

Measuring State Vaccine Exemption Laws for Evaluation Research

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Presenter Disclosures

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(1) The following personal financial relationships with commercial interests relevant to this presentation existed during the past 12 months:

No relationships to disclose

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Larger Study Overview



- The Evaluation of State Vaccine Exemption Laws analysis was undertaken in service to our project's main study
 - Fatal Exemptions? A Longitudinal Analysis of the Effect of Non-medical Exemptions to State School Immunization Laws on Vaccine-Targeted Diseases*
- The ratings reported here were used to assess the effect of state law variation on vaccine uptake and disease incidence for vaccine-targeted diseases.

Problem Statement

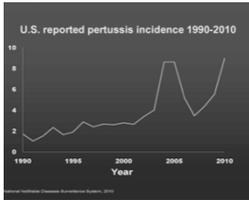


- Reports of vaccine-targeted disease outbreaks, concerns about vaccine safety and use of alternative vaccination schedules and non-medical exemptions (NME) to vaccination are increasing.
- Dozens of vaccines are in development, a growing CDC recommended vaccine schedule, \$2B in Vaccine Injury Compensation Program payouts.
- Complex network of variable state NME laws that create different state restrictiveness climates and effects on parents that are not clearly understood.

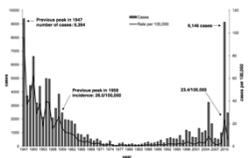
Source: Generation Rescue

Vaccine-Targeted Disease Outbreaks *Pertussis*

US, 1990-2010



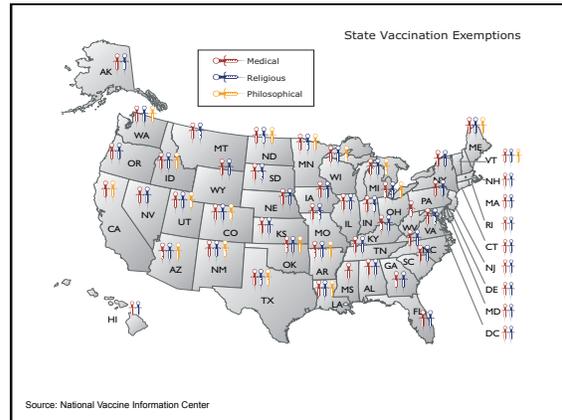
California, 1947-2010



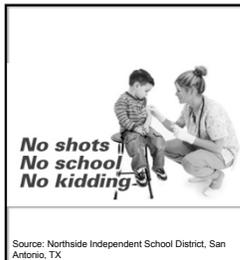
Sources: Centers for Disease Control and Prevention, NNDSS, 2010; California Department of Public Health, Immunization Branch, 9/5/2011

Background

- CDC recommended vaccination schedule is automatically adopted by many states
- State vaccine-related laws and regulations...
 - Mandate vaccination as a condition of obtaining public education and employment
 - Exempt some individuals from vaccination on medical grounds and sometimes on non-medical grounds



How Restrictive Are Various State NME Laws?



Source: Northside Independent School District, San Antonio, TX



Source: VaxTruth Billboard Project

Project Objective

- To produce evidence-based state NME law restrictiveness ratings
 - Collect and analyze all relevant NME statutes and regulations
 - Accurately measure NME restrictiveness
 - Identify and characterize variation in NMEs



Literature Review

- No comprehensive, validated and publicly available repositories of vaccination-related law
- No published and current legal analysis of all state NME statutes and regulations
- Two relevant published studies
 - Rota (2001) surveyed immunization managers in 48 states and classified states according to their "ease of granting exemptions" (difficult, medium and easy).
 - Omer (2006) used Rota's findings and re-classified states according to their "ease of granting exemptions" (difficult, medium and easy) to evaluate exemption ease and pertussis incidence.
 - Neither study was an analysis of current state laws, potential for inter-rater variability which could yield imprecise estimates.

JS Rota et al., "Processes for obtaining nonmedical exemptions to state immunization laws," Am J Public Health 91, no. 4 (April 1, 2001): 645-648. Saad B. Omer et al., "Nonmedical Exemptions to School Immunization Requirements," JAMA: The Journal of the American Medical Association 296, no. 14 (October 11, 2006): 1757-1763.

