parental vaccine hesitancy.

Limitations of this study result from the quasi-experimental nature of the assessment. We are not able to rule out other unmeasured confounders that may have affected parental behaviors differently over time, including whether more parents sought exemptions in 2008 to avoid the additional vaccination requirements. We did not measure public awareness regarding the state law changes as they were proposed or once they were passed and did not measure parental reasons for obtaining exemptions beyond

whether they chose a philosophical or religious. We did not assess antigen-specific exemption requests. The increase in exemption rates seen after adding new vaccine requirement may be a result of exemptions to these new requirements and not reflect more exemptions for vaccines historically required. We were not able to partition provisional admittance rates into children on catch-up schedules, alternative/delayed schedules, or those without records permitted to attend school. The parental attitudes and behaviors of children provisionally admitted for different reasons may vary over time.

Though there were only a few years to measure a state-level impact following each change-point, the multiple immunization bills proposed from 2008-2016 demonstrates the incremental nature of public health safety laws. As an example, the early versions of the 2012 proposed bill would have removed philosophical and religious exemptions; and in 2015, a successful bill removed philosophical exemptions leaving only religious and medical exemptions available in 2016. The two most recent legislative sessions (2013-2014 and 2015-2016) included a record seven new proposals to modify immunization and exemption requirements in schools.

Removing philosophical exemption availability in 2016 forces parents pursuing non-medical exemptions in both public and private schools to declare a religious reason for obtaining an exemption, which may mitigate exemption rate switching among secular parents or parents who strongly identify with non-religious reasons for exempting.

#### **4.7 Conclusion**

This analysis shows the importance of longitudinally examining public and private school patterns within a state. High exemption rates in private schools create

susceptible populations at-risk of outbreaks, and this analysis indicates both public and private school parents in Vermont were requesting philosophical exemptions more frequently than medical or religious exemptions and may have been influenced by legislative and non-legislative changes to the immunization and exemption process.

California's drastic change of eliminating all non-medical exemptions was endorsed by the American Academy of Pediatrics, and other states may be watching legal and epidemiological outcomes in both California and Vermont as two possible avenues to strengthen school laws. Vermont has less than 2% of the population of California, though general conclusions can be applied to other US states similarly experiencing high rates of parental vaccine hesitancy and exemptions, as well as disease outbreaks.

State legislatures or health departments considering legislative action must be aware of the possibility of short-term increases in exemptions following law or policy changes adding new vaccines or changing the exemption processes. States considering non-medical exemption changes may consider strengthening religious exemption requirements in-line with removing philosophical exemptions to mitigate convenience switching, or when removing non-medical exemptions may not be politically feasible, administratively strengthening a single non-medical exemption process with educational or other requirements.[21]

Continued monitoring of medical and non-medical exemption rate changes in Vermont as Act 37 is implemented will show whether the elimination of the philosophical exemption will reduce overall exemption rates in public and private schools

going forward, and may indicate whether this policy change and impact analysis will be useful in guiding legislators in other US states.

#### 4.8 References

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**Table 4-1: Immunization Legislation Introduced or Passed Specific to School Immunization Exemptions; Vermont 1989-2016**

<b>Legislative session/ date</b>	<b>Act # (if passed)</b>	<b>Vermont Policy Changes/Summary</b>
<b>1993-1994</b>	Act 75	Established immunization requirements for college students
<b>1997-1998</b>	Act 91	Vermont Department of Health created Vermont Immunization Registry
<b>2003-2004</b>		Proposed requiring meningitis information to parents; Bill did not pass.
<b>2007-2008</b>		Proposed requiring Human papillomavirus (HPV) vaccines for all girls entering 6 <sup>th</sup> grade; Bill did not pass
<b>2007-2008</b>	Act 204	Applied immunization requirements to childcare centers, changed language of non-medical exemption from “religious beliefs or moral convictions” to “religious beliefs or philosophical convictions” in law.
<b>8/2008</b>	Vermont Department of Health policy change	Department of Health added varicella and Hepatitis B (HBV) vaccines to kindergarten requirements, tetanus/diphtheria/pertussis (Tdap) booster & varicella to 7 <sup>th</sup> grade requirements, meningitis to residential and college student requirements
<b>2011-2012</b>		Proposed to eliminate the philosophical exemption; Bill did not pass
<b>2011-2012</b>	Act 157	Law required schools & child care facilities to report standard immunization data to Department of Health and make publicly available the aggregated immunization rates of the student body for each required vaccine; added parental education requirement prior to submitting <u>annual</u> exemption forms for philosophical and religious exemptions; limited provisional admittance to 6 months
<b>2013-2014</b>		Proposed to suspend non-medical exemptions if coverage for vaccine is <90% in a school; Bill did not pass
<b>2013-2014</b>		Proposed removing non-medical exemptions for pertussis; requiring school staff vaccinated against pertussis; Bill did not pass;
<b>2015-2016</b>		Proposed requiring all students, teachers, administrators, and staff members in schools to be vaccinated with only medical exemptions permitted; Bill did not pass
<b>2015-2016</b>	Act 37	Passed 2015: Removed philosophical exemptions effective 2016, increased reporting requirements, created Vermont Immunization Advisory Council, mandated reporting to Federal Vaccine Adverse Event Reporting System (VAERS), requested reports from Department of Health regarding mandatory immunization of school personnel

