

Mandatory Immunization Laws and the Role of Medical, Religious and Philosophical Exemptions

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Background

Immunizations are among the successful public health interventions in preventing morbidity, mortality and health care costs. One of the strategies used in the US to control vaccine-preventable diseases (VPDs) has been state laws mandating vaccination for school entrance. There are no federal laws mandating vaccinations. All laws requiring vaccination are and always have been at the state or local level. Massachusetts passed the first immunization law in the US in 1809, requiring smallpox vaccination.¹ Over time, many other jurisdictions and states enacted similar laws. Twenty states required immunization against certain diseases for school entrance in 1963. In 1970, 29 states had such laws. A landmark study by Robbins, et al, in 1969 demonstrated that states with laws covering the total school population and that actively enforce such laws were correlated with lower rates of measles.² This study prompted attention to be paid not only to the existence and nature of school immunization requirements, but additionally the importance of enforcement.³ By 1980, all 50 states had school immunization laws.

The primary intent of modern immunization requirements is to reduce or prevent school-based outbreaks of VPDs. During the 1950s-1970s, school-aged children were the predominant age group affected by measles and schools were the major site of transmission.⁴ Retrospectively examining immunization laws indicates that there are many other benefits of such laws. Laws were originally written for school entrance. Later, many laws were amended to include the entire school population to catch those students who entered school before or slipped through the entrance laws. State laws provide a safety net ensuring that all, or nearly all, children over 5 years of age are fully vaccinated (as defined by said laws). State laws also demonstrate public and public health commitment to vaccination – supporting both the individual and community benefit of vaccinating. School laws allow immunization programs to benefit from additional school system resources. Additionally, as described by Dr. Walter Orenstein, Director of the National Immunization Program, Centers for Disease Control and Prevention (CDC), “school laws establish a system for immunization, a system that works year in and year out, regardless of political interest, media coverage, changing budget situations, and the absence of vaccine-preventable disease outbreaks to spur interest”.⁴ Recently, school laws have also been used to implement new vaccine recommendations including hepatitis B and varicella. The constitutionality of school laws has been upheld by the US Supreme Court.⁴

Currently, all states in the US require documentation of vaccination for school entrance. Many states also have laws requiring vaccination for licensed day care and college. Some states specify which vaccines and how many doses are required in the law itself, while other states authorize the State Health Officer or Health Board to determine the nature of required vaccinations.⁴

While there are many benefits to state requirements for vaccination, there are limitations to what they can achieve. School-based laws do not ensure vaccination for children under the age of applicable laws. Thus, immunization programs must focus particular attention on children ages 2 to 5, although, as mentioned,

the existence of laws for school entrance may be useful in demonstrating to parents the value of vaccinations and the need to address the issue. State laws requiring immunization for school entrance also come at somewhat of a price. Some have viewed these laws as a coercive measure by the state (big brother) to interfere with parental medical decisions.⁵ While this view is clearly in the minority, as demonstrated by the vast majority of parents who comply with the laws without complaint, the use of legislation to ensure a medical and public health preventative intervention risks public backlash, particularly in a country that emphasizes individual freedoms.

Immunization laws permit certain exemptions. All states permit medical exemptions for individuals who are immunocompromised, have allergic reactions to vaccine constituents, have moderate or severe illness, or other medical contraindications to vaccination. To qualify for medical exemptions, parents or guardians must provide a letter or other documentation from a physician. As of 10/17/032, forty-eight states permit religious exemptions (all but Mississippi and West Virginia) and 19 states provide philosophical or personal exemptions (Arkansas, California, Colorado, Idaho, Louisiana, Maine, Michigan, Minnesota, New Mexico, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Texas, Utah, Vermont, Washington and Wisconsin).⁶ While debate often centers around the type of exemption offered (religious vs. philosophical), a recent study by Rota, et al⁷, found great variation in the ways states implement non-medical exemptions. Among states with religious but not philosophical exemptions (n=34), only 21 states indicate that requests for exemptions were ever denied. The remaining states are, by defacto, allowing philosophical or personal belief exemptions.

