Assessing State Immunization Requirements for Healthcare Workers and Patients

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Background: Laws requiring vaccination for school entry have resulted in high coverage and reduced disease incidence; however, few data exist on the use of similar laws in other settings. This study reviews laws regulating vaccination of healthcare workers (HCWs) and patients in selected healthcare delivery settings.

Methods: From September 2004 to June 2005, Lexis-Nexis and other web-based databases were searched for laws pertaining to HCW and patient vaccination in 50 states and Washington DC. Laws were grouped by population, setting, vaccine type, and voluntary versus mandatory vaccination. Data were analyzed in 2006.

Results: Over half of states (n=32) have laws for HCW vaccination in traditional healthcare settings (hospitals, ambulatory care), while only seven states have laws for patients in these settings. Most laws regulating vaccine administration for HCWs were voluntary; requirements for mandatory immunization were most common for institutionalized populations.

Conclusions: Significant state-to-state variation exists in laws for vaccination of HCWs and patients. Additional data are needed on how such vaccination requirements affect coverage in these populations. Model legislation may be helpful to states wishing to implement immunization requirements.

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Introduction

The constitutionality of laws requiring immunization was affirmed by the United States Supreme Court over a century ago in *Jacobson v Massachusetts*.[1] The Court held that mandatory vaccination is justified by the necessity to protect public health and welfare. In the 1950s and 1960s, evidence that strictly enforced laws mandating immunization with measles and polio vaccines led to significant reductions in disease and laid the groundwork for today's school entry requirements for immunization.[2,3] School entry laws have proven extremely successful in maintaining high vaccination coverage levels among schoolchildren and reducing incidence of vaccine-preventable diseases that were once common among children in the U.S.[3] Furthermore, such laws have been repeatedly upheld by courts at the state and federal levels.[4]

The success of laws requiring immunizations for school entry has increased interest in the potential use of immunization laws for other populations and other settings, such as requiring influenza vaccinations for healthcare workers (HCWs).[5] The literature shows that outbreaks of influenza in healthcare facilities are a significant source of patient illness and death, and that vaccination of HCWs can reduce patient death rates in these facilities by preventing transmission of influenza from HCWs to patients.[6] Furthermore, influenza vaccination coverage among people aged 65 and older has remained relatively stable in the past decade,[7] and increasing influenza vaccination coverage among HCWs may motivate HCWs to promote vaccination to their patients. Finally, influenza vaccination coverage among HCWs is less than 50% and has remained stagnant since 1997.[8] However, few data are available on the extent to which laws requiring immunization for employees and patients in healthcare settings are already in place in the U.S., or to whom these laws apply. The purpose of this study was to conduct a detailed review of laws, regulations, legal opinions, and other legal requirements (hereinafter, "laws") relating to immunization for employees and patients in healthcare settings, and selected other settings in which health care is provided, in order to determine the nature and prevalence of these laws.

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Methods

A team of legal analysts in the Centers for Disease Control and Prevention's (CDC) Public Health Law Program (PHLP) searched Lexis-Nexis and online databases of state codes and regulations for laws pertaining to vaccination of HCWs or patients in all 50 states and Washington DC (hereinafter, "states"). Sources of law examined included state statutes, regulations, case law, and opinions of state attorneys general. Federal and municipal laws were excluded. The data were collected between September 2004 and June 2005, and analyzed in 2006.

The types of facilities included in the review were selected with the goal of including a variety of healthcare settings as well as other settings that serve as the primary source of healthcare delivery for certain populations. Correctional facilities and facilities for the developmentally disabled were selected because they are considered high-risk settings for transmission of vaccine-preventable diseases such as hepatitis B and influenza. Requirements for healthcare workers in hospitals and ambulatory care facilities (ACFs), and for patients or residents in hospitals, ACFs, individual providers' practices, correctional facilities, and facilities for the developmentally disabled were examined. (Requirements for HCWs in correctional facilities and facilities for the developmentally disabled were not studied due to resource constraints.) Standard definitions for "hospital," "ambulatory care facility," and "provider" were developed, and facilities whose legal definitions were consistent with these standard definitions were included in the review. Ambulatory care facilities included, among others, ambulatory surgery centers, renal dialysis centers, birthing centers, and pediatric day health facilities, although requirements for ACFs were often determined from general requirements for "medical facilities" or "health facilities." Long-term care facilities such as nursing homes and skilled nursing facilities were excluded because these settings were examined in a previous review.[9]