**Table 4-2: State-wide Kindergarten Exemption Rates by Exemption Type, Vermont 1989-2016**

**Combined Public & Private Schools**

Year	School Enrollment	All Exemptions	Medical Exemptions	Philosophical Exemptions	Religious Exemptions	Provisional Admittance
1989	8586	0.50%	0.05%	0.45%	.	.
1990	8589	0.51%	0.03%	0.48%	.	.
1991	8590	0.64%	0.09%	0.55%	.	.
1992	8368	0.75%	0.07%	0.68%	.	.
1993	8178	0.79%	0.16%	0.64%	.	.
1994	.	.	.	.	.	.
1995	8736	0.95%	0.03%	0.92%	.	.
1996	8656	0.95%	0.05%	0.90%	.	.
1997	8092	1.32%	0.04%	1.29%	.	.
1998	7822	1.21%	0.05%	1.16%	.	.
1999	7613	1.67%	0.25%	1.42%	.	7.20%
2000	7368	2.01%	0.31%	1.59%	0.11%	6.05%
2001	6853	1.71%	0.19%	1.44%	0.07%	6.54%
2002	7154	1.73%	0.28%	1.34%	0.11%	5.30%
2003	6974	2.05%	0.27%	1.71%	0.07%	5.64%
2004	7065	2.18%	0.21%	1.90%	0.07%	5.05%
2005	6773	2.42%	0.25%	2.11%	0.06%	4.47%
2006	6838	2.76%	0.29%	2.40%	0.07%	5.19%
2007	6766	3.03%	0.24%	2.72%	0.07%	6.15%
2008	6794	6.46%	0.68%	5.48%	0.31%	12.48%
2009	6713	5.79%	0.52%	5.08%	0.19%	9.50%
2010	6695	6.12%	0.57%	5.38%	0.18%	10.71%
2011	6548	5.68%	0.32%	5.22%	0.14%	7.32%
2012	6792	6.11%	0.44%	5.46%	0.21%	7.04%
2013	6771	6.25%	0.16%	5.89%	0.19%	7.92%
2014	6277	6.15%	0.21%	5.81%	0.13%	6.17%
2015	6366	5.67%	0.14%	4.60%	0.93%	4.65%
2016	6344	3.92%	0.24%	0	3.69%	6.43%

**Table 4-3: Public and Private Kindergarten Exemption Rates by Exemption Type, Vermont 2007-2016**

<b>Private Schools</b>	<b>School Enrollment</b>	<b>All Exemptions</b>	<b>Medical Exemptions</b>	<b>Philosophical Exemptions</b>	<b>Religious Exemptions</b>	<b>Provisional Admittance</b>
2007	420	13.57%	0.24%	13.33%	0.00%	9.05%
2008	557	14.90%	0.90%	13.29%	0.72%	25.67%
2009	487	14.37%	0.62%	12.94%	0.82%	17.66%
2010	420	11.90%	1.19%	9.76%	0.95%	14.76%
2011	433	14.09%	0.46%	13.16%	0.46%	11.55%
2012	460	9.35%	0.22%	8.26%	0.87%	11.96%
2013	467	15.63%	0.43%	14.13%	1.07%	12.21%
2014	389	14.65%	0.51%	13.62%	0.51%	7.71%
2015	432	18.52%	0.00%	13.43%	5.09%	6.02%
2016	456	11.62%	0.22%	0	11.40%	11.40%
<b>Public Schools</b>	<b>School Enrollment</b>	<b>All Exemptions</b>	<b>Medical Exemptions</b>	<b>Philosophical Exemptions</b>	<b>Religious Exemptions</b>	<b>Provisional Admittance</b>
2007	6346	2.33%	0.24%	2.02%	0.08%	5.96%
2008	6237	5.71%	0.66%	4.78%	0.27%	11.30%
2009	6226	5.12%	0.51%	4.47%	0.14%	8.87%
2010	6275	5.74%	0.53%	5.08%	0.13%	10.44%
2011	6115	5.09%	0.31%	4.66%	0.11%	7.02%
2012	6332	5.87%	0.46%	5.26%	0.16%	6.68%
2013	6304	5.55%	0.14%	5.28%	0.13%	7.60%
2014	5888	5.59%	0.19%	5.30%	0.10%	6.06%
2015	5934	4.74%	0.15%	3.96%	0.62%	4.55%
2016	5888	3.33%	0.24%	0	3.09%	6.05%

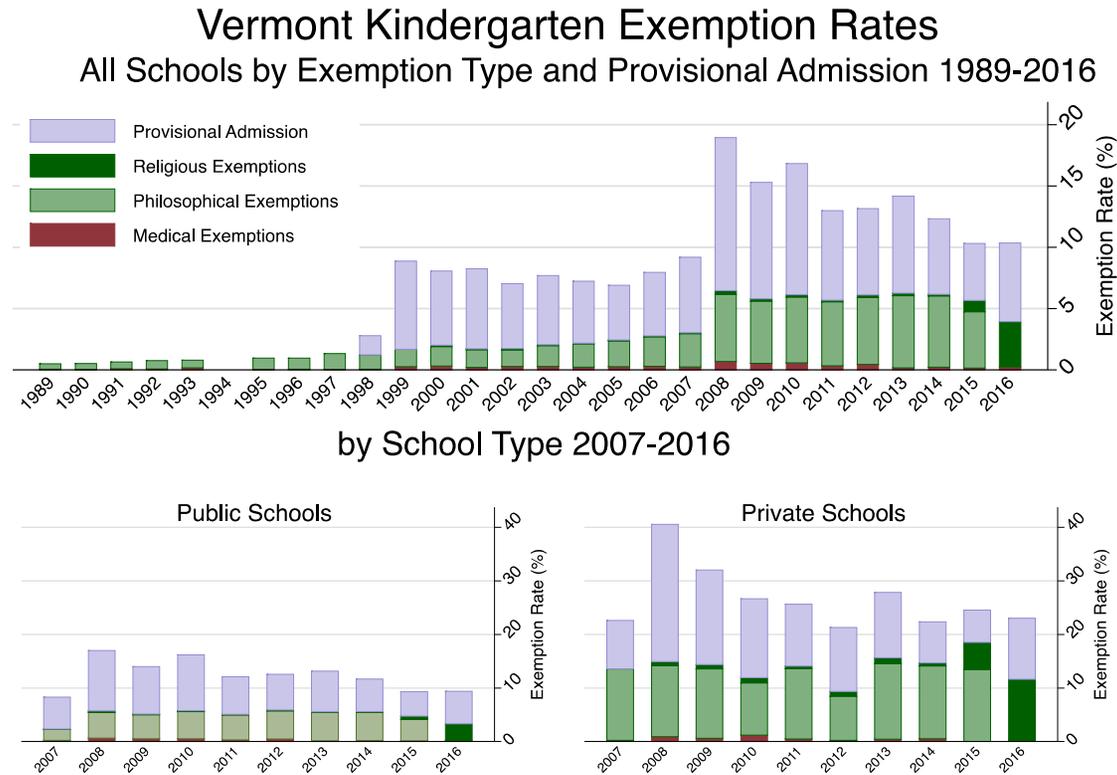
**Table 4-4: Exemption Rate Regression Trend Estimates (95% CI) of Kindergarten Student in Vermont, by Exemption Type and School Type, 1989-2014**