The primary benefit to offering non-medical exemptions is to accommodate the desires of the small minority of parents who do not believe, for whatever reasons, in immunizations. Currently, this represents less than 1% of the US population. In this light, non-medical exemptions represent an effort on the part of the state to accommodate the views of the minority. Additionally, non-medical exemptions may diffuse the viewpoint that school-based laws represent state coercion and thus furthers the integrity and sustainability of state laws.

Individual and Societal Risks of Exemptions

There are individual and societal risks inherent to offering non-medical exemptions. Salmon et al.⁸ conducted a population-based, retrospective cohort study of measles utilizing data (1985 through 1992) collected by the Measles Surveillance System of CDC as well as from annual state immunization program reports on the prevalence of exemptors and vaccination coverage. The study group was restricted to individuals aged 5 to 19 years. To empirically determine and quantify community risk, a mathematical model was developed that examines the spread of measles through communities with varying proportions of exemptors and vaccinated children.

On average, exemptors were 35 times more likely to contract measles than vaccinated persons (95% confidence interval (CI), 34-37). Relative risk (RR) varied by age and year. Comparing the

incidence among exemptors with vaccinated children and adolescents during the years 1985-1992 indicated that the 1989-1991 measles resurgence may have occurred one year earlier among exemptors. Mapping of exemptors by county in California indicated that exempt populations tended to be clustered in certain geographic regions, increasing their individual and community risk. Depending on assumptions of the model about the degree of mixing between exemptors and non-exemptors, an increase or decrease in the number of exemptors would affect the incidence of measles in nonexempt populations. For example, if the number of exemptors doubled, the incidence of measles infection in nonexempt individuals would increase between 5.5% and 30.8%. Disease in non-exempt individuals could be a result of a lack of vaccination for a reason other than non-medical exemptions or vaccine failure. This study was the first to quantitatively assess the risks associated with exemptions.

Feikin et al. validated and expanded upon the findings of Salmon by conducting a population-based, retrospective cohort study using data collected on standardized forms on all reported cases of measles and pertussis occurring in Colorado between 1987 and 1998.⁹ Feikin assessed the relative risk of the incidence of measles and pertussis among exemptors and vaccinated children aged 3-18 years, and the association between the incidence rates among vaccinated children and the frequency of exemptors in Colorado counties. On average, exemptors were 22 times [95% CI, 15.8-30.8] more likely to acquire measles and 5.9 times (95% CI, 4.2-8.2) more likely to acquire pertussis. After adjusting for confounders, the frequency of exemptors in a county was associated with the incidence rate of measles [RR =1.6; 95% CI 1.0 -2.4] and pertussis (RR=1.9; 95% CI 1.7-2.1) in vaccinated children. Schools with pertussis outbreaks had more exemptors (4.7% students) than schools without outbreaks (1.3% students, p<.001). At least 11% of vaccinated children in measles outbreaks (cases were vaccine failures) were infected through contact with an exemptor.

This increase in community risk is due to pockets of unprotected or susceptible people who create a weakness in our armor against infectious diseases. The likelihood of an outbreak to occur and be sustained is increased. Particularly vulnerable, in addition to exemptors themselves, are those that cannot be immunized for medical reasons or individuals who do not develop a sufficient immunological response to the vaccine. The geographical (e.g., county) or social (e.g., school) clustering of exemptors increases the community risk. There is the potential for increases in the number and clustering of exemptions (increasing individual and community risk) due to current success of immunization programs in reducing the incidence of VPDs, leading to misinformation and an under-appreciation of the risks of disease.

Beyond the direct individual and societal risks associated with non-medical exemptions, there are also certain indirect risks. Some parents may interpret allowing non-medical exemptions as an indication of lack of importance to vaccinate, leading to complacency on the part of the parent. Additionally, in some jurisdictions it is easier to claim an exemption than to vaccinate, potentially motivating some parents to pursue an exemption as the path of least resistance. Non-medical exemptions also pose a social equity issue. While vaccines cause fewer complications than VPDs, no vaccine is perfectly safe. High immunization levels therefore permit some unvaccinated individuals to reap the benefits of immunization (through herd immunity) without facing risks, however small, of vaccinating.