Both assessment and administration requirements for immunization were reviewed; however, the presentation of results focuses on administration requirements because such laws ultimately play a more direct role in vaccine delivery. An assessment requirement was identified if any included facility is required to assess the immunization status of any employee or resident or to screen for any vaccine-preventable disease. Requirements for vaccine administration were divided into "offer" laws, indicating optional vaccination, and "ensure" laws, indicating that vaccination of non-immune persons is mandatory in the absence of a specified exemption or a refusal. An offer law was identified if the facility is required to offer or make available any vaccine to any employee or resident. An ensure law was identified if the facility is required to arrange for vaccination of, or make certain that any employee or resident has been vaccinated for, any vaccine-preventable disease. In states and settings with ensure laws, medical, religious, or philosophical exemptions to requirements were recorded.

Vaccine-specific laws as well as more general laws requiring persons to be up-to-date with all age-appropriate vaccinations were collected. Laws were grouped by population and setting, type of vaccine required, and whether the law was an offer or ensure law.

Certain laws—for example, those pertaining to the assessment and administration of vaccines following exposure incidents—were not the primary goal of this project and were therefore excluded from the review. Additionally, it was felt that the bulk of post-exposure vaccination requirements are addressed under the federal Occupational Safety and Health Administration (OSHA) standards, 29 Code of Federal Regulations (CFR) §1910.1030 [2006].[10] This regulation also specifies pre-exposure requirements for covered employers to offer hepatitis B vaccination to all employees at risk of occupational exposure to hepatitis B.

Questions regarding interpretation of ambiguous statutory language were resolved through telephone and e-mail contact with the legal counsel designated by each state as its primary public health attorney. In addition, legal counsel from every state was given the opportunity to comment on the accuracy, completeness, and interpretation of findings at the conclusion of the review.

Results

The database searches provided information on laws from all 50 states and the District of Columbia. A summary of relevant laws was provided to all states' legal counsel, and 24 of the 51 states (47%) responded to the request for review. Unless otherwise specified, the number of states having any kind of vaccination law designated below is based on 51 total states. States could have multiple laws meeting study criteria, so the number of states with offer laws and the number with ensure laws may sum to more than the total number of states with any administration law for certain populations and settings. At the time the study was conducted, 12 of 51 states had no laws pertaining to assessment of vaccination status, and 4 of 51 states had no laws pertaining to administration of any vaccine, in any of the settings or populations examined (data not shown). Table 1 shows the status of administration laws for HCWs and patients in each state. A searchable database containing vaccine-specific requirements identified for each setting and population by state, with legal citations and relevant text, can be found at http://www.cdc.gov/nip/vaccine/statereqs.htm#cdc.

Healthcare Worker Vaccination: Assessment

Only three states had laws for the assessment of vaccination status among HCWs; all three laws pertained to assessing hepatitis B status. Laws in two states applied specifically to renal dialysis or transplant facilities, while one law applied to all staff with risk of exposure to blood or other infectious material.

Healthcare Worker Vaccination: Administration

Thirty-two states had some type of administration law for HCWs: of these, 21 states had offer laws for HCWs, and 15 had ensure laws. The vast majority of offer laws for HCWs concerned hepatitis B immunization (20 states); only three states had offer laws for influenza vaccination of HCWs (Table 2). By contrast, the major-

Table 1. Administration laws by population, facility type, and state (any immunization)[a]