NME Restrictiveness

- The concept of restrictiveness has been used to develop scales and indices in several fields:
 - in economics, health services, psychology, social work and public policy to measure how policies and laws limit behavior
 - tariff restrictiveness indices, health plan restrictiveness, scope of nursing license restrictiveness, taxing authority restrictiveness, restrictiveness of living environments and the restrictiveness of laws related to voting ballot access, state lobbying and hunting laws
- Restrictiveness for non-medical exemption of state mandated vaccines is defined for this project as:
 - the extent to which a State's statutes and regulations discourage or prevent parents from claiming a non-medical exemption to mandated vaccinations.





NME Law Collection and Preparation

- Systematic search of Lexis ("US Legal," "State Statutes, Codes & Regulations") by two licensed attorneys using standardized and consistent search terms ("immunizations, children, and schools")
- All vaccine exemption-related laws (statutes and regulations) related to school or childcare entry for 51 jurisdictions (50 states and District of Columbia) were collected
- Comparison of retrieved laws to laws listed on four websites
- A total of 236 laws and additional legal documents (2-14 documents per state) were organized by state into review binders
- Binders were created containing state-specific restrictiveness rating sheets, summary characteristics tables, statute overview sheets and copies of all relevant laws and other exemption-related materials

NME Characteristics

- State NME laws were detailed in 51 jurisdiction-specific summary tables.
- 26 different NME characteristics were identified and grouped by category
- 5 major categories:
 - *Basic NME Structure* (30%)
 - *Applicable Populations and Institutions* (5%)
 - *NME Forms, Evidence, Documentation, Filing Processes* (30%)
 - *NME Review, Appeals and Penalties* (30%)
 - *Potentially Relevant Medical Exemption Characteristics* (5%)



Texas Summary Characteristics Table



5 Major Categories

26 Characteristics

Characteristic Descriptions

Yes/No Data for 2000-2007

Data Source

Establishing Restrictiveness Ratings



- Two public health law experts, both with expertise in vaccine-related law, independently rated each state
- If ratings were not identical, a third impartial senior public health law expert adjudicated rating differences.
- Reviewers were asked to determine an overall NME rating for each state-year between 2000-2007 as either:
 - *Very low level restrictiveness (Level 1)*
 - *Low level restrictiveness (Level 2)*
 - *Medium level restrictiveness (Level 3)*
 - *High level restrictiveness (Level 4)*
 - *Very high level restrictiveness (Level 5)*

Pre-test Method and Findings



- Pre-test conducted March 2000
- Binders with prepared materials were provided to all three public health law experts
- 3 states were rated – Vermont, West Virginia, and Arkansas
- Results discussed on a conference call
- Close agreement on the ratings
- Expert suggestions were noted
- Review and rating procedures were clarified and finalized

Final Review and Rating of NME Laws August – November 2000



Formal Evaluation Method

- Final adjudicated state overall restrictiveness ratings and 26 characteristic scores for eight state-years were entered into a database (STATA)
- State-level scores for 26 NME characteristics, raw and weighted major NME categories and total NME characteristic scores were computed
- Individual characteristics, raw and weighted major NME categories and total NME characteristic scores were correlated with overall state restrictiveness ratings

Results

- Overall Ratings
- Total Characteristic Scores
- Correlations of Major Categories with Overall Ratings
- Correlations of Individual Characteristics with Overall Ratings

State Non-medical Vaccine Exemption Statute and Regulation Restrictiveness Rating Worksheet

STATE: Delaware
 DATE OF REVIEW: 10/20/11
 REVIEWER: Shane S. Hoffman

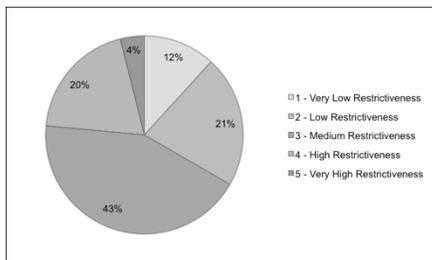
Instructions:
 Please review all of the enclosed materials and then, for each year, select an overall rating for the level of restrictiveness found in the State's statute, regulation and policies related to non-medical vaccination exemptions. Please feel free to make comments in the section below.