Legal Issues Pertaining to Non-Medical Exemptions

To assist the public health community and those responsible for maintaining and implementing state immunization laws in optimally reaching this balance, Salmon and Siegel examined the constitutional basis of religious and philosophical exemptions from state laws and considered issues pertaining to conscientious objectors (COs) from conscription as a possible model.¹⁰ According to this analysis, it is well established as a matter of constitutional law that police powers authorize states to compel vaccination in the interest of public health.¹¹ However, the U.S. Supreme Court has never ruled on the constitutionality of religious exemptions from vaccination requirements. There are two central constitutional questions: (1) Does the First Amendment right to free exercise of religion require states to provide religious exemptions from vaccination? (2) Do states have the constitutional authority to enact religious exemptions from compulsory vaccination?

The jurisprudence the Court has developed in cases in which religious beliefs conflict with public or state interests suggests that mandatory immunization against dangerous diseases does not violate the First Amendment right to free exercise of religion. In a recent case, the Court stated, "We have never held that an individual's religious beliefs excuse him from compliance with an otherwise valid law prohibiting conduct that the State is free to regulate."¹² The Court held that a law does not interfere with the right to free exercise of religion as long as it is religion-neutral and generally applicable. The Court has specifically struck the balance in favor of public health concerns where they were in conflict with religious beliefs, and underscored the importance of protecting children from the potentially harmful consequences of parents deciding for them on the basis of those beliefs: "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. Parents may be free to become martyrs themselves. But it does not follow that they are free in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves."¹³

A number of state courts have applied this reasoning in holding that mandatory vaccination of school children does not interfere with the right to religious freedom. As the Arkansas Supreme Court noted in one such instance, "In cases too numerous to mention, it has been held, in effect, that a person's right to exhibit religious freedom ceases where it overlaps and transgresses the rights of others."¹⁴

While it is widely agreed that states do not have a constitutional obligation to enact religious exemptions, it is somewhat less settled whether states have the constitutional authority to enact them in the vaccination context. The Mississippi supreme court has held that religious exemptions to compulsory vaccination violate equal protection of the laws under the Fourteenth Amendment inasmuch as the exemptions "require the great body of school children to be vaccinated and at the same time expose them to the hazard of associating in school with children exempted . . . who had not been immunized as required by the statute."¹⁵ Mississippi is one of two states that do not permit non-medical exemptions (as of 7/1/02).

Even if it is assumed -- as it generally is -- that states do possess the constitutional authority to enact religious exemptions from vaccination, there remains an issue concerning what limitations a legislature can place on the scope of the exemptions. There is some disagreement among courts whether religious exemptions requiring those seeking the exemption to be members of a

recognized or established religious organization violate the First Amendment prohibition against laws 'respecting an establishment of religion'. Some courts have upheld exemptions for the children of parents with 'sincere religious beliefs', but found that the requirement that the parents be members of an established or recognized religious organization entails preferential treatment for certain religious views and thus violates the Establishment Clause of the First Amendment.¹⁶ Other courts have held that such requirements are compatible with the Establishment Clause.¹⁷

The U.S. Western District Court of Arkansas recently determined Arkansas religious exemption to be unconstitutional as it "clearly runs afoul of the Establishment and Free Exercise Clauses of the First Amendment and the Equal Protection Clause of the Fourteenth Amendment, because the exemption benefits only those who are members or adherents of a church or religious denomination recognized by the State".¹⁸ The Court severed the religious exemption from the school requirement, thus leaving the school requirement intact but no longer permitting parents to opt out of the requirement through the religious exemption. The Court recognized that "This decision will also be of understandable concern to those who previously enjoyed the immunization exemption as adherents or members of a recognized church or religious denomination. However, the recourse of both groups is to communicate their concerns to the Arkansas Legislature, for it is within the province of the legislature and not this Court to enact a religious exemption provision that comes within constitutional boundaries". The Arkansas Legislature is currently considering adopting a philosophical exemption. For now, Arkansas is the third state that only permits medical exemptions.

