

Background on Immunization Exemption Issues and Proposed Solutions



Background

- All states and the District of Columbia (DC) have immunization requirements for children enrolling in childcare facilities and schools.¹
- Most (44) states and DC allow for exemptions due to religious beliefs and 20 states, including Minnesota, allow for exemptions based on personal beliefs of the child's parent or guardian.
- States that have easily-obtained non-medical exemptions have higher rates of pertussis and measles.^{2,3}
- In Minnesota, obtaining an exemption based on the parent's "conscientiously held beliefs" is simple – the only requirement is that the parent's statement be notarized.⁴
- In recent years, 5 states (CA, MI, OR, VT, WA) have strengthened their immunization requirements to add an education component for parents seeking a non-medical exemption for their child.

What is the problem in Minnesota?

- Statewide non-medical exemptions for kindergarteners remained stable for the 2010-11 through 2013-14 school years at just slightly more than 1.6%; however, rates in some Minnesota counties are 1.5 to 2 times the statewide average.⁵ Studies have shown an increased risk of disease when there is clustering of unvaccinated children.^{6,7} To see a list of kindergarten exemption rates by county, school district, and individual school, visit www.health.state.mn.us/divs/idepc/immunize/stats/school/pervaxkind1314.xlsx.
- An outbreak of **measles** in 2011 found that 16 of the 21 cases had not been vaccinated. While 9 of the cases were old enough to have received the vaccine, 7 of those 9 had not been vaccinated due to their parents' concern over vaccine safety issues.⁵
- An outbreak of 14 cases of **chickenpox** occurred in school children in a central-Minnesota town in 2013. Of the 14 cases, 8 were unvaccinated due to a conscientious belief exemption and were enrolled in school.⁵
- A total of 4,144 confirmed and probable cases of **pertussis** (whooping cough) were reported in 2012—more than any year since 1938.⁵ Although waning immunity of the new acellular vaccine may have contributed to many of these cases, a completely unvaccinated child can serve as an entry point in introducing the disease into a community.
- An analysis based on the 2012—13 school year by the Minnesota Department of Health of geographic clusters grouped by zip codes found that those with high rates of conscientious exemptions to the pertussis vaccine were 2.6 times more likely to overlap with zip codes that had high rates of pertussis disease, when compared to zip codes that were not part of an exemption cluster.

How would HF393/SF380 address these issues?

- The bill requires a parent or guardian seeking a personal belief exemption for their child to receive education regarding vaccines and the diseases they prevent from a physician or other authorized healthcare provider.
- The bill preserves a parent's option to exempt their child from immunizations, but also ensures that such a decision is an informed one and that the parent is aware of the individual and public health risks of choosing to not immunize their child.
- For students in elementary schools, the personal belief exemption would expire at the end of grade 6 and would need to be resubmitted, if desired, at the student's entrance to grade 7 when additional vaccinations are also required.

Current Minnesota Immunization Requirements and Proposed Changes



What immunizations are currently mandated in Minnesota?

- The immunizations that are mandated include vaccines to protect against diphtheria, tetanus, pertussis (whooping cough), polio, measles, mumps, rubella, hepatitis B, varicella (chickenpox), meningococcus and, for childcare enrollees only, *Haemophilus influenzae* type b (Hib) and hepatitis A. Exemptions are permitted for either medical reasons or due to the conscientiously held beliefs of the parent or guardian.⁴

What documentation is required?

- Minnesota Statutes, section 121A.15 requires that, in order to enroll or remain enrolled in any public or private Minnesota school or childcare facility, a parent or guardian must submit a statement that the child has
 - received all required immunizations, as documented by a physician or public immunization clinic,
 - received at least 1 of each of the required immunizations and is on schedule to complete those that are given in a series, as documented by a physician or public immunization clinic,
 - received some of the immunizations but has a medical exemption for the others, as documented by a physician, or
 - not been vaccinated against some or all of the required immunizations due to the parents' conscientiously held beliefs, as documented by a notarized statement from the parent or guardian.
- In Minnesota, it is currently easier to opt out of immunizations for non-medical reasons than it is to prove that a child has been vaccinated.

What would the proposed legislation require?

- No changes would be made to the statute in regard to children who meet the vaccination requirements or who cannot receive vaccines due to medical reasons.
- Parents wanting to opt out of immunization because of personal beliefs would be required to discuss the risks and benefits of vaccines with a healthcare provider (i.e., physician, physician assistant or advanced practice registered nurse) and obtain the healthcare provider's signature on a certificate of exemption.
- Parents who choose not to have their child vaccinated would need to present a certificate of a personal belief exemption at the child's entrance to a childcare facility, school-based early childhood program, or private or public elementary or secondary school. The exemption would expire when the child is enrolling in grade 7, and would need to be re-submitted.

Immunization – saving lives and improving the public's health

- Immunization has been called one of the ten greatest achievements of the 20th century in improving the health and life expectancy of people living in the U.S.⁸
- Because of vaccines, smallpox has been eradicated from the world and polio is close to being eradicated.^{9,10} In the United States, diseases like measles, rubella, tetanus, diphtheria, and Hib are no longer endemic.
- Compulsory vaccination for children enrolled in childcare facilities and schools has been a major contributor to the success of the immunization program in the United States.¹¹
- The constitutionality of mandatory vaccination was upheld by the U.S. Supreme Court in 1905 in a Massachusetts case.¹²

Are vaccines safe?