	Hospital employees	Hospital inpatients	Ambulatory care facility employees	Ambulatory care facility patients	Individual providers' patients	Correctional facilities residents	Facilities for developmentally disabled residents
AL	E	—	—	—	—	—	E
AK	E[b]	—	—	—	—	E	E
AZ	O	—	O	—	—	E	E
AR	O	—	O	—	—	E	E[b]
CA	O	—	—	E[b]	—	E	E
CO	—	—	—	—	—	—	E[b]
CT	O	E[b]	O	E[b]	—	—	E[b]
DC	—	—	—	—	—	E	E
DE	—	—	O	—	—	E[b]	O/E[b]
FL	—	—	—	O	—	—	—
GA	—	—	—	—	—	—	E[b]
HI	O	—	O	—	—	—	—
ID	—	—	—	—	—	—	—
IL	O/E	—	O	—	—	E	E[b]
IN	—	—	—	—	—	—	E[b]
IA	—	—	—	—	—	—	E
KS	—	—	E	—	—	E[b]	E[b]
KY	—	—	—	—	—	E[b]	E[b]
LA	—	—	—	—	—	E[b]	E[b]
ME	O/E[b]	—	—	—	—	—	—
MD	E[b]	—	—	—	E[b]	—	E
MA	E	—	E	—	—	E	E
MI	O	—	O	—	—	—	E[b]
MN	O	—	—	—	—	—	—
MS	—	—	—	—	—	—	—
MO	O	—	O	—	E	—	E
MT	—	—	—	—	—	—	E
NE	—	—	—	—	—	—	E
NH	E[b]	E[b]	—	—	O/E	—	E[b]
NJ	O	O	O	O/E[b]	E	—	O/E[b]
NM	E	—	—	—	—	—	E[b]
NY	O/E[b]	E[b]	O/E[b]	E[b]	E[b]	—	—
NV	—	—	O	—	E	—	E[b]
NC	—	—	—	—	E	E[b]	E[b]
ND	—	—	—	—	—	—	E[b]
OH	—	—	E[b]	—	—	—	—
OK	E	—	—	—	—	—	O/E[b]
OR	O	—	O	—	—	E	E[b]
PA	—	—	—	—	E[b]	E	E
RI	O/E[b]	—	O/E[b]	—	—	—	—
SC	—	—	E[b]	—	—	—	O
SD	O	—	O	—	—	E[b]	E[b]
TN	—	—	—	—	—	—	E[b]
TX	O	—	O	O/E[b]	E[b]	E[b]	E[b]
UT	—	—	O	—	E[b]	E	E
VT	O	—	O	—	—	—	E
VA	—	—	—	—	—	—	—
WA	O	—	O	—	—	E	E
WV	—	—	—	—	—	—	E
WI	E	—	E	—	—	E[b]	E[b]
WY	—	—	—	—	—	—	—
Total	**26**	**4**	**23**	**6**	**10**	**19**	**40**

[a]A searchable database of the laws summarized above can be found at www.cdc.gov/nip/vaccine/statereqs.htm#cdc.
[b]This state specifies an exemption(s) to the ensure law noted.
O, state has "offer" law for the population and setting noted; E, state has "ensure" law for the population and setting noted; O/E, state has multiple laws for the population and setting noted, of which some are "offer" laws and some are "ensure" laws.

ity of ensure laws for healthcare workers (11 states) required administration of the measles, mumps, and rubella (MMR) vaccine; only three states had laws ensuring influenza vaccination of HCWs.

Sixteen states with administration laws for hepatitis B vaccine cited or incorporated by reference federal OSHA standards (29 CFR §1910.1030 [2006]) pertaining to employees with potential occupational exposure

Table 2. Number of states with administration laws, by population and type of vaccine specified

	Healthcare workers[a]		Patients/ residents	
Vaccine type	**Offer**	**Ensure**	**Offer**	**Ensure**
Hepatitis B	20	3	2	8
Influenza	3	3	2	5
Pneumococcal	0	0	2	4
Measles/mumps/rubella	1	11	2	1
Varicella	0	3	0	0
Routine/age-appropriate immunizations[b]	0	1	3	38
Overall number of states with law[c]	21	15	7	40

[a]Oregon and Washington DC have general requirements for hospitals to provide immunizations against diseases that employees are at risk of contracting while working at the hospital, and for which vaccines are available. Because these requirements are nonspecific, they are not included as immunization requirements for HCWs in the table above. However, Oregon is included in the above count of states with any "offer" law for HCWs, as Oregon requires offering hepatitis B vaccination to HCWs.

[b]Some state laws provide lists of specific vaccines that encompass most or all routinely recommended vaccines, while others refer more generally to "routinely recommended" or "age-appropriate" immunizations for the population in question.

