Delivering New Vaccines to Adolescents: The Role of School-Entry Laws

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ABSTRACT

In the United States, state-based school-entry vaccination laws have been used effectively to rapidly increase vaccination rates among adolescents, in particular, for hepatitis B vaccine. New vaccines for adolescents raise the question of whether and under what circumstances school-entry laws may be used to increase coverage rates with these vaccines. The new vaccines differ somewhat from their predecessors and raise policy and legal issues. For example, some of the new vaccines prevent diseases for which the primary mode of transmission is sexual contact. Mandating these vaccines before school entry has been met with concern by those who believe that mandates for this type of vaccine not only intrude on parental decision-making rights but might also lead to sexual promiscuity among youth. In this article we explore (1) the possible utility of school-entry requirements to increase the delivery of the new vaccines for adolescents, including the legal basis for US school-entry laws, (2) arguments in favor and concerns about the adoption of laws for adolescent vaccination, and (3) the importance of including diverse stakeholders in the deliberative process and formulating and implementing laws in a way that maximizes their acceptance and effectiveness.

STATE-BASED SCHOOL-ENTRY VACCINATION laws and administrative regulations (hereinafter referred to as school-entry laws) have proven to be an effective way to rapidly raise vaccination rates among children and adolescents.1-6 In 1999, the Task Force on Community Preventive Services reviewed studies on the effectiveness of school-entry vaccination laws.7,8 Finding that studies supported the effectiveness of school-entry laws in reducing disease rates and disease outbreaks and improving vaccination coverage and immunity, the task force recommended laws or policies that require vaccinations in schools as a strategy to improve immunization coverage.9

Until 1989 only 1 vaccine, the tetanus-diptheria (Td) booster, was routinely recommended for adolescents (10 years after the last dose of diphtheria-containing vaccine, most often given at age 4–6 years). In 1989, the American Academy of Pediatrics recommended that 11- to 12-year-olds receive a second dose of measles-mumps-rubella (MMR) vaccine.10 In 1996, the Advisory Committee on Immunization Practices reiterated its 1994 recommendation that all adolescents aged 11 to 12 years receive the Td booster and that those who were not already immune be brought up to date for hepatitis B, the second dose of MMR, and varicella vaccines.11 After this, numerous states enacted school-entry laws that required 1 or more of these vaccines for adolescents (Fig 1). Laws that now enforce catch-up vaccinations against hepatitis B, MMR, or varicella among adolescents will fade in importance, because these vaccines are now part of universal vaccine recommendations for infants and young children.12 Given the 3 recently licensed vaccines for adolescents and the ongoing effort in many states to determine whether to enact new school-entry laws, online resources are the most up-to-date source for the status of school-entry laws in each state. For example, the Immunization Action Coalition Web site (www.immunize.org/laws) provides current information on state school-entry laws.

Three new vaccines have been licensed and recommended in 2005–2007 for use among adolescents: the tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine (formulated with pertussis antigens and intended
In its 1905 decision on the Jacobson case, the Supreme Court affirmed the decision of the Massachusetts Supreme Judicial Court and upheld the right of the state to mandate vaccination against smallpox. The court reaffirmed a principle it had established in Crowley v Christensen, an 1890 case that addressed the right of police commissioners to grant or refuse a liquor license. The same principle underlies nearly all of public health law: "... the possession and enjoyment of all rights are subject to such reasonable conditions as may be deemed by the governing authority of the country essential to the safety, health, peace, good order and morals of the community. Even liberty itself, the greatest of all rights, is not an unrestricted license to act according to one’s own will." Since Jacobson, courts have consistently upheld the constitutionality of laws that require vaccination for school entry. In 1922, in Zucht v King, the US Supreme Court upheld the constitutionality of Texas city ordinances that required vaccination as a prerequisite for school attendance.