<b>Combined Public &amp; Private Schools</b>	<b>All Exemptions</b>	<b>Medical Exemptions</b>	<b>Provisional Admittance</b>	<b>Philosophical Exemptions</b>	<b>Religious Exemptions</b>
1989-2007	2.08% (1.69-2.47)	0.23% (0.18-0.29)	5.32% (4.22-6.41)	1.78% (1.42-2.14)	0.06% (0.04-0.09)
2008-2011	6.02% (5.46-6.58)	0.52% (0.28-0.76)	10% (6.55-13.45)	5.29% (5.01-5.57)	0.2% (0.09-0.32)
2012-2014	6.17% (5.99-6.34)	0.27% (-0.1-0.64)	7.04% (4.87-9.21)	5.72% (5.15-6.29)	0.18% (0.07-0.28)
2008-2014	6.02% (5.78-6.25)	0.37% (0.2-0.55)	8.11% (6.33-9.88)	5.47% (5.14-5.81)	0.17% (0.14-0.21)
<b>Private Schools</b>	<b>All Exemptions</b>	<b>Medical Exemptions</b>	<b>Provisional Admittance</b>	<b>Philosophical Exemptions</b>	<b>Religious Exemptions</b>
2008-2011	13.82% (11.72-15.91)	0.79% (0.28-1.3)	17.41% (7.79-27.03)	12.29% (9.6-14.98)	0.74% (0.41-1.07)
2012-2014	13.21% (4.81-21.61)	0.39% (0.01-0.77)	10.62% (4.35-16.9)	12.01% (3.92-20.09)	0.82% (0.12-1.52)
2008-2014	13.33% (10.91-15.75)	0.57% (0.22-0.92)	12.64% (9.13-16.15)	11.98% (9.48-14.48)	0.78% (0.53-1.04)
<b>Public Schools</b>	<b>All Exemptions</b>	<b>Medical Exemptions</b>	<b>Provisional Admittance</b>	<b>Philosophical Exemptions</b>	<b>Religious Exemptions</b>
2008-2011	5.41% (4.85-5.98)	0.5% (0.27-0.73)	9.41% (6.4-12.41)	4.75% (4.33-5.16)	0.16% (0.05-0.28)
2012-2014	5.67% (5.23-6.11)	0.26% (-0.16-0.69)	6.78% (4.86-8.7)	5.28% (5.23-5.33)	0.13% (0.06-0.2)
2008-2014	5.49% (5.16-5.83)	0.36% (0.18-0.53)	7.78% (6.08-9.47)	5.01% (4.63-5.38)	0.13% (0.11-0.15)

**Table 4-5: Kindergarten Exemption Rate Absolute Difference Regression Estimates (95% CI) Following Policy Changes in Vermont 2008, 2012, 2015 and 2016 Absolute Difference**

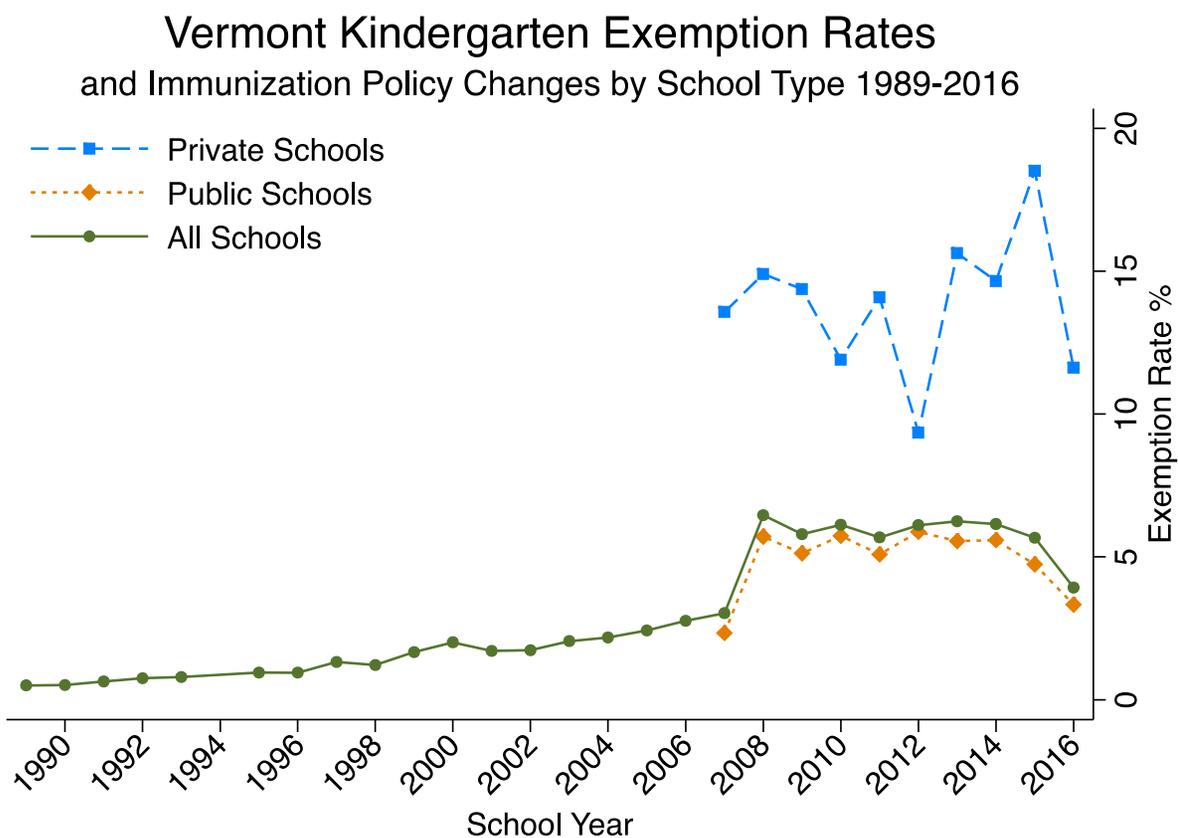
<b>Combined Public &amp; Private Schools</b>	<b>All Exemptions</b>	<b>Medical Exemptions</b>	<b>Provisional Admittance</b>	<b>Philosophical Exemptions</b>	<b>Religious Exemptions</b>
2008	3.84% (3.36; 4.31)	0.49% (0.41; 0.57)	8.59% (6.76; 10.41)	3.10% (2.70; 3.49)	0.27% (0.21; 0.34)
2012	0.42% (0.18; 0.65)	0.14% (-0.07; 0.34)	0.05% (-1.97; 2.07)	0.15% (-0.15; 0.45)	0.13% (0.09; 0.16)
2015	-0.54% (-0.67; -0.41)	0.11% (-0.07; 0.28)	-1.52% (-2.96; -0.07)	-1.47 (-1.75; -1.20)	0.83% (0.80; 0.86)
2016 (absolute)	-1.75%	-0.10%	1.78%	-4.60%	2.76%
<b>Private Schools Estimates (95% CI)</b>	<b>All Exemptions</b>	<b>Medical Exemptions</b>	<b>Provisional Admittance</b>	<b>Philosophical Exemptions</b>	<b>Religious Exemptions</b>
2008	1.47% (0.16; 2.79)	0.74% (0.42; 1.05)	19.68% (15.85; 23.51)	-0.16% (-1.99; 1.66)	0.90% (0.59; 1.21)
2012	-5.17% (-9.76; -0.59)	-0.59% (-1.08; -0.10)	4.25% (1.14; 7.36)	-5.11% (-9.71; -0.52)	0.53% (-0.01; 1.08)
2015	0% (-4.11; 4.11)	-0.68% (-0.75; -0.61)	-0.36% (-3.05 ; 2.32)	-3.94% (-7.55; -0.33)	4.63% (4.20; 5.06)
2016 (absolute)	-6.90%	0.22%	5.38%	-13.43%	6.31%
<b>Public Schools</b>	<b>All Exemptions</b>	<b>Medical Exemptions</b>	<b>Provisional Admittance</b>	<b>Philosophical Exemptions</b>	<b>Religious Exemptions</b>
2008	3.39% (2.94; 3.85)	0.52% (0.47; 0.58)	6.27% (4.85; 7.69)	2.66 % (2.32; 3.01)	0.21% (0.12; 0.30)
2012	0.73% (0.29; 1.17)	0.19% (-0.03; 0.41)	-0.31% (-2.50; 1.87)	0.45% (0.12; 0.79)	0.09% (0.05; 0.13)
2015	-0.65% (-0.85; -0.45)	0.16% (-0.04; 0.36)	-1.61% (-3.00; -0.23)	-1.36 % (-1.36; -1.36)	0.55% (0.55; 0.55)
2016 (absolute)	-1.41%	0.09%	1.50%	-3.96%	2.47%