Overall Restrictiveness Score

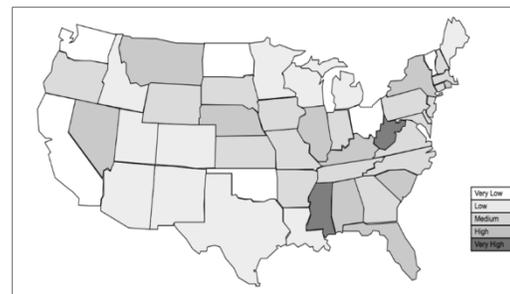
Year	1	2	3	4	5
2007	0	0	0	0	0

Reviewer Comments:
 Restrictiveness - High - Medium (My assessment)
 Religious exemption but no philosophical objection; more restrictive than Arkansas post 2010. Conscience for children.
 Less restrictive in that vaccination statutes only apply to public schools and noncompliant/unvaccinated students may enter school; parents need not complete an educational program; parents need not sign a statement related to removal from school during an outbreak; all evidence may be submitted in lieu of proof of vaccination; exemption from most not be reviewed.
 More restrictive in that forms must be notarized.
 Learning towards medium as seems slightly more restrictive than Arkansas post 2010 and is less restrictive than Arizona. The form of an in-utero foetus Arkansas post 2010 as Medium and 1 ranked Alabama as High) so fit in medium range. Also seems comparable to Alaska.
 Less restrictive in that vaccination statute only applies to public schools; more restrictive in that forms not easy to obtain; (No DOR) not permitted to sign medical exemption forms (about the same) - so about the same.
 Free Answer: MED/HL

Distribution of State NME Restrictiveness Ratings, 2007



US State NME Laws by Restrictiveness Level, 2007



State NME Characteristics and Correlations, 2007

Major Categories and Characteristics	Characteristic Descriptions	Percent of States with Characteristic	Characteristic and Restrictiveness Correlation
Basic NME Structure			
Religious	NME permitted on the basis of religion	49 (96%)	-0.35*
Philosophical	NME permitted on the basis of conscientious belief	19 (37%)	-0.92**
Applicable Populations and Institutions			
Childcare	Childcare access w/o vaccination documentation	2 (4%)	0.01
Pre-school	Pre-school access w/o vaccination documentation	1 (2%)	-0.23
Elementary	Elementary school access w/o vaccination documentation	0 (0%)	n/a
Public	NME laws apply only to public schools	4 (8%)	0.08
Provisional	Provisional admission of partly vaccinated students allowed	47 (92%)	-0.20

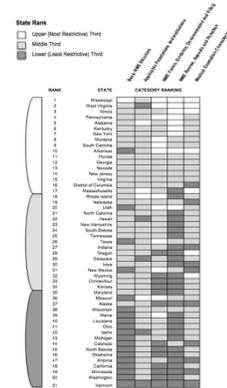
State NME Characteristics and Correlations, 2007 (cont.)

NME Forms, Application, Evidence, Documentation and Filing Processes			
State Form	State provides a standard NME application form	35 (69%)	-0.22
Availability	NME forms are available electronically	22 (43%)	-0.35
Submission	NME applications can be submitted electronically	0 (0%)	n/a
Notarization	Notarization of NME applications not required	31 (61%)	-0.31*
Frequency	Annual submission of NME application not required	40 (76%)	-0.73**
Education	Pre-NME filing parental education not required	41 (80%)	-0.07
Informed Refusal	Pre-NME filing informed refusal not required	40 (78%)	0.03
Removal	Pre-NME filing outbreak removal understanding not required	29 (57%)	0.08
Scalable	NME required for only one required vaccine permitted	19 (37%)	0.99**
Parent Statement	Written parent statement not required	35 (69%)	0.29*
Professional Statement	Written professional statement not required	48 (94%)	-0.40**
Laboratory Tests	Laboratory evidence of immunity permitted	38 (75%)	-0.04
NME Review, Appeals and Penalties			
Review Process	NME application is not subject to review and approval	38 (75%)	-0.02
Belief Sincerity	Belief sincerity is not subject to examination	46 (90%)	-0.44**
Belief Content	Belief content is not subject to examination	45 (88%)	-0.35**
Appeals Process	Appeals process is in place for denied NME applications	3 (6%)	0.00
Penalties	Criminal or civil penalties not required by law	33 (65%)	-0.40**
Potentially Relevant Medical Exemption Characteristics			
Non-physician	Physicians not required to authorize medical exemptions	11 (22%)	-0.11
Medical Review	DOH not required to approve medical exemptions	43 (84%)	-0.31**