In 1999, the Task Force on Community Preventive Services reviewed studies on the effectiveness of school-entry laws and found 6 regional studies of school-entry laws for young children that were associated with reductions in disease rates and outbreaks and 3 national studies that showed that states with school-entry laws had lower incidence rates for mumps and measles than states without such laws. These effects were particularly strong where the laws were enforced by excluding unvaccinated, nonexempt children from school. Studies have shown the effectiveness of school-entry laws in hastening the implementation of new recommendations that impact adolescents, as well as vaccine coverage for MMR and Td. Studies have also shown that hepatitis B vaccine coverage is higher in states with school-entry laws than in states without such laws.

Studies have demonstrated that when parents comply with school-entry laws, disease in a community decreases accordingly. Without school-entry laws to buttress child immunization rates, the incidence of many vaccine-preventable diseases in the United States would likely remain at much higher levels. If parents considered only their own child’s situation, then for some diseases individual costs and benefits might not justify vaccination. For example, because polio was eliminated from the Western Hemisphere in 1991, the chance that a child in the Western Hemisphere will ever be exposed to the disease is near zero. Thus, the benefit of polio vaccination to the individual child (ie, avoidance of disease) is extremely low and may seem to be outweighed by the cost, inconvenience, and risk of an adverse effect from polio vaccine itself. Thus, in economic theory, the “rational” parent would decide to “free ride” on the herd immunity created by the polio vaccination of other children. Of course, if a significant proportion of parents followed this course, the disease might reestablish itself in the Western Hemisphere by importation. Laws that require polio immunization are justifiable because they are a disincentive against such free-riding that could, on a large scale, lead to reintroduction of polio, which would be a dangerous situation for society.

Another potential benefit is the savings accrued to

to replace the Td booster); the meningococcal conjugate vaccine; and the human papillomavirus vaccine (HPV). Similar to the Td booster, the new vaccines are routinely recommended, that is, they are permanent additions to the adolescent vaccination schedule.

In this article we discuss the legal basis for school-entry laws that require vaccination in the United States, arguments in favor and concerns about such laws for adolescent vaccination, and practical considerations for adopting such requirements in the states. We also discuss the importance of including diverse stakeholders in the deliberative process and formulating and implementing laws in a way that maximizes their acceptance and effectiveness.

LEGAL AND PHILOSOPHICAL RATIONALES FOR SCHOOL-ENTRY LAWS IN THE UNITED STATES

Under American constitutional principles, state and federal governments may not interfere with the liberty of individuals unless they comply with the Constitution’s requirement of “due process of law.” This includes, at a minimum, a rational relationship between the government’s interest and the governmental action to be taken. Laws that require parents to ensure vaccination of their children as a prerequisite for school entry are consistent with the American jurisprudential precepts of government “necessity” and the common good.

In the landmark Jacobson v Massachusetts decision, mandatory vaccination was found justified by the government’s need to protect the whole population from communicable diseases. The Jacobson case arose from a 1902 outbreak of smallpox in Cambridge, Massachusetts. The Cambridge Board of Health required the vaccination and revaccination of all residents who had not been successfully vaccinated against smallpox since March 1, 1897, and the board provided all residents with free vaccine. The Reverend Henning Jacobson was concerned about the safety of the vaccination and believed that the Massachusetts statute that allowed Cambridge to require vaccination violated his personal liberties and his constitutional right to due process. He refused to be vaccinated and was convicted and fined 5 dollars. He appealed unsuccessfully to the Massachusetts Supreme Judicial Court. He then appealed to the US Supreme Court."
society by vaccination. In particular, childhood vaccines introduced before 2000 have been demonstrated to be cost-saving from the societal perspective.\textsuperscript{19,20} However, starting with the pneumococcal conjugate vaccine, first recommended in 2000, this situation changed.\textsuperscript{21} This vaccine, in particular, was cost-effective but not cost-saving. Newer adolescent vaccines are often expensive and may be cost-effective but not cost-saving. For some of these new adolescent vaccines, such as HPV, the long-term cancer-prevention benefits may result in cost-savings (see the article by Ortega-Sanchez et al\textsuperscript{23} in this issue).