[c]The overall numbers cited here represent the number of states with any law for this population. A state may have multiple laws pertaining to a given population, or a single law addressing several vaccine types; therefore, columns do not sum to the overall number of states in the last row of the table.

to bloodborne pathogens. However, all states are required to adhere to federal OSHA requirements, whether or not these freestanding requirements are directly incorporated into state law. Most states requiring administration of MMR vaccine for HCWs had laws that specifically mention only rubella or measles and rubella (n=8), rather than MMR. In four states, MMR vaccine laws applied only to persons working in maternal/newborn areas, or to those in contact with pediatric patients or women of childbearing age. Many laws regulating vaccine administration for HCWs were restricted to employees with direct patient contact, working with specific groups of patients, or at risk of specific exposures (27 states), while others covered all employees at the specified type of facility (10 states). States with administration laws for influenza vaccine frequently referred to CDC or Advisory Committee on Immunization Practices (ACIP) recommendations in the text of these laws. Such references were included in laws concerning patients and residents (6 states) more often than those concerning HCWs (2 states).

Patient or Resident Vaccination: Assessment

Thirty-eight states had laws for assessment of patients or residents. Most of these laws were for individual providers' patients or residents of facilities for the developmentally disabled—only two states had laws pertaining to assessment of hospital inpatients, and seven had laws for assessment of patients at ACFs. Like HCWs, the majority of assessment laws for patients or residents (25 of 38 states) were specific to hepatitis B vaccination. Twenty-two states had laws for assessment of general immunization history among patients or residents, eight had laws specifically for assessment of rubella vaccination status, and two states had laws for assessment of influenza and pneumococcal vaccination status.

Patient or Resident Vaccination: Administration

Forty-two states had some type of administration law for patients or residents: only 7 states had offer laws for patients or residents, while 40 states had ensure laws. The majority of these ensure laws pertained to residents of facilities for the developmentally disabled (39 states), although 19 states had laws for inmates in correctional facilities, and 10 had laws for individual providers' patients (Table 1). Offer laws for patients and residents were fairly evenly divided among several vaccines. The majority of ensure laws (38 states) required patients or residents to be up-to-date on most or all age-appropriate vaccinations. Several states also had ensure laws for patients pertaining to hepatitis B, influenza, and pneumococcal vaccines (Table 2).

Most administration laws for individual providers' patients (7 of 10 states) ensured the administration of hepatitis B vaccine to the children of hepatitis B–infected mothers (7 of 7 states), or to mothers whose hepatitis B status is unknown (3 of 7 states). Two states had general requirements ensuring that individual providers administer all needed vaccinations to children seen in their practices. Administration laws for patients at ACFs were the most variable, covering age-appropriate and specific vaccinations for special populations including children, pregnant women, and end-stage renal disease patients. For both correctional facilities (16 of 19 states) and facilities for the developmentally disabled (29 of 40 states), the majority of administration laws pertained to age-appropriate vaccinations, and were specific to juveniles residing in such facilities: only 3 of 19 states required vaccine administration for all residents of correctional facilities regardless of age, while 14 of 40 states had these broader requirements in facilities for the developmentally disabled.

Exemptions

Among states with ensure requirements for vaccination of HCWs (n=15), 8 states provided medical exemptions to at least one of those requirements, 3 states provided religious exemptions, and only 1 state provided philosophical exemptions. Among states with ensure requirements for patient or resident vaccination (n=40), 25 provided a medical exemption to at least one of those requirements, 18 provided religious ex-

Table 3. Number of states with exemptions to ensure laws and number requiring documentation, by population and exemption type

	Healthcare workers (n=15)[a]		Patients/residents (n=40)[a]	
Exemption type	**Exemption offered?**	**Documentation required?**	**Exemption offered?**	**Documentation required?**
Medical exemption	8	5/8	25	21/25
Religious exemption	3	1/3	18	16/18
Philosophical exemption	1	1/1	5	5/5
Overall number of states with exemption or required documentation	8	5/8	28	24/28

[a]Represents the number of states with any ensure law applying to this population (exemptions apply only to mandatory requirements, i.e., ensure laws).

emptions, and 5 provided philosophical exemptions (Table 3).