**Figure 4-1: Vermont Kindergarten Exemption Rates 1989-2016**



Description of Figure: 1: Kindergarten exemptions rates by exemptions type and school type (number of students with exemptions/total kindergarten enrollment), (top) Bar graphs of annual medical, philosophical, and religious exemption rates (%) and provisional admission rates (%) in kindergartens in Vermont schools 1989-2016 (missing 1994). (bottom) Bar graphs of annual medical, philosophical, and religious exemption rates (%) and provisional admission rates (%) in public and private schools 2007-2016.

**Figure 4-2: Vermont Kindergarten Exemption Rates and Immunization Policy Changes by School Type 1989-2016**



Description of Figure 2: Statewide exemption rate (%) for Vermont 1989-2016 (missing 1994). Private and public schools annual exemption rate (%) 2007-2016 and Vermont legislative and policy changes to immunization and exemptions requirements. In 2008, increases in public and private school exemption rates occurred following substantial changes to the immunization schedule for kindergarteners. Subsequent changes in 2012 and 2015 are identified.

## **Chapter 5 Discussion**

### **5.1 Summary of Key Findings**

This research examined state mandatory immunization law changes over time in the United States. We reviewed the literature on school law enactment across states and Washington DC, comprising professional reports of new immunization mandates, descriptive observational studies, and studies assessing the impact and implementation of immunization and exemption law changes. We found that the variability in school law expansions over time followed several themes, including (1) increasing number of antigens mandated; (2) specific boosters included; (3) the school populations covered; (4) how closely requirements match ACIP recommendations; (5) the authority delegated to health departments; (6) school level implementation and enforcement; (7) and how schools track and exclude non-compliant children.

Previous reviews examining school health laws have shown an association between effective implementation of laws and health outcomes, such as local school exemption rates and vaccine-preventable disease outbreak rates. This analysis describes the expansion of immunization mandates for routinely recommended childhood vaccines over 115 years (1902 – 2017), by the school age populations included and by specific antigen following routine recommendations. We also describe exemption requirement changes over time for medical, religious, and philosophical exemptions in each state and Washington DC. The broad variability detected in school mandate laws and administrative requirements provide context for the variability seen across states in immunization related outcomes, such as in vaccine coverage and exemption rates.

We also evaluated the new law implementation process in four states with recent changes to state immunization laws restricting exemptions. We used qualitative methods for investigating

factors influencing the implementation of exemption law changes through a stratified thematic analysis of the data generated from in-depth interviews. The individuals involved in the process of policymaking as well as the administrative and legislative structures in the state influenced effective implementation of new laws in these four states. Stakeholders with direct experiences implementing law changes at state and local health departments and at schools informed data-driven recommendations for effective law change to be utilized by stakeholders in states experiencing similar problems associated with high exemption rates, low coverage, and disease outbreaks.

Finally, we examined increasing exemption rates in Vermont between 1989 and 2016, measuring exemption rate changes following law and policy changes in 2008, 2012, and 2015. We found state-level exemption rates doubled when new immunization requirements for varicella and hepatitis B were implemented in 2008. Exemption rates in public and private Vermont schools remained high through 2012 in spite of a new legislative attempt to restrict high exemption rates by increasing the administrative complexity of the process for obtaining a non-medical exemption. Further restrictions implemented in 2016 removed philosophical exemptions, resulting in a significant increase in religious exemptions and provisional admissions.