Laws are also used to require vaccinations against diseases for which herd immunity and free-riding do not play a role (ie, tetanus, because there is no human-to-human transmission). The principal justification for a law in this setting is not to build herd immunity or prevent free-riding but simply to protect the child against an infection. Also, an argument can be made that these non–herd-immunity vaccines do prevent harm to others by reducing the burden of health care costs caused by the diseases prevented. However, the principal rationale for the laws is simply the determination by society that the beneficence (avoidance of disease in the individual vaccine recipient) represented by a legal requirement outweighs the infringement on individual autonomy. Society has made the same determination for many other public health interventions, including, for example, motorcycle and bicycle helmet laws.\textsuperscript{23}

**CONCERNS ABOUT SCHOOL-ENTRY LAWS**

Since the beginning of modern public health, various segments of the population have viewed many public health laws as unnecessary or illegal intrusions into the autonomy and liberty of individuals. At various times, individuals and groups have fought against laws on insect abatement, motorcycle helmets, fluoridation, and many other public health issues.\textsuperscript{24–26} Thus, opposition to school-entry laws is not a unique phenomenon in public health but merely a reflection of the ancient tension between the duty of the state to require actions to protect the whole population and the right of individuals to make decisions about their own (or their children’s) fate.

Vogel\textsuperscript{27} described factors that can lead to consumer backlash against public health laws or requirements. The risk is highest for laws that (1) have a high visibility to consumers, (2) are perceived to be very relevant to the consumer’s life, (3) intrude on peoples’ daily lives, (4) interfere with freedom of choice on matters in which consumers believe they are in a better position to judge their self-interest than the state, and (5) upset large numbers of voters.

In terms of visibility and relevance, school-entry laws that are likely to meet the least resistance are those that help prevent diseases that are common, highly infectious in schools, and cause substantial mortality or absenteeism, whereas laws that are likely to meet the most resistance are those that help prevent less severe diseases, less common diseases, diseases that are not readily transmitted, or diseases that may be prevented by behavior.

Vaccine mandates are viewed by some as intrusive and an interference with freedom of choice. Thus, throughout the history of vaccination, a persistent and vocal minority has resisted compulsory school-entry laws.\textsuperscript{23} With new vaccines, it may be that individuals or parents view the high cost of a required vaccine, or time lost from work or other activities to obtain the vaccine, to be unduly intrusive. Other more long-standing concerns about school-entry laws have focused on the potential adverse effects of vaccines, particularly for diseases that are seen as rare or innocuous by the public.\textsuperscript{23} Because the diseases that many older vaccines prevent have ceased to be major killers in the United States, attention has shifted more readily to vaccination risks.

Because some persons view compulsory vaccination as a violation of fundamental personal autonomy, almost half of US states offer philosophical or personal exemptions for required vaccinations.\textsuperscript{28} Some parents may see school-entry laws as displacing their traditional authority to decide what medical treatments their children should receive. These parents assert that they are in a better position to judge the medical needs of their children than the state.

The hepatitis B vaccine is a case in point. Since the enactment of hepatitis B vaccine school-entry laws in the early 1990s, concerns have been raised that vaccination mandates are not justified if they are meant to prevent diseases that can be avoided primarily by behavior, such as abstinence from illegal drug use and certain sexual behaviors.\textsuperscript{24} The HPV vaccine may be considered by some to fall in the category of diseases that may be avoided by behavior. Concerns have also been raised that vaccination against sexually transmitted diseases in adolescents can increase premarital sexual activity.\textsuperscript{25} However, studies have not supported the contention that there will be an increase in unsafe behavior in response to the introduction of a preventive intervention.\textsuperscript{26–30} Studies indicate that other preventive programs (eg, condom availability, prescribed emergency contraception) did not result in an increase in the initiation or frequency of sexual activity among teenagers and young adults.\textsuperscript{26–30}

Public health authorities have also countered these arguments by emphasizing that children and adults can acquire hepatitis B infection in ways other than through drug abuse or sexual contact (eg, perinatal infection and occupational exposure) and that reliance on behavior may not be effective because many children will, at some time during their lives, pursue activities that place them at risk for sexually transmitted diseases. Despite these counterarguments, a segment of parents believe that compulsory vaccination against diseases transmitted by sexual contact or illegal drug abuse is an impermissible infringement on parental autonomy. Recent studies, however, have found that the majority of parents supported vaccines for sexually transmitted infections for their adolescent children, although these studies did not address compulsory vaccination.\textsuperscript{29–32}

Certainly, some vaccine requirements may be cause for concern to voters; however, there has been no sub-
stantiation of major impacts among voters caused by politicians’ stands on vaccine requirements.