Among the 15 states with ensure laws for HCW vaccination, 5 of 8 states providing medical exemptions and 1 of 3 states providing religious exemptions specified documentation needed to obtain an exemption. Among states with ensure requirements for vaccination of patients or residents, 21 of 25 states providing a medical exemption and 16 of 18 states providing a religious exemption required documentation. All states providing philosophical exemptions for vaccination of HCWs or patients (n=6) required written documentation to obtain this exemption.

For medical exemptions, the required documentation was nearly always a certification or statement of a licensed healthcare provider; for religious and philosophical exemptions, the documentation was usually an affidavit of beliefs from the person or parent/guardian of the person for whom an exemption is sought. States did not necessarily offer the same kinds of exemptions to all mandatory vaccination requirements in that state, nor require the same documentation to obtain exemptions offered for different settings or populations.

Discussion

This study is the first review of state laws for immunization of HCWs and patients in a variety of healthcare settings in all 50 states and Washington DC. Laws pertaining to vaccination of HCWs and patients vary widely by state in terms of the vaccines, healthcare settings, and persons covered. Over half of states had laws for HCWs in traditional healthcare settings (hospitals or ACFs), while few states (n=7) had laws for patients in these settings. Laws were more often found for patients or residents in institutional settings, specifically persons housed in correctional facilities or facilities for the developmentally disabled. Most laws pertaining to vaccine administration for HCWs were voluntary (offer laws); requirements for mandatory immunization (ensure laws) were most common for institutionalized populations. Most administration laws for HCWs concerned hepatitis B vaccination, while laws for patients were more variable, covering a wide range of populations and vaccines. Although ACIP and the Healthcare Infection Control Practices Advisory Committee strongly recommend annual influenza vaccination for all HCWs,[8] the decision to implement mandatory vaccination policies is ultimately left to individual states or facilities. Few states (n=6) had laws covering influenza vaccination of HCWs.

Model legislation outlining standards for HCW and patient vaccination may be of interest to states wishing to institute immunization requirements for these populations. Model statutes pertaining to other aspects of public health are already in use in many states. For example, the Model State Emergency Health Powers Act, developed at the behest of CDC and other national organizations to improve states' ability to respond to bioterrorism, was the basis for proposed legislation in nearly 40 states within 15 months of its completion.[11] To date, 37 states and Washington DC have passed laws including provisions based on the Act.[12] However, use of the Act as a guide to legislation did not necessarily promote uniformity in state laws.[13] Interestingly, many states in this review directly cited or incorporated by reference OSHA requirements for hepatitis B vaccination of employees who might be exposed to bloodborne pathogens. These requirements are federal law rather than model legislation, and states are bound—with few exceptions—to adhere to them. However, it is notable that many states chose to include this language in state-specific statutes, and suggests that federal guidance for public health laws can be useful to state legislatures.

Although consistency in legislative requirements for vaccination could prove beneficial, requirements that are not enforced are unlikely to lead to increased levels of vaccination coverage. Enforcement has proven crucial to the success of school entry laws.[3] Legal requirements to offer influenza and pneumococcal vaccinations in New Jersey hospitals,[14] and restriction of daycare admission to fully vaccinated children in Pennsylvania,[15] failed to significantly affect immunization practices in these settings. In both instances, lack of enforcement was hypothesized as an important reason

for this failure. This review did not measure enforcement of laws. Further research into how existing vaccination requirements for HCWs and patients are enforced, and the relationship of these laws to vaccination coverage, will be important.

Vaccination practices are also regulated at the national level, both by the federal government and by non-governmental bodies. Federal OSHA standards requiring employers to offer pre-exposure hepatitis B vaccination to staff with occupational exposure risk became effective in 1992,[10] and resulted in increased hepatitis B vaccination coverage among HCWs.[16] In mid-2006, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) announced a new accreditation standard for hospitals, critical access hospitals, and long-term care facilities, effective January 2007.[17] Under this standard, JCAHO-accredited facilities will be required to offer annual influenza vaccination to staff, volunteers, and others with direct patient contact. National policies regulating HCW vaccination are likely to significantly affect vaccination coverage among HCWs, and could encourage creation and enforcement of state laws promoting compliance with these standards.