## **5.2 Limitations**

The limitations of the descriptive and policy analyses of quantitative data primarily concern data collection, outcome assessment, and confounding. Compiling a novel database from multiple sources collected over 115 years provided the potential for error in data collection and by utilizing administrative data for research purposes. Sources of data for the school law review included professional and government reports, research publications, historical documents, and legislative code.

Exemption rate data were obtained for state health department reports of school health data and should be assessed as administrative data rather than data collected for the purposes of research. As such, we should not interpret individual student exemptions as confirmation that the child has not received the antigen; extrapolating exemption data to immunization coverage interpretations likely underestimates coverage. Confirming exemption status of children over time could only be accomplished by reviewing individual student medical records. Confounders include unmeasured regional or national influences on parental vaccine hesitancy and confidence, such as changes in media exposure, new scientific and pseudoscientific information, and unidentified determinants. Such confounders are mitigated by the use of longitudinal analysis methods unless the confounder is increasing or decreasing over time.

In the qualitative analysis, the limitations are more likely to be associated with data collection and data analysis. In-depth interviews are a valuable source of data but require an investigator using effective interpersonal communication as data collection and an ability to minimize personal bias in the interpretation of transcript data.

### **5.3 Recommendations for Future Research**

Parental trust in government vaccine experts and officials is at risk, and increasingly parents are obtaining vaccine information from non-professional sources.[1] Parental lack of trust in government, medical, and academic sources of information may be associated with parental decisions to delay or skip vaccines[2]. Increasing public confidence in evidence-based sources of information may impact the willingness of the general population to participate in mandated vaccination programs, though interventions for increasing public trust in vaccines experts are yet to be explored in depth.

This study provided historical context, qualitative recommendations, and quantitative evidence supporting the effective implementation of well-crafted immunization and exemption laws and policies in response to high exemption rates and disease outbreaks. The four states included in this analysis are the first states in recent history to implement more restrictive exemption laws and future research will be necessary to evaluate immunization coverage and exemption rates over time. While we found transient increases in exemption requests for several years following law changes, further studies to track immunization outcomes should be performed in each of these four states for at least five years following implementation to identify more stable changes.

Comparing trends in states increasing education requirements with states removing non-medical exemptions may identify more effective strategies for reducing exemptions, while a comparison of similar policy changes between California and Vermont may also reveal if effective policy implementation varied from the most populated state to the 49<sup>th</sup> most populated state. Future research will be needed to assess law and policy changes as additional states use legislative options to impact vaccine-preventable disease outbreaks associated with high exemption rates among children in schools.

#### **5.4 Policy Implications**

The Supreme Court of the United States has affirmed the right of states to require mandatory vaccinations for school entry[3–5]. The question then is not whether such mandates are legal but how they must be implemented in a way the best preserves individual and parental autonomy without significantly and negatively impacting public opinion. Several analyses have addressed the importance of balancing parental autonomy to make decisions about a child's health with the national need to maintain appropriately high rates of up-to-date vaccination

coverage for pre-school and school aged children.[6–10] Salmon et al. justifies the restriction on individual rights for the benefit provided to both the individual and the community, but suggests the burden is on governments to provide the ethical rationale for the restrictions[9,11]. The vaccine supply must be adequate, effective, and safe in order to justify these restrictions, and the involvement of the federal government in industry regulation and oversight is by that argument justified and essential.[9,11]

In order for school immunization laws to be effective, “the great majority of the population must be willing to be vaccinated.”[11] Therefore, maintaining a high level of public support and high immunization rates falls to government advocacy and education programs. Federal support for a national immunization program and the normalization of up-to-date vaccination by parents is reinforced by state requirements to complete the series before kindergarten. Finally, exemptions in the legal framework maintain individual autonomy by providing for families willing to comply with administrative exemption requirements.

The results of these analyses should inform state legislators and health department personnel considering proposing more complex administrative procedures for obtaining exemptions to restrict exemptions in their state. Several of the most recently introduced antigens have not achieved high coverage across childcare, elementary school, middle school, and college/university age populations in spite of recommendations by the ACIP for states to include the vaccines in school entry requirements. The variability across state immunization law evolution and implementation has influenced the effectiveness of school mandates and the ease of the exemption requirements. States interested in reducing exemption rates should reflect on how their individual state immunization and exemption requirements are structured and have

developed when proposing changes, especially changes that trigger increased parental vaccine hesitancy.

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## Chapter 6 Appendices

### 6.1 Study Team Members, March 2015

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## 6.2 SILVEA Interview Guide, version 2\_02 September 2015

Interview Guide Usage: This guide is an investigator tool to be used during qualitative interviews. Questions are not intended to be asked exactly as written. Main and follow-up questions provide sample language to be used in the interviews and provide an outline to the topics we intend to explore during interviews. Questions may be added or omitted during the interview. This interview guide should be periodically reviewed and updated during the interview process.

General Introduction and overview of informed consent process:

- Provide an introductory explanation of the objectives of the study and the aims of an in-depth interview.
- Describe the design of the study and other informants for each state case study.
- Explain why this interview is important and what will happen with the notes and recordings. Focus on the confidentiality of the interview and provide examples of how this interview will provide data, including how the informant may be quoted or identified anonymously.
- Explain any risks of participating in the interview
- Ask if informant has any questions about the interview process or providing consent.

Ensure informed consent has been provided

Background Questions:

You have been asked to participate in this interview because you have been identified as an individual who has experience with the issue of state immunization laws. I would like to ask you questions about your experience and opinions on this topic.

Q1: First I'd like to start with some of the basics. Could you tell me a few details about you and your job?

- Follow-up Job title
- Employer
- Years in position

Q2: Now, I am going to ask you some questions about your experiences as a <<JOB>> ?

What does a typical day look like for you in 2015 (all responsibilities, not just vaccine related)?

Follow-up: What kinds of responsibilities do you have specific to vaccines? Systems or processes you oversee? What proportion of your time is spent on vaccine related efforts? What other groups or individuals do you interact with as a <<job>>? probe: other health department, stakeholders, public groups, schools?

Probes: What locations do you work? What do you spend most of your time doing?

Probes: What times of the year do you have the most immunization related activities? Could you estimate a percentage of your work during the year you spend on immunization activities?

Q3: The laws about vaccine exemptions to school immunization laws recently changed here in <<state>>.