Notwithstanding the differences between conscription and vaccination issues, the many similarities and considerable legislative and judicial thought invested in the issue of COs allows this model to be particularly useful in thinking about efforts by the state to balance individual freedoms with societal interests in the vaccination realm. Since 1864, Congress has always included a CO exemption for military service.¹⁹ Congressional enactment of CO status has required specific conditions to be met. Individuals claiming CO status must meet the burden of proof by establishing that they: 1) are conscientiously opposed to war in any form; 2) this opposition is based upon religious training; and 3) the objection is sincere.²⁰ Once the individual has satisfactorily met the burden of proof for these three issues, the government must prove an overwhelming need to draft such individuals. One definition of 'overwhelming need', in this context, is that the government must have a compelling interest in universal enforcement of the regulation.¹³ It is generally agreed that the US has never met this burden of proof.²¹

The Supreme Court has directly addressed the question of the conditions under which conscientious objections to war are grounded in "religious belief". In its most recent ruling on the issue,²² the Court held that federal legislation that excludes those with "essentially political, sociological, or philosophical views or a merely personal moral code" from exemption applies to "those whose beliefs are not deeply held and those whose objection to war does not rest at all upon moral, ethical, or religious principle but instead rests solely upon considerations of policy, pragmatism, or expediency." Thus, a sincere objection based upon "moral, ethical, or religious beliefs about what is right or wrong" would be allowed as it falls within the Courts' definition of "religion".

The Courts holding is, however, controversial. In his concurring opinion, Justice Harlan states that the Court "performed a lobotomy and completely transformed the statute by reading out of

it any distinction between religiously acquired beliefs and those deriving from 'essentially political, sociological, or philosophical views or a merely personal moral code'." Harlan nonetheless concurs in the Courts ruling because he holds that it is unconstitutional to permit exemptions for only religious reasons: "However, having chosen to exempt, it (Congress) cannot draw the line between theistic or nontheistic religious beliefs on the one hand and secular beliefs on the other. Any such distinctions are not, in my view, compatible with the Establishment Clause of the First Amendment." Thus, even if we reject that philosophically-based beliefs count as religious beliefs, permitting religious but not philosophical exemptions may be unconstitutional.

Legislative and judicial decisions regarding conscientious objectors offers a useful model for considering issues related to mandatory vaccination and non-medical exemptions and the fair allocation of burdens and benefits. The burden of proof as established by Congress for COs has not been universally or comprehensively applied to exemptors from mandatory immunization requirements. Immunization exemptions are granted through the state legislature. Doctors verify the sincerity of medical exemptions by providing needed documentation. Some states only allow religious exemptions and require applicants to provide a letter from a religious leader who explicitly states that immunizations are contrary to their doctrine. This is at least a partial application of the burden of proof for individuals claiming exemption. However, other states require no substantiation of beliefs. For example, California has a clause on the back of their immunization forms that raises the question whether immunizations are contrary to the 'personal beliefs' of the individuals (or more appropriately, their parents). Signing this clause constitutes an exemption, but no burden of proof has been required. In such a case, the parent, by signing, may simply be pursuing the path of least resistance. It is certainly easier to sign your name than to make an appointment with a doctor or at a clinic, arrange to take the child to the clinic, and spend time (and perhaps money) to have a child immunized.

It is particularly difficult to address sincerity of beliefs: How does one prove sincerity? One approach that can be considered is the willingness of an individual to overcome barriers to achieving their goal (claiming an exemption). If the process is very simple, as is in some states, anyone with even the slightest desire to claim an exemption can easily do so. Conversely, if the state demands more proof of sincerity for claiming an exemption, those whose beliefs are not as strong may decide not to pursue an exemption. What would have been the frequency of COs from conscription had the Selective Service granting CO status as easily as California does immunization exemptions?