CONSIDERATIONS FOR DEVELOPING NEW LAWS FOR NEW VACCINES

To understand the factors that are likely to make new school-entry laws successful, it is important to appreciate the place of school-entry laws in the United States public health system and how they are created. Although laws are effective in promoting adolescent vaccination, they represent only 1 of many components necessary to implement a vaccination program. Many countries around the world rely on other factors rather than law to increase vaccination coverage. For example, the United Kingdom relies on the individual’s sense of responsibility to society to seek vaccination. However, comparisons between the United States and other countries have been complicated by differences in cultural context; what works in one society may not work in another. The United States has a historical tradition of individualism and freedom from government influence. Also, immunization programs in the United States and the United Kingdom differ in some key respects, which may impact implementation of new vaccines; for example, in the United Kingdom, vaccines are available at no charge. Other strategies, including vaccination in the medical home, health care system changes such as first-dollar coverage for preventive services, and implementing proven strategies such as reminder-recall systems, are also very desirable regardless of whether school-entry laws are put into place, and they help to ensure timely immunization.

In the United States, all school-entry laws are created by the states. Under our federalist constitutional scheme, decisions about childhood school-entry laws are part of the states’ traditional police powers, which were left undisturbed when the Constitution was ratified at the nation’s birth. In some states, the list of vaccines required for school entry is established by the legislature and the requirements are embodied in statutes. In other states, the requirements are adopted by the health or education departments as administrative rules under a grant of authority from the legislature.

The development of school-entry laws usually begins with public health recommendations made by national vaccination advisory groups such as the Advisory Committee on Immunization Practices, a Centers for Disease Control and Prevention advisory committee, which itself is advised by representatives from many medical and health care professional organizations. After recommendations are made, stakeholders use a variety of methods for attaining high coverage, including school-entry laws. Traditional stakeholders for decision-making include state health departments, state-based professional organizations, and medical societies. These stakeholders consider topics such as the medical and public health justification for a new school-entry law, considering the epidemiology of the disease in the state, the strategic and political timing of a proposed law, the likely political proponents and opponents of a law, and the costs of implementation. As this process moves forward, other stakeholders (eg, legislators, citizens, and vaccine manufacturers) may play a role.

In many states, the most important consideration in adopting a new school-entry law is the cost. When a new school-entry law is proposed, health department administrators and legislators are obliged to focus on the costs (both in vaccine acquisition and administration) and who will pay them. The Vaccines for Children program, a federal entitlement program, provides vaccine for eligible children, but state funds, health plans, providers, and families bear the cost of vaccination for children who are not eligible for this program. Schools may also bear some additional costs in terms of higher administrative expenses for checking immunization records and excluding children from attending school if they lack the newly required vaccine.

Even after state leaders have decided that a new school law is warranted, several challenges remain. For example, if leaders try to adopt a new school-entry law without first engaging their constituents in an open dialogue and political conversation, the proposal may trigger a backlash among parents and others who are concerned about vaccination. Professional and public health organizations, parents’ organizations, health plans and insurance companies, manufacturers, and politicians will all want to weigh in on the proposed requirement. Sometimes, the process moves smoothly under the leadership of a key health official, a legislator, or other credible proponent. At other times, however, the process is thwarted by poor communications or failure to include key parties in decision-making. Even when the process is working at its best, it is inevitable that it will be influenced, to at least some extent, by media coverage, anecdotal stories, and politics. Manufacturers, special interest groups, and professional organizations may conduct educational campaigns and advocacy efforts based on their own priorities. To balance these efforts, public health professionals are responsible for speaking out about the rationale for the proposed law by using clear, consistent messages that are based on sound scientific evidence, law, and public policy.

