SPECIAL ARTICLE

Vaccine Refusal, Mandatory Immunization, and the Risks of Vaccine-Preventable Diseases

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ABSTRACT

Vaccines are among the most effective prevention tools available to clinicians. However, the success of an immunization program depends on high rates of acceptance and coverage. There is evidence of an increase in vaccine refusal in the United States and of geographic clustering of refusals that results in outbreaks. Children with exemptions from school immunization requirements (a measure of vaccine refusal) are at increased risk for measles and pertussis and can infect others who are too young to be vaccinated, cannot be vaccinated for medical reasons, or were vaccinated but did not have a sufficient immunologic response. Clinicians can play a crucial role in parental decision making. Health care providers are cited as the most frequent source of immunization information by parents, including parents of unvaccinated children. Although some clinicians have discontinued or have considered discontinuing their provider relationship with patients who refuse vaccines, the American Academy of Pediatrics Committee on Bioethics advises against this and recommends that clinicians address vaccine refusal by respectfully listening to parental concerns and discussing the risks of nonvaccination.

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Vaccines are among the most effective tools available for preventing infectious diseases and their complications and sequelae. High immunization coverage has resulted in drastic declines in vaccine-preventable diseases, particularly in many high- and middle-income countries. A reduction in the incidence of a vaccine-preventable disease often leads to the public perception that the severity of the disease and susceptibility to it have decreased.[1] At the same time, public concern about real or perceived adverse events associated with vaccines has increased. This heightened level of concern often results in an increase in the number of people refusing vaccines.[1,2]

In the United States, policy interventions, such as immunization requirements for school entry, have contributed to high vaccine coverage and record or near-record lows in the levels of vaccine-preventable diseases. Herd immunity, induced by high vaccination rates, has played an important role in greatly reducing or eliminating continual endemic transmission of a number of diseases, thereby benefiting the community overall in addition to the individual vaccinated person.

Recent parental concerns about perceived vaccine safety issues, such as a purported association between vaccines and autism, though not supported by a credible body of scientific evidence,[3-8] have led increasing numbers of parents to refuse or delay vaccination for their children.[9,10] The primary measure of vaccine refusal in the United States is the proportion of children who are exempted from school immunization requirements for nonmedical reasons. There has been an increase in state-level rates of nonmedical exemptions from immunization requirements.[11] In this article, we review

the evidentiary basis for school immunization requirements, explore the determinants of vaccine refusal, and discuss the individual and community risks of vaccine-preventable diseases associated with vaccine refusal.

EVOLUTION OF U.S. IMMUNIZATION REQUIREMENTS

Vaccination was introduced in the United States at the turn of the 19th century. The first U.S. law to require smallpox vaccination was passed soon afterward, in 1809 in Massachusetts, to prevent and control frequent smallpox outbreaks that had substantial health and economic consequences.[12-14] Subsequently, other states enacted similar legislation.[13] Despite the challenges inherent in establishing a reliable and safe vaccine delivery system, vaccination became widely accepted as an effective tool for preventing smallpox through the middle of the 19th century, and the incidence of smallpox declined between 1802 and 1840.[15] In the 1850s, "irregular physicians, the advocates of unorthodox medical theories,"[16] led challenges to vaccination. Vaccine use decreased, and smallpox made a major reappearance in the 1870s.[15] Many states passed new vaccination laws, whereas other states started enforcing existing laws. Increased enforcement of the laws often resulted in increased opposition to vaccination. Several states, including California, Illinois, Indiana, Minnesota, Utah, West Virginia, and Wisconsin, repealed compulsory vaccination laws.[15] Many other states retained them.

In a 1905 landmark case, *Jacobson v. Massachusetts,* which has since served as the foundation for public health laws, the U.S. Supreme Court endorsed the rights of states to pass and enforce compulsory vaccination laws.[17] In 1922, deciding a case filed by a girl excluded from a public school (and later a private school) in San Antonio, Texas, the Supreme Court found school immunization requirements to be constitutional.[18] Since then, courts have been generally supportive of the states' power to enact and implement immunization requirements.