- An analysis of over 1,000 studies by the independent Institute of Medicine found that **side effects from vaccines are usually mild and short-lasting**.¹³ Serious side effects from vaccines are extremely rare, sometimes so rare that it is hard to tell if vaccines actually cause those side effects.
- Many studies over the years have proven that **vaccines do not cause autism**.¹⁴
 - Another Institute of Medicine report found that **the childhood immunization schedule is safe** and that children vaccinated on-schedule are not at risk of harm.¹⁵
- **Vaccines undergo rigorous study on hundreds of thousands of people** before being licensed by the FDA.¹⁶
- After licensure, **vaccines are monitored through multiple safety mechanisms** by the FDA and CDC. These include on-site testing of all lots of vaccines, monitoring of Vaccine Adverse Event Reporting System (VAERS) which collects reports from healthcare providers, parents, and others who may believe that a vaccine caused a problem.¹⁷ Another safety system is the Vaccine Safety Datalink (VSD), comprised of a group of large health maintenance organizations (including Minnesota-based HealthPartners).¹⁸ VSD links computerized medical records of patients representing about 6 percent of the U.S. population. Together, VAERS can raise the question of whether a vaccine caused a particular problem, and the VSD can answer it.

The bottom line . . .

- A majority of parents trust their child's doctor for vaccine-safety information.¹⁹
- Parents' questions are important and they deserve to have reliable information to support the healthcare decisions they make for their family.
- Children who are exempted from vaccine requirements are at significant risk for disease.³
- Diseases can spread quickly in schools and childcare facilities. It is important that all children are protected against vaccine-preventable disease, both for themselves and for those around them.
- Public health officials want to ensure that requests for exemptions from immunization are based on conviction, not convenience.

References

- ¹ Vaccine refusal, mandatory immunization, and the risks of vaccine-preventable diseases. Omer SA, Salmon DA, Orenstein WA, deHart MP, and Halsey N. *New England Journal of Medicine* 2009;1981—1988.
- ² Nonmedical exemptions to school immunization requirements: secular trends and association of state policies with pertussis incidence. Omer SB, Pan WK, Halsey NA, et al. *JAMA* 2006;296(14):1757—63.
- ³ Individual and community risk of measles and pertussis associated with personal exemptions to immunizations. Feikin DR, Lezotte DC, Hamman RF, Salmon DA, Chen RT, Hoffman RE. *JAMA*. 2000;284(24):3145-50.
- ⁴ Minnesota Statutes, section 121A.15
- ⁵ Minnesota Department of Health, personal communication.
- ⁶ Geographic clustering of nonmedical exemptions to school immunization requirements and association with geographic clustering of pertussis. Omer SB, Enger KS, Moulton LH, Halsey NA, Stokley S, Salmon DA. *American Journal of Epidemiology* 2008;168:1389—96.
- ⁷ Geographic Clusters in Underimmunization and Vaccine Refusal. Lieu TA, Ray GT, Klein NP, Chung C, Kulldorff M. *Pediatrics* 2015;135(2):281—289.
- ⁸ Ten Great Public Health Achievements—United States, 1900-1999. *Morbidity and Mortality Weekly Report*. 1999;48(12):241-243.
- ⁹ The Smallpox Eradication Programme – SEP (1966-1980). World Health Organization (accessed February 7, 2014 at www.who.int/features/2010/smallpox/en/)
- ¹⁰ Global Polio Eradication Initiative. (Accessed February 7, 2014 at www.polioeradication.org/)
- ¹¹ The immunization system in the United States – the role of school immunization laws. Orenstein WA, Hinman AR. *Vaccine* 1999;S19-24.
- ¹² *Jacobson v. Massachusetts*, 197 U.S. 11 (1905)
- ¹³ Adverse Effects of Vaccines – Evidence and Causality, Institute of Medicine, August 2011 (Accessed on February 5, 2014 at www.iom.edu/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx)
- ¹⁴ Immunization Safety Review: Vaccines and Autism. Vaccines do not cause autism. Institute of Medicine, May 2004 (Accessed on February 6, 2014 at www.iom.edu/Reports/2004/Immunization-Safety-Review-Vaccines-and-Autism.aspx.)
- ¹⁵ The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies, Institute of Medicine, January 2013. (Accessed on February 5, 2014 at www.iom.edu/reports/2013/the-childhood-immunization-schedule-and-safety.aspx.)
- ¹⁶ *Biologic Development: A Regulatory Overview*. Mathieu M (ed); Waltham MA: Paraxel; 1993.
- ¹⁷ Understanding Vaccine Safety Information from the Vaccine Adverse Event Reporting System. Varricchio F, Iskander J, Destefano F, Ball R, Pless R, Braun MM, Chen RT. *Pediatric Infectious Disease Journal*. 2004;23(4):287-94.
- ¹⁸ The Vaccine Safety Datalink: Immunization Research in Health Maintenance Organizations in the USA. Chen RT, et al. *Bulletin of the World Health Organization*, 2000;78:186-94.
- ¹⁹ Parents trust doctors most when it comes to information about vaccine safety. Greed GL, Clark SJ, Butchart AT, Singer DC, Davis MM. *Pediatrics* 2011;S107—S112.