Are you aware of the law changes? Could you summarize for me how the how the law(s) affecting exemptions changed in <<state>>?

Follow-up: When did the laws change and how? Who (groups or individuals) advocated for the change? What happened in <<state>> to lead to the change?

What was the goal or the purpose of the changes?

Q4: How are the new exemption laws being implemented?

Follow-up: Were you involved in the implementation? How were you responsible for implementing the law? Did you create any new processes or systems that were used, or work on any policies or procedures? Please walk me through a typical example of this implementation process.

In thinking about the implementation process, what is working well?

To what do you attribute this positive aspect of implementation?

Probes: Are there aspects of the law that were well-written/insightful? Are there systems in place or created that support implementation? Are there particular individuals (front line workers or leaders) who have made the implementation process work well? Is there a supportive environment for this law?

Q5: Please describe any challenges or problems in implementing the change to the exemption law? (prompt for descriptions/details)

Was there any pushback or obstacles at any point during the roll out of the law? (prompt for descriptions/details)

Do you have any success stories you'd like to share about what has worked well, or is any part of the process now better than before? (prompt to assure that the interviewee reflects on WHY these success stories worked – what are the lessons learned?)

Q6: I'd like you to think about how much time and effort has gone into changing the process for dealing with exemptions. How much effort do you think you have spent dealing with the changes?

How much of this was one-time effort to making initial changes, and how much of your annual work has changed since the new exemption law? How have your daily responsibilities changed since the law was changed? How much does your effort reflect the overall effort in the state invested in these changes?

Q7: Given what you know now, what would you have done differently to achieve the goal of this law?

What changes would you make to the language of the law? What changes would you make to the way the law has been implemented? (prompt: Changes to who/which agency has implementing authority; changes in administrative structure; changes in exemption criteria; etc.)

What advice would you give to someone in your position in a state considering changing its exemption laws? How should that person prepare or what should they anticipate?

Q8: How effective do you think was the law at meeting its goals?

<this question refers to the goals described in Q3>

Q9: Is there anything else about the vaccine exemptions you think is important that we have not talked about?

Q10: (DOH personnel only) Is there anyone that you think I should speak with about this topic, someone who may have had a unique or different experience?

Q11: (School health personnel) Do you feel that it is your responsibility to enforce the vaccine requirements? Do you think the requirements are fair?

Prompts/Follow-up questions:

Ask about strictness, do you feel you are empowered, can you enforce the rules, do you feel you are strict or lenient? How much discretion do you have?

California:: Whose responsibility is it to enforce the vaccine requirements? Who should have this responsibility? Do you think the requirements are fair? Do you think the requirements are important?

Closing

I'd like to review some of the major details we've covered <summarize>

If you want to follow-up on any of this information or have any questions <provide contact information>

Thank you for participating

### **6.3 Informed Consent (Verbal Consent Language)**

**Study Title: A mixed methods assessment of recent compulsory school immunization law changes in four US states**

**Principal Investigators: Saad Omer (Emory), Daniel Salmon (JHSPH), Amber Bickford Cox (JHSPH), Steven Teret (JHSPH), Shannon Frattaroli (JHSPH)**

**PI Version/Date: 23 March 2015**

**Funding Source: Robert Wood Johnson Foundation**

Hello. I am an investigator from the Johns Hopkins Bloomberg School of Public Health and would like to talk to you about a research study on school immunization laws in the United States. Researchers from Johns Hopkins and Emory are working together on a project to learn about school immunization laws. We are interested in your experiences around the issue of school immunization laws in your state. I would like to ask you questions about your experience and your opinions on this topic. This study is funded by the Robert Wood Johnson Foundation.

We ask you to join this study because you have professional experience on this topic. You do not have to agree to this interview, it is your choice. If you say yes, we will ask you to participate in an interview. I will ask you questions about your experience and record your answers. The interview should take approximately one hour of your time. You may stop the interview at any time. I would like to audio and/or video-record the interview. This will allow me to properly understand and record your responses. The recording will be used for the purposes of data

collection only and any audio or video files created will not be shared with anyone outside the team.

It is possible that you may be uncomfortable answering questions. You do not have to answer all questions and you may stop the interview at any time. There is a risk that someone outside the study will see your information, including your interview. However, we will do our best to keep your information safe by using password-protected computers and storing all data in a locked location. We will not intentionally release your information to anyone outside the study without your permission.

There are no direct benefits to you by participating in this study. You may be contributing to public health research by helping us understand changes to state laws, but you will not receive any payment or compensation for your participation.

Your privacy is very important to us. Your health information that identifies you is your “protected health information” (PHI). Identifiers collected will include your name and initials, and your phone and email contact information.

To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act (HIPAA). The following persons or groups may use and/or disclose your PHI for this study:

- The Principal Investigator and the research staff.
- The Robert Wood Johnson Foundation, who funds this Research, and people or companies they use to carry out the study

- Emory offices who are part of the Human Research Participant Protection Program, and those who are involved in research-related administration and billing

We will disclose your PHI when required to do so by law in the case of reporting child abuse or elder abuse, in addition to subpoenas or court orders. You may revoke your authorization at any time by calling the Principal Investigator, Saad Omer, or by writing to the address listed on the information sheet that we will send to you.

If identifiers (like your name and telephone number) are removed from your PHI, then the remaining information will not be subject to the Privacy Rules. This means that the information may be used or disclosed with other people or organizations, and/or for other purposes. If we share your PHI with other groups who do not have to follow the Privacy Rule, then they could use or disclose your PHI to others without your authorization. Let me know if you have questions about this.

Your authorization will not expire because your PHI will need to be kept indefinitely for research purposes.

Do you have any questions? You may ask me now, or contact Dr. Omer, the Emory Investigator about your questions or problems with this study. Saad Omer; Principal Investigator: (404) 727-8462

Contact Information: If you have questions about this study, your part in it, your rights as a research participant, or if you have questions, concerns or complaints about the research you may contact the following: Emory Institutional Review Board: 404-712-0720 or toll-free at 877-503-9797 or by email at [irb@emory.edu](mailto:irb@emory.edu)

Consent: Do you have any questions about anything I just said? Were there any parts that seemed unclear?

Do you agree to take part in the study?