Difficulties with efforts to control measles in the 1960s and 1970s ushered in the modern era of immunization laws in the United States.[12] In 1969, a total of 17 states had laws that required children to be vaccinated against measles before entering school, and 12 states had legally mandated requirements for vaccination against all six diseases for which routine immunization was carried out at the time.[13] During the 1970s, efforts were made to strengthen and strictly enforce immunization laws.[12,13] During measles outbreaks, some state and local health officials excluded from school those students who did not comply with immunization requirements, resulting in minimal backlash, quick improvement in local coverage, and control of outbreaks.[19-22] Efforts by the public health community and other immunization advocates to increase measles vaccine coverage among school-age children resulted in enforcement of immunization requirements for all vaccines and the introduction of such requirements in states that did not already have them. By the beginning of the 1980s, all 50 states had school immunization requirements.

RECENT SCHOOL IMMUNIZATION REQUIREMENTS

Because laws concerning immunization are state-based, there are substantial differences in requirements across the country. The requirements from state to state differ in terms of the school grades covered, the vaccines included, the processes and authority used to introduce new vaccines, reasons for exemptions (medical reasons, religious reasons, philosophical or personal beliefs), and the procedures for granting exemptions.[23]

State immunization laws contain provisions for certain exemptions. As of March 2008, all states permitted medical exemptions from school immunization requirements, 48 states allowed religious exemptions, and 21 states allowed exemptions based on philosophical or personal beliefs.[23] Several states (New York, Arkansas, and Texas) have recently expanded eligibility for exemptions.

SECULAR AND GEOGRAPHIC TRENDS IN IMMUNIZATION REFUSAL

Between 1991 and 2004, the mean state-level rate of nonmedical exemptions increased from 0.98 to 1.48%. The increase in exemption rates was not uniform.[11] Exemption rates for states that allowed only religious exemptions remained at approximately 1% between 1991 and 2004; however, in states that allowed exemptions for philosophical or personal beliefs, the mean exemption rate increased from 0.99 to 2.54%.[11]

Like any average, the mean exemption rate presents only part of the picture, since geographic clustering of nonmedical exemptions can result in local accumulation of a critical mass of susceptible children that increases the risk of outbreaks. There is evidence of substantial geographic heterogeneity in nonmedical-exemption rates between and within states.[24] For example, in the period from 2006 through 2007, the state-level nonmedical-exemption rate in Washington was 6%; however, the county-level rate ranged from 1.2 to 26.9% (Fig. 1).[25] In a spatial analysis of Michigan's exemption data according to census tracts, 23 statistically significant clusters of increased exemptions were identified.[26] Similar heterogeneity in exemption rates has been identified in Oregon[27] and California (unpublished data).

The reasons for the geographic clustering of exemptions from school vaccination requirements are not fully understood, but they may include characteristics of the local population (e.g., cultural issues, socioeconomic status, or educational level), the beliefs of local health care providers and opinion leaders (e.g., clergy and politicians), and local media coverage. The factors known to be associated with exemption rates are heterogeneity in school policies[28] and the beliefs of school personnel who are responsible for compliance with the immunization requirements.[29]

Instead of refusing vaccines, some parents delay vaccination of their children.[30-32] Many parents follow novel vaccine schedules proposed by individual physicians (rather than those developed by expert committees with members representing multiple disciplines).[32,33] Most novel schedules involve administering vaccines over a longer period than that recommended by the Advisory Committee on Immunization Practices and the American Academy of Pediatrics or skipping the administration of some vaccines.

INDIVIDUAL RISK AND VACCINE REFUSAL

Children with nonmedical exemptions are at increased risk for acquiring and transmitting vaccine-preventable diseases.[34,35] In a retrospective cohort study based on nationwide surveillance data from 1985 through 1992, children with exemptions were 35 times as likely to contract measles as nonexempt children (relative risk, 35; 95% confidence interval [CI], 34 to 37).[34] In a retrospective cohort study in Colorado based on data for the years 1987 through 1998, children with exemptions, as compared with unvaccinated children, were 22 times as likely to have had measles (relative risk, 22.2; 95% CI, 15.9 to 31.1) and almost six times as likely to have had pertussis (relative risk, 5.9; 95% CI, 4.2 to 8.2).[35] Earlier data showed that lower incidences of measles and mumps were associated with the existence and enforcement of immunization requirements for school entry.[12,36-38]

The consequences of delayed vaccination, as compared with vaccine refusal, have not been studied in detail. However, it is known that the risk of vaccine-preventable diseases and the risk of sequelae from vaccine-preventable diseases are not constant throughout childhood. Young children are often at increased risk for illness and death related to infectious diseases, and vaccine delays may leave them vulnerable at ages with a high risk of contracting several vaccine-preventable diseases. Moreover, novel vaccine schedules that recommend administering vaccines over a longer period may exacerbate health inequities, since parents with high socioeconomic status are more likely to make the extra visits required under the alternative schedules than parents with low socioeconomic status.[39]

CLUSTERING OF VACCINE REFUSALS AND COMMUNITY RISK

Multiple studies have shown an increase in the local risk of vaccine-preventable diseases when there is geographic aggregation of persons refusing vaccination. In Michigan, significant overlap between geographic clusters of nonmedical exemptions and pertussis clusters was documented.[26] The odds ratio for the likelihood that a census tract included in a pertussis cluster would also be included in an exemptions cluster was 2.7 (95% CI, 2.5 to 3.6) after adjustment for demographic factors.