The Supreme Court expansion of COs to include those with strongly held philosophical beliefs poses some difficult issues for immunization exemptions. In principle, scrutinizing sincerity of parents' beliefs based on a perhaps arbitrary boundary (religion vs. philosophy) may not be just and risks public backlash. Moreover, as Justice Harlan argued, such a boundary may fail to be neutral and thus violate the Establishment Clause of the First Amendment. Yet, expansion of philosophical exemptions could easily lead to more exemptions and consequently greater risk of disease.^{8,9} If states are able to expand the definition of non-medical exemptions to include philosophically-based beliefs, and at the same time ensure a system that requires individuals who are applying for exemptions to meet carefully constructed criteria demonstrating strong sincerity of beliefs, it may be possible to have little or no effect on the overall number of exemptions. This approach, if successful in changing the criteria for permitting exemptions

without affecting the frequency of exemption, would have no effect on total disease incidence, but assist in fair and equitable allocation of exemptions. This is a very fine line to walk; yet it may offer states a strategy in addressing these difficult and often controversial issues.

A viable approach states should consider is to require parents who are considering philosophical or religious exemptions for their children to attend individual educational counseling provided by a nurse or health educator knowledgeable of vaccine issues, outlining the individual and societal risks of not vaccinating. This approach will ensure that parents understand the health consequences of the choice they are considering, resulting in better-informed parents able to make more meaningful choices that are not only in their children's best interests but the interests of society as well. The proposed process also ensures that there will be rigor and uniformity which are often lacking in the current process in administering these exemptions.⁷ The process proposed will make it less likely that mothers make the exemption choice because it is easier, and will ensure that the exemption process is not perfunctory as it often is now.

While the state (historically) could likely not meet the burden of proof demonstrating overwhelming need for universal enforcement of conscription, this may not be the case for universal enforcement of immunization requirements. If the state maintains a zero tolerance for societal risk due to exemptions, the state could likely demonstrate the need for universal application of mandatory vaccination. Additionally, disease eradication efforts may constitute a situation requiring universal coverage of vaccination, as illustrated by the fact that the last significant outbreaks of polio in the US have occurred in religiously exempt communities (although elimination of polio was achieved in the US without compelling complete immunization of these groups). Conversely, the present success of our immunization program in reaching record low rates of most VPDs, and the relatively small frequency of exemptions, suggests that universal coverage may not be necessary. The question is: How much societal risk is needed to prove the need for universal application? Policies on exemptions from conscription do not assist us in understanding this issue, as the state has never tried to demonstrate overwhelming need for universal application.

It is critical to recognize the importance of state flexibility in the administration of immunization exemptions. All school immunization requirements are state based – there are no federal laws mandating vaccination. As indicated by a representative of the Association of State and Territorial Health Officers¹⁰, “variations in State laws reflect differing constituencies and political cultures among the States, and decisions regarding the balance of individual vs. State rights are best left at the State level”. This analysis is intended to offer a legal review of the topic and subsequent policy recommendations are intended to assist policy makers in considering these often-controversial issues. State autonomy is critical. The strategies proposed in this analysis maintain considerable flexibility in state implementation of immunization exemptions.

These policy considerations are consistent with currently available data. The NVAC Working Group found no statistical relationship between type of exemption and frequency of exemptions or vaccination coverage (e.g., states that offer philosophical exemptions in addition to religious exemptions were not more likely to have more exemptions or lower coverage). The Rota study⁷ found that states that easily permitted exemptions had significantly more exemptions than states that made the process

more difficult. Furthermore, this study found that about half of the states that did not offer philosophical exemptions have never denied an exemption request. These states are de facto permitting philosophical exemptions. States and localities may find that carefully monitoring and evaluating the process by which exemptions are granted, rather than focusing on the basis for granting exemptions (religious vs. philosophical), may more fairly balance the rights of individuals with the protection of the community from VPDs. Additionally, the Rota study found that only nine states (19%) reported having a written policy to inform parents requesting an exemption of the risks of not immunizing. This is clearly a missed opportunity for vaccine risk communication.

Concluding Remarks

More research is needed to understand local variations in the implementation of exemptions and the underlying reasons why some parents refuse to immunize their children and turn to non-medical exemptions.²³ Better understanding the reasons why parents refuse to vaccinate could lead to improved vaccine risk communication, greater demand for vaccination and less reliance on immunization laws. We are currently conducting a study that will assist in understanding these issues.

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