Participant agrees to participate:      Yes                  No

If Yes:

Name of Participant

Signature of Person Conducting Informed Consent Discussion      Date      Time

Name of Person Conducting Informed Consent Discussion

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## Chapter 8 Curriculum Vitae

### Amber Bickford Cox

Global Disease Epidemiology and Control  
Department of International Health  
Johns Hopkins Bloomberg School of Public Health  
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coxsackie@jhu.edu

### EDUCATION AND TRAINING

<b>Degree</b>	<b>Year</b>	<b>Institution</b>	<b>Field</b>
PhD	2018	Johns Hopkins Bloomberg School of Public Health	Vaccine Science and Policy Certificate Global Disease Epidemiology and Control; International Health
MPH	2004	Tulane School of Public Health and Tropical Medicine, New Orleans, Louisiana, US	Mitigating Complex Emergencies; International Health and Development; Peace Corps Master's Internationalist Program 2002
BA	2000	Smith College, Northampton, Massachusetts, US	African History; Five College Certificate in African Studies
	1999	University of Kwa-Zulu Natal, Pietermaritzburg, South Africa	South African History

### CERTIFICATION

2008, 2009, 2010, 2011, 2012	Bloodborne Pathogen Training Health, Safety and Environment Department of Johns Hopkins Medicine
October 2007, 2010, 2011	IATA/DOT training JHU Health, Safety, & Environment
September 2007-present	Certified Clinical Research Coordinator Association of Clinical Research Professionals
2005-present	Good Clinical Practice, CITI, updated annually
2005-present	Human Subjects Protection Training, CITI, updated annually
October 2005	Research Coordinator Training Program Johns Hopkins Bloomberg School of Public Health

## PROFESSIONAL EXPERIENCE

- 2014            **GlaxoSmithKline, Health Outcomes Internship**  
Summer internship with the pertussis vaccine team within Health Outcomes Research, assisted with literature reviews, protocol writing, and focus on project management of current and planned GSK pertussis vaccine research projects
- 2008-2013     **Research Associate, Faculty**  
**Center for Immunization Research, Department of International Health**  
**Global Disease Epidemiology and Control (GDEC) Program**  
**Johns Hopkins Bloomberg School of Public Health**
- Responsible for overall design and implementation of QA systems for National Institute of Health Laboratory of Infectious Diseases (LID) clinical vaccine trials, including phase I and II respiratory and flavivirus studies conducted at the Center for Immunization Research
  - Submission of semi-Annual and Annual Report to NIH detailing technical and clinical activities during reporting period for respiratory and flavivirus vaccine trials at Center for Immunization Research
  - Senior Trainer for domestic and international GCP certification workshops
  - Co-Instructor for “Clinical Vaccine Trials and Good Clinical Practice” online 3-credit JHSPH graduate course, Co-Instructor for “Vaccine Science and Policy” Seminar, and management of Vaccine Science and Policy Certificate
- 2008-2013     **Research Associate, Faculty**  
Center for Immunization Research  
Department of International Health  
Global Disease Epidemiology and Control (GDEC) Program  
Johns Hopkins Bloomberg School of Public Health
- Responsible for overall design and implementation of QA systems for National Institute of Health Laboratory of Infection Disease (LID) clinical vaccine trials, including phase I and II respiratory and flavivirus studies conducted at the Center for Immunization Research
  - Submission of semi-Annual and Annual Report to NIH detailing all technical and clinical activities during reporting period for respiratory and flavivirus vaccine trials at Center for Immunization Research
  - Senior Trainer for domestic and international Good Clinical Practice certification workshops
  - Co-Instructor for “Clinical Vaccine Trials and Good Clinical Practice” online course taught 4<sup>th</sup> term.
  - Co-Instructor for “Vaccine Science and Policy” Seminar
  - Faculty management of Vaccine Science and Policy Certificate Program
  - Advising of MSPH students
- 2005-2008     **Senior Research Program Coordinator**

Center for Immunization Research  
Johns Hopkins Bloomberg School of Public Health

**Senior GCP Trainer**

- Developed and delivered comprehensive GCP and HIV vaccine trial training curricula, educational materials and activities for interactive workshops in international HIV research centers with over 300 vaccine researchers in either domestic and international workshops

**Course Coordinator: “Clinical Vaccine Trials and Good Clinical Practice”**

- Course Coordinator for distance education course offered by JHSPH training graduate students and international research professionals: <http://distance.jhsph.edu/vactrial/>
- Facilitated and hosted online and live interactive discussion with students, assignment grading, student feedback
- Developed and updated curricula and lectures

**Clinical Study Coordinator**

- Primary Coordinator of HIV and *staph aureus* vaccine trials
- Protocol development and implementation for phase I and II clinical vaccine research studies
- Management of essential documents, development of study documents for submission to IRB and ongoing IRB communication
- Design of study source documents, informed consents, educational and recruitment material
- Training of staff in proper data collection, GCP and CFR guidelines
- Development of internal quality improvement system, data handling guidelines, SOPs
- Recruitment and enrollment of volunteers
- Coordination of AE/SAE reporting to IRB, Sponsors, DSMB
- Performs QA and QC of source data and study systems

2004-2005

**Senior Clinic Assistant, Seneca Women’s Health Care**  
Baltimore, Maryland

- Supervised clinic staff and volunteers; developed systems to increase office efficiency; developed education programs and clinic SOPs
- Counseled patients regarding contraception, pre/post HIV/AIDS testing and counseling, pre/post abortion and options counseling, emergency contraception, and managed on-call 24 hour pager
- Performed venipuncture, obtained and processed specimens, assisted in routine GYN and abortion procedures

2003

**Peace Corps Volunteer, Witbank, South Africa**

Non-Governmental Capacity Building Project for HIV/AIDS Programs

- Assisted SisterLove, Inc HIV/AIDS Capacity Building Project for NGOs, focus on reducing Mother-to-Child Transmission of HIV/AIDS, supported program manager in development and organization of capacity building activities
- Performed field work, community research, administering needs

assessment and analyzing data and results, strategic planning, community profiling, grant writing and office organization

- Designed knowledge, attitude and practice needs assessment for peer educators in local community
- Designed eight day training module focused on increasing skills and knowledge of peer educators dealing with HIV/AIDS counseling and education, financial planning for Life Skills project
- Early Termination in late 2003 due to deteriorating safety and security conditions at assignment