In Colorado, the county-level incidence of measles and pertussis in vaccinated children from 1987 through 1998 was associated with the frequency of exemptions in that county.[35] At least 11% of the nonexempt children who acquired measles were infected through contact with an exempt child.[35] Moreover, school-based outbreaks in Colorado have been associated with increased exemption rates; the mean exemption rate among

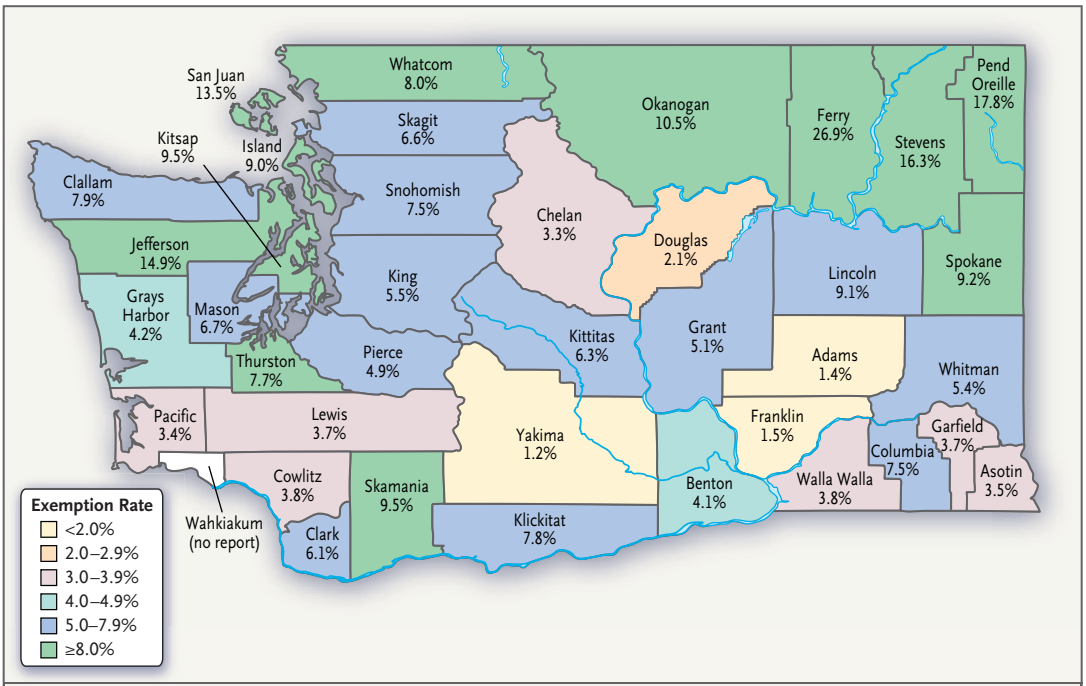

Figure 1. Rates of Exemption from Vaccination for Nonmedical Reasons in Washington Counties, 2006–2007.
Data are from the Washington State Department of Health, School Status Reports, 2006–2007.[25]

schools with outbreaks was 4.3%, as compared with 1.5% for the schools that did not have an outbreak (P=0.001).[35]

High vaccine coverage, particularly at the community level, is extremely important for children who cannot be vaccinated, including children who have medical contraindications to vaccination and those who are too young to be vaccinated. These groups are often more susceptible to the complications of infectious diseases than the general population of children and depend on the protection provided by the vaccination of children in their environs.[40-42]