After the adoption of a new school-entry law, the need for clear communication from government officials remains undiminished. Implementation of the new school-entry law and acceptance by parents depends on the dissemination of accurate information about the requirement from a trusted source, rapid response to rumors and misinformation, and good communication to key legislators and other thought leaders. To avoid backlash to a new school-entry law, public health officials should keep channels of communication open to all the diverse parties involved in the issue, such as advocates, groups that voice concern about the law, manufacturers, and others. Inclusiveness, attentive listening, and sincere consideration of all viewpoints may make the difference between a successful implementation and an unsuccessful one. Partners should come to some agreement on the timing of the implementation of the school-entry law, procedures for handling unvaccinated children at school, vaccine supplies, coverage goals, and appropriate informational and educational campaigns.
LIMITATIONS ON THE EFFECTIVENESS OF SCHOOL-ENTRY LAWS

One limitation of school-entry laws is that they do not cover all students. Not all states have laws, and laws are variably enforced. Moreover, some laws (such as those for Td vaccine) primarily target adolescents in high schools, which have higher drop-out rates than those of middle schools. Some state laws (eg, in Virginia and New Mexico) require children who are educated at home to comply with school-entry laws that require immunizations, but these laws may not be enforced. In addition, some homeless children, runaways, adolescents who attend alternative schools, and others may be unaffected by school-entry laws, although they may be at risk for vaccine-preventable diseases (see the article by Sneller et al in this issue).

Religious and philosophical exemptions may also impact the effectiveness of school-entry laws. In 2004, 48 states offered religious exemptions from school-entry vaccination laws, and at least 19 states offered personal or philosophical exemptions. Only a small proportion of parents (<5% on average) seek these exemptions for their children. In some communities, however, the proportion of exempted children has reached a high enough level to reduce the ability of school-entry laws to help achieve herd immunity. The relationship between exemptions and disease outbreaks has been well documented. Pockets of population with a high incidence of exemptions, such as the Amish, have experienced outbreaks of vaccine-preventable diseases.

The relative ease with which parents in many states can obtain philosophical and religious waivers and insufficient enforcement of exemption requirements both serve to reduce the effectiveness of school-entry laws. One study showed that the complexity of paperwork or effort required to complete the exemption process was inversely related to the proportion of exemptions filed. Commentators have observed that, in many states, “the actions required to obtain an exemption are simpler and less time consuming than the effort needed to meet the immunization requirements.”

Consistent enforcement of school-entry laws is another challenge. School-entry laws are only as effective as their enforcement. In 2002, Hinman et al, in a summary of studies that revealed a negative correlation between incidence of disease and extent of enforcement, stated that “[i]n 1977 and 1978, the incidence rate of measles in six states strictly enforcing school entry laws was 50% to 90% lower than the rates in the rest of the country.” Furthermore, in a 1981 analysis of 13 low- and 10 high-measles-incidence states, Robbins et al concluded that the 13 low-incidence states were significantly more likely to have school immunization laws that were comprehensive and strictly enforced.

CONCLUSIONS

School-entry laws have been well accepted by the US population since the 1960s. These laws have been effective in rapidly increasing childhood and adolescent vaccination rates and decreasing rates of disease. Even so, the medical and public health rationale for each new law must be evaluated carefully.

Despite their history of effectiveness, school-entry laws are not panacea for the delivery of adolescent vaccinations. There are many evidence-based strategies for implementing new vaccines; laws are just 1 strategy that may be effective in certain circumstances if other approaches do not achieve desired immunization rates. Some new vaccines for adolescents raise philosophical, legal, policy, and political issues that are more complex than those associated with traditional childhood vaccines and may affect consideration of the appropriateness of school-entry laws. In the future, it will be even more important for all the participants in the adoption of school-entry laws to communicate openly, early, and often to ensure that new laws are carefully conceived and well accepted by the public.

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