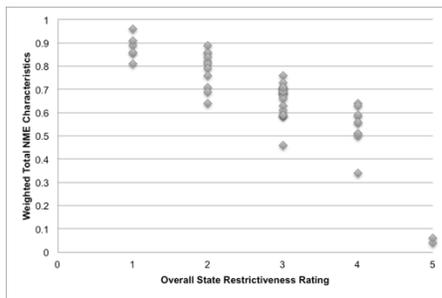
Key Findings

Characteristic	Percent of States with Characteristic	Correlation with Restrictiveness
Religious Exemption	49 (96%)	-0.35**
Philosophical Exemption	19 (37%)	-0.082**
Provisional Admission	47 (92%)	-0.20
State NME forms	35 (69%)	-0.22
Notarization	31 (61%)	-0.31*
Scalability	17 (37%)	-0.59**
Parent Religion Statement	35 (69%)	-0.27*
Clergy Religion Statement	48 (94%)	-0.40**
Religious Belief Sincerity Exam	46 (90%)	-0.42**
DOH or School Review	43 (84%)	-0.40**
Civil or Criminal Penalties	33 (65%)	-0.40**

State Scorecard Summary of NME Laws Across Restrictiveness Categories, 2007



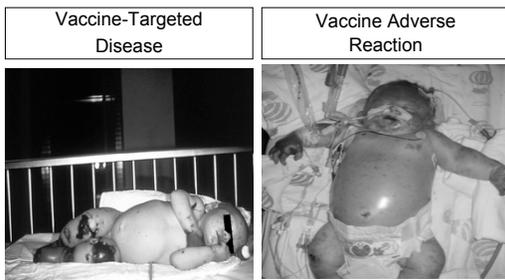
Restrictiveness and Weighted Total NME Characteristics , 2007



Study Limitations

- The measurement of restrictiveness was assumed to be valid and reliable
 - Selection of anchor states
 - Assignment of major category weights
 - Equal weight assumption for characteristics
 - Retrieval of "adjacent" relevant laws
 - Additional specification for some characteristics
 - Inferences

Why Are The Specifics of NME Laws Important? Vaccination Exemptions Are Consequential



Source: Centers for Disease Control and Prevention

Source: <http://iansvoice.org/gallery.aspx>

Discussion

- In response to concerns about either overuse of NMEs (or lack of NME access) states are making changes to NME laws
 - Some are making laws more restrictive
 - Some are making laws less restrictive
 - Some are creating new types of NME laws
- Changes are being made without information about the effects of various NME structures
- Clear objective metrics are needed to rationalize policy deliberations and policy analyses

Future Research

- Consider new types of NME - "opt-out" laws
- General psychometric properties of the rating method
- Statistical analysis NME component interactions
- Independent and inter-dependent effects of demographic, economic and political factors on state restrictiveness
- Effect of state restrictiveness on vaccine uptake rates, vaccine-targeted infectious disease incidence rates, and variation in parental, medical and school official vaccination-related attitudes, decisions and behaviors.



Conclusions

- States vary in terms of overall NME restrictiveness
- Within a given restrictiveness level, states vary in terms of the underlying NME law structures
- Implications of these findings for state policymakers is unclear without further research
- Research on the effect of overall restrictiveness and specific NME characteristics and vaccine uptake, disease incidence and health outcomes is needed

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PHLR

Making the Case for Laws that Improve Health

Happy Halloween Thank You for Your Interest!

SK

IT'S NOT A COSTUME—
MY FOLKS JUST DECIDED TO
OPT OUT OF ANY GETTING
THE SWINE FLU VACCINE.