VACCINE REFUSAL AND THE RECENT INCREASE IN MEASLES CASES

Measles vaccination has been extremely successful in controlling a disease that previously contributed to considerable morbidity and mortality. In the United States, the reported number of cases dropped from an average of 500,000 annually in the era before vaccination (with reported cases considered to be a fraction of the estimated total, which was more than 2 million) to a mean of 62 cases per year from 2000 through 2007.[43-45] Between January 1, 2008, and April 25, 2008, there were five measles outbreaks and a total of 64 cases reported.[45] All but one of the persons with measles were either unvaccinated or did not have evidence of immunization. Of the 21 cases among children and adolescents in the vaccine-eligible age group (16 months to 19 years) with a known reason for nonvaccination, 14, or 67%, had obtained a nonmedical exemption and all of the 10 school-age children had obtained a nonmedical exemption.[45] Thirteen cases occurred in children too young to be vaccinated, and in more than a third of the cases (18 of 44) occurring in a known transmission setting the disease was acquired in a health care facility.[45]

Outbreaks of vaccine-preventable disease often start among persons who refused vaccination, spread rapidly within unvaccinated populations, and also spread to other subpopulations. For example, of the four outbreaks with discrete index cases (one outbreak occurred by means of multiple importations) reported January through April 2008, three out of four index cases occurred in people who had refused vaccination due to per-

sonal beliefs; vaccination status could not be verified for the remaining cases.[45,46] In Washington State, a recent outbreak of measles occurred between April 12, 2008, and May 30, 2008, involving 19 cases. All of the persons with measles were unimmunized with the exception of the last case, a person who had been vaccinated. Of the other 18 cases, 1 was an infant who was too young to be vaccinated, 2 were younger than 4 years of age, and the remaining 15 were of school age (unpublished data).

WHO REFUSES VACCINES AND WHY

Using data from the National Immunization Survey for the period from 1995 through 2001, Smith et al. compared the characteristics of children between the ages of 19 and 35 months who did not receive any vaccine (unvaccinated) with the characteristics of those who were partially vaccinated (undervaccinated).[47] As compared with the undervaccinated children, the unvaccinated children were more likely to be male, to be white, to belong to households with higher income, to have a married mother with a college education, and to live with four or more children.[47] Other studies have shown that children who are unvaccinated are likely to belong to families that intentionally refuse vaccines, whereas children who are undervaccinated are likely to have missed some vaccinations because of factors related to the health care system or sociodemographic characteristics.[48-51]

In a case–control study of the knowledge, attitudes, and beliefs of parents of exempt children as compared with parents of vaccinated children, respondents rated their views of their children's vulnerability to specific diseases, the severity of these diseases, and the efficacy and safety of the specific vaccines available for them. Composite scores were created on the basis of these vaccine-specific responses. As compared with parents of vaccinated children, significantly more parents of exempt children thought their children had a low susceptibility to the diseases (58% vs. 15%, $P<0.05$), that the severity of the diseases was low (51% vs. 18%, $P<0.05$), and that the efficacy and safety of the vaccines was low (54% vs. 17% for efficacy and 60% vs. 15% for safety, $P<0.05$ for both comparisons).[52] Moreover, parents of exempt children were more likely than parents of vaccinated children both to have providers who offered complementary or alternative health care and to obtain information from the Internet and groups opposed to aspects of immunization.[52] The most frequent reason for nonvaccination, stated by 69% of the parents, was concern that the vaccine might cause harm.[52]

Other studies have also reported the importance of parents' concerns about vaccine safety when they decide against vaccination.[53-56] A national survey of parents from 2001 through 2002 showed that although only 1% of respondents thought vaccines were unsafe, the children of these parents were almost three times as likely to not be up to date on recommended vaccinations as the children of parents who thought that vaccines were safe.[54] In a separate case–control study with a national sample, underimmunization was associated with negative perceptions of vaccine safety (odds ratio, 2.0; 95% CI, 1.2 to 3.4).[55] And in another case–control study, Bardenheier et al. found that although concerns regarding general vaccine safety did not differ between the parents of vaccinated children and the parents of undervaccinated or unvaccinated children, more than half of the case and control parents did express concerns about vaccine safety to their child's health care provider.[57] Moreover, parents of undervaccinated or unvaccinated children were more likely to believe that children receive too many vaccines.[57]

THE ROLE OF HEALTH CARE PROVIDERS

Clinicians and other health care providers play a crucial role in parental decision making with regard to immunization. Health care providers are cited by parents, including parents of unvaccinated children, as the most frequent source of information about vaccination.[52]