### **PROFESSIONAL ACTIVITIES**

2007, 2008, 2009, 2010, 2011, 2012	NFID Annual Conference on Vaccine Research Baltimore, Maryland
September 2006	Merck MKV520-027 HIV Vaccine Investigator's Meeting Dallas, Texas
November 2005	Merck V710-001 <i>Staph aureus</i> Investigator's Meeting Philadelphia, Pennsylvania

### **HONORS AND AWARDS**

2002	Tulane School of Public Health Dean's Merit Grant for Master's International Peace Corps MPH Students
1996-2000	Alumnae Merit Scholarship Smith College

**CURRICULUM VITAE**  
**Amber Bickford Cox, MPH, CCRC**  
PART II Teaching and Research

**TEACHING**

**Advisee**

Joy Chebet, MHS candidate  
2010-2011

Saira Paredes, MHS candidate  
2010-2011

Elisabeth Fackler, MHS candidate  
2009-May 2011 graduate

**Co-Instructor, 2008-2013**

Johns Hopkins Bloomberg School of Public Health  
223.867: Special Topics in Vaccine Science Seminar  
Vaccine Science and Policy Certificate

**Co-Instructor, 2008-2013**

Johns Hopkins Bloomberg School of Public Health  
223.705.81: Clinical Vaccine Trials and Good Clinical Practice

**Instructor, 2012**

**Coursera Vaccine Trials: Methods and Best Practices**

Mega online class offered by Coursera.org and sponsored by JHSPH  
Online enrollment 11,000+ students, October-December 2012

**Instructor, International Good Clinical Practice Workshops for Clinical Vaccine Trial Sites**  
Sponsor: IAVI (International AIDS Vaccine Initiative)

November 2008      “Advanced AIDS Vaccine and Good Clinical Practice” Nairobi, Kenya  
3-Day workshop training 30 senior investigators from clinical trials sites on advanced techniques of GCP applications for HIV vaccine trials, including development of site management plans, adverse event management and reporting guidelines

July 2007      “AIDS Vaccine and Good Clinical Practice” Nairobi, Kenya  
3-Day workshop training 50 investigators, coordinators and research staff of HIV vaccine clinical trial and epidemiological sites in East Africa on basic principles of GCP and vaccine trials

- January 2007 “AIDS Vaccine and Good Clinical Practice” Nairobi, Kenya  
3-Day workshop training 50 investigators, coordinators and research staff of HIV vaccine clinical trial and epidemiological sites in East Africa on basic principles of GCP and vaccine trials
- July 2006 “Advanced AIDS Vaccine and Good Clinical Practice” Chennai, India  
3-Day workshop training 37 senior investigators from clinical trials sites on advanced techniques of GCP applications for HIV vaccine trials, including development of site management plans, adverse event management and reporting guidelines
- March 2006 “AIDS Vaccine and Good Clinical Practice” Nairobi, Kenya  
3-Day workshop training 45 investigators, coordinators and research staff of HIV vaccine clinical trial and epidemiological sites in East Africa on basic principles of GCP and vaccine trials
- January 2006 “Advanced AIDS Vaccine and Good Clinical Practice” Nairobi, Kenya  
3-Day workshop training 26 senior investigators from clinical trials sites on advanced techniques of GCP applications for HIV vaccine trials, including development of site management plans, adverse event management and reporting guidelines
- September 2005 “GCP Training for HIV Vaccine Feasibility Studies.” Entebbe, Uganda  
3-Day workshop training 50 investigators, coordinators and research staff epidemiological sites in East Africa on basic principles of GCP and HIV vaccine clinical trials
- June 2005 “AIDS Vaccine and Good Clinical Practice” Chennai, India  
3-Day workshop training 36 investigators, coordinators and research staff of HIV vaccine clinical trial and epidemiological sites in East Africa on basic principles of GCP and vaccine trials
- Instructor, Domestic Good Clinical Practice Workshops**
- December 2007 “Good Clinical Practice and Clinical Vaccine Trials”  
3-Day GCP Certification training program for 52 Johns Hopkins Bloomberg School of Public Health Center for Immunization Research clinical staff and investigators conducting clinical research trials
- April 2008 “GCP Training in International Settings: Techniques for Developing and Delivering Successful Trainings” JHSPH, Baltimore, Maryland  
Global Disease Epidemiology and Control Program MHS Seminar
- April 2007 “A Contextual Approach to International Site Development: Bringing GCP to Life” JHSPH, Baltimore, Maryland  
Global Disease Epidemiology and Control Program MHS Seminar
- 2007, 2006 “Top Ten Characteristics of a Premier Vaccine Trials Site”

Fogarty AIDS International Training and Research Program Bridging  
Prevention to Care: Summer Vaccine Training Institute  
JHSPH, Baltimore, Maryland

**GRADUATE TEACHING EXPERIENCE (2013-2017)**

**Special Topics in Vaccine Science Seminar (223.867)**

Johns Hopkins Bloomberg School of Public Health

Faculty: Dr. Anna Durbin & Dr. Louis Bourgeois

- Faculty Instructor, 2008-2013
- TA & Certificate Manager 2013, 2014, 2015, 2016

**Clinical Vaccine Trials and Good Clinical Practice (223.705)**

Johns Hopkins Bloomberg School of Public Health

Faculty: Karen Charron

- Faculty Instructor, 2008-2013
- TA 2015, 2016

**Vaccine Development and Application (223.662)**

Johns Hopkins Bloomberg School of Public Health

Faculty: Dr. Neal Halsey, Dr. Ruth Karron & Dr. Laura Hammitt

- TA 2013, 2014, 2015

**Vaccine Policy Issues (223.687)**

Johns Hopkins Bloomberg School of Public Health

Faculty: Dr. Dan Salmon & Dr. Andrea Sutherland

- TA 2013, 2014

**Global Disease Control Program and Policy (223.680)**

Johns Hopkins Bloomberg School of Public Health

Faculty: Dr. Alain Labrique, Dr. Chris Coles

- TA 2014

**Instructor, Coursera Vaccine Trials: Methods and Best Practices**

Massive online class offered by Coursera.org and sponsored by JHSPH amaama

Online enrollment 11,000+

- Faculty Instructor 2012, 2013