The greatest challenges encountered during this review were determining which laws should be included, and elucidating the meaning of laws. First, state laws frequently use similar terms to describe certain facilities or settings, but define these facilities in different ways. For example, a "child caring institution" in South Carolina is any facility providing residential care to at least 10 children (S.C. Code Annotated Regulations 114-590(A)(5) [2006]), while in Georgia, there is no minimum number of children that defines such an institution, but all residents must be aged less than 17 years (official Compilation Rules and Regulations of the State of Georgia [GA Comp. R. & Regs 290-2-7-.01(e)[2006]). Conversely, some states use different terms to describe facilities that serve essentially identical functions. Standard definitions developed by legal researchers conducting the review were helpful in maintaining consistency. A second challenge was that statutory language is often broad or unclear, and necessitated interpretation by researchers, often with the assistance of state legal counsel. For example, several states had vaccination requirements for institutions that, generally defined, included those caring for delinquent children. Following a plain reading of the legal language, such states were included in the results as having vaccination requirements for residents of juvenile correctional facilities, although these laws did not explicitly refer to correctional facilities. Legal counsel in some states agreed with this interpretation, but it was rejected by counsel in at least one state, underscoring the ambiguity that can exist in the language of immunization requirements and the importance of review by state counsel.

Legal requirements may not fully reflect vaccination practices in states, due to variation in enforcement, legal procedure and interpretation, and/or principles of medical ethics. For example, the ethical principle of harm avoidance stipulates a de facto medical exemption to all immunization requirements, because persons with contraindications may be harmed by vaccination. The need to exempt persons with true contraindications to vaccination was suggested in the *Jacobson* decision,[4] but not all states have written laws to this effect. However, the majority of states with ensure requirements provided legal exemptions to at least one of those requirements, and medical exemptions were the most commonly specified. Another instance in which written requirements and vaccination practices may diverge is in states whose requirements for vaccine administration imply assessment, but do not specifically state that assessment must occur before vaccination. Our results reflect vaccination requirements and exemptions as written into state law.

Results of this review are subject to at least two limitations. First, although state counsel in all states were given the opportunity to review results, fewer than 50% provided feedback. Therefore, the interpretation of laws in this review may not always agree with that offered by state agencies in states that did not respond, as noted above. However, the majority of state counsel who did respond agreed with the proposed interpretations of laws in their states. Second, state laws are constantly in flux, and vaccination requirements in states are likely to have changed since this research was conducted. Rapid change in state requirements is especially probable given increased interest in influenza vaccination of HCWs, and study results will need to be updated periodically to maximize their utility. Future updates will be made directly to the online database. These results were current as of June 30, 2005.

Despite ACIP recommendations for vaccination and persistent low rates of influenza vaccination among HCWs, few states had laws pertaining to influenza vaccination of HCWs. Current influenza vaccination rates among healthcare providers are estimated at 37% using data from the 2005 Behavioral Risk Factor Surveillance System.[18] In the absence of legal requirements, recommendations for immunization are unlikely to be fully adopted. A study conducted 19 months after the ACIP recommended hepatitis B vaccination beginning at birth showed that just over half of CDC grantees recommended this "birth dose" in their infant hepatitis B vaccination schedule, and less than half of surveyed hospitals routinely offered hepatitis B immunization at birth.[19] It is possible that in some settings, establishment and enforcement of vaccination requirements may be necessary to improve vaccination rates in certain populations, such as HCWs.[5]

In conclusion, significant state-to-state variation exists in vaccination laws for HCWs and patients. Model

legislation could be helpful to states wishing to implement vaccination requirements in healthcare settings, although the uptake of model public health laws varies depending on subject matter. Vaccination requirements for HCWs and patients that are properly implemented and enforced should be an effective tool in future efforts to reduce healthcare-associated infections and increase overall quality of medical care. Washington's Virginia Mason Medical Center reported 96% staff coverage following implementation of a hospital policy requiring annual influenza vaccination as a condition of employment.[20] Substantial coverage increases due to enforcement of school vaccination requirements and OSHA standards[3,16] suggest that legal requirements can improve vaccine uptake. States with existing immunization laws for HCWs and patients should collect and disseminate data on enforcement and resulting vaccination coverage to provide evidence for the use of such laws to improve healthcare quality.

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