In a study of the knowledge, attitudes, and practices of primary care providers, a high proportion of those providing care for children whose parents have refused vaccination and those providing care for appropriately vaccinated children were both found to have favorable opinions of vaccines.[58] However, those providing care for unvaccinated children were less likely to have confidence in vaccine safety (odds ratio, 0.37; 95% CI, 0.19 to 0.72) and less likely to perceive vaccines as benefitting individuals and communities.[58] Moreover, there was overlap between clinicians' unfa-

vorable opinions of vaccines and the likelihood that they had unvaccinated children in their practice.[58]

There is evidence that health care providers have a positive overall effect on parents' decision making with regard to vaccination of their children. In a study by Smith et al., parents who reported that their immunization decisions were influenced by their child's health care provider were almost twice as likely to consider vaccines safe as parents who said their decisions were not influenced by the provider.[59]

In focus-group discussions, several parents who were not certain about vaccinating their child were willing to discuss their immunization concerns with a health care provider and wanted the provider to offer information relevant to their specific concerns.[56] These findings highlight the critical role that clinicians can play in explaining the benefits of immunization and addressing parental concerns about its risks.

CLINICIANS' RESPONSE TO VACCINE REFUSAL

Some clinicians have discontinued or have considered discontinuing their provider relationship with families that refuse vaccines.[60,61] In a national survey of members of the American Academy of Pediatrics, almost 40% of respondents said they would not provide care to a family that refused all vaccines, and 28% said they would not provide care to a family that refused some vaccines.[61]

The academy's Committee on Bioethics advises against discontinuing care for families that decline vaccines and has recommended that pediatricians "share honestly what is and is not known about the risks and benefits of the vaccine in question."[62] The committee also recommends that clinicians address vaccine refusal by respectfully listening to parental concerns, explaining the risk of nonimmunization, and discussing the specific vaccines that are of most concern to parents.[62] The committee advises against more serious action in a majority of cases: "Continued refusal after adequate discussion should be respected unless the child is put at significant risk of serious harm (e.g., as might be the case during an epidemic). Only then should state agencies be involved to override parental discretion on the basis of medical neglect."[62]

POLICY-LEVEL DETERMINANTS OF VACCINE REFUSAL

Immunization requirements and the policies that ensure compliance with the requirements vary considerably among the states; these variations have been associated with state-level exemption rates.[11,63] For example, the complexity of procedures for obtaining exemption has been shown to be inversely associated with rates of exemption.[63] Moreover, between 1991 and 2004, the mean annual incidence of pertussis was almost twice as high in states with administrative procedures that made it easy to obtain exemptions as in states that made it difficult.[11]

One possible way to balance individual rights and the greater public good with respect to vaccination would be to institute and broaden administrative controls. For example, a model law proposed for Arkansas suggested that parents seeking nonmedical exemptions be provided with counseling on the hazards of refusing vaccination.[64]

States also differ in terms of meeting the recommendations for age-appropriate coverage for children younger than 2 years of age.[65] School immunization requirements ensure completion by the time of school entry, but they do not directly influence the timeliness of vaccination among preschoolers. However, there is some evidence that school immunization laws have an indirect effect on preschool vaccine coverage. For example, varicella vaccine was introduced in the United States in 1995 and has played an important role in reducing the incidence of chickenpox.[66] In 2000, states that had implemented mandatory immunization for varicella by the time of school entry had coverage among children 19 to 35 months old that was higher than the average for all states. Having an immunization requirement could be an indicator of the effectiveness of a state's immunization program, but the effect of school-based requirements on coverage among preschoolers cannot be completely discounted.

CONCLUSIONS

Vaccine refusal not only increases the individual risk of disease but also increases the risk for the whole community. As a result of substantial gains in reducing vaccine-preventable diseases, the memory of several infectious diseases has faded from

the public consciousness and the risk–benefit calculus seems to have shifted in favor of the perceived risks of vaccination in some parents' minds. Major reasons for vaccine refusal in the United States are parental perceptions and concerns about vaccine safety and a low level of concern about the risk of many vaccine-preventable diseases. If the enormous benefits to society from vaccination are to be maintained, increased efforts will be needed to educate the public about those benefits and to increase public confidence in the systems we use to monitor and ensure vaccine safety. Since clinicians have an influence on parental decision making, it is important that they understand the benefits and risks of vaccines and anticipate questions that parents may have about safety. There are a number of sources of information on vaccines that should be useful to both clinicians and parents (e.g., Appendix 1 in the fifth edition of *Vaccines*, edited by Plotkin et al.; the list of Web sites on vaccine safety posted on the World Health Organization's Web site; and the Web site of the National Center for Immunization and Respiratory Diseases).[67